EMERGENCY REGISTRATION REPORT

Product name: Cruiser SB

Active substance:

thiamethoxam 600 g/L

To protect sugar beet against beet virus yellows complex by controlling the virus vector *Myzus persicae*

England

Applicant: NFU Sugar and British Sugar

Submission date: 06/06/2024

Finalisation date: 18/10/2024

HSE Ref Number: COP 2024/01181

Version history

When	What
30/08/2024	Version for ECP send out
18/10/2024	Post ECP updates
17/01/2025	Redactions

Summary and Purpose of this document:

Presentation of HSEs consideration of an application made jointly by British Sugar and NFU sugar for emergency use of 'Cruiser SB' to treat sugar beet seed for planting in 2025.

It includes a mixture of:

- HSEs new consideration in 2024 (for use in 2025) on an orange background such as this
- Extracts from the 2024 application form submitted by British Sugar/ NFU Sugar included on a white background within sections 1.1.1 to 1.1.6 and 1.2)
- HSE's previous risk assessments where they remain valid on a green background

The updated assessments for use in 2025 relate to:

- The tests for an emergency authorisation (sections 1.1.1 to 1.1.6).
- Changed classification of thiamethoxam and impact on groundwater risk assessment
- Validation of new method of analysis
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- Updated summary of Environment Agency surface water monitoring data from three Catchment Sensitive Farming sites (data up to 1st March 2024 included). (section 2.6.2.) Updated soil, vegetation and pollen monitoring data collected as part of the stewardship scheme. This included completely new monitoring of 6 sites treated in spring 2023 and a continuation of monitoring at the sites treated in 2022 (initial results following the 2022 applications were reported in the previous application for use in 2024). Both studies used a more sensitive analytical method than the original monitoring study. (section 2.6.3.) An updated groundwater exposure assessment. This is in response to the 2023 GB classification of thiamethoxam as a suspected human reproductive toxicant, suspected of damaging fertility and the unborn child (Repr.2 (H361fd). and the subsequent need to consider the groundwater metabolites as toxicologically relevant in line with SANCO guidance on the assessment of relevance of metabolites in groundwater (Sanco/221/2000 – rev. 11). (section 2.6.2.)

Following the reclassification of thiamethoxam and in the absence of additional information, reproductive toxicity, HSE concludes that an acceptable risk to groundwater has not been demonstrated due to the toxicologically relevant metabolite NOA459602 exceeding the 0.1 µg/l limit.

The ecotoxicology assessment concludes that it has not been clearly established that there will be no unacceptable effects on adult or larval honeybee survival and behaviour following the use of 'Cruiser SB', and that the impact on the survival, development or productivity of the colony is unknown.

Very high spring rainfall in 2024, kept aphid numbers low which highlighted the difficulties in predicting virus threat on 1 March, as the actual threat was much lower than predicted.

The applicant has not been able to propose how use may be further limited beyond the overall predicted virus threat on 1 March. Once the threshold is exceeded the option of using 'Cruiser SB' is left to grower choice. It remains unclear why some growers choose to use 'Cruiser SB' treated seed, whilst a significant proportion choose not to.

Table of Contents

1 Details of the application

Name of authority	**Health and Safety Executive (HSE), UK**
Navigating this document: This is a long document and it may be sensible to use the links within the table of contents to navigate, for this reason a link to the table of contents can be found in the footer for each page.	
Reviewer's comments	This Emergency registration report (eRR) is for the evaluation of an application requesting emergency authorisation for the use of the plant protection product 'Cruiser SB' in England in 2025. An emergency authorisation may be granted under Article 53 of assimilated Regulation (EC) No 1107/2009 (the Regulation) in special circumstances, for limited and controlled use, where the authorisation appears necessary because of a danger which cannot be contained by any other reasonable means. This eRR has been prepared by the Health and Safety Executive (HSE) based on the information provided by the applicant, the product manufacturer, Defra and the Environment Agency. It includes an assessment of risk in accordance with the standard criteria and uniform principles applicable for a commercial authorisation as well as considering the various elements of the derogation from the standard requirements, set out in Article 53 of the Regulation. These article 53 requirements are; 'special circumstances' (section 1.1.1 of this eRR), 'danger' (section 1.1.2) 'any other reasonable means' (section 1.1.4), 'limited and controlled use' (section 1.1.5 and 1.1.6) and 'is necessary' (covered in the overall conclusions section 3.2). A judgement on whether an authorisation appears necessary to address the danger involves consideration of whether the likely benefits of granting the authorisation to address the identified danger outweigh the potential adverse impacts of granting it. The draft eRR is to be presented to the Expert Committee on Pesticides (ECP) which will be asked questions relating to the updates to the HSE assessment. The ECP will produce independent scientific advice to Government which will be presented to Defra and the Devolved Governments in Scotland, Wales and Northern Ireland.

1.1 Background of Application

Name of authority	**Health and Safety Executive.**

British Sugar and NFU Sugar (with the support of the British Beet Research Organisation (BBRO) and Syngenta UK Limited have jointly applied for an Article 53 emergency authorisation for the use of 'Cruiser SB' as a seed treatment for sugar beet for sugar production sown in England in 2025.

The proposed use of 'Cruiser SB' (contains the neonicotinoid thiamethoxam) is for the control of peach potato aphid (*Myzus persicae* (MYZUPE)), which is the main vector of Beet Virus Yellows complex (BVY). The yellows virus complex consists of three dominant virus yellows (the persistent Beet mild yellowing virus (BMYV), and Beet Chlorosis virus (BChV); and semi-persistent Beet yellows virus (BYV)). There is extensive information on the impact of virus yellows on yield, and further effects by increasing a range of impurities in the storage roots, which then impact on the sugar extraction process.

Thiamethoxam was withdrawn as an approved active substance in 2018 due to concerns with sub-lethal effects on pollinators. There are no other active substances of co-formulants within the formulation that require specific attention under the Article 53 emergency procedures.

This is the fifth consecutive application for emergency authorisation for this use

The applicant again proposes that in 2025, 'Cruiser SB' is only used when the predicted cost of loss in yield due to virus yellows complex is greater than the cost of 'seed treatment. The applicant therefore anticipates that, in line with previous years, any authorisation would be subject to an economic treatment threshold based on the current crop price, cost of 'Cruiser SB' seed treatments and the economic impact assessment of virus yellows complex. At the time of writing the economic treatment threshold for 2025 is not known with the applicant indicating that this will be proposed in due course.

The Rothamsted virus yellows forecasting model is an established tool which in early spring predicts virus levels likely to appear in sugar beet crops in August if no plant protection intervention were made. The 'Cruiser SB' authorisations issued in 2021, 2022, 2023 and 2024 included conditions which only allowed 'Cruiser SB' to be used if the virus levels predicted by the model on 1 March, exceeded the threshold set for that year . Details of the economic thresholds proposed by the applicants in previous years and the subsequent thresholds set are given in the application history section below.

In the UK sugar beet is grown in the areas around the four sugar beet factories in the east of England. All sugar beet grown for sugar production is grown under contact to British Sugar. The applicant reports that since the virus yellows outbreak in 2020, grower confidence has decreased and that in 2021 the area contracted for sugar beet production reduced by 12%, with 91,000 ha grown. However, as recognised in the Defra economic analysis the overall area has been in decline since the mid 1990s. British Sugar has introduced a number of measures to try and promote farmers to grow sugar beet. This included; a 48% price increase, more flexibility around the previous compensation scheme and a cash advance scheme (see Beet price of £40/t agreed for 2023/24 sugar beet contract | News (britishsugar.co.uk)).

The following table shows the area of sugar beet planted in the years that emergency authorisations were used, along with the approximate proportion of crop treated with 'Cruiser SB'.

Year	Hectares of sugar beet for sugar production	Ratio ‘Cruiser SB’ treated/ non treated	Total area planted with ‘Cruiser SB’ treated seed
2022	87,300	71/29	61,983 hectares
2023	98,700	60/40	59,220 hectares
2024	102,293	60/40	61,376 hectares

There is unlikely to be one factor which has resulted in the increase in sugar beet grown in 2023 and 2024 compared to previous years. The increase in sugar price and other measures such as mid-year payments and the revised compensation scheme are all likely to have influenced grower choices. HSE has no evidence whether the availability of 'Cruiser SB' in recent high virus risk years influenced grower decisions.

Although the area planted with sugar beet increased in 2023 and 2024, the proportion of seed treated with ‘Cruiser SB’ has decreased from 2022 and therefore the overall area planted with ‘Cruiser SB’ treated seed was slightly less in 2023 and 2024 than in 2022.

A decision on the 2024 application (for use in 2025) is needed to inform grower choices and the issuing of contracts in advance of planting in 2025.

Status of product in the UK

‘Cruiser SB’ is a flowable concentrate (FS) formulation containing the active substance thiamethoxam at 600 g/L. Thiamethoxam is no longer an approved active substance and no authorised UK plant protection products contain this active substance.

‘Cruiser SB’ was previously fully authorised in the United Kingdom according to (Directive 91/414/EEC) taking into account Uniform Principles. However authorisation was withdrawn in 2018 as outlined below.

The notifier (for the EU approval) responded to the requirement for confirmatory information in Commission Implementing Regulation (EU) No 485/2013. The requirement covered a range of issues regarding the risk to honey bees and other pollinators. The Commission reviewed the information submitted and concluded that the necessary information was not provided. The Commission also considered that on the basis of the updated thiamethoxam risk assessment provided by EFSA, risks to bees cannot be excluded without imposing further restrictions.

As a result Commission Implementing Regulation (EU) 2018/785 prohibited all outdoor uses of thiamethoxam which resulted in the withdrawal of the ‘Cruiser SB’ authorisation in the UK. Paragraph 11 of this regulation stated:

> Having reviewed the information submitted by the applicant, the Commission has concluded that the further confirmatory information required by Implementing Regulation (EU) No 485/2013 has not been provided, and having also considered the conclusion on the updated risk assessment for bees, the Commission has concluded that further risks to bees cannot be excluded without imposing further restrictions. Bearing in mind the need to ensure a level of safety and protection consistent with the high level of protection of animal health that is sought within the Union, it is appropriate to prohibit all outdoor uses. Therefore, it is appropriate to limit the use of thiamethoxam to permanent greenhouses and to require that the resulting crop stays its entire life cycle within a permanent greenhouse, so that it is not replanted outside.

In line with the Article 53 emergency authorisations granted in the UK in 2021-2024 the proposed use is 75% of the application rate previously commercially authorised.

Application History

‘Cruiser SB’ was previously authorised in the UK following consideration by the Advisory Committee on Pesticides (ACP) in 2006 (plus subsequent re-registration). The ‘Cruiser SB’ authorisation (MAPP 15012) was withdrawn following an EU restriction in 2018 requiring treated seed to remain under protection for the entirety of the plant life-cycle, due to concerns regarding its impact on bee health. Following implementation of this restriction, the applicant withdrew support for the active substance renewal process and the EU approval for the active substance thiamethoxam expired.

A useful background to the regulatory history of Neonicotinoids in Europe is given on the European Commission Website at Neonicotinoids (europa.eu).

Article 53 emergency authorisations for this use in England were previously granted in 2021, 2022, 2023 and 2024 following decisions by Defra Ministers. Authorisation in 2025 would therefore represent the fifth emergency authorisation and potentially the fourth consecutive year of emergency use. Details of the 2024 decision by the Minister for Food, Farming and Fisheries area available at Neonicotinoid product as seed treatment for sugar beet: emergency authorisation application - GOV.UK (www.gov.uk). Each year's authorisation decision was subject to a treatment threshold set by Ministers which restricted use of 'Cruiser SB' to when the Rothamsted Research virus yellows forecast indicated a high virus risk.

The forecast is run on 1 March each year and predicts the level of virus infection in August if there is no plant protection intervention.

A summary of the treatment thresholds set with the emergency authorisations, along with the predicted virus incidence from the Rothamsted Model (as run on 1 March each year) is presented below

Year	Treatment threshold	Virus Yellows Forecast	Use triggered
2021	9%	8.37%	No
2022	19%	68.9%	Yes
2023	63%	67.51%	Yes
2024	65%	83.04%	Yes

In recent years a number of EU countries also granted Article 53 emergency authorisations for thiamethoxam seed treatments to control a range of pests on emerging sugar beet plants. (The EU Commission list of Emergency authorisations indicates that 12 EU Member States (MS) issued such emergency authorisations for use in 2022). The European Commission had previously asked the European Food Safety Agency (EFSA) to assess the justification for earlier emergency authorisations (issued in 2020 and 2021) and the conclusions are presented at Neonicotinoids: EFSA assesses emergency uses on sugar beet in 2020/21 | EFSA (europa.eu). The EU Member State emergency authorisations did not appear to contain treatment thresholds for the seed treatment (we are not aware that any other country has a predictive model supporting a treatment threshold). Some documents (e.g. Belgian decision) refer to a treatment threshold for foliar spray applications. It is also noted that a preliminary ruling by the European Court of Justice (ECJ) was issued on 19 January 2023 in Case C-162/21. This judgement followed a request by the Belgian courts in response to their consideration of a case against the Belgian State by two environmental groups and a bee keeper ('the applicants'):

> The applicants sought suspension/ annulment of Article 53 authorisations issued by the Belgian government in 2018 for use of thiamethoxam (as 'Cruiser SB') and clothianidin (as Poncho Beta) as seed treatments on sugar beet and other crops. The applicants expressed concern regarding increased use of Article 53 (1) of Regulation (EC) No 1107/2009 by Member States which routinely grant emergency authorisations for several years in a row without any proven danger to the crops. The applicants seem to have highlighted that by their nature seed

treatments are prophylactic and the emergency authorisations were therefore not linked to a proven danger to the crop.

In referring the case to the ECJ the Belgian courts sought advice on the scope of the derogation that Article 53 in relation to the specific prohibitions under Commission implementing Regulations (EU) 2018/784 and 2018/785. The Regulations specifically prevented the placing on the market or use of seed treated with clothianidin and thiamethoxam respectively, unless the seed was intended to be planted in permanent greenhouses and the resulting crop stayed in permanent greenhouses for the entirety of its life cycle.

Taking into account various elements of Regulation (EC) No1107/2009 including its recitals, the requirements of the Sustainable Use Directive and the requirements of the above referenced implementing regulations, the opinion of the court was:

"Article 53 (1) of Regulation (EC) No 1107/2009 must be interpreted as not permitting a Member State to authorise the placing on the market of plant protection products for seed treatment, or the placing on the market and use of seeds treated with those products where placing on the market has been expressly prohibited by an implementing regulation."

The EU position was reinforced by the European Commission at the January 2024 Standing Committee (Legislation Section)

In addition to GB not being an EU Member State at the time of this judgement, Defra has confirmed to HSE that the Commission Implementing Regulations 2018/784 and 2018/785 do not form part of the EU assimilated law and are therefore not applicable in GB. This is because part 4 of the EU exit Statutory Instrument 556 of 2019 The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (legislation.gov.uk) revokes a range of older PPP legislation including implementing regulations relating to active substances which were not approved in GB at the date of exit.

1.1.1 Special Circumstances

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of Authority	**Health and Safety Executive.**
Special Circumstances	The applicant's explanation of special circumstances (from the application form) is presented below this 'box'. For over 25 years *Myzus persicae* and other aphid vectors, and the Yellows Virus complex, was controlled by the neonicotinoid seed treatments 'Cruiser SB' (MAPP 12958) and 'Poncho Beta' (MAPP 12076) (beta-cyfluthrin + clothianidin), and prior to that 'Gaucho FS' (containing imidacloprid). These products also controlled the range of other sugar beet insect/soil pests and consequently, few if any other follow up insecticide foliar sprays were required during the season. Since the withdrawal of these products in 2018, there has been limited time for the industry to gain experience in developing new strategies (and largely without sufficient available alternative insecticides) to manage the aphid/virus yellows complex. These strategies must also adapt to varying and increasingly less predictable, seasonal conditions. 2019 was the first year following the withdrawal of the neonicotinoid seed treatments. Aphid populations and virus incidence levels were moderate, and where control measures were required, one or two foliar sprays against

	aphids were used (flonicamid, or an Article 53 authorisation for thiacloprid). There was little impact on national yield. However, this was followed in 2020 by the largest virus epidemic since the 70's (pre-neonicotinoid seed treatments), with unprecedented aphid numbers. Industry estimated over £40 million in yield losses to growers, and over £20 million to processors. 78% of surveyed crop received two to four foliar sprays (using either flonicamid, or Article 53 authorisations for thiacloprid and acetamiprid). The 2021 season was preceded by a cold winter, reducing aphid populations and delaying migration. This was the first season a 'Cruiser SB' Article 53 authorisation was issued. However, the model prediction on levels of virus incidence, influenced particularly by the cold weather period, indicated the treatment threshold would not be met and the seed was not treated. This forecast was proven to be accurate, with low levels of virus incidence and only localised areas needed a second of the authorised foliar sprays The 2022 season was again very different. The aphid forecast for 2022 predicted virus incidence level (without any plant protection intervention) at 68.9% with the predicted date of first aphid arrival on 19th April 2022. Aphids were subsequently first recorded on 18th April 2022. The threshold was met, and 'Cruiser SB' used. However, the season had exceptionally unusual weather, with record temperatures, low rainfall and drought conditions. This restricted crop development, with crops suffering great stress, evident in leaf yellowing, senescence and nutritional deficiencies. The conditions made any identification of virus expression in the beet crop difficult. And whilst there was a later recovery, it caused a number of issues at harvest. Highly unusually, the conditions also saw damage from the beet moth. Although present in the UK this pest is usually of concern in Mediterranean countries but was evident in UK sugar beet crops this year due to the hot and dry conditions. In 2023 and 2024 again the model prediction exceeded the treatment threshold, and 'Cruiser SB' was applied in both seasons to around 60% of the crop. Each season was distinctly different; with 2023 wet conditions impacting drilling and establishment, followed by later cold periods affecting aphid populations. In this 2024 season, aphid population growth was checked by prolonged rainfall events. (Both seasons are described in more detail below). *Myzus persicae* is particularly challenging, with evidence provided of its longer term background build-up of populations, particularly following mild winters, which can then cause significant problems in seasons with favourable conditions. The seasons described above illustrate the importance of having cold winters as a mechanism to decrease populations, which only happened once in the five seasons described. Equally, when conditions are conducive for population build up there can be very significant yield losses. It is acknowledged that uncertainty for growers will be a key element to decision making when considering whether to grow sugar beet.

	The very different seasons are also illustrative of the experience required and challenge in developing robust, long term solutions and integrated programmes. A further challenge is that the range of other foliar and soil sugar beet pests which were controlled by the neonicotinoid seed treatments now need additional insecticide sprays. The only option for these additional pests are pyrethroids, which themselves may impact on beneficial arthropods and impair their contribution to controlling *M. persicae* and other pests. The management of virus yellows also therefore needs to be considered in the wider challenges for the whole insect/soil pest complex. British Sugar and BBRO have put in place a multimillion pound research programme, with focus on developing commercial resistant varieties using conventional breeding programmes, and more recently exploring the potential of gene editing techniques. The latter has been supported by Innovate UK funding in 2024. This was originally initiated before neonicotinoids were withdrawn, when the need to find alternatives was recognised (full details in section 'repeat applications'). Developing commercial resistant varieties is proving challenging because the complex consists of three viruses and there is no one single trait conferring resistance/tolerance. 'Maruscha KWS' variety has been developed with partial tolerance to one of the three viruses. In the last year, significant progress has been made by breeders identifying VY tolerant genetics, with one trial 'Goliath' indicating tolerance to all three yellows viruses. But it will be at least 2 years before it may make the recommended varieties list. This breeding programme is one of several areas of on-going research to develop a range of integrated approaches. To minimise the reduction in UK sugar production, British Sugar and NFU Sugar introduced the Virus Yellows crop assurance fund from 2021. This compensates growers for a proportion of yield losses suffered where a grower has virus yellows present in their crop. This is a three-year, £12 million fund, underwritten by British Sugar covering all new and existing contracts. The applicant noted previously the 2021 contracted area decreased by 12% due to the yield losses of 2020 and was further reduced by 4% in the 2022. As recognised in the Defra economic analysis the overall area has been in decline since the mid 1990s. However, figures for 2023 and 2024 seasons confirm an increase in the contracted area, reflecting higher agreed sugar price (see background). **Taking into account the above points HSE consider that there are special circumstances supporting this proposed Article 53 Authorisation for use as a seed treatment in 2025.**

Part D - Emergency Situation For help completing these sections, read the Applicant Guide to Emergency Authorisations.	
16	Special Circumstances
Please state the special circumstances which apply to your application.	

British Sugar and NFU Sugar (on behalf of sugar beet growers in the UK) are submitting this application for emergency authorisation of Cruiser SB to be used to protect the English sugar beet crop in 2025. If an emergency authorisation for Cruiser SB is granted, the industry would only use this treatment if the established Virus Yellows forecast, produced by Rothamsted Research, exceeds the economic threshold, and subject to further strict conditions on use. Recent years show the incidence of Virus Yellows has been high, with the Rothamsted Model predicting an incidence of 83% in 2024. In the absence of further mitigating controls and measures, British Sugar and NFU Sugar believe an emergency authorisation is necessary because of the serious threat that Virus Yellows complex poses to the industry and viability of the entire UK sugar beet sector. Confidence in the domestic sector is key given the economic importance of the domestic crop and growers.

We continue to focus our attention and investment on finding solutions to Virus Yellows through our industry 'Virus Yellows Taskforce' and the 'Virus Yellows Pathway'. This is a multi-million pound collaborative project with BBRO, British Sugar and NFU Sugar pushing forward with long-term, sustainable solutions. We are pleased to be able to report progress in several areas (see below), including gene editing, grower practices and conventional breeding. However, the industry urgently requires this derogation as an interim solution as it remains the situation, notwithstanding the industry's investments, that currently there is no effective alternative non-chemical control method commercially available. Interactions and collaborations with European sugar beet researchers towards alternative IPM approaches are ongoing, but these continue to be limited in their effectiveness for Virus Yellows control at present. This emergency authorisation will allow us further time to continue our research activities to look for a longer-term solution.

We are committed to investing in the long-term viability of the industry. British Sugar has invested in a collaboration project to explore how gene editing (GE) can be used to specifically target the three yellowing viruses through new breeding technology. This work has been supported by an Innovate UK grant in 2024. It is anticipated that Virus Yellows resistance can be achieved by employing minimal gene editing to precisely redirect the silencing activity of existing non-coding RNA, towards a new target of choice. It is expected that a Virus Yellows resistant sugar beet seed will not be commercially available for use before 2030.

Whilst we work to deliver a fully resistant GE solution, we expect traditionally bred, partially tolerant varieties to continue to be developed, alongside new chemical seed treatments that will help to bridge the gap from 2026 onwards. Currently, there is one partially tolerant sugar beet variety (Maruscha KWS) commercially available for 2024 which has mild resistance to just one of the three yellowing viruses that form the Virus Yellows complex. However, the yield potential in the absence of virus remains low compared to existing, elite susceptible varieties. BBRO has calculated (from inoculated trials in 2019 and 2020) that growers would have to sustain 62% infection within fields before such varieties become economically viable. This means that Maruscha KWS would only become economically viable at the point at which the actual incidence of VY reached is 62% (rather than the predicted incidence using the Rothamsted model).

In addition, Maruscha KWS does not yet provide an economically viable alternative as it is only commercially available in limited quantities from seed breeders, which would be insufficient to treat the anticipated infection in 2025 and as highlighted above, only protects against one of the three viruses. Hence the industry seeking a Cruiser SB derogation in 2025 as an interim, emergency solution.

BBRO variety trials suggest several breeders are making considerable progress with regards the identification of VY tolerant genetics. Two varieties of note from the 2023 "Goliath" trials displayed tolerance to multiple of the 3 yellowing viruses and yields, in the absence of disease, much closer to elite non-tolerant varieties. However, neither variety will be eligible for the sugar beet Recommended List until 2026 at the earliest, with commercial availability likely to be extremely limited at first.

Our application for 2025 includes an economic threshold again and is a limited, controlled, interim solution to ensure the sector can continue to develop the appropriate longer-term pathways of aphid and Virus Yellows control to protect the future of our homegrown UK sugar industry. Information on Virus Yellows incidence in the 2024 crop will be provided as supplementary information as soon as available. BBRO weekly bulletins are available to reference in the interim. A copy of the cross-industry Virus Yellows Pathway brochure can be found here.

1.1.2 Danger

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of Authority	**Health and Safety Executive.**
The Danger	The applicant's explanation of 'The danger' (from the application form) is presented below this 'orange box'. Previous Article 53 applications have described and evidenced in depth the danger to the production of sugar beet stemming from the yellows virus complex and principle aphid vector, the peach-potato aphid (*Myzus persicae*, MYZUPE), if control measures are not in place. The yellows virus complex consists of three dominant virus yellows (the persistent Beet mild yellowing virus (BMYV), and Beet Chlorosis virus (BChV); and semi-persistent Beet yellows virus (BYV)). There is extensive information on the impact of virus yellows on yield, and further effects by increasing a range of impurities in the storage roots, which then impact on the sugar extraction process. Detailed information has also been previously provided and assessed on the development, and historical review, of the Rothamsted virus yellows forecasting model used for predicting virus incidence (with neonicotinoid seed treatments compared to no control measures). However, the model does not now account for the recent authorised foliar spays and their contribution as a control measure to reducing aphid populations. The pre-season forecast on incidence and abundance of aphids and virus levels is provided February-March. This is based on the relationship between virus incidence and winter temperature (January and February mean temperatures being critical to the analysis), the timing and size of the spring aphid migration, crop emergence date. The experience from previous seasons and the current 2024 season, illustrates the influence that weather, at key times, has when predicting the likely threat, but also on its subsequent impact during the season. Cold weather (frost) over the winter is now a critical tool in reducing aphid populations and virus incidence. Particularly since the loss of (and lack of any new) authorised seed treatments. However, when a potential high level of virus threat is indicated on 1 March, increasingly atypical weather conditions during the season make the model predictions and outcomes in terms of actual yield losses, more complex.

	HSE recognises that the virus yellows/aphid vectors represent a threat and economic danger to the yield production of sugar beet and therefore the production of sugar. Following the withdrawal of the neonicotinoid seed treatments in 2018*, the only commercially authorised effective use for control of peach potato aphid (*Myzus persicae*) (main vector of beet virus yellows complex) was one foliar application of 'Teppeki' (MAPP 12402), 500 g/kg WG flonicamid. *('Cruiser SB' (MAPP 12958) and 'Poncho Beta' (MAPP 12076) (beta-cyfluthrin + clothianidin) Teppeki (containing flonicamid) has a persistence of up to three weeks and is insufficient under sustained pest pressure to provide protection (and subsequent yield losses) for the 12 – 16 week period (from emergence to 16 true leaf stage) when sugar beet seedlings remain most susceptible to virus yellows. At the 12 leaf stage the plants start to reach maturity and natural plant resistance develops, and by 16 leaf further control of the virus vectors is not required. This is reflected in having two foliar spray thresholds: 5 wingless aphids per 20 plants up to 12 true leaf stage, and 1 wingless aphid per plant between 12-16 true leaves. This lack of alternatives where pest populations are high and there is sustained migration into the crop has resulted in a series of Article 53 applications for both 'Cruiser SB' and additional foliar sprays to supplement the authorised 'Teppeki'. These used products containing the neonicotinoids thiacloprid or acetamiprid, and spirotetremat. Insyst (acetamiprid) has since gained on label authorisation for one spray application, and there are now two foliar spray applications available from authorised products ('Teppeki' and 'Insyst'). Foliar sprays during early establishment are inherently not as effective as a seed treatment. This is because there are practical challenges; in targeting the emerging seedlings with sufficient contact on the leaves, and on growers being reliant on favourable weather conditions at point of germination to be able to spray. In contrast, a seed treatment is more targeted as it may provide active substance as the seed germinates and moves systemically through the plant including to new growth areas. In the specific case of 'Cruiser SB', when previously authorised it could provide protection for the full period of susceptibility. The proposed rate is lower than that previously commercially authorised and supported by a full regulatory data package, however under a previous Article 53 application, evidence was provided to demonstrate effectiveness of this lower rate for up to 10 weeks. The level of persistent activity of the lower rate beyond 10 weeks is not fully evidenced. **In conclusion, the test of danger is considered met should a high risk from beet yellow viruses be predicted for the 2025 season**.

17	Danger
Please provide evidence on the nature of the 'danger'.	

As set out above, the anticipated incidence of VY in 2025, could have a significantly adverse impact on growers and the wider sugar beet industry. Without means to control such incidence of virus it poses a serious threat to the viability of the industry.

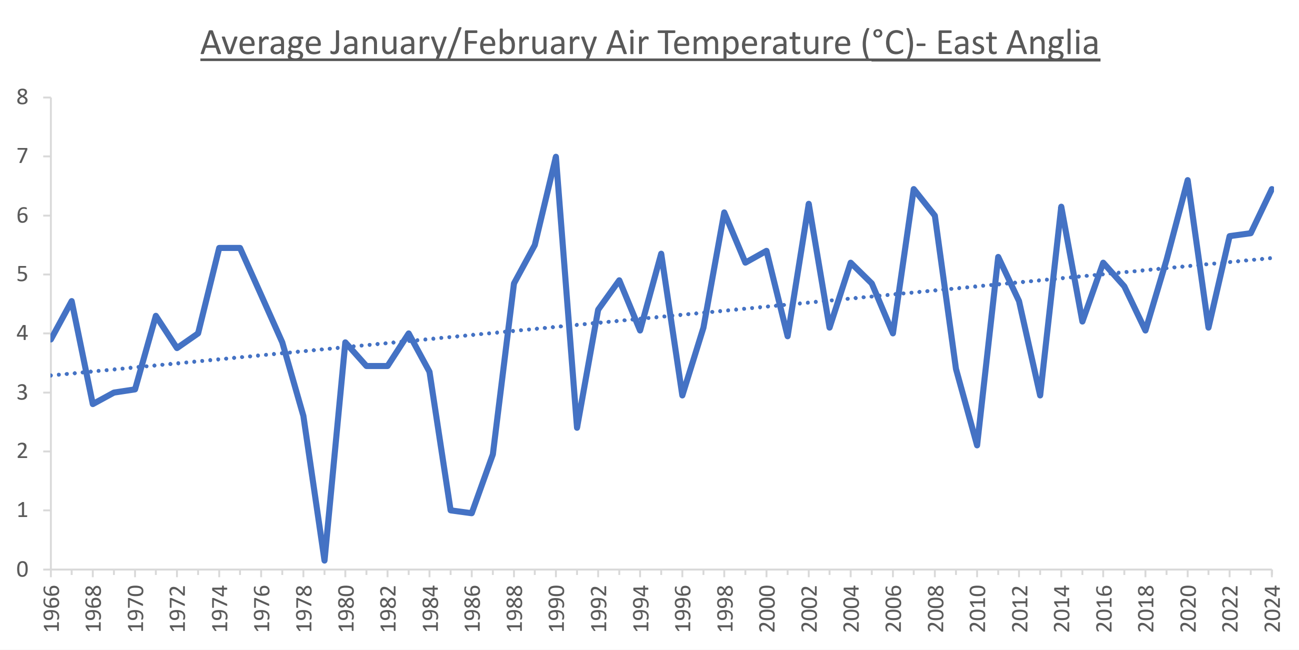
In 2020, the UK sugar beet sector experienced its worst Virus Yellows epidemic since the mid-1970s, causing a 25% loss in yield nationally. The cost to growers in the 2020 season was approximately £43m and subsequent impact to the processor of a further £24m. 38.1% of the national crop was infected with Virus Yellows. Many growers in Cambridgeshire, Norfolk, Suffolk and South Lincolnshire experienced up to 100% infection despite the use of up to four aphicide sprays applied at the BBRO recommended aphid spray threshold. Virus Yellows also compromised the BBRO R&D trials programme and eight of the 13 Recommended List trials, used to assess up to 120 entries each year to select future elite varieties for UK growers, failed independent inspections primarily due to virus infection with the loss of critical performance data.

This crisis was brought about by the extremely mild winter of 2019/20 and unprecedented aphid numbers surviving, migrating and reproducing on young beet plants throughout April to June, despite the judicious and timely use of aphicide sprays to prevent re-colonisation and limit virus spread. Affected growers saw significant yield losses of up to 50% from decreased root weights and sugar content (and in some cases as much as 80%); sugar extraction was also impacted by increased impurities caused by the virus infection.

In September 2020, a Virus Yellows Taskforce was established between British Sugar, NFU Sugar and the BBRO to accelerate and develop ongoing, innovative and novel pathways of research to limit the future impact of this disease across the UK industry. However, grower confidence is still being impacted; in 2021 the contracted area reduced by around 12%, largely due to the impact of Virus Yellows. We anticipate further consolidation if growers believe that yields are likely to be further decimated by Virus Yellows disease. 2020 is referenced here as it was a particularly difficult year for growers who saw wide scale yield losses from Virus Yellows disease as a result of the mild weather and high aphid populations. Thankfully, a colder winter in 2021 resulted in a much lower virus burden and Cruiser SB was not required.

However, milder winters in 21/22, 22/23 and again in 23/24 have led to the need for and use of Cruiser SB, via emergency authorisations, to limit the impact of Virus Yellows whilst alternative methods are identified and evaluated for commercial use.

The mean 2023/24 Winter temperature in East Anglia was the second highest on record with February the warmest on record. This provided optimum conditions for overwintering aphids, resulting in a Rothamsted forecast of 83.04%; the highest forecast incidence in the absence of controls since 2020. Steady rising temperatures in January and February (Met Office Data) since the inception of the Rothamsted model underline the ongoing threat posed by overwintering aphid populations.

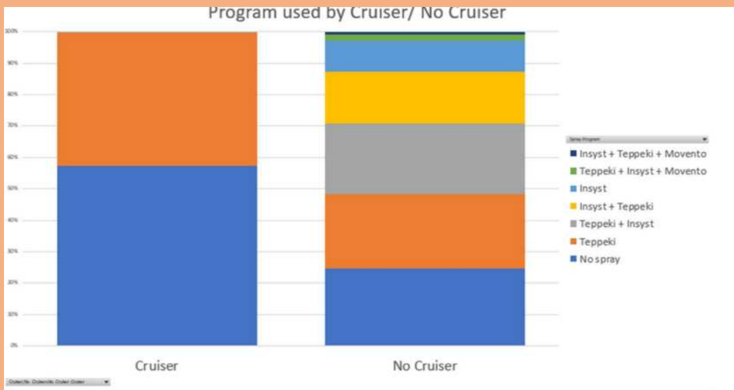


The limited incidence of Virus Yellows in the 2023 crop indicated by the British Sugar National Crop Survey does not constitute an accurate picture of the disease pressure faced by untreated crops in high pressure years. Exceptional weather and an early Spring cold snap disrupted the aphid migration, reducing aphid pressure at the critical early stages of development at which untreated crops are most susceptible to infection. A full review of aphid pressure through the 2023 season was published by the BBRO in the Beet Review.

1.1.3 Benefit and necessity of the proposed use

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of Authority	**Health and Safety Executive.**
Benefit and necessity	The applicant's description of 'The benefit and necessity' (from the application form) is presented below this 'orange box'. In previous applications, evidence has been provided on the need for further control measures in addition to the authorised foliar sprays. This is under conditions when aphid populations, migration, and incidence of virus yellows, is such that the crop cannot be protected for the full period of susceptible crop growth stages. Evidence of the benefit of 'Cruiser SB' has been demonstrated in these circumstances. In this application for the 2025 season, much of the same summary has been provided as in previous years, focussing in detail on the first three seasons (2019 – 2021) since the 'Cruiser SB' authorisation was withdrawn, including the 2020 epidemic year. Having been previously assessed by CRD, this information is not considered in detail again here. The 2022 season was not discussed in this application, and is briefly re-summarised here. As noted above the predicted virus levels (in absence of any

control measures) was 68.9%, significantly above the 19% treatment threshold set by the Secretary of State. Of the 87,300 ha drilled 71% (61,893 ha) was treated with ‘Cruiser SB’. Where ‘Cruiser SB’ was used, 42% of that crop received a single foliar spray, with the remainder not receiving any follow up foliar sprays. For the non ‘Cruiser SB’ treated crop, 34.5% received a single aphicide spray, 38% received 2 sprays, and 3.5% received 3 sprays, 24% did not receive any aphicide spray. (A balance of the spray programmes including the Article 53 authorised ‘Movento’ is provided in the graph below, originally submitted in the 2023 application). The season had exceptionally unusual weather, with record temperatures, low rainfall and drought conditions. The crop was under significant stress and it was not possible to distinguish visually between virus and other symptoms.



Spray programme by Cruiser/non-Cruiser treated crop (2022 National Crop Survey Data)

The information provided under benefit/necessity should have been appropriately updated, including a more detailed review summarising the 2023 season and explaining how the data requirements were met; and what is known at the time of submission (in June) of the ongoing experience of this 2024 season. In not doing so, this section does not help to build an understanding across all the seasons on aphid and virus pressures, and the use of ‘Cruiser SB’ and foliar sprays. Which should consider not only the epidemic year, but other years when the model prediction for treatment threshold was met.

A summary of 2023 based on available information at that time was presented last August, and HSE assessed this under the 2023/00999 application. Therefore, the HSE assessment of the 2023 evidence is provided again below and updated as appropriate.

<u>2023 Aphid Monitoring Survey</u>

For 2023 season, a data requirement was set for submission by October 2023 of information relating to the use of ‘Cruiser SB’(see 1.1.8):

- *How much ‘Cruiser SB’ treated seed was drilled and in which locations.*
- *Information on the use of all follow up foliar aphicide sprays, with details on what product was applied, timing of application (days after drilling, beet growth stage) and which relevant foliar treatment threshold was met for the growth stage. This information should be used to give an indication of the level of persistence of ‘Cruiser SB’; activity in sugar beet plants grown from treated seed.*

British Beet Research Organisation (BBRO) submitted (late August 2023) a presentation (provided in Appendix 4) summarising the 2023 annual aphid monitoring results.

A brief synopsis is provided below. It was confirmed that 'Cruiser SB' was applied to around 60% of the crop, with those not using 'Cruiser SB' describing a variety of reasons including the following crop restrictions, and control measures based around not using insecticides. The applicant did not provide, as requested, a summary of locations where 'Cruiser SB' was drilled. This information would have been helpful to compare with for example the aphid survey maps produced during the season.

The data presented come from 46 of the BBRO monitoring sites, based around the four sugar beet factories: Bury and Newark (13 sites each), Wissington (11 sites) and Cantley (9 sites). Some of the data presented are from a sub-set of 13 sites spread across the four areas. Aphids were caught and counted in yellow water pans, emptied twice a week. There were two species recorded, peach potato aphid (*Myzus persicae,* the principal virus vector) and potato aphid (*Macrosiphum euphorbiae*).

The weather again had a significant influence on sugar beet crop in 2023. The very wet weather in March delayed drilling at the sites, which was pushed back to beginning of April through to 18th May. The original model prediction was for first aphid flight on 22nd April, and then revised to 24th April, which was the first date aphids were caught at the BBRO monitoring traps.

This was followed by variable temperatures across the beet growing region, with below average temperatures towards the east and above average towards the west. The cold weather in the middle two weeks of May significantly affected aphid populations. There were 2 clear population migration peaks recorded at the 13 sites, with one early-mid May, and another mid-late June. This pattern was repeated both at the Rothamsted suction trap (slide 3) and when presenting numbers of green wingless aphids across all 46 sites (slide 7).

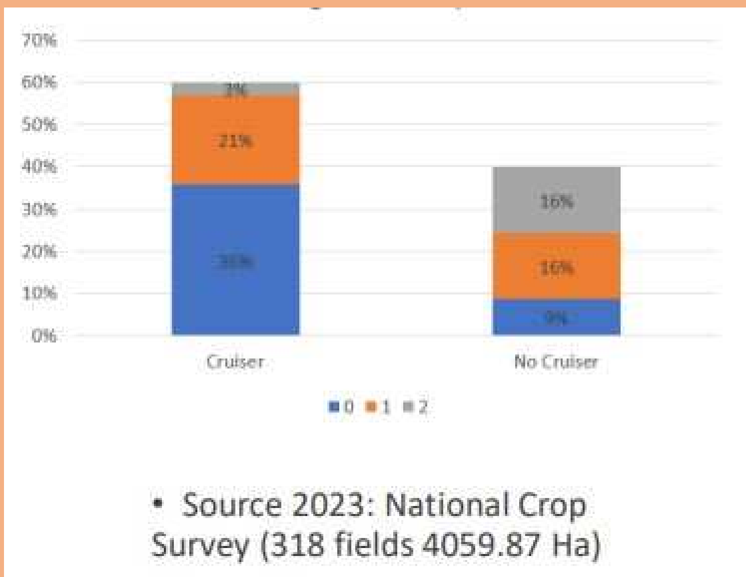
One of the sites, Sutton Bonnington, was drilled at the latest date (18th May), and proved very attractive at the early growth stages to aphid migration, with significantly larger numbers recorded than other sites (illustrative of the importance and challenge in protecting early growth). The data presented for the 13 sites therefore included information on aphid counts both with and without this site, to give a more realistic assessment (slides 4-6).

A comparison across the 4 factory areas (both the initial 13 sites and then the total 46 sites – slides 6 and 8) showed the highest % of the aphids trapped were found at the Newark sites (around 54%), with Bury the next highest (24%).

A comparison of populations was available (slide 9) from the Cruiser SB' sites (11 sites) with non-Cruiser sites (35 sites). The average number per site was 12 and 26 green wingless aphids, respectively, demonstrating the effectiveness of 'Cruiser SB' in supressing population numbers. The data do not however provide a direct comparison of effectiveness with foliar sprays, because not all of the non-Cruiser sites applied insecticides.

A summary provided (slide 10) indicated around half of the 35 non-Cruiser sites reached the aphid foliar threshold (not specified for which growth stage), of which five applied two foliar sprays and one site applied three foliar sprays (i.e. also included the Article 53 'Movento' spirotetramat). Of the 11 sites with Cruiser treated seed, only one site still reached foliar threshold and applied an additional foliar spray. (It is not possible to estimate how many of these sites would have reached threshold if 'Cruiser SB' has not been applied, but indications from the non-Cruiser sites suggests not all these sites would have developed sufficient population levels).

The following graphical summary has now been provided in this section of the application form:

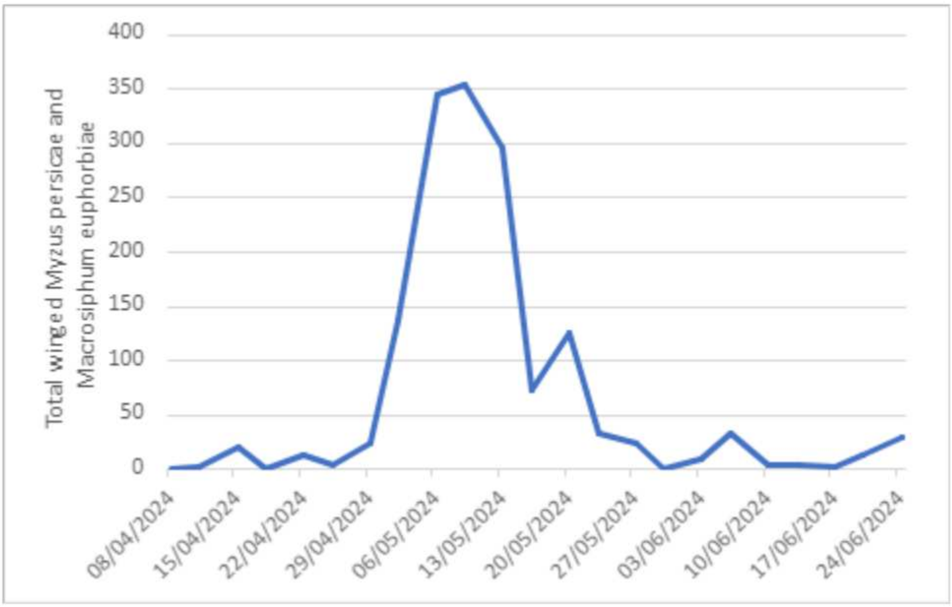


Assessments (slide 11) of aphids caught in the yellow traps indicated around 0.4% (5 of 1246 aphids sampled) were carrying beet poleroviruses (Beet Mild Yellowing Virus or Beet Chlorosis Virus). Which is a level of infection consistent with previous years.

There is also reference in the 'danger' section, and a link, to the 2023 Beet review summary (provided here below), but no summary provided. The review states that only 18 of the total 46 monitoring sites reached the foliar threshold, and suggests this was through a combination of weather, use of 'Cruiser SB', and contribution of

	beneficial insects providing aphid control. It is also noted that at a national level the use of 'Cruiser SB' significantly reduced the number of required foliar sprays (as illustrated above). The review noted the influence of temperature across the monitoring sites (and Rothamsted survey), with two distinct peaks and the greatest number recorded at the warmer Newark site. The National field survey (318 sites) in September 2023 confirmed the National virus incidence level to be 1%. This is much lower than predicted – reflecting a variety of factors including the availability of both treatments and the weather. The review also noted regional differences in the mean maximum temperature, reflecting wind patterns, also impacted aphid numbers at the different sites. Refer to Appendix 4 for the submitted aphid review 2023 survey results The above information did not address part of the data requirement above, with no details on the timing of application or beet growth stage. Whilst it notes when threshold was met, it doesn't summarise whether this was the (12 leaf stage) or later (16 leaf stage) threshold. This information was given to provide evidence of 'Cruiser SB' persistence. Previously evidence has been provided with this lower rate (than was authorised) of effectiveness up to 10 weeks. **2024 Season** No information was collated on the current 2024 season. Whilst the submission of the application at the beginning of June was too early for the National survey results, there was still very useful information available from the aphid monitoring bulletins prepared for growers Advisory Bulletin - BBRO. Again, the application provided this link (under 'special circumstances' section) but did not attempt to provide any summary. This information (up to end of May) should certainly have been summarised here. Brief extracts of key points have therefore been taken from these bulletins (in italics), to indicate aphid population development during this 2024 season, along with a summary that was provided on the 3rd July when aphid monitoring ended. The impact of the developing cold/wet conditions is highlighted in bold: • ***25th April Bulletin****:* *In week 22-28 April, aphids were detected at monitoring sites, but only reached threshold at 1 of the BBRO monitoring sites* • **8th May Bulletin**. *Many non-Cruiser SB crops are reaching aphid threshold (5 green wingless, per 20 plants)…. As of the 8th May 201 aphids (Myzus persicae and Macrosiphum euphorbiae) have been caught in the yellow water pan network. Of those, 156 have been tested for polerovirus (BMYV and BChV) and 1 has been found to be carrying polerovirus. (Due to the relationship of BYV within the aphid it isn't possible to detect this virus reliably in individuals at present). Recent warmer temperatures of 21-23°C are conducive to aphid population growth and careful management is now critical.* • **17th May bulletin**. *As of the 17th May over a 1,000 aphids (Myzus persicae and Macrosiphum euphorbiae) have been caught in the yellow water pan network. Of those, 708 have been tested for polerovirus (BMYV and BChV) and 3 have been found to be carrying virus. 1 of those testing positive was*

	from a previous catch at Yaxley, however, the other 2 were both found amongst 62 collected from a water pan based in the Biggleswade area. This shows an infection rate in that area of 3%, higher than the national average seen over previous years of less than 1%. ***This week, numbers of aphids have dropped slightly due to colder temperatures, rain and wind, however, forecasted warmer temperatures of 21-23°C will be conducive to aphid population growth****.* • **30th May Bulletin**: *As of midday on the 29th May, 1412 Myzus persicae and Macrosiphum euphorbiae have been caught in the yellow water pans. Of those, 1168 have been tested for the beet poleroviruses (BMYV and BChV). No further positives have been found since the last bulletin was sent (total of 3 positives so far this season).* ***Currently, winged aphid numbers migrating into crops are being heavily influenced (and in many cases supressed) by the current showery, blustery conditions. Consequently, over the last seven days, numbers of green wingless aphids have not generally triggered the need for spraying at most of the BBRO monitoring sites*** • **7th June Bulletin**: *In general, Cruiser seed treatment has held aphid populations. Expect Cruiser treatment to be effective for 8-10 weeks from drilling. If nearing or beyond 8 weeks check crops, especially if below the 12-leaf stage. ¬* ***Over last 7 days the generally cooler and windy weather has helped limit further aphid build up*****.** *The first virus yellows symptoms have been recorded in commercial crops in both Norfolk and Suffolk this week, reflecting aphid activity and virus infection about 4-5 week ago. To date 1535 aphids have been tested of which, 4 were found positive for beet poleroviruses.* ***Aphid numbers have dropped in the yellow water pan network*** *with no Myzus persicae or macrosiphum identified in the 30th May catch and only 6 Myzus persicae identified so far in the 3rd June catch.* • **19th June:** *The cool, wet and windy weather over the past few weeks has helped to limit aphid build up. We are therefore not expecting the aphid numbers to build hugely in the coming week. As of 9am on 19th June 1575 aphids have been tested for virus. 4 found positive for beet polerovirus (BMYV and/or BChV). No positives found since 13th May. The number of aphids caught in the YWP network remains low, with a total of 4 Myzus persicae in the 10th June catch and 3 in the 13th June.* ***This is due to the unseasonably cold and wet weather, that has effectively halted aphid population growth***. • **19th June**: *As of 9am on 19th June 1575 aphids have been tested for virus. 4 found positive for beet polerovirus (BMYV and/or BChV). No positives found since 13th May. The number of aphids caught in the YWP network remains low, with a total of 4 Myzus persicae in the 10th June catch and 3 in the 13th June. This is due to the unseasonably cold and wet weather, that has effectively halted aphid population growth* • ***3rd July****: The aphid threat has subsided, and BBRO monitoring completed for this year. However, there are still a few pockets of aphids being observed, particularly in the Newark factory area, and any late drilled crops would be worth watching. As of 9am on 19th June 1575 aphids have been*

	tested for virus. 4 found positive for beet polerovirus (BMYV and/or BChV). No positives found since 13th May. The number of aphids caught in the YWP network remains low, with a total of 4 Myzus persicae in the 10th June catch and 3 in the 13th June. This is due to the unseasonably cold and wet weather, that has effectively halted aphid population growth • **SUMMARY - 3rd July (BBRO monitoring finished)** *Aphid numbers picked up slightly thanks to the warmer, drier weather last week with a total of 29 caught in the 24/6/24 YWP catch. A total of 1554 aphids (Myzus persicae and Macrosiphum euphorbiae) were caught in the BBRO yellow water pan network. All of these aphids were tested via qPCR and 4/1554 were found positive for the beet poleroviruses (BMYV and/or BChV). These aphids were caught at: • Yaxley 25/4/24 • Biggleswade 7/5/24, 9/5/24 • East Ruston 13/5/24 (As a control all aphids were also tested for the closely related non-beet virus 'Turnip yellows virus', 1414/1554 aphids were found positive for TuYV). Fig 1: Graph clearly shows the peak of aphids in the first week of May and the impact of the following cooler weather. Yellowing in crop Whilst there are a few small pockets of virus yellows showing, there are a number of other potential causes for yellowing in the field.*  Fig 1: Graph clearly shows the peak of aphids in the first week of May and the im the following cooler weather. **Post application submission** - The applicant has now recently provided the 2024 aphid monitoring site data (26th July), (provided in Appendix 4), in a series of graphs. This provides some more detail in the breakdown between sites and winged/wingless aphids. Slide 10 demonstrates the effectiveness of the 'Cruiser SB' applications, with lower total green wingless aphid numbers (mean 2.8) compared to non-Cruiser treated sites (mean 10). And the same pattern when expressed as average per site (slide 11). Particularly useful is the comparison of 2023 and 2024 season (slide 12) which shows the impact of the weather on the total weekly counts. In 2023 the population continued to rise and peaked in mid June (around 300 weekly total) . Whereas this year, the cold weather in May stalled the developing population (when weekly count was between 100-150), which then rapidly declined. This was reflected in the insecticide use, with no 'Cruiser SB' sites using foliar

	sprays (slide 13). And of the 34 non-Cruiser sites, 22 sites applied one foliar spray (Insyst) and 2 sites applied Insyst followed by Tepekki. This was also reflected in the beet yellows virus, where of the 1546 tested (*M.persicae* and *M. euphorbiae*), only 4 individuals carried BMYV and/or BChV). Interestingly, as noted in the July summary, nearly all individuals (95%) carried Turnip yellows virus (TuYV). Information on the National incidence level is not yet available. **OVERALL SUMMARY** The 2023 aphid monitoring data illustrated similar issues as in previous seasons. As previously discussed the long established model provides accurate predictions on the **potential** virus yellows threat and provides accurate predictions on the date of first aphid flights. For example reflected in the correct decision not to treat seed with 'Cruiser SB' in 2021 following critical periods of cold weather in the previous winter; and equally predicting the epidemic of 2020, reflecting the mild winters with build up of aphid populations/virus levels, and subsequent favourable weather during that season. However, the experience across the seasons also demonstrate that where the model is predicting a virus risk higher than the agreed treatment threshold, the actual development of virus yellows during the season and potential yield losses is interdependent on a number of factors. And in particular the seasonal weather patterns, where evidence suggests 'atypical' conditions may occur more frequently, and their impact on crop/aphid interactions. The vulnerability of the crop is very much linked to conditions at time of drilling. Delays in drilling, or slow growth, leave the crop at the susceptible early growth stages, potentially coinciding with peak aphid migrations (as demonstrated at the one 2023 site not drilled until mid-May). However the 2023 data also indicate, as in previous seasons, there is significant variability across sites, both in the level of populations reaching foliar spray treatment thresholds, and the number of sprays used. In 2023, whilst the trigger for treating seed with 'Cruiser SB' was met, around only half of the non-Cruiser treated sites reached foliar treatment thresholds. With only 6 out of 17 sites receiving foliar sprays. The 2023 review also acknowledged the number of sites where aphid numbers reach threshold levels is dependent on a number of factors. Including the use of wider integrated measures, which can combine to reduce aphid populations, background virus levels, and seasonal levels In 2024 the impact of adverse weather conditions on aphid populations and associated virus transmission was also demonstrated. Developing population levels were halted by cold, wet weather that ultimately meant there was little threat, virus incidence, and limited required treatment with foliar sprays. Therefore although the model predicted virus levels above the treatment threshold set by the Defra Minister, ultimately it can be argued that 'Cruiser SB' treated seed was not required. The benefit and effectiveness of 'Cruiser SB' has been previously demonstrated, and was so again in the 2023 season in providing effective control and reducing the required number of foliar sprays. Authorised foliar sprays provide important levels of control, combined with integrated measures, in reducing population levels to below treatment thresholds. This combination may not be sufficient as a seed treatment at very early growth stage, particularly under high, sustained aphid population levels. However, in most seasons there is a complex interaction of factors, both regionally and locally, that influence aphid populations, virus incidence and ultimately any economic yield impacts. Whilst the applicant provided estimates of economic losses incurred during the 2020 epidemic year, no information has been provided on the National yield (and any losses) during subsequent years. (Accepting that in

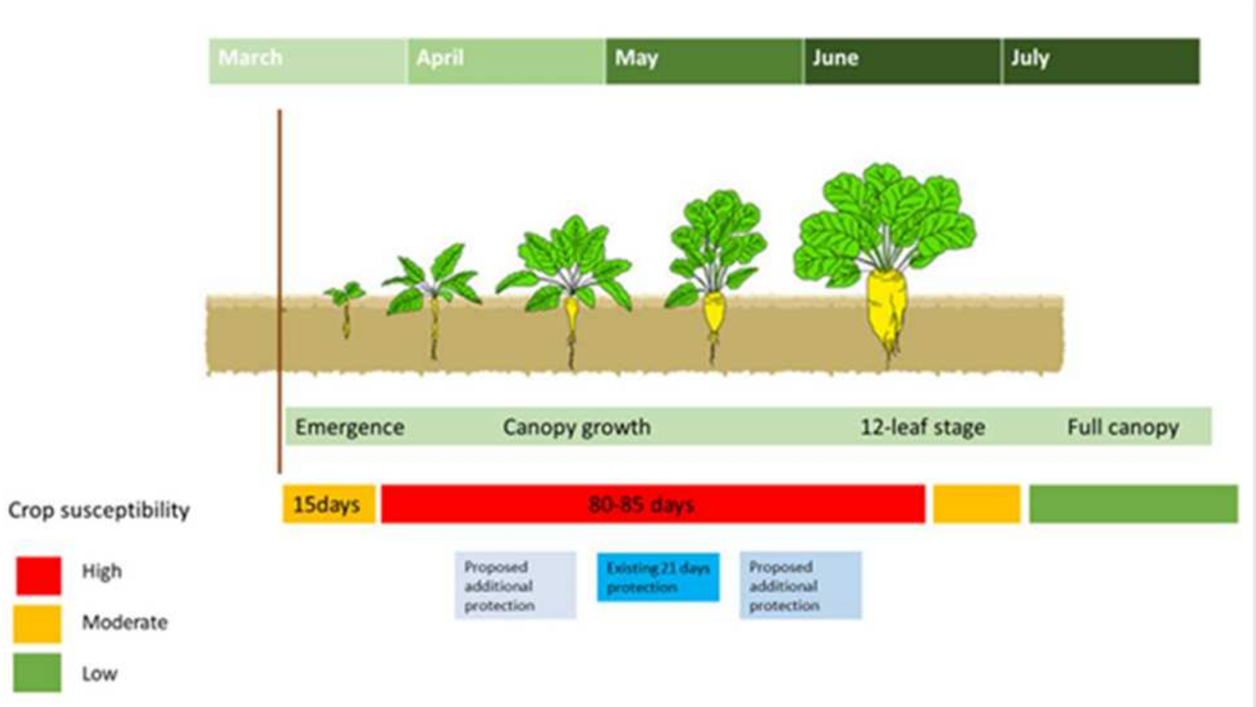
	2022 the extreme dry conditions put the crop under significant stress, and losses through virus yellows could not be differentiated). This is the important consideration when considering meeting the tests for the need of the Article 53. Particularly the case for 'limiting' the authorisation, and when the weakness of the model is that it compares use and costs of neonicotinoids against an assumed 'untreated' with no other available treatments. It has not been able to factor in a comparison against control provided by the more recently authorised foliar sprays. The 2023 HSE assessment for the repeat application of 'Cruiser SB' during the 2024 season noted that *For any future Article 53 applications further refinement is required to support the case for limiting any 'Cruiser treatment by targeting the distribution treated seed into areas identified to be at highest risk. Using where possible the experience of previous seasons, and outputs from the Rothamsted project researching further regional refinement of the model*. Evidence to consider this point, alongside understanding more the contribution of the various available control measures, were reflected in the 2024 authorisation data requirements (see 1.1.9). • *The report on the BBRO funded Rothamsted project (started autumn 2019) examining the further refinement and regionalisation of the model. In addition, the applicant is requested to discuss how the outcomes of the project will be used in any future applications to further refine proposals for 'Cruiser SB' to be restricted to areas of higher risk.* • *Where possible, consideration should be given to estimate the contribution of each control option to overall yield. This should include use of the authorised foliar sprays (products containing flonicamid and acetamiprid), and any authorised use of 'Cruiser SB'. Or consideration of generating yield data comparing different treatment regimes in specific studies. BBRO should discuss with HSE the feasibility of generating data to address this point.* The data submission deadline for both of the above is November 2024, and therefore no further information is as yet available. BBRO and HSE have agreed that consideration of the yield point will be met through BBRO trials. **In summary, 'Cruiser SB' provides sufficiently effective control up to the 12 leaf susceptible growth stages. And where pest pressures justify, the trigger for treating with 'Cruiser SB' is considered more effective than the foliar sprays against young plants. Where 'Cruiser SB' has been used it also reduces the requirements for any further sprays. However, the degree of benefit in comparison with using foliar sprays alone or in integrated programmes, in terms of overall crop yield is not fully demonstrated.** In addition, noting that a significant proportion of growers chose not to use 'Cruiser SB' treated seed even when available (in the 2023 and 2024 season 40% crop was not treated), it is important that growers have specific guidance collating all the available information on the alternative integrated control measures. **Resistance management of 'Cruiser SB' if used with foliar sprays** Peach potato aphid (*Myzus persicae*) has developed resistance historically to the various insecticide classes/modes of action, including organophosphates, carbamates and pyrethroids. The long-term monitoring of various resistance

	mechanisms, led by Rothamsted Research (an Agricultural Research institution primarily funded by government), confirms the consistent high level occurrence of pyrethroid resistance at the target site (kdr and super-kdr forms, see above under 'danger'). The pyrethroid products authorised in sugar beet are therefore not considered as effective alternatives. BBRO advice to growers is to '*Avoid using pyrethroid foliar insecticides during the season. Aphids are widely resistant to these and BBRO work has shown that the use of these reduce the number of beneficials, therefore increasing the aphid numbers*' (Sugar Beet Reference Book, 2022, BBRO). It is also noted that grower contracts with British Sugar state '*Decisions should be based on BASIS qualified agronomists/growers supported by BBRO data'*. Therefore it is expected that growers would not use pyrethroid sprays to control *M. persicae*. *M. persicae* is therefore a high-risk pest with resistance management strategies required. These strategies need to reflect the multitude of potential routes of exposure across both arable and horticultural host crops. When neonicotinoids were first authorised as seed and then foliar treatments, proactive statutory restrictions on number of applications were introduced to limit exposure. Following the withdrawal of imidacloprid, thiamethoxam, clothianidin, and most recently thiacloprid, the only remaining neonicotinoid is acetamiprid (as foliar sprays). Overall therefore the exposure of *Myzus* to neonicotinoids is very significantly reduced. (New actives in the same mode of action group (4), where cross-resistance could be anticipated are in very different situations of use: sulfoxaflor (protected uses); and an amateur product (flupyradifurone)). *Myzus* resistance cases for neonicotinoids have been reported in Southern Europe, firstly on the primary host plant (peach), and then spreading to populations on other horticultural crops. And more recently one case was confirmed in Belgium. UK individuals are clones with no sexual reproduction, which occurs in populations in Southern Europe. Therefore the development and establishment of resistant populations in the UK is more related to selection pressures in mainland Europe. The establishment of these migrating populations arriving in the UK depends on the fitness of the clone to UK conditions. The continuing monitoring and research programmes in the UK confirm that at present UK clones remain fully susceptible and therefore use of thiamethoxam under an Article 53 authorisation would remain effective. However, whilst exposure to neonicotinoids may be much reduced, acetamiprid is a critical mode of action with *M. persicae* having such a wide host range. There are limited insecticide options on most crops now across horticulture/agriculture, with few available modes of action left. The stewardship plan specifically states not to use 'Insyst' (acetamiprid) as the first foliar spray where 'Cruiser SB' has been used, to avoid consecutive neonicotinoid treatments. Because 'Insyst' is now authorised it is considered appropriate to take the same approach as outlined above. The following 'other specific restriction', as in previous years, would appear on any authorisation notice: *Where 'Cruiser SB treated seed is used, if subsequent foliar sprays are required, the first foliar spray must be a flonicamid (IRAC 29) containing product. It is not permitted to spray 'Insyst' (containing acetamiprid – IRAC 4a) as the first foliar spray.*

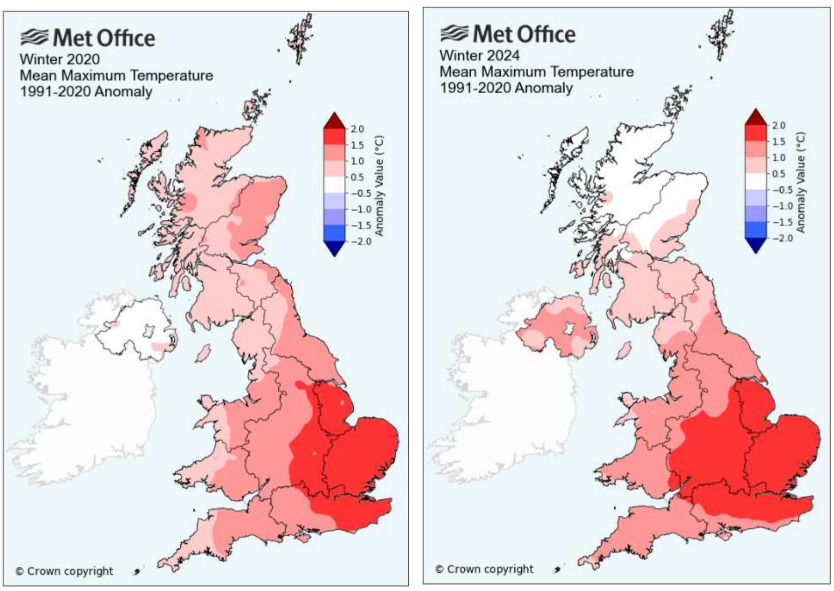
Please provide evidence on the benefit and necessity of the proposed use in terms of addressing the identified danger.

Why a seed treatment emergency authorisation is requested for 2025 to prevent another potential Virus Yellows epidemic.

Without additional protection from sowing until the 12-leaf stage (the period when beet is most susceptible to colonisation by aphids and virus infection) there currently remain limited alternative control options for 2025 to prevent an increased threat from virus-carrying aphids in sugar beet.



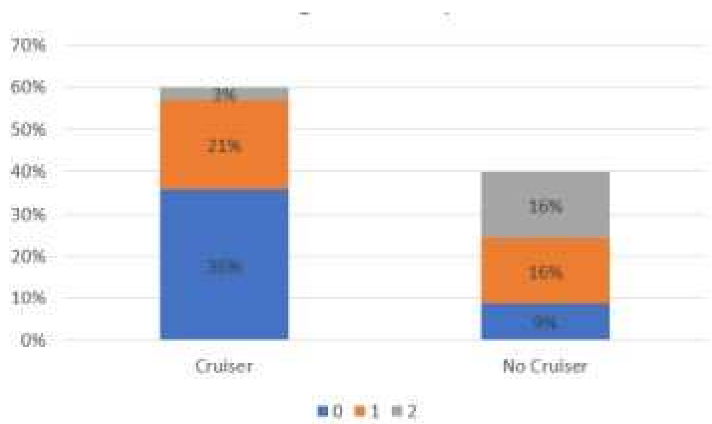
Recent mild winters, with few significant frost events, are leading to the development of continuing high pest pressure situations for spring-sown crops such as sugar beet.



Without a cold winter or the additional insecticidal seed treatment protection for 2025 the UK sugar beet sector will again be at high risk of widespread Virus Yellows infection. Previously, seed treatments provided effective and targeted aphid control, for up to 12 weeks from sowing, until the onset of mature plant resistance.

In 2020, 2021, 2022, 2023, and 2024 growers and agronomists have had some success (albeit limited in 2020) in controlling aphids using aphicide sprays. BBRO 2020 aphicide trials in Suffolk and Lincolnshire showed that aphicide sprays provided control, but treatments lacked persistence commercially, **particularly at early growth stages** when large numbers of aphids were invading crops, leading to high levels of virus infection and significant yield loss. It is difficult to know how treated seed would have fared in 2020 given the unprecedented aphid levels experienced. However, we do know that seed treatments will protect this critical early period of growth and will decrease the overall need for foliar sprays (which clearly had to be applied frequently under the sustained immense aphid pressure of 2020).

The experiences from 2022, 2023 and 2024 provide a valuable insight in building a picture as to the value of these treatments and foliar sprays in future years. For the current sugar beet crop, data will be available by October 2024 and will be submitted to CRD as supplementary information. 2024 data will be particularly valuable in evidencing the efficacy of Cruiser SB with 40% of the UK crop untreated and forecast aphid pressure similar to that of the epidemic year of 2020. However, it is important to note that fields with untreated seed are often interspersed with Cruiser-treated fields and that wholly untreated fields are likely benefit to an extent from herd immunity. A perhaps more telling indication of the efficacy of Cruiser will derive from the Virus Yellows pressure suffered on the continent in the absence of any treated seed, notably in France where forecast incidence was similar to that of the UK for the 2024/25 season.



• Source 2023: National Crop Survey (318 fields 4059.87 Ha)

% number of sprays (Cruiser/No Cruiser) using national split. (2023 National Crop Survey Data)

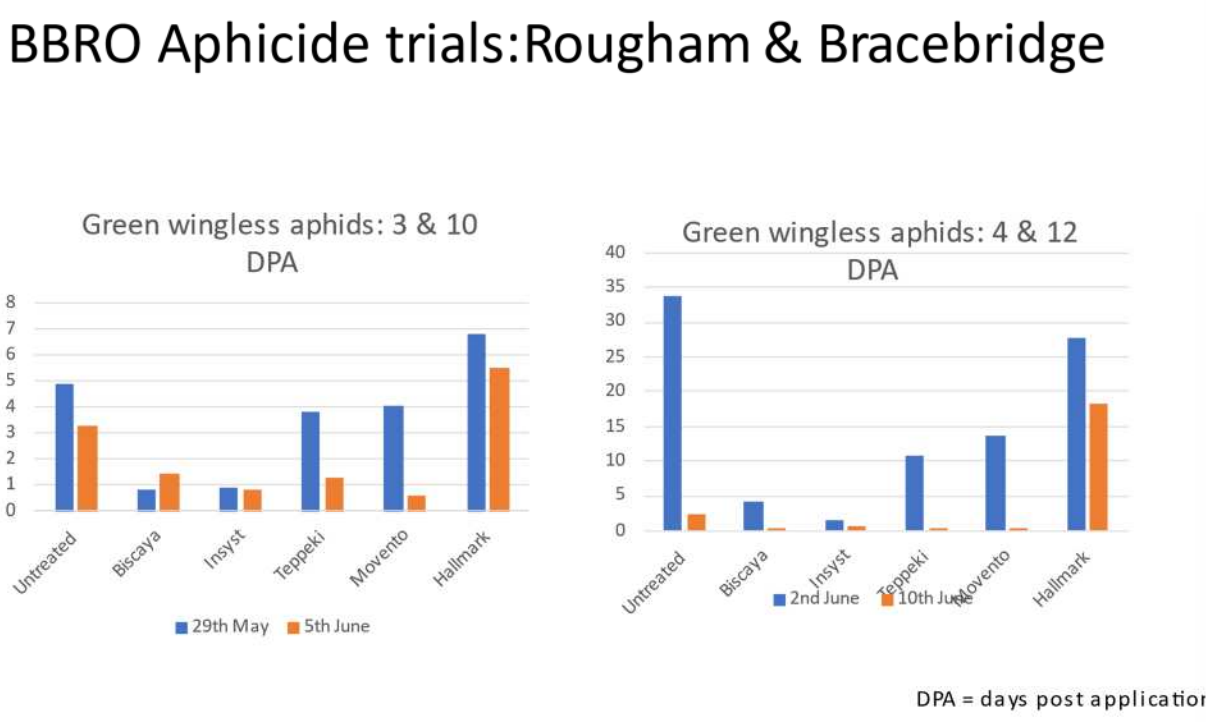
Through the limited and controlled use of Cruiser seed treatment, diligent crop monitoring and strict adherence to science led spray thresholds the industry has successfully demonstrated a judicious Virus Yellows control strategy.

Following the 2019 season (first season without neonicotinoid seed treatments being fully approved), Virus Yellows was observed in 55% of crops inspected and the national incidence was 1.8%. In 2020, Virus Yellows was observed in 99% of crops surveyed and the national incidence was 38.1%. In 2021, Virus Yellows was predicted to be observed in 8.3% of the crop (without any pest management); in reality it was 2% because appropriate aphicide sprays were still used where the threshold was met. However, there are now increasing sources of infection available from which aphids could acquire virus and infect the 2024 crop.

As highlighted, in 2021 the trigger for the use of thiamethoxam was not reached due to the impact of the previous cold winter, demonstrating the limited and controlled use of the product. Cruiser SB will only be used if the Rothamsted forecast triggers its use, as was the case in 2024.

Given the limited efficacy of authorised aphicide sprays such as Teppeki/Afinto and Insyst when crops are small, the only way to effectively protect sugar beet plants through the early stages of development is the use of Cruiser SB. As noted by the HSE in relation to the application for 2024, the permitted use of aphicide sprays (limited to one spray of Teppeki/Afinto, followed by one spray of InSyst) would be insufficient under sustained pest pressure to provide protection from April – early July, i.e. the period when sugar beet remain most susceptible to Virus Yellows (and subsequent yield losses). Seed treatment guarantees targeted protection for the whole plant (early stage of development plants are very difficult to target with sprays).

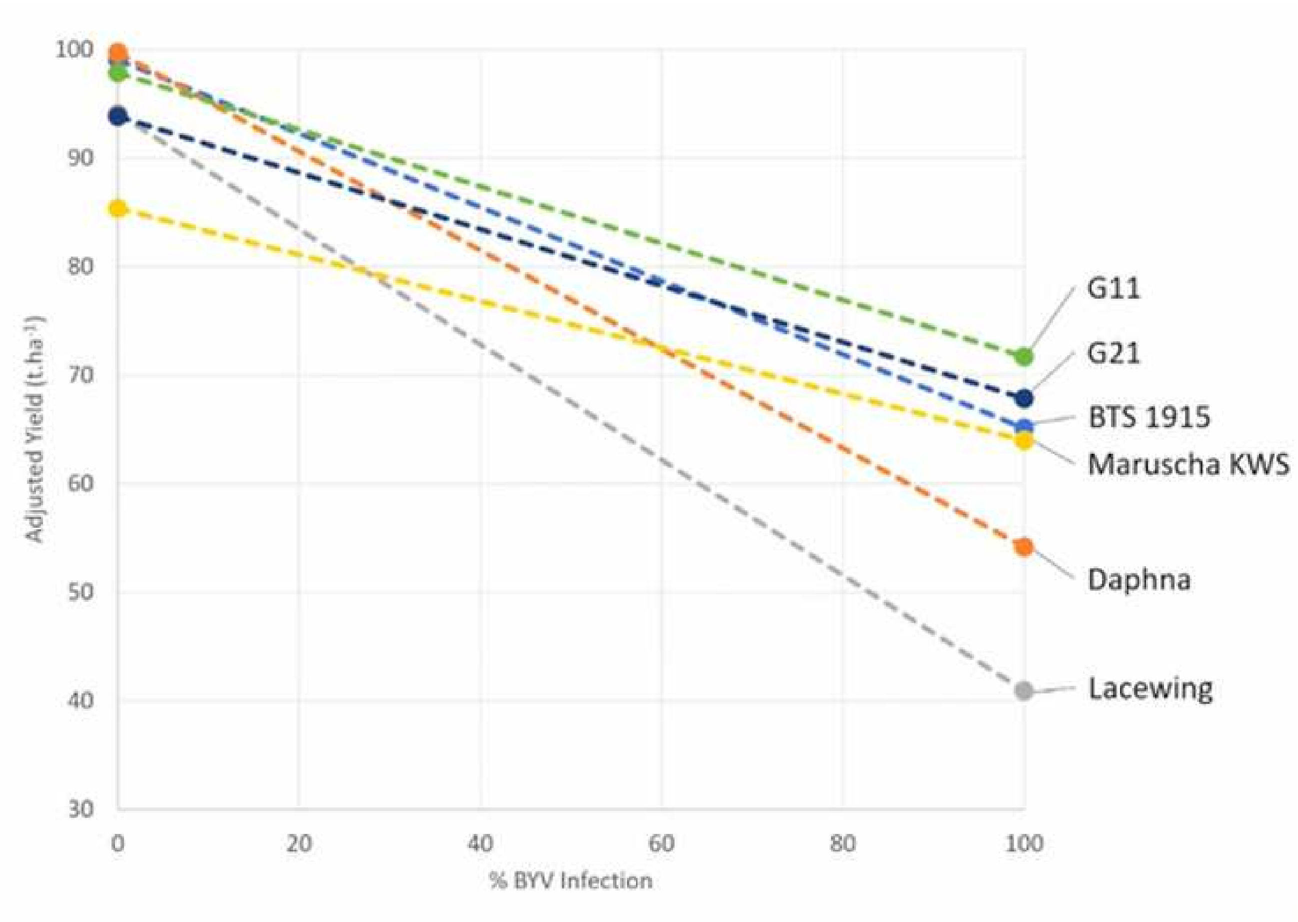
Pyrethroid treatments (e.g. Hallmark) are available for pest control in sugar beet but these sprays are known to have a negative impact on beneficial insects that will naturally limit aphid build up as seen in BBRO trials in 2020 (see below). As a result, the BBRO does not recommend the use of these treatments for sugar beet.



Trials from 2020
Over 80% of peach-potato aphids are also resistant to these pyrethroid treatments which would antagonise aphid control if used for this purpose, as seen in BBRO trials and commercial crops in 2020.

Some progress is being made with the development of virus tolerant sugar beet varieties and there has been one partially tolerant BMYV sugar beet variety (Maruscha KWS) commercially available since 2023. BMYV is one of the three yellowing viruses that form the Virus Yellows complex (BMYV, BChV and BYV). However, the yield potential of Maruscha KWS (in the absence of BMYV) is relatively low compared to existing, elite (susceptible) varieties. BBRO has calculated (from inoculated trials in 2019 and 2020) that growers would have to sustain 62% infection within fields before Maruscha KWS is economically viable. It is not a solution for the immediate future but a positive development.

There has been further progress in developing conventionally bred seed varieties with increased resistance to Virus Yellows. Delepanque (Strube) have announced their first conventionally bred VY tolerant (BMYV and BYV) variety in Europe – [redacted] However, in trials this shows a 25% yield drag, and it is not currently available commercially. We understand there is also a pipeline variety (2024/25) showing progress against all 3 viruses with reduced yield drag (in absence of disease). This remains a core part of our Virus Yellows Pathway. BBRO continue to assess new genetics that breeders are bringing to the UK market and there are some encouraging signs that significant progress is being made.



Selected Results from BBRO Goliath Trials in 2023

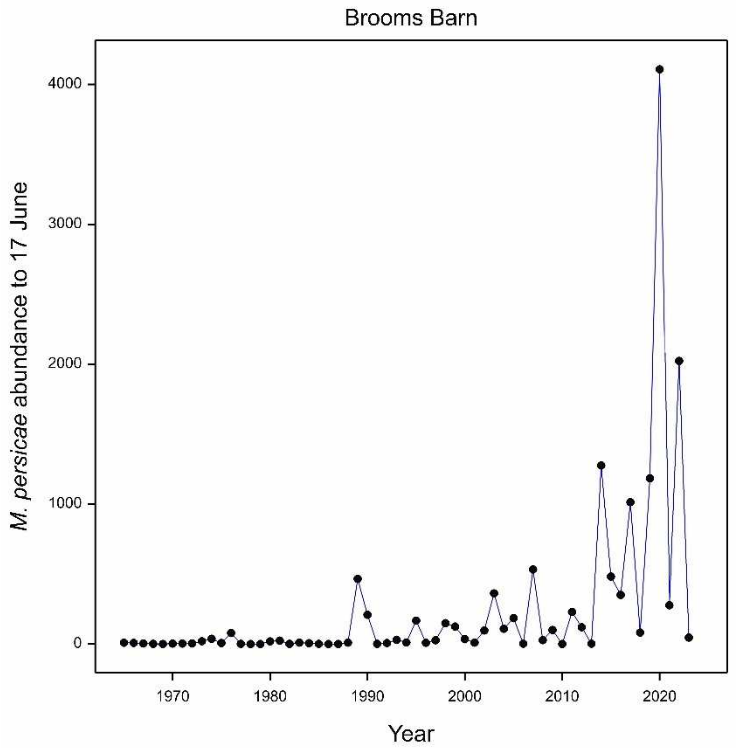
Results from BBRO's Goliath trials in 2023 show coded varieties G11 and G21 yield drags significantly decreased when exposed to 100% infection compared to conventional named varieties BTS 1915, Lacewing and Daphna.

Sources of infection and the number of Virus Yellows carrying aphids are likely to increase each year unless there is significant cold weather, despite the adoption of wider integrated pest management strategies to limit their build-up. Growers strive to follow BBRO best practice to ensure sources of infection are kept to a minimum.

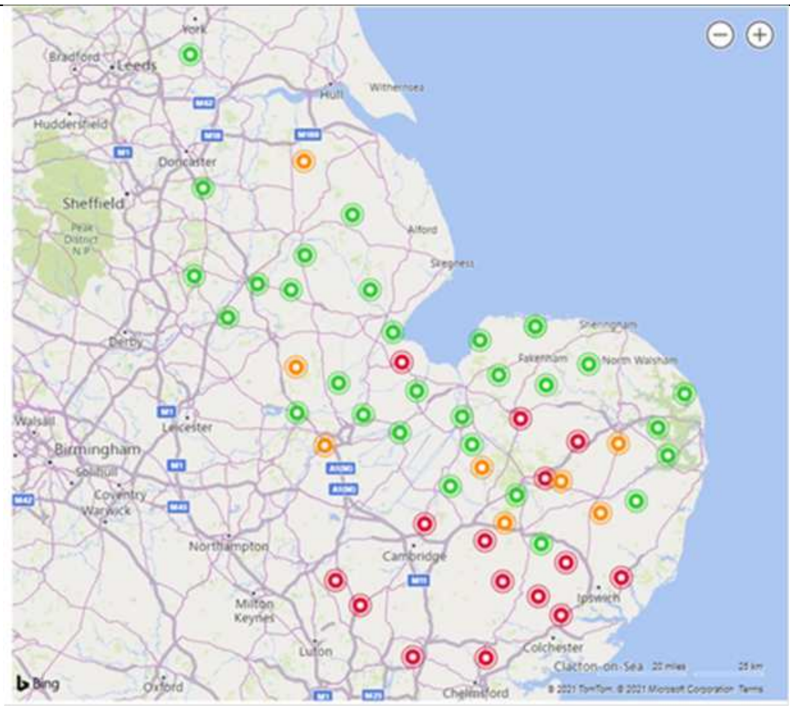
The 2020 season clearly highlighted the limitations of current control strategies without an effective replacement for the neonicotinoid seed treatments. The 2020 virus situation was unprecedented, following the exceptionally mild January and February. Initially, this was reflected in the Virus Yellows forecast issued by BBRO showing that 72-95% of the crop could become infected with virus without any control strategies applied. The warm, dry spring further compounded the situation and encouraged an early and sustained migration of large numbers of aphids, particularly *Myzus persicae*, to build up in spring crops such as sugar beet.

Agronomists and growers were finding the first crops above aphid threshold (one green wingless aphid per four plants up until 12 leaves) from early April and in many cases when plants were only at the cotyledon growth stage or the first pair of true leaves. In BBRO aphicide trials green wingless aphid numbers reached up to 40 per plant, and, in May, reports of over 100 per plant were received from agronomists in commercial crops. Consequently, growers were forced to use a range of sprays (including those products gained through emergency approval), and depending on if and when thresholds were reached, used between 0 and 4 sprays. The mean number of sprays applied, as determined from the British Sugar specific field survey, was 2.5. The wide variation in the number of sprays applied reflects the fact that growers were highly active in monitoring aphid numbers field by field and only applying foliar insecticides where appropriate, in line with thresholds. Aphid populations are typically heterogenous in their distribution and strongly influenced by many factors such as wind strength and direction, topography, surrounding crops and field boundaries.

The 2020 Rothamsted Insect Survey data from the suction trap at Broom's Barn, Suffolk also highlighted the unprecedented numbers of winged aphids compared to the previous 58 years. Almost 4,000 *M. persicae* were trapped by the reference date of 17 June 2020.

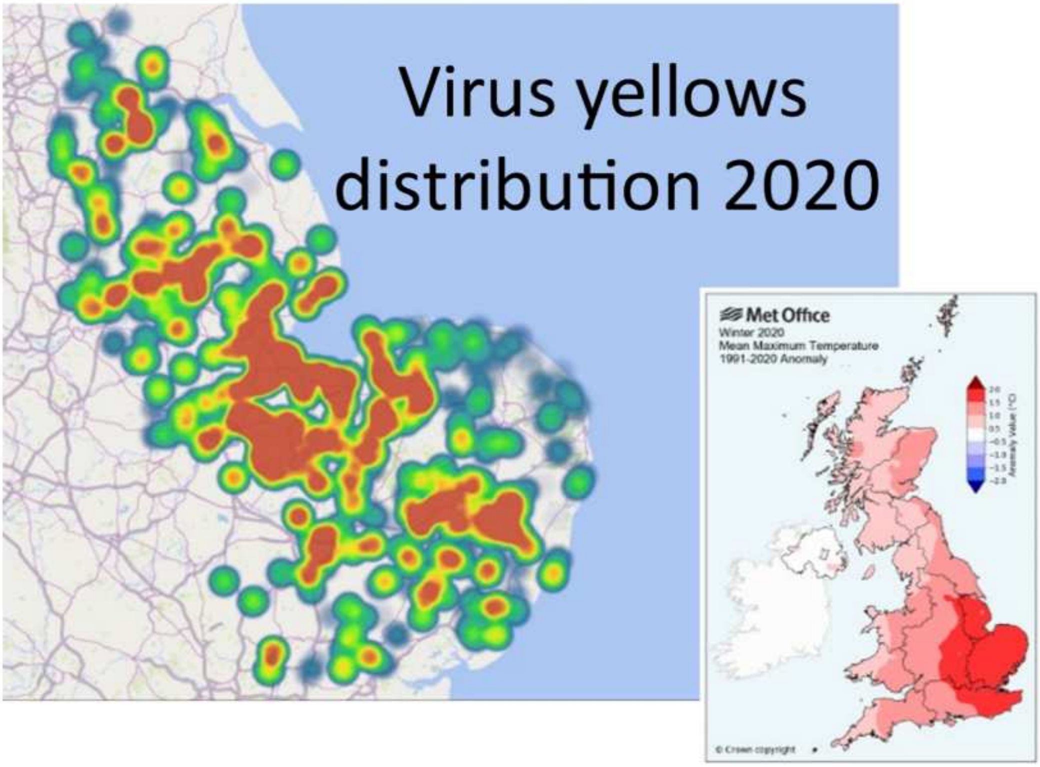


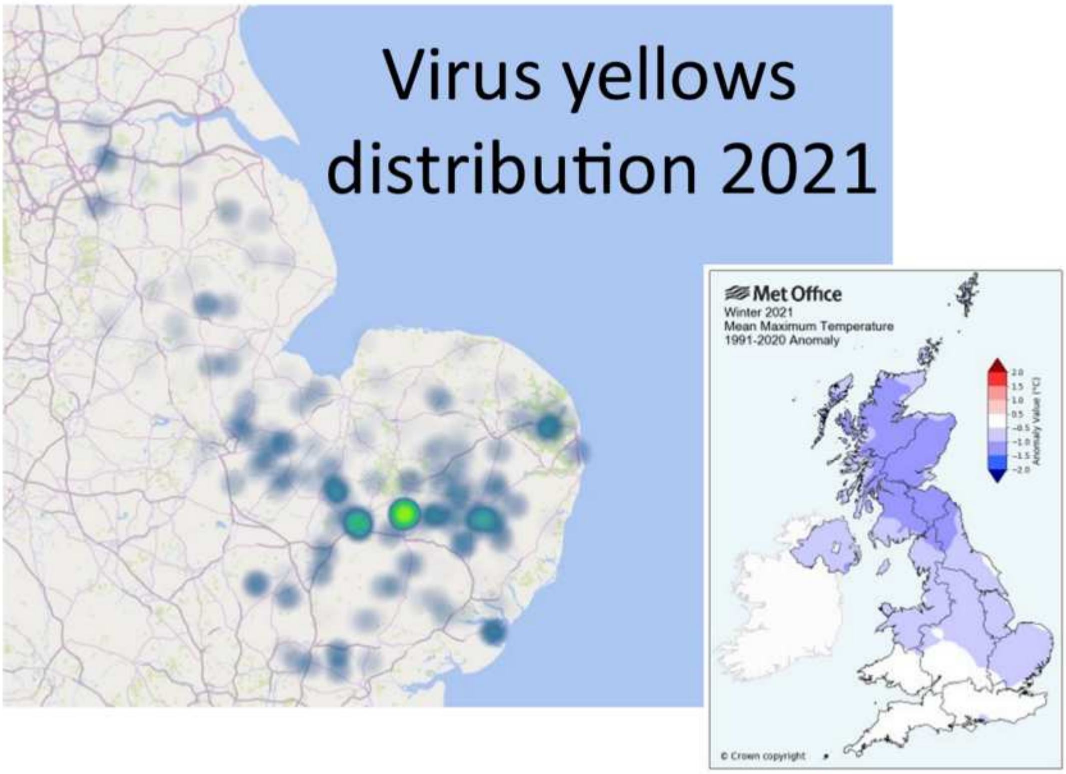
BBRO selected 51 sites across the sugar beet growing region for the 2020 yellow water pan and aphid monitoring survey. Although COVID-19 affected the ability to collect some of these data, sites were visited by British Sugar Contract Managers or agronomists twice a week (April to July), to photograph and empty the yellow water pans. Selected samples were then sent to the BBRO laboratories to confirm aphid species and to determine the infectivity of any *M. persicae* caught. Additional aphid counts were also made of the number of winged and wingless aphids on 2 sets of 10 plants within each field and this information was used to trigger spray programmes at these sites (e.g. Lawshall, Suffolk example below). This information was uploaded onto the daily aphid risk maps published on the BBROplus website (see example below) and included in the regular BBRO information bulletins that were sent to all growers and agronomists.



2020 Aphid Survey Map

Due to the early and sustained aphid pressure in 2020, the first virus symptoms were observed by mid-June 2020. Widespread symptom development continued throughout the summer. British Sugar undertook the annual Virus Yellows survey at the end of August/early September 2020 across 484 sites (the annual Specific Field Survey). Nationally 38.1% of the crop was infected with virus although infection levels ranged from 7% (Cantley) to 61% (Wissington) between the four factory areas. A comparison of the incidence and distribution of Virus Yellows in the UK from 2020 to 2021 is highlighted below. Beet yellows virus (BYV), the most damaging of the yellowing viruses capable of decreasing yields by up to 50%, also appears to be the most prevalent of the three yellowing viruses.





Currently, for 2025, the UK industry only has full authorisation for one foliar spray of Teppeki/Afinto and one spray of Insyst available for aphid control. Sprays are valuable, but not sufficiently successful, in controlling unprecedented numbers of aphids as seen in 2020 as set out below under "Other Reasonable Means of Control".

Grower vigilance, good on-farm hygiene, monitoring and targeted treatments will all be key to protecting the 2025 crop from virus infection and yield loss. The industry is committed to disseminating these messages to growers to minimise infection spread.

The UK industry submits this Cruiser SB emergency authorisation application as a limited, short-term solution, to ensure the sector can continue to develop the appropriate longer-term pathways of aphid and Virus Yellows control to protect the future of the UK sugar sector.
This application is made to protect the English sugar beet crop from Virus Yellows in 2025.

1.1.4 Other Reasonable Means of Control

Name of Authority	**Health and Safety Executive.**
Other Reasonable Means of Control	The applicant's description of 'Other Reasonable Means of Control' (from the application form) is presented below this 'orange box'. Alternative chemical control options There are no alternative authorised PPP seed treatments for use against aphids. There are two active substances authorised for use as foliar insecticide sprays on sugar beet. The accepted foliar treatment threshold is 1 aphid per 4 plants up to 12 true leaves; 1 aphid per plant between 12 and 16 true leaves. Flonicamid (e.g. 'Teppeki' (MAPP 12402), containing 500 g/kg flonicamid (WG)), is authorised for one foliar spray, controlling both *Myzus persicae* and black bean aphid (*Aphis fabae*, APHIFA). The protection given by flonicamid lasts up to 21 days. A single foliar spray of 'Teppeki' will be insufficient for a season where there is sustained aphid pressure. In addition to flonicamid, growers also have the option of using 'Insyst' (M19873) containing 200g/kg acetamiprid which is also authorised for a single application in sugar beet against *Myzus persicae*. It is considered that in a "normal" year 'Teppeki' and 'Insyst' would provide sufficient control. But, as explained above, in years where there is a higher risk (indicated by the threshold trigger being met), their combined two foliar sprays are considered insufficient for the period of susceptible growth. The only other authorised foliar sprays are actives from the pyrethroid group, which are ineffective against *Myzus* because of widespread resistance. Whilst pyrethroids may still be used on sugar beet to control other foliar pests (where again there is no alternative) their use has a detrimental impact on natural predators and BBRO advise against this. (Refer to resistance section 2.2.3 for additional information)

In 2022 and 2023, growers who chose not to use 'Cruiser SB' also had the option to use a single application of 'Movento' (M18345) against *Myzus* in sugar beet under an Article 53 authorisation. A condition of use was the Movento could only be applied as a third spray (following the use of the authorised products) if the threshold was met. Movento contains 150 g/l spirotetramat and is authorised for use against a range of insect pests including *Myzus persicae* in a range of crops including brassicas (Brussels sprout, broccoli/calabrese, cabbage, cauliflower, collards and kale Whilst in 2022, 3.5% of the crop not treated with 'Cruiser SB' received the third Movento spray, in 2023 the information provided suggests no untreated crops required a third spray (due to the weather related decline in aphid populations and virus risk). In 2024, the option of having a third foliar spray if required was met through an Article 53 authorisation for a second foliar application of 'Insyst'. (Although because of the season conditions, this was not required).

<u>Alternative non-chemical control options</u>

The current application provides an update on the ongoing work looking at more integrated approaches, and BBRO actively promote a variety of measures to reduce virus presence. (These are included in the draft stewardship plan). The main strategy remains the research into developing resistant varieties. Maruscha KWS as discussed in the application has only partial BMYV tolerance, but this variety has an adjusted yield rating of 92.1, being the lowest rated of the varieties available to order for the 2023 season. (The remaining varieties yield ratings range from 97.3 to 107.1).

Further progress has been made in developing other commercial varieties, with a BMYV and BYV tolerant variety [redacted]. But again there are yield penalties, and this variety is not yet commercially available. Other varieties (see long term solutions) are also in development. Recently breeders identifying VY tolerant genetics, have developed one trial 'Goliath' indicating tolerance to all three yellows viruses. But this will be at least 2 years before it may make the recommended varieties list.

Novel alternative methods being investigated include weed buffer strips to attract aphids out of the crop, and/or further encourage natural beneficial arthropod populations to assist in controlling aphid populations. The mechanism of the transmission of viruses means that whilst natural predators have a role in aphid control, they will not be fully effective in preventing transmission which occurs in a few seconds (non-persistent viruses) or minutes (persistent viruses) of feeding.

Another technique being looked at is under-sowing with barley. Although primarily used to reduce wind erosion of the soil it was noted that it also appeared to have reduced virus levels and this is being further investigated.

Physical barriers such as using plastic covers are impractical because of economics, disposal and environmental concerns.

Plant hygiene remains extremely important as part of integrated measures to reduce infection foci, and also manipulating drilling date to sow as near to 1st

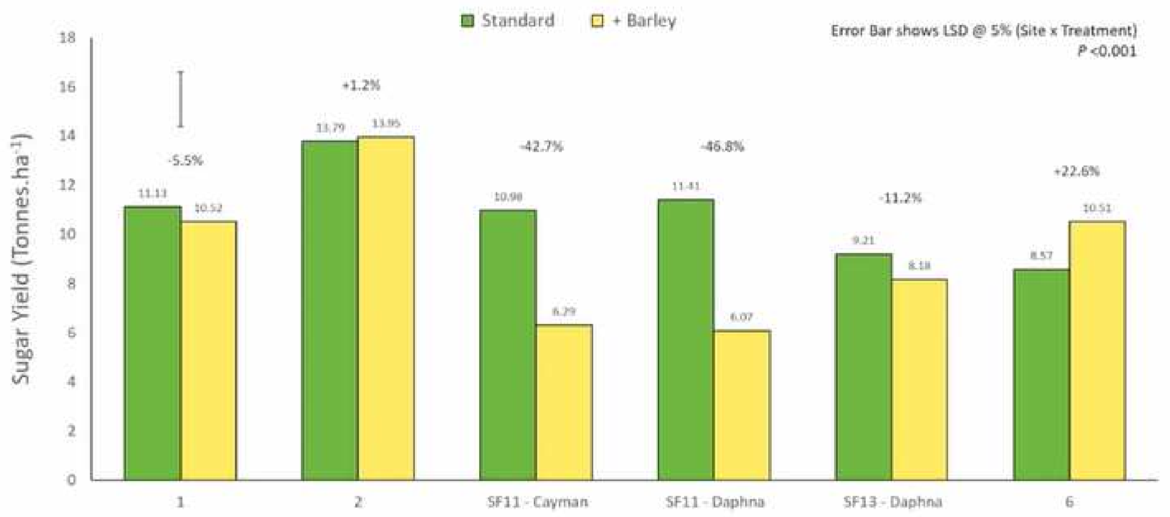
	March (taking care to avoid bolters and early flowering) so plants are older and less attractive and susceptible when winged aphid migration starts. However, the virus does have other host plants which could remain as a source and attaining a 1st March sowing date may not be practical for many reasons. Due to the fact that both *Myzus* and the virus have multiple-hosts, both crop and non-crop, the success of measures by individual growers to impact local population levels will be subject to other factors outside their influence. For example, rotations in other locally grown crops, and non-crop hosts, vicinity to other host plants, control measures in those other crops. All of which can lead to migration into the crop, and build-up of *Myzus* populations. Therefore, whilst all the non-chemical methods are very important (and their contribution is actively promoted by BBRO each season), when combined there is still insufficient, consistent measures to prevent significant spread of virus when conditions favour prolonged aphid population development during the susceptible stages of the crop. **The case for lack of reasonable means when the trigger threshold is met, both PPP and non-PPP, is considered met.**

18	Other Reasonable Means of Control
Please detail whether there are any other potential means of addressing the danger.	

We refer above to some of the reasons why no other reasonable means are available, and detail these further below.

In 2020 growers and agronomists had access to Teppeki, and after the approval of emergency authorisations in April and May, Biscaya (now withdrawn), Insyst and/or Gazelle. However, many growers had limited success in controlling the unprecedented numbers of aphids when these products were applied, especially at early growth stages. BBRO trials showed that these products provided control but lacked persistence commercially when under sustained and prolonged aphid migration as experienced in 2020. The only foliar sprays available to growers in 2022 and 2023 were Teppeki/Afinto, Insyst and Movento (via an EA for non-Cruiser SB treated crops).

There are currently no effective alternative non-chemical control options for virus-carrying aphids in sugar beet. However, growers are increasingly interested in trying additional novel solutions to limit virus spread such as the use of weed buffer strips within or around crops to encourage beneficial insects or to ‘push’ aphids away from beet plants or by introducing beneficial insects directly (such as lacewings) into fields. In 2020, the use of under sown barley in beet to prevent wind-blow damage appeared to have decreased virus infection in some fields too by affecting the attractiveness of beet as a host for aphids at an early growth stage. See: undersown-opinions.pdf (bbro.co.uk). BBRO is currently investigating this concept further, but crop growth stage is critical for success as has been highlighted by EU researchers too.



Variety	Jura		Cayman	Daphna	Daphna	SMART Janninka
Barley sow date	18/03/2020		23/04/2020	23/04/2020	23/04/2020	10/04/2020
Barley seed rate	50Kgs/Ha		55Kgs/Ha	55Kgs/Ha	55Kgs/Ha	60Kgs/Ha
Sugar Beet drill date	17/4/20 & 20/4/20		24/04/2020	24/04/2020	24/04/2020	12/04/2020
Barley kill date	09/06/2020		End May/mid June	End May/mid June	End May/mid June	21/05/2020

Following interesting work in New Zealand, BBRO are looking into the use of endophyte grasses to boost natural resistance in the sugar beet crop. There has been good data to support this theory for soil borne pests and the industry is interested to see if this can be replicated on aphids. Field trials were conducted in 2022 and are being repeated in 2023.

Winged *M. persicae* cannot be prevented from entering sugar beet crops and feeding on individual plants and covering plants with plastic as a barrier is uneconomic. Therefore, crops are potentially at risk from virus infection every year until a long-term solution is found through the sustainable pathway being delivered by the 'VY Taskforce' referred to earlier.

The BBRO provides advice to the industry on minimising the development of initial foci of infection and subsequent secondary virus spread. The BBRO provides such advice to the industry via bulletins, real-time information from the plant clinic and current trials, conferences, workshops and open days to adopt relevant, commercially available and appropriate integrated control options. These options include removing sources of infection and the use of cultural practices to help reduce, but not eliminate, the risk of infection.

Growers are advised to sow early, where possible after the 1st March and when soil/weather conditions allow while balancing the risk of plants bolting and then flowering and not developing a storage root if they experience too many cold days during the spring), to achieve maximum yields. Older plants are known to be less physiologically attractive to aphids (Williams, 1995). Therefore, by sowing early there is a greater chance that plants will have gained increasing mature plant resistance before peak aphid migrations. Later sown crops are more susceptible to infection as winged *M. persicae* are attracted to the yellowish-green leaves of younger sugar beet plants and these will not have reached the appropriate growth stage for inherent mature plant resistance. The reason for the resistance of mature plants is still unclear but is the subject of ongoing investigation and PhD research.

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Hauer, M., Hansen, A.L., Manderyck, B., Olsson, A., Raaijmakers, E., Hanse, B., Stockfish, N. Marlander, B. (2016). Neonicotinoids in sugar beet cultivation in Central and Northern Europe: Efficacy and environmental impact of neonicotinoid seed treatments and alternative measures. Crop Protection 93, 132-142.
LMC International (2017). The economic impact of a ban on neonicotinoids on the EU sugar beet sector. 1-10.
Williams, C. T. (1995). Effects of plant age, leaf age and virus yellows infection on the population dynamics of *Myzus persicae* (Homoptera: Aphididae) on sugar beet in field plots. Bulletin of Entomological Research 85, 557-567.

1.1.5 Limited Use

Name of Authority	**Health and Safety Executive.**
Limited Use	The applicant's description of 'Limited Use' (from the application form) is presented below this 'orange box'. Any use of 'Cruiser SB' in 2025 would , as in previous years, be limited by using an agreed threshold restricting use only to when the predicted virus incidence provided by the virus yellows forecasting model is above the level of this threshold. In addition use would also be restricted to sugar beet sown under contract to British Sugar for processing to sugar. Other beet crops, such as red beet and fodder beet, would not be treated neither would sugar beet grown for bio-fuel production or for use in anaerobic digestion. As mentioned in previous considerations and applications, the pre-season forecast is provided by Rothamsted Research and the model's output is based on a number of factors: • incidence and abundance of aphids and virus levels (using Rothamsted and BBRO/British Sugar monitoring from the previous season); • the relationship between virus incidence and winter temperature (January and February mean temperatures being critical to the analysis); • the timing and size of the spring aphid migration (as recorded by the suction traps managed by the Insect Survey group at Rothamsted Research); • crop emergence date and • the use of insecticides, including neonicotinoid seed treatments since their first introduction (Qi et al 2004). The ECP gave consideration of this model in June 2022 when it was indicated that "*the underlying model is not constructed to quantify the effects of management interventions"* and that "t*he use of the Rothamsted model as a mitigating factor in justifying authorisation is the responsibility of Government"*

	The model provided predictions for virus incidence with or without pest control measures and this is validated at the end of the season by the observations made in the nearly 500 sites used in the British Sugar National crop survey. Historically, there has been a close correlation between the prediction of virus incidence where available pest control (PPP) measures would be used, and the actual incidence observed over the last 50+ years. The model was adapted to reflect changing PPP from OP/pyrethroids to use of neonicotinoid seed treatments. The prediction is now based on assuming no control measures, it is no longer possible to include a figure with pest control measures since the withdrawal of neonicotinoids. It is acknowledged that this is an over-estimate, with the relatively recent authorisations of one spray of flonicamid , and one spray of acetamiprid, there is an insufficient robust evidence base as yet to adapt the model. BBRO have however funded a Rothamsted project to refine the model onto a more regional basis, with the project due to end in autumn 2024 and a data requirement to summarise the findings was included in the 2024 authorisation. It is acknowledged that the validated model allows control in deciding when to treat seed with 'Cruiser SB'. This is evidenced by the experience of the 2021 season, where 'Cruiser SB' was authorised for use should the threshold trigger been met. A threshold of 9% virus incidence was used as the trigger for use. The cold winter experienced in 2020/21 meant that the trigger was not reached in the forecast and no seed treated with 'Cruiser SB' was sown in 2021. This demonstrates therefore that the model can provide effective 'control' on the use of 'Cruiser SB' where pest pressures and virus incidence are predicted to be below a justified treatment threshold. Growers retain the option when placing their seed order to request seed treated with 'Cruiser SB' (if available) or not. However, , the accuracy of predicting ahead of the season what levels of aphid/ incidence levels will actually develop is more complex. Because of the influence subsequent seasonal weather conditions will have on both crop and pest. Calculations of the economic threshold for the trigger are based on the current crop price, cost of 'Cruiser SB' seed treatments and the economic impact assessment of virus yellows (**Qi et al., 2001**) where the cost of crop damage for the grower is greater than the cost of seed treatment. For 2023/2024 contracts the agreed price was increased from £27 to £40/tonne. Again a Defra economic analysis was undertaken, estimating a break-even point of 62%https://www.gov.uk/government/publications/neonicotinoid-product-as-seed-treatment-for-sugar-beet-emergency-authorisation-application/defra-economic-analysis-evidence-report-on-the-impacts-of-virus-yellows-on-sugar-beet-production. The decision to authorise set a treatment threshold of 63%. The model prediction was for 67.51% incidence, and therefore the use of 'Cruiser SB' was triggered for 2023. The first aphids were predicted from 22nd April. The application form indicated this was around 60%, and in the recent update provided on the annual aphid monitoring (see 'benefit and necessity' above), this figure was confirmed. As described above, the monitoring data indicate that 'Cruiser SB' sites suppressed aphid numbers by around half that found

	in non-'Cruiser SB' sites. However, only half of the latter reached treatment thresholds for foliar sprays. The National aphid monitoring 2023 results indicated virus incidence was 1%. This in part reflects that the treatment threshold in the model does not incorporate other control measures, including the authorised foliar sprays. As well as the influence of weather. In this 2024 season the treatment threshold was set at 65%, and the model predicted 83.04%. As described, because of the unusual cold weather, aphid populations crashed and whilst the National aphid monitoring figures does not yet include virus incidence, the aphid samples indicate less than 0.5% carried the virus. The 2025 sugar price has yet to be agreed and therefore at this point no treatment threshold has been proposed. Any seed treatment would be delayed allowing the model prediction to be provided on 1st March, even though this delay may have a yield penalty as a result of drilling taking place later than the 1st March optimum drilling date. It is possible that a significant proportion of growers may be choosing not to select 'Cruiser SB' treatment because of; uncertainties on when treated seed will be delivered, planting later than optimum time and practicalities of planting restrictions. Overall figures from past seasons suggest the proportion of sugar beet seed treated with 'Cruiser SB' is declining (and therefore another limitation on use). With both 2023 and 2024 suggesting 60% of the crop was treated. The stewardship scheme is specific to crops grown from seed treated with 'Cruiser SB'. It is an important point that those growers not using 'Cruiser SB' and relying on foliar sprays and other measures are as fully informed as possible on optimising integrated programmes. Because the model has been validated by long term comparisons with actual experience each season and has been further refined to reflect changes in control practices to using neonicotinoid seed treatments, it is recognised that the use of this treatment threshold has provided an appropriate mechanism to limit the use of 'Cruiser SB' only when high levels of virus are predicted in the forthcoming season's sugar beet crop. No other European country, including those issuing Article 53 authorisations for sugar beet neonicotinoid treatments in the last few years, has as far as HSE can determine, such a model that allows this limitation. However, as noted, the comparison is still based around neonicotinoid use against no other control measures. And does not factor in the contribution to reducing aphid populations with the combination of now available authorised foliar insecticide sprays and other integrated measures. it is also clear from the 2023 aphid monitoring survey (and previous seasons), that even when the threshold is met, there is significant variation around the factory areas on the population numbers and degree to which

	other control measures may be needed. For example, significant proportions of untreated crop have received no foliar sprays, or only one foliar spray. And there is a complex number of factors, critically the weather conditions during the season that impact on the relationship between crop/aphid population and eventual virus incidence/yield reductions. If an authorisation is granted for 2025 season, then as for the 2024 season, it will include an additional restriction limiting the planting density to a maximum of 115,000 seeds/ha (based on the environmental and consumer exposure assessments). This has previously been reflected in the agreed stewardship plan. In conclusion, the test of limited is met primarily through setting as a condition of any authorisation that the seed is only treated if the appropriate treatment threshold is triggered. And, as recognised, the UK sugar beet industry is the only country to have a long established (over 40 years) validated model. However, for the purposes of meeting an Article 53 requirement for limited, it is noted to be an over estimate because it compares neonicotinoid to no treatment and cannot account for the contribution of the foliar sprays now authorised, along with other integrated measures. It is also recognised that the data gathered in the last few seasons indicates there can be significant variations in aphid population pressures, virus transmission, and other local conditions that impact risk factors. A project looking to refine further regionally has been conducted (but not yet reported). In addition, whilst the model can accurately predict low risks (based on the impact of cold weather in the preceding winter), it is clear and understandable that it is more problematic as a tool by itself in limiting a 'Cruiser SB' authorisation. Because of the subsequent impact of the seasonal conditions. **For these reasons the test of limited is considered not met. The applicant would need to consider for any future authorisation how the use of 'Cruiser SB' may be further limited, building on the experience and knowledge gained in the last few seasons of use.**

19	Limited Use
Please provide details of how the use of the product will be limited.	

As in previous years, to address a potential emergency facing the UK industry in 2025, the UK sugar beet sector is committed to the following proposed limitations and controls on use, should the authorisation for Cruiser SB be granted, and the threshold for use met. The industry is committed to the responsible use of plant protection products.

Sugar beet is precision sown which avoids soil surface contamination. We also acknowledge the previous HSE analysis in 2018 regarding Hanslope soils flow exceedances if late winter/spring is wet. If sugar beet was sown after the drain flow period of approximately 30th April on these soil types it would be economically unviable for those growers with this soil type. **Consequently, the industry is proposing to maintain the reduced rate of thiamethoxam applied from (the normal) 60g to 45g per 100,000 plants to lower potential risks. This would be to ensure that any use would be limited and controlled to the amount necessary.**

Our approach highlighted below is based on forecasting and threshold trigger points for seed treatment application. The successful trigger mechanism in 2021 showed IPM in practice – the industry did not treat sugar beet seed with Cruiser SB as the Rothamsted Virus Yellows forecast predicted low levels of infection for the 2021 season.

In addition to the robust trigger mechanism, if Cruiser SB is used, the industry is committed to multiple measures, outlined below, with the specific intention of reducing the level of risk to pollinators.

Outline of the proposed limited use
Under the proposed limited use, the neonicotinoid treatments would be applied at any of the following treatment sites (may be subject to change):

[redacted]

This is a significant undertaking by the sugar sector, as the neonicotinoid seed treatment would only be used if deemed necessary (as described below). Once again, it is hoped that this commitment will be seen as a step-change to developing a greater integrated approach, using the Virus Yellows model to rationalise seed treatment usage and moving away from prophylactic application, while alternative approaches are developed, verified and registered for the crop.

If seed had to be treated, the exact amount required would be known from the seed ordering process between growers and British Sugar by the end of 2024/ early 2025. This is anticipated to be around 60% of the crop (based on 2024 uptake) because of the serious threat that Virus Yellows complex poses to the impact and viability of the entire UK sugar beet sector. However, no further additional seed would be treated for any fields that may have to be resown in 2025 due to poor weather conditions affecting germination and/or crop establishment.

Once treated and packaged, seed would be delivered to growers from March 2025 onwards. A direct consequence of this approach is that the seed could be delivered and sown later than recommended (usually the crop is sown from 1st March onwards once temperatures are at or above 5C). Delaying sowing due to later on-farm seed delivery, especially into April, will decrease the biological yield potential of the crop, affecting both grower returns and British Sugar income. A yield loss of 6, 8, 13, and 21% is experienced for every week of delay throughout April (BBRO communications). However, the industry is prepared to accept any delay to using Cruiser SB notwithstanding this yield penalty, given the absence of any other reasonable means to ensure the crop is protected against the more damaging Virus Yellows infection.

As in previous years, to determine whether neonicotinoid seed treatments would need to be used on the 2025 crop, the Virus Yellows forecast will be produced by Rothamsted Research and a decision will be taken as to whether a seed treatment should be applied to the crop based on the outputs of the model available on 1st March 2025. Due to the maritime climate of the UK, and the small footprint of the UK sugar beet crop within the eastern counties of the UK, the Virus Yellows model usually predicts, when conditions are unfavourable, that the whole cropping area would be at economic risk from virus infection. BBRO funding continues to support collaborative projects with Rothamsted Research to further refine and develop the model.

This decision has been taken on the strength and robustness of the model outcomes since its first introduction in 1965 and its value to provide an integrated pest management approach, although, a consequence of this approach, as already highlighted, is seed delivery could be delayed. However, if the UK experiences a cold winter in the months of January and February 2025 and the Virus Yellows forecast **is below the threshold determined by DEFRA** then these treatments will **not** be applied. **Therefore, under these conditions, neonicotinoids would not be used under the emergency authorisation in 2025 by the sugar beet Industry, even if approved by DEFRA.**

Calculations of the threshold should be based on the current crop price, cost of neonicotinoid seed treatments and the economic impact assessment of Virus Yellows (**Qi et al., 2001**) where the **cost of crop damage for the grower is greater than the cost of seed treatment**. The 2025 economic threshold for use of neonicotinoid seed treatments for Virus Yellows will be agreed in due course.

1.1.6 Controlled Use

Name of Authority	**Health and Safety Executive.**
Controlled Use	The applicant's description of 'Controlled Use' (from the application form) is presented below this 'orange box'. Sugar beet for sugar production is grown under contract to British Sugar. If used 'Cruiser SB' will be applied at one of a small number of established seed treatment houses (one in UK). Grower seed orders are made six to eight months before drilling commences and determine the sugar beet variety and the different seed dressings applied. The decision to order seed treatments (where available) depends on growers' own risk analysis and previous on farm experience. If 'Cruiser SB' is authorised, seed fulfilling orders where the 'Cruiser SB' option is chosen, cannot have the final treatments applied until after the model forecast is available on 1 March. If the threshold is met only sufficient seed to fulfil the orders will be treated with 'Cruiser SB'. Therefore, if there is any replanting necessary due to failure of the crop to establish there would be no option to use 'Cruiser SB'. Supply of the treated seed is managed as part of the contract with British Sugar. The applicant has advised that the pelleting process ensures 100% traceability of the product. Pelleted sugar beet seed is precision sown and covered, usually at 2.5 cm depth, 18 cm apart and 50cm between rows (to achieve a final BBRO recommended field population of 100,000 plants per hectare). Spill kits will be provided and instructions for dealing with spillages are detailed in the draft stewardship scheme. BBRO provide detailed and extensive advice on all aspects of sugar beet growing and provide exhaustive information on crop management, Integrated Pest Management (IPM) measures, monitoring aphid populations/virus incidence throughout the season, as well as technical advice and plant clinics. Should an Article 53 be authorised for 'Cruiser SB', 60 sites will be monitored for infectivity and resistance status (15 sites in each of the 4 factory areas).

	A draft stewardship plan for 2025 has been submitted, including the range of communication that will be undertaken, reinforcing the messaging at timely points in the season. As with previous years, specific guidelines are produced for drill operators, various IPM measures to promote beneficial insects, along with advice on how to manage flowering weeds within the cropped area (not around the crop, for example in field margins) and requirements with respect to following crops. Should an authorisation be issued, this stewardship scheme will be reviewed by HSE to ensure it reflects the final conclusions which lead to any authorisation. **All of these combined measures, are considered robust in supporting growers and meet the test for controlled use.**
	Consideration of the stewardship scheme with respect to reducing risk to bees and other non-target arthropods The stewardship includes mitigation relating to the area in which the crop is grown (the sugar beet crop itself and subsequent crops grown in the same area). No mitigation is proposed specifically to protect bees and other non-target arthropods foraging in off-crop field margins (noting that HSE did not previously identify a concern for off-field non-target arthropods and only updated the risk assessment for risk to honey bees). Sugar beet plants are harvested before they flower and do not generally guttate, given this and the standard grower practice to control weeds within the cropped area, the sugar beet crop is considered by HSE to be unattractive to bees. This is further reinforced by the proposed requirement in the stewardship scheme for growers to use BASIS recommended weed control strategies to ensure that flowering weeds are controlled within the cropped area. A further proposed mitigation measure (again relating to the cropped area only) was to restrict the following or subsequent crops grown in the same area to only non-flowering crops for 32 months after drilling a sugar beet crop treated with 'Cruiser SB'. It is noted that due to the lack of chronic toxicity data on adult forager honey bees, as well as residues in pollen and nectar, it was not possible to determine if this is an appropriate interval. Post ECP advice in September 2021, modifications to this list of flowering crops were made to better accommodate agri-environment schemes. Whilst bees foraging on guttation fluid in following crops is also a potential route of exposure, there is a lack of information regarding which crops guttate, under what conditions and to what extent. Data are, however, available on the concentration of the active substance in guttation fluid formed on maize seedlings. These data were used in the risk assessment carried out by HSE, and indicate that there is a margin of safety between the exposure and the toxicity endpoints for acute exposure to adults and larvae, however due to the lack of chronic toxicity data for adult honey bees, it was not possible to conclude. Due to the lack of knowledge regarding the likelihood of occurrence of guttation fluid in other crops as well as the associated concentration and use by honey bees, it is not possible to conclude as to the likely risk to honey bees.

	Mitigating to protect bees and other pollinators foraging in flowering field margins is more difficult (noting that HSE's off-field assessment only covered honey bees). The stewardship scheme encourages establishment of floristically diverse margins to encourage beneficial arthropods in both the margin and the crop itself. It also actively discourages the use of pyrethroid foliar insecticides to which many aphids are resistant and which may significantly impact on the beneficial arthropods. Such margins therefore form a very important part of an integrated pest management strategy as well as providing greater biodiversity than if the total field was cropped and should therefore be encouraged. Whilst movement of thiamethoxam residues from the cropped to the non-cropped area may occur, removal of these flowering margins and the habitat and food source they provide is not a viable mitigation and would not be recommended. The standard practice to protect off-crop non-target arthropods from spray applications is for growers to 'respect an unsprayed buffer zone of 5 m to non-crop land'. Whilst this works for spray applications (to protect against potential spray drift) it is not currently an option for seed treatments. If buffer strips were to be required between the crop and the field margin, consideration is required as to what size this would need to be. On the basis of the current information, it is not possible to determine the width required to reduce the exposure to an appropriate level (noting the lack of chronic toxicity data). Hence the effectiveness of any such mitigation measure is not known. Consideration would also be required as to what this strip should consist of. A bare soil "sterile" strip is ecologically undesirable as it would prevent non-target arthropods (and potential beneficials) moving into the crop, would be at risk of wind and water erosion and may need additional crop protection measures and other management operations e.g. cultivations to maintain the bare soil. A potential solution would be to drill a strip of untreated crop, however it is likely to be difficult and costly to drill different sugar beet seed in a strip at the edge of the field only, and if it were possible, the plants may become a reservoir for virus and aphids increasing the risk for the main crop area. Another potential solution would be the planting of a strip of a different but non-flowering crop between the sugar beet and the flowering field margins but this is also not likely to be practical. Therefore the benefits of retaining or planting new floristically diverse field margins (as proposed in the stewardship scheme) potentially outweigh the unquantified risks for pollinators and beneficials living and foraging within these margins which may contain thiamethoxam residues. If 'Cruiser SB' is used in 2024, as in previous years there are no obvious practical solutions for mitigating against the unquantified risks to bees, but any reduction in or removal of these floristically diverse field margins is likely to be counter-productive. Natural England and Rural Payments Agency may wish to consider whether these unquantified risks should be taken into account for agri-environment schemes. During 2023, HSE received enquiries about use of 'Cruiser SB' in relation to Sustainable Farming Initiatives (SFI). HSE consider that questions such as these should be addressed to the scheme operators. In light of the two questions raised with HSE, Natural England advised:

	1. **Can flowering plants be included in the herbal ley option (within the 32 month window), providing they are not allowed to flower (i.e. mowed before flowering)?** Mowing would be regarded as a method of preventing flowering. Provided a mowing regime can be maintained which prevents the emergence of flowers for the required 32 month period then mowing would be acceptable. Growers should consider any environmental scheme obligations (e.g. option prescriptions) that have to be met and other factors which may prevent the mowing such as ground conditions (not too wet, etc). If the herbal ley option is part of an environmental scheme such as the Countryside Stewardship scheme and if the mowing would be a breach of the option prescription, it would not be acceptable to request an extended period of mowing through a Minor and Temporary Adjustment (MTA). 2. **Are weedy stubbles (as defined in the SFI definitions) included in the 32 month restriction when the main cover crop being grown is not restricted e.g. turnip?** Yes, weedy stubbles generally contain weeds which have the potential to flower and so should be considered as coming under the 32-month restriction which applies to those agri-environment options that allow flowers to grow or appear on the same ground on which 'Cruiser SB' treated seed was sown. This is not dissimilar to the requirement to prevent weeds flowing within the 'Cruiser SB' treated sugar beet crop area.

20	Controlled Use

Please provide details of how the use of the product will be controlled.

As highlighted, all UK sugar beet is grown under contract to a single customer – British Sugar. Grower contracts are negotiated annually between British Sugar and NFU Sugar. This contractual situation affords a unique level of control over production.

The proposed steps to enable the UK sugar beet sector to control neonicotinoid use under an Emergency Authorisation are as follows:

- The 2025 seed contract offer letter, jointly agreed by British Sugar and NFU Sugar, will be re-issued to all sugar beet growers post-decision taken by HSE/CRD/ECP/DEFRA regarding any future emergency use of neonicotinoid seed treatments in sugar beet.
- If the emergency authorisation is granted growers will be given the option to treat some or all of their original seed variety order, but it will be stipulated that neonicotinoid treatments will only be available if the economic threshold for treatment is triggered in March 2025.
- Growers will always have the option to buy untreated seed.
- The seed and neonicotinoid seed dressing will be delivered to the ESTA accredited and the UK processing facility at Germains, Kings Lynn and other European seed processors as highlighted.
- Seed will be processed, primed and pelleted but not neonicotinoid treated, or film coated.
- The pelleting process ensures 100% traceability of product. This procedure is an exact process leading to minimal dust levels (the industry led (ESTA) reference value for dust

emission from seed treatment, at point of despatch, is 0.25 g dust/100,000 pelleted seeds) limiting any impact to both operator and environment. (In 2024, the average dust level at the Germains factory was well below this minimum dust level at 0.04g/100,000 seeds).

- Similarly, the seed purchased by growers from KWS will be treated and imported into the UK following guidelines and restrictions as above.
- Await the Virus Yellows forecast to be issued at the beginning of March 2025.
- The 2025 threshold for use of neonicotinoid seed treatments will be agreed in due course.
- BBRO to monitor winter aphid and virus levels on weeds, cover crops and unharvested beet (e.g. for anaerobic digestion) in January to April 2025.
- March 2025 onwards treated seed delivered and sown on farm following BBRO recommended guidelines in the BBRO Reference book provided to all growers and agronomists.
- All treated crops and associated field-areas to be recorded via the growers submitted crop declaration
- Beet is precision sown and covered, usually at 2.5cm depth, which avoids the ecotoxicological risks to birds from eating pelleted seed. However, the industry will provide spill kits to contractors and growers in case any seed accidentally remains on the soil surface.
- The same following crop restriction will be used as in 2024 and there will be a clause added into the Inter Professional Agreement (IPA) between British Sugar and NFU (the IPA is an extensive document that governs the relationship between NFU Sugar and British Sugar, the terms of the IPA are incorporated into each grower's contract) that stipulates that **growers must follow the following crop rules summarised in the table below.**

The following-crop restrictions apply for subsequent crops planted on the same area of land as Cruiser SB sugar beet drilled in 2024.

- **Any crop excluded from the below table should be considered 'restricted' i.e. a minimum of 32 months from drilling of Sugar Beet.**
- **The 32-month restriction applies to those agri-environment options that allow flowers to grow or appear on the same ground on which Cruiser SB treated seed was sown in 2024.**
- **Cover crops (including mixes) must also follow the 32-month restrictions.**

	Non-restricted	*Restricted*
Rules	*No restrictions following Sugar Beet*	*A minimum of 32 months from drilling of Sugar Beet*

Crops	1. *Wheat (including Durum Wheat)* 2. *Barley* 3. *Millet* 4. *Sorghum* 5. *Oat* 6. *Maize / Corn* 7. *Rye* 8. *Triticale* 9. *Canary seed* 10. *Spelt* 11. *Potato* 12. *Cabbage* 13. *Kale* 14. *Swede* 15. *Lettuce / Babyleaf / Spinach* 16. *Onions* 17. *Leeks* 18. *Carrots* 19. *Parsnips* 20. *Cauliflower* 21. *Broccoli* 22. *Turnip*	23. *Oilseed Rape* 24. *Linseed* 25. *Mustard* 26. *Soya Bean* 27. *Pea* 28. *Bean* 29. *Buckwheat* 30. *Clover* 31. *Phacelia* 32. *Chicory* 33. *Radish* 34. *Vetch* 35. *False Flax* 36. *Lucerne* 37. *Sunflower* 38. *Borage* 39. *Sainfoin* 40. *Nyger* 41. *Lupins*

- Fodder, energy, and red beet are not included as part of the derogation to ensure the 'controlled and limited' element of the Emergency Authorisation.
- It has also been made very clear that no further use of thiamethoxam seed treatments (including any re-drilling of treated sugar beet if crop lost due to wind blow or capping) is permitted on the same field area for 46 months from the date of sowing treated sugar beet seed in 2024 – a requirement of the Cruiser SB EA. This is to minimise the risk of any residues being acquired by succeeding bee-attractive crops or weeds and hence exposing bees and/or other pollinators to the neonicotinoid seed treatment.
- Alongside the use of Cruiser SB treated seed, it is a condition of use that robust BASIS recommended herbicide programmes must be adopted by growers and their agronomists to minimise the number of flowering weeds in treated sugar beet crops to reduce the risk of indirect exposure of pollinators to neonicotinoids. This applies in treated fields only (NOT next to or around sugar beet field drilled with Cruiser SB seed).
- Monitor aphids, their resistance and infectivity at up to 15 sites in each of the four factory areas from first flights until the end of migration each year to provide advice on future control strategies for Virus Yellows and analyse existing data sets to 'fine-tune' the advice currently given to the industry so new thresholds for treatment can be evaluated and developed if required.
- Post-monitoring of a statistically robust sample of neonicotinoid-treated sugar beet fields to determine any neonicotinoid seed treatment residue levels in soil and plants.

It must be re-iterated that this application is **only being made for the sugar beet crop of England** (and not for fodder or bioenergy beet grown more extensively across the whole of the UK).

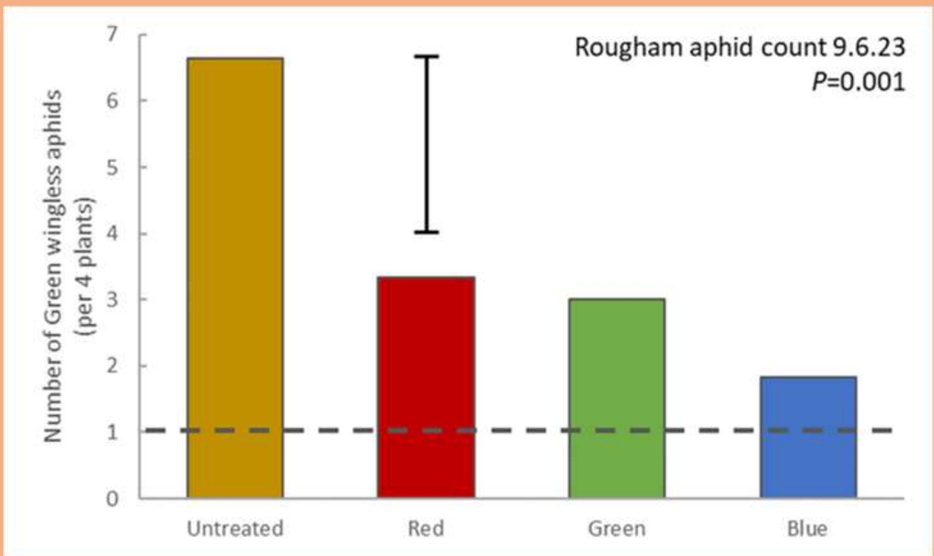
Consequently, the extent and use of the neonicotinoid products would be limited to those counties that grow the sugar crop, and treatments then only applied if needed, on the trigger of the Virus Yellows forecast in March 2025.

References

Qi, A., Dewar, A., Werker, R. and Harrington, R. (2001). Virus Yellows forecasting in sugar beet and the impact of Gaucho. British Sugar Beet Review, 69, 36-39.

1.1.7 Development of Long-Term Solutions

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of Authority	**Health and Safety Executive.**
Development of Long-Term Solutions	The applicant's description of 'Development of Long-Term Solutions' (from the application form) is presented below this 'orange box'. A range of research is being undertaken to find integrated long-term solutions and is described in the application. A key strategy is to continue to build on the five-year, £1.13 million project with sugar beet breeders (described in section 33). This project aimed to exploit the genetic diversity in sugar beet relatives, identifying candidates exhibiting resistance and tolerance to virus yellows. This project was initiated before the remaining uses of thiamethoxam were withdrawn, in anticipation of the need to reduce dependence on insecticides for virus control in sugar beet. The project finished in 2020 and the first generation of BMYV partially resistant sugar beet varieties (Marushka KWS) became available in 2022. However, as mentioned above, it is noted the yield potential in the absence of virus is low compared to existing, elite susceptible varieties. BBRO have calculated (from inoculated trials in 2019) that growers would have to sustain 62% infection within fields before such varieties become economically viable. Therefore whilst this is a positive step this variety is unlikely to be used commercially. Additionally the variety is only conferring resistance to one of the three viruses making up the virus yellows complex However, significant positive progress has been made this year with breeders identifying VY tolerant genetics, have developed one trial 'Goliath' indicating tolerance to all three yellows viruses and without significant yield penalties. But this will be at least 2 years before it may make the recommended varieties list. Results were presented under 'benefit and necessity' section of the latest BBRO Goliath trials, with two further varieties showing similar yields to commercial varieties, but again these are not yet ready for commercial adoption on the BBRO recommended list. This is in addition to other development work (summarised in the application form) being done in conjunction with other significant European sugar beet breeding companies. A collaboration project has also been instigated to explore how gene editing can be used to target the complete virus complex and it is currently expected results will be available in 2024. However there will be a further 5 years to integrate the GE knowledge into plant breeding and virus resistant beet is commercially available and is dependent on the Genetic Technology (Precision Breeding) Bill.

	In September 2020, a new Virus Yellows Taskforce was established between British Sugar, NFU Sugar and the BBRO to accelerate and develop ongoing and novel pathways of research to limit the future impact of this disease across the UK industry. The application details a number of initiatives and strategies around conventional and possible (gene editing) breeding solutions, and identifying alternative existing or novel active substances which aphid activity. In addition, a range of integrated approaches are being explored, including encouraging beneficials, using camouflage techniques (soil/plant), use of endophyte plants boosting sugar beet resistance, under sown crops, and flowering margins to encourage natural predators are being researched. In an update for this year, the applicant has noted the results from 2023 of the camouflage techniques using food dyes to reduce plant/soil has been particularly promising. And provided a summary of the results indicating fewer aphids:  In addition, there are further studies on the infection cycle within the plant in relation to drilling date as well as PhD research projects, looking at: 1) Understanding the molecular strain variability of the virus yellows complex present in the UK and how this relates to breeding programmes 2) The mechanism of how mature plant resistance is triggered in plants and whether this can be used to identify novel control strategies Work is also continuing to refine the prediction model, with the possibility of making more specific, accurate forecasts, at regional level. New molecular (qPCR) techniques will be used to monitor all three viruses to improve understanding of risks. BBRO and British Sugar have also produced a 'Virus yellows pathway brochure' summarising the various work and research outlined here, along with monitoring, use of foliar sprays and 'Cruiser SB'. (See Appendix 3)

	In conclusion, BBRO are undertaking extensive, and wide ranging studies across multiple areas to develop a series of integrated approaches, and demonstrated they are consistently monitoring new research to identify possible new areas and techniques. It does remain challenging and it is noted that developing resistant varieties alone without wide ranging other integrated approaches could compromise/breakdown such varieties resistance if the sole component against virus yellows.

21	Development of Long-Term Solutions

Please provide details of work being undertaken (with timeframes) to develop long-term alternative solutions, which avoid the need to use an emergency authorisation.

There remains significant research and trial work being undertaken on an accelerated basis to develop alternative, sustainable solutions to the use of neonicotinoids. The industry-wide Virus Yellows taskforce was established to identify pathways to provide new and integrated aphid and virus mitigation strategies for the future.

In 2022, growers had access to the first generation of virus tolerant sugar beet. Maruscha KWS is partially tolerant to BMYV. As set out above, as with all new traits, this variety is lower yielding than conventional varieties, and should not be sown until after mid-March due to its higher levels of bolting. This is clearly a positive step to finding alternative integrated solution to Virus Yellows. However, it is important to remember that there are at least three yellowing viruses that affect sugar beet and this trait is only against one of these, highlighting the ongoing challenges of breeding for virus (and vector) resistance. BBRO continues to screen new genetics from breeders that are showing some positive signs of reduced yield dray in the presence of the yellowing virus.

The industry continues to use advanced seed technology for enhanced germination/establishment to ensure plants reach the 12-leaf stage as quickly as possible and currently Enrich 200/300 (Germains), EPD 2 (KWS), 3D+(Strube) SV1 (Sesvanderhave) and UltiPro (Limagrain) treatments are available to growers when they purchase their seed. In addition, BBRO is working with all breeders and seed technology providers alongside the British Sugar/NFU seed working group, to evaluate additional approaches for improved pelleting and further enhanced germination/ establishment.

BBRO continues to support ongoing glasshouse and larger-scale field trials to determine the efficacy of existing and novel aphicides as well as other novel products and botanicals (e.g. AgriOdor, garlic-based products, silicone and jasmonic acid, RNAi, peptide technology) and potential viricides. The products being analysed are currently not approved for use on sugar beet, but do not have resistance issues within current *M. persicae* populations in the UK, so could be potentially exploited for their control in the future. These trials are in addition to specific company confidential trials that the agrochemical sector commission with the BBRO utilising our inhouse trials and science teams. Ultimately, this information will be used to support and/or accelerate registration or the extension of use of these products for sugar beet in the future.

The field trials either use natural populations of *M. persicae*, representing the local insecticide resistance status or, if necessary, aphids are introduced into the field (if the natural population remain below the spray threshold) from the BBRO insectary. Aphid populations are then assessed at specific time points post application to determine the efficacy and ultimately virus control of the different aphicides. Data from 2017-2020, showed that several key aphicide products continue to be effective at controlling *M. persicae* when applied as a foliar spray to sugar beet. However, as anticipated, the

use of Hallmark 'increased' the number of aphids significantly and is likely the result of the aphicide decreasing the numbers of beneficial insects within these pyrethroid-treated plots.
To accelerate the outcomes of this work and to maximise data capture, the BBRO have undertaken additional trials in the autumn by sowing beet in early September and taking aphid assessments during October/November. These autumn data reinforced the summer findings regarding aphid control, and this pro-active approach enables the industry to gain additional information within the same year.

More detailed laboratory and growth room assays and assessments are also ongoing in the BBRO facilities in Norwich. We are investigating further aphicides that are currently in their earlier stages of development and determining whether specific products, currently registered as foliar aphicides, could be deployed as alternative seed treatments. There is some optimism that the next generation of sustainable aphicide sprays may be approved for use by 2026.

The BBRO has been working with breeding companies since the early 1990s to identify alternative genetic solutions for controlling Virus Yellows. Although progress has been made and is accelerating, this is a complex problem compounded by the need to identify resistance genes to three different viruses. To date no single major sources of virus resistance or tolerance has been identified to the three viruses BMYV, BChV or BYV (in contrast to rhizomania and beet cyst nematode sugar beet varieties that are now used widely in the UK).

BBRO led a five year, £1.13M collaboration with two sugar beet breeders (SES Vanderhave and MariboHilleshog) via an InnovateUK project (project number 102098; a novel pre-breeding strategy to reduce dependence on insecticides for Virus Yellows control in sugar beet; 2015-2020) which exploited the genetic diversity found in beet relatives and identifying candidates exhibiting resistance and tolerance to Virus Yellows. The outputs from this pre-breeding project are currently being exploited and may be reflected in future new varieties produced by the breeding companies.

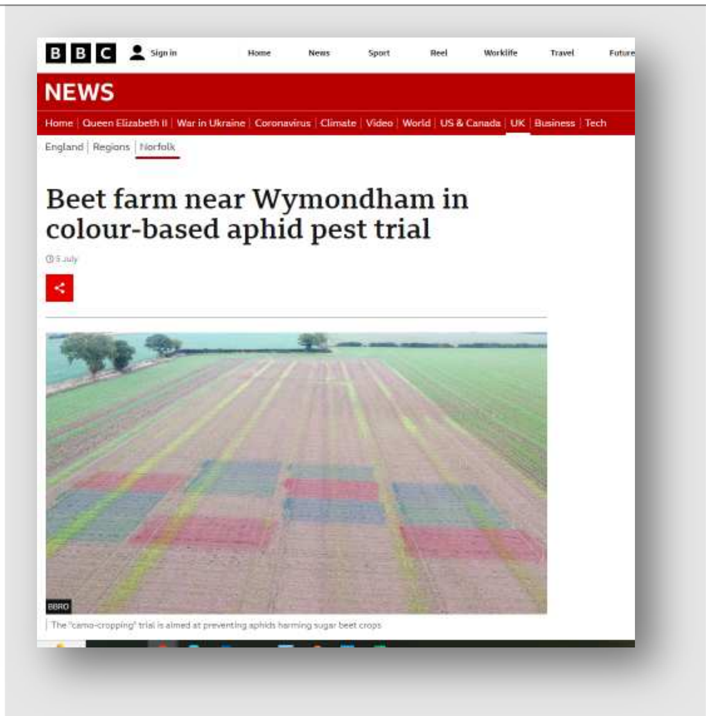
In addition, BBRO continue to work under specific confidentiality agreements with three of the main European sugar beet breeding companies directly to develop and assist with their own in-house breeding efforts with the identification of additional Virus Yellows resistance (see picture below). In 2020, 2021 2022,2023 and again in 2024, the BBRO produced sufficient viruliferous aphids to inoculate over 100,000 plants in a number of separate field trials across East Anglia to accelerate breeding efforts to continue to identify solutions for this problem.

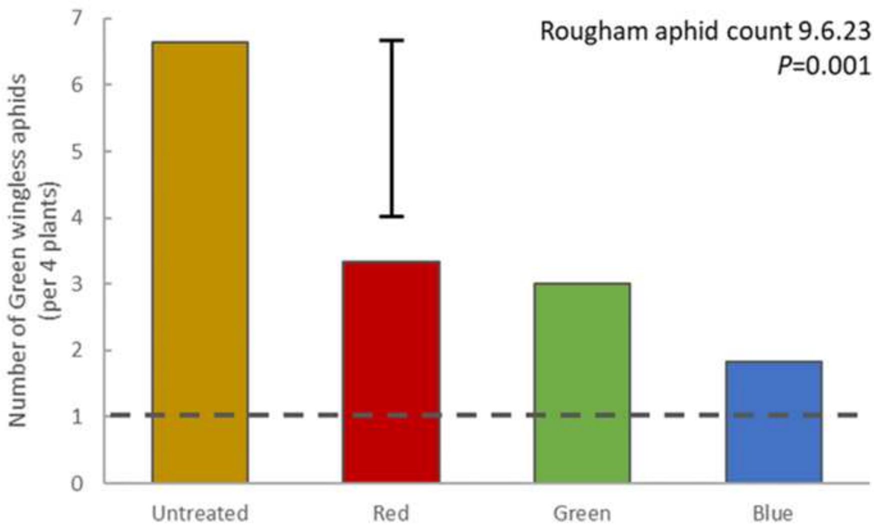
Due to the complex nature of this disease and the lack of major sources of virus disease resistance developing commercial varieties is very difficult. Even then these varieties will potentially only provide resistance to the individual viruses; stacking of any resistance traits alongside yield and bolting resistance would then need to be developed further.

Alongside our variety screening work, we have an extensive series of projects and trials looking at other aspects of virus reduction. BBRO has placed aphid and virus research at the very centre of its research programme to accelerate new pathways to provide an integrated approached for the future. Examples of new/ongoing projects include:

• Evaluating the effects of undersown cover crops to help protect the sugar beet from aphids, especially the impact of undersowing with barley which has shown some positive effects in 2020 (Stevens & Bowen, 2021, Bowen, 2021, undersown-opinions.pdf (bbro.co.uk).

- Other approaches to the camouflaging approach be investigated is looking at establishing replicated trials to assess the impact of using food dyes on the soil to reduce plant-soil contrast at a range of field sites. The theory is the same as for the barley camouflage as it is hoped the dyes will reduce the plant-soil contrast. Results from the 2023 trials are particularly promising (see below).

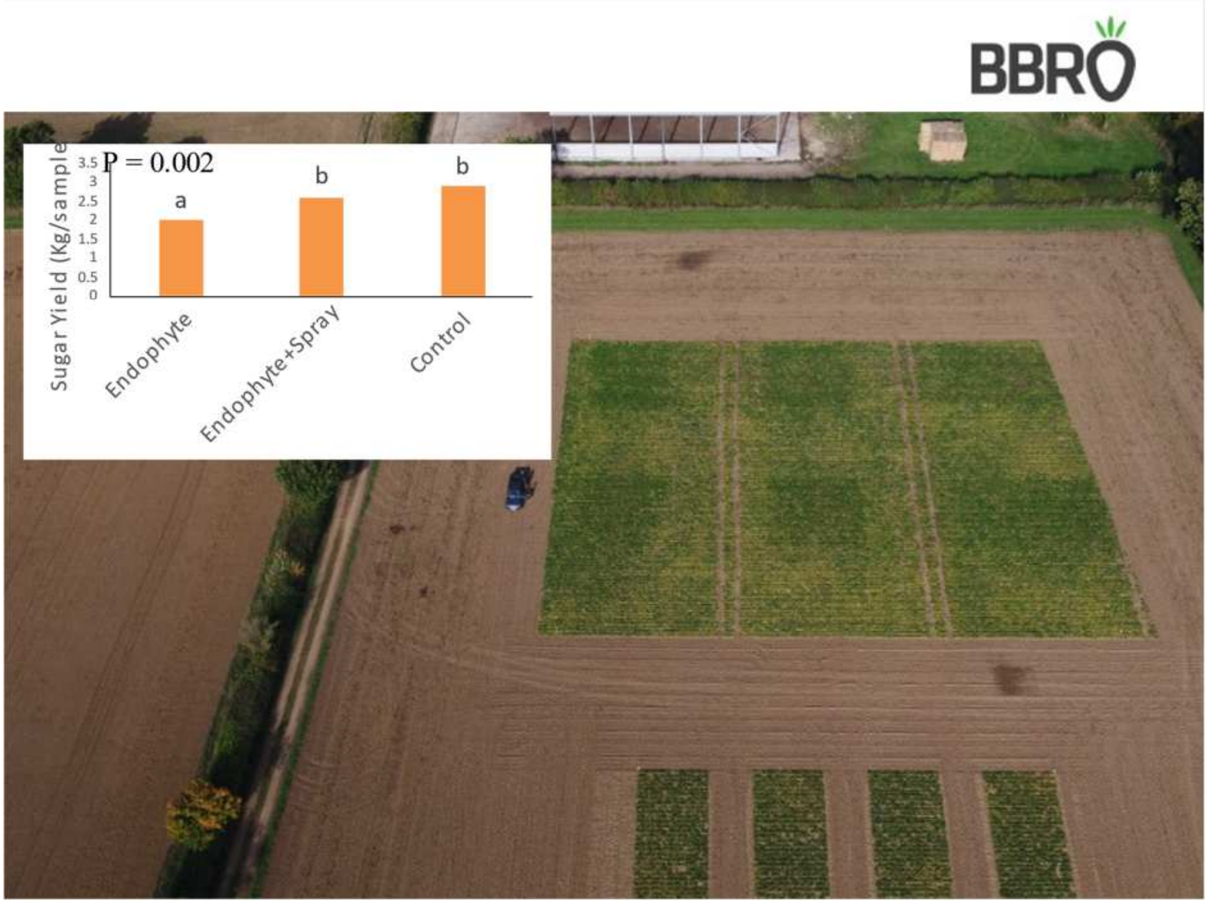




• Studying a range of flowering mixes to attract beneficial insects in the autumn to help boost beneficial numbers in the spring, ensuring they are present in sufficient numbers at the right time.

• Alongside flowering mixes, we are looking at the use of brassica species between rows to act as an attractant to aphids to pull them away from the sugar beet at the vulnerable time for infection.

• Following interesting work in New Zealand, BBRO are looking into the use of endophyte grasses to boost natural resistance in the sugar beet crop. There has been good data to support this theory for soil borne pests and the industry is interested to see if this can be replicated on aphids. Field trials were conducted in 2022 and 2023 and will be repeated in 2024.



• We are also trying to understand more about the infection cycle within the plant and how this can change with different drilling and harvest dates to see if there are any local mitigation strategies that can be deployed.

In tandem with these practical approaches BBRO have been involved in three PhD projects, which are at the University of East Anglia, Wageningen University, and the University of Lincoln targeting some of the underlying science around aphids and virus (Beet Review May 2021 pages 34, 35). These are looking at:

1) Understanding the molecular strain variability of the Virus Yellows complex present in the UK and how this relates to breeding programmes
2) The mechanism of how mature plant resistance is triggered in plants and whether this can be used to identify novel control strategies.
3) Using artificial intelligence for sugar beet aphid identification

This highlights the various and wide-ranging approaches BBRO is taking to help combat Virus Yellows in sugar beet. There is no quick solution, but complimentary activities, as highlighted above, could hold the key.

The recent passage of the Precision Breeding (Genetic Technology) Act is welcomed and should permit us to take advantage of new genomic techniques when the regulatory environment allows.

British Sugar has invested in a collaboration project to explore how gene editing can be used to specifically target the 3 yellowing viruses through new breeding technology. It is expected that Virus

Yellows (VY) resistance can be achieved by employing minimal gene editing to precisely redirect the silencing activity of existing non-coding RNA, towards a new target of choice.

The project aims to produce a number of gene editing (GE) targets that can be used in a collaboration with sugar beet breeders to develop VY resistance in sugar beet. Armed with these targets, the breeders will have the expertise and facilities to carry out the genetic editing, grow the edited material and apply this to their current superior germplasm for commercial use. This would result in elite commercial beet varieties with genetic resistance to yellowing viruses.

We have completed the initial stages of the project, mapping the sugar beet genome sequence, and have produced short interfering RNA (siRNA) expression data. Computational designs for gene editing have been produced and shortlisted, with *in vitro* silencing validation of these designs expected in Q3 of 2024. In anticipation of these designs, we have launched a major collaboration with our technical partners, the John Innes Centre, who are to develop a beet transformation platform and technical protocols to enable proof of concept experiments. This work has begun and will be conducted through 2024-26. Its aims are to deliver the GE designs into sugar beet plants, enabling validation of their silencing capability using viruses delivered by aphid vectors.

Following this, the targets can be passed to commercial seed breeders who can undertake the editing process and integrate the VY resistance into their commercial seed varieties. It is expected that this process will take at least another 5 years before VY resistant sugar beet seed is commercially available for use.

Whilst we work to deliver a fully resistant GE solution, we expect traditionally bred, partially tolerant varieties to continue to be developed, alongside new chemical seed treatments that will help to bridge the gap from 2026 onwards.

1.1.8 Repeat Applications: Monitoring and Stewardship

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of Authority	**Health and Safety Executive.**
Repeat applications: Monitoring and stewardship	A number of conditions and requirements were attached to the 2023 Article 53 authorisation relating to the use of ‘Cruiser SB’ in the 2023 season. The deadline for submission of all of these has passed. Slightly different data requirements were set for use in the 2024 season, and whilst some have been addressed, some are not due until later this year, the 2024 data requirements are reported in the following section (1.1.9: Repeat applications data requirements). (1) By 3 March 2023, details of whether the threshold for treatment was met and the quantity of ‘Cruiser SB’ treated seed ordered, treated and supplied must be submitted to HSE. *Addressed and discussed in the history section above* (2) By 31 March 2023 the residues monitoring requirements for 2023 as proposed in Annex 2 of the Stewardship document must be discussed and agreed with Defra.

	Addressed and results discussed in the environmental fate section below. (3) By end of October 2023 (and ideally earlier), a report summarising: - How much 'Cruiser SB' treated seed was drilled and in which locations. - Information on the use of all follow up foliar aphicide sprays, with details on what product was applied, timing of application (days after drilling, beet growth stage) and which relevant foliar treatment threshold was met for the growth stage. This information should be used to give an indication of the level of persistence of 'Cruiser SB'; activity in sugar beet plants grown from treated seed. - Evidence to show that the conditions stipulated in the stewardship document were; a) clearly explained to the industry, b) that the requirements were understood by the industry c) that individuals who opted to grow 'Cruiser SB' treated sugar beet in 2023 complied with the requirements and the stewardship - An assessment of how successful the stewardship document (Appendix 3 of the authorisation) has been in achieving its aims and clearly list recommendations for improvement as necessary. *Information on the quantity of 'Cruiser SB' treated seed drilled was provided, but not by location. Information on the use of foliar sprays was provided, although not all the requested details were summarised. This is discussed further under Section 1.1.3 'Benefit and necessity of the proposed use'.* *The second part of the requirement relating to stewardship has been addressed by submission of the 2023 Stewardship report (provided below). HSE can confirm that appropriate stewardship messages were published throughout the season in the BBRO Advisory bulletins, and a range of appropriate advice and support services and wider communications were available to growers. Growers ordering 'Cruiser SB' treated seed completed a DocuSign certifying they understood and would comply with the requirements. British Sugar confirmed that all documents were signed.* (4) By end of November 2023 a summary report of the pre-harvest residues monitoring in soil and non-crop vegetation as described in Annex 2 of the stewardship document and agreed with Defra. *Addressed and discussed in the environmental fate section below.* (5) By end of March 2024 a final report of all of the soil and non-crop vegetation residue monitoring as described in Annex 2 of the stewardship document and agreed with Defra. *Addressed and discussed in the environmental fate section below.*

22	Repeat Applications: Monitoring and Stewardship
Please provide details of how you have addressed any monitoring or stewardship requirements set under previous emergency authorisations.	

2023 Cruiser Stewardship report

The 2023 Cruiser Stewardship Agreement provided a successful framework for responsible use of Cruiser SB in 2023, partnering an effective and timely package of grower communications with rigorous data collection and reporting procedures to ensure comprehensive due diligence across the sugar sector. As part of the 2023 stewardship process and with a view to enhancing the efficacy of future stewardship agreements, British Sugar, NFU Sugar and the BBRO have undertaken a review of the 2023 agreement, drawing together evidence from across the sector to evaluate performance and showcase compliance.

1. **The 2023 Virus Yellows Forecast**

Annually Rothamsted Research conducts a Virus Yellows forecast for sugar beet under contract to BBRO. This provides an indication of the incidence and abundance of aphids and Virus Yellows. The Virus Yellows forecast has been in operation for the UK sugar beet crop since 1965 and is one of the longest running predictive models available anywhere in the world, used to indicate the level and potential impact of an economically important plant disease.

The Cruiser SB EA required the submission of the 2023 Virus Yellows forecast to HSE at the beginning of March 2023. This was shared with HSE and Defra on **01/03/23**, forecasting Virus Yellows incidence of 67.5% and thus triggering use of Cruiser SB.

Alongside the forecasted VY levels for the forthcoming crop the model also predicts the timing of aphid first flights, which is key in monitoring aphids in the field and helping growers to be prepared for when they may reach their spray thresholds. First flights were initially predicted for 22nd April 2023 but this was revised to 1st May 2023 following a particularly cold March delaying predicted flights and then brought back again to 24 April 2023 following a milder spell. The first aphid was caught in the Broom's Barn suction trap on 22 April, the first aphid caught at the BBRO yellow water pan sites was on 24 April 2023. Again, these were incredibly close to the model prediction for the first aphid flight.

2. **Reducing potential sources of VY infection**

The sugar beet industry is committed to communicating grower best practice for infection control. Whilst aphid vector activity will be reduced following spells of very cold/freezing weather, it remains critical to ensure potential sources of virus on the farm are removed, especially before temperatures start to rise as we go into late spring and early summer.

In 2023, the BBRO Sugar Beet Reference Book was only updated electronically via a 2023 supplement (full reprint and hard copy is sent out biannually). This was published on the BBRO website on 9th January 2023. It urged that any cover crops were destroyed thoroughly so that no green material was left on which aphids could survive. A comprehensive schedule of BBRO Advisory Bulletin's and tweets throughout **April** and **May** reminded growers of the requirement to remove or manage sources of potential virus-infected material carefully to prevent virus-spread.

3. **Drill Operator guidance and seed rates**

Drilling restrictions were promoted concertedly from the outset, incorporated within the British Sugar/NFU Sugar final seed pack which was delivered from **26/01/23**.

The sugar beet industry is committed to communicating Cruiser SB stewardship information to all growers and drill operators therefore the stewardship group developed a specific and targeted guidance document for drill operators which was distributed to growers from **22/03/23**. This explained the importance of efficient drilling, equipment maintenance, understanding seed rates and optimising plant populations to ensure the established plant population doesn't exceed the optimum of 100,000 plants per hectare, in line with the Emergency Authorisation for Cruiser SB treated seed.

Further reminders of drilling rate restrictions incorporated within the Emergency Authorisation were communicated to growers and operators through BBRO Advisory Bulletins, BBRO Drill Training events, tweets and British Sugar operator guide reminders through **March** and **April**.

4. **Pesticide spill kits**

The use of Cruiser SB treated seed requires growers to have access to a spill kit. As part of industry due diligence spill kits were sent to all growers on **08/03/23** in case of any accidental spillage of Cruiser SB treated seed. The requirements around spillage clean up were laid out within the Drill Operators Guide, with reminders issued in **March** and **April**.

5. **Late drilling/re-drilling of sugar beet**

In accordance with the 120-day approval period of the Emergency Authorisation, no Cruiser SB treated seed was authorised for use following the 1st of June 2023. Growers and operators were informed of the terms of the EA in the British Sugar Drill Operators Guide on **22/03/23** as well as via reminders in **March** and **April**. Texts, tweets and BBRO Advisory Bulletins through until **August** continued to cover crop and redrilling restrictions incorporating a list of eligible and restricted follow-on crops and reiterating that Cruiser SB may not be used on the same field area for 46 months from the date of sowing treated sugar beet seed in 2023.

6. **Weed control in sugar beet fields**

In conjunction with the vast resources available to growers across the BBRO website, the Sugar Beet Review, and other affiliated literature, growers were regularly reminded of their weed control obligations throughout the growing season and signposted to BASIS recommended herbicide programmes as part of the stewardship package. The BBRO Advisory Bulletin #5, published at the start of drilling on **31/03/23** outlined herbicide options and grower responsibilities and referred growers back to the BBRO Sugar Beet Reference Book. The BBRO Advisory Bulletin #6, published on **11/04/23** was a weed control special edition. Advisory Bulletins throughout the season issued timely reminders to growers of the requirement for a BASIS recommended herbicide programme.

7. **Aphid monitoring, thresholds and subsequent aphicide applications**

Data collection remained ongoing throughout the growing season. Within the British Sugar database, industry recorded all treated crops and associated field-areas for monitoring by agricultural contract managers. This information also provides a valuable log with which to monitor responsible drilling next year. All growers who ordered Cruiser treated seed were required to complete a DocuSign certifying that they had both understood and complied with the requirements attached to the use of Cruiser SB in 2023. Grower compliance documents were circulated to 1511 growers on **22/08/23** and 100% were signed and returned to British Sugar, with **zero** instances of non-compliance.

Growers retained access to rolling results from the BBRO annual yellow pan network which served to highlight aphid pressure across the growing area via the On-Farm section on the BBRO website. Timely reminders of aphid pressure and monitoring were issued to growers via the BBRO Agronomy Bulletin (**26/04/23**) and the BBRO Beetcast (**02/05/23**). The BBRO Advisory Bulletin of **22/05/23** reiterated the foliar spray restrictions attached to Cruiser SB treated crops.

8. **Integrated pest management (IPM) to boost beneficial insects**

Growers retained access to a wealth of IPM information and practical advice via the BBRO website. BBRO Bulletin #4 issued **02/03/23** highlighted the value of beneficials and the importance of preserving them in the crop. The Beet Review issues in **January 2023** also highlighted the importance of beneficials and IPM and the ongoing work at BBRO, pp21-22.

1. Following crop restrictions

	Non-restricted	Restricted
Rules	**No restrictions** following Sugar Beet	A **minimum of 32 months** from drilling of Sugar Beet
Crops	1. *Wheat (including Durum Wheat)* 2. *Barley* 3. *Millet* 4. *Sorghum* 5. *Oat* 6. *Maize / Corn* 7. *Rye* 8. *Triticale* 9. *Canary seed* 10. *Spelt* 11. *Potato* 12. *Cabbage* 13. *Kale* 14. *Swede* 15. *Lettuce/ Babyleaf/ Spinach* 16. *Onions* 17. *Leeks* 18. *Carrots* 19. *Parsnips* 20. *Cauliflower* 21. *Broccoli* 22. *Turnip*	23. *Oilseed Rape* 24. *Linseed* 25. *Mustard* 26. *Soya Bean* 27. *Pea* 28. *Bean* 29. *Buckwheat* 30. *Clover* 31. *Phacelia* 32. Chicory 33. Radish 34. Vetch 35. False flax 36. Lucerne 37. Sunflower

The above table was shared with growers, operators, and agronomists throughout the growing season reminding them of the crop restrictions following Cruiser SB treated sugar beet. First published as part of the Drill Operators Guide on **22/03/23**, reminders were issued via email, text message, Advisory Bulletin, and tweet from **March** through until **August**.

10. **BBRO soil and plant residue monitoring**

A programme of sampling of neonicotinoid-treated sugar beet fields, to determine any neonicotinoid seed treatment residue levels in soil and plants, was established and commissioned by BBRO to [redacted] between **February** and **March 2023**. The project covered in-field soil samples, in-field vegetation samples, field-margin soil samples, field-margin vegetation samples, and pollen samples. Interim datasets have flagged no cause for concern relating to the seed coating residue levels of this year's drilled crop. It must be noted the lower Limit of Detection (LOD) requested by Defra for Clothianidin has resulted in more detectable residues, but they are still below the Limit of Quantification (LOQ). The complete set of results and accompanying contextual analysis will be delivered by [redacted] post-harvest of all monitored sites. The latest dataset was circulated to BBRO and Defra on **12/10/23** and included pre-drilling and within-season soil analysis, and within-season vegetation and pollen analysis.

11. **BBRO liaison with relevant water companies/organisations**

The BBRO has actively sought liaison with relevant water companies and organisations such as [redacted] to understand what monitoring they are doing and review any data they hold regarding neonicotinoids in water. Neonicotinoid residue levels don't appear to be something regularly monitored or reported on by such groups at present, but the Stewardship group has fostered valuable communication channels that will remain open moving forward. Emails were sent to relevant water companies and organisations on **29/08/23,** only [redacted] replied.

12. **Knowledge Exchange (KE) activities**

British Sugar, NFU Sugar, and the BBRO have managed and administered an effective Knowledge Exchange package with the BBRO successfully leading distribution to the grower and agronomy base. A comprehensive log, meticulously kept over the course of the year, evidences the posted, emailed, tweeted, and texted information that was shared with the industry throughout the growing season and into the beginning of the campaign.

1.1.9 Repeat Applications: Data Requirements

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of Authority	**Health and Safety Executive.**
Repeat Applications: Data Requirements	Refer to 'Repeat Applications: Monitoring and Stewardship' section above for information regarding the data requirements associated with use in 2023 (where all deadlines for submission have passed). **Data Requirements previously set for the 2024 Emergency Authorisation** The numbered requirements below were attached to the authorisation granted for use in 2024 (COP 2023/00999). Requirements 1-3 have been addressed as described *in italics* below. The deadlines for requirements 4-7 have not yet been reached and the information is not yet available. 1. **<u>By 4 March 2024</u>, details of whether the threshold for treatment was met and the quantity of 'Cruiser SB' treated seed ordered, treated and supplied must be submitted to HSE.** *On 4 March (HSE ref w 002119784) HSE were advised that:* *The threshold for treatment was met with the Rothamsted model output of 83.04% for 2024.* *The total planned Cruiser Force production via the UK Seed account will be 62,529 units. This is planned production, but will be subject to any over and under runs. When treatment has been completed, I will confirm the actual number of units produced.* *We also have KWS Smart seed that sits outside of the UK seed account (not ordered through British Sugar). We have been informed that approximately 9,441 units will be treated by KWS. Again, we will give a more accurate figure when production is completed.* *Therefore the approximate total no. of units we expect to be treated with Cruiser SB is 71,970 for 2024*. 2. **<u>By 4 April 2024</u> the residues monitoring requirements for 2024 as proposed in Annex 2 of the Stewardship document must be discussed and agreed with Defra.** *On 7 March (HSE ref w 0021197786) HSE were provided with copies of contracts to undertake the sampling and residue analysis for 2024 as agreed with HSE and Defra.* *(Defra will continue to monitor the 2022 Cruiser SB sites again in 2024)*

	3. **<u>By 31 July 2024</u>, Results from the BBRO aphid monitoring programme for 2024 must be submitted. This should include information on the areas where 'Cruiser SB' treated seed was used and additionally where the foliar treatment threshold was met for both treated and untreated seed.** *Provided and included at Appendix 4 of this report* **4.** **<u>By end of November 2024, or earlier in 2024</u>, the following information must be submitted:** (a) How much 'Cruiser SB' treated seed was drilled and in which areas. (b) Information on the use of all follow up foliar aphicide sprays, with details on what product was applied, timing of application (days after drilling, beet growth stage) and which relevant foliar treatment threshold was met for the growth stage. This information should be used to give an indication of the level of persistence of 'Cruiser SB'; activity in sugar beet plants grown from treated seed. (c) Where possible, consideration should be given to estimate the contribution of each control option to overall yield. This should include use of the authorised foliar sprays (products containing flonicamid and acetamiprid), and any authorised use of 'Cruiser SB'. Or consideration of generating yield data comparing different treatment regimes in specific studies. BBRO should discuss with HSE the feasibility of generating data to address this point. *Discussion has taken place and HSE have agreed with BBRO that this information is more practical to address via BBRO trials.* (d) Data collated in 2022 and 2023 from trials on the use of endophyte grasses to boost sugar beet natural resistance. (e) The report on the BBRO funded Rothamsted project (started autumn 2019) examining the further refinement and regionalisation of the model. In addition, the applicant is requested to discuss how the outcomes of the project will be used in any future applications to further refine proposals for 'Cruiser SB' to be restricted to areas of higher risk. (f) Evidence to show that the conditions stipulated in the stewardship document were: i) Clearly explained to the industry, ii) that the requirements were understood by the industry iii) that individuals who opted to grow 'Cruiser SB' treated sugar beet in 2023 complied with the requirements and the stewardship (g) An assessment of how successful the stewardship document (Appendix 3 of the authorisation) has been in achieving its aims and clearly list recommendations for improvement as necessary.

	5. **A consolidated guide for the 2024 season to support those growers using integrated measures and PPP foliar sprays only. Clearly setting out tools for alternative control strategies could potentially form part of any future consideration of limiting use of 'Cruiser SB by encouraging growers to adopt strategies which do not rely on 'Cruiser SB' in high virus risk years..** 6. **By end of November 2024 a summary report of the pre-harvest residues monitoring in soil and non-crop vegetation as described in Annex 2 of the stewardship document and agreed with Defra.** 7. **By end of March 2025 a final report of all of the soil and non-crop vegetation residue monitoring as described in Annex 2 of the stewardship document and agreed with Defra.** **Future data requirements for any potential authorisation and use of 'Cruiser SB' in 2025:** If a decision to grant authorisation is made in 2025, it is likely this would also be subject to data requirements. It is anticipated these would be based on the 2024 requirements and adapted based on any final decision and conditions of authorisation.

23	Repeat Applications: Data Requirements
Please provide details of how you have addressed any data requirements set under previous emergency authorisations.	
We acknowledge the requirements expected of us in the HSE letter from 2nd February 2024. Action is captured elsewhere in the application..	

1.2 Proposed use

The risk assessment was conducted at application rate of 51.75 g thiamethoxam/ hectare. This is based on an application rate of 75 ml product (45 g thiamethoxam)/ 100 000 seeds and a maximum drilling density of 115,000 seeds/ha).

Part C: Comparison table of the proposed emergency use and any current or previously authorised uses
Please complete the proposed emergency use / situation section of the table below. Please use the comparable product / use section of the table when providing details of a product or use (including previous emergency authorisation) which your application is based on.

12 Product	Proposed emergency use / situation	Comparable product / use
On-label / Extension of Authorisation for Minor Use/ Previous Emergency authorisation		EA granted in 2024
Product	Cruiser SB	Cruiser SB
MAPP number	15012	15012
Active substance(s) (a.s.) and content	600g / l thiamethoxam	600g / l thiamethoxam
Formulation type		
Field of use (for example, fungicide)	A flowable concentrate for seed treatment formulation	A flowable concentrate for seed treatment formulation

13	Uses	Proposed emergency use / situation		Comparable product / use	
Crop details	Identity of crop or situation of use[1]	Sugar beet		Sugar beet	
	Situation of crop[2]	indoor (non-crop production)	☐	indoor (non-crop production)	☐
		outdoor	X	outdoor	X
		protected (permanent or temporary cover)[2]	☐	protected (permanent or temporary cover)[2]	☐
		permanent protection with full enclosure (PPFE)	☐	permanent protection with full enclosure (PPFE)	☐
	Growing media used for protected uses	organic media (for example soil or compost, either in containers or on impervious surfaces)	☐	organic media (for example soil or compost, either in containers or on impervious surfaces)	☐
		soil (crops planted directly into the ground)	☐	soil (crops planted directly into the ground)	☐
		synthetic rooting media (for example rockwool or perlite)	☐	synthetic rooting media (for example rockwool or perlite)	☐
	Height of crop	N/A applied as a seed treatment		N/A applied as a seed treatment	
	Number of crops per year[3]	1		1	
Individual target pest/disease/weed[4]		Virus Yellows-carrying aphids, principally the peach-potato aphid (*Myzus persicae*). MYZUPE		Virus Yellows-carrying aphids, principally the peach-potato aphid (*Myzus persicae*). MYZUPE	
Maximum individual dose (grams or litres a.s./hectare)[5]		75 ml product / 100 000 seeds		75 ml product / 100 000 seeds	
Maximum total dose (grams or litres a.s./hectare)[5]		75 ml product / 100 000 seeds		75 ml product / 100 000 seeds	
Maximum individual dose (grams or litres product/hectare)[5]		75 ml product / 100 000 seeds		75 ml product / 100 000 seeds	

<table>
<tr><td>Maximum total dose (grams or litres product/hectare)[5]</td><td colspan="3">75 ml product / 100 000 seeds</td><td colspan="3">75 ml product / 100 000 seeds</td></tr>
<tr><td>Maximum number of treat-ments</td><td colspan="3">1</td><td colspan="3">1</td></tr>
<tr><td>Water volumes (range)</td><td colspan="3">N/A</td><td colspan="3">N/A</td></tr>
<tr><td>Earliest time of application (estimated date and growth stage BBCH code[5])</td><td colspan="3">BBCH 00 – seed treatment before drilling</td><td colspan="3">BBCH 00 – seed treatment before drilling</td></tr>
<tr><td>Latest time of application (es-timated date and growth stage BBCH code[5])</td><td colspan="3">BBCH 00 – seed treatment before drilling</td><td colspan="3">BBCH 00 – seed treatment before drilling</td></tr>
<tr><td>Interval between applications</td><td colspan="3">Not applicable</td><td colspan="3">Not applicable</td></tr>
<tr><td>Proposed period of use (dates)</td><td colspan="3">From March 2025</td><td colspan="3">From March 2024</td></tr>
<tr><td rowspan="2">Application method(s) to be used[6]</td><td></td><td>Protected/ Permanent protection with full enclosure)</td><td>Outdoor</td><td></td><td>Protected/ Permanent protection with full enclosure</td><td>Outdoor</td></tr>
<tr><td>Other – please provide details and provide photographs if possible</td><td>X
Seed treatment</td><td>☐</td><td>Other – please provide details and provide photographs if possible</td><td>X
Seed treat-ment</td><td>☐</td></tr>
</table>

14	Seed Treatments							
	Proposed Use as a Seed Treatment				Comparable product / use			
Crop[1]	Sugar beet				Sugar beet			
Product and MAPP number	15012				15012			
Active substance(s) (a.s.) and content	600g / l thiamethoxam				600g / l thiamethoxam			
Formulation type	A flowable concentrate for seed treatment formulation				A flowable concentrate for seed treatment formulation			
Field of use (for example: fungicide)	Professional – seed treatment				Professional – seed treatment			
On-label or minor use (Notice of Authorisation Number if known)					On label	☐	NANUM	
					Minor /EAMU use	☐	NANUM	
Seed weight (milligrams)								
Is the seed pelleted?	Yes	X	No	☐	Yes	X	No	☐
Application method for treating seeds	Film-coating				Film-coating			
Amount of product per hectare (grams)								
Amount of product per 100,000 seeds (grams)	75 ml product / 100 000 seeds				75 ml product / 100 000 seeds			
Application rate to seeds (milligrams a.s. per seed)	0.45mg				0.45mg			

Concentration on seeds (milli-grams a.s. per kg seeds)		
Concentration on seeds (grams a.s. per 100000 seeds)		
Seed sowing density (seeds per hectare) [7]	115,000 seeds per hectare	115,000 seeds per hectare
Thousand seed weight (grams)		
Depth of seed sowing	Average target depth of 2.5 cm	Average target depth of 2.5 cm
Soil loading (grams a.s. per hectare)	51.75g/ha	51.75g/ha
Is this treated seed precision drilled?	Yes	Yes
Number of crops on the same land within a given year [8]		
Are the treated seeds sown under protection? If so, give details of what kind of protec-tion? [2]	Not applicable	Not applicable
At what growth stage is the protection removed or the seedlings transplanted out-side? [2]	Not applicable	Not applicable

15	Crop Area / Amount	Proposed emergency use / situation	Comparable product / use
Total amount of crop grown in the UK	Hectares	[redacted]	[redacted]
	Tonnage	7.5mn tonnes (estimate)	7.5mn tonnes (estimate)
	Value (£)	[redacted]	[redacted]
Total amount of crop treated	Hectares	0-99,000 depending on 2025 Virus Yellows forecast	c.60,000ha tbc
	Tonnage	0-7.5mn	c. 4.5mn
	Value (£)	TBC	c. £180m
% Area of UK crop to be treated		0-99% depending on 2025 Virus Yellows forecast	60% from the 2024 BS crop declarations
Geographical location(s) of use (min. county level)		Yorkshire, Lincolnshire, Nottinghamshire, Norfolk, Suffolk, Cambridgeshire, Hertfordshire, Rutland, Bedfordshire, Herefordshire, Essex, Leicestershire, Northamptonshire	Yorkshire, Lincolnshire, Nottinghamshire, Norfolk, Suffolk, Cambridgeshire, Hertfordshire, Rutland, Bedfordshire, Herefordshire, Essex, Leicestershire, Northamptonshire
% yield or quality retained due to emergency use			

2 Risk Assessment

2.1 Physical and chemical properties

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	**Health and Safety Executive**
Reviewer's comments	No new assessment has been undertaken. The physical /chemical properties of the formulation were considered acceptable in the original assessment for 'Cruiser SB' considered by the ACP on 9 May 2006 and concluded the following: 'Cruiser SB' is a light beige liquid with a weak sweetish odour. It is not explosive, not oxidising, not highly flammable and shows no auto-ignition below 455^{0}C. Its pH is 6.6. The results of the storage stability conducted at 54^{0}C show that the active ingredient concentration was within specification, no physico chemical studies were conducted on the formulation stored at 54^{0}C. The results for stability studies conducted for 18 weeks at 30^{0}C showed that the formulation and packaging was stable. The results of storage stability studies on the formulation and packaging conducted at ambient temperature for 2 years will be required for standard approval. Shelf-life formulation data were submitted at reregistration (COP 2008/00049). These data indicate that the formulation remains stable during storage. These data were acquired using a 20 litre size pack which also supports the large pack sizes required. Adhesion to treated seed data were also submitted at reregistration. These data indicate acceptable adhesion to treated seed. A formulation change was previously considered acceptable (HSE internal ref: COP 2010/00740) A new set of formulation data requirements (in accordance with Regulation 284/2013) apply compared to those under which these assessments were undertaken. However in the area of physical, chemical and technical properties (section 2) there are no new data requirements or changes relevant to the 'Cruiser SB' seed treatment formulation. Syngenta has confirmed (HSE internal ref: W002007631) that if authorisation is granted under Article 53, the product will be supplied in the same packaging as previously authorised: i) 5 to 25 litre high density polyethylene container. ii) 5 to 20 litre high density polyethylene returnable container. iii) 100 to 200 litre high density polyethylene returnable container. iv) 1000 litre high density polyethylene container with a top-mounted discharge valve for use with a closed transfer system (the container must not be fitted with any other type of outlet).
Conclusion	The previous assessment remains valid.

2.2 Methods of Analysis

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	**Health and Safety Executive**
Reviewer's comments	Suitable methods for the determination of the active substance thiamethoxam in the product are available and were considered acceptable in the original assessment for 'Cruiser SB' which was considered by the ACP on 9 May 2006 and also considered in the re-registration application (HSE internal ref: COP 2008/00049) where the following summary was presented: 'The Thiamethoxam content of 'Cruiser SB' (both in the formulation and on treated seed) was determined by reverse phase HPLC-UV according to method reference AF-1331/1. This method was evaluated nationally as part of ACP application ACP 6 (319/2006), COP 2006/00175, and found to be acceptable. No further considerations were required. There are no relevant impurities, isomers or co-formulants in the formulation that require an analytical method. The supporting residues analytical method, method reference REM 179.01, was evaluated nationally as part of ACP application ACP 6 (319/2006), COP 2006/00175 and found to be acceptable. No further considerations were required.' A new set of formulation data requirements (in accordance with Regulation 284/2013) apply compared to those under which these assessments were undertaken. However in the area of analytical methods there are no new data requirements or changes relevant to the 'Cruiser SB' seed treatment formulation. Assessment of the validated methods to support the environmental risk assessment is presented below, this includes previously evaluated studies to support the ecotoxicology assessment and environmental fate assessment. A new study [redacted] is considered to support updated environmental fate consideration for this application for use in 2025 and is shown below in orange Previous assessments that remain unchanged for use in 2025 are shown in green boxes ______________________ <u>Method validation to support ecotoxicological assessment</u> Under a previous Article 53 emergency application (HSE internal ref: COP 2020/01677) the following residue study on pollen, nectar and guttation fluid from crops succeeding sugar beet treated with 'A9765R' ([redacted] 2020), and supporting method validation data ([redacted] 2007) were evaluated to support the ecotoxicological assessment. These data have not been reconsidered as part of this application. **Title:** "*Thiamethoxam (CGA293343) and CGA322704 – Validation of Residue Analytical Method REM 179.07 for the Determination of Residues in Bee and Hive Products and Storage Stability in Hive Pollen, Wax and Nectar, Stored Deep Frozen for 12 Months*" **Author/Year:** [redacted] 2007 **Study/Report No.**: T003891-05-REG In this GLP study, pollen, nectar and wax samples were fortified with thiamethoxam and CGA322704 at 0.01 mg/kg (10 µg/kg) of each analyte. The samples were stored for up to 12 months in a freezer at <-18 °C. Subsamples were taken at time zero and 1, 3, 6 and 12 months after fortification and analysed alongside freshly prepared procedural recovery samples for both analytes.

Samples were analysed for both analytes using validated analytical method REM 179-7 (also known as method GRM009.13A – See Section 5 for details of the validation of this method).

The results are provided in the tables below. Results are reported uncorrected and after correction for procedural recovery and the zero day analysed result. From the uncorrected (and corrected) results, it can be concluded that residues of both thiamethoxam and its metabolite CGA322704 are stable for at least 12 months when stored frozen in pollen, wax and nectar matrices.

Stability of thiamethoxam in pollen, wax & nectar samples stored frozen for 12 months

Matrix	Interval		Uncorrected Residue µg kg^{-1}	Mean Uncorrected Residue µg kg^{-1}	Corrected Residue µg kg^{-1}	Mean Corrected Residue µg kg^{-1}	Mean Procedural Recovery* %	Mean Recovered Uncorrected Residue %
	Months (Nominal)	Days (Actual)						
Pollen	Zero time	0	7.6, 8.2, 6.8	7.5	10.1, 10.9, 9.1	10.0	75	100
	1	33	8.4, 7.9	8.1	10.0, 9.4	9.7	84	108
	3	97	7.3, 6.2	6.7	8.2, 6.9	7.6	89	89
	6	188	9.8, 8.8	9.3	8.5, 7.6	8.0	116	124
	12	364	10.4, 7.5	9.0	13.4, 9.7	11.5	78	119
Wax	Zero time	0	9.9, 9.8, 9.8	9.9	10.1, 10.0, 10.0	10.0	99	100
	1	33	9.5, 9.1	9.3	9.6, 9.1	9.3	100	94
	3	97	8.4, 7.0	7.7	8.7, 7.3	8.0	97	78
	6	188	9.9, 10.7	10.3	9.5, 10.3	9.9	104	104
	12	364	11.9, 10.7	11.3	11.4, 10.3	10.9	104	115
Nectar	Zero time	0	9.3, 9.2, 9.2	9.2	10.0, 10.0, 10.0	10.0	92	100
	1	33	8.8, 10.1	9.5	9.2, 10.6	9.9	96	103
	3	97	9.6, 9.5	9.5	10.3, 10.2	10.3	93	103
	6	188	9.9, 9.4	9.6	8.8, 8.4	8.6	112	104
	12	364	9.3, 9.2	9.3	9.1, 9.0	9.1	102	100

Stability of CGA322704 in pollen, wax & nectar samples stored frozen for 12 months

Matrix	Interval		Uncorrected Residue µg kg^{-1}	Mean Uncorrected Residue µg kg^{-1}	Corrected Residue µg kg^{-1}	Mean Corrected Residue µg kg^{-1}	Mean Procedural Recovery* %	Mean Recovered Uncorrected Residue %
	Months (Nominal)	Days (Actual)						
Pollen	Zero time	0	9.1, 9.5, 9.3	9.3	9.8, 10.2, 10.0	10.0	93	100
	1	33	8.9, 9.1	9.0	8.5, 8.7	8.6	105	97
	3	97	7.9, 7.9	7.9	9.2, 9.2	9.2	86	85
	6	188	10.7, 10.0	10.3	10.8, 10.1	10.4	99	111
	12	364	8.7, 7.4	8.0	10.9, 9.2	10.1	80	86
Wax	Zero time	0	10.2, 9.9, 9.9	10.0	10.2, 9.9, 9.9	10.0	100	100
	1	33	9.5, 9.8	9.7	9.5, 9.7	9.6	101	97
	3	97	8.2, 6.7	7.4	8.6, 7.0	7.8	96	75
	6	188	10.4, 11.6	11.0	9.9, 11.0	10.5	105	110
	12	364	10.8, 10.8	10.8	10.9, 10.8	10.9	99	108
Nectar	Zero time	0	9.5, 9.6, 9.4	9.5	10.0, 10.1, 9.9	10.0	95	100
	1	33	8.7, 10.0	9.3	9.2, 10.6	9.9	95	98
	3	97	9.3, 9.2	9.2	10.1, 10.0	10.0	92	97
	6	188	10.6, 10.2	10.4	9.7, 9.3	9.5	109	109
	12	364	9.5, 9.1	9.3	10.1, 9.7	9.9	95	98

Method validation:

	Title: *Thiamethoxam – Residue Study on Pollen, Nectar, and Guttation Fluid from Crops Succeeding Sugar Beet Treated with A9765R in Germany, the United Kingdom, Poland, Austria and Italy in 2017-2018* **Author/Year:** [redacted] **Study/Report No.**: SPK-17-29052 This is a GLP residues study which consists of 8 field trials conducted in Europe (2 DE, 2 UK, 2 PL, 1 AT, 1 IT) in 2017-18. In each trial, sugar beet seeds were treated with thiamethoxam at the nominal rate of 0.450 mg a.s./seed (actual: 0.462 mg a.s./seed) using 'A9765R', a 600 g a.s./L flowable concentrate (FS) formulation – this matches the application rate being proposed for the emergency use and the formulation type is the same. Seeds were drilled "according to normal commercial practice" (equivalent to 57-64 g a.s./ha), grown to maturity and harvested at normal commercial harvest. The following spring, each plot was divided into 4 subplots and replanted with maize, potato, oilseed rape and phacelia, selected as representative succeeding crops. Appropriate control plots were planted with untreated sugar beet seed and subsequently followed the same protocol as the test plots. It should be noted that sugar beet will be harvested before flowering, hence the study is designed to assess the potential of residues to be present in following crops that bees may forage. Three insect proof tunnels were placed over each sub plot containing oilseed rape or phacelia, prior to flowering. Honey bee colonies were introduced into each tunnel at the start of flowering. Samples (from both the treated and untreated plots) of the following were taken at various time points throughout the study: • Soil • Maize guttation fluid • Maize pollen (from the plant) • Potato anthers • Oilseed rape pollen (from foraging bees) • Oilseed rape nectar (from foraging bees) • Phacelia pollen (from foraging bees) • Phacelia nectar (from foraging bees) Samples were deep frozen shortly after sampling and remained so until analysis. Samples were stored frozen for the following maximum time periods: 649 days (21 months) for soil samples 192 days (6 months) for guttation fluid 268 days (9 months) for anthers 245 days (8 months) for pollen 253 days (8 months) for nectar Samples of pollen and nectar have been shown to remain stable for at least 12 months frozen storage, hence the storage periods for pollen and nectar are acceptable. Samples were analysed for thiamethoxam and its CGA322704 metabolite using the following analytical methods. See below for details of the acceptable validation of the method for pollen and

	nectar, water (representing guttation fluid) and soil. The study claims that the methods for anther are also appropriately validated, but this has not been confirmed): Analytical methods: **Soil**: Method GRM009.09A for both analytes. LOQ: Thiamethoxam: 0.0010 mg/kg CGA322704: 0.0001 mg /kg **Pollen and nectar**: Method GRM009.13A for both analytes. LOQ: Thiamethoxam: 0.0010 mg/kg for pollen 0.0005 mg/kg for nectar CGA322704: 0.0010 mg/kg for pollen and nectar **Anther**: Method GRM009.14A for both analytes. LOQ: Thiamethoxam: 0.0010 mg/kg CGA322704: 0.0010 mg /kg **Guttation fluid**: Method GRM009.10A for both analytes. LOQ: Thiamethoxam: 0.01 µg/L CGA322704: 0.01 µg/L A summary of the results from each matrix type is provided in the tables below. See Appendix 2 for full details of the results obtained from each trial site. **Pollen and nectar:** NB: In 3 of the trials, the oilseed rape crop did not produce sufficient viable flowers for pollen or nectar samples to be collected. The number of trials on which the ranges are based are highlighted in the table below. Number of trials which produced results: 8 for maize pollen 5 for oilseed rape pollen and nectar 8 for phacelia pollen and nectar

Sampling Interval (days)	Thiamethoxam Residues in the Range (mg/kg)	CGA322704 Residues in the Range (mg/kg)
Treated Plot (P2): at a rate of 57 – 64 g ai/ha		
Maize Pollen		
0 DAF	< 0.0010	< 0.0010 – 0.0011
3-4 DAF	< 0.0010	< 0.0010 – 0.0012
6-9 DAF	< 0.0010	< 0.0010
Oilseed Rape Pollen		
0-1 DAF	< 0.0010 – 0.0026	< 0.0010
3-4 DAF	< 0.0010 – 0.0024	< 0.0010
6-8 DAF	< 0.0010 – 0.0015	< 0.0010
***Phacelia* Pollen**		
0 DAF	< 0.0010	< 0.0010
7–15 DAF	< 0.0010	< 0.0010
12–21 DAF	< 0.0010	< 0.0010
Oilseed Rape Nectar		
0 DAF	< 0.0005	< 0.0010
3 DAF	< 0.0005 – 0.0006	< 0.0010
6-8 DAF	< 0.0005	< 0.0010
***Phacelia* Nectar**		
0 DAF	< 0.0005	< 0.0010
7–15 DAF	< 0.0005	< 0.0010
12–21 DAF	< 0.0005	< 0.0010

DAF = days after start of flowering

No residues >LOQ were identified in untreated control samples of pollen or nectar apart from a residue of CGA322704 (0.0024 mg/kg) being found in one maize pollen control sample. This is not expected to have affected the results of the study.

Potato anthers:
NB: Results were not obtained in two of the trials, where the potatoes did not produce sufficient viable flowers for pollen or nectar sampling.

Number of trials which produced results = 6

Sampling Interval (days)	Thiamethoxam Residues in the Range (mg/kg)	CGA322704 Residues in the Range (mg/kg)
Treated Plot (P2): at a rate of 57 – 64 g ai/ha		
Potato Anthers		
0 DAF	< 0.0010	< 0.0010 – 0.0013
2-4 DAF	< 0.0010	< 0.0010 – 0.0031
7-9 DAF	< 0.0010	< 0.0010

DAF = days after start of flowering

Soil:
NB: Soil samples were taken and analysed for all trials which produced results – trials which did not produce sufficient viable flowers for pollen and nectar sampling did not have soil samples taken:

Number of trials which produced results:
8 for maize
5 for oilseed rape
6 for potato
8 for phacelia

Sampling Interval (days)	Thiamethoxam Residues in the Range (mg/kg)	CGA322704 Residues in the Range (mg/kg)
Treated Plot (P2): at a rate of 57 – 64 g ai/ha		
Soil – Total Plot		
0-3 DBD1	< 0.0010 – 0.0033	< 0.0001 – 0.0039
0-1 DBD2	< 0.0010 – 0.0034	<0.0010 – 0.0040
Maize Soil		
0-16 DAE	< 0.0010 – 0.0029	0.00019 – 0.0039
0-8 DAF	< 0.0010 – 0.0070	0.00067 – 0.0043
Oilseed Rape Soil		
-1-0 DAF	< 0.0010 – 0.0023	0.00078 – 0.0037
***Phacelia* Soil**		
-1-7 DAF	< 0.0010 – 0.0061	0.00043 – 0.0056
Potato Soil		
0 DAF	< 0.0010 – 0.0024	0.00052 – 0.0035

DBD = days before drilling
DAE = days after emergence
DAF = days after start of flowering

No residues of thiamethoxam >LOQ (0.001 mg/kg) were detected in control soil samples, but residues of CGA322704 >LOQ (0.0001 mg/kg), up to 0.0039 mg/kg were detected in soil control samples from 6 of the 8 trials. Whilst these were at low levels, they were within the range of residues identified in the actual test samples so it is worth bearing this in mind when considering the results.

Guttation fluid:
All 8 trials produced results for maize guttation fluid.

Sampling Interval (days)	Thiamethoxam Residues in the Range (µg/L)	CGA322704 Residues in the Range (µg/L)
Treated Plot (P2): at a rate of 57 – 64 g ai/ha		
Guttation Fluid		
0 DAE	< 0.01 – 17	0.042 – 3.6
5-8 DAE	< 0.01 – 20	0.13 – 3.7
12-15 DAE	< 0.01 – 32	0.14 – 3.2
19-22 DAE	0.025 – 34	0.31 – 5.9
27-29 DAE	0.010 – 42	0.38 – 9.0
33-35 DAE	0.023 – 33	0.97 – 8.5
40-42 DAE	0.011 – 18	0.48 – 11

DAE = days after emergence

Residues of thiamethoxam and CGA322704 were found in some of the control samples analysed from the trials. These were as high as 1.9 mg/kg for CGA322704 in one trial and 1.0 mg/kg for thiamethoxam in the same trial. The presence of these is not explained. The analytical results reported in the table above have not been corrected for the residues in the control samples and the levels found in the control samples are generally well below the maximum levels found in the test samples. Hence, they can still be considered to represent the worst case situation.

Appropriate example chromatograms were provided for all matrices.

A full consideration of these studies from an ecotoxicological perspective is presented within the ecotoxicology section of the evaluation.

Method validation to support environmental fate and behaviour assessment

	To support the environmental fate assessment for use in 2024 new method validation data were provided for thiamethoxam and clothianidin in soil and non-crop vegetation [redacted] **Title:** "*Method validation and sample analysis of thiamethoxam and clothianidin in soil and non-crop vegetation*" **Author/Year:** [redacted] **Study/Report No.**: 3203301 The aim of this study was to validate a method for the analysis of thiamethoxam and clothianidin in clay loam soil, vegetation and pollen samples. Additionally the frozen storage stability of thiamethoxam and clothianidin in soil, vegetation (brassica) and pollen was investigated. The method previously validated for sandy loam soil under [redacted] 2022 (SM 3203177-02V.S) was validated in clay loam soil (see below for further details). *Clay loam soil sample preparation:* Samples of soil were received frozen. Soil samples were homogenised by passing through a 2 mm sieve and stored frozen (< -10°C, nominally -20°C). 10 g (± 0.1 g) of soil were weighed into a plastic pot (175 mL). 50 mL of acetonitrile:10 mM ammonium acetate (80:20 v/v) were added. The sample is swirled to mix, ultrasonicated for 10 minutes, shaken for 30 minutes and centrifuged at 3500 rpm for 5 minutes. The supernatant extract is transferred through a filter paper into a round bottomed flask (250 mL). A further 50 mL of acetonitrile:10 mM ammonium acetate (80:20 v/v) were added. The sample is swirled to mix, ultrasonicated for 10 minutes, shaken for 30 minutes and centrifuged at 3500 rpm for 5 minutes. The supernatant extract is transferred through the same filter paper into the same round bottomed flask. The filter paper is rinsed with approximately 10 mL of acetonitrile. The flask is placed on a rotary evaporator under vacuum over a water bath, set to 40°C until 15-20 mL remains (approximately 30 mins). The sample is then transferred into a 25 mL volumetric flask and the round bottomed flask is rinsed with 2.5 mL of methanol followed by 2.5 mL of Milli-Q water. The sample is made to 25 mL volume with Milli-Q water and mixed well. A portion of the extract is filtered through a 0.2 µm PTFE syringe filter into a glass vial and the remaining extract is transferred into a 50 mL centrifuge tube. 0.05 mL of the filtered sample extract is added to 0.95 mL of methanol:50 mM ammonium acetate (10:90 v/v) and mixed well. This sample is then analysed by LC-MS/MS under the following conditions:

HPLC Parameters:

Instrument:	Shimadzu Nexera HPLC system		
Column#:	Atlantis dC18 4 µm 2.1 × 50 mm		
Mobile Phase A#:	0.1% formic acid in water		
Mobile Phase B#:	0.1% formic acid in methanol/acetonitrile (30:70 v/v)		
Flow rate:	0.4 mL/min		
Gradient:	Time (min)	MP A (%)	MP B (%)
	0	90	10
	1	90	10
	2.5	10	90
	3.9	10	90
	4	90	10
	5	90	10
Run Time:	5 minutes		
Column Temperature:	40°C		
Autosampler Temperature:	5°C		
Injection Volume:	20 µL		
Approx.Retention Times:	Thiamethoxam: 2.2 minutes Clothianidin: 2.4 minutes		
Valco Valve Diverter:	Time (min)		Position
	0		A (to waste)
	0.5		B (to MS)
	4.5		A (to waste)

MS/MS Parameters:

Instrument:	Sciex API 5000 MS/MS				
Ionisation Type#:	Electrospray (ESI)				
Polarity#:	Positive				
Scan Type#:	Multiple reaction monitoring (MRM)				
Ion Spray Voltage:	3200 V				
Collision Gas (CAD):	4				
Curtain Gas (CUR):	21				
Gas Flow 1 (GS1):	55				
Gas Flow 2 (GS2):	55				
Vaporiser Temperature (TEM):	450°C				
Interface Heater (ihe):	On				
Entrance Potential (EP):	10				
Resolution Q1/Q3:	Unit/Unit				
Transition Name:	Q1/Q3 masses (amu)	Dwell Time (ms)	Collision Energy (CE)	Declustering Potential (DP)	Collision Cell Exit Potential (CXP)
Thiamethoxam (Primary)	292.2/211.1	100	17	56	13
Thiamethoxam (Confirmatory)	292.2/181.1	100	30	56	13
Clothianidin (Primary)	250.0/169.3	100	18	46	13
Clothianidin (Confirmatory)	250.0/132.0	100	22	46	13

Parameters marked # may not be modified. Minor adjustments to the remaining parameters may be required in order to fully optimise the system.

Analytical validation data for the determination of thiamethoxam and clothianidin in clay loam soil

Matrix	Analyte	LOQ (mg/kg)	Recovery fortification level (mg/kg)	Recoveries % range (mean)	Repeatability % RSD (n)	Linearity
Clay loam soil	Thiamethoxam (primary transition Q1/Q3 mass: 292/211)	0.01	0.01 0.1 Overall	91.6 – 93.7 (92.6) 87.3 – 93.3 (89.7) 87.3 – 93.7 (91.1)	1.00 (5) 2.61 (5) 2.49 (10)	0.00006 – 0.0024 µg/mL (0.003 – 0.12 mg/kg) n=6 $Y = 8.93x10^7x - 387$ R = 1.0000
	Thiamethoxam (confirmatory transition Q1/Q3 mass: 292/181)	0.01	0.01 0.1 Overall	84.2 – 92.2 (89.0) 87.9 – 92.5 (89.8) 84.2 – 92.5 (89.4)	3.57 (5) 2.38 (5) 2.90 (10)	0.00006 – 0.0024 µg/mL (0.003 – 0.12 mg/kg) n=6 $Y = 3.97x10^7x - 209$ R = 0.9999
	Clothianidin (primary transition Q1/Q3 mass: 250/169)	0.01	0.01 0.1 Overall	85.4 – 97.4 (92.2) 88.0 – 90.7 (89.1) 85.4 – 97.4 (90.6)	5.28 (5) 1.15 (5) 4.08 (10)	0.00006 – 0.0024 µg/mL (0.003 – 0.12 mg/kg) n=6 $Y = 4.92x10^7x - 143$ R = 0.9997
	Clothianidin (confirmatory transition Q1/Q3 mass: 250/132)	0.01	0.01 0.1 Overall	102 – 104 (103) 89.4 – 91.7 (90.0) 89.4 – 104 (96.3)	0.87 (5) 1.06 (5) 6.94 (10)	0.00006 – 0.0024 µg/mL (0.003 – 0.12 mg/kg) n=6 $Y = 5.05x10^7 - 323$ R = 0.9998

Specificity:
Specificity was demonstrated by retention time match with reference standards. Analysis of unfortified control soil samples and reagent blanks demonstrated no significant interference (> 30% of the LOQ) at the retention time of interest.

Confirmation:
Confirmation of identity was achieved simultaneously to the primary detection by monitoring an additional mass transition for each analyte. The selection of ions is justified based on the mass spectrum presented. Acceptable calibration, specificity, recovery and precision data have been presented. Note: confirmation of identity is not required for risk assessment methods but has been demonstrated so has been reported.

Matrix Effects:

The difference between the clay loam soil matrix matched standard and solvent based standard peak areas were not greater than 20% of the non-matrix matched (solvent) based standard. Matrix effects are not considered significant and therefore non-matrix matched standards were used.

Extraction efficiency:

Currently not required for soil.

Linearity:
Linearity was demonstrated by the analysis of six standards of increasing concentration. The range of standard concentrations used was 0.00006 – 0.0024 µg/mL, equivalent to 0.003 – 0.12 mg/kg thiamethoxam and clothianidin in the soil samples. The response was linear with a correlation coefficient (r) of at least 0.9997. A visual inspection of the residual plots shows that the calibration is sufficiently linear (points randomly distributed).

Accuracy:
Recovery samples were prepared by fortifying samples of control clay loam soil with known amounts of the active substances and analysing them by the method described. The fortification concentrations were 0.01 and 0.1 mg/kg for both active substances. Five samples were prepared at each fortification level. Mean recovery levels were within the range 89-103% and are acceptable.

Precision:
Precision was determined from the accuracy recovery data. Five samples were prepared at each fortification level. The % RSD at each fortification level was < 20%.

LOQ and LOD:
The LOQ is defined at the lowest validated level with sufficient recovery and precision. In this case, this is 0.01 mg/kg for both thiamethoxam and clothianidin. The LOD is defined as the lowest detectable concentration or amount of an analyte in a sample, and should be expressed as the lowest calibration standard, preferably in matrix. In this case, the LOD is 0.003 mg/kg, based on the lowest calibration standard for both thiamethoxam and clothianidin. Matrix matched standards were not used for quantification, however, were tested to determine matrix effects which were not considered significant (max. 2.3% testing a concentration of 0.0012 µg/mL, equivalent to 0.06 mg/kg).

Extract stability:
Five determinations of recovery were made at two fortification levels (0.01 and 0.1 mg/kg) for thiamethoxam and clothianidin (primary transition only). Individual and mean recoveries were within the acceptable range of 70-120% after 6 days of refrigerated storage (2-8°C) and 8 days frozen storage (<-10°C, nominally -20°C):

Storage conditions	Storage time (days)	Analyte	0.01 mg/kg Mean Recovery (%)	0.1 mg/kg Mean Recovery (%)
Refrigerated	6	Thiamethoxam (Primary)	93.7	95.1
		Clothianidin (Primary)	90.7	89.9
Frozen	8	Thiamethoxam (Primary)	93.6	92.2
		Clothianidin (Primary)	99.3	88.5

Standard/stock solution stability:

Primary stock solutions at 1000 µg/mL in methanol were demonstrated to be stable when stored refrigerated (2-8°C) for 96 days for thiamethoxam and 291 days for clothianidin. Secondary stocks of 0.01 µg/mL thiamethoxam and clothianidin in methanol were demonstrated to be stable when stored refrigerated (2-8°C) for 98 days. Secondary stocks at concentrations higher than 0.01 µg/mL were considered to also be stable for 96 days, based upon the 0.01 and 1000 µg/mL stocks both being stable for at least this time. Stability was determined by diluting stock solutions which had been stored refrigerated and analysing them against freshly prepared solutions. Stability over the period of storage was considered acceptable if the difference was not greater than 10%.

Procedural recoveries:

The following recoveries were determined during the determination of the test sample results:

Matrix	Analyte	Recovery fortification level (mg/kg)	Recoveries % range (mean)
Soil	Thiamethoxam	0.01	71.1 – 118 (90.0, n=17)
		0.1	72.9 – 95.9 (87.2, n=17)
	Clothianidin	0.01	70.9 - 118 (89.0, n=17)
		0.1	71.2 – 100 (88.0, n=17)

These recoveries were determined in soil. It is unclear from the study report which samples were clay loam and which were sandy loam.

The clothianidin confirmatory transition was reported for soil sample 19 due to a marginal failure of the primary transition procedural recoveries. Soil sample 1 failed the procedural recovery for clothianidin and was not reported but was repeated in soil sample 3 giving acceptable results. Soil sample 2 was not reported due to procedural recovery failure but were repeated in soil sample 4 giving acceptable results.

The individual recoveries reported were all within the acceptable range (70-120%) and the mean recoveries were also well within the acceptable range.

Conclusion

The method is satisfactorily validated in accordance with SANTE/2020/12830, Rev. 1 for the determination of thiamethoxam and clothianidin in clay loam soil, with an LOQ of 0.01 mg/kg for each analyte.

Soil sample concentrations determined in the study ranged from <LOQ to 0.0674 mg/kg for thiamethoxam and <LOQ to 0.0468 mg/kg for clothianidin. The method validation data presented supports the range of results determined in the study.

Title: "*Method validation and sample analysis of thiamethoxam and clothianidin in soil and non-crop vegetation*"
Author/Year: [redacted]
Study/Report No.: 3203177

The aim of this study was to validate a method for the analysis of thiamethoxam and clothianidin in soil, broccoli and pollen.

Control samples were sandy loam soil, organic broccoli and pine pollen. Test samples were received frozen. Soil samples were homogenised by passing through a 2 mm sieve and stored frozen (< -10°C, nominally -20°C). Vegetation samples were homogenised by blending with dry ice and stored frozen (< -10°C, nominally -20°C). Flowers were dried in an oven set to 60°C. Once sufficiently dry, the pollen was isolated from the flowers by passing through sieves of decreasing sizes, with a final aperture of 250 µm. The resulting yellow powder was identified as pollen. The isolated pollen was stored refrigerated (2-8°C).

Soil sample preparation:
Identical to sample preparation and HPLC conditions given for study [redacted] 2023, ref: 3203301 (summarised above).

Vegetation sample preparation (broccoli):
10 ± 0.1 g of vegetation were weighed into a 250 mL plastic pot. 100 mL of methanol: water (50:50 v/v) were added. The sample was homogenized for approximately 3 minutes, centrifuged at 4750 rpm for 5 minutes and the supernatant extract transferred to a plastic pot (175 mL). 0.1 mL of extract is diluted to 10 mL with methanol: 50 mM ammonium acetate (10:90 v/v) in a 15 mL plastic centrifuge tube. The final sample is mixed well and transferred to a glass vial for LC-MS/MS analysis under the following conditions:

HPLC Parameters:

Instrument:	Shimadzu Nexera HPLC system		
Column#:	ACE 5 C18 50 × 2.1 mm 5 µm		
Mobile Phase A#:	0.1% formic acid in water		
Mobile Phase B#:	0.1% formic acid in methanol/acetonitrile (30:70 v/v)		
Flow Rate:	0.4 mL/min		
Gradient:	Time (min)	MP A (%)	MP B (%)
	0	90	10
	1	90	10
	2.5	10	90
	3.9	10	90
	4	90	10
	5	90	10
Run Time:	5 minutes		
Column Temperature:	40°C		
Autosampler Temperature:	5°C		
Injection Volume:	50 µL		
Approx.Retention Times:	Thiamethoxam: 2.1 minutes		
	Clothianidin: 2.3 minutes		
Valco Valve Diverter:	Time (min)		Position
	0		A (to waste)
	0.5		B (to MS)
	4.5		A (to waste)

MS/MS Parameters:

Instrument:	Sciex API 5000 MS/MS				
Ionisation Type#:	Electrospray (ESI)				
Polarity#:	Positive				
Scan Type#:	Multiple reaction monitoring (MRM)				
Ion Spray Voltage:	3200 V				
Collision Gas (CAD):	4				
Curtain Gas (CUR):	21				
Gas Flow 1 (GS1):	55				
Gas Flow 2 (GS2):	55				
Vaporiser Temperature (TEM):	550°C				
Interface Heater (ihc):	On				
Entrance Potential (EP):	10				
Resolution Q1/Q3:	Unit/Unit				
Transition Name:	Q1/Q3 masses (amu)	Dwell Time (ms)	Collision Energy (CE)	Declustering Potential (DP)	Collision Cell Exit Potential (CXP)
Thiamethoxam (Primary)	292.2/211.1	100	17	56	13
Thiamethoxam (Confirmatory)	292.2/181.1	100	30	56	13
Clothianidin (Primary)	250.0/169.3	100	18	46	13
Clothianidin (Confirmatory)	250.0/132.0	100	22	46	13

Parameters marked # may not be modified. Minor adjustments to the remaining parameters may be required in order to fully optimise the system.

Pollen sample preparation:

0.1 g of pollen were weighed into a plastic centrifuge tube (15 mL) and 10 mL of methanol: 0.2% formic acid in water (50:50 v/v) were added. The sample was shaken vigorously by hand, vortex mixed for approximately 30 seconds and centrifuged at 4750 rpm for 5 minutes. 1 mL of extract was added to 4 mL of Milli-Q water and mixed well.

An SPE cartridge (Oasis HLB 60 mg 3 mL) was conditioned with 3 mL of methanol followed by 3 mL of Milli-Q water. The sample extract was loaded onto the SPE cartridge and the eluent discarded. The sample tube was rinsed with 1 mL of Milli-Q water and washed through the SPE cartridge. Excess water from the walls of the SPE cartridge is dried using paper towel and full vacuum is applied for approximately 20 minutes. The SPE cartridge was washed with 2 mL of hexane and the eluent discarded. Full vacuum is applied for 20-30 seconds to remove any remaining solvent from the cartridge. The SPE cartridge is eluted with 6 mL of acetonitrile. The sample is evaporated to dryness in a Turbo-Vap set to 45°C under a gentle stream of nitrogen. The sample is reconstituted with 10 mL of methanol: 50 mM ammonium acetate (10:90 v/v) and ultrasonicated for approximately 5 minutes. The final sample is transferred to a glass vial for HPLC-MS/MS analysis under the conditions detailed above for vegetation analysis.

Analytical validation data for the determination of thiamethoxam and clothianidin in soil, vegetation and pollen

Matrix	Analyte	LOQ (mg/kg)	Recovery fortification level (mg/kg)	Recoveries % range (mean)	Repeatability % RSD (n)	Linearity
Sandy loam soil	Thiamethoxam (primary transition Q1/Q3 mass: 292/211)	0.01	0.01 0.1 Overall	96.3 – 111 (101) 94.6 – 101 (97.2) 94.6 – 111 (99.3)	5.83 (5) 2.78 (5) 4.91 (10)	0.00006 – 0.0024 µg/mL (0.003 – 0.12 mg/kg) n=5 Y = 1.21×10^{8}x – 341 R = 0.9998
	Thiamethoxam (confirmatory transition Q1/Q3 mass: 292/181)	0.01	0.01 0.1 Overall	91.2 – 100 (97.2) 91.7 – 99.8 (96.5) 91.2 – 100 (96.9)	3.89 (5) 3.34 (5) 3.44 (10)	0.00006 – 0.0024 µg/mL (0.003 – 0.12 mg/kg) n=5 Y = 5.64×10^{7}x – 72.7 R = 0.9994
	Clothianidin (primary transition Q1/Q3 mass: 250/169)	0.01	0.01 0.1 Overall	92.7 – 99.0 (95.5) 96.9 – 100 (98.5) 92.7 – 100 (97.0)	2.75 (5) 1.34 (5) 2.59 (10)	0.00006 – 0.0024 µg/mL (0.003 – 0.12 mg/kg) n=6 Y = 6.61×10^{7}x + 919 R = 0.9983
	Clothianidin (confirmatory transition Q1/Q3 mass: 250/132)	0.01	0.01 0.1 Overall	88.4 – 97.3 (91.5) 96.7 – 101 (98.0) 88.4 – 101 (94.8)	3.92 (5) 1.99 (5) 4.59 (10)	0.00006 – 0.0024 µg/mL (0.003 – 0.12 mg/kg) n=6 Y = 6.31×10^{7}x $+1.18 \times 10^{3}$ R = 0.9981
Vegetation (broccoli)	Thiamethoxam (primary	0.01	0.01	72.2 – 85.4 (78.9)	6.52 (5)	0.003 – 0.12 ng/mL

		transition Q1/Q3 mass: 292/211)		0.1 Overall	82.5 – 88.3 (84.9) 72.2 – 88.3 (81.9)	2.80 (5) 6.03 (10)	(0.003 – 0.12 mg/kg) n=6 Y = $3.37x10^5x$ + 358 R = 0.9937
		Thiamethoxam (confirmatory transition Q1/Q3 mass: 292/181)	0.01	0.01 0.1 Overall	68.2 – 94.9 (79.1) 79.0 – 90.0 (86.8) 68.2 – 94.9 (82.9)	12.5 (5) 5.11 (5) 10.0 (10)	0.003 – 0.12 ng/mL (0.003 – 0.12 mg/kg) n=6 Y = $1.57x10^5x$ + 125 R = 0.9978
		Clothianidin (primary transition Q1/Q3 mass: 250/169)	0.01	0.01 0.1 Overall	69.2 – 86.6 (79.2) 71.8 – 79.9 (77.0) 69.2 – 86.6 (78.1)	7.91 (5) 4.28 (5) 6.24 (10)	0.003 – 0.12 ng/mL (0.003 – 0.12 mg/kg) n=6 Y = $1.2x10^5x$ + 9.29 R = 0.9993
		Clothianidin (confirmatory transition Q1/Q3 mass: 250/132)	0.01	0.01 0.1 Overall	98.7 – 113 (106) 78.0 – 84.3 (82.0) 78.0 – 113 (93.9)	5.73 (5) 3.05 (5) 14.1 (10)	0.003 – 0.12 ng/mL (0.003 – 0.12 mg/kg) n=6 Y = $1.05x10^5x$ – 34.1 R = 0.9997
	Pollen	Thiamethoxam (primary transition Q1/Q3 mass: 292/211)	0.01	0.01 0.1 Overall	79.0 – 93.8 (85.2) 77.0 – 83.9 (80.4) 77.0 – 93.8 (82.8)	7.71 (5) 3.45 (5) 6.51 (10)	0.003 – 0.12 ng/mL (0.003 – 0.12 mg/kg) n=6 Y = $4.04x10^5x$ + 178 R = 0.9964
		Thiamethoxam (confirmatory transition	0.01	0.01 0.1	64.4 – 78.4 (72.0)	8.52 (5) 4.42 (5)	0.003 – 0.12 ng/mL (0.003 –

	Q1/Q3 mass: 292/181)		Overall	76.3 – 85.4 (82.5) 64.4 – 85.4 (77.2)	9.44 (10)	0.12 mg/kg) n=6 Y = $1.87 \times 10^5 x + 150$ R = 0.9965
	Clothianidin (primary transition Q1/Q3 mass: 250/169)	0.01	0.01 0.1 Overall	83.8 – 101 (89.4) 74.3 – 78.5 (76.5) 74.3 – 101 (82.9)	8.58 (5) 1.97 (5) 10.3 (10)	0.003 – 0.12 ng/mL (0.003 – 0.12 mg/kg) n=6 Y = $1.35 \times 10^5 x - 114$ R = 0.9998
	Clothianidin (confirmatory transition Q1/Q3 mass: 250/132)	0.01	0.01 0.1 Overall	74.6 – 96.2 (86.1) 76.0 – 79.0 (77.5) 74.6 – 96.2 (81.8)	8.89 (5) 1.68 (5) 8.40 (10)	0.003 – 0.12 ng/mL (0.003 – 0.12 mg/kg) n=6 Y = $1.19 \times 10^5 x + 11.9$ R = 0.9999

Specificity:
Specificity was demonstrated by retention time match with reference standards. Analysis of unfortified control soil, vegetation and pollen samples and reagent blanks demonstrated no significant interference (> 30% of the LOQ) at the retention times of interest.

Confirmation:
Confirmation of identity was achieved simultaneously to the primary detection by monitoring an additional mass transition for each analyte. The selection of ions is justified based on the mass spectrum presented. Acceptable calibration, specificity, recovery and precision data have been presented. Note: confirmation of identity is not required for risk assessment methods but has been demonstrated so has been reported.

Matrix Effects:

The difference between soil, vegetation and pollen matrix matched standards and solvent based standard peak areas were not greater than 20% of the non-matrix matched (solvent) based standard. Matrix effects are not considered significant and therefore non-matrix matched standards were used for all determinations (soil, vegetation and pollen). It is noted that some analyses were repeated for pollen and vegetation as the replicate results were not sufficiently similar, or, the calibration line was not sufficiently linear. These issues were addressed and no longer a concern in the repeat analysis.

Extraction efficiency:

Not currently required for soil. For pollen and vegetation, which are products of plant origin, further consideration is required. In the plant metabolism studies, a range of solvents are used to extract

	the radioactive residues: methanol, water, acetonitrile. As these solvents are used in the above analytical method (primarily methanol and water), this provides confidence that the residues in these matrices are likely to be sufficiently extracted. **Linearity:** Soil: Linearity was demonstrated by the analysis of six standards of increasing concentration. The range of standard concentrations used was 0.00006 – 0.0024 µg/mL, equivalent to 0.003 – 0.12 mg/kg thiamethoxam and clothianidin in the soil samples. The response was linear with a correlation coefficient (r) of at least 0.99. A visual inspection of the residual plots shows that the calibration is sufficiently linear (points randomly distributed). For thiamethoxam, the 0.00012 µg/mL calibration standard was excluded from the graph due to visual deviation from the line of best fit. Calibration based on 5 standards is sufficient. Pollen and vegetation: Linearity was demonstrated by the analysis of six standards of increasing concentration. The range of standard concentrations used was 0.003 – 0.12 µg/mL, equivalent to 0.003 – 0.12 mg/kg thiamethoxam and clothianidin in the pollen and vegetation samples. The response was linear with a correlation coefficient (r) of at least 0.99. A visual inspection of the residual plots shows that the calibration is sufficiently linear (points randomly distributed). **Accuracy:** Recovery samples were prepared by fortifying samples of control soil, vegetation (broccoli) and pollen with known amounts of the active substances and analysing them by the method described. The fortification concentrations were 0.01 and 0.1 mg/kg for both active substances. Five samples were prepared at each fortification level. For soil, the individual and mean recoveries were within the acceptable range. For pollen and vegetation the mean recoveries were within the acceptable range, however some individual recoveries were outside of this range: 64-69% for thiamethoxam confirmatory transition at 0.01 mg/kg for vegetation and pollen, and for clothianidin quantification transition at 0.01 mg/kg for vegetation. As the mean recoveries are within the acceptable range, and these recoveries are not significantly outside of the acceptable range, this is considered acceptable. **Precision:** Precision was determined from the accuracy recovery data. Five samples were prepared at each fortification level. The % RSD at each fortification level was < 20%. **LOQ and LOD:** The LOQ is defined at the lowest validated level with sufficient recovery and precision. In this case, this is 0.01 mg/kg for both thiamethoxam and clothianidin. The LOD is defined as the lowest detectable concentration or amount of an analyte in a sample, and should be expressed as the lowest calibration standard, preferably in matrix. In this case, the LOD is 0.003 mg/kg, based on the lowest calibration standard for both thiamethoxam and clothianidin in soil, vegetation and pollen. Matrix matched standards were not used for quantification, however, were tested to determine matrix effects which were not considered significant (max. 17.6% testing a concentration of 0.0012 µg/mL, equivalent to 0.06 mg/kg for soil, max. 18.5% testing a concentration of 0.12 ng/mL equivalent to 0.12 mg/kg for vegetation and pollen). **Extract stability:** Five determinations of recovery were made at two fortification levels (0.01 and 0.1 mg/kg) for thiamethoxam and clothianidin (primary transition only). Mean recoveries were within the acceptable range of 70-120% after 11 days (pollen), 18 days (soil) and 27 days (broccoli) frozen storage (<-10°C, nominally -20°C). Some individual recoveries were outside of the acceptable range (132% for clothianidin at 0.01 mg/kg in soil, 66.5% for thiamethoxam at 0.01 mg/kg in soil and 122% for thiamethoxam at 0.01 mg/kg in pollen). As the mean recoveries were within the acceptable range and these were single recoveries at each level/matrix/analyte combination, this is considered acceptable.

Matrix	Storage (days)	Analyte	0.01 mg/kg Mean Recovery (%)	0.1 mg/kg Mean Recovery (%)
Soil	18	Thiamethoxam (Primary)	97.5	97.8
		Clothianidin (Primary)	105	90.1
Broccoli	27	Thiamethoxam (Primary)	80.6	76.3
		Clothianidin (Primary)	88.6	79.7
Pollen	11	Thiamethoxam (Primary)	109	80.6
		Clothianidin (Primary)	86.1	82.0

Standard/stock solution stability:

Primary stock solutions at 1000 µg/mL in methanol were demonstrated to be stable when stored refrigerated (2-8°C) for 43 days for thiamethoxam and clothianidin. Secondary stocks of 0.01 µg/mL thiamethoxam and clothianidin in methanol were demonstrated to be stable when stored refrigerated (2-8°C) for 24 days. Secondary stocks at concentrations higher than 0.01 µg/mL were considered to also be stable for 24 days, based upon the 0.01 and 1000 µg/mL stocks both being stable for at least this time. Stability was determined by diluting stock solutions which had been stored refrigerated and analysing them against freshly prepared solutions. Stability over the period of storage was considered acceptable if the difference was not greater than 10%.

Procedural recoveries:

The following recoveries were determined during the determination of the test sample results:

Matrix	Analyte	Recovery fortification level (mg/kg)	Recoveries % range (mean)
Soil	Thiamethoxam	0.01 0.1	88 - 111 (98.8. n=4) 90.7 – 108 (100.9, n=4)
	Clothianidin	0.01 0.1	94.7 - 108.2 (101.5, n=4) 91.7 - 97.5 (93.6, n=4)
Vegetation	Thiamethoxam	0.01 0.1	71.6, 76.5 (74.1, n=2) 69.4, 70.3 (69.9. n=2)
	Clothianidin	0.01 0.1	66.1, 68.3 (67.2, n=2) 71.2, 73.9 (72.6, n=2)
Pollen	Thiamethoxam	0.01 0.1	91.8 95.8
	Clothianidin	0.01 0.1	92.4 80.7

For soil samples, sample 4 failed the procedural recovery for both analytes and the results were not reported. The samples were re-analysed in sample 5 giving acceptable results. For soil, based on four determinations, the individual and mean recoveries were within the acceptable range (70-120%).

For vegetation, both samples initially failed recovery criteria for both analytes. The frozen sample extracts were re-analysed with fresh calibration standards. The overall mean recovery for thiamethoxam considering both fortification levels combined, give an acceptable recovery (72%). The mean recovery at the 0.1 mg/kg fortification level is only very slightly outside of the acceptable range (69.9%). For clothianidin, both individual recoveries at the 0.01 mg/kg fortification level were below 70%. However, in accordance with SANTE/2020/12830, Rev. 1, for fortifications at 0.01 mg/kg, recoveries in the range 60-130% are acceptable. Therefore these recoveries may be considered acceptable at this low level. The overall mean recovery for clothianidin considering both fortification levels combined is 69.88% which is slightly below the lower limit of the acceptable range (70%).

For pollen, sample 1 initially failed recovery criteria for both analytes. Samples were re-analysed and gave acceptable results. Note the clothianidin results were reported based on the confirmatory transition, due to interference with the primary transition during analysis of the samples. This was not observed in the method validation but as both transitions were sufficiently supported by validation data, either transition could be used for quantification.

Conclusion

The method is satisfactorily validated in accordance with SANTE/2020/12830, Rev. 1 for the determination of thiamethoxam and clothianidin in sandy loam soil, vegetation (broccoli) and pollen, with an LOQ of 0.01 mg/kg for each analyte.

Soil sample concentrations determined in the study ranged from <LOQ to 0.11 mg/kg for thiamethoxam and <LOQ to 0.0146 mg/kg for clothianidin. Vegetation and pollen sample results were <LOQ for thiamethoxam and clothianidin. The method validation data presented supports the range of results determined in the study.

It should be noted that there were some low recoveries reported during the analysis of test samples (procedural recoveries), based on a limited number of samples. This will be considered further in the relevant section where the results from the study and use of the method are reported.

Title: "*Method validation and sample analysis of thiamethoxam and clothianidin in soil and non-crop vegetation*"
Author/Year: [redacted] 2024
Study/Report No.: 3203568 [Evaluated to support the data submitted in 2024 (for use in 2025]

The aim of this study was to validate a method for the analysis of thiamethoxam and clothianidin in soil, vegetation (broccoli) and pollen. The analytical conditions have changed slightly compared to previous method used for the determination of thiamethoxam and clothianidin in soil, vegetation and pollen. Additionally, data has been provided to support lower LOQs of the method.

Control samples were clay loam soil, sandy loam soil, broccoli and pine pollen. Test samples were received frozen. Soil samples were homogenised by passing through a 2 mm sieve and stored frozen (< -10°C, nominally -20°C). Vegetation samples were homogenised by blending with dry ice and stored frozen (< -10°C, nominally -20°C). Flowers were dried in an oven set to 60°C. Once sufficiently dry, the pollen was isolated from the flowers by passing through sieves of decreasing sizes, with a final aperture of 250 µm. The isolated pollen was stored frozen (< -10°C, nominally -20°C).

__Soil sample preparation:__
(Reference: analytical procedure SM 3203568-03V.S)

10 g (± 0.1 g) of soil were weighed into a plastic pot (175 mL). 50 mL of acetonitrile:10 mM ammonium acetate (80:20 v/v) were added. The sample was swirled to mix, ultrasonicated for 10 minutes, shaken for 30 minutes and centrifuged at 3500 rpm for 5 minutes. The supernatant extract was transferred into a glass jar (120 mL). A further 50 mL of acetonitrile:10 mM ammonium acetate (80:20 v/v) were added. The sample was swirled to mix, ultrasonicated for 10 minutes, shaken for 30 minutes and centrifuged at 3500 rpm for 5 minutes. The supernatant extract was transferred into the same glass jar used for the first extract. The sample was made to 100 mL volume with acetonitrile: 10 mM ammonium acetate (80:20 v/v). A 1 mL aliquot of the sample extract was transferred into a glass tube and evaporates to approximately 0.2 mL using a sample concentrator set to 45°C under a gentle flow of nitrogen. 5 mL of Milli-Q water was added and the sample ultrasonicated to mix.

An SPE cartridge (Oasis HLB 60 mg 3 mL) was conditioned with 3 mL of methanol followed by 6 mL of Milli-Q water. The sample extract was loaded onto the SPE cartridge and the eluent discarded. The sample tube was rinsed with 1 mL of Milli-Q water and washed through the SPE cartridge. Excess water from the walls of the SPE cartridge is dried using paper towel and full vacuum is applied for approximately 20 minutes. The SPE cartridge was washed with 2 mL of hexane and the eluent discarded. Full vacuum was applied for 20-30 seconds to remove any remaining solvent from the cartridge. The SPE cartridge was eluted with 6 mL of acetonitrile. The sample was evaporated to dryness using a sample concentrator set to 45°C under a gentle stream of nitrogen. The sample was reconstituted with 10 mL of methanol: 50 mM ammonium acetate (10:90 v/v) and ultrasonicated for approximately 5 minutes. The sample is diluted into the calibration range, if necessary, with methanol: 50 mM ammonium acetate (10:90 v/v). The final sample was transferred into a glass HPLC vial for LC-MS/MS analysis under the following conditions:

HPLC Parameters:

Instrument:	Shimadzu Nexera HPLC system		
Column#:	Atlantis dC18 4 µm 2.1 × 50 mm		
Mobile Phase A#:	0.1% formic acid in water		
Mobile Phase B#:	0.1% formic acid in acetonitrile		
Flow rate:	0.4 mL/min		
Gradient:	Time (min)	MP A (%)	MP B (%)
	0	90	10
	1	90	10
	2.5	10	90
	3.9	10	90
	4	90	10
	5	90	10
Run Time:	5 minutes		
Column Temperature:	40°C		
Autosampler Temperature:	5°C		
Injection Volume:	50 µL		
Approx. Retention Times:	Thiamethoxam: 2.1 minutes		
	Clothianidin: 2.3 minutes		
Valco Valve Diverter:	Time (min)		Position
	0		A (to waste)
	0.5		B (to MS)
	4.5		A (to waste)

MS/MS Parameters:

Instrument:	Sciex API 5000 MS/MS				
Ionisation Type#:	Electrospray (ESI)				
Polarity#:	Positive				
Scan Type#:	Multiple reaction monitoring (MRM)				
Ion Spray Voltage:	3200 V				
Collision Gas (CAD):	4				
Curtain Gas (CUR):	21				
Gas Flow 1 (GS1):	55				
Gas Flow 2 (GS2):	55				
Vaporiser Temperature (TEM):	550°C				
Interface Heater (ihe):	On				
Entrance Potential (EP):	10				
Resolution Q1/Q3:	Unit/Unit				
Transition Name:	Q1/Q3 masses (amu)	Dwell Time (ms)	Collision Energy (CE)	Declustering Potential (DP)	Collision Cell Exit Potential (CXP)
Thiamethoxam (Primary)	292.2/211.1	100	17	56	13
Thiamethoxam (Confirmatory)	292.2/181.1	100	30	56	13
Clothianidin (Primary)	250.0/169.3	100	18	36	13
Clothianidin (Confirmatory)	250.0/132.0	100	22	36	13

Parameters marked # may not be modified. Minor adjustments to the remaining parameters may be required in order to fully optimise the system.

__Vegetation sample preparation (broccoli):__
(Reference: SM 3203568-01V.V)
10 ± 0.1 g of vegetation were weighed into a 250 mL plastic pot. 100 mL of methanol: water (50:50 v/v) were added. The sample was homogenized for approximately 3 minutes and

centrifuged at 4750 rpm for 5 minutes. A 1 mL aliquot of the sample extract was transferred into a glass tube. 5 mL of Milli-Q water were added are ultrasonicated to mix.

An SPE cartridge (Oasis HLB 60 mg 3 mL) was conditioned with 3 mL of methanol followed by 6 mL of Milli-Q water. The sample extract was loaded onto the SPE cartridge and the eluent discarded. The sample tube was rinsed with 1 mL of Milli-Q water and washed through the SPE cartridge. Excess water from the walls of the SPE cartridge is dried using paper towel and full vacuum is applied for approximately 20 minutes. The SPE cartridge was washed with 2 mL of hexane and the eluent discarded. Full vacuum was applied for 20-30 seconds to remove any remaining solvent from the cartridge. The SPE cartridge was eluted with 6 mL of acetonitrile. The sample was evaporated to dryness using a sample concentrator set to 45°C under a gentle flow of nitrogen. The sample was reconstituted with 10 mL of methanol: 50 mM ammonium acetate (10:90 v/v) and ultrasonicated for approximately 5 minutes. The final sample is transferred to a glass vial for LC-MS/MS analysis under the following conditions:

HPLC Parameters:

Instrument:	Shimadzu Nexera UPLC system		
Column#:	Atlantis dC18 3 µm, 2.1 × 150 mm		
Mobile Phase A#:	0.1% formic acid in water		
Mobile Phase B#:	0.1% formic acid in methanol		
Flow Rate:	0.4 mL/min		
Gradient:	Time (min)	MP A (%)	MP B (%)
	0	90	10
	1	90	10
	4	10	90
	5	10	90
	5.1	90	10
	6	90	10
Run Time:	6 minutes		
Column Temperature:	50°C		
Autosampler Temperature:	5°C		
Injection Volume:	15 µL		
Approx.Retention Times:	Thiamethoxam: 3.8 minutes		
	Clothianidin: 4.1 minutes		
Valco Valve Diverter:	Time (min)		Position
	0		A (to waste)
	0.5		B (to MS)
	5.5		A (to waste)

MS/MS Parameters:

Instrument:	Sciex API 5000 MS/MS					
Ionisation Type#:	Electrospray (ESI)					
Polarity#:	Positive					
Scan Type#:	Multiple reaction monitoring (MRM)					
Ion Spray Voltage:	3200/2700 V (Thiamethoxam/Clothianidin)					
Collision Gas (CAD):	4					
Curtain Gas (CUR):	21/36 (Thiamethoxam/Clothianidin)					
Gas Flow 1 (GS1):	55/60 (Thiamethoxam/Clothianidin)					
Gas Flow 2 (GS2):	55					
Vaporiser Temperature (TEM):	450°C					
Interface Heater (ihe):	On					
Resolution Q1/Q3:	Unit/Unit					
Transition Name:	Q1/Q3 masses (amu)	Dwell Time (ms)	Collision Energy (CE)	Declust-ering Potential (DP)	Collision Cell Exit Potential (CXP)	Entrance Potential (EP)
Thiamethoxam (Primary)	292.2/211.1	200	17	56	13	10
Thiamethoxam (Confirmatory	292.2/181.1	200	30	56	13	10
Clothianidin (Primary)	250.0/169.0	200	19	36	13	12
Clothianidin (Confirmatory)	250.0/132.0	200	19	36	13	10

Separate instrument sequences are used to collect data for Thiamethoxam and Clothianidin.
Parameters marked # may not be modified. Minor adjustments to the remaining parameters may be required in order to fully optimise the system.

Pollen sample preparation:
(Reference: SM 3203568-01V.P)
0.1 ± 0.005 g of pollen were weighed into a plastic centrifuge tube (15 mL) and 5 mL of 0.2% formic acid in methanol: water (50:50 v/v) were added. The sample was shaken vigorously by hand, vortex mixed for approximately 30 seconds and centrifuged at 4750 rpm for 5 minutes. A 1 mL aliquot of extract was transferred to a glass tubes and 5 mL of Milli-Q water added, and mixed by ultrasonication.

An SPE cartridge (Oasis HLB 60 mg 3 mL) was conditioned with 3 mL of methanol followed by 6 mL of Milli-Q water. The sample extract was loaded onto the SPE cartridge and the eluent discarded. The sample tube was rinsed with 1 mL of Milli-Q water and washed through the SPE cartridge. Excess water from the walls of the SPE cartridge is dried using paper towel and full vacuum is applied for approximately 20 minutes. The SPE cartridge was washed with 2 mL of hexane and the eluent discarded. Full vacuum is applied for 20-30 seconds to remove any remaining solvent from the cartridge. The SPE cartridge is eluted with 6 mL of acetonitrile. The sample is evaporated to dryness using a sample concentrator set to 45°C under a gentle flow of nitrogen. The sample is reconstituted with 10 mL of methanol: 50 mM ammonium acetate (10:90 v/v) and ultrasonicated for approximately 5 minutes. The final sample is transferred to a glass vial for LC-MS/MS analysis under the conditions detailed above for vegetation analysis.

Analytical validation data for the determination of thiamethoxam and clothianidin in soil, vegetation and pollen

Matrix	Analyte	LOQ (mg/kg)	Recovery fortification level (mg/kg)	Recoveries % range (mean)	Repeatability % RSD (n)	Linearity
Clay loam soil	Thiamethoxam (primary transition Q1/Q3 mass: 292/211)	0.001	0.001 0.01 0.1 Overall	76.6 – 85.5 (82.2) 85.6 – 96.9 (90.0) 69.9 – 95.6 (84.3) 69.9 – 96.9 (85.5)	4.20 (5) 4.92 (5) 11.3 (5) 7.99 (15)	0.003 – 0.3 ng/mL (0.0003 – 0.03 mg/kg[$]) n=7 Y = $3.87476x10^5$x + 374 R = 0.99909
	Thiamethoxam (confirmatory transition Q1/Q3 mass: 292/181)	0.001	0.001 0.01 0.1 Overall	73.5 – 99.0 (83.8) 85.2 – 97.0 (91.0) 69.5 – 121 (93.9) 69.5 – 121 (89.6)	11.4 (5) 4.68 (5) 19.5 (5) 13.54 (15)	0.003 – 0.3 ng/mL (0.0003 – 0.03 mg/kg[$]) n=7 Y = $1.8204x10^5$x + 41.708 R = 0.99906
	Clothianidin (primary transition Q1/Q3 mass: 250/169)	0.001	0.001 0.01 0.1 Overall	81.8 – 111 (102) 78.8 – 93.1 (87.9) 79.2 – 103 (89.7) 78.8 – 111 (93.2)	11.3 (5) 6.55 (5) 9.93 (5) 11.41 (15)	0.003 – 0.3 ng/mL (0.0003 – 0.03 mg/kg[$]) n=7 Y = $2.2327x10^5$x + 147.9 R = 0.99983
	Clothianidin (confirmatory transition Q1/Q3 mass: 250/132)	0.001	0.001 0.01 0.1 Overall	71.1 – 84.5 (77.2) 79.9 – 94.1 (87.9) 83.4 – 119 (96.5) 71.1 – 119 (87.2)	8.10 (5) 6.12 (5) 14.9 (5) 13.75 (15)	0.003 – 0.3 ng/mL (0.0003 – 0.03 mg/kg[$]) n=7 Y = $2.03784x10^5$x + 390.36 R = 0.99994

	Sandy loam soil	Thiamethoxam (primary transition Q1/Q3 mass: 292/211)	0.001	0.001	86.9 – 89.6 (88.3)	1.20 (5)	See clay loam soil linear range; same calibrations used
				0.01	89.3 – 94.1 (92.2)	2.12 (5)	
				0.1	75.7 – 123 (104)	18.1 (5)	
				Overall	75.7 – 123 (94.7)	12.80 (15)	
		Thiamethoxam (confirmatory transition Q1/Q3 mass: 292/181)	0.001	0.001	78.5 – 98.9 (89.5)	8.47 (5)	See clay loam soil linear range; same calibrations used
				0.01	88.2 – 95.7 (91.6)	3.13 (5)	
				0.1	73.5 – 110 (89.9)	18.9 (5)	
				Overall	73.5 – 110 (90.4)	11.24 (15)	
		Clothianidin (primary transition Q1/Q3 mass: 250/169)	0.001	0.001	83.6 – 106 (95.1)	10.3 (5)	See clay loam soil linear range; same calibrations used
				0.01	86.2 – 92.2 (89.3)	2.37 (5)	
				0.1	71.4 – 106 (86.2)	15.3 (5)	
				Overall	71.4 – 106 (90.21)	10.73 (15)	
		Clothianidin (confirmatory transition Q1/Q3 mass: 250/132)	0.001	0.001	90.1 – 107 (96.8)	7.03 (5)	See clay loam soil linear range; same calibrations used
				0.01	84.5 – 90.1 (86.5)	2.45 (5)	
				0.1	91.4 – 110 (102)	7.39 (5)	
				Overall	84.5 – 110 (95.2)	9.25 (15)	
	Vegetation (broccoli)	Thiamethoxam (primary transition Q1/Q3 mass: 292/211)	0.001	0.001	67.7 – 86.2 (78.9)	8.81 (5)	0.003 – 0.3 ng/mL (0.0003 – 0.03 mg/kg) n=7 $y=2.1035x10^{5}x + 166.062$ r = 0.99806
				0.01	76.6 – 89.9 (85.3)	6.24 (5)	
				Overall	67.7 - 89.9 (82.1)	8.19 (10)	

		Thiamethoxam (confirmatory transition Q1/Q3 mass: 292/181)	0.001	0.001 0.01 Overall	69.9 – 92.7 (78.0) 77.3 – 86.1 (81.6) 69.9 – 92.7 (79.8)	12.0 (5) 3.84 (5) 8.55 (10)	0.003 – 0.3 ng/mL (0.0003 – 0.03 mg/kg) n=7 $y=9.96575 x 10^4 x + 34.0899$ r = 0.99644
		Clothianidin (primary transition Q1/Q3 mass: 250/169)	0.001	0.001 0.01 Overall	75.1 – 89.8 (80.1) 73.5 – 78.1 (75.6) 73.5 – 89.8 (77.8)	7.46 (5) 2.74 (5) 6.21 (10)	0.003 – 0.3 ng/mL (0.0003 – 0.03 mg/kg) n=7 $y=2.2838 x 10^5 x + 364.87$ r = 0.99965
		Clothianidin (confirmatory transition Q1/Q3 mass: 250/132)	0.001	0.001 0.01 Overall	54.5 – 69.6 (60.8) 70.0 – 75.3 (72.8) 54.5 – 75.3 (66.8)	10.2 (5) 2.98 (5) 11.5 (10)	0.003 – 0.3 ng/mL (0.0003 – 0.03 mg/kg) n=7 $y=2.32607 x 10^5 x + 679.53$ r = 0.99937
	Pollen	Thiamethoxam (primary transition Q1/Q3 mass: 292/211)	0.005	0.005 0.05 Overall	60.6 – 86.1 (75.1) 78.1 – 97.3 (85.7) 60.6 – 97.3 (80.4)	12.7 (5) 8.32 (5) 12.1 (10)	See vegetation (broccoli) linear range; same calibrations used. Linear range equivalent to 0.0015 – 0.15 mg/kg in pollen
		Thiamethoxam (confirmatory transition Q1/Q3 mass: 292/181)	0.005	0.005 0.05 Overall	74.3 – 104 (92.7) 92.7 – 104 (97.1) 74.3 – 104 (94.9)	13.6 (5) 4.41 (5) 9.64 (10)	See vegetation (broccoli) linear range; same calibrations used. Linear range equivalent to 0.0015 – 0.15 mg/kg in pollen
		Clothianidin (primary transition Q1/Q3 mass: 250/169)	0.005	0.005 0.05 Overall	76.0 – 89.1 (82.9) 80.8 – 86.9 (83.1) 76.0 – 89.1 (83.0)	5.79 (5) 3.20 (5) 4.41 (10)	See vegetation (broccoli) linear range; same calibrations used. Linear range equivalent to 0.0015 – 0.15 mg/kg in pollen

	Clothianidin (confirmatory transition Q1/Q3 mass: 250/132)	0.005	0.005	71.5 – 91.6 (80.6)	9.91 (5)	See vegetation (broccoli) linear range; same calibrations used. Linear range equivalent to 0.0015 – 0.15 mg/kg in pollen
			0.05	79.5 – 83.9 (81.7)	1.96 (5)	
			Overall	71.5 – 91.6 (81.1)	6.73 (10)	

$ Samples diluted to be within the linear range. The range 0.0003 – 0.03 mg/kg is based on no further dilutions being performed.

Specificity:

Specificity was demonstrated by retention time match with reference standards. Analysis of unfortified control soil, vegetation and pollen samples and reagent blanks demonstrated no significant interference (> 30% of the LOQ) at the retention times of interest.

Confirmation:

Confirmation of identity was achieved simultaneously to the primary detection by monitoring an additional mass transition for each analyte. The selection of ions is justified based on the mass spectrum presented. Acceptable calibration, specificity, recovery and precision data have been presented. Note: confirmation of identity is not required for risk assessment methods but has been demonstrated so has been reported.

Matrix Effects:

The difference between soil, vegetation and pollen matrix matched standards and solvent based standard peak areas were not greater than 20% of the non-matrix matched (solvent) based standard. Matrix effects are not considered significant and therefore non-matrix matched standards were used for all determinations (soil, vegetation and pollen).

Extraction efficiency:

Not currently required for soil. For pollen and vegetation, which are products of plant origin, further consideration is required. In the plant metabolism studies, a range of solvents are used to extract the radioactive residues: methanol, water, acetonitrile. As these solvents are used in the above analytical method (primarily methanol and water), this provides confidence that the residues in these matrices are likely to be sufficiently extracted.

Linearity:

Soil:
Linearity was demonstrated by the analysis of seven solvent based standards of increasing concentration. The range of standard concentrations used was 0.003 – 0.3 ng/mL, equivalent to 0.0003 – 0.03 mg/kg thiamethoxam and clothianidin in the soil samples. The response was linear with a correlation coefficient (r) of at least 0.99. A visual inspection of the residual plots shows that the calibration is sufficiently linear (points randomly distributed). The same instrument method and solvent based calibration was used for both clay loam and sandy loam soil validations, therefore the calibration presented for clay loam is applicable to sandy loam also.

Pollen and vegetation:
Linearity was demonstrated by the analysis of seven standards of increasing concentration. The range of standard concentrations used was 0.003 – 0.3 ng/mL, equivalent to 0.0003 – 0.03 mg/kg thiamethoxam and clothianidin in vegetation samples and 0.0015 – 0.15 mg/kg in pollen samples. The response was linear with a correlation coefficient (r) of at least 0.99. A visual inspection of the residual plots shows that the calibration is sufficiently linear (points randomly distributed). The same instrument method and solvent based calibration was used for the pollen and vegetation

validations, therefore the calibration presented for vegetation (broccoli) is applicable to pollen also.

Accuracy:

Recovery samples were prepared by fortifying samples of control soil, vegetation (broccoli) and pollen with known amounts of the active substances and analysing them by the method described. Five samples were prepared at each fortification level. The overall range and mean of recoveries across all fortification levels has been reported also.

Clay loam soil:
The fortification concentrations were 0.001, 0.01 and 0.1 mg/kg for both thiamethoxam and clothianidin. **The mean recoveries were within the acceptable range at each fortification level**. Some individual recoveries were outside of this range: 69.9% at 0.1 mg/kg for thiamethoxam primary transition (sufficiently close to the lower acceptable limit of 70% recovery to be considered acceptable), 69.5% and 121 % at 0.1 mg/kg for thiamethoxam confirmatory transition (mean recovery acceptable and confirmatory transition not relied upon, therefore these individual recoveries outside of the acceptable range are acceptable), and 119% at 0.1 mg/kg fortification for clothianidin confirmatory transition (mean recovery acceptable and confirmatory transition not relied upon therefore considered acceptable in this case).

Sandy loam soil:
The fortification concentrations were 0.001, 0.01 and 0.1 mg/kg for both thiamethoxam and clothianidin. **The mean recoveries were within the acceptable range at each fortification level.** Some individual recoveries were outside of this range: 111%, 114% and 123% at 0.1 mg/kg for thiamethoxam primary transition (mean recovery within acceptable range and results from the monitoring studies did not determine residues at levels close to this fortification level (max. approximately 0.017 mg/kg) therefore this is considered acceptable).

Vegetation:
The fortification concentrations were 0.001 and 0.01 mg/kg for both thiamethoxam and clothianidin. **The mean recoveries were within the acceptable range at each fortification level.** Some individual recoveries were outside of this range: 54.5, 56 and 59.7% at 0.001 mg/kg for clothianidin confirmatory transition (mean recovery within acceptable range and confirmatory transition not relied upon therefore this is considered acceptable).

Pollen:
The fortification concentrations were 0.005 and 0.05 mg/kg for both thiamethoxam and clothianidin. **The individual and mean recoveries were within the acceptable range at each fortification level.**

Precision:
Precision was determined from the accuracy recovery data. Five samples were prepared at each fortification level. The % RSD at each fortification level was < 20%.

LOQ and LOD:
The LOQ is defined at the lowest validated level with sufficient recovery and precision. In this case, this is 0.001 mg/kg for both thiamethoxam and clothianidin in soil and vegetation, and 0.005 mg/kg in pollen.

The LOD is defined as the lowest detectable concentration or amount of an analyte in a sample, and should be expressed as the lowest calibration standard, preferably in matrix. In this case, the LOD is 0.0003 mg/kg, based on the lowest calibration standard for both thiamethoxam and clothianidin in soil and vegetation and 0.0015 mg/kg in pollen. Matrix matched standards were not used for quantification, however, were tested to determine matrix effects which were not considered significant (max. 12.9% testing a concentration of 0.1 ng/mL, equivalent to 0.01 mg/kg for soil, max. 19.2% testing a concentration of 0.1 ng/mL equivalent to 0.01 mg/kg for vegetation, and max. 14.9% testing a concentration of 0.1 ng/mL equivalent to 0.05 mg/kg for pollen).

Extract stability:
Sample extracts were demonstrated to be stable in previously evaluated studies: Ref 3203177 and 3203301.

Standard/stock solution stability:
Stock solutions were demonstrated to be stable in a previously evaluated study: Ref 3203301.

Procedural recoveries:

The following recoveries were determined during the determination of the test sample results:

Matrix	Analyte	Recovery fortification level (mg/kg)	Recoveries % range (mean)
Soil	Thiamethoxam	0.001 0.01 0.1	69.7 – 105.5 (84.4. n=18) 78.4 – 109.9 (95.3, n=18) 85.7 – 101.5 (95.3, n=12)
	Clothianidin	0.001 0.01 0.1	65.9 - 127.7 (95.1, n=20) 72.7 - 111.5 (93.5, n=20) 81 – 112 (98.3, n=13)
Vegetation	Thiamethoxam	0.001 0.01	88.4 – 101.9 (94.2, n=4) 88.3 – 90.8 (89.4, n=4)
	Clothianidin	0.001 0.01	62.3 – 75.3 (68.7, n=4) 76.7 – 84.0 (81.0, n=4)
Pollen	Thiamethoxam	0.005 0.05	90.4, 91.9 (91.2, n=2) 91.1, 94.1 (92.6, n=2)
	Clothianidin	0.005 0.05	85.3, 87.1 (86.2, n=2) 82.6, 90.5 (86.6, n=2)

For soil, for both analytes, the mean recoveries were within the acceptable range considering the fortification level (60 – 120% at 0.001 and 0.01 mg/kg, 70-110% at 0.1 mg/kg). Some individual recoveries were outside of these acceptable ranges but as the mean recoveries based on at least 12 samples are within the acceptable range, this is considered acceptable.

For vegetation, for both analytes, the mean and individual recoveries were within the acceptable range (60 – 120%). For pollen, for both analytes, the mean and individual recoveries were within the acceptable range considering the fortification level (60 – 120% at 0.005 and 70-110% at 0.05 mg/kg).

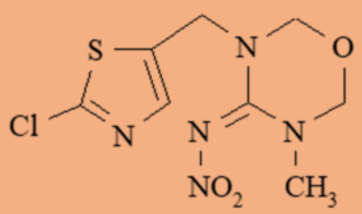
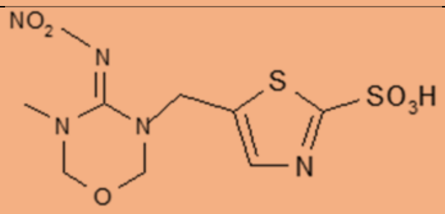
	For some samples of pollen and soil, the confirmatory transition for both thiamethoxam and clothianidin was relied upon due to failure of the control samples or interference in the primary transition. This was not observed in the method validation. As both transitions were supported by validation data in these matrices, either transition could be used for quantification. **<u>Conclusion</u>** The method is satisfactorily validated in accordance with SANTE/2020/12830, Rev. 1 for the determination of thiamethoxam and clothianidin in clay loam soil, sandy loam soil and vegetation (broccoli), with an LOQ of 0.001 mg/kg for each analyte, and for the determination of thiamethoxam and clothianidin in pollen, with an LOQ of 0.005 mg/kg for each analyte. Soil sample concentrations determined in the study this method validation supports ranged from <LOQ to 0.01698 mg/kg for thiamethoxam and <LOQ to 0.01447 mg/kg for clothianidin. Vegetation sample concentrations determined in the study ranged from <LOQ to 0.00144 mg/kg for thiamethoxam and <LOQ to 0.00177 mg/kg for clothianidin. Pollen sample results were all <LOQ for thiamethoxam and clothianidin. The method validation data presented supports the range of results determined in the study.

2.3 Mammalian Toxicology

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	**Health and Safety Executive**
Reviewer's comments	The toxicological properties of 'Cruiser SB' were previously considered in the original assessment considered by the ACP on 9 May 2006. The assessment concluded: Based on the results of the acute oral and dermal toxicity studies performed using 'CRUISER 70WS', 'CRUISER 350FS' and 'ADAGE 5FS', the acute oral LD50 of the proposed product 'CRUISER SB' is predicted to be >2000 mg/kg bw. The proposed formulation is considered to be toxicologically comparable to 'ADAGE 5FS' and contains thiamethoxam, water and <10% of mainly toxicologically inert components. Similarly, the acute dermal LD50 of 'CRUISER SB' can be predicted to be >2000 mg/kg bw, based on the results of the studies performed using 'CRUISER 70WS', 'CRUISER 350FS' and 'ADAGE 5FS'. Studies performed with the proposed product show that it is a minimal eye irritant, a slight skin irritant and not a skin sensitiser. Since this time, an EU RAC opinion has been published and thiamethoxam has an EU harmonized classification as Repr.2 (H361fd) which is applicable in Northern Ireland. By virtue of ATP 17 applied from 17 December 2022. According to the GB MCL list, thiamethoxam is classified Repr.2 (H361fd) with a date of entry into legal effect of 23 October 2023. This is a change from when last assessed in 2023 (to support use in 2024). 'CRUISER SB' is therefore classified Repr.2 (H361fd) effects and must be labelled with H361fd 'Suspected of damaging fertility and the unborn child. Furthermore, if metabolites are present in groundwater in excess of 0.1 µg/l, a groundwater assessment will be required.

NOA 459602 is predicted to occur in groundwater at concentrations of >0.1 µg/l following its use on sugar beet (see fate section below). The guidance for the assessment of the relevance of groundwater metabolites (SANCO /221/2000 – rev. 11), indicates that where parent active substances are classified for reproductive toxicity according to Regulation 1272/200816 (as it applies in GB) it must be shown by an appropriate test or convincing other evidence that the metabolite does not qualify for the same classification.

No data on the reproductive toxicity of NOA 459602 are available. Furthermore, NOA 459602 has previously been considered to be structurally similar to thiamethoxam, being a simple sulphate derivative of the parent molecule and it might be anticipated that it shares the same toxicological properties. In the absence of any further data on NOA 459602, HSE consider it to share the same reproductive toxicity profile of the active substance and therefore to be a relevant groundwater metabolite at Stage 3 of Step 3 of the evaluation scheme in SANCO/221/2000 – rev. 11.

Thiamethoxam	NOA 459602
	

An authorisation is not possible when in line with the SANCO guidance a metabolite that is considered relevant based on hazard only (step 3) is predicted to occur in groundwater at or above 0.1µg/l. However since this application is for an emergency use, HSE has further considered NOA 459602 from a risk perspective, proceeding to steps 4 and 5 of SANCO/221/2000 – rev 11. Step 4 of the guidance is to compare the toxicological threshold of concern of 0.75µg/l with the concentration of the metabolite in groundwater. Step 5 of the guidance is to perform a chronic dietary risk assessment for the metabolite. Given the structural similarity between NOA 459602 and thiamethoxam, the ADI of the parent can be applied to the risk assessment. Taking this approach dietary exposure via drinking water is acceptable (see section 3.5.

HSE notes that the GB Technical Report for thiamethoxam agreed with the RAC Opinion (adopted in December 2019), but the classification of Repr. 2 (H361fd) does not yet apply in Great Britain.

The following critical toxicological endpoints for the active substance were established in the EU 2007 assessment for thiamethoxam and have been used in the consumer and non-dietary exposure assessments.

	Value	**Study**	**Safety factor**
ADI	0.026 mg/kg bw/day	18-month mouse study	100
AOEL systemic	0.08 mg/kg bw/day	90 day dog study	100

	AOEL inhalation	Not required	-	-
	AOEL dermal	Not required	-	-
	ARfD (acute reference dose	0.5 mg/kg bw	Rabbit developmental toxicity study	100
Conclusion	The previous assessment with respect to acute toxicity, skin and eye irritation, and skin sensitisation remains valid, however, additional classification and labelling for Repr. 2 (H361fd) is required.			

2.4 Non-Dietary Exposure (Operator/Worker/Bystander and Resident)

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	**Health and Safety Executive** ***Where the assessment below indicates that the risk is either acceptable or unacceptable, this conclusion is reached within the framework of the standard criteria for a commercial authorisation based on assessment to uniform principles. Article 53 allows a derogation from the standard criteria providing specific tests are met. Therefore, whilst (for example) reference to unacceptable risks in the assessment below may highlight the areas of greatest concern, this is not the test under Article 53 and does not necessarily reflect the conclusions for this emergency authorisation application. The discussion of the overall risks and benefits from the proposed use and assessment against the requirements of Article 53 is presented in "Section 3 Conclusion of Emergency Authorisation".*** Thiamethoxam is not currently approved in GB or EU. The endpoints used in this non-dietary exposure assessment are the ones previously agreed in the context of the most recent approval of the active substance. The Seed Tropex model is the latest available model and the product risk presented below would be the same whether or not it was considered under the 'old' or 'new' product data requirements.
	Non-Dietary Exposure (Operator/Worker/Bystander and Resident) Estimates using the Seed TROPEX model were undertaken previously and presented to the ACP in May 2006. These indicated that the proposed uses of 'Cruiser SB' will result in an acceptable level of exposure to thiamethoxam for seed treatment plant operators, bystanders in seed treatment plants and workers handling and drilling treated seed. There have been no changes to the Seed TROPEX assessment methods since this time. The classification of 'Cruiser SB' as Repr.2 (H361fd) in Northern Ireland does not apply to this use in England only. (Even if it did it does not require further non-dietary exposure consideration as there are no additional PPE requirements, and the classification effects are considered when setting the AOEL.) The following PPE would be required if treating seed in accordance with the proposed use:

	(a) Operators must wear suitable protective clothing (coveralls) and suitable protective gloves when handling the concentrate or handling contaminated surfaces. (b) Operators must wear suitable protective clothing (coveralls), suitable protective gloves and suitable respiratory protective equipment* when cleaning machinery. *Disposable filtering facepiece respirator to at least EN149 FFP3 or equivalent. (c) Operators must wear suitable protective clothing (coveralls) when bagging treated seed. (d) Workers must wear suitable protective clothing (coveralls) and suitable protective gloves when handling treated seed and contaminated seed sowing equipment. **Extracts from 2006 assessment are presented in the following rows for completeness:**
Operator exposure	This estimate indicates that the proposed use of ‘Cruiser SB’ through specialist pellet treating equipment will result in a level of systemic exposure to thiamethoxam of 0.0291 mg/kg bw/day for an operator wearing coveralls and gloves (coveralls only during bagging) as in the ‘Seed TROPEX’ studies. This level of exposure is equivalent to 36% of the short term systemic AOEL of 0.08 mg/kg bw/day proposed in this evaluation and is considered to be acceptable.
Worker exposure	<u>Predicted exposure levels (geometric mean) when drilling treated seed</u> **Exposure when loading and drilling treated seed** — **Geometric mean value (assuming a 10 hour working day)** Potential dermal exposure — 14.787 mg a.s./person/day (0.246 mg/kg bw/day) Actual dermal exposure* — 7.331 mg a.s./person/day (0.122 mg/kg bw/day) Inhalation exposure — 0.200 mg a.s./person/day (0.003 mg/kg bw/day) *coveralls but not gloves were worn by workers in the Seed TROPEX drilling study Assuming no protective clothing is worn and that, as a worst case, normal clothing provides no exposure reduction, the handling and drilling of seed treated with ‘Cruiser SB’ is estimated to result in a systemic exposure to thiamethoxam of 0.00305 mg/kg bw/day (equivalent to 4% of the systemic AOEL of 0.08 mg/kg bw/day proposed in this evaluation). On this basis, the level of exposure for an unprotected worker handling and drilling seed treated with ‘Cruiser SB’ is considered to be acceptable.
Bystander and resident exposure	The treatment of seeds is usually performed in professional plants where access is restricted to people working at the plant. Therefore, it is considered that bystanders and residents will not be exposed to thiamethoxam during the seed treatment process. Exposure to people within the seed-treatment plant not directly involved in treatment, for example forklift truck drivers, was historically considered as part of the bystander exposure assessment. The exposure assessment is provided below:

	Using the 'Seed TROPEX' values and assuming a duration of exposure of 8 hours, a bystander body weight of 60 kg and no protection provided by normal work wear, systemic bystander exposure to thiamethoxam resulting from the proposed use of 'Cruiser SB' is calculated to be: $\frac{(0.000756 \text{ x } 8 \text{ x } 600 \text{ x } 0.02\%) + (0.0000086\ 5 \text{ x } 8 \text{ x } 600)}{60}$ = 0.000704 mg/kg bw/day (this is equivalent to less than 1% of the systemic AOEL of 0.08 mg/kg bw/day proposed in this evaluation). On this basis, the level of exposure for an unprotected bystander resulting from the proposed use of 'Cruiser SB' is considered to be acceptable.
Conclusion	The previous assessment remains valid and exposure is within acceptable levels. The same PPE as previously required are relevant (see above).

2.5 Residues and consumer exposure

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	**Health and Safety Executive** ***Where the assessment below indicates that the risk is either acceptable or unacceptable, this conclusion is reached within the framework of the standard criteria for a commercial authorisation based on assessment to uniform principles. Article 53 allows a derogation from the standard criteria providing specific tests are met. Therefore, whilst (for example) reference to unacceptable risks in the assessment below may highlight the areas of greatest concern, this is not the test under Article 53 and does not necessarily reflect the conclusions for this emergency authorisation application. The discussion of the overall risks and benefits from the proposed use and assessment against the requirements of Article 53 is presented in "Section 3 Conclusion of Emergency Authorisation".***
Reviewer's comments	This application is for an emergency authorisation of 'Cruiser SB' under Article 53 of Regulation (EC) No 1107/2009. This is a GB application for use in England only. 'Cruiser SB' is a flowable concentrate (FS) formulation containing 600 g/L thiamethoxam. The proposed use in GB is summarised in section 1.2. The applicants 'NFU Sugar and British Sugar plc.' have access to the data considered in the DAR for thiamethoxam and relevant product data for 'Cruiser SB' via a letter of access. Thiamethoxam is not currently approved in either GB or EU. The endpoints used in this assessment are the ones agreed in the context of the most recent approval of the active substance. Consequently, the 'old' active substance data requirements as laid down in Commission Regulation (EU) No. 544/2011 have been applied. The assessment presented has not been updated to reflect the data requirements which entered into force in 2016. The consumer exposure assessment indicates a level of exposure well within acceptable levels and it is clear that fully addressing the latest data requirements would not change the overall conclusion of acceptable exposure. This approach may be re-visited in future. NB: thiamethoxam has a metabolite – clothianidin (also known as CGA322704) - that is itself an active substance (also not currently approved in GB). EFSA conducted an Article 12 MRL review relating jointly to thiamethoxam and clothianidin and published their Reasoned Opinion in 2014 (EFSA Journal 2014;12(12):3918). Relevant conclusions regarding the available data relating to the EU review of the active substances

are presented. As the EFSA Reasoned Opinion was published and the EU decision (Implementing Regulation (EU) 2016/156) were both implemented prior to 01/01/2021, the EU decision forms part of the EU retained law and it is directly relevant to the GB assessment.

Please see the references listed below for details of the EU/GB documents relied on to support the evaluation.

Acceptable plant and animal metabolism data were submitted in the EU DAR for thiamethoxam. Acceptable rotational crop metabolism data was submitted in the EU DAR for thiamethoxam. No residues above the LOQ of 0.01 mg/kg are expected in rotational crops. Processing data is not required given residues in treated crops are <0.1 mg/kg (actually <0.02 mg/kg for both thiamethoxam and clothianidin)

Residues data from the DAR are relied on to support the proposed uses. Sufficient storage stability data is presented in the EU DAR to support the proposed uses.

For details of the MRL considerations relating to the product, see the green box below.

No chronic or acute consumer risk issues are expected for the proposed uses based on the PRIMo and UK NEDI and NESTI calculations.

Conclusion

No consumer health effects are expected from the proposed use of ‘Cruiser SB’.

Summary of the evaluation

‘Cruiser SB’ contains 600 g/L of thiamethoxam as the only active substance.

Toxicological reference values for the dietary risk assessment of thiamethoxam

Reference value	Source	Year	Value	Study relied upon	Safety factor
Thiamethoxam					
ADI	EC (07/6/EC)	2006	0.026 mg/kg bw/day	18 month study on mouse	100
ARfD	EC (07/6/EC)	2006	0.5 mg/kg bw	Rabbit development	100
Clothianidin					
ADI	EC (06/41/EC)	2005	0.097 mg/kg bw/day	2 year rat	100
ARfD	EC (06/41/EC)	2005	0.1 mg/kg bw	Rat and rabbit developmental	100

Summary for thiamethoxam

Use-No.	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Sugar beet	Yes	Yes (11)	Yes	Yes	Yes	No	No

Information on 'Cruiser SB' (KCA 6.8)

Crop	PHI for 'Cruiser SB' proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for 'Cruiser SB' proposed by HSE	HSE Comments (if different PHI proposed)
		Thiamethoxam		
Sugar beet	F** N/A (application at BBCH 00)	Yes	F** N/A (application at BBCH 00)	N/A

NR: not relevant

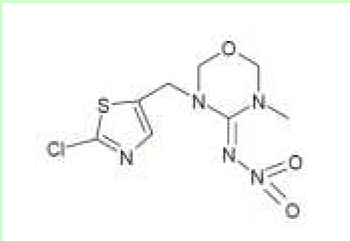
* Purpose of withholding period to be specified

** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

No consideration of waiting periods before planting succeeding crops is required as the consideration of residues in rotational crops in this assessment did not lead to a requirement for waiting periods to be set.

General data on thiamethoxam are summarized in the table below.

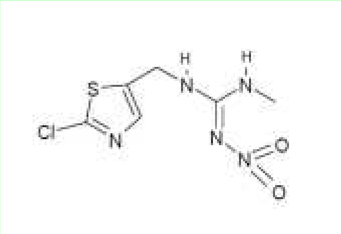
General information on thiamethoxam

Active substance (ISO Common Name)	Thiamethoxam
IUPAC	(EZ)-3-(2-chlorothiazol-5-ylmethyl)-5-methyl-1,3,5-oxadiazinan-4-ylidene(nitro)amine
Chemical structure	
Molecular formula	$C_8H_{10}ClN_5O_3S$
Molar mass	291.7
Chemical group	Neonicotinoid compounds
Mode of action (if available)	Insecticide: contact, stomach and systemic activity. Interact with the receptor protein of nicotinic acetyl choline receptors in the nerve fiber membrane of insects.
Systemic	Yes
Company	Syngenta
Rapporteur Member State (RMS)	Spain
Approval status	Not approved – approval expired (EU) Not approved – not included in the GB active substance approvals register (GB)
Restriction	Not approved
Review Report	SANCO/10591/2013 rev 8 27/04/2018

Current MRL regulation	GB GB MRL 2023/019 EU (NI) Regulation (EU) No 671/2017. (Note: new MRL values for thiamethoxam will apply on 07/03/2026 in line with Regulation (EU) 2023/334) The use is for England only and hence the GB MRLs are applicable to the assessment.
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed†	GB MRL Yes EU (NI) MRL Yes
EFSA Journal: Conclusion on the peer review‡	Yes (EFSA Journal 2018;16(2):5179)
Current MRL applications on intended uses	N/A

NB: thiamethoxam has a metabolite – clothianidin (also known as CGA322704) - that is itself an active substance therefore has been summarised below.

General information on clothianidin

Active substance (ISO Common Name)	Clothianidin
IUPAC	(E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine
Chemical structure	
Molecular formula	$C_6H_8ClN_5O_2S$
Molar mass	249.7 g/mol
Chemical group	Neonicotinoid compounds
Mode of action (if available)	Insecticidal, with contact and stomach action.
Systemic	Yes
Company	Sumitomo Chemical Takeda Agro Company Ltd.
Rapporteur Member State (RMS)	Belgium
Approval status	Not approved – approval expired (EU) Not approved – not included in the GB active substance approvals register (GB)
Restriction	Not approved
Review Report	SANCO/10589/2013 rev 8 28/04/2018
Current MRL regulation	GB GB MRL 2023/019 EU (NI)

	Regulation (EC) No 671/2017. (Note: new MRL values for thiamethoxam will apply on 07/03/2026 in line with Regulation (EU) 2023/334)
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed†	GB MRL Yes EU (NI) MRL Yes
EFSA Journal: Conclusion on the peer review‡	Yes (EFSA Journal 2018;16(2):5177)
Current MRL applications on intended uses	N/A

References:

EU DAR for thiamethoxam, RMS Spain, 2001

EU DAR for clothianidin, RMS Belgium, 2003

EFSA, 2014, Reasoned opinion on the review of the existing maximum residue levels (MRLs) for clothianidin and thiamethoxam according to Article 12 of Regulation (EC) No 396/2005, EFSA Journal 2014;12(12):3918

EFSA, 2018, Modification of the existing maximum residue level for clothianidin in potatoes, EFSA Journal 2018;16(9):5413

EFSA, 2018, Peer review of the pesticide risk assessment for bees for the active substance clothianidin considering the uses as seed treatments and granules, EFSA Journal 2018;16(2):5177

EFSA, 2018, Peer review of the pesticide risk assessment for bees for the active substance thiamethoxam considering the uses as seed treatments and granules, EFSA Journal 2018;16(2):5179

Stability of residues during storage of samples

Stability of residues during storage of samples was considered in a number of crop matrices and animal commodities for the approval of both thiamethoxam and clothianidin (EU DARs, 2001). Storage stability of all compounds in the residue definition for risk assessment in plant and animal commodities was considered.

As stated by the EFSA RO on the Art 12 MRL review:

"In the framework of the peer review, storage stability of thiamethoxam was demonstrated for a period of 24 months at -18 °C in commodities with high water content (apples, tomatoes, potatoes), high oil content (rape seed) and dry commodities (maize grain) (Spain, 2001)."

"In the framework of the peer review, storage stability of clothianidin was demonstrated for a period of 24 months at -18 °C in commodities with high water content (sugar beet root, maize forage, apples, tomatoes, potatoes), high oil content (canola, rape seed) and dry commodities (maize grain) (Belgium, 2003; Spain, 2001)."

"The storage stability of clothianidin and thiamethoxam residues in animal products was evaluated under the peer review of Directive 91/414/EEC (Spain, 2001, 2003). Studies demonstrated storage stability of clothianidin and thiamethoxam in milk, muscle, liver and eggs for up to 16 months when stored deep frozen."

	The available storage stability data is sufficient to support the proposed use of 'Cruiser SB' on sugar beet (data in the proposed crop, sugar beet roots and a diverse range of high water and high starch crops for clothianidin and a diverse range of high water and high starch crops for thiamethoxam); the storage periods cover those employed in the field trials being relied upon. **<u>Stability of residues in sample extracts</u>** Stability of residues in sample extracts has not been considered in this assessment as it relies on residues trials data previously evaluated (EU DAR, 2001), for which stability of extracts were considered acceptable. **<u>Nature of residue in primary crops</u>** Metabolism in primary crops was investigated following foliar spray treatment in rice (cereals), pears, cucumbers (fruits and fruiting vegetables), lettuce and tobacco (leafy vegetables), and following seed treatment on maize (cereals) and potato (root and tuber vegetables) for the approval of thiamethoxam (EU DAR, 2001). As stated in the EFSA RO on the Art 12 MRL review: *"Metabolism of thiamethoxam was investigated for foliar application on cereals (rice), fruits and fruiting vegetables (pears, cucumbers), and leafy vegetables (lettuce, tobacco); for soil application on cereals (maize, rice), fruits and fruiting vegetables (cucumbers), and leafy vegetables (tobacco); and for seed treatment on cereals (maize) and on root and tuber vegetables (potatoes), using [14C-oxadiazin] or [14C-thiazolyl] labelled thiamethoxam (Spain, 2001)* *…* *The metabolism of thiamethoxam in plants is complex, but adequately determined. Even though metabolic route seems to be very similar among different plants, the composition of the final residue is very dependent on the method of application, the plant, the plant parts analysed (leaves, grain, fruit) and the PHI. Residues were higher in the leafy parts of the crop. The parent compound degraded slowly but extensively with up to 20 metabolites formed. However, thiamethoxam and clothianidin were considered as the most relevant compounds because their occurrence was consistently observed throughout the different studies".* As acceptable metabolism data was presented for potato (root and tuber crops), this is sufficient to support use on sugar beet from this group. Seed treatment was tested in these studies, which is the same application type for the proposed use. The PHI in the studies is comparable to that in the proposed GAP. On this basis all proposed uses of 'Cruiser SB' are supported by the available metabolism data. The residue definition for enforcement in plants is: 1) Thiamethoxam 2) Clothianidin (CGA 322704) Since clothianidin is an active substance in its own right, and GB and EU MRLs are set for this substance then both enforcement residue definitions should be considered separately. The residue definition for risk assessment in plants is: 1) Thiamethoxam 2) Clothianidin (CGA 322704) Thiamethoxam and clothianidin have different ADIs and ARfDs and so separate risk assessments should be conducted for each, with an additional consideration of potential combined exposure. **<u>Nature of residue in rotational crops</u>**

	Based on the Fate and Behaviour assessment for this emergency use, the sowing rate of the seeds (115,000 seeds/ha) will produce an application rate of 51.75 g a.s./ha. The EFSA RO on the Art 12 MRL review states the following (based on studies reported in the DARs): *"The potential incorporation of clothianidin and thiamethoxam soil residues into succeeding and rotational crops was investigated in Swiss chard, lettuce, turnip, radish and wheat. These studies showed a metabolism comparable to the one in primary crops and significant residues in rotational crops are not expected, provided that clothianidin and thiamethoxam are applied according to the GAPs supported in the framework of this review."* It should be noted that that many of the uses considered in the Article 12 were significantly more critical with respect to rotational crops (e.g. up to 120 g as thiamethoxam/ha applied outdoors to potatoes) than the proposed seed treatment on sugar beet seeds. Metabolism in rotational crops was found to be via a similar pathway to primary crops, therefore specific residue definitions for rotational crops are not required. <u>Thiamethoxam:</u> As the application rate in the rotational crop metabolism study is greater than that in the proposed GAP (at least 3.9 N), it is considered that the results of these studies are applicable to 'Cruiser SB'. The metabolism study demonstrates that residues in rotational crops are expected to be <0.01 mg/kg for all crops at all plant back intervals. On this basis no further consideration of rotational crops is required. <u>Clothianidin:</u> As the application rate in the rotational crop metabolism study is greater than that in the proposed GAP (at least 3.1 N), it is considered that the results of these studies are applicable to 'Cruiser SB'. The metabolism study demonstrates that residues in rotational crops are expected to be <0.01 mg/kg for all crops at all plant back intervals. On this basis no further consideration of rotational crops is required. **<u>Nature of residues in processed commodities</u>** No consideration of residues in processed commodities is required, as residues of both clothianidin and thiamethoxam in the RAC are <0.1 mg/kg (in accordance with Commission Regulation (EU) No 544/2011) and are actually <LOQ (<0.02 mg/kg). As stated in the EFSA Art 12 MRL review RO: *"As residues of clothianidin are all below 0.1 mg/kg (except fresh legumes and fresh herbs) and contribution of these residues to chronic consumer exposure is generally low, there was no need to investigate the effect of industrial and/or household processing on the nature and magnitude of clothianidin residues. Regarding thiamethoxam however, a study was provided demonstrating that residues are stable during pasteurisation, cooking, brewing and sterilisation."* **Summary of the nature of residues in commodities of plant origin**

Endpoints	
Plant groups covered	Fruits and fruiting vegetables, leafy vegetables, root and tuber vegetables and cereals
Rotational crops covered	Yes: leafy vegetables, root and tuber vegetables, cereals
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Not required as residues <0.1 mg/kg

Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	1) Thiamethoxam 2) Clothianidin (CGA 322704) *(Commission Regulation (EU) 2017/671)*
Plant residue definition for risk assessment	1) Thiamethoxam 2) Clothianidin (CGA 322704) *(EFSA, 2014)*
Conversion factor from enforcement to RA	N/A

Nature of residues in livestock

As stated by the EFSA RO on the Art 12 MRL review (based on studies reported in the DAR):

"Metabolism of clothianidin and thiamethoxam in lactating ruminants and poultry was investigated and findings on ruminants can be extrapolated to pigs. The relevant residue definition for enforcement and risk assessment in ruminants and pig products was defined as parent thiamethoxam and its metabolite clothianidin, to be expressed independently.

….

For poultry products, no residue definition is proposed and no MRLs are required because there is no significant exposure of poultry to clothianidin or thiamethoxam residues."

The residue definition for enforcement in animals is:

1) Thiamethoxam

2) Clothianidin (CGA 322704)

Since clothianidin is an active substance in its own right, and EU MRLs are set for this substance then both enforcement residue definitions should be considered separately.

The residue definition for risk assessment in animals is:

1) Thiamethoxam

2) Clothianidin (CGA 322704)

Thiamethoxam and clothianidin have different ADI and ARfD and so separate risk assessment should be conducted for each, with an additional consideration of potential combined exposure.

Given that the active substance is not approved in GB, further consideration of the JMPR residue definitions has been made. It is noted that for the evaluation of CXLs (EFSA, 2014), the following residue definition for risk assessment was considered for poultry products:

1) sum of thiamethoxam, TZNG and ATG-Ac, expressed as thiamethoxam

2) clothianidin

As the consideration in this application is for a GB use and significant residues are not expected in products of animal origin (see animal dietary burden section below), this residue definition supported by the JMPR has not been considered further.

Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	Not determined
	Not determined
Animal residue definition for monitoring	1) Thiamethoxam 2) Clothianidin (CGA 322704) *(Reg. (EU) 2017/671)*
Animal residue definition for risk assessment	1) Thiamethoxam 2) Clothianidin (CGA 322704) *(EFSA, 2014)*
Conversion factor	N/A
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

<u>Magnitude of residues in plants</u>

<u>CROP: Sugar beet</u>

The UK cGAP for use on sugar beet of 'Cruiser SB' is tabulated below:

GAP #	**Crop**	**Application rate**	**Growth stage**	**No. of apps (and interval)**	**PHI (days)**
1	Sugar beet	75 mL product per 100,000 seeds (0.45 mg a.s./seed) Equivalent to 51.75 g a.s./ha (based on seeding rate of 115,000 seeds/ha)	BBCH 00	1 (seed treatment)	N/A

11 GLP trials conducted outdoors in the NEU are available. The trials applied thiamethoxam to sugar beet seed at the rate of 0.46 – 0.9 mg a.s./seed using a WS product. Whilst the formulation type differs from that being proposed (FS), this is acceptable since the proposed application is as a seed treatment at BBCH 00 and hence the formulation type is not expected to have a significant influence on the residues found at harvest.

The trials analysed for residues of thiamethoxam and clothianidin in sugar beet roots and tops. No significant deviations were noted in the trials.

No residues above the method LOQ of 0.02 mg/kg were identified in roots or tops in any of the trials for either analyte.

Most of the trials were overdosed (>125%) of the proposed application rate – this is acceptable since no residues >LOQ were identified.

STMR = HR = <0.02 mg/kg for thiamethoxam and clothianidin in roots and tops.

The current GB and EU MRLs for both actives in sugar beet roots are 0.02* mg/kg. These are sufficient to accommodate the proposed use.

These trials have previously been evaluated and accepted in the DAR for the first approval of the active substance and therefore no further assessment has been conducted in the context of this evaluation.

Commodity	**Residues RD-RA and RD-Mo** (mg/kg)	**STMR** (mg/kg)	**HR** (mg/kg)	**MRL** (mg/kg)	**Current MRL (mg/kg)** Reg. (EU) 2017/671 for both GB and EU
Sugar beet (roots)	11 x <0.02 (for both analytes)	<0.02	<0.02	0.02* (thiamethoxam) 0.02* (clothianidin)	0.02* (thiamethoxam) 0.02* (clothianidin)
Sugar beet (leaves)	11 x <0.02 (for both analytes)	<0.02	<0.02	Not currently set for animal feed items	

The trials are considered sufficient to support the proposed GAP for sugar beet, as they are overdosed, which represents a worst case. As the trials are overdosed with respect to application rate, they would not be appropriate for MRL setting.

The current GB (and EU) MRLs for clothianidin and thiamethoxam in sugar beet roots is 0.02* mg/kg and the calculated MRL is also 0.02* mg/kg for both active substances, therefore the current MRLs are sufficient to support the use.

Sufficient residues trials are available to address the data requirement and establish that residues in plants are not expected to exceed the MRL.

Magnitude of residues in livestock

Dietary burden calculation

Sugar beet tops and processed by-products of refined sugar production can be fed to livestock.

The Article 12 Reasoned Opinion considered significantly higher animal dietary intakes which triggered feeding studies in ruminants (but not in poultry). Regarding the ruminant feeding data, it concluded that for both thiamethoxam and clothianidin:

"…the available data are considered sufficient to demonstrate that significant residues in tissues and milk of ruminants and pigs are not expected and MRLs for these commodities can be established at the LOQ. Considering however that a storage stability study is still required for thiamethoxam in fat, this MRL in fat is tentative only."

Given that no residues above the LOQ of 0.02 mg/kg of thiamethoxam or clothianidin were detected in sugar beet roots or tops, it is not expected that livestock would be exposed to significant levels through their diet and therefore detectable residues are not expected in animal commodities.

A dietary burden calculation has been undertaken for 'Cruiser SB', which includes only the GB use. The dietary burden calculation has been undertaken using the Dietary Burden Calculator 3.2 (as the assessment is in line with the data requirements outlined in Reg. (EU) 544/2011).

The following assumptions have been made.

1) The highest likely inclusion rate of all crops which may have been treated has been used with the proviso that the aggregate does not exceed 100% diet;

2) All produce eaten which may have been treated, has been treated and contains residues at the STMR/HR found in the trials considered to support the GAP

3) There is no loss of residue during transport, storage, preparation of feed prior to consumption.

Input values are given below. The highest and median calculated animal intakes based on these input values are reported below.

Input Values

Commodity	STMR (mg/kg)	HR (mg/kg)	Post Harvest?
Green Forage			
Beet tops	0.020	0.020	N/A
Roots and Tubers			
Beet Pulp	0.020	0.020	N/A

Intakes calculated using STMR input (median dietary burden)

Animal	mg/kg DM Basis	mg/kg AR Basis	mg/animal/day	mg/kg bw/day
Dairy cattle *	0.068	0.018	1.350	0.0025
Beef cattle *	0.098	0.020	1.463	0.0042
Pig *	0.091	0.019	0.274	0.0037
Chicken *	0.020	0.010	0.002	0.0013

* Less than 100% of diet employed (DM diet)

Intakes calculated using HR input (maximum dietary burden)

Animal	mg/kg DM Basis	mg/kg AR Basis	mg/animal/day	mg/kg bw/day
Dairy cattle *	0.068	0.018	1.350	0.0025
Beef cattle *	0.098	0.020	1.463	0.0042
Pig *	0.091	0.019	0.274	0.0037
Chicken *	0.020	0.010	0.002	0.0013

* Less than 100% of diet employed (DM diet)

Based on the dietary burden calculations consideration of the likely residues in food of animal origin for ruminants and poultry is not required as the trigger of 0.1 mg/kg as received in the diet and 0.1 mg/kg dry matter are not exceeded.

No further consideration is necessary, and the consumption of animal commodities is not included in the consumer risk assessment presented below.

Livestock feeding studies

No consideration of livestock feeding studies are required, as the dietary burden is calculated to be <0.1 mg/kg DM for all groups (Reg. (EU) 544/2011).

Magnitude of residues in processed commodities

No consideration of residues in processed commodities is required, as residues in the RAC for both analytes (thiamethoxam and clothianidin) are <0.1 mg/kg and specifically <0.02 mg/kg).

Magnitude of residues in representative succeeding crops

No consideration of residues in rotational crops is required, as the available metabolism studies on rotational crops demonstrate residues <LOQ across all crops and plant back intervals for the proposed GAP.

Other / special studies

No consideration of residues in honey is required, as the application is to 'old' data requirements set out under Reg. (EU) 544/2011.

Under a previous emergency application (HSE internal ref: COP 2020/01677) a residue study on pollen, nectar and guttation fluid from crops succeeding sugar beet treated with 'A9765R', and supporting method validation data were evaluated to support the ecotoxicological assessment. The study indicates that residues in honey are expected to be less than the default LOQ MRL of 0.05* mg/kg (given residue levels lower than this were determined in aerial parts of the crops: nectar and pollen). A full consideration of the study from a residues perspective is not required at this time.

Estimation of exposure through diet and other means

UK NEDI and NESTI

The UK NEDI and NESTI have been calculated based only on the supported uses of 'Cruiser SB'.

The UK NEDIs and NESTIs for the active and commodities listed below have been calculated for ten consumer groups as detailed in the Regulatory Update 21/2005. The following assumptions have been made:

1) Upper range of normal (97.5th percentile) consumption of each individual crop which may have been treated.

2) All produce eaten which may have been treated has been treated and contains residues at the STMR (NEDI) / HR (NESTI) found in the trials considered to support GAP, as given below.

3) There is no loss of residue during transport or storage, or processing of foods prior to consumption.

Input values for the UK consumer risk assessment are given below

Model outputs for the UK acute and chronic models run by HSE are presented below.

Thiamethoxam:

Chronic intakes for all consumer groups are below the ADI of 0.026 mg/kg bw/day therefore no health effects are expected (critical diet toddlers with 4% of the ADI).

Acute intakes for all consumer groups are below the ARfD of 0.5 mg/kg bw therefore no health effects are expected (critical consumer toddlers with 0.3 % of the ARfD).

Clothianidin:

Chronic intakes for all consumer groups are below the ADI of 0.097 mg/kg bw/day therefore no health effects are expected (critical diet toddlers with 1% of the ADI).

	Acute intakes for all consumer groups are below the ARfD of 0.1 mg/kg bw therefore no health effects are expected (critical consumer toddlers with 1.6 % of the ARfD). **<u>PRIMo</u>** The PRIMo IESTIs and PRIMo IEDIs for thiamethoxam and clothianidin, and the commodities listed below have been calculated using PRIMo v3.1 – Pesticide Residues Intake Model. As the application was received by the UK after 1st February 2018, PRIMo 3.1 has been used. A full description of PRIMo and the underlying assumptions is in the document: 'Use of EFSA pesticide residues intake model 'EFSA PRIMo revision 3.1' available at the following link: http://www.efsa.europa.eu/en/applications/pesticides/tools. Information is also included in the PRIMo model in the tab 'background information'. A PRIMo consumer risk assessment has been undertaken for 'Cruiser SB', which includes only GB uses. The UK considers that there is only a need to conduct the risk assessment for the uses under consideration. A full consideration of the dietary risk assessment for all uses should only be undertaken when setting a new MRL or in an MRL review. Therefore, as no new MRLs are required as a result of this product evaluation, the consumer risk assessments outlined below only include the commodities on which this product is proposed for use in this application. The risk assessment is undertaken using STMR and HRs determined for all plant products based on the proposed uses of 'Cruiser SB' which are adequately supported by data. The following assumptions have been made: 1) All produce eaten which may have been treated, has been treated and contains residues at the MRL/HR/STMR as given below. 2) There is no loss of residue during transport or storage, or processing of foods prior to consumption. Input values for the PRIMo consumer risk assessment are given below. Model outputs for EFSA PRIMO Rev 3.1, run by HSE are presented below. <u>Thiamethoxam</u> The maximum IEDI was 0.6% of the ADI. As chronic intakes for all consumer groups are below the ADI of 0.026 mg/kg bw/day therefore no health effects are expected. The maximum contribution of a commodity to ARfD was sugar beet (root)/sugar at 0.4% for children. Acute intakes for all consumer groups are below the ARfD of 0.5 mg/kg bw therefore no health effects are expected. <u>Clothianidin</u> The maximum IEDI was 0.2% of the ADI. As chronic intakes for all consumer groups are below the ADI of 0.097 mg/kg bw/day therefore no health effects are expected. The maximum contribution of a commodity to ARfD was commodity at 2% for children. Acute intakes for all consumer groups are below the ARfD of 0.1 mg/kg bw therefore no health effects are expected.

Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Thiamethoxam				
Sugar beet	0.02	Median residue (also the MRL)	0.02	Highest residue
Clothianidin				
Sugar beet	0.02	Median residue (also the MRL)	0.02	Highest residue

Consumer risk assessment summary

Thiamethoxam	
IEDI (% ADI) according to EFSA PRIMo	0.6 % (based on NL child)
IESTI (% ARfD) according to EFSA PRIMo*	Sugar beet: 0.4 % (based on children)
NEDI (% ADI)**	4 %
NESTI (% ARfD) **	Sugar beet: 0.3 %
Clothianidin	
IEDI (% ADI) according to EFSA PRIMo	0.2 % (based on NL child)
IESTI (% ARfD) according to EFSA PRIMo*	Sugar beet: 2 % (based on children)
NEDI (% ADI)**	1 %
NESTI (% ARfD) **	Sugar beet: 1.6 %

* include raw and processed commodities if both values are required for PRIMo

** if national model is available

<u>Drinking water assessment</u>

Metabolite ‘NOA459602’ (a metabolite of thiamethoxam) could be present in groundwater at levels requiring further consideration (above the trigger value of 0.1 µg/L in groundwater); Metabolite ‘NOA459602’ is predicted to occur above 0.1 µg/l in all 4 scenarios considered in the environmental fate and behaviour section (maximum PECgw = 0.321 µg/l in the Hamburg scenario). Metabolite ‘NOA459602’ is considered a relevant metabolite at step 3 in accordance with SANCO/221/2000 –rev.10 (see toxicology section), however, a chronic human dietary exposure assessment has been presented since this application is for an emergency use.

Metabolite ‘NOA459602’ is not included in the plant or animal residue definitions for risk assessment; it was not considered in food as part of the consumer risk assessment.

In relation to the drinking water contribution, the highest intake is expected for infants (<4 months). EFSA Guidance on pesticides in foods for infants and young children estimates the water consumption of bottle-fed infants as 1.135L/day, equating to 227 mL/kg bw/day (EFSA 2018). Estimated intakes of ‘NOA459602’ from drinking water for the critical consumer group ‘infants’ are 0.00007 mg/kg bw/day. This is <1% of the ADI for parent thiamethoxam (0.026 mg/kg bw/day - see mammalian toxicology section for justification of using this toxicological reference value).

As the estimated intake of ‘NOA459602’ from drinking water is <100% of the ADI for thiamethoxam and dietary intakes of ‘NOA459602’ from other sources are not expected, no further consideration is required. As the estimated intake of ‘NOA459602’ following the proposed use of ‘Cruiser SB’ is below the ADI for thiamethoxam (<1%), based on steps 4 and 5, no effects on health are expected.

[It is noted that residues above the hazard-based limit would result in water requiring treatment before supply to consumers, to comply with relevant drinking water quality requirements.]

Combined exposure and risk assessment

A combined risk assessment for thiamethoxam and clothianidin in food is required.

Combined chronic assessment

The NEDIs/IEDIs for the UK and PRIMO Rev 3.1 have been calculated using the inputs below.

Thiamethoxam: STMR for proposed use

Commodity	STMR	Reference
Sugar beet root	0.02	Current assessment

Clothianidin: STMR for proposed use

Commodity	STMR	Reference
Sugar beet root	0.02	Current assessment

The maximum sum of the total chronic intakes for thiamethoxam and clothianidin (each expressed as a % of its own ADI) using the UK NEDI model is 5% in the toddler consumer group.

The maximum sum of the total chronic intakes for thiamethoxam and clothianidin (each expressed as a % of its own ADI) using the EFSA PRIMo model is <1% in NL child consumer group.

The maximum sum of the total chronic intakes (UK and PRIMo Rev 3.1) for thiamethoxam and clothianidin each expressed as a % of its own ADI is <100%. No health effects are expected.

Combined acute assessment

The maximum sum of the acute intakes for both thiamethoxam and clothianidin (each expressed as a % of its own ARfD) using the UK NESTI model is 1.9% for sugar beet in the toddler consumer group.

	The maximum sum of the acute intakes for both thiamethoxam and clothianidin (each expressed as a % of its own ARfD) using the PRIMo model is 2.4% for sugar beet in the children consumer group. For the proposed use (and relevant commodities) the sum of the acute intakes (UK and PRIMo Rev 3.1) for thiamethoxam and clothianidin each expressed as a % of its own ARfD is <100%. No health effects are expected.
Conclusion	**The previous conclusion that no health effects are expected from the consumption of commodities treated in accordance with the proposed use remains valid.**

2.5.1 Maximum Residue Levels

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	**Health and Safety Executive**
Reviewer's comments	**Maximum residue levels (MRLs)**

GB MRLs

GB MRLs in force

The GB MRLs listed in Table 7.1-0a and b are relevant to the proposed uses of 'Cruiser SB' in GB.

Active: Thiamethoxam**Error! Reference source not found.**
Plant residue definition for enforcement: 1) Thiamethoxam; 2) Clothianidin (CGA 322704)
Animal residue definition for enforcement: 1) Thiamethoxam; 2) Clothianidin (CGA 322704)

Table 7.1-0a GB MRLs in force for thiamethoxam relevant to the proposed uses in GB

Code	Commodity to which MRL applies	MRL required for proposed use (mg/kg)	GB MRL in force (GB MRL 2023/019)) (mg/kg)	Potential future GB MRL (mg/kg)‡
0900010	Sugar beet roots	0.02*	0.02*	N/A

‡ *Agreed future MRLs outlined in the Register or proposed MRLs outlined in the Published MRL reviews List*

Table 7.1-0b GB MRLs in force for clothianidin relevant to the proposed uses in GB

Code	Commodity to which MRL applies	MRL required for proposed use (mg/kg)	GB MRL in force (GB MRL 2023/019) (mg/kg)	Potential future GB MRL (mg/kg)‡
0900010	Sugar beet roots	0.02*	0.02*	N/A

‡ *Agreed future MRLs outlined in the Register or proposed MRLs outlined in the Published MRL reviews List*

	MRL supplementary information requirements (MRL confirmatory data) for GB MRLs An MRL review relevant to GB has been conducted (EFSA, 2014). No GB MRL data gaps relevant to the use on sugar beet were identified in the MRL review. **Conclusion on GB MRLs** **On the basis of this evaluation, the authorisation will result in residues that are at or below the current MRLs in force for GB.** **EU MRLs (for NI)** As this application is GB only no further consideration of MRLs for NI has been made. It is noted that at this time (checked July 2024), the MRLs in NI (EU) are the same as those currently in force in GB for sugar beet roots for thiamethoxam and clothianidin. However, new MRL values will enter into force in the EU on 07/03/2026 under Reg. (EU) 2023/334, and the MRL for sugar beet roots will reduce to 0.01* mg/kg for both thiamethoxam and clothianidin.

UK and Pesticide Residue Intake Model (PRIMo) consumer risk assessments

NEDI calculations

Thiamethoxam

Active substance: Thiamethoxam **ADI:** 0.026 mg/kg bw/day **Source:** 07/6/EC

	TOTAL INTAKE based on 97.5th percentile									
	ADULT	INFANT	TODDLER	4-6 YEARS	7-10 YEARS	11-14 YEARS	15-18 YEARS	VEGETARIAN	ELDERLY (OWN HOME)	ELDERLY (RESIDENTIAL)
mg/kg bw/day	0.00028	0.00067	0.00111	0.00067	0.00063	0.00040	0.00039	0.00024	0.00021	0.00030
% of ADI	1%	3%	4%	3%	2%	2%	1%	<1%	<1%	1%

Commodity	**STMR (mg/kg)**	**P**	**COMMODITY INTAKES (mg/kg bw/day)**									
Sugar beet	0.02		0.00028	0.00067	0.00111	0.00067	0.00063	0.00040	0.00039	0.00024	0.00021	0.00030

* 0.00000 corresponds to <0.000005 mg/kg bw/day (any value ≥0.000005 is rounded to 0.00001

L/C Low consumption (<0.1 g/day) or low number of consumers (<4)

Clothianidin

Active substance: Clothianidin **ADI:** 0.097 mg/kg bw/day **Source:** 06/41/EC

	TOTAL INTAKE based on 97.5th percentile									
	ADULT	INFANT	TODDLER	4-6 YEARS	7-10 YEARS	11-14 YEARS	15-18 YEARS	VEGETARIAN	ELDERLY (OWN HOME)	ELDERLY (RESIDENTIAL)
mg/kg bw/day	0.00028	0.00067	0.00111	0.00067	0.00063	0.00040	0.00039	0.00024	0.00021	0.00030
% of ADI	<1%	<1%	1%	<1%	<1%	<1%	<1%	<1%	<1%	<1%

Commodity	STMR (mg/kg)	P	COMMODITY INTAKES (mg/kg bw/day)									
Sugar beet	0.02		0.00028	0.00067	0.00111	0.00067	0.00063	0.00040	0.00039	0.00024	0.00021	0.00030

* 0.00000 corresponds to <0.000005 mg/kg bw/day (any value ≥0.000005 is rounded to 0.00001

L/C Low consumption (<0.1 g/day) or low number of consumers (<4)

NESTI calculations

Thiamethoxam

Acute Intakes (97.5th percentiles)

			adult		infant		toddler		4-6 year old child		7-10 year old child	
commodity	HR	P	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Sugar Beet	0.02		0.00052	0.1	0.00111	0.2	0.00156	0.3	0.00128	0.3	0.00105	0.2

			11-14 year old child		15-18 year old child		vegetarian		Elderly - own home		Elderly - residential	
commodity	HR	P	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Sugar Beet	0.02		0.00078	0.2	0.00072	0.1	0.00042	0.1	0.00028	0.1	0.00038	0.1

Pesticide	Thiamethoxam	
ARfD	0.500	mg/Kg bw/day
Source	07/6/EC	

* 0.00000 corresponds to <0.000005 mg/kg bw/day (any value ≥0.000005 is rounded to 0.00001

Clothianidin

Acute Intakes (97.5th percentiles)

			adult		infant		toddler		4-6 year old child		7-10 year old child	
commodity	HR	P	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Sugar Beet	0.02		0.00052	0.5	0.00111	1.1	0.00156	1.6	0.00128	1.3	0.00105	1.0

			11-14 year old child		15-18 year old child		vegetarian		Elderly - own home		Elderly - residential	
commodity	HR	P	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Sugar Beet	0.02		0.00078	0.8	0.00072	0.7	0.00042	0.4	0.00028	0.3	0.00038	0.4

Pesticide Clothianidin
ARfD 0.100 mg/Kg bw/day
Source 06/41/EC
* 0.00000 corresponds to <0.000005 mg/kg bw/day (any value ≥0.000005 is rounded to 0.00001

TMDI/IEDI calculations

Thiamethoxam

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Thiamethoxam			
LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):	0.026	ARfD (mg/kg bw):	0.5
Source of ADI:	EC 07/6/EC	Source of ARfD:	EC 07/6/EC
Year of evaluation:	2006	Year of evaluation:	2006

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
0.6%	NL child	0.17	0.6%	Sugar beet roots						
0.4%	NL toddler	0.10	0.4%	Sugar beet roots		Grapefruits				
0.4%	DE women 14-50 yr	0.09	0.4%	Sugar beet roots		Grapefruits				
0.3%	DE general	0.08	0.3%	Sugar beet roots		Grapefruits				
0.3%	FR child 3 15 yr	0.07	0.3%	Sugar beet roots		Grapefruits				
0.2%	UK toddler	0.06	0.2%	Sugar beet roots		Grapefruits				
0.2%	NL general	0.06	0.2%	Sugar beet roots		Grapefruits				
0.2%	FR toddler 2 3 yr	0.06	0.2%	Sugar beet roots		Grapefruits				
0.1%	GEMS/Food G06	0.03	0.1%	Sugar beet roots		Grapefruits				
0.1%	UK infant	0.03	0.1%	Sugar beet roots		Grapefruits				
0.1%	FR infant	0.03	0.1%	Sugar beet roots		Grapefruits				
0.1%	RO general	0.03	0.1%	Sugar beet roots		Grapefruits				
0.1%	FR adult	0.02	0.1%	Sugar beet roots		Grapefruits				
0.0%	UK adult	0.01	0.0%	Sugar beet roots		Grapefruits				
0.0%	UK vegetarian	0.01	0.0%	Sugar beet roots		Grapefruits				
0.0%	ES child	0.00	0.0%	Sugar beet roots		Grapefruits				
0.0%	ES adult	0.00	0.0%	Sugar beet roots		Grapefruits				
0.0%	GEMS/Food G07	0.00	0.0%	Sugar beet roots		Grapefruits				
0.0%	GEMS/Food G07	0.00	0.0%	Sugar beet roots		Grapefruits				
	DE child			Grapefruits		Grapefruits				
	DE child			Grapefruits		Grapefruits				
	DE child			Grapefruits		Grapefruits				
	DE child			Grapefruits		Grapefruits				
	DE child			Grapefruits		Grapefruits				
	DE child			Grapefruits		Grapefruits				
	DE child			Grapefruits		Grapefruits				
	DE child			Grapefruits		Grapefruits				
	DE child			Grapefruits		Grapefruits				
	DE child			Grapefruits		Grapefruits				
	DE child			Grapefruits		Grapefruits				
	DE child			Grapefruits		Grapefruits				
	DE child			Grapefruits		Grapefruits				
	DE child			Grapefruits		Grapefruits				
	DE child			Grapefruits		Grapefruits				
	DE child			Grapefruits		Grapefruits				
	DE child			Grapefruits		Grapefruits				

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Thiamethoxam is unlikely to present a public health concern.

Clothianidin

European Food Safety Authority
EFSA PRIMo revision 3.1; 2019/03/19

Clothianidin

LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):	**0.097**	ARfD (mg/kg bw):	**0.1**
Source of ADI:	**EC 06/41/EC**	Source of ARfD:	**EC 06/41/EC**
Year of evaluation:	**2005**	Year of evaluation:	**2005**

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
0.2%	NL child	0.17	0.2%	Sugar beet roots						
0.1%	NL toddler	0.10	0.1%	Sugar beet roots		Grapefruits				
0.1%	DE women 14-50 yr	0.09	0.1%	Sugar beet roots		Grapefruits				
0.1%	DE general	0.08	0.1%	Sugar beet roots		Grapefruits				
0.1%	FR child 3 15 yr	0.07	0.1%	Sugar beet roots		Grapefruits				
0.1%	UK toddler	0.06	0.1%	Sugar beet roots		Grapefruits				
0.1%	NL general	0.06	0.1%	Sugar beet roots		Grapefruits				
0.1%	FR toddler 2 3 yr	0.06	0.1%	Sugar beet roots		Grapefruits				
0.0%	GEMS/Food G06	0.03	0.0%	Sugar beet roots		Grapefruits				
0.0%	UK infant	0.03	0.0%	Sugar beet roots		Grapefruits				
0.0%	FR infant	0.03	0.0%	Sugar beet roots		Grapefruits				
0.0%	RO general	0.03	0.0%	Sugar beet roots		Grapefruits				
0.0%	FR adult	0.02	0.0%	Sugar beet roots		Grapefruits				
0.0%	UK adult	0.01	0.0%	Sugar beet roots		Grapefruits				
0.0%	UK vegetarian	0.01	0.0%	Sugar beet roots		Grapefruits				
0.0%	ES child	0.00	0.0%	Sugar beet roots		Grapefruits				
0.0%	ES adult	0.00	0.0%	Sugar beet roots		Grapefruits				
0.0%	GEMS/Food G07	0.00	0.0%	Sugar beet roots		Grapefruits				
0.0%	GEMS/Food G07	0.00	0.0%	Sugar beet roots		Grapefruits				
	DE child			Grapefruits		Grapefruits				
	DE child			Grapefruits		Grapefruits				
	DE child			Grapefruits		Grapefruits				
	DE child			Grapefruits		Grapefruits				
	DE child			Grapefruits		Grapefruits				
	DE child			Grapefruits		Grapefruits				
	DE child			Grapefruits		Grapefruits				
	DE child			Grapefruits		Grapefruits				
	DE child			Grapefruits		Grapefruits				
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	DE child			Grapefruits		Grapefruits				
	DE child			Grapefruits		Grapefruits				
	DE child			Grapefruits		Grapefruits				
	DE child			Grapefruits		Grapefruits				
	DE child			Grapefruits		Grapefruits				
	DE child			Grapefruits		Grapefruits				
	DE child			Grapefruits		Grapefruits				

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Clothianidin is unlikely to present a public health concern.

IESTI calculations

Thiamethoxam

Acute risk assessment /children	Acute risk assessment / adults / general population	Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

Show results for all crops

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI): ---	**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI): ---	IESTI new **Results for children** No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---	IESTI new **Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI				IESTI				IESTI new				IESTI new			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)		**Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation)**	

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---	**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---	**Results for children** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---	**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI				IESTI				IESTI new				IESTI new			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.4%	Sugar beets (root) / sugar	0.02 / 0.24	2.2	0.2%	Sugar beets (root) / sugar	0.02 / 0.24	0.88	0.4%	Sugar beets (root) / sugar	0.02 / 0.24	2.2	0.2%	Sugar beets (root) / sugar	0.02 / 0.24	0.88
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Expand/collapse list

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Thiamethoxam is unlikely to present a public health risk
For processed commodities, no exceedance of the ARfD/ADI was identified.

Clothianidin

Acute risk assessment /children	Acute risk assessment / adults / general population	Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)

Expand/collapse list

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)

IESTI new
Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)

IESTI new
Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation)

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI (children)				**IESTI** (adults)			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Sugar beets (root) / sugar	0.02 / 0.24	2.2	0.9%	Sugar beets (root) / sugar	0.02 / 0.24	0.88
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Expand/collapse list

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI new (children)				**IESTI new** (adults)			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Sugar beets (root) / sugar	0.02 / 0.24	2.2	0.9%	Sugar beets (root) / sugar	0.02 / 0.24	0.88
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
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#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Clothianidin is unlikely to present a public health risk
For processed commodities, no exceedance of the ARfD/ADI was identified.

COMBINED RISK ASSESSMENTS

See estimates presented above.

2.6 Environmental Fate and Behaviour

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	**Health and Safety Executive** ***Where the assessment below indicates that the risk is either acceptable or unacceptable, this conclusion is reached within the framework of the standard criteria for a commercial authorisation based on assessment to uniform principles. Article 53 allows a derogation from the standard criteria providing specific tests are met. Therefore, whilst (for example) reference to unacceptable risks in the assessment below may highlight the areas of greatest concern, this is not the test under Article 53 and does not necessarily reflect the conclusions for this emergency authorisation application. The discussion of the overall risks and benefits from the proposed use and assessment against the requirements of Article 53 is presented in "Section 3 Conclusion of Emergency Authorisation".***

2.6.1 Update for proposed use in 2025	**Update and summary of new information submitted to support proposed use in 2025** The HSE assessment in the area of environmental fate and behaviour has been updated for the proposed use in 2025 in the following three areas:- • Updated summary of Environment Agency surface water monitoring data from three Catchment Sensitive Farming sites (data up to 1st March 2024 included) • Updated soil, vegetation and pollen monitoring data collected as part of the 'Cruiser SB' stewardship scheme. This included completely new monitoring of 6 sites treated in spring 2023 and a continuation of monitoring at the sites treated in 2022 (initial results following the 2022 applications were reported in the previous application for use in 2024). Both studies used a more sensitive analytical method than the original monitoring study. • An updated groundwater exposure assessment. This has been considered by HSE due to the change in classification of thiamethoxam (Repr.2 (H361fd)) and the subsequent need to consider the groundwater metabolites as toxicologically relevant in line with SANCO guidance on the assessment of relevance of metabolites in groundwater (Sanco/221/2000 – rev. 11). Updated consideration for this application for use in 2025 is shown in orange boxes. Previous assessments that remain unchanged for use in 2025 are shown in green boxes. With the exception of the changes summarised above, the standard regulatory assessment remains unchanged. The guidance and exposure models remain unchanged from the versions used when considering the Article 53 application for 'Cruiser SB' in 2020, 2021 and 2022, and the previous (2023) assessment is re-presented here (see green boxes). This considers predicted environmental concentrations (PECs) for thiamethoxam and its metabolite clothianidin in: soil and surface water (via drainflow only as spray drift is not relevant for a seed treatment). Due to the change in the classification of thiamethoxam for reproductive toxicity, and the presence of a toxicologically relevant metabolite in groundwater above the 0.1µg/l limit HSE do not consider the risks to groundwater to be acceptable based on the standard criteria for a commercial authorisation. **<u>Surface water</u>:** As identified in previous years, using standard pesticide assessment methodology, the exposure to aquatic organisms falls within acceptable limits. However this does indicate that the Predicted No Effect Concentration (PNEC) set under the Water Framework Directive may be exceeded in some small ditches at the edge of treated fields. A consideration of updated monitoring data provided by the Environment Agency from Catchment sensitive farming sites (data up to 1st March 2024) is provided. Concentrations so far in 2024 are in general low, reflecting the more limited and controlled use of thiamethoxam on sugar beet only. There is potentially some indication that concentrations were higher in the latest data period (i.e. May 2023 to March 2024), particularly for clothianidin in the Waveney catchment. But HSE considers that a longer time span of data would ideally be needed to confirm any significant changes. There was also a single detection of thiamethoxam above the Water Framework Directive PNEC of 0.042 µg/l at these sites (at 0.044 µg/l on 1st May 2023 in Waveney catchment). Again the data set is probably too small to draw significant conclusions, and would ideally include more detailed site specific analysis to better understand the levels. Note that for 2024, data is only available for samples taken up to 1st March and there is always the potential for higher concentrations to occur as a result of the onset of winter drainflow periods. HSE considers it would be sensible to continue to review data as long as emergency uses are authorised. **<u>Soil, vegetation and pollen monitoring:</u>**

	The final report of monitoring conducted during the 2022 sugar beet season covering thiamethoxam and clothianidin in soil, non-crop vegetation and pollen residues was evaluated to support use in 2024. Due to limitations with the limit of quantification in the analysis it was not possible to use the results in the risk assessment. However it was noted that there were detections of thiamethoxam and clothianidin which were higher than previously assumed in the HSE assessment. At one of the monitored sites clothianidin was present at levels comparable to when it was approved for commercial use – even though the field had not been treated with relevant products for 5 years. There were also two occasions where thiamethoxam was found at concentrations higher than the intended application rate (i.e. up to 78 g/ha when the rate should be limited to 51.75g/ha). Also at a couple of sites thiamethoxam levels peaked in post-harvest samples at least 9 months after drilling. This could reflect variability in the field and the difficulties sampling fields with treated seeds, for example as a result of sampling an area containing a high number of seed casings or ungerminated treated seeds. It may also be evidence of greater persistence in the field sites than has been used in the current regulatory risk assessment. Analysis is complicated by the limited sampling and the unusually hot and dry weather experienced in 2022 that might have affected degradation and dissipation in the treated fields. For the Article 53 evaluation in the previous year, HSE considered that there was not a reliable or long enough time series of data to draw more definitive conclusions at that stage. HSE recommended that monitoring be continued at these sites, utilising a more sensitive analytical method to aid better understanding of the long term behaviour of both thiamethoxam and clothianidin following use of 'Cruiser SB' For the use in 2025 additional data from a programme of continuation monitoring of the sites treated in 2022 was provided. In addition a new study sampling 6 new sites treated in 2023 was also provided. Both studies used an improved analytical method and findings are briefly summarised below. The absence of a reliable baseline soil level pre-drilling in 2022 is unfortunate and complicates analysis and interpretation of the continuation sampling of the 2022 treated sites. As an example, whilst quantifiable levels of clothianidin were detected for samples in the continuation monitoring in 2023 and 2024, the levels were at concentrations equal to, or lower than, that of the LOD of the analytical method used in original sampling programme. Therefore attributing clothianidin to 'Cruiser SB' treated seeds was difficult without a clear and consistent baseline level (ie pre-drilling). However there was evidence across multiple sites of persistence of both compounds. For example, for thiamethoxam, the DT_{90} had not necessarily been reached within sampling approximately 2 years after drilling at 3 of the 5 sites that continued to be sampled up to February 2024. Quantifiable residue levels of thiamethoxam in the untreated field margins at two sites nearly 2 years after drilling represented between 12-18% of the initial ''Cruiser SB' in-field application rate. Noting the difficulties in interpretation caused by the change in analytical method and lack of clear baseline levels, movement of residues into the field margins cannot be completely ruled out based on the data available. Although pollen residues were always below the quantifiable limit, where they were detected they were detected at levels broadly consistent with pollen samples collected from bees foraging directly in flowering thiamethoxam treated crops (based on information taken from the open literature). As there is currently no regulatory acceptable limit in place for pollen, the risk to bees, and other sensitive species, cannot be definitively assessed. Results from the new study, monitoring soil, vegetation and pollen after application in spring 2023 to 6 new sites, were easier to interpret because this used the more sensitive analytical method at all sampling times. Soil monitoring confirmed the potential persistence of both substances. Residues of thiamethoxam remained above 10% applied (i.e. it had not declined

	to its DT90) at all 6 sites, and remained above or around 50% applied (i.e. it had not yet reached its DT50) at 3 sites, 8-10 months after drilling treated seed. Quantifiable residues of clothianidin were detected in the baseline (pre-drilling) soil cores of 5 out of 6 sites, despite the pesticide use history only indicating that one site had received an application of a clothianidin containing product in 2018. The high level of clothianidin detection pre-drilling, and throughout the study was consistent with the earlier monitoring, and is indicative of the high persistence of this substance in soils. The field margins only had quantifiable levels of thiamethoxam in the growth season and post-harvest phases at a single site (equivalent to 2.6-3.6 g thiamethoxam/ha). No other site had quantifiable levels of thiamethoxam during any sampling occasion in the field margins. Whilst this provides some reassurance that transfer from in field to field margin is low, due to the relatively high levels of thiamethoxam remaining within the in-field area at harvest, it would be sensible to continue to monitor to ensure further transfer does not occur (noting that in the continuation monitoring conducted following the spring 2022 applications, field margin detections were still being found up to 2 years after drilling). The recovery of thiamethoxam and clothianidin from pollen, extracted from field margin flower head samples obtained at each site were determined to be <LOD for both compounds, except for a detected, but non-quantifiable, clothianidin residue at Site 6. Although the low detections are somewhat reassuring, it should be noted that concentrations of clothianidin in pollen collected from bees foraging in treated oil seed rape crops were only around 1µg/kg (based on literature reports), and therefore quantifiable residues above the specific pollen LOQ of 0.005mg/kg (5 µg/kg) used here would not be expected anyway. **Overall HSE summary on environmental fate and behaviour** HSE does not consider the monitoring data from either the 2022 or 2023 application campaigns provides sufficient reassurance to change the regulatory assessment from last year (2023). The soil monitoring confirms the potential persistence of both thiamethoxam and clothianidin. Noting the difficulties in interpretation caused by the change in analytical method and lack of clear baseline levels, movement of residues into the field margins cannot be ruled out based on the data currently available from the 2022 applications. Continuation of monitoring at the sites treated in 2023 may be useful to confirm the current low field margin detections in the new campaign (noting that in the continuation monitoring conducted following the spring 2022 applications, field margin detections were still being found up to 2 years after drilling). Although pollen residues were always below the quantifiable limit, where they were detected they were detected at levels broadly consistent with pollen samples collected from bees foraging directly in flowering thiamethoxam treated crops (based on information taken from the open literature). As there is currently no regulatory acceptable limit in place for pollen, the risk to bees, and other sensitive species, cannot be definitively assessed. In addition for the use in 2025, the groundwater assessment has been updated for the proposed use in 2025. Due to the change in the classification of thiamethoxam for reproductive toxicity, and the presence of a toxicologically relevant metabolite in groundwater above the 0.1µg/l limit in all 4 GB relevant FOCUS scenarios, HSE do not consider the risks to groundwater to be acceptable using the standard criteria for a commercial authorisation. Further details of the new information for use in 2025 (soil, vegetation, and pollen monitoring from the stewardship campaign, surface water monitoring from the Environment Agency, and groundwater modelling prepared by HSE) is provided in the orange boxes below. The previous assessments that remain unchanged for use in 2025 are shown in green boxes.

Summary of assessment

When this use was considered in 2020, ECP advised that HSE's assessments were based on a sowing rate that might be less than that typically used in commercial situations and so underestimated any potential risks. The HSE assessment was based on the standard assumption used for regulatory risk assessment for sugar beet drilled at 115,000 seed/ha. HSE accepts that drilling rates will be dependent on many factors, including the variety, row and seed spacings and expected germination rates. However, HSE efficacy specialists have reviewed the latest information in this area and consider that higher sowing rates are not necessarily representative of typical widescale commercial recommendations. Noting the previous ECP member concerns, HSE do not consider that there is enough evidence to change the standard drilling rate assumptions and have therefore retained the figure of 115,000 seeds/ha as being representative of a realistic worst-case appropriate for regulatory risk assessment. If authorised, a restriction limiting the maximum drilling rate to 115,000 seeds per hectare will be included on the authorisation.

2022 Assessment

The previous assessment performed under COP 2018/01509 (also an Article 53) considered a GAP of 1 x 69 g a.s./ha, based on a seed treatment rate of 100ml per 100,000 seeds and a sugar beet drilling rate of 115,000 seeds/ha.

This rate resulted in an unacceptable risk to aquatic organisms, but an acceptable risk to soil and groundwater.

The current application proposes a reduction to 75% of the rate considered in 2018. Based on a seed treatment rate of 75ml per 100,000 seeds and identical drilling rate, the application rate considered here will be 51.75 g a.s./ha.

The following exposure assessment uses existing agreed endpoints and latest versions of guidance and exposure models. Where appropriate relevant exposure values from existing assessments will also be included.

[Information in this section for the 2022 assessment on the approach to aquatic risk assessment and surface water monitoring has been moved to the surface water section below]

Predicted environmental concentrations in soil (PECsoil)

The proposed use of 'Cruiser SB' is within that considered previously for active substance approval, and the 2018 Article 53 assessment which considered a higher application rate (69 g a.s./ha compared with 51.75g a.s./ha). An acceptable risk to soil organisms was identified and no further assessment is therefore required from a fate and behaviour perspective.

To assist in assessing the risk to bees foraging in following, flowering crops, predicted environmental concentrations at a range of intervals have been provided. These calculations use the longest field DT_{50} from the regulatory database which is 172 d (DT_{90} = 570 d).

Based on an application rate of 51.75 g a.s./ha, the initial PECsoil immediately after application of treated seed would be 0.069 mg/kg over 5cm.

Based on the longest field soil DT_{50} of 172 d and single first order kinetics, residues in soil after 13 months (395 d) would be predicted to be 0.014 mg/kg over 5cm. This concentration would be reduced to 0.0035 mg/kg over 20 cm. Calculating soil residues over a 20cm soil depth would be a reasonable assumption due to the natural disturbance of soil following harvest and lifting of mature beets. Residues for a 13-month interval are provided here to match the approximate planting interval in a succeeding crop study discussed in the ecotoxicology section.

The applicant has proposed a restriction of 32 months from planting sugar beet to growing a following, flowering crop (updated from the 22-month restriction considered in 2020). This restriction is intended to mitigate risks to bees foraging in flowering crops. Based on the longest field soil DT_{50} residues in soil after 32 months (973 d) would be predicted to be 0.0014 mg/kg over 5cm and 0.00035 mg/kg over 20 cm.

The applicant has also proposed a restriction of 46 months between planting a further crop of 'Cruiser SB' treated sugar beet. Based on the longest field soil DT_{50} residues in soil after 46 months (1400 d) would be predicted to be 0.0002 mg/kg over 5cm and 0.00005 mg/kg over 20 cm. These levels are so low compared to the initial PECsoil of 0.069 mg/kg following application (less than 1% based on residues over 20cm and 46 months after application) that accumulation in soil following repeated use can be excluded if this restriction is followed.

Further consideration of these levels of soil exposure is provided in the ecotoxicology section.

Predicted environmental concentrations in surface water (PECsw)

The most recent consideration of exposure levels of thiamethoxam from 'Cruiser SB' in 2018 indicated an unacceptable risk to aquatic organisms. Since the proposed use rate is 75% of the rate considered in 2018, a revised assessment considering the lower rate has been prepared.

A tiered approach to assessing risks to aquatic organisms is presented. A first-tier assessment uses an agreed Regulatory Acceptable Concentration (RAC) of 0.14 µg/l for thiamethoxam. A higher tier assessment compares the same surface water exposure values against a thiamethoxam RAC of 5 µg/l derived from a higher tier mesocosm study. Both RAC values consider effects against aquatic invertebrates. For further details on the derivation of RAC values refer to the ecotoxicology section.

As this is a seed treatment, no consideration of spray drift has been made. The formulation is applied to pelleted seed that is treated with a film coating, therefore the levels of dust generated at the point of application are minimal and no consideration of dust drift is required. The main route of surface water exposure is via drainflow and this has been assessed using the standard MACRO modelling approach and following published guidance.

The MACRO model simulates exposure arising from a single use pattern (i.e. single crop, application timing and application rate) across a range of soil-climate scenarios that are representative of the conditions vulnerable to pesticide losses via drainflow across the UK agricultural landscape. The standard regulatory soil scenarios representative of sugar beet growing areas are Hanslope, Brockhurst and Clifton in dry, medium and wet climate scenarios.

The results from all soil-climate scenarios relevant to the crop are considered, with peak annual PECsw values from 30 years of model simulation data compared against the Regulatory Acceptable Concentration (RAC). The number of years where the RAC is exceeded is determined. The probability of exceeding the RAC can be weighted spatially based on the proportion of crop associated with each scenario to give an overall exceedance value. This calculation accounts for areas of the crop which are not drained or are not vulnerable to drainflow losses (for example peaty soils) as well as drained areas where no exceedances occurred. The individual number of exceedances for each soil-crop scenario is reported for comparison against regulatory triggers. The overall spatially weighted exceedance level must be less than 10%, consistent with a 90^{th} percentile exposure assessment goal.

An application rate of 51.75 g thiamethoxam/ha has been considered with an earliest sowing date of 1^{st} March and latest sowing date of 1^{st} April being considered in separate assessments. The agreed substance endpoints for modelling thiamethoxam were as follows: DT_{50} = 37 d (normalised to 20˚C and pF2), K_{foc} = 69.5 ml/g, 1/n = 0.88. The output results are compared to the agreed thiamethoxam RAC of 0.14 µg/l which is based on effects on aquatic invertebrates in a first-tier assessment. A higher tier assessment compares the same surface water exposure values against a higher tier thiamethoxam RAC of 5 µg/L derived from a mesocosm. For further details on the derivation of RAC value refer to the ecotoxicology section.

PECsw via drainflow for March 1st applications against first tier thiamethoxam RAC

Table 1: Number of exceedance years following application of 51.75 g a.s./ha on **1st March**. These are the years when the largest concentration is greater than the first tier RAC of 0.14 µg/l on at least one day for each scenario. Total years modelled = 30; values in parentheses are percentages of exceedance years. In the standard HSE MACRO model very wet climate scenarios (>850 mm rainfall) are not modelled. Results from the wet scenarios are used as a surrogate for results from these very wet scenarios.

Soil	Dry (<625 mm per annum)	Medium (625-750 mm per annum)	Wet (750-850 mm per annum)	Very wet (> 850 mm per annum)
Hanslope	18/30 (60.0)	18/30 (60.0)	25/30 (83.3)	25/30 (83.3)
Brockhurst	7/30 (23.3)	12/30 (40.0)	18/30 (60.0)	18/30 (60.0)
Clifton	0/30 (0)	4/30 (13.3)	2/30 (6.7)	2/30 (6.7)

Information on the extent of crop likely to be grown in each soil and climate scenario is used to weight the individual percentage of exceedance years. Based on this weighting procedure, overall levels of exceedance are calculated as follows: -

RAC exceeded	=	10.26%
Undrained	=	51.01%
Drained but ‘safe’	=	38.72%
Total ‘safe’	=	89.74%
Total	=	100%

In considering the overall acceptability of the assessment, the number of exceedance years for each scenario should be considered, alongside a consideration of the overall level of weighted scenario years exceedances. When the RAC is based on effects on fish or aquatic invertebrates (as in the case for thiamethoxam) there is a lower limit threshold value for the number of exceedance years for each scenario. The risk is considered acceptable if there are no more than 3 years out of 30 exceeding the RAC. If the exceedance years are above this level, it may still be possible to show an acceptable risk based on a more detailed case-by-case assessment. But in this case for applications from 1st March the maximum number of exceedance years is 25/30 (Hanslope wet scenario). This level of exceedance is so high (even above the absolute upper limit of 18/30 years that would be acceptable when the RAC is based on effects on aquatic plants and algae) that in this case no detailed further assessment would be able to demonstrate an acceptable risk when the RAC is based on effects on aquatic invertebrates. In addition, the overall level of weighted scenario years considering the extent of sugar beet grown on each scenario indicates that an unacceptable risk occurs in more than 10% of the cropping area (10.26%). Since this is above the threshold value of 10% and the total acceptable area is less than 90% (89.74%) an acceptable risk has not been demonstrated on the basis of the first-tier RAC.

PECsw via drainflow for April 1st applications against first-tier thiamethoxam RAC

Table 2: Number of exceedance years following application of 51.75 g a.s./ha on **1st April**. These are the years when the largest concentration is greater than the RAC of 0.14 µg/l on at least one day for each scenario. Total

years modelled = 30; values in parentheses are percentages of exceedance years. In the standard HSE MACRO model very wet climate scenarios (>850 mm rainfall) are not modelled. Results from the wet scenarios are used as a surrogate for results from these very wet scenarios.

Soil	Dry (<625 mm per annum)	Medium (625-750 mm per annum)	Wet (750-850 mm per annum)	Very wet (> 850 mm per annum)
Hanslope	18/30 (60.0)	14/30 (46.6)	22/30 (73.3)	22/30 (73.3)
Brockhurst	7/30 (23.3)	3/30 (10.0)	10/30 (33.3)	10/30 (33.3)
Clifton	0/30 (0)	0/30 (0)	2/30 (6.7)	2/30 (6.7)

Based on the scenario weighting procedure, overall levels of exceedance are calculated as follows: -

RAC exceeded	=	7.98%
Undrained	=	51.01%
Drained but ‘safe’	=	41.01%
Total ‘safe’	=	92.02%
Total	=	100%

Applications from the 1st April show marginally lower levels of exceedance – both in terms of individual scenarios, where the maximum number of exceedances was 22 out of 30 years (Hanslope wet), and for the overall weighted scenario years where the RAC was estimated to be exceeded in 7.98% of the cropping area. Although the weighted scenario years exceedance level was within the acceptable threshold level of 10% and thus the acceptable area was greater than 90% (92.02%), the number of exceedances within an individual scenario was still above acceptable thresholds. Overall, although the risks were lower for the April application, an acceptable risk has not been demonstrated on the basis of the first-tier RAC.

Due to the level of exceedances from the estimated exposure from the proposed use of thiamethoxam alone using the first-tier RAC, no further consideration has been made of the additional contribution to the overall risk posed by the major soil metabolite CGA 322704 (clothianidin), which may also be subject to drainflow losses.

PECsw via drainflow for March 1st applications against higher-tier thiamethoxam RAC

Table 3: Number of exceedance years following application of 51.75 g a.s./ha on **1st March**. These are the years when the largest concentration is greater than the higher tier RAC of 5 µg/l on at least one day for each scenario. Total years modelled = 30; values in parentheses are percentages of exceedance years. In the standard HSE MACRO model very wet climate scenarios (>850 mm rainfall) are not modelled. Results from the wet scenarios are used as a surrogate for results from these very wet scenarios.

Soil	Dry (<625 mm per annum)	Medium (625-750 mm per annum)	Wet (750-850 mm per annum)	Very wet (> 850 mm per annum)
Hanslope	0/30 (0)	0/30 (0)	0/30 (0)	0/30 (0)
Brockhurst	0/30 (0)	0/30 (0)	0/30 (0)	0/30 (0)
Clifton	0/30 (0)	0/30 (0)	0/30 (0)	0/30 (0)

Information on the extent of crop likely to be grown in each soil and climate scenario is used to weight the results from individual scenarios. Based on this weighting procedure, overall results are as follows: -

RAC exceeded	=	0%
Undrained	=	51.01%
Drained but 'safe'	=	48.99%
Total 'safe'	=	100%
Total	=	100%

With the higher tier thiamethoxam RAC of 5 µg/l there are zero exceedances. The maximum predicted concentration was 2.799 µg/l for the Hanslope medium scenario.

Using the first-tier RAC an acceptable risk could not be demonstrated based on thiamethoxam levels alone and therefore no further consideration was made of the additional contribution to the overall risk posed by the major soil metabolite CGA 322704 (clothianidin). Since the higher tier RAC removes concerns over thiamethoxam, further consideration of the contribution from clothianidin is required.

Additional modelling was conducted to simulate the formation of clothianidin from the thiamethoxam seed treatment application. The agreed substance endpoints for modelling clothianidin were as follows: DT_{50} = 120.1 d (normalised to 20˚C and pF2), K_{foc} = 160 ml/g, 1/n = 0.83 and molar formation fraction of 0.3 (corrected to 0.257 to reflect a mass fraction value for use in the MACRO model). The output results are compared to an agreed clothianidin RAC of 0.493 µg/L which is based on effects on aquatic invertebrates in a first-tier assessment.

PECsw via drainflow for clothianidin (March 1st application of thiamethoxam)

Table 4: Number of exceedance years following application of 51.75 g a.s./ha on **1st March**. These are the years when the largest clothianidin concentration is greater than the RAC of 0.493 µg/l on at least one day for each scenario. Total years modelled = 30; values in parentheses are percentages of exceedance years. In the standard HSE MACRO model very wet climate scenarios (>850 mm rainfall) are not modelled. Results from the wet scenarios are used as a surrogate for results from these very wet scenarios.

Soil	Dry (<625 mm per annum)	Medium (625-750 mm per annum)	Wet (750-850 mm per annum)	Very wet (> 850 mm per annum)
Hanslope	0/30 (0)	0/30 (0)	0/30 (0)	0/30 (0)
Brockhurst	0/30 (0)	0/30 (0)	0/30 (0)	0/30 (0)
Clifton	0/30 (0)	0/30 (0)	0/30 (0)	0/30 (0)

Information on the extent of crop likely to be grown in each soil and climate scenario is used to weight the results from individual scenarios. Based on this weighting procedure, overall results are as follows: -

RAC exceeded = 0%

Undrained = 51.01%

Drained but 'safe' = 48.99%

Total 'safe' = 100%

Total = 100%

Considering clothianidin with a RAC of 0.493 µg/l there are zero exceedances. The maximum predicted concentration was 0.118 µg/l for the Hanslope dry scenario.

For completeness, HSE considered the potential combined exposure arising from residues of both thiamethoxam and clothianidin based on annual peak daily concentrations. In this case there were no exceedances considering thiamethoxam and clothianidin individually, and no exceedances considering combined residues. An acceptable risk has been demonstrated for March applications utilising the higher tier RAC for thiamethoxam.

The modelling and risk assessment exercise was repeated for the April 1st applications and confirmed the results from the March timing, that is there are no exceedances individually or combined. Therefore an acceptable risk has also been demonstrated for applications for both March and April application timings using the higher tier RAC for thiamethoxam.

Clothianidin formation from thiamethoxam seed treatments

In the applicant's submission they provided further information on the potential for clothianidin formation from thiamethoxam seed treatments. The applicant's brief case is provided in full below.

Formation of clothianidin: *The degradation of thiamethoxam in the field in a range of European soils is considered by Hilton et al (2019)[1]. There was no clear difference in the rate of degradation of thiamethoxam following use as a seed treatment in the field (DT_{50} 16.5 days) as against use as a spray application (DT_{50} 18.3 days). However, the formation of the metabolite clothianidin was far lower in seed treatments (3.4% mol/mol) compared to spray applications (17.4% mol/mol). Therefore, the movement of clothianidin to surface water is likely to be far lower following use of seed treatments than spray applications. As shown in Hilton et al (2019[2]. degradation does not vary across soil types and thiamethoxam is not converted to clothianidin in surface water (Pickford et al 2018)[3].*

In the limited time available, HSE have briefly reviewed the published study referenced above and concluded that the work appeared to be well conducted and followed standard regulatory study guidelines for the conduct of both laboratory and field dissipation studies. In side-by-side trials at 4 field locations clothianidin formation was observed to be much lower when thiamethoxam was applied as a seed treatment compared to formation from a spray application. The authors speculated that this difference was due to the areas of soil being exposed being variable depending on application method. Following spray application soil exposure is principally expected in the upper layers of bulk soil. In contrast for seed treatment applications, following initial transport of residues from the seed surface to the surrounding soil, it is the soil immediately around the treated seed and roots of the growing plant (rhizosphere) that would be initially exposed to the highest concentrations. The authors suggested that the narrow area of soil around plant roots is chemically and biologically different to the remaining bulk soil, due to secretions from the roots, sloughed off root cells and subsequent colonisation by micro-organisms. Therefore, bacterial communities in the rhizosphere form a subset of the total bacteria community present in bulk soils, and hence, a rhizosphere effect can be observed on the microbial community. The authors conclude that thiamethoxam applied as a seed treatment may be subjected to different degradation processes when compared to spray applied thiamethoxam, resulting in the lower levels of clothianidin formation. In addition to the potential effect of differing microbial communities, the HSE evaluator considered that a further effect may be introduced by greater plant uptake from seed treatments compared to bare soil spray applications. Although overall dissipation rates may be similar in trials conducted with both application methods, greater dissipation via plant uptake from seed treatment applications which removes thiamethoxam from the soil may also contribute to the lower levels of clothianidin formation in the field.

Although the trial appeared well conducted, the HSE evaluator noted that the field trial used treated maize seeds. If the principal cause of the lower levels of clothianidin formation was a specific localised rhizosphere effect, then the fact that the study has only investigated the impact around maize seeds adds a degree of uncertainty to the relevance of the findings to behaviour in the immediate vicinity of pelleted sugar beet seeds. In addition, as part of the thiamethoxam data considered during active substance approval, clothianidin formation fractions were derived from a mix of field trials involving both spray applications and seed treatments. No difference in clothianidin formation fraction was observed and the agreed formation fraction was therefore taken as a mean value from all trials, irrespective of method of application. Therefore, the agreed clothianidin formation fraction endpoint already includes some consideration of the formation from seed treatments (noted that at active substance level cereal seed treatment were typically used in the studies supporting approval).

Overall the study referenced by the applicant appears well conducted and the explanations for the lower levels of clothianidin formation seem plausible. However, when assessing the risks to surface water using the agreed first-tier RAC for thiamethoxam alone, this resulted in an unacceptable risk assessment. Refinement of the clothianidin formation fraction would not alter the regulatory conclusion of the first-tier assessment. In addition,

[1] Hilton, M.J., Emburey, S.N., Edwards, P.A., Dougan, C. and Ricketts, D.C. (2019), The route and rate of thiamethoxam soil degradation in laboratory and outdoor incubated tests, and field studies following seed treatments or spray application. Pest. Manag. Sci., 75: 63-78. doi:10.1002/ps.5168

[2] Hilton, M.J., Emburey, S.N., Edwards, P.A., Dougan, C. and Ricketts, D.C. (2019), The route and rate of thiamethoxam soil degradation in laboratory and outdoor incubated tests, and field studies following seed treatments or spray application. Pest. Manag. Sci., 75: 63-78. doi:10.1002/ps.5168

[3] Pickford, D.B., Finnegan, M.C., Baxter, L.R., Böhmer, W., Hanson, M.L., Stegger, P., Hommen, U., Hoekstra, P.F. and Hamer, M. (2018), Response of the mayfly (*Cloeon dipterum*) to chronic exposure to thiamethoxam in outdoor mesocosms. Environ Toxicol Chem, 37: 1040-1050. doi:10.1002/etc.4028

considering the higher tier RAC of thiamethoxam and agreed endpoints for clothianidin (including a formation fraction of 0.3) no exceedances were calculated for either compound individually or in combination. Refinement of the clothianidin formation fraction would therefore not alter the regulatory conclusion at the higher tier.

Applicant FOCUS surface water modelling

The applicant's 2020 submission also included a brief summary of exposure modelling. However, the summary referenced results from previous FOCUS surface water modelling, a model that is not used to support UK authorisations. The maximum PECsw value of 0.486 µg/l was above the first tier RAC of 0.14 µg/l for an application pattern comparable to that proposed here (sugar beet seed treatment was modelled at 58.5 g a.s./ha in FOCUSsw). However, this concentration was below the higher tier RAC of 5 µg/l. The applicant's submission also referenced the use of vegetative buffer strips. However, this is a form of risk mitigation not yet adopted in the UK, and since this form of mitigation may principally reduce risks from runoff events, the relevance to the drainflow route of exposure is limited. The implementation of a 10-12 m vegetative buffer strip did not reduce exposure values below the first tier RAC (maximum PECsw value of 0.222 µg/l in runoff scenarios according to FOCUS surface water). For completeness the applicant's text has been provided below in full.

Exposure: *Sugar beet is primary grown in a one in 3-year cropping cycle on undrained and peaty soils in the UK. FOCUS Tier 3 modelling* [redacted][4] *showed a maximum PEC_{sw} of 0.486 µg thiamethoxam /L and 0.002 µg clothianidin /L occurred following run-off events with use of thiamethoxam as a sugar beet treatment (58.5 g ai/ha). This value is below the insect EC50 SSD HC5 of 1.3 µg a.s./L. Maximum time-weighted average (TWA) PEC_{sw} values (Tier II Step 3) were 0.039 µg thiamethoxam /L over 7 days*
(≤ 0.001 µg clothianidin /L) which is well below the NOEC of 0.3 µg thiamethoxam /L from 35 days continuous exposure (Pickford et al 2018). However, run-off events can also be mitigated by the presence of vegetative buffer strips with significant reduction in the mass of pesticide transported in both the aqueous phase and sediment phase. Use of a 10-12m vegetative buffer strip in FOCUS Step 4 modelling using the ECPA SWAN tool[5] *resulted in a maximum PEC_{sw} of 0.222 µg thiamethoxam /L and 0.001 µg clothianidin /L.*

Environment Agency surface water monitoring

A brief review of surface water monitoring data also considers monitored levels against a concentration 0.14 µg/l for thiamethoxam which was the PNEC used in the 1st Watch List developed under the Water Framework Directive (WFD) in 2015[1]. This watch list of substances (including neonicotinoids) was established by the EU but applies in the UK[2]. The purpose of the watch list is to generate high-quality monitoring data for substances that may pose a significant risk to or via the aquatic environment, but for which monitoring data are presently insufficient to come to a conclusion on the actual risk posed. The intention is that, in the future, the data will support the risk assessments that underpin the identification of priority substances. Monitoring data has also been considered against an updated PNEC of 0.042 µg/l proposed by a review and recommendations for the 2nd Watch List under the WFD[3].

[1] the WFD's provisions still apply in the UK via:

The Water Environment (Water Framework Directive) (England and Wales) Regulations 2017

[4] Thiamethoxam - A FOCUS Surface Water Exposure Assessment at Step 3 for Parent and Metabolite CGA322704 Following Seed Treatment Applications. SYN/28/08-SW08
[5] Ford S (2016e) Thiamethoxam - A FOCUS Surface Water Exposure Assessment at Step 4 for Parent and Metabolite CGA322704 Following Seed Treatment Applications to Sugar Beet. SYN/28/08-SW13

The Water Environment (Water Framework Directive) Regulations (Northern Ireland) 2017

Water Environment and Water Services (Scotland) Act 2003

[2] Commission Implementing Decision (EU) 2018/840 of 5 June 2018 establishing a watch list of substances for Union-wide monitoring in the field of water policy pursuant to Directive 2008/105/EC of the European Parliament and of the Council and repealing Com

[3] JRC Technical Reports. Review of the 1st Watch List under the Water Framework Directive and recommendations for the 2nd Watch List. April 2018.

The final part of the applicant's submission in 2020 included a brief summary of Environment Agency monitoring data from 2016. In each of the reported metrics used to describe the monitoring data, concentrations above the first tier RAC of 0.14 µg/l but below the higher tier RAC of 5 µg/l were reported. For example, the maximum reported concentration was 0.77 µg/l, the 95th percentile daily concentration was 0.30 µg/l and the maximum mean residue over a 1-month period was 0.25 µg/l. The first tier RAC of 0.14 µg/l is consistent with the PNEC used in the 1st Watch List developed under the Water Framework Directive (WFD) in 2015. An updated PNEC of 0.042 µg/l has been proposed by a review and recommendations for the 2nd Watch List under the WFD and since this is lower than the value used in the 1st Watch List, each of the reported metrics would also exceed this updated PNEC.

The most detailed information was provided for the River Waveney Catchment Sensitive Farming site (see applicant's Figure 1 below – noting that the effect concentrations plotted on this figure do not correspond to the agreed PNEC of 0.14 µg/l from the 1st Watch List or the updated PNEC of 0.042 µg/l recommended for the 2nd Watch List).

Data from the River Waveney site has been subject to more in depth analysis by HSE in the past, supported by detailed contextual analysis by the Environment Agency, and this was all presented to ECP 20 in March 2018 (see ECP 20 papers ECP 3-12, 3-13 and 3-14 for details). In data presented by the Environment Agency, the maximum thiamethoxam concentration in the River Waveney in 2016 was 1.8 µg/l (higher than the value of 0.77 µg/l reported by the applicant). The peak levels were detected in June 2016 and the Environment Agency analysis attributed these levels to run-off after a prolonged period of exceptionally heavy rain (a 1 in 30-year rainfall period). Samples from the River Waveney were taken at the bottom of this large, 863 km^2 catchment. The Environment Agency contextual analysis revealed that the principal uses of thiamethoxam during the 2016 sampling period were on beet crops and potatoes which represented less than 4% of arable cropping across the catchment. Noting the relatively low level of usage of thiamethoxam across the catchment and that sampling was taken from the bottom of the catchment, concentrations in small ditches adjacent to treated fields during drainflow events would be expected to be higher. Concentrations above either of the WFD PNEC values (0.14 or 0.042 µg/l) may be expected to occur at the edge of field scale (as demonstrated by the outputs of the regulatory modelling) and at the larger catchment scale as demonstrated by the monitoring data. For completeness the applicant's summary of monitoring data is provided below.

Surface water monitoring data: *A weight of evidence can also be provided by investigating UK surface water monitoring data. According to the Watchlist 1 data (2016) collected by the Environment Agency from 16 rivers in England under the WFD[6], based on 116 analyses when thiamethoxam was detected above the LOD (0.001 µg/L), the 95th percentile of environmental concentrations in samples with detects was 0.16 µg/L. For the River Waveney, which had the highest number of detects in any of the sampled rivers within typical sugar beet growing areas, the thiamethoxam residue was above the ETO $RAC_{sw.ch}$ in one sample (0.77 µg/L) collected over the course of the 10-month sampling period. However, the 95th percentile reported daily residue was 0.3 µg/L and the maximum mean residue over a 1-month period was 0.25 µg/L. As Figure 1 demonstrates these monitoring residues indicate that populations of C. dipterum and similarly sensitive aquatic insects are unlikely to be*

[6] https://www.eionet.europa.eu/ accessed Jan 2018 (excel spreadsheet data available on request)

significantly impacted by thiamethoxam exposure in natural systems represented by the conditions in the Pickford et al 2019 study (35-day continuous exposure NOEC 0.3 µg/L).

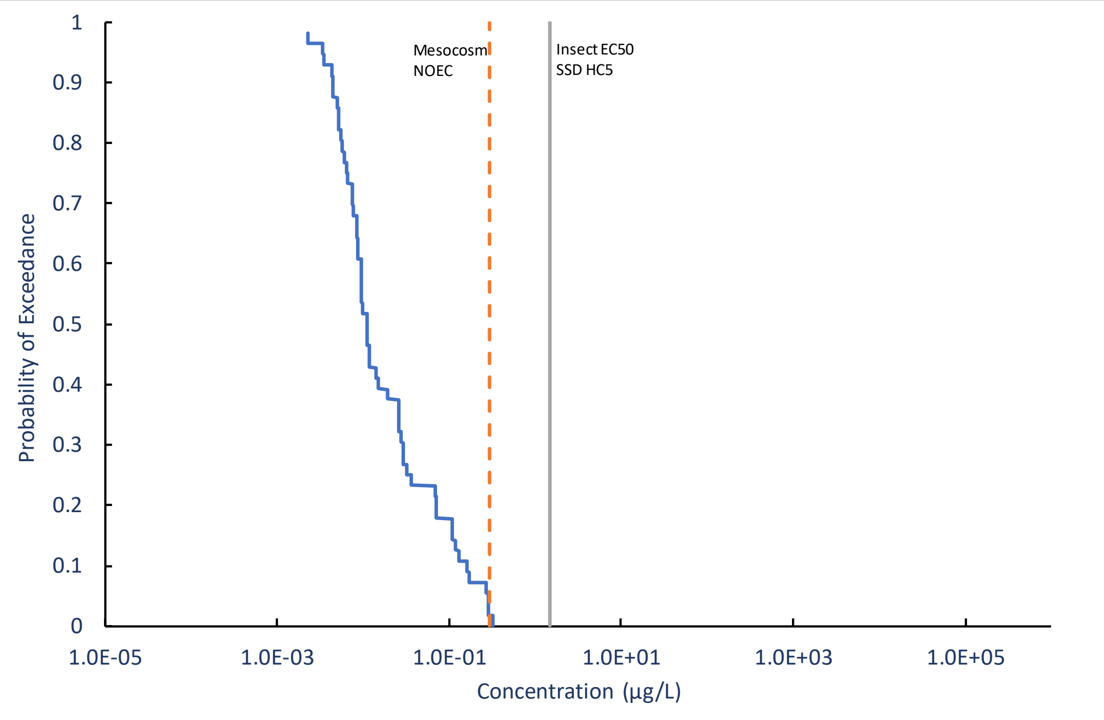


Figure 1 Distribution curve for thiamethoxam detection in daily samples collected from the River Waveney (Watchlist 1 data) compared with the mesocosm NOEC from continuous thiamethoxam exposure (Pickford et al. (2018) and the insect EC50 SSD HC5 from Finneghan et al (2017) (note these effect concentrations do not correspond to the agreed WFD PNEC of 0.14 µg/l or proposed PNEC of 0.042 µg/l)

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY
Name of authority: Health and Safety Executive.

2.6.2 Environment Agency surface water monitoring (update to support proposed use in 2025)

The 2020 application for emergency use of 'Cruiser SB' in 2021 included a brief summary of Environment Agency surface water monitoring data for thiamethoxam from 2016. The most detailed information in terms of frequency of sampling and detections came from Catchment Sensitive Farming (CSF) sites (samples taken twice weekly). Data from the River Waveney CSF site for both thiamethoxam and clothianidin had already been subject to more in depth analysis by HSE and was presented to the ECP 20 meeting in March 2018 (see ECP 20 papers ECP 3-12, 3-13 and 3-14 for details).

The previous HSE assessment highlighted the key difference in the spatial scale of Environment Agency monitoring versus regulatory exposure modelling. Monitoring is typically based on river samples taken from the outlets of large agricultural catchments whilst regulatory modelling is based on predicted concentrations in small ditches at the edge of treated fields. Monitoring therefore represents an average concentration across the catchment, reflecting inputs from a mix of soil and crop uses as well as dilution as a result of water inputs from untreated and/or non-agricultural land. This means that monitoring data cannot be directly compared to the outputs of the standard regulatory assessment.

In order to provide an updated assessment for proposed use in 2025, the Environment Agency provided the latest summary monitoring data available (provided to HSE at the beginning of July 2024). These data provided results for thiamethoxam and clothianidin up to a latest sampling date of 1st March 2024, and therefore extended the data range from the previous report for use in 2024 which covered a period up to the 1st May 2023 (data for clothianidin from the Wensum catchment was previously available and reported up to the 1st June 2023). HSE has extracted results for the 3 CSF sites that have been shown to result in the highest number and concentration of detections of both thiamethoxam and clothianidin. The relevant sites were the Rivers Waveney, Wensum and Ancholme.

Monitoring data is presented below in Figure 1 for clothianidin and Figure 2 for thiamethoxam with data from 2016 to 2024 to illustrate longer term trends. Note that intensive monitoring of neonicotinoids started in 2016 and that fewer samples were taken in 2020 and 2021 due to COVID-19 restrictions.

	In general clothianidin was detected at higher concentrations more frequently than thiamethoxam over this period. For both substances the data shows a general trend for reducing concentrations year on year since 2016. This is as expected since concentrations being detected earlier in this period reflected a much wider range of use patterns authorised at that time, including uses on major crops such as cereals (clothianidin) and potatoes (thiamethoxam). Concentrations in 2024 are in general low, reflecting the more limited and controlled use of thiamethoxam on sugar beet only. There is potentially some indication that concentrations were higher in the latest data period (i.e. May 2023 to March 2024) Than the previous reporting period, particularly for clothianidin in the Waveney catchment. But HSE considers that a longer time span of data would ideally be needed to confirm any significant changes. There was a single detection of thiamethoxam above the Water Framework Directive PNEC of 0.042 µg/l at these sites (at 0.044 µg/l on 1st May 2023 in Waveney catchment). Note that for 2024, data is only available for samples taken up to 1st March and there is always the potential for higher concentrations to occur as a result of the onset of winter drainflow periods. HSE considers it would be sensible to continue to review data as long as emergency uses are authorised to confirm the current trends. Since the current standard regulatory assessment for 'Cruiser SB' demonstrated an acceptable risk to aquatic organisms from combined thiamethoxam and clothianidin exposure, the updated monitoring data does not alter the regulatory decision.	

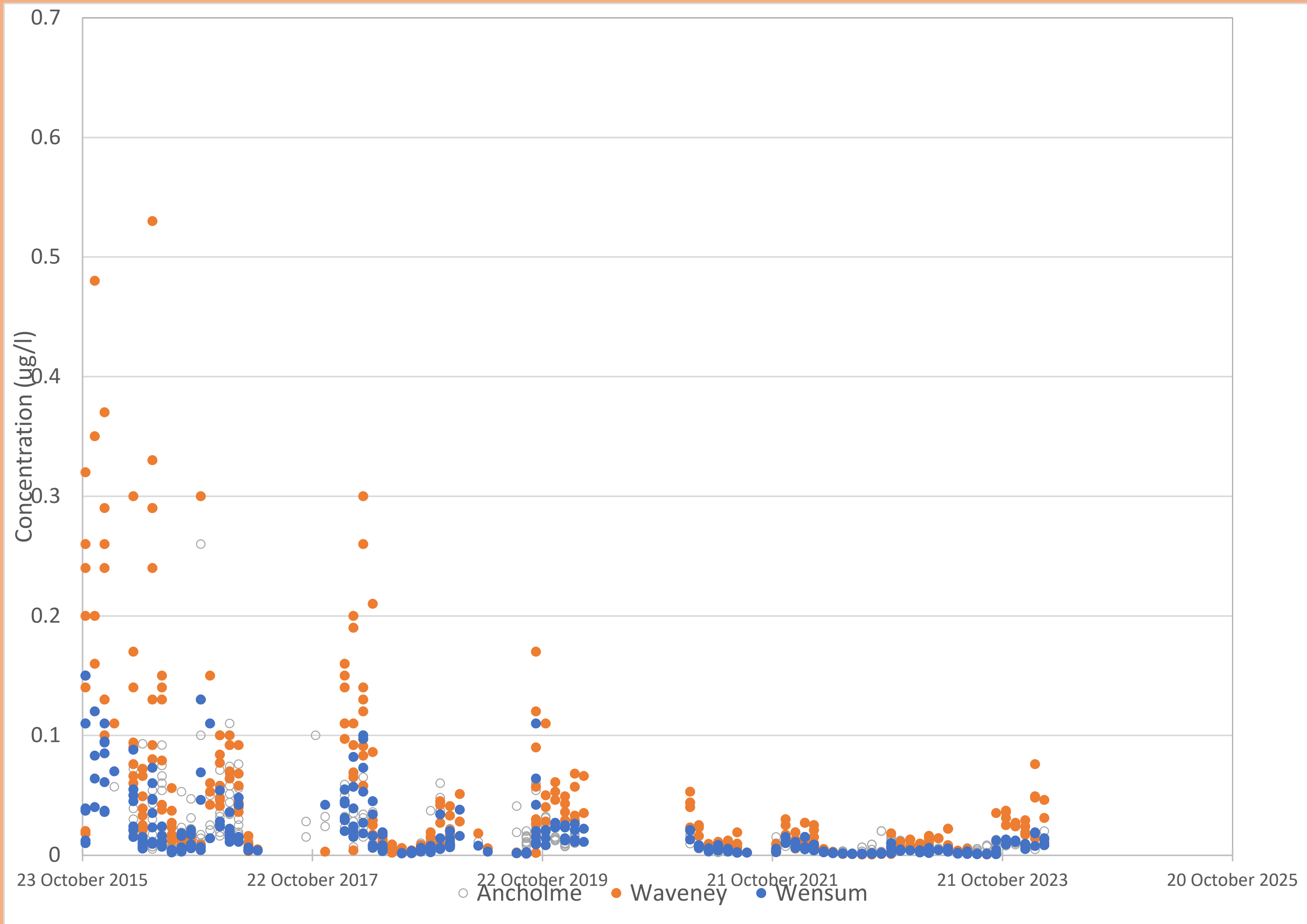


Figure HSE 2.6-1: Clothianidin surface water monitoring (Environment Agency LCMS screening data for three CSF sites)

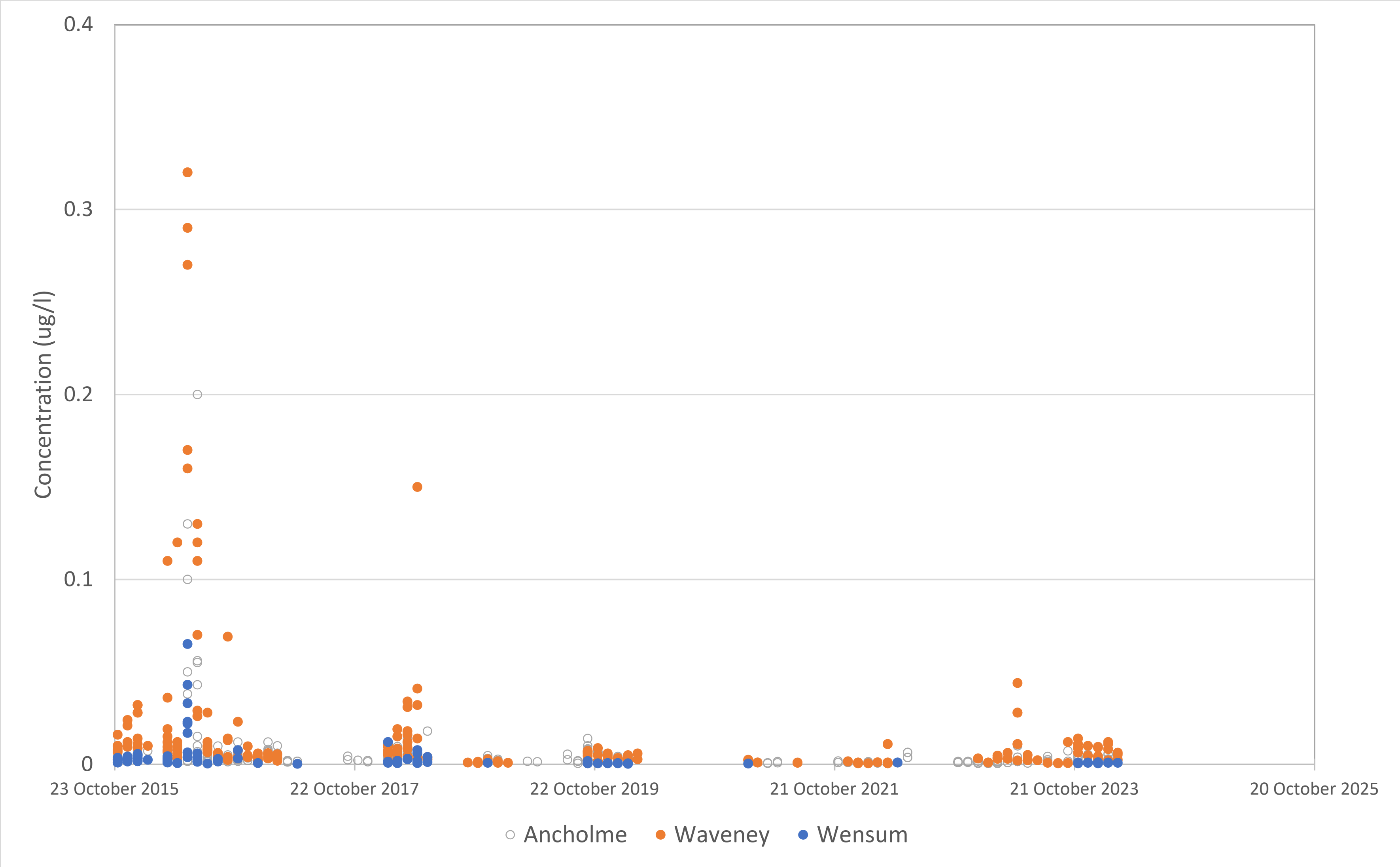


Figure HSE 2.6-2: Thiamethoxam surface water monitoring (Environment Agency LCMS screening data for three CSF sites) (Note that the scale of the y-axis has been capped at 0.4 µg/l to improve visibility of low level detections from 2019 onwards)

Groundwater exposure – PECgw – updated for use in 2025

The proposed use of 'Cruiser SB' is within that considered previously for active substance approval, and the 2018 Article 53 assessment which considered a higher application rate (69 g a.s./ha compared with the 51.75g a.s./ha rate now being considered). An acceptable risk to groundwater resources was identified as part of the previous assessments and no detailed assessment had been included in any of the recent Article 53 assessments.

However through the recent Mandatory Classification and Labelling process for GB thiamethoxam has been confirmed as requiring classification with regards reproductive toxicity (Repr.2 (H361fd). In line with SANCO guidance on the assessment of relevance of metabolites in groundwater (Sanco/221/2000 – rev. 11), in the absence of metabolite specific data, the parent classification for reproductive toxicity means that any groundwater metabolites must also be considered as toxicologically relevant. This means these metabolites must therefore comply with the 0.1µg/l groundwater limit value. To support the assessment of use for 2025 HSE has performed an updated groundwater exposure assessment.

Standard FOCUS groundwater modelling was performed using the latest FOCUS PEARL model version 5.5.5. Single applications of 51.75g thiamethoxam/ha were simulated to sugar beet at the 4 GB relevant scenarios. Applications were assumed to be incorporated into soil at a depth of 2.5cm and applied 7 days prior to the crop emergence dates parameterised into the FOCUS models to simulate seed treatment use. Applications were assumed to be made to sugar beet crops 1 year in 3 (the longest rotation that can be modelled within the standard FOCUS framework). This is slightly more frequent than would be allowed under the previous emergency authorisation use, which restricted further applications of ''Cruiser SB' treated seeds to the same area of land to a period of 46 months. The implications of this are briefly discussed further below.

Input parameters are listed below (Table HSE 2.6-1). These parameters have been taken from the 2005 Addendum to the EU DAR and are also consistent with those reported in the original UK authorisation presented in ACP doc (2006). Note that there has not been any modern reassessment or renewal of substance endpoints since the original active substance approval assessments in the mid-2000s, but HSE considers these endpoints appropriate for the purposes of a tier 1 groundwater assessment.

Table HSE 2.6-1: Input parameters used in FOCUS groundwater modelling

Substance	DT_{50} (d)*	K_{foc} (ml/g)	1/n	Molar formation fraction
Thiamethoxam	37 (field)	69.5	0.88	-
Clothianidin	77 (field)	85	0.81	0.30 (from thiamethoxam)
NOA459602[1]	19 (lab)	0**	0.90	0.18 (from thiamethoxam)
SYN501406[2]	24 (lab)	6	0.75	0.53 (from NOA459602)

*DT_{50} values normalised to a soil temperature of 20°C and field capacity soil moisture
**not measurable due to negligible sorption seen in laboratory study
[1]5-(5-methyl-4-nitroimino-[1,3,5]oxadiazinan-3-ylmethyl)-thiazole-2-sulfonic acid
[2]5-(N'-methyl-N''-nitro-guadinomethyl)-thiazole-2-sulfonic acid

Results are shown below (Table HSE 2.6-2).

Table HSE 2.6-2: FOCUS groundwater exposure values based on 1 x 51.75 g a.s./ha to sugar beet (1 year in 3): 80th percentile triennial average concentrations reported

Substance	Chateaudun (µg/l)	Hamburg (µg/l)	Kremsmunster (µg/l)	Okehampton (µg/l)
Thiamethoxam	0.0168	0.0089	0.0073	0.0112
Clothianidin	0.0106	0.0057	0.0039	0.0065
NOA459602	**0.1969**	**0.3210**	**0.1560**	**0.1525**
SYN501406	0.0807	0.0799	0.0662	0.0503

Parent thiamethoxam and metabolites clothianidin and SYN501406 result in PECgw values <0.1 µg/l in all 4 GB relevant scenarios and are therefore considered acceptable.

Metabolite NOA459602 is predicted to occur above 0.1 µg/l in all 4 scenarios (maximum PECgw = 0.321 µg/l in the Hamburg scenario). In the absence of further information on the reproductive toxicity of this metabolite, it is assumed by default to be toxicologically relevant and the 0.1 µg/l limit must be applied in a standard regulatory assessment. An acceptable risk to groundwater has therefore not been demonstrated for this metabolite.

As noted above the standard modelling has assumed a 1 in 3 year application pattern to sugar beet, which is slightly shorter than would be possible based on the current Article 53 restrictions which only allows a further application after 46 months. But the standard FOCUSgw exposure values for a 1 in 3 rotation are triennial averages and, based on expert judgement, HSE does not consider that NOA459602 exposure values would reduce from a peak of 0.321 µg/l to less than 0.1 µg/l if the longer rotation had been modelled.

HSE also notes that the K_{foc} for NOA459602 has been set to zero based on agreed endpoints. This assumes no sorption to soil occurs and is the most conservative assumption that can be made with regards sorption potential. The K_{foc} of zero was set on the basis that in the preliminary stage of a standard OECD 106 batch sorption study, 100% of the test material remained in the liquid phase (Nicollier, 2002). NOA459602 contains a sulfonic acid group, and therefore high water solubility / low soil sorption may be expected. Furthermore, during the active substance approval stage NOA459602 was detected in lysimeter leachates at comparable concentrations to those predicted above via the standard FOCUS groundwater modelling. For example, NOA459602 was detected at concentration of 0.112 µg/l in the first year and 0.332 µg/l in the second year of a three year lysimeter study that received an application of 52.5g a.s./ha to spring barley in year 1 (comparable soil loading and timings to the sugar beet uses proposed here) followed by an application of 63 g a.s./ha to winter wheat and 21 g a.s./ha to oilseed rape in the following year (Nicollier, 2001a,b).

Although it is possible that the FOCUS groundwater exposure assessment could be refined either by a reassessment of existing data to modern standards, or by the provision of additional data to refine the agreed endpoints, HSE considers it likely that metabolite NOA459602 would still be predicted to exceed the 0.1 µg/l based on the likely high mobility, supported by the existing lysimeter studies.

Overall HSE concludes that an acceptable risk to groundwater has not been demonstrated due to the toxicologically relevant metabolite NOA459602 exceeding the 0.1 µg/l limit.

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY
Name of authority Health and Safety Executive.

2.6.3 Monitoring data on soil, non-crop vegetation and pollen residues

– Phase II Summary Report [redacted]

The 2021 'Cruiser SB' neonicotinoid stewardship document included a requirement for a monitoring programme in treated sugar beet fields to determine any thiamethoxam residues in soils and plants. Monitoring data from the stewardship programme (extended by the Defra funded programme which included analysis of clothianidin and additional pollen sampling) was provided to HSE and is summarised here [redacted]. Data were available from 6 sites receiving 'Cruiser SB' (containing 600 g/l thiamethoxam) treatments in spring 2022 at an effective target rate of 51.75 g/ha.

The objective of the study was to determine if thiamethoxam and clothianidin residues were detectable prior to (pre-drilling), during (within growth season), and following (post-harvest), the use of Cruiser treated seeds for the sugar beet crop 2022 cultivation season. Control samples were collected in March or April prior to drilling, samples taken within the sugar beet growing season at full 'growth stage' (GS39) were taken in early August (one site sampled end of June) and post-harvest sampling was conducted between December and the following March, dependent on individual crop harvest dates. Six different sites were selected for the monitoring programme that met the following broad requirements:

• Representative of the range of soil types used for sugar beet cultivation (3 sandy soils, 2 clay soils, and 1 silty soil)
• Differing geographical locations (as far as possible)
• Different expected climatic conditions (e.g., low/high rainfall areas), if possible
• A full pesticide use history (5 years) of the selected sites should be available

The selection of sites, along with obtaining the agreement of the individual growers, was conducted prior to the start of this study (CEA study number 1060845).

Pesticide use history indicated that no thiamethoxam containing products had been used at any site in the previous 5 years. Clothianidin containing products had been used at site 1 and site 5 in 2018 and 2017 respectively.

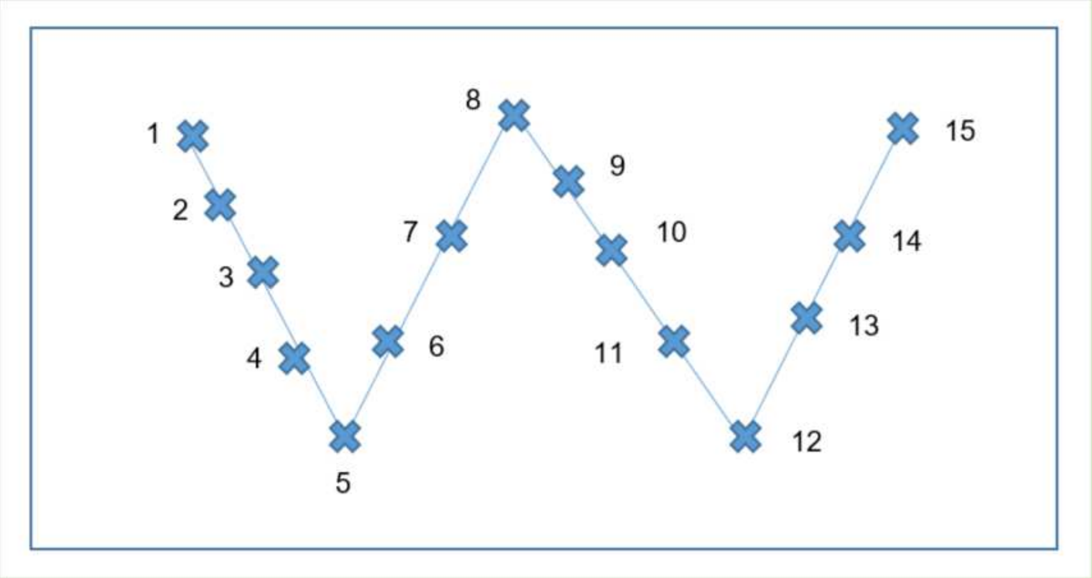
Soil sampling was conducted in both the in-field and the field margin areas of the crop fields, with non-crop vegetation and pollen samples also collected from the field margin area at each site. Samples were stored frozen following collection and all study samples were shipped to the Test Facility for GLP residue analysis of thiamethoxam and its primary metabolite clothianidin. No claim of GLP compliance was made for the sampling procedures detailed in the summary report.

Materials and methods

Sampling programme

The in-field soil cores were collected along four transects within the field, spaced to be representative within the planted field area, in a “W” pattern (see Figure 1). The same pattern was used for each soil sampling occasion, to within 1 m of the core position, to avoid sampling the exact same soil section each time . The field margin soil cores and the vegetation samples were obtained from around the field margins, from each edge and in regular spacings, where possible, as determined by the layout at each individual site.

Figure 1. Example schematic of the soil core locations



At each of the six sites, the following sampling regime for soil and field margin vegetation was followed:

Soils

There were three soil sampling occasions: pre-drilling (baseline), within growth season (GS39), and post-harvest (within 1 month of harvesting). For all six sites 15 in-field cores and 15 field margin cores were obtained on each sampling occasion. For the pre-drilling sampling occasion, 40 cm depth cores (50 mm diameter) were collected and then split into two depths (0-20 and 20-40 cm). All other soil sampling occasions used a 30 cm depth gauge corer sampling approximately a 30 mm diameter soil core (with the exception of the within growth season cores at site 2, where the 40 cm corer was used), due to dry weather conditions preventing the use of the wider 40 cm corer. The 30 cm gauge corer was used in triplicate at each coring position to obtain enough material within the sample replicate.

Field margin vegetation

There were two vegetation sampling occasions: firstly, when most plants were in flower (samples taken in early August, one site in late July), and secondly, in advance of harvesting (samples taken mid-September). For each sampling occasion, 3 individual replicate samples were obtained from each site.

Pollen

There were two pollen sampling occasions, coinciding with the field margin vegetation samplings outlined above. For each sampling occasion, approximately 1 Kg of flower heads were obtained from the field margin vegetation at each site.

Soil samples
Soil cores were collected as detailed above. All soil cores were frozen on arrival at the test facility. Where 40 cm depth cores were obtained, the frozen cores were split into 0-20 cm and 20-40 cm cores prior to being bulked into composite samples. The 15 in-field soil cores were bulked to provide 3 composite in-field soil samples and 3 composite field margin samples for analysis. All bulk samples were assigned a unique sample ID and returned to frozen storage prior to being shipped to the analytical laboratory (frozen) for residue analysis.

Vegetation samples
All vegetation samples were frozen on arrival at the CEA facility and remained frozen until being transported (frozen) to the analytical laboratory.

Pollen samples
All flower head samples were frozen on arrival at the CEA facility and remained frozen until being transported (frozen) to the analytical laboratory. The extraction of pollen from the flower heads took place at the analytical test facility.

Residue analysis
Residue analysis was performed, to GLP, at the separate Test Facility [redacted]. Sample analysis was carried out under GLP. Validated methods were used to analyse the samples for thiamethoxam and its metabolite, clothianidin. In addition, soil bulk density analyses for each site, and storage stability studies for each matrix were performed. Full validation of the analytical methods is provided in the chemistry specialist section [redacted]. In general the analytical methods were acceptably validated in the opinion of HSE, however it was noted that procedural recoveries were occasionally slightly below the guideline acceptable limit of 70% in all matrices. Of greater significance is the respective Limit of Quantification and Detection. The Limit of Quantification (LOQ) was reported to be 0.01 mg/kg and the Limit of Detection (LOD) was reported to be 0.003 mg/kg. The majority of soil samples, all vegetation and all but one pollen sample returned values of < LOD. All sites had some soil samples with residues >LOD but < LOQ, and 4 out of 6 sites had soil samples with residues > LOQ.

It is important to note that a LOQ of 0.01 mg/kg over a 30cm soil horizon (the same depth of soil layer sampled in the full growth time point) and assuming a default soil bulk density of 1.5 g/cm^3 is equivalent to a soil loading of 45 g thiamethoxam (or clothianidin)/ha. Using the same assumptions, the LOD of 0.003 mg/kg is equivalent to a soil loading of 13.5 g thiamethoxam (or clothianidin)/ha. The Article 53 emergency use for ‘Cruiser SB’ should result in a maximum application rate of 51.75 g thiamethoxam/ha. The LOQ is therefore approximately 87% of the intended application rate, and the LOD is approximately 26% of the intended application rate. Since the first post-application samples were not taken until the full growth stage (generally in August around 5 months after drilling in March) HSE would not have expected there to be significant findings of soil residues of thiamethoxam or clothianidin above the LOQ (equivalent to 45 g/ha). The LOQ is therefore too high to generate meaningful information on the long term dissipation behaviour of either analyte at these sites. Residues reported as below the LOD could also represent relatively significant levels, equivalent to up to 25% of the initial application rate.

Although the analytical phase report did include numerical concentration values for peaks <LOQ but >LOD, these are by their nature not strictly quantifiable and any concentration value reported between the LOQ and LOD should be treated with caution. However, if values are only reported as ‘less than LOQ’, this would render the soil monitoring part of the study largely meaningless. In the consolidated results tables below it has therefore been chosen to report the actual number (based on average measured residue) associated with soil residues between the LOD and LOQ and the results tables report when this is the case. As stated above, these values should be treated with caution, and HSE advises that the analytical method be further developed and validated with a lower LOQ to enable greater use of any future monitoring work undertaken.

Results

Validated methods for soil, vegetation, and pollen were employed to determine levels of thiamethoxam and clothianidin. As stated above, for both compounds the limit of quantification (LOQ) was 0.01 mg/kg and the limit of detection (LOD) was 0.003 mg/kg. Bulk soil density for each site were also determined at the analytical facility to enable the conversion of residue concentrations from mg/kg to g/ha for the soil samples (see Table 1). All analytical runs were QC checked and found to be broadly within the acceptable range for procedural recoveries (raw data provided in the analytical report). Storage stability studies for each matrix confirmed no additional losses occurred between sampling and extraction.

Table 1. Soil bulk density values and conversion for each site

Site (soil type)	Bulk density (g/cm^3)	Conversion calculations
1 (Bilsthorpe, sandy)	1.503	**Correction factor** = (soil core depth [cm]) *100 *bulk density value **Measured residue in g/ha** = measured value in mg/kg * correction factor
2 (Attleborough, sandy)	1.576	
3 (Weybourne, sandy)	1.760	
4 (Holbeach, silt)	1.283	
5 (Bury, clay)	1.514	
6 (Thorney, clay)	1.277	

Soil sample analysis results

The recovery of thiamethoxam and clothianidin from soil samples obtained from each site is detailed in Tables 2 to 7 below. All data are presented as the mean of the three bulk samples obtained on each sampling occasion. Results are briefly summarized below, and notable findings are also highlighted below each individual result table.

The baseline measures of thiamethoxam (i.e. from pre-drilling control samples) were found to be below the LOD, except for Site 4, where residues were detected in-field. Quantifiable levels of thiamethoxam (i.e. above the LOQ) were found during the growth season at Sites 2 and 5, and after the harvest in site 6. Detectable levels of thiamethoxam, below the LOQ, were also determined at Sites 3 and 4 during and after the season and at Site 1 within the growth season. No thiamethoxam residues were detected in the field margins at any of the test sites, during or after the sugar beet season.

There were no quantifiable residues of clothianidin detected in the baseline soil cores from Sites 1 to 5 inclusive, although there were some residues detected above the LOD at some of these sites, both within the field and in the field margin. Site 6 was found to have quantifiable levels of clothianidin within the beet field cores prior to drilling; detectable clothianidin levels were also found in the field margin at this time. Site 6 continued to have quantifiable levels of clothianidin detected in the in-field samples throughout and following the sugar beet season, with residue levels comparable to those determined in the pre-drilling samples.

Table 2: Monitoring data for Site 1: Bilsthorpe (sandy soil)

Sample Matrix	Sampling occasion	Mean thiamethoxam concentration (mg/kg)	Equivalent thiamethoxam soil loading (g/ha)[a]	Mean clothianidin concentration (mg/kg)	Equivalent clothianidin soil loading (g/ha)[a]
Soil in-field 0-20cm	Pre-drilling	< LOD		>LOD<LOQ (0.0033)	9.9
Soil in-field 20-40cm	Pre-drilling	< LOD		< LOD	
Soil field-edge 0-20cm	Pre-drilling	< LOD		< LOD	
Soil field edge 20-40cm	Pre-drilling	< LOD		< LOD	
Soil in-field 0-30cm	Full growth	>LOD<LOQ (0.0050)	22.5	>LOD<LOQ (0.0051)	23.0
Soil field-edge 0-30cm	Full growth	< LOD		< LOD	
Soil in-field 0-30cm	Post-harvest	< LOD		< LOD	
Soil field-edge 0-30cm	Post-harvest	< LOD		< LOD	
Vegetation	Full growth	< LOD		< LOD	
Pollen	Full growth	< LOD		< LOD	
Vegetation	Pre-harvest	< LOD		< LOD	
Pollen	Pre-harvest	< LOD		< LOD	

[a]calculated using a soil specific bulk density of 1.503 g/cm^3 (where rate in g/ha = conc. mg/kg * 100 * depth (cm) * bulk density (g/cm^3))

Residues of thiamethoxam in the pre-drilling (control) soil samples were less than the LOD in both in-field and edge of field samples. The mean measured concentration of clothianidin pre-drilling in-field was just above the LOD (equivalent to a soil loading of 9.9 g/ha). Pesticide use history indicated that products containing clothianidin had been used at this site in 2018 and low level residues of clothianidin might be expected due to the high persistence of this substance (worst case DT_{90} > 1000 d).

Thiamethoxam soil residues at the full growth stage (sampled approximately 5 months after the pre-drilling samples were collected) were also between LOD and LOQ in-field, equivalent to a soil loading of 22.5 g thiamethoxam/ha. Similar levels of the major metabolite clothianidin were also seen at this time point, elevated from levels seen in control samples. Assuming an application rate of 51.75 g thiamethoxam/ha, residues equivalent to 22.5 g/ha 5 months later is indicative of a DT_{50} of slightly less than 150 d. In comparison, a worst case soil DT_{50} of 172 d was used in the HSE regulatory risk assessment for soil. Residues of both compounds were below the LOD in the post-harvest samples (sampled 22/03/2023, approximately 7 months after the detections observed in the full growth samples, and 12 months after drilling). However at this site, the LOD was equivalent to 13.5 g/ha (or 26% of the initial intended application rate) and the limitations of the analytical method mean it is not possible to draw further conclusions on persistence at this site, other than indicating the DT_{75} is likely to be less than around 1 year. Behaviour at this site is broadly consistent with the known behaviour of the substances, and would be addressed by the standard regulatory risk assessment.

Table 3: Monitoring data for Site 2: Attleborough (sandy soil)

Sample Matrix	Sampling occasion	Mean thiamethoxam concentration (mg/kg)	Equivalent thiamethoxam soil loading (g/ha)[a]	Mean clothianidin concentration (mg/kg)	Equivalent clothianidin soil loading (g/ha) [a]
Soil in-field 0-20cm	Pre-drilling	< LOD		>LOD<LOQ (0.0034)	10.7
Soil in-field 20-40cm	Pre-drilling	< LOD		< LOD	
Soil field-edge 0-20cm	Pre-drilling	< LOD		< LOD	
Soil field edge 20-40cm	Pre-drilling	< LOD		< LOD	
Soil in-field 0-20cm	Full growth	< LOD		>LOD<LOQ (0.0032)	26.2 (sum of layers)
Soil in-field 20-40cm	Full growth	**0.025**	**78.8**	>LOD<LOQ (0.0051)	
Soil field-edge 0-20cm	Full growth	< LOD		< LOD	
Soil field edge 20-40cm	Full growth	< LOD		< LOD	
Soil in-field 0-30cm	Post-harvest	< LOD		< LOD	
Soil field-edge 0-30cm	Post-harvest	< LOD		< LOD	
Vegetation	Full growth	< LOD		< LOD	
Pollen	Full growth	< LOD		< LOD	
Vegetation	Pre-harvest	< LOD		<LOD	
Pollen	Pre-harvest	< LOD		< LOD	

[a]calculated using a soil specific bulk density of 1.576 g/cm^3. Bold values represent quantified residue levels ≥ LOQ.

Pre-drilling soil results were comparable to Site 1, with mean measured clothianidin concentrations just above LOD, equivalent to a soil loading of 10.7 g/ha and no detectable residues of thiamethoxam. No use of clothianidin products at this site was listed in the preceding 5 year period.

At the full growth sampling point in-field, there was a notable finding of thiamethoxam above the LOQ in the 20-40cm horizon equivalent to a soil loading of 78.8 g/ha. This was higher than the theoretical maximum application rate of 51.75 g/ha, even though this sample was taken approximately 3 months after the pre-drilling sample collection. This level was higher than that assumed in the standard regulatory risk assessment. Clothianidin loading at this sample point was equivalent to 26.2 g/ha, leading to a combined neonicotinoid residue of over 100 g/ha – again higher than levels assumed in the regulatory risk assessment. Residues of both compounds were below the LOD in the post-harvest samples (sampled 09/01/2023, approximately 4.5 months after the detections observed in the full growth samples). The study report author suggested that a higher than application rate detection would be possible if the soil cores obtained on these sampling occasions contained a high number of seed casings or ungerminated treated seeds. There was no information provided to suggest that seed drilling rates at this site exceeded the level allowed by the emergency authorisation and the levels detected may therefore simply reflect variability in the field.

Table 4: Monitoring data for Site 3: Weybourne (sandy soil)

Sample Matrix	Sampling occasion	Mean thiamethoxam concentration (mg/kg)	Equivalent thiamethoxam soil loading (g/ha)[a]	Mean clothianidin concentration (mg/kg)	Equivalent clothianidin soil loading (g/ha)[a]
Soil in-field 0-20cm	Pre-drilling	< LOD		< LOD	
Soil in-field 20-40cm	Pre-drilling	< LOD		< LOD	
Soil field-edge 0-20cm	Pre-drilling	< LOD		< LOD	
Soil field edge 20-40cm	Pre-drilling	< LOD		< LOD	
Soil in-field 0-30cm	Full growth	>LOD<LOQ (0.0043)	22.7	< LOD	
Soil field-edge 0-30cm	Full growth	< LOD		< LOD	
Soil in-field 0-30cm	Post-harvest	>LOD<LOQ (0.0086)	45.4	< LOD	
Soil field-edge 0-30cm	Post-harvest	< LOD		< LOD	
Vegetation	Full growth	< LOD		< LOD	
Pollen	Full growth	< LOD		< LOD	
Vegetation	Pre-harvest	< LOD		< LOD	
Pollen	Pre-harvest	< LOD		< LOD	

[a]calculated using a soil specific bulk density of 1.76 g/cm^3

No soil residues of either substance above the LOD were detected in the pre-drilling sample (the only site where this was the case).

At full growth stage residues of thiamethoxam in-field were equivalent to 22.7 g/ha. In the post-harvest samples (taken on 23/02/2023 11 months after drilling) thiamethoxam levels were higher than detected during the full growth sample (at 45.4 g/ha, close to the intended maximum application rate). This is difficult to explain but could reflect variability in the field, or sampling an area containing a high number of seed casings or ungerminated treated seeds, or it could indicate greater persistence of thiamethoxam than has been assumed in the regulatory risk assessment (worst case DT_{50} of 172 d). Continued sampling at the site may be beneficial to better understand long term residue behaviour.

Table 5: Monitoring data for Site 4: Holbeach (silt soil)

Sample Matrix	Sampling occasion	Mean thiamethoxam concentration (mg/kg)	Equivalent thiamethoxam soil loading (g/ha)[a]	Mean clothianidin concentration (mg/kg)	Equivalent clothianidin soil loading (g/ha)[a]
Soil in-field 0-20cm	Pre-drilling	>LOD<LOQ (0.0048)	22.8 (sum of layers)	>LOD<LOQ (0.0091)	46.7 (sum of layers)
Soil in-field 20-40cm	Pre-drilling	>LOD<LOQ (0.0041)		>LOD<LOQ (0.0091)	
Soil field-edge 0-20cm	Pre-drilling	< LOD		>LOD<LOQ (0.0077)	30.3 (sum of layers)
Soil field edge 20-40cm	Pre-drilling	< LOD		>LOD<LOQ (0.0041)	
Soil in-field 0-30cm	Full growth	>LOD<LOQ (0.0060)	23.1	**= LOQ (0.01)**	**38.5**
Soil field-edge 0-30cm	Full growth	< LOD		>LOD<LOQ (0.0059)	22.7
Soil in-field 0-30cm	Post-harvest	>LOD<LOQ (0.0078)	30.0	>LOD<LOQ (0.0093)	35.8
Soil field-edge 0-30cm	Post-harvest	< LOD		>LOD<LOQ (0.0045)	17.3
Vegetation	Full growth	< LOD		< LOD	
Pollen	Full growth	< LOD		< LOD	
Vegetation	Pre-harvest	< LOD		< LOD	
Pollen	Pre-harvest	>LOD<LOQ (0.00488)		< LOD	

[a]calculated using a soil specific bulk density of 1.283 g/cm^3. Bold values represent quantified residue levels ≥ LOQ.

Accepting that residues between the LOD and LOQ should be treated with caution, HSE considered there were potentially notable findings in the pre-drilling (control) samples. In-field residues of thiamethoxam were equivalent to 22.8 g/ha (approximately 45% of the maximum use rate under the emergency authorization. Pesticide history provided for each test site showed that no thiamethoxam based products were used within the last 5 years at any of the locations. Clothianidin residues were also high in both in-field (49.7 g/ha) and field edge (30.3 g/ha) samples.

Similar levels of both compounds were detected in the full growth sample time (approximately 4 months later) and were still present in the post-harvest samples (12/12/2022, a further 4 months later). Note that pre-drilling samples were taken down to 40 cm, and full growth sampling was only conducted to 30 cm. The study author explained that deeper sampling was not possible due to the extremely dry soil conditions. Although understandable given the very dry soil conditions, this does hamper comparison between control and post application samples, especially when detectable residues down to 40 cm were found in the controls and this sampling depth could not be replicated at the later time point. This means that later sampling may not have measured all of the available residue due to the shallower sampling horizon.

The Holbeach site was also notable as the only site where a detectable level of thiamethoxam was found in pollen (in the pre-harvest sample). Note that the field edge soil sample returned a <LOD value and therefore it was not possible to link findings in pollen with detectable levels in the same soil.

Table 6: Monitoring data for Site 5: Bury (clay soil)

Sample Matrix	Sampling occasion	Mean thiamethoxam concentration (mg/kg)	Equivalent thiamethoxam soil loading (g/ha)[a]	Mean clothianidin concentration (mg/kg)	Equivalent clothianidin soil loading (g/ha)[a]
Soil in-field 0-20cm	Pre-drilling	< LOD		>LOD<LOQ (0.0071)	33.9 (sum of layers)
Soil in-field 20-40cm	Pre-drilling	< LOD		>LOD<LOQ (0.0041)	
Soil field-edge 0-20cm	Pre-drilling	< LOD		< LOD	
Soil field edge 20-40cm	Pre-drilling	< LOD		< LOD	
Soil in-field 0-30cm	Full growth	**0.011**	**50.0**	>LOD<LOQ (0.0075)	34.1
Soil field-edge 0-30cm	Full growth	< LOD		< LOD	
Soil in-field 0-30cm	Post-harvest	< LOD		>LOD<LOQ (0.0052)	23.6
Soil field-edge 0-30cm	Post-harvest	< LOD		< LOD	
Vegetation	Full growth	< LOD		< LOD	
Pollen	Full growth	< LOD		< LOD	
Vegetation	Pre-harvest	< LOD		< LOD	
Pollen	Pre-harvest	< LOD		< LOD	

[a]calculated using a soil specific bulk density of 1.514 g/cm^3. Bold values represent quantified residue levels ≥ LOQ.

Thiamethoxam residues were above the LOQ in-field at the full growth sample time (equivalent to 50.0 g/ha). These samples were taken approximately 4 and a half months after the pre-drilling samples and show little decline relative to a maximum application rate of 51.75g thiamethoxam/ha. By the post-harvest sampling time residues had declined to < LOD (noting this was equivalent to 13.6 g/ha or 26% of intended application rate).

Residues of clothianidin were similar between pre-drilling and full growth samples in-field, with some decline by the post-harvest sample time noted (also noting that the differences in soil depths sampled makes it difficult to directly compare sample times).

Table 7: Monitoring data for Site 6: Thorney (clay soil)

Sample Matrix	Sampling occasion	Mean thiamethoxam concentration (mg/kg)	Equivalent thiameth-oxam soil loading (g/ha)[a]	Mean clothianidin concentration (mg/kg)	Equivalent clothi-anidin soil loading (g/ha)[a]
Soil in-field 0-20cm	Pre-drilling	< LOD		**0.040**	**127.7 (sum of layers)**
Soil in-field 20-40cm	Pre-drilling	< LOD		**0.010**	
Soil field-edge 0-20cm	Pre-drilling	< LOD		>LOD<LOQ (0.0077)	19.7
Soil field edge 20-40cm	Pre-drilling	< LOD		< LOD	
Soil in-field 0-30cm	Full growth	< LOD		**0.026**	**99.6**
Soil field-edge 0-30cm	Full growth	< LOD		>LOD<LOQ (0.0064)	24.5
Soil in-field 0-30cm	Post-harvest	**0.017**	**65.1**	**0.026**	**99.6**
Soil field-edge 0-30cm	Post-harvest	< LOD		>LOD<LOQ (0.0084)	32.2
Vegetation	Full growth	< LOD		< LOD	
Pollen	Full growth	< LOD		< LOD	
Vegetation	Pre-harvest	< LOD		< LOD	
Pollen	Pre-harvest	< LOD		< LOD	

[a]calculated using a soil specific bulk density of 1.277 g/cm^3. Bold values represent quantified residue levels ≥ LOQ.

Thiamethoxam residues were below the LOD in all pre-drilling and full growth samples. However quantifiable residues were found in the post-harvest samples (taken 12/12/2022), and the equivalent level (65.1 g/ha) was noted to be higher than the intended application rate of 51.75 g/ha. Similar to site 3, this is difficult to explain but could reflect variability in the field, or sampling an area containing a high number of seed casings or ungerminated treated seeds, or increased persistence of thiamethoxam. Continued sampling at the site may be beneficial to better understand long term residue behaviour.

In contrast, clothianidin soil residues were very high at this site at all sampling times – up to 127.7 g/ha in pre-drilling (control) samples in field, and 19.7 g/ha in field edge control samples. No use of clothianidin containing products was shown in the pesticide use history spanning the previous 5 years at this site. Similar levels were observed at both the full growth and post-harvest sampling stage, noting that residues pre and post application are difficult to compare directly due to differences in horizon depths. When authorised as a seed treatment, rates of clothianidin typically ranged from 78-100 g/ha, so the background levels of clothianidin at this site were comparable to levels expected from previously authorised uses.

Note that such high background levels of clothianidin have not been accounted for in the current standard regulatory risk assessment.

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY
Name of authority Health and Safety Executive.
Summary of Monitoring data on soil, vegetation and pollen residues Update to December 2022 ECP As previously noted, there were significant limitations in the analytical method in terms of LOQ and LOD. Numerical values have been reported between the LOD and LOQ, but since these are below the validated limit of quantification, these should be treated with caution. HSE recommends that any future monitoring work use an analytical method with significantly (i.e. 10x) lower quantification and detection limits. Residues in soil in field edge areas were generally below the LOD (noting that the LOD is equivalent to approximately 25% of the maximum application rate allowed for 'Cruiser SB' under the emergency authorisation). Therefore, in the majority of field edge samples, all that can be concluded is that residues were less than 25% of the maximum initial in-field rate. Significant migration into field margins following application of a pelleted seed treatment would not be expected. Therefore the sensitivity of the methodology used has limited the usefulness of this part of the monitoring program when put into the context of the emergency in-field use. Thiamethoxam was never detected in field edge areas. Where detectable residues of clothianidin were found in field edge areas (at sites 4 and 6), these were always also found in the pre-drilling (control) samples at similar levels. It was therefore difficult to link detections in field edge areas to recent usage of Cruiser SB. These data are of limited use in informing on the potential exposure in field edge areas in the opinion of HSE. The analytical method should be further developed and validated with a lower LOQ to enable better use of future reported values. As expected, in-field soil residues were higher. Data were available for two sample times post application, at full growth stage generally sampled between 4 to 5 months after drilling and then post-harvest, generally sampled after at least a further 4 months. For thiamethoxam, the limited data only allows qualitative estimates of thiamethoxam persistence across these sites and cannot be used to refine the standard regulatory field dissipation data. Residues at the Bilsthorpe site (site 1) were potentially indicative of a DT_{50} in the range of 150 d. Note that the HSE regulatory exposure assessment for soil used a worst case DT_{50} of 172 d, so behaviour at this one site was broadly in line with the assumptions used in the regulatory assessment. Thiamethoxam residues quantified at the Attleborough site (site 2) were in excess of the maximum application of 51.75g a.s./ha - quantified at 78.8 g/ha 3 months after drilling. At the Bury site (site 5), thiamethoxam residues equivalent to 50.0 g/ha approximately 4 and a half months after drilling showed little decline from the assumed maximum application rate of 51.75 g/ha. At both these sites residues had declined to < LOD in post-harvest sampling taken 4 to 5 months later (noting that residues below the LOD could still be up to 25% of the initial applied amount). At the Weybourne (site 3) and Thorney (site 6) sites the maximum thiamethoxam concentrations were not detected until the final post-harvest samples (and at the Thorney site the thiamethoxam concentration post-harvest of 65.1 g/ha 9 months after drilling was higher than the initial intended application rate). Behaviour at these four sites (sites 2, 3, 5 and 6) are difficult to explain but could reflect variability in the field and the difficulties sampling fields with treated seeds, for example as a result of sampling an area containing a high number of seed casings or ungerminated treated seeds. The behaviour of thiamethoxam at the sites where levels were detected above expected concentrations, or levels peaking in post-harvest samples 9 to 12 month post drilling are not consistent with the assumptions used in the regulatory exposure assessment and may also be evidence of greater persistence in the field sites than has been used in the current regulatory risk assessment. The Holbeach site (site 4) was the only

site to record detectable residues of thiamethoxam in the pre-drilling (control) samples, at levels equivalent to 22.8 g/ha. No thiamethoxam based products had been applied at any site within the last 5 years. Residues of thiamethoxam at this site were noted to remain relatively stable in full growth and post-harvest samples. Continued sampling at all these sites may be beneficial to better understand long term residue behaviour and to determine whether this is evidence of adverse behaviour that should be accounted for in updated regulatory assessments in the future.

Although detailed site specific climate data was not available, it is known that 2022 was one of the driest and hottest on record, particularly in the sugar beet growing regions. The very dry soil conditions in particular could have significantly reduced degradation over the summer months and behaviour at these sites may not be typical of behaviour in average years.

With regards clothianidin, it was also notable that detectable concentrations were found at 5 out of 6 sites. Clothianidin residues were particularly high at the Thorney site (site 6) equivalent to 127.7 g/ha in field and 19.7 g/ha in field edge areas in pre-drilling samples even though no clothianidin containing products had been applied at this site in the previous 5 years. Levels at this site remained high throughout the full growth and post-harvest sampling. The levels at this site were equivalent to the levels that would have been expected following previously authorised uses of clothianidin containing products. Clothianidin residues equivalent to 33.9 and 46.7 g/ha were also detected in the Bury (site 5) and Holbeach (site 4) pre-drilling in field samples and again persisted into the post-harvest samples. The detections in pre-drilling samples makes it difficult to attribute clothianidin levels to the use of ''Cruiser SB' treated seed. From the pesticide histories provided, it was determined that Sites 1 and 5 applied products containing clothianidin in 2018 and 2017, respectively, but no other test sites used clothianidin based products in the preceding 5 years. Standard regulatory field dissipation studies indicate clothianidin persistence is variable but potentially long in some soils (DT_{50}s ranging from 13.3 to 305 d and DT_{90}s between 44.2 to 1018 d) and therefore low level background detections would be expected in sites showing the highest persistence with previous historical use of clothianidin containing products.

Residues in vegetation or pollen were also below the LOD (0.003 mg/kg or 3 µg/kg for each substance) in all samples except a single detection of thiamethoxam in the pollen taken pre-harvest from the Holbeach site (4.88 µg thiamethoxam/kg). To put this limit into context, Pilling et al (2013) reported the following findings as part of a four-year program investigating long-term effects of repeat exposure of honey bee colonies in flowering crops treated with thiamethoxam:-

Median residues of thiamethoxam in pollen collected from honey bees after foraging on flowering seed treated maize were found to be between 1 and 7 µg/kg, median residues of the metabolite CGA322704 (clothianidin) in the pollen were between 1 and 4 µg/kg. In oilseed rape, median residues of thiamethoxam found in pollen collected from bees were between <1 and 3.5 µg/kg. Median residues of CGA322704 in pollen in the oilseed rape trials were all below the limit of quantification (1 µg/kg).

Although it is good that positive detections above the LOD were not found in any of the edge of field vegetation or the majority pollen samples, based on a brief review of pollen data from crops treated with thiamethoxam, all that can be concluded is that residues here are less than levels previously found in pollen of directly treated crops. Since significant migration of residues into field margins following application of a pelleted seed treatment would not be expected, the vegetation and majority of pollen findings below LOD levels are largely as expected. The data therefore adds little to our understanding of this exposure route via field margin flowering plants in the opinion of HSE.

Putting this monitoring work into the context of acceptable values regarding environmental exposure is difficult in the absence of a clear understanding of either soil or pollen residue levels that would give rise to unacceptable sublethal effects in bees. Without a clearly defined residue level that would result in acceptable (or unacceptable) effects, it is difficult to see how these data could be used directly in the current regulatory assessment. However HSE considers it important to at least highlight that the current sensitivity of the methodology being used is a major shortcoming, in that the analysis is not really interrogating the soil or pollen levels to an extent that will support future decision making or provide reassurance on environmental levels in practice. In general the analytical method should be further developed and validated with a lower LOQ to enable use of reported values.

Due to the limited data available (and limitations of the analytical methods) HSE does not consider it appropriate to utilise any of these results in a revised environmental exposure assessment at this stage. However the in-field residues of thiamethoxam at Attleborough (78.8 g/ha) were noted to be in excess of the rate that was used in the regulatory risk assessment. At other sites (Bury, Weybourne and Thorney) there was some evidence of thiamethoxam persistence potentially in excess of the rate used in the regulatory risk assessment, for example where peak detections occurred in the post-harvest samples at two of these sites (accepting that this could be linked to the very dry soil conditions experienced this year, or simply due to greater variability in sampling fields receiving seed treatments). More generally it should be noted that the regulatory risk assessment does not take account of background residues of clothianidin or thiamethoxam, but only considers the contribution from application of 'Cruiser SB' treated seeds in the year of application. Significant findings of clothianidin (up to a maximum of 127.7 g/ha in the Thorney site comparable to levels expected when clothianidin was authorised) were found in the pre-drilling control samples and detectable levels were found in 5 out of 6 sites. This has not be accounted for in the current risk assessment and is not part of standard regulatory assessments.

Overall HSE proposes that monitoring be continued at these sites, utilising a more sensitive analytical method to aid better understanding of the long term behaviour of both thiamethoxam and clothianidin following use of Cruiser SB.

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY
Name of authority Health and Safety Executive.
For the proposed use in 2025, new data following the continuation of soil, vegetation and pollen monitoring of sites treated in Spring 2022 has been provided. This continuation monitoring used an analytical method with a more sensitive LOQ of 0.001 mg/kg and LOD of 0.0003 mg/kg for both thiamethoxam and clothianidin in soil and vegetation (0.005 mg/kg LOQ and 0.0015 mg/kg LOD in pollen). A summary based on the submitted report is provided below. Although the change in analytical method makes it challenging to interpret the results from across the two studies the results here should be read in conjunction with the results reported above. **Report title:** Stage 2 monitoring programme for thiamethoxam and clothianidin residues in soil and non-crop vegetation in relation to the application of ''Cruiser SB' treated seeds in sugar beet fields in 2022. Summary Report **Report authors:** [redacted] **CEA Report Number:** CEA.2515

CEA Project Number: 1060953
Final report completion date: 31 May 2024

A monitoring programme was implemented in 2022, where soil and non-crop vegetation samples were taken to see if thiamethoxam (TMX) and clothianidin were detectable prior to (pre-drilling), during (within growth season), and following (post-harvest), the use of 'Cruiser SB' treated seeds for the sugar beet crop cultivation season (CEA Report CEA.2457, project 1060849). This monitoring programme is here termed 'Stage 1' and was sponsored by the British Beet Research Organisation (BBRO). The Stage 1 study identified the need for further monitoring of these sites, at lower levels of detection, to ascertain accurate residue data for both TMX and clothianidin, over a longer period.

Following this, Defra sponsored the continuation of this monitoring programme through 2023 and early 2024, which is here termed 'Stage 2'. Stage 2 followed the same method as Stage 1, on the same fields, but with some improvements. The analytical methodology used in stage 1 employed a limit of quantification (LOQ) of 0.01 mg/kg whereas the continued monitoring programme employed a more sensitive LOQ of 0.001 mg/kg, to provide a more accurate determination of TMX and clothianidin in soil, vegetation, and pollen samples. Assuming a bulk density of 1.5 g/cm^3 and a typical sampling depth of 30cm, the analytical method used in 2022 was able to quantify residues equivalent to an application rate of 45 g/ha (LOQ) and detect residues equivalent to an application rate of 13.5 g/ha (LOD) of TMX. Although these levels are below the intended application rate of 51.75 g/ha TMX, they did not allow residues levels equivalent to those predicted at a DT50 to be reliably quantified, or for residues beyond those at a DT90 degradation rate to be detected. The analytical methodology employed in stage 2 of the programme used an LOQ equivalent to 4.5 g/ha and an LOD equivalent to 1.35 g/ha . This improved analytical method allowed greater confidence in residues detected around the DT_{50} and for residues beyond the DT_{90} to be detected.

Five of the six sites monitored in Stage 1 were utilised for the Stage 2 continued monitoring programme. One site was removed due to reassignment as a solar farm. The remaining 5 sites had either spring barley, wheat or maize during the summer season, with mostly short grass in the field in the winter (Site 2 used stubble turnip as a winter crop). Samples were obtained during September 2023 and February 2024 and analysed for TMX and clothianidin. No claim of GLP compliance is made for the sampling procedures detailed in this summary report.

As expected, an increased number of residue detections of thiamethoxam were determined during this monitoring programme as a consequence of the increased analytical sensitivity. Despite this increase in detection, the data for the in-field and field margin soil samples in the Stage 2 programme returned detections of comparable, or lower, concentrations to those determined (though not always quantified) in the Stage 1 programme. A similar trend was found for clothianidin, an increase in the number of detections across in-field and field margin samples at all sites, however the levels were generally comparable to the data obtained in the Stage 1 programme when the increase in analytical sensitivity was considered. It should be noted that these sites did not receive any further applications of ''Cruiser SB' following the original spring 2022 application.

There is an indication from the data in both programmes that the persistence of clothianidin, in particular, may be related to soil type, with the clay soils showing more continued residue detections, and the two sandy sites displaying approximately half of the clothianidin levels compared to the silt and clay fields.

In this programme, only the upper soil layer (0-30 cm) was analysed and, therefore, no inferences regarding any vertical migration can be made. Continued monitoring, including deeper soil layers, will now take place to investigate both persistence and vertical migration potential of these two compounds (project number 1061034).

Results

The recovery of TMX from soil samples obtained from each site is detailed in the table below (Table HSE 2.6-3), and the recovery of clothianidin is given in the further table below (see Table HSE 2.6-4). These tables also include the residue levels determined in the final sampling occasion of the 2022 programme (ie Stage 1 monitoring, and already reported above). All data are presented as the mean of the three bulk samples obtained on each occasion. Only the 0-30 cm soil cores were analysed for TMX or clothianidin.

Table HSE 2.6-3: Levels of thiamethoxam detected in soil cores at each site, including final sampling occasion from previous study.

Site (soil type		Stage 1: 2022 post-harvest (mg/kg [g/ha])	Stage 2: September 2023 (mg/kg [g/ha])	Stage 2: February 2024 (mg/kg [g/ha])
2 (sandy)	In-field	0-30cm: <LOD*	0-30cm: >LOD<LOQ (0.0009) [4.26]	0-30cm: >LOD<LOQ (0.0003) [1.42]
	Field margin	0-30cm: <LOD*	0-30cm: <LOD	0-30cm: **0.0013 [6.15]**
3 (sandy)	In-field	0-30cm: >LOD<LOQ* (0.0086) [45.4]	0-30cm: **0.0028 [14.78]**	0-30cm: **0.0018 [9.5]**
	Field margin	0-30cm: <LOD*	0-30cm: <LOD	0-30cm: >LOD<LOQ (0.0004) [2.11]
4 (silt)	In-field	0-30cm: >LOD<LOQ* (0.0078) [30.0]	0-30cm: **0.0088 [33.87]**	0-30cm: **0.0095 [36.57]**
	Field margin	0-30cm: <LOD*	0-30cm: **0.001 [3.85]**	0-30cm: **0.0024 [9.24]**
5 (clay silt)	In-field	0-30cm: <LOD*	0-30cm: **0.0021 [9.54]**	0-30cm: >LOD<LOQ (0.0007) [3.18]
	Field margin	0-30cm: <LOD*	0-30cm: <LOD	0-30cm: >LOD<LOQ (0.0004) [1.82]
6 (clay)	In-field	0-30cm: **0.017 [65.13]**	0-30cm: **0.0034 [13.03]**	0-30cm: **0.0038 [14.56]**
	Field margin	0-30cm: <LOD*	0-30cm: <LOD	0-30cm: >LOD<LOQ [1.92]

*values from Stage 1 analytical methodology: LOD = 0.003mg/kg and LOQ = 0.01 mg/kg
Bold values represent quantified residue levels >LOQ
LOD = 0.0003 mg/kg. LOQ = 0.001 mg/kg (Stage 2 analytical method)

Table HSE 2.6-4: Levels of Clothianidin detected in soil cores at each site, including final sampling occasion from previous study.

Site (soil type		Stage 1: 2022 post-harvest (mg/kg [g/ha])	Stage 2: September 2023 (mg/kg [g/ha])	Stage 2: February 2024 (mg/kg [g/ha])
2 (sandy)	In-field	0-30cm: <LOD*	0-30cm: **0.0038 [17.97]**	0-30cm: **0.0031 [14.66]**
	Field margin	0-30cm: <LOD*	0-30cm: **0.001 [4.73]**	0-30cm: **0.001 [4.73]**
3 (sandy)	In-field	0-30cm: <LOD*	0-30cm: **0.0027 [14.26]**	0-30cm: **0.0024 [12.67]**
	Field margin	0-30cm: <LOD*	0-30cm: >LOD<LOQ (0.0007) [3.70]	0-30cm: >LOD<LOQ (0.0009) [4.75]
4 (silt)	In-field	0-30cm: >LOD<LOQ* (0.0093) [35.8]	0-30cm: **0.01 [38.49]**	0-30cm: **0.01 [38.49]**
	Field margin	0-30cm: >LOD<LOQ* (0.0045) [17.3]	0-30cm: **0.0049 [18.86]**	0-30cm: **0.0056 [21.55]**
5 (clay silt)	In-field	0-30cm: >LOD<LOQ* (0.0052) [23.6]	0-30cm: **0.0057 [25.89]**	0-30cm: **0.0051 [23.16]**
	Field margin	0-30cm: <LOD*	0-30cm: **0.0014 [6.36]**	0-30cm: **0.0019 [8.63]**
6 (clay)	In-field	0-30cm: **0.026 [99.6]**	0-30cm: **0.028 [107.27]**	0-30cm: **0.022 [84.28]**
	Field margin	0-30cm: >LOD<LOQ* (0.0084) [32.2]	0-30cm: **0.011 [42.14]**	0-30cm: **0.010 [38.31]**

*values from Stage 1 analytical methodology: LOD = 0.003mg/kg and LOQ = 0.01 mg/kg
Bold values represent quantified residue levels >LOQ
LOD = 0.0003 mg/kg. LOQ = 0.001 mg/kg (Stage 2 analytical method)

Both TMX and clothianidin were found at all sites within the in-field soil samples, across both the September 2023 and February 2024 continuation sampling events. TMX was found at quantifiable levels at all sites, except Site 2, within the in-field samples during September 2023. Site 2 had detectable, but unquantifiable, levels of TMX in the in-field samples. TMX residues were lower in the February 2024 sampling event for Sites 2 (unquantifiable), 3 and 5, compared to the September 2023 sampling occasion. At Sites 4 and 6, TMX residues were marginally higher in February 2024 than in September 2023.

Clothianidin residues were detected from all in-field samples, in both September 2023 and February 2024. At each site, the detections of clothianidin in the February 2024 samples were similar or marginally lower than, detections in the September 2023 samples.

For the field margin, all sites, with the exception of Site 4, had no detectable levels of TMX (<LOD) during the September 2023 sampling event. In February 2024, all sites had detectable residues of TMX, although these were only quantifiable residue levels at Sites 2 and 4, marginally above the LOQ.

Clothianidin was found in the field margin at quantifiable levels across all sites, on both occasions, with the exception of Site 3 where levels were detectable, but not quantifiable, on both occasions.

Vegetation

The recovery of TMX and clothianidin from field margin vegetation samples obtained at each site are detailed below (see Table HSE 2.6-5). The Table also includes the residue levels determined in the final sampling occasion of the Stage 1 programme. All samples were determined to be <LOD, for both compounds, with the exception of Site 3, where clothianidin was detected but not at a quantifiable level.

Table HSE 2.6-5: Levels of thiamethoxam and clothianidin detected in field margin vegetation at each site, including final sampling occasion from previous study

Site	Mean measured thiamethoxam (mg/kg)	Mean measured thiamethoxam (mg/kg)	Mean measured clothianidin (mg/kg)	Mean measured clothianidin (mg/kg)
	Stage 1: 2022 Full growth	Stage 2: 2023 pre-harvest	Stage 1: 2022 Full growth	Stage 2: 2023 pre-harvest
2	<LOD*	<LOD	<LOD*	<LOD
3	<LOD*	<LOD	<LOD*	>LOD<LOQ (0.00036)
4	<LOD*	<LOD	<LOD*	<LOD
5	<LOD*	<LOD	<LOD*	<LOD
6	<LOD*	<LOD	<LOD*	<LOD

LOD = 0.0003 mg/kg. LOQ = 0.001 mg/kg.
* Values from Stage 1 analytical methodology: LOD=0.003 mg/kg and LOQ=0.01 mg/kg.

Pollen

The recovery of TMX and clothianidin from pollen, extracted from field margin flower head samples obtained at each site are detailed below (see Table HSE 2.6-6). The Table also includes the residue levels determined in the final sampling occasion of the 2022 programme. Detectable, but not quantifiable, levels were detected at Sites 3, 5 and 6 for clothianidin.

Table HSE 2.6-6: Levels of thiamethoxam and Clothianidin detected in pollen samples from each site, including final sampling occasion from previous study.

Site	Mean measured thiamethoxam (mg/kg)	Mean measured thiamethoxam (mg/kg)	Mean measured clothianidin (mg/kg)	Mean measured clothianidin (mg/kg)
	Stage 1: 2022 Full growth	Stage 2: 2023 pre-harvest	Stage 1: 2022 Full growth	Stage 2: 2023 pre-harvest
2	<LOD*	<LOD	<LOD*	<LOD
3	<LOD*	<LOD	<LOD*	>LOD<LOQ (0.0028)
4	>LOD<LOQ* (0.0049)	<LOD	<LOD*	<LOD
5	<LOD*	<LOD	<LOD*	>LOD<LOQ (0.0037)
6	<LOD*	<LOD	<LOD*	>LOD<LOQ (0.0032)

LOD = 0.0015 mg/kg. LOQ = 0.005 mg/kg.
*Values from Stage 1 analytical methodology: LOD=0.003 mg/kg and LOQ=0.01 mg/kg.

Discussion

The intention of this continued monitoring programme was to ascertain the persistence of TMX and/or clothianidin residues following the use of ''Cruiser SB' treated seed in spring 2022. The increase in sensitivity of the analytical methods employed in this programme, means that a true comparison of the Stage 1 (2022) and Stage 2 (2023 and early 2024) data is difficult, however, inferences can be made between the two studies.

In Stage 1, only Site 4, in-field soil, was determined to have detectable, but unquantifiable, levels of TMX prior to drilling of the ''Cruiser SB' seed. All other sites were below the LOD of the method employed at the time, and therefore, any detections of TMX could be attributed to the use of the seed. At the end of the Stage 1 programme, Sites 3 and 4 had detectable, but unquantifiable, in-field soil levels of TMX, while Site 6 had quantified residues of TMX. There were no detections of TMX in any field margin soil samples at the end of the Stage 1 programme.

In Field soil – thiamethoxam
In this Stage 2 programme, a significantly more sensitive analytical method was employed, meaning that residues were quantifiable to 0.001 mg/kg, a concentration lower than the LOD of the original method (0.003 mg/kg). It was therefore expected that the number of quantified residue detections would increase in this current programme, and the data in the soil tables above reflect this. By the end of stage 2, TMX was detected at all sites, both in-field and in the field margins. There were quantifiable levels of TMX in the in-field samples from Sites 3, 4 and 6. Although at sites 3 and 4 the residues detected at the end of Stage 1 could not be quantified (due to the less sensitive analytical methods) the residues detected at site 3 in were much reduced in stage 2 compared to Stage 1, and could be considered comparable for Site 4. Similarly for Site 6, the quantified residues were much reduced compared those measured at the end of Stage 1 . The TMX residues in field at sites 3, 4 and 6 had still not declined to less than 10% of the initial ''Cruiser SB' application rate by February 2024 (ie the DT90 had not necessarily been reached within approximately 2 years). There was previously concern following the Stage 1 programme that the lack of sensitivity in the analytical methodology did not accurately reflect residue levels less than 50% or 10% of the applied dose i.e. representative of the DT50 or DT90 of the Cruiser SB. Therefore, there was increased uncertainty in understanding persistence, movement and any decline to non-significant levels within the biological matrices. However, there is still the concern of some persistence, particularly for clothianidin in the clay soils and some evidence of TMX persistence across multiple sites. Longer term monitoring may allow predictions of persistence to be made across sites.

Field Margins soil- thiamethoxam
In contrast to Stage 1 , there were detectable levels of TMX found in the field margin samples at all sites, by the end of Stage 2. At Sites 3, 5 and 6 these detections were not quantifiable and were only marginally above the LOD of the current method. Residues of TMX at Sites 2 and 4 were quantifiable, but were at concentrations lower than that of the LOD of the analytical method used in Stage 1. It is, therefore, not possible to infer whether these are true increases in residue detections or just comparable to those that couldn't be detected in the previous year. The absence of a reliable baseline level pre-drilling is unfortunate, noting that the quantifiable residue levels in the field margins at sites 2 and 4 nearly 2 years after drilling represent between 12-18% of the initial ''Cruiser SB' in-field application rate. Movement of residues into the field margins can therefore not be completely ruled out based on the data available.

In field and field margin soil - clothianidin
Clothianidin was monitored here as a metabolite of TMX, but is also the active ingredient in other pesticide products that have been historically approved for outdoor use in the UK, with previous application rates up to 120 g a.s./ha. No detection of clothianidin above this concentration was determined in these data. It was difficult to attribute detections to the use of the ''Cruiser SB' treated seed in 2022, due to detections in the pre-drilling samples at the majority of sites, potentially from historical use of clothianidin containing products. At the end of the Stage 1, no detections of clothianidin were observed in either the in-field or field margin samples at Sites 2 and 3 or in the field margin samples at Site 5. Quantifiable levels of clothianidin were detected for

these sites in Stage 2 however, the levels were at concentrations equal to, or lower than, that of the LOD of the analytical method used in Stage 1. Similarly, all samples for Site 4, in-field samples for Site 5 and field margin samples for Site 6 showed unquantifiable detections in Stage 1, residues using the more sensitive methods employed in Stage 2 were quantifiable; however irrespective of the analytical method used, the results at Stage 1 and Stage 2 were broadly comparable for these sites. Only the in-field samples from Site 6 showed quantified detections of clothianidin at the end of Stage 1, these were also detected at similar concentrations in Stage 2 – suggesting minimal decline between post-harvest sampling in 2022 and February 2024. Although the presence of clothianidin at the sites cannot be directly attributed to the use of the ''Cruiser SB' treated seed in 2022, the Stage 2 data indicates that there is no significant build-up of these residues in the soil, but there is clearly potential for persistence. During 2022, clothianidin was found to be at greater levels in the clay soils and less in the sandy soils. This trend remains the same in the Stage 2 data, where the levels of clothianidin in the sandy soils were at least half the concentration of the residues detected the clay type soils.

Field margin vegetation and pollen – thiamethoxam and clothianidin
For the field margin vegetation and pollen, no quantifiable residues of TMX or clothianidin were found at any of the sites by the end of Stage 2, as was the case in Stage 1 . The increased sensitivity of the analytical method meant that more unquantifiable detections occurred in Stage 2 compared to Stage 1, however these levels were less than, or similar to, the LOD of the original method. These residues detections could be considered comparable, however, further monitoring with the more sensitive analytical methodology would allow for a better assessment of persistence in non-target vegetation. Again, to put this limit into context, Pilling et al (2013) reported the following findings as part of a four-year program investigating long-term effects of repeat exposure of honey bee colonies in flowering crops treated with thiamethoxam:-

Median residues of thiamethoxam in pollen collected from honey bees after foraging on flowering seed treated maize were found to be between 1 and 7 µg/kg, median residues of the metabolite CGA322704 (clothianidin) in the pollen were between 1 and 4 µg/kg. In oilseed rape, median residues of thiamethoxam found in pollen collected from bees were between <1 and 3.5 µg/kg. Median residues of CGA322704 in pollen in the oilseed rape trials were all below the limit of quantification (1 µg/kg).

Although pollen residues were always below the quantifiable limit (0.005 mg/kg/ 5 µg/kg), where they were detected they were detected at levels broadly consistent with the pollen samples collected from bees foraging in flowering treated crops (i.e. 4.9 µg/kg for TMX at site 4, and between 2.8 and 3.7 µg/kg for clothianidin across sites 3, 5 and 6).

Conclusions
An increased number of detections of both TMX and clothianidin were determined during Stage 2. This is as expected due to the much more sensitive analytical methodology. A comparison with the Stage 1 (although often unquantified) data reveals that there is no indication of a significant build-up of either residue in any of the biological compartments. However, there is evidence of persistence of both compounds. It should also be noted that only the top soil layer (0-30 cm) was investigated during this programme, and no inferences about potential vertical migration can be made. Without data from deeper soil layers it is also not possible to confirm that the bulk of residues were captured by this monitoring programme.

Following Stage 1, detections of TMX in the soil samples could be attributed to the use of the 'Cruiser SB' treated seed, as no quantifiable levels were detected prior to drilling. The presence of clothianidin was not directly attributable to the use of the ''Cruiser SB' seed as detectable levels were found during the pre-drilling sampling occasion. However, the significant increase in sensitivity of the analytical methodology employed in the Stage 2 programme could mean that pre-drill detections of TMX may have been possible had this method been employed in Stage 1. The pesticide history provided for each site confirmed that no TMX, or clothianidin, containing products were applied to the fields prior to drilling of 'Cruiser SB' treated seed in 2022, therefore all detections in pre-drilling samples from 2022 should be attributed to historical usage of products containing these active ingredients. The presence of clothianidin in pre-drilling samples in particular is further indication of this substances persistence.

Residue analysis determined that neither TMX or clothianidin could be quantifiably measured in any of the pollen or vegetation samples across either of the stages. Although pollen residues were always below the quantifiable limit, where they were detected, they were detected at levels broadly consistent with pollen samples collected from bees foraging directly in flowering thiamethoxam treated crops (based on information taken from the open literature). As there is currently no regulatory acceptable limit in place for pollen, the risk to bees, and other sensitive species, cannot be definitively assessed.

Further soil monitoring of these sites, where possible, is to take place in 2024, to investigate the persistence of TMX and clothianidin in each biological compartment. This programme will continue to employ the more sensitive analytical methodology used within this Stage 2 programme to enable a better comparison between the latter two years of sampling. In addition, the deeper soil layer will also be analysed to investigate the potential of vertical migration of these compounds.

Monitoring data on soil, non-crop vegetation and pollen residues

Report title: Monitoring programme for Thiamethoxam and Clothianidin residues in soil and non-crop vegetation in relation to the application of Cruiser treated seeds in sugar beet fields: Phase III Summary Report
Report authors: [redacted]
CEA Report Number: CEA.2512
CEA Project Number: 1060953
Final report completion date: 14 May 2024

The objective and conduct of this study were largely identical to that reported above (2.6.3) in the Phase II summary report [redacted]. Six different sites were selected for the monitoring programme, chosen to be representative of the soil types, geographical locations and climatic conditions used to grow sugar beet in the UK. The Level of Quantification (LOQ) was lowered by a factor of 10, compared to the 2022 cultivation season analysis, to enable a more in depth understanding of the presence of thiamethoxam and clothianidin.

Whilst the specific sampling fields differed from those monitored during the original 2022 programme, each site monitored in this current programme was located in the same geographical area, in most cases within the same farm, as those in the 2022 programme. Therefore, some comparison can be made to the data obtained from the 2022 programme. Due to the increase in sensitivity of the analytical methods used in 2023, far more residue detections were found in the 2023 programme soil samples, as would be expected. Unlike in 2022, there were no points during the entire 2023 programme in field and field margin samples, where thiamethoxam was determined to be above the intended application rate of 51.75 g/ha.

There were detections of clothianidin in the majority of in-field pre-drill samples, and comparable levels in the growth season and post-harvest soil samples meaning that it was not possible to directly attribute these detections to the use of the ‘‘Cruiser SB’ treated seed drilled in 2023 . There is an indication that the persistence of clothianidin residues may be related to soil type, with the clay type soils showing more continued residue detections.

Residue analysis determined that neither TMX nor clothianidin could be quantifiably detected in any of the pollen or vegetation samples on any sampling occasion. TMX was only quantifiable in the field margin soil at one site, in the growth season and post-harvest sampling occasions. Clothianidin was detected within four of the six field margins, however, three of these sites (silt and clay soils) also had clothianidin detections in the baseline, pre-drilling, samples.

Validated methods for soil, vegetation, and pollen were employed to determine levels of TMX and clothianidin. The limit of quantification (LOQ) for soil and vegetation analysis was 0.001 mg/kg with the LOQ for pollen set at 0.005 mg/kg. The limit of detection (LOD) was 0.0003 mg/kg for all matrices.

Materials and methods
The methodology used in the Phase III study was largely consistent with the Phase II report reported earlier.

For the soil sampling regime, there were three soil sampling occasions: pre-drilling (baseline), within growth season (GS39), and post-harvest (within 1 month). For all six sites 15 in-field cores and 15 field margin cores were obtained on each sampling occasion. For all 3 soil sampling occasions, 40 cm depth cores (50 mm diameter) were collected and then split into two depths (0-20 and 20-40 cm). At Site 5, on the post-harvest occasion, a 30 cm depth gauge corer sampling approximately a 30 mm diameter soil core was used due to frozen, hard ground. At Site 6, in the pre-drilling sampling occasion, the 30 cm corer was used to obtain the field margin samples due to compacted, hard ground. The 30 cm gauge corer was used in triplicate at each coring position to obtain enough material within the sample replicate. Soil bulk density information used in converting concentrations to g/ha levels is reported below.

Table HSE 2.6-7: Soil bulk density values and conversion for each site

Site (soil type)	Bulk density (g/cm^3)	Conversion calculations
1 (sand)	1.344	**Correction factor** = (soil core depth [cm]) *100 *bulk density value
2 (sand)	1.289	
3 (sand)	1.421	
4 (silt)	1.185	**Measured residue in g/ha** = measured value in mg/kg * correction factor
5 (clay)	1.304	
6 (clay)	1.058	

A pesticide history check showed Site 2 to have used a product containing clothianidin in 2018 but no other flagged pesticides were used on the other sites.

Results

The recovery of TMX from soil samples obtained from each site are detailed in the table below, and the recoveries of clothianidin are given in the further table below (see Tables HSE 2.6-8 and 2.6-9 respectively). All data are presented as the mean of the three bulk samples obtained on each occasion.

Pre-drilling samples were collected in April 2023. Growth season sampling took place in July 2023. Post harvest sampling ranged from 20th November 2023 through to 25th January 2024 dependent on harvest dates at each site.

Table HSE 2.6-8: Levels of thiamethoxam detected in soil cores at each site.

Site (soil type		1: Pre-drilling (mg/kg [g/ha])	2: Growth season (mg/kg [g/ha])	3: Post-harvest (mg/kg [g/ha])
1 (sand)	In-field	0-20cm: <LOD	0-20cm: **0.0022 [5.9]**	0-20cm: **0.0026 [7.0]**
		20-40cm: <LOD	20-40cm: <LOD	20-40cm: >LOD<LOQ
	Field margin	0-20cm: <LOD	0-20cm: <LOD	0-20cm: >LOD<LOQ
		20-40cm: <LOD	20-40cm: <LOD	20-40cm: <LOD
2 (sand)	In-field	0-20cm: <LOD	0-20cm: >LOD<LOQ	0-20cm: **0.0063 [16.2]**
		20-40cm: <LOD	20-40cm: >LOD<LOQ	20-40cm: >LOD<LOQ
	Field margin	0-20cm: <LOD	0-20cm: <LOD	0-20cm: <LOD
		20-40cm: <LOD	20-40cm: <LOD	20-40cm: <LOD
3 (sand)	In-field	0-20cm: >LOD<LOQ	0-20cm: **0.0022 [6.3]**	0-20cm: **0.0018 [5.1]**
		20-40cm: >LOD<LOQ	20-40cm: >LOD<LOQ	20-40cm: **0.0021 [6.0]**
	Field margin	0-20cm: <LOD	0-20cm: <LOD	0-20cm: <LOD
		20-40cm: <LOD	20-40cm: <LOD	20-40cm: <LOD
4 (silt)	In-field	0-20cm: **0.0014 [3.3]**	0-20cm: **0.0033 [7.8]**	0-20cm: **0.0100 [23.7]**

		20-40cm: **0.0011 [2.6]**	20-40cm: **0.0020 [4.7]**	20-40cm: **0.0024 [5.7]**
	Field margin	0-20cm: >LOD<LOQ	0-20cm: **0.0015 [3.6]**	0-20cm: <LOD
		20-40cm: <LOD	20-40cm: >LOD<LOQ	20-40cm: **0.0011 [2.6]**
5 (clay)	In-field	0-20cm: <LOD	0-20cm: **0.0010 [2.6]**	0-30cm: **0.0053 [20.7]**
		20-40cm: <LOD	20-40cm: >LOD<LOQ	
	Field margin	0-20cm: <LOD	0-20cm: <LOD	0-30cm: <LOD
		20-40cm: <LOD	20-40cm: <LOD	
6 (clay)	In-field	0-20cm: **0.0029 [6.1]**	0-20cm: **0.0040 [8.5]**	0-20cm: **0.0110 [23.1]**
		20-40cm: >LOD<LOQ	20-40cm: >LOD<LOQ	20-40cm: **0.0016 [3.4]**
	Field margin	0-30cm: >LOD<LOQ	0-20cm: >LOD<LOQ	0-20cm: >LOD<LOQ
			20-40cm: <LOD	20-40cm: <LOD

LOD= 0.0003mg/kg; LOQ = 0.001 mg/kg

HSE 2.6-9: Levels of clothianidin detected in soil cores at each site.

Site (soil type		**1: Pre-drilling (mg/kg [g/ha])**	**2: Growth season (mg/kg [g/ha])**	**3: Post-harvest (mg/kg [g/ha])**
1 (sand)	In-field	0-20cm: >LOD<LOQ	0-20cm: 0.0010 [2.7]	0-20cm: **0.0016 [4.3]**
		20-40cm: >LOD<LOQ	20-40cm: >LOD<LOQ	20-40cm: **0.0012 [3.2]**
	Field margin	0-20cm: >LOD<LOQ	0-20cm: >LOD<LOQ	0-20cm: >LOD<LOQ
		20-40cm: >LOD<LOQ	20-40cm: >LOD<LOQ	20-40cm: >LOD<LOQ
2 (sand)	In-field	0-20cm: **0.0040 [10.3]**	0-20cm: **0.0039 [10.1]**	0-20cm: **0.0040 [10.3]**
		20-40cm:**0.0044 [11.3]**	20-40cm: **0.0032 [8.2]**	20-40cm: **0.0035 [9.0]**
	Field margin	0-20cm: >LOD<LOQ	0-20cm: **0.0026 [6.7]**	0-20cm: >LOD<LOQ
		20-40cm: >LOD<LOQ	20-40cm: >LOD<LOQ	20-40cm: <LOD
3 (sand)	In-field	0-20cm: **0.0023 [6.5]**	0-20cm: **0.0020 [5.7]**	0-20cm: **0.0025 [7.1]**
		20-40cm: **0.0020 [5.7]**	20-40cm: **0.0017 [4.8]**	20-40cm: **0.0022 [6.3]**
	Field margin	0-20cm: >LOD<LOQ	0-20cm: >LOD<LOQ	0-20cm: >LOD<LOQ
		20-40cm: >LOD<LOQ	20-40cm: <LOD	20-40cm: <LOD
4 (silt)	In-field	0-20cm: **0.0066 [15.6]**	0-20cm: **0.0062 [14.7]**	0-20cm: **0.0086 [20.4]**
		20-40cm: **0.0057 [13.5]**	20-40cm: **0.0041 [9.7]**	20-40cm: **0.0070 [16.6]**
	Field margin	0-20cm: **0.0012 [2.8]**	0-20cm: **0.0022 [5.2]**	0-20cm: >LOD<LOQ

		20-40cm: >LOD<LOQ	20-40cm: >LOD<LOQ	20-40cm: <LOD
5 (clay)	In-field	0-20cm: **0.0092 [24.0]**	0-20cm: **0.0062 [16.2]**	0-30cm: **0.0096 [37.6]**
		20-40cm: **0.0044 [11.5]**	20-40cm: **0.0052 [13.6]**	
	Field margin	0-20cm: **0.0051 [13.2]**	0-20cm: **0.0063 [16.4]**	0-30cm: **0.0033 [12.9]**
		20-40cm: **0.0032 [8.3]**	20-40cm: **0.0042 [11.0]**	
6 (clay)	In-field	0-20cm: **0.0440 [93.1]**	0-20cm: **0.0700 [148.1]**	0-20cm: **0.0510 [107.9]**
		20-40cm: **0.0051 [10.8]**	20-40cm: **0.0086 [18.2]**	20-40cm: **0.0081 [17.1]**
	Field margin	0-30cm: **0.0152 [47.6]**	0-20cm: **0.0237 [50.1]**	0-20cm: **0.0180 [38.1]**
			20-40cm: **0.0055 [11.6]**	20-40cm: **0.0094 [19.9]**

LOD= 0.0003mg/kg; LOQ = 0.001 mg/kg

In field soil - thiamethoxam

The baseline in-field measures of TMX (pre-drilling) were found to be below the LOD for Sites 1, 2 and 5. Residues were detected at Site 3, and in the 20-40 cm samples for Site 6, however, these values were below the LOQ of the method. Quantifiable levels of TMX were found pre-drilling at Site 4 and in the 0-20 cm samples for Site 6 (equivalent to 5.9-6.1 g TMX/ha). During the growth season, quantifiable levels of TMX were found in the 0-20 cm cores at all sites, except Site 2, where residues were detected but not quantifiable. TMX was also detected in the 20-40 cm cores for Site 4 only. All sites had quantifiable levels of TMX in the 0-20 cm cores at the post-harvest occasion, Sites 3, 4 and 6 also had detections in the 20-40 cm layer. Only Sites 4 and 6 had levels of TMX above the previous less sensitive LOQ (0.01 mg/Kg), detected in the post-harvest samples. Residues remained above 10% applied (i.e. TMX had not declined to its DT90) in all sites, and TMX remained above or around 50% applied (i.e. TMX had not reached its DT50) in three sites, 8-10 months after drilling treated seed.

Field margins soil– thiamethoxam

The field margin only had quantifiable levels of TMX in the growth season and post-harvest phases at Site 4 (equivalent to 2.6-3.6g TMX/ha), these detections were below the previous LOQ. No other site had quantifiable levels of TMX during any sampling occasion in the field margins. Whilst this provides some reassurance that transfer from in field to field margin is low, due to the relatively high levels of TMX remaining in field at harvest, it would be sensible to continue to monitor to ensure further transfer does not occur (noting that in the continuation monitoring conducted following the spring 2022 applications, field margin detections were still being found up to 2 years later). In contrast to the previous year, there were no points during the entire programme, including both in field and field margin samples, where TMX was determined to be above the intended application rate of 51.75 g/ha.

In field soil – clothianidin

For in-field sampling, there were quantifiable residues of clothianidin detected in the baseline soil cores of all sites, except Site 1. All sites had quantifiable levels of clothianidin in the growth season and the post-harvest samples. Clothianidin concentrations remained comparable, or reduced, compared to the baseline values except at Sites 4 and 6, where levels had increased compared to the baseline.

Field margins soil – clothianidin

The edge of field cores showed clothianidin in the baseline cores at the non-sandy sites (4, 5, and 6). Quantifiable levels of clothianidin in the growth season were found at Sites 2, 4, 5, and 6. Clothianidin concentrations in the growth season and post-harvest samples remained comparable to the baseline values, or decreased to below the LOQ. Due to most sites containing clothianidin in the baseline samples, the use of ''Cruiser SB' cannot be directly attributed to these concentrations.

The high level of clothianidin detection pre-drilling, and throughout the study is indicative of the high persistence of this substance in soils.

Vegetation
The recoveries of TMX and clothianidin from field margin vegetation samples obtained at each site are detailed below (see Table HSE 2.6-10). Full growth samples were collected in July 2023 and pre-harvest samples were collected from 28th August to 4th October 2023.

Table HSE 2.6-10: Levels of thiamethoxam and clothianidin detected in field margin vegetation at each site.

Site	Mean measured thiamethoxam (mg/kg)	Mean measured thiamethoxam (mg/kg)	Mean measured clothianidin (mg/kg)	Mean measured clothianidin (mg/kg)
	Full growth	Pre-harvest	Full growth	Pre-harvest
1	<LOD	<LOD	<LOD	<LOD
2	<LOD	<LOD	<LOD	>LOD<LOQ
3	<LOD	<LOD	<LOD	>LOD<LOQ
4	>LOD<LOQ	<LOD	<LOD	>LOD<LOQ
5	<LOD	<LOD	>LOD<LOQ	>LOD<LOQ
6	<LOD	<LOD	<LOD	<LOD

LOD= 0.0003mg/kg; LOQ = 0.001 mg/kg

All vegetation samples were determined to be <LOQ for both compounds.

Pollen sample analysis
The recovery of TMX and clothianidin from pollen, extracted from field margin flower head samples obtained at each site are detailed below (see Table HSE 2.6-11). Full growth samples were collected in July 2023 and pre-harvest samples were collected from 28th August to 4th October 2023.

Table HSE 2.6-11: Levels of thiamethoxam and clothianidin detected in pollen samples at each site.

Site	Mean measured thiamethoxam (mg/kg)	Mean measured thiamethoxam (mg/kg)	Mean measured clothianidin (mg/kg)	Mean measured clothianidin (mg/kg)
	Full growth	Pre-harvest	Full growth	Pre-harvest
1	<LOD	<LOD	<LOD	<LOD
2	<LOD	<LOD	<LOD	<LOD
3	<LOD	<LOD	<LOD	<LOD
4	<LOD	<LOD	<LOD	<LOD
5	<LOD	<LOD	<LOD	<LOD
6	<LOD	<LOD	>LOD<LOQ	>LOD<LOQ

LOD = 0.0003mg/Kg. LOQ = 0.005 mg/Kg

The recovery of TMX and clothianidin from pollen, extracted from field margin flower head samples obtained at each site are detailed above. All samples were determined to be <LOD for both compounds, except for a detected, but non-quantifiable, clothianidin residue at Site 6. Although the low detections are somewhat reassuring, it should be noted that concentrations of

clothianidin in pollen collected from bees foraging in treated oil seed rape crops were only around 1 µg/kg, and therefore quantifiable residues above the LOQ of 0.005 mg/kg (5 µg/kg) used here would not be expected anyway.

Discussion

In this programme, the LOQ of the analytical method was reduced to provide more accurate, robust results, compared to the 2022 programme. The previous LOQ was set at the guideline standard 0.01 mg/kg, whereas this season the LOQ was set at 0.001 mg/kg. Therefore, it was expected that an increased number of residue detections would occur within this current programme.

Thiamethoxam
Sites 4 and Site 6 had quantifiable residues in the pre-drilling in-field, soil samples (despite no evidence of TMX applications in the previous 5 years), meaning the subsequent detections of TMX at these two sites during growth and in the post-harvest samples cannot be completely attributed to the use of the ‘‘Cruiser SB' treated seed in 2023. However, at both these sites the post-harvest soil residues were well above the baseline level (and still represented more than 50% of the theoretically applied thiamethoxam via Cruiser in 2023). At all other sites, the pre-drilling baseline for TMX was established to be <LOQ of the method, therefore any subsequent quantifiable residues of TMX within these fields could be attributed to the use of the ‘‘Cruiser SB' treated seed.

Quantifiable levels of TMX in the growth season samples, with the exception of Site 2, were detected primarily in the top, 0-20 cm, layer samples. TMX was detected in the post-harvest in field samples from all sites, with an increased number of detections in the 20-40 cm layer. This could indicate that TMX may infiltrate vertically through the soil over time (or residues may be being redistributed during harvesting activities). Where quantifiable levels of TMX were detected, no sites were calculated to include TMX levels higher than the maximum application rate of 51.75 g/ha. There were only two samples (0-20 cm; Sites 4 and 6) which were above the previous, less sensitive, LOQ, both in the post-harvest sampling. Similarly, TMX was detected at Site 6, post-harvest, during the 2022 programme. All sites had comparable, or increased, residues in comparison to the previous sampling occasion. With the soil DT50 of TMX in the field noted to be variable based on literature and agreed substance endpoints. Continued monitoring of these in-field soils, and potentially the succeeding crops, would be necessary to investigate residues over time at these sites. No discernible correlation between TMX residue detection and soil type is apparent from this data and the pesticide history provided for each test site showed no TMX based products were used within the last 5 years at any of the locations.

No quantifiable residues were found in the field margin at any site on the pre-drilling sampling occasion, thus, establishing a true zero baseline and indicating any subsequent detection of TMX in the field margins could be a direct result of the use of the ‘‘Cruiser SB' treated seed within the field. TMX was only quantifiably detected at Site 4 during the growth season and post-harvest sampling occasions, these detection levels were very marginally above the LOQ of the analytical method. No other site had quantifiable TMX residues in the field margin samples, as was the case in the 2022 programme. Whilst this provides some reassurance that transfer from in field to field margin is low, due to the relatively high levels of TMX remaining in field at harvest, it would be sensible to continue to monitor to ensure further transfer does not occur (noting that in the continuation monitoring conducted following the spring 2022 applications, field margin detections were still being found up to 2 years later). Residues of TMX in the field margin vegetation and pollen samples were always either not detectable or not quantifiable, at any site, throughout this monitoring programme.

Clothianidin
For clothianidin, the residue detections were more widespread and variable than for TMX. In this programme, clothianidin was monitored as it is a metabolite of TMX, however, it is also an active

ingredient in other pesticidal products. As there were baseline detections of clothianidin in the pre-drilling soil samples, these residue detections are harder to attribute directly to the current use of the ‘‘Cruiser SB’ treated seeds. In addition, clothianidin was generally detected at both soil depths, rather than primarily in the top layer, including in the detections in the pre-drilling, baseline samples. From the pesticide histories provided, it was determined that Site 2 applied products containing clothianidin in 2018, no other documentation provided indicates that the other test sites used any clothianidin based products in the preceding 5 years. The data from this monitoring programme indicated that the silt and clay soil types presented with higher clothianidin residues in comparison to the sandy soil sites; a trend that was also suggested by the data obtained in the 2022 programme. This might be explained by the soil DT50 for clothianidin, which has been reported to range from negligible to over 1300 days, with a clay soil type having the longest DT50.

For the in-field samples, from the sandy soil sites, Site 1 did not have any quantifiable levels of clothianidin on the pre-drilling sampling occasion. There were very marginal detections of clothianidin (just above the LOQ) in the growth season and post-harvest samples. This follows a similar trend to the TMX detections at this site, and strongly suggests a direct consequence of the ‘‘Cruiser SB’ seed use. The very low-level detections would not be a major cause for concern in this case.

At Sites 2 and 3, quantifiable residues of clothianidin were detected in the baseline samples, with slightly increased residues detected during the growth season and post-harvest occasions. This was again comparable to the TMX residue data for these sites. Additionally, Site 2 is known to have used a clothianidin based product in 2018, which may explain the increased detection of this analyte in the pre-drilling samples.

At Sites 4, 5, and 6 there were quantifiable levels of clothianidin found, in-field, on all 3 sampling occasions, at both soil depths. The levels of clothianidin varied throughout the growth and post-harvest samplings. Site 4 had a general increase throughout the 3 soil sampling occasions, whilst Site 5 had a reduced level of clothianidin in the growth season which then increased again in the post-harvest season to levels comparable to the pre-drill samples. Site 6 had the greatest levels of clothianidin on all occasions, where levels increased during the growth season and reduced in post-harvest. In this case, all three occasions were above the previous, less sensitive, LOQ (0.01 mg/kg). The presence of clothianidin at these sites could not be explained using the pesticide history. The consistent presence of residues at the 20-40 cm depth also suggests that this may be related to historical clothianidin application, rather than solely as a result of metabolic breakdown of TMX, which was generally found primarily in the upper soil layer samples.
When investigating the field margin soil data, only one quantifiable detection of clothianidin was found at any of the three sandy soil sites (Sites 1, 2 and 3). This was at Site 2, during the growth season, which then reduced to below LOQ in the post-harvest season. Site 2 was known to have used a pesticide containing clothianidin in 2018. This follows a similar trend to the 2022 programme. Quantifiable residues of clothianidin were found in the silt type soil (Site 4) during pre-drilling and growth season but decreased to below LOQ at post-harvest. The clay type soils (Sites 5 and 6) had quantifiable levels of clothianidin on all sampling occasions with a notable increase in the growth season samples, decreasing again in the post-harvest samples. As with TMX, Site 6 had clothianidin levels above the previous, less sensitive, LOQ. This follows the same trend as the 2022 monitoring where silty soils show some clothianidin detection and clay fields appear to retain clothianidin residues through all sampling occasions.

RECOMMENDATIONS from standard regulatory assessment

For soil an acceptable risk can be concluded for the proposed use of ‘Cruiser SB’ on sugar beet, based on reference to assessments supporting substance approval and the considerations of the original Article 53 application in 2018 under Cop no. 201801509. Soil exposure values at 13, 32- and 46-month intervals have been calculated to assist consideration of risks to bees foraging in future flowering crops. Based on the standard regulatory persistence end points, the proposed 46-month restriction between planting a further crop of ‘Cruiser SB’ treated seed is sufficient to exclude the risk of significant accumulation of thiamethoxam residues in soil following repeated use.

For surface water an acceptable risk has not been demonstrated using the first tier RAC for thiamethoxam. For early uses from March 1st, both the level of exceedance within individual scenarios (maximum of 25 out of 30) and the overall weighted level of exceedance (10.26%) is outside levels that would be considered acceptable. For applications from 1st April, although the weighted scenario years exceedance level was within the acceptable threshold level of 10% (7.98%) and thus the acceptable area was greater than 90% (92.02%), the number of exceedances within an individual scenario was still above acceptable thresholds (22 out of 30 years).

Acceptable risks to surface water were demonstrated using a higher tier RAC for thiamethoxam of 5 µg/l. The assessment did not identify any exceedances of the RAC based on individual concentrations of thiamethoxam, the metabolite clothianidin alone or in combination with thiamethoxam. Acceptable risks were shown for both early (March) and late (April) application timings.

For groundwater, an acceptable risk has not been demonstrated due to the toxicologically relevant metabolite NOA459602 exceeding the 0.1 µg/l limit in all four GB relevant FOCUS scenarios. The high leaching risk demonstrated by the modelling is consistent with the levels of leaching observed during lysimeter studies considered during thiamethoxam approval.

2.7 Ecotoxicology

<table>
<tr><td colspan="2">EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY</td></tr>
<tr><td>Name of authority</td><td>Health and Safety Executive

Where the assessment below indicates that the risk is either acceptable or unacceptable, this conclusion is reached within the framework of the standard criteria for a commercial authorisation based on assessment to uniform principles. Article 53 allows a derogation from the standard criteria providing specific tests are met. Therefore, whilst (for example) reference to unacceptable risks in the assessment below may highlight the areas of greatest concern, this is not the test under Article 53 and does not necessarily reflect the conclusions for this emergency authorisation application. The discussion of the overall risks and benefits from the proposed use and assessment against the requirements of Article 53 is presented in “Section 3 Conclusion of Emergency Authorisation”.</td></tr>
<tr><td>Background</td><td>The proposed use of ‘Cruiser SB’ (containing 600 g/L thiamethoxam) is at 75 mL product/100000 seeds as a seed treatment, noting that when sugar beet seed is treated it is in the form of a pelleted seed.

The application rate expressed in terms of active substance is 45 g a.s.[7]/100000 seeds.

The weight of sugar beet seeds is assumed to be 6 g per 100 seeds equivalent to one seed weighing 60 mg.

<table>
<tr><td>Content of a.s. in product (g a.s./L)</td><td>Seed loading (g a.s./100000 seeds)</td><td>Seeds/ha</td><td>Seed loading (mg/kg seed)</td><td>Application Rate (g a.s./ha)</td></tr>
<tr><td>600</td><td>45</td><td>115000</td><td>7500</td><td>51.75</td></tr>
</table>

The following ecotoxicology assessment has used existing agreed endpoints from the Review Report for thiamethoxam (European Commission 2006[8]) and any additional data evaluated for the HSE re registration of this product. In addition, data from subsequent assessments carried out by the EU and in particular EFSA have been considered in the assessment of the risk to bees (see below for further details). Previously evaluated studies have not been re-evaluated for this application; it is possible however that if re-evaluated to modern standards then the endpoints may differ.

Thiamethoxam has a major soil metabolite, known as CGA 322704. This is also the pesticide active substance clothianidin. The risk from this metabolite will also be considered where there is exposure via the soil.</td></tr>
<tr><td>2024 update</td><td>No new information is available to update the risk assessment for 2025.

Additional monitoring data is available for 2022 and this is considered in detail in the Environmental Fate section. The outcome of the monitoring does not change the risk assessment in this section, so is not considered further here.

Below represents the same assessment as presented when considering the application for use in 2024 (assessed in 2023).

Summary of assessment</td></tr>
</table>

[7] a.s. = active substance

[8] European Commission (2006) Review report for the active substance thiamethoxam SANCO/10390/2002 - rev. 2

Risks to non-target organisms from ‘Cruiser SB’ were previously considered by HSE under the Article 53 application for use of this product on sugar beet in 2022, 2023, and 2024 (COP 2021/01344, COP 2022/01221 and COP 2023/00999). No new information regarding toxicity or exposure to non-target organisms have been submitted since these previous evaluations.

These previous assessments provided an update to the original (2005) evaluation which supported the previous commercial use. Updates were restricted to areas where guidance has changed (e.g., birds, mammals and aquatic organisms) or additional data have been provided (e.g., bees). The original evaluation was circulated with the 2020 application for ‘Cruiser SB’, see ECP 4-7 (39/2020), HSE internal reference WIS 001072834).

There have been no changes in noted guidance or agreed toxicity endpoints for thiamethoxam or clothianidin since the evaluation for emergency use in 2023. In light of this, a new assessment of the risks from use of ‘Cruiser SB’ on sugar beet has not been conducted for use in 2025. The previous 2022 (for use in 2023) evaluation is still valid (HSE ref: 002067954). The conclusions from the assessment for use in 2023 are therefore applicable to the application for use in 2025.

Immediately below is brief summary of the 2022 (for use in 2023) conclusions, with further details of each area of the assessment below that.

Birds and mammals – Acute and long-term/reproductive risks to birds and mammals via consumption of treated seed and germinated seedlings have been assessed and are considered to be low.

Aquatic organisms - Risks to aquatic organisms from exposure to thiamethoxam and the metabolite clothianidin via drainflow are considered acceptable. It is noted that exposure above the PNEC under the WFD would be expected in some small, edge of field water bodies.

Bees - The outcome of the risk assessment is summarised in the table below:

Foraging scenario	**Honeybees**				**Other bee species (bumble bees, wild bees)**
	Acute risk to adults	**Chronic risk to adults**	**Sublethal effects on adults**	**Risks to larvae**	
Treated crop	Low risks due to crop being harvested before flowering				
Flowering weeds within treated field	Low risks where weeds are controlled through herbicide use programme				
Flowering weeds in field margins	Low risk indicated	Low risk indicated	Low risk likely but toxicity endpoint is unbound*	Low risk indicated	No assessment performed due to insufficient toxicity data and lack of suitable risk assessment methodology
Adjacent crops	Low risk indicated	Low risk indicated	Low risk likely but toxicity endpoint is unbound*	Low risk indicated	
Succeeding crops	Low risk indicated	Insufficient margin to conclude low risk	Insufficient margin to conclude low risk	Low risk indicated	
Guttation fluid	Low risk indicated	Insufficient margin to conclude low risk for	Insufficient margin to conclude low risk for	Insufficient margin to conclude low risk for	

		succeeding crops	succeeding crops	thiamethoxam and the metabolite clothianidin from succeeding crops	

* There were effects at the lowest concentration tested, hence effectively the endpoint is a 'less than' value

(red)	Exposure higher than toxicity
(orange)	Exposure similar to toxicity
(green)	Exposure an order of magnitude or more lower than toxicity

HSE remains of the view that it has not been clearly established that there will be no unacceptable effects on adult or larval honeybee survival and behaviour after use of the plant protection product in accordance with the proposed conditions of use. It has also not been clearly established that any such effects would not negatively impact the survival, development or productivity of the colony.

Other non-target arthropods – On the basis of the first tier data a potential risk is highlighted. This is considered further using field data; while some initial impact on collembolans is anticipated, recovery of affected populations is expected. On this basis an acceptable risk to non-target arthropods (other than bees) is concluded.

Soil macro-organisms - The acute and long term risks of thiamethoxam and the soil metabolite, clothianidin to earthworms are considered acceptable when used as proposed on sugar beet. The risk of thiamethoxam and clothianidin to other soil organisms involved in organic matter breakdown is also acceptable.

Soil micro-organisms – Comparison of the available laboratory toxicity data with predicted soil concentrations from sugar beet use indicate there are not expected to be any significant effects on soil microbial function when 'Cruiser SB' is applied at label recommended doses to sugar beet.

Terrestrial non-target plants – Given the seed treatment use, exposure of non-target plants to thiamethoxam should be negligible. Additionally, the available efficacy studies indicate low risks to non-target plants.

Effects on terrestrial vertebrates

The guidance in place to assess the risk to birds and mammals has changed since the original evaluation of this product[9], however the toxicity endpoints have not changed. In light of the change in guidance, a new assessment is presented below. However, the original assessment was presented in the document circulated with the 2020 application for 'Cruiser SB' (see ECP 4-7 (39/2020), HSE internal reference WIS 001072834).

The following risk assessment below is based on EFSA (2009)[10] using the EU agreed endpoints (European Commission (2006)[1]).

Toxicity

Toxicity endpoints have been taken from the latest EU review (European Commission (2006)):

[9] Guidance has changed from SANCO 4145/2001 to EFSA (2009)

[10] European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA. EFSA Journal 2009; 7(12):1438. doi:10.2903/j.efsa.2009.1438.

Active	Group	Timescale	Endpoint	Toxicity	Units
thiamethoxam	Birds	Acute	LD50	576	mg/kg bw
		Reproductive	NOEL	29.4	mg/kg bw/d
	Mammals	Acute	LD50	783	mg/kg bw
		Reproductive	NOEL	46	mg/kg bw/d

According to the EFSA bird and mammal guidance document (EFSA (2009)) the risk to birds and mammals from eating treated seed and from eating the seedlings that grow from the treated seed both need to be considered.

For pelleted seeds an assessment for **mammals** eating the seeds is not required (see Step 1 of Section 5.2.1 of EFSA (2009)).

According to Section 5.2.1 of EFSA (2009), "work by Prosser (2001) indicated that some pelleted seeds were not readily taken as a food source by birds. However, the potential for pelleted seeds to be taken as source of grit must also be considered when making a risk assessment for birds", therefore in light of this, an assessment is required following the scheme for birds ingesting granules with / as grit should be used (see Section 5.1 of EFSA (2009)).

Exposure

Exposure to birds and mammals from eating pelleted sugar beet seeds

Mammals

As stated above, an assessment for **mammals** eating the seeds is not required (see Step 1 of Section 5.2.1 of EFSA (2009)).

Birds

As an initial step, EFSA (2009) considers the size of the granule/pelleted seed and in particular whether the granule is small, i.e., has a size between 0.75 and 2 mm or large, i.e., between 2 and 6 mm. The former is taken by small birds (e.g., finches), whilst the latter are taken by larger birds (e.g., partridge and wood pigeon). Sugar beet granules are 3.50 mm – 4.75 mm and according to EFSA (2009), would fit into the large granule category.

The risk assessment considers the daily grit intake for birds and calculates the dose received based on the proportion of granules that will be the treated product based on random selection. This is called the daily grit dose ($DGritD_{acute}$ and $DGritD_{repro}$). The formulae for determining both the acute and long-term/reproductive exposure are presented below.

Acute exposure:

$$DGritD_{acute}\,(\text{large granules})^{64} = 2453 \times \frac{G_{density}}{(71 + G_{density})} \times G_{loading}$$

Long-term/reproductive exposure:

$$DGritD_{repro}\,(\text{for large granules}) = 1306 \times \frac{G_{density}}{(71 + G_{density})} \times G_{loading}$$

With:
$G_{density}$ = number of granules on soil surface (this number should be based on real practice and not on theoretical incorporation efficiencies; see Appendix 21 of EFSA, 2008)
$G_{loading}$ = the amount of the active substance in one granule

TERs are then calculated by dividing the relevant toxicity endpoint (corrected for the body weight of the bird – assumed to be 300g for the large bird) by the DGritD.

The grit density is expressed in number of granules/m^2, which is 11.5 (115000 granules/ha).

The exposure assessments for both products are summarised below:

Product	Active substance	Timescale	$G_{density}$ (granules/m^2)	$G_{loading}$ (mg/granule)	DGritD (mg/kg/bird)
'Cruiser SB'	thiamethoxam	Acute	11.5	0.45	153.76
		Reproductive/long-term			81.9

Exposure to birds and mammals from eating sugar beet seedlings

According to EFSA (2009)[11], the risk assessment scheme for seedlings grown from treated seed considers the following generic focal species:

- Small omnivorous bird (FIR/bw[12] = 0.5)
- Large herbivorous bird (FIR/bw = 0.3)
- Small omnivorous mammal (FIR/bw = 0.24)
- Large herbivorous mammal (FIR/bw = 0.4)

The exposure is calculated using the concentration on the seed and a "dilution factor" of 5 based on the total mass of the seed and seedling being 5 times as high as the original seed.

On the basis of the above assumptions, the exposure estimates for the seedlings grown from treated seed are as follows:

Active substance	**Group**	**Timescale**	**FIR/bw[1]**	**Seed loading (mg/kg)**	**Ftwa[2]**	**DDD[3] (mg/kg bw/d)**
thiamethoxam	Birds	Acute	0.5	7500	-	750
		Reproductive	0.5	7500	0.53	397.5
		Acute	0.3	7500	-	450
		Reproductive	0.3	7500	0.53	238.5
	Mammals	Acute	0.24	7500	-	360
		Reproductive	0.24	7500	0.53	190.8
		Acute	0.4	7500	-	600
		Reproductive	0.4	7500	0.53	318

[1] FIR/bw – food intake rate/body weight
[2] time weighted average factor
[3] daily dietary dose

Risk

Risk to birds and mammals from eating pelleted sugar beet seeds

Mammals

As stated above, an assessment for **mammals** eating the seeds is not required (see Step 1 of Section 5.2.1 of EFSA (2009)).

[11] In addition to EFSA (2009), further details are provided in https://www.hse.gov.uk/pesticides/pesticides-registration/data-requirements-handbook/birds.htm.
[12] FIR/bw = food intake rate/body weight

Birds

The TERs calculated with the agreed toxicity endpoints from EC (2006) and calculated exposure values from EFSA (2009) are shown below:

Product	Active substance	Timescale	DGritD (mg/300 g bird)	Toxicity (mg/300 g bird)	TER	Trigger
‘Cruiser SB’	thiamethoxam	Acute	153.76	172.8	1.12	10
		Reproductive	81.9	8.82	0.11	5

All TERs are below the trigger, so the risk from birds consuming pelleted seeds as grit has **not** been shown to be acceptable.

In order to help put these TERs into context the number of pelleted seeds required to reach the toxicity endpoint (corrected for the body weight of the bird and with the relevant assessment factor of 10 for acute risk and 5 for reproductive risk) has also been calculated. The results are shown below:

Product	Active substance	Timescale	Number of seeds
‘Cruiser SB’	thiamethoxam	Acute	38.4
		Reproductive	3.9

It is noted that the previous UK view has been that birds will not take pelleted seed as a source of food based on Prosser (2001), however it is feasible that they could take them as a source of grit.

No further information has been submitted to refine the risk to birds from the consumption of pelleted sugar beet seed as grit. However, given that the constituency of the pellet, it is considered unlikely that birds will seek pellet seed out as a source of grit.

The overall acute and long-term/reproductive risk to birds from the consumption of pelleted seed is considered to be low based primarily on field data from Prosser (2001).

Risk to birds and mammals from eating sugar beet seedlings

On the basis of the toxicity values from EC (2006) and the worst-case exposure estimates from EFSA (2009) (see above), the following TERs have been determined:

Product	Active substance	Group	Timescale	DDD (mg/kg bw/d)	Toxicity (mg/kg/d)	TER	Trigger
‘Cruiser SB’	thiamethoxam	Birds	Acute	750	576	0.77	10
			Reproductive	397.5	29.4	0.07	5
		Mammals	Acute	360	783	2.18	10
			Reproductive	190.8	46	0.24	5

All TERs are below the trigger, so the risk from birds and mammals consuming seedlings grown from treated seed has not been shown to be acceptable.

Refined risk assessment for birds and mammals from eating sugar beet seedlings

Residue data in sugar beet seedlings was considered in the previous risk assessment of ‘Cruiser SB’ (this previous assessment was circulated with the 2020 application for ‘Cruiser SB’, see ECP 4-7 (39/2020), HSE internal reference WIS 00107283).

Extract from previous evaluation:

> *Residue data are available for sugar beet seedlings (Sole 2004). These have been used to estimate exposure to birds eating germinating seedlings. In this study pelleted sugar beet seeds were treated with the formulation 'Cruiser 70WS' at the rate of 1200 g a.s./100 kg seed. The proposed rate of 'Cruiser SB' is 1579 g a.s./100 kg seed. Due to this difference the Notifier has multiplied the residues by a factor of 1.3.*

A peak concentration of 42.3 mg/kg was used for the acute assessment and a 21-day time weighted average concentration of 6.5 mg/kg was used for the reproductive assessment. This concentration was used for an application rate of 60 g a.s./100000 seeds, which is higher than the proposed rate of 45 g a.s./100000 seeds, so will cover the risk from the proposed use. The resulting TERs are shown below:

Group	Timescale	FIR/bw	C (mg/kg)	DDD (mg/kg bw/d)	Toxicity (mg/kg/d)	TER	Trigger
Birds	Acute	0.5	42.3	21.15	576	27.23	10
	Reproductive	0.5	6.5	3.25	29.4	9.05	5
Mammals	Acute	0.24	42.3	10.152	783	77.13	10
	Reproductive	0.24	6.5	1.56	46	29.49	5

The TERs are above the trigger value, so the risk to birds and mammals from eating seedlings grown from treated seed is acceptable.

Wildlife monitoring

For the first approval of 'Cruiser SB' an assessment under COP 2006/00175 considered by the ACP concluded that authorisation could be issued for the use of 'Cruiser SB' as a seed treatment on sugar beet but required post-approval monitoring studies on birds and mammals. These studies were considered under COP 2008/00049 and consisted of a wildlife study [redacted] primarily considering acute effects on birds) and a wood mouse monitoring study [redacted]. The ACP considered that the wildlife study addressed the requirement for birds, but that further monitoring of wood mice was required. An additional wood mouse study was submitted under COP 2009/01381. This study involved trapping woodmice on 3 consecutive nights before and after drilling. No dead woodmice were found and numbers recaptured in the control and treated plots were similar. This study did not show any adverse effects on woodmice and was considered to address the outstanding data requirement, although it is noted that only short-term effects could be covered in this short monitoring study. It should be noted that this study has not be re-evaluated for this application.

Conclusion for birds and mammals

The risk to birds and mammals from consuming young sugar beet seedlings grown from treated seed is acceptable. The standard risk assessment for the pelleted seeds is based on the consideration for birds consuming grit and this did not show an acceptable risk. However, it is not expected that birds will take pelleted seed as a source of grit on the basis of Prosser (2001) and the above monitoring data. A monitoring study did not identify any adverse, i.e. acute, effects.

Effects on aquatic life

The guidance in place to assess the risk to aquatic life has changed since the original evaluation of this product[13], however the endpoints have not changed. In light of the change in guidance, a new assessment is presented below. However, the original assessment and associated studies are presented in the document circulated with the 2020 application for 'Cruiser SB', see ECP 4-7 (39/2020), HSE internal reference WIS 001072834).

The toxicity endpoints used in the following assessment have been taken from the latest EU review (European Commission (2006)[1]), whilst the risk assessment has been conducted according to the EFSA aquatic guidance document (EFSA (2013)[14]).

For each taxonomic group and timescale, a Regulatory Acceptable Concentration (RAC) has been determined by dividing the lowest toxicity endpoint by the relevant assessment factor. An overall RAC is then determined by identifying the lowest RAC.

Toxicity

<u>Thiamethoxam</u>

The first-tier toxicity endpoints are summarised below:

Group	Timescale	Toxicity (µg/L)	AF	RAC (µg/L)	Overall RAC (µg/L)
Fish	Acute	125000	100	1250	0.14
Fish	Chronic	20000	10	2000	
Invertebrates	Acute	14	100	0.14	
Invertebrates	Chronic	100000	10	10000	
Sediment	Chronic	10	10	1	
Algae	Chronic	81800	10	8180	
Lemna	Chronic	90200	10	9020	

In addition, a mesocosm was submitted and evaluated as part of a previous UK assessment (this previous assessment was circulated with the 2020 application for 'Cruiser SB', see ECP 4-7 (39/2020), HSE internal reference WIS 001072834). The overall NOEC from the study was 10 – 30 µg thiamethoxam/l (the lower value is based on non-significant trends in responses observed and should be considered as conservative).

According to the EFSA (2013), the NOEC from the mesocosm can be used to set at an ecological threshold option-regulatory acceptable concentration (or ETO-RAC). According to EFSA (2013), an assessment of the minimum detectable difference, or MDD, should be carried out to assist in the interpretation of the mesocosm and more importantly derivation of an appropriate endpoint and assessment factor. However, when this study was submitted and evaluated an MDD analysis was not required, and as a result it is not possible to take this into account when setting the Assessment Factor (AF). According to EFSA (2013), when the RAC is set on the basis of a NOEC or class 1 effects, then an AF of 2 can be applied to the RAC. It is considered that the proposed NOEC of 10 µg a.s./L is based on class 1 effects and therefore, the Tier 3 **ETO-RAC is 5 µg a.s./L**. This endpoint covers the toxicity and hence risk to aquatic invertebrates.

(It should be noted that the mesocosm study has not been re-evaluated.)

[13] Changed from SANCO/3268/2001/rev.4 – Guidance Document on Aquatic Ecotoxicology, to EFSA (2013).
[14] EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2013. Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. EFSA Journal 2013;11(7):3290, 268 pp. doi:10.2903/j.efsa.2013.3290.

Clothianidin

Clothianidin is a soil metabolite of thiamethoxam and may, due to drainflow, enter surface water, hence there is a need to assess the risk to aquatic life from this metabolite.

The first-tier toxicity endpoints are summarised below and have been taken from (European Commission (2005)[15]):

Group	Timescale	Toxicity (µg/L)	AF	RAC (µg/L)	Overall RAC (µg/L)
Fish	Acute	104200	100	1042	0.072
Fish	Chronic	20000	10	2000	
Invertebrates	Acute	29[1]	100	0.29	
Invertebrates	Chronic	120	10	12	
Sediment	Chronic	0.72	10	0.072	
Algae	Chronic	55000	10	5500	

[1] Sediment dweller endpoint

In addition, a mesocosm was evaluated for the EU review and an "ecologically acceptable concentration" or EAC of 3.1 µg a.s./l was determined. In order to assess this use to modern standards, it is, as indicated above for thiamethoxam, necessary to determine an ETO-RAC. The NOEC from this mesocosm is 0.986 µg a.s./L (see HSE internal reference WIS 001329815. As, was the case above for thiamethoxam no MDD assessment was carried out, however, it is proposed to apply an assessment factor of 2 to the NOEC as for thiamethoxam. This gives a Tier 3 **ETO-RAC is 0.493 µg a.s./L**. This endpoint covers the toxicity and hence risk to aquatic invertebrates.

(It should be noted that the mesocosm study has not been re-evaluated.)

Exposure

As this product is a seed treatment no consideration of spray drift has been made.

It is feasible that dust drift may occur from a seed treatment, however this is not part of the regulatory assessment, furthermore, as these formulations are pelleted seed that is treated with a film coating, the levels of dust generated at the point of application should be minimal and no consideration of dust drift is required for these formulations. The main route of surface water exposure is via drainflow and this has been assessed using the standard MACRO modelling approach and following published guidance.

The standard regulatory soil scenarios representative of sugar beet growing areas are Hanslope, Brockhurst and Clifton in dry, medium and wet climate scenarios.

An application rate of 51.75 g thiamethoxam/ha has been considered with an earliest sowing date of 1st March and latest sowing date of 1st April being considered in separate assessments.

Risk

Thiamethoxam

[15] Clothianidin SANCO/10533/05-rev. 2 18 January 2005 Review report for the active substance clothianidin Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 27 January 2006 in view of the inclusion of clothianidin in Annex I of Directive 91/414/EEC.

The results from all soil-climate scenarios relevant to the crop are considered, with peak annual PECsw values from 30 years of model simulation data compared against the Regulatory Acceptable Concentration (RAC). The number of years where the RAC is exceeded is determined.

The risk assessment using the **overall RAC of 0.14 µg/L** is summarised below:

The number of years where the RAC is exceeded along with the percentage (in brackets) is presented below. This assessment in this eRR has assumed an application rate of 51.75 g a.s./ha made on **1st March** and as stated above, using first-tier RACs.

Soil	Dry	Medium	Wet	Very wet
Hanslope	18/30 (60.0)	18/30 (60.0)	25/30 (83.3)	25/30 (83.3)
Brockhurst	7/30 (23.3)	12/30 (40.0)	18/30 (60.0)	18/30 (60.0)
Clifton	0/30 (0)	4/30 (13.3)	2/30 (6.7)	2/30 (6.7)

Information on the extent of crop likely to be grown in each soil and climate scenario has been used to weight the individual percentage of exceedance years. Based on this weighting procedure, overall levels of exceedance are calculated as follows: -

RAC exceeded = 10.26%
Undrained = 51.01%
Drained but 'safe' = 38.72%
Total 'safe' = 89.74%
Total = 100%

Based on previous assessments, the risk is considered acceptable if there are no more than 3 years out of 30 exceeding the RAC; this is not the case for the proposed use. In addition, the overall level of weighted scenario years considering the extent of sugar beet grown on each scenario indicates that an unacceptable risk occurs in more than 10% of the cropping area (10.26%). The risk has not been shown to be acceptable using first tier toxicity values.

Presented below is a further assessment which has assumed the same application rate, however a slightly later application date, i.e., **1st April**, the first-tier RAC have also been used.

Soil	Dry	Medium	Wet	Very wet
Hanslope	18/30 (60.0)	14/30 (46.6)	22/30 (73.3)	22/30 (73.3)
Brockhurst	7/30 (23.3)	3/30 (10.0)	10/30 (33.3)	10/30 (33.3)
Clifton	0/30 (0)	0/30 (0)	2/30 (6.7)	2/30 (6.7)

As above, information on the extent of crop likely to be grown in each soil and climate scenario has been used to weight the individual percentage of exceedance years. Based on this weighting procedure, overall levels of exceedance are calculated as follows: -

RAC exceeded = 7.98%
Undrained = 51.01%
Drained but 'safe' = 41.01%
Total 'safe' = 92.02%
Total = 100%

As stated above, the risk is considered acceptable if there are no more than 3 years out of 30 exceeding the RAC; this is not the case in this situation. The risk has not been shown to be acceptable using first tier toxicity values.

Presented below, is an assessment assuming an application rate of 51.75 g a.s./ha made on 1st March and using the **ETO-RAC of 5 µg a.s./L**. As above the number of years where the ETO-RAC has been exceeded, along with the percentage (in brackets) is presented.

Soil	**Dry**	**Medium**	**Wet**	**Very wet**
Hanslope	0/30 (0)	0/30 (0)	0/30 (0)	0/30 (0)
Brockhurst	0/30 (0)	0/30 (0)	0/30 (0)	0/30 (0)
Clifton	0/30 (0)	0/30 (0)	0/30 (0)	0/30 (0)

As above, information on the extent of the crop likely to be grown in each soil and climate scenario is used to weight the individual percentage of exceedance years. Based on this weighting procedure, overall levels of exceedance are calculated as follows: -

RAC exceeded = 0%
Undrained = 51.01%
Drained but 'safe' = 48.99%
Total 'safe' = 100%
Total = 100%

With the ETO-RAC of 5 µg/l for thiamethoxam there are zero exceedances. The maximum predicted concentration was 2.799 µg/l for the Hanslope medium scenario. It should be noted that when using higher tier data, like a mesocosm study, along with higher tier drainflow data, there should be some form of consideration of the exposure profiles. This consideration is required to ensure that the exposure pattern in the effects study is in line, or comparable to, that expected. In this instance, this has not been possible, however given that the highest predicted concentration is just over half the ETO-RAC, consideration of the profiles is not considered essential. Therefore, the risk from thiamethoxam for the use on 1st March is acceptable. Since this is the worst-case exposure scenario the risk is also acceptable for the remainder of the sowing period.

Clothianidin

The number of years where the higher-tier ETO-RAC of 0.493 µg/L is exceeded is presented below along with the percentages (in brackets). This has assumed an application rate of the parent (thiamethoxam) and a timing of 1st March.

Soil	Dry	Medium	Wet	Very wet
Hanslope	0/30 (0)	0/30 (0)	0/30 (0)	0/30 (0)
Brockhurst	0/30 (0)	0/30 (0)	0/30 (0)	0/30 (0)
Clifton	0/30 (0)	0/30 (0)	0/30 (0)	0/30 (0)

As presented above, formation on the extent of crop likely to be grown in each soil and climate scenario has been used to weight the individual percentage of exceedance years. Based on this weighting procedure, overall levels of exceedance are calculated as follows: -

RAC exceeded = 0%
Undrained = 51.01%
Drained but 'safe' = 48.99%
Total 'safe' = 100%
Total = 100%

	With the ETO-RAC for clothianidin RAC of 0.493 µg/l there are zero exceedances. The maximum predicted concentration was 0.118 µg/l for the Hanslope medium scenario, therefore whilst it would have been ideal to consider the profiles (as outlined above) in this instance, it is not considered essential. Therefore, the risk from clothianidin for the use on 1st March is acceptable. <u>Combined risk</u> HSE considered the potential combined exposure arising from residues of both thiamethoxam and clothianidin based on annual peak daily concentrations. In this case there were no exceedances considering thiamethoxam and clothianidin individually, and no exceedances considering combined residues. An acceptable risk has been demonstrated for March applications utilising the higher tier RACs for thiamethoxam and clothianidin. <u>Consideration of the RAC used for thiamethoxam and the Water Framework Directive (WFD) PNEC</u> Two sets of PNECs are available (JRC Technical Report 2018[16]): • PNECs from the 2015 JRC report entitled "Development of the 1st Watch List under the Environmental Quality Standards Directive" by Raquel N. Carvalho, Lidia Ceriani, Alessio Ippolito and Teresa Lettieri. • Updated PNECs, based on the prioritisation exercise and on additional information received from Germany, Switzerland, and Netherlands. The first of these is 0.14 µg/L, which is in line with the first tier RAC used in the above assessment. The second, updated PNEC is lower at 0.042 µg/L, but the basis for this PNEC has not been identified. The RAC used for the higher tier risk assessment is higher than either of the PNECs identified under the WFD. This is due to the availability of a mesocosm study. The guidance for assessing the risk to aquatic organisms in edge of field surface water (EFSA 2013[3]) uses a tiered approach where if additional data are available the first tier RAC can be replaced by a refined RAC using the additional data. It should be noted, however, that neither the mesocosm that assessed the toxicity of thiamethoxam, nor the one on clothianidin, were revisited for this application and hence the original assessment considered during the EU review was used; this latter assessment was prior to the use of EFSA (2013). Based on the first tier drainflow assessment it can be concluded that exposure above the PNEC under the WFD would be expected in some small, edge of field water bodies. **Conclusion** Based on higher tier effects and exposure assessment, the risk to aquatic organisms from the proposed use of 'Cruiser SB' is acceptable, but it is noted exposure above the PNEC under the WFD would be expected in some small, edge of field water bodies.

[16] JRC Technical Reports. Review of the 1st Watch List under the Water Framework Directive and recommendations for the 2nd Watch List. April 2018

Effects on bees	The risk to bees from the use of thiamethoxam has been considered in detail by EFSA (2013a[17], 2015[18] and 2018[19]) and in light of this, the conclusions from these assessments are considered in the following assessment and in particular the most recent evaluation presented in EFSA (2018). EFSA (2018) considered, amongst other uses, the use as a sugar beet seed treatment at a range of rates (including the rate considered in this eRR, i.e. 0.45 mg a.s./seed) and the assessment was carried out using EFSA (2013b[20]). This EFSA assessment has been considered by HSE. However, it should be noted that the guidance (i.e., EFSA (2013b)) used was not noted by the EU when the UK left the EU. In light of this, the information from the latest assessment by EFSA has only been used to inform our assessment in terms of determining exposure values, however HSE has made no consideration of the protection goals and associated trigger values quoted in EFSA (2013b). As summarised in EFSA (2018), the European Commission requested EFSA to provide conclusions concerning an updated risk assessment for bees for the three neonicotinoids (namely clothianidin, imidacloprid and thiamethoxam), taking into account: • the new relevant data collected in the framework of the specific open call for data; • any other new data from studies, research and monitoring activities that are relevant to the uses under consideration; • the EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus spp*. and solitary bees); In order to collect all published scientific literature relevant for the current evaluation, EFSA also considered the data available from a systematic literature review performed in June 2016. **Outcome of EFSA (2018) risk assessment** Presented below are the key conclusions relevant to the proposed use on sugar beet of the review conducted by EFSA (2018). ***Risk via systemic translocation in plants – residues in nectar and pollen*** EFSA (2018), stated: *<u>Treated crop scenario</u>* *A risk assessment for the treated crop scenario was not considered relevant for uses of thiamethoxam on broccoli, Brussel sprout, cauliflower, head cabbage, kale, lettuce, carrot and sugar beet, as these crops are harvested before flowering. As such, a low risk to all bee species was concluded for the treated crop scenario.* *<u>Succeeding crop scenario</u>* *A high risk at the Tier-1 was concluded for all crops and all bee groups.*

[17] European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment for bees for the active substance thiamethoxam. EFSA Journal 2013;11(1):3067. [68 pp.] doi:10.2903/j.efsa.2013.3067.
[18] EFSA (European Food Safety Authority), 2015. Conclusion on the peer review of the pesticide risk assessment for bees for the active substance thiamethoxam considering all uses other than seed treatments and granules. EFSA Journal 2015;13(8):4212, 70 pp. doi:10.2903/j.efsa.2015.4212
[19] EFSA (European Food Safety Authority), 2018. Conclusions on the peer review of the pesticide risk assessment for bees for the active substance thiamethoxam considering the uses as seed treatments and granules. EFSA Journal 2018;16(2):5179, 59 pp. https://doi.org/10.2903/j.efsa.2018.5179
[20] EFSA (European Food Safety Authority), 2013. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera, Bombus* spp. and solitary bees). EFSA Journal 2013;11(7):3295, 268 pp. doi:10.2903/j.efsa.2013.3295

	Risk from contamination of adjacent vegetation via dust drift EFSA (2018), stated: Field margin and adjacent crop scenarios *For the uses on sugar beet (both seeding rates[21]), the risk assessment could not be finalised in (sic) lack of data about chronic toxicity to adults and HPG development (whereas a low risk was indicated for acute toxicity to adults and prolonged toxicity to larvae for all bee groups – for bumblebees and solitary bees only when a deflector is used).* *The available data did not allow performing any refined risk assessment for exposure via dust drift.* ***Risk via consumption of contaminated water*** EFSA (2018), stated: Guttation fluids *A low risk to honey bees was concluded for the uses on sugar beet, in agreement with the evaluation of the confirmatory data for imidacloprid and clothianidin (EFSA, 2016b,c[22]) and confirmed during the expert meeting related to this assessment.* *For all other crops, a low risk to honey bees could not be demonstrated using the screening assessment based on the solubility of thiamethoxam. Nevertheless, lettuce could be sown and transplanted in greenhouses, without ever be placed in the field. When these operations happen in permanent structures, the exposure to any bee species is considered negligible, and a low risk is concluded.* Puddle water *A low risk is concluded to honey bees from residues in puddles for the seed treatment uses under consideration.* Surface water *In the absence of agreed input parameters for FOCUS surface water modelling, no exposure assessment for the representative uses could be performed. Therefore, the risk to honey bees consuming residues in surface water could not be finalised.* ***Risk from foraging flowering weeds in the crop*** It should be noted that according to Table 8 of EFSA (2013b), there is no need to consider the risk to bees foraging weeds in the treated field, consequently this is not covered in EFSA (2018). Despite this, it is feasible that flowering weeds may occur in the crop and that these may pose a risk to foraging honey bees. The Applicant has proposed that a:

[21] The rates considered by EFSA (2018) were 0.45 mg a.s./seed and 0.6 mg a.s./seed, equivalent to 58.5 g a.s./ha and 78 g a.s./ha.

[22] EFSA (European Food Safety Authority), 2016b. Conclusion on the peer review of the pesticide risk assessment for the active substance clothianidin in light of confirmatory data submitted. EFSA Journal 2016;14(11):4606, 34 pp. https://doi.org/10.2903/j.efsa.2016.4606 and EFSA (European Food Safety Authority), 2016c. Conclusion on the peer review of the pesticide risk assessment for the active substance imidacloprid in light of confirmatory data submitted. EFSA Journal 2016;14(11):4607, 39 pp. https://doi.org/10.2903/j.efsa.2016.4607

"Robust herbicide programmes (following guidance from the pest, weed and disease charts published and distributed annually by the BBRO) to be adopted by growers and their agronomists to minimise the number of flowering weeds in treated sugar beet crops and reduce the risk of indirect exposure of pollinators to neonicotinoids."

Whilst it is not standard practice to use weed control as mitigation to protect pollinators from flowering weeds (because the loss of food can cause more harm than the pesticide and because not all farmers successfully control weeds) in the case of Article 53 applications, novel risk mitigation measures can be employed. Therefore, as controlling the presence of flowering weeds in a sugar beet field will reduce the potential risk to honey bees, then the mitigation measure proposed in the stewardship scheme is considered to be appropriate.

Toxicity data

According to EFSA (2018), the key toxicity endpoints are presented below:

Risk assessment type	Endpoint	Honeybee	Bumble bee	Solitary bee
Acute contact	LD_{50} (μg a.s./bee)	0.0121	0.0275	0.00121[(a)]
Acute oral	LD_{50} (μg a.s./bee)	0.005	0.005	0.0005[(a)]
Chronic oral	10-day LDD_{50} (μg a.s./bee/day)	No endpoint available	No endpoint available	No endpoint available
Larval	NOEL (μg a.s./larva/ developmental period)	0.0217	0.00217[(a)]	0.00217[(a)]
HPG	NOEC (μg a.s./bee)	No endpoint available	Not applicable	Not applicable

NOEL: no observed effect level; NOEC: no observed effect concentration.
Note. From the previously EU agreed endpoints, only the acute contact endpoint and the larvae endpoint for honeybees bees were changed
(a): Extrapolated from the endpoint for honeybee by using a factor of 10.

The following assessment will only cover the risk to honey bees; however, it should be noted that EFSA (2018) did not conclude an acceptable risk to either bumble bees or solitary bees from the use on sugar beet seed.

Previous assessments of thiamethoxam, both at the EU and UK level, have considered other toxicity endpoints, for example, in 2020, HSE considered the chronic endpoint of >0.2 ng a.s./bee/day as presented in EFSA (2013a).

In the EU review of the active substance thiamethoxam the available studies investigating chronic effects of thiamethoxam on adult honeybees were not considered suitable for use in the risk assessment. A new adult chronic honeybee toxicity study with thiamethoxam has now been submitted [redacted] to address this point. In the following sections the reliability of the [redacted] study is assessed by HSE, and the key study findings are summarised in a new section following the risk assessment. Results from this study are then considered in comparison to the other available data on chronic toxicity of thiamethoxam to adult honeybees. The impact of the new data on the previous honeybee risk assessment performed by HSE for emergency use of 'Cruiser SB' on sugar beet is then assessed. Initial monitoring summary results on residues of thiamethoxam and clothianidin in whole plants and pollen are also now available and are discussed (though the reliability of these data is still to be confirmed). Additionally, data on residues of thiamethoxam and clothianidin in honey samples from 2020 are now available and can be included.

New data were submitted in 2022 to supplement the chronic toxicity data available for the EU review. The study summary (included in the 2022 emergency application) has been included in a

	separate section below with summaries of all bee data submitted since the last EU review and last full product assessment. Results from the new study [redacted] are summarised below: the key endpoints (including 95% confidence limits) for consideration in the risk assessment are as follows: • LDD_{50} **3.816** ng a.s./bee/day (3.416 – 4.263); • LDD_{10} **2.553** ng a.s./bee/day (2.139 – 3.048); • LOEED **3.733** ng a.s./bee/day; • NOEED **2.055** ng a.s./bee/day; • LC_{50} **0.1525** mg a.s./kg (0.1343 – 0.1732); • LC_{10} **0.1039** mg a.s./kg (0.08586 – 0.1257); • LOEC **0.131** mg a.s./kg; • NOEC **0.0660** mg a.s./kg. **Residue data** A new study of residues in following crops was submitted for a previous application (HSE internal ref: COP202001677). This study was evaluated for that application; however, the evaluation is presented in the new study summary section following this section for information. **Available guidance** The current guidance document being applied is SANCO/10329/2002[23]. The guidance includes a comment on the data required under Directive 91/414/EEC, i.e., acute oral and contact studies, bee brood study, aged residue test and higher tier studies. As regards assessing the risk, reference is made to the “Hazard Quotient (HQ) approach” for products applied as sprays, whilst for products applied to the soil, like seed treatments, note is made that the acute oral toxicity of the active substance has to be determined and that “if potential risks to honey bees are identified (i.e. very low LD50) realistic exposure conditions should be taken into account, i.e. realistic exposure concentrations as expected in nectar and pollen as indicated by residue studies. If a risk is indicated, higher tier studies (cage/tent/tunnel or field studies) with realistic exposure scenarios should be performed.” In addition, it states that “for systemic plant protection products, exposure considerations and calculations should be based on the a.s. (or metabolite) present in the respective plant parts (e.g., nectar, pollen) to which honey bees could be exposed. However, it should be noted that estimates of these concentrations are rarely available.” Exposure in higher tier studies is already considered within the experimental design (e.g., honey bees foraging on treated field crops).” There is no consideration of protection goals in this guidance document and the only reference is to a first-tier decision making criterion or “HQ” of 50 for applications made by spray. As regard higher tier risk assessment for bees, reference is made to there being no clearly defined endpoints and that “a degree of expert judgement is required to interpret both semi-field and field study results”. It should be noted that the above risk is only assessed for the cropped area.

[23] SANCO/10329/2002[23] rev 2 final 17 October 2002 DRAFT Working Document Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC

	It should further be noted that there is a mismatch between the data that are required under 1107/2009 and the above guidance. According to Regulation 283/2013 and 284/2013 data are required on the toxicity of an active substance and product to various life stages of bee. The data that are required are: 1. acute oral and acute contact to bees 2. chronic toxicity to bees 3. effects on honey bee development and other honey bee life stages 4. sub-lethal effects to bees 5. cage/tunnel test 6. field studies Data on points 1-4 are required for the active substances and possibly the formulation as well; points 5 and 6 are related to the formulation and are dependent upon risks being highlighted with the first-tier data, i.e., points 1 to 4. Associated with 283/2013 and 284/2013 are "Commission Communications" which specify the test methods and the associated guidance[24, 25]. In light of the above, and in particular the lack of agreed/noted relevant guidance especially with regard to the assessment of chronic risk to adult bees and to larvae, use has been made of the assessment presented in EFSA (2018), noting that this is based on an un-noted guidance document (i.e., EFSA (2013b)). **An additional guidance document for bees has since been published by EFSA (2023)[26]. This document has not been noted in the EU or considered in detail for potential use in GB. Therefore, the risk assessment has not been updated according to this guidance.** **First-tier exposure assessment** Presented below is an exposure assessment based on EFSA (2013b), in the first instance the exposure from contact is considered, followed by estimates of oral exposure. **Contact exposure assessment for sugar beet seed** EFSA (2018) concluded that the acute risk to honey bees from **dust drift** was acceptable with or without a deflector for both the rate of 58.5 and 78 g a.s./ha. The proposed application rate, assuming sowing density of 115000 seeds/ha and a seed loading of 7500 g a.s./kg seed, is equivalent to 51.75 g a.s./ha. This rate is less than that considered by EFSA. No data have been submitted on the likely levels of dust for 'Cruiser SB'; however, the EFSA assessment assumed default worst-case first-tier assumptions of deposition rates of 0.003 and 0.03 (see Table H1b of EFSA (2013b)). If it is assumed that dust from 'Cruiser SB' will not be

[24] Commission Communication in the framework of the implementation of Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (1) (2013/C 95/01)

[25] Commission communication in the framework of the implementation of Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (1) (2013/C 95/02)

[26] EFSA (European Food Safety Authority), Adriaanse P, Arce A, Focks A, Ingels B, J ¨ olli D, Lambin S, Rundl¨of M, S¨ußenbach D, Del Aguila M, Ercolano V, Ferilli F, Ippolito A, Szentes Cs, Neri FM, Padovani L, Rortais A, Wassenberg J and Auteri D, 2023. Revised guidance on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees). EFSA Journal 2023;21(5):7989, 133 pp. https://doi.org/10.2903/j.efsa.2023.7989

greater than the default values used, then assuming an application rate of 51.75 g a.s./ha will give exposure values of 0.0155 g a.s./ha and 0.00155 g a.s./ha. The acute contact toxicity value as presented above is 0.0121 µg a.s./bee, and the resulting hazard quotient is 0.13 and 1.3 for use with and without a deflector respectively. As stated above, the decision-making criteria related to hazard quotient is a trigger value of 50, however this was developed with respect to applications made via a spray and not solid formulations like seed treatments.

EFSA (2013b) did specify protection goals along with associated trigger values, however these protection goals and the associated trigger values have not been agreed.

Whilst, noting that the trigger value has not been agreed, Appendix L of EFSA (2013b) argues that it may be feasible to read across the concept of the hazard quotient, if this is accepted, then as the above hazard quotient is less than the uniform principles trigger value of 50, then the risk can be considered to be acceptable.

Oral exposure assessment resulting from use on sugar beet seed

EFSA (2018) stated that for the risk to honey bees **via systemic translocation into crop plants** was not assessed for the treated crop scenario as it was not deemed relevant as the crops were harvested before flowering. HSE agrees with this conclusion.

As regards the risk to honey bees from foraging on **flowering plants in the field margin**, **adjacent crops** and **succeeding crops**, EFSA (2018) assessed the acute oral route for adult bees as well as the risk to larvae, however due to the lack of data on the chronic toxicity to adult bees, no assessment was undertaken.

As stated above, due to the lack of agreed guidance, it is proposed to use elements of EFSA (2013b) to determine the likely exposure values and then compare them to the acute adult oral and contact toxicity endpoints as well as the larval endpoints and determine the likely margin of safety.

If the same approach regarding determining the likely exposure values for adult and larvae is taken here as in EFSA (2013b) and EFSA (2018), then the exposure values are as presented below.

Acute oral – honey bee

According to EFSA (2013b), the formula for the exposure component for both adult and larva is:

AR * Ef * SV

where

AR = Application Rate
Ef = Exposure factor
SV = Shortcut Value

Information on the default worst-case values is provided in EFSA (2013b) and are presented below for the key areas of the assessment, i.e., flowering plants in the field margin, adjacent crops and succeeding crops

According to Table X1b of EFSA (2013b), Exposure factors (Ef) are as follows:

Plants at the field margin

Sugar beet with deflector = 0.00003

	Sugar beet without a deflector = 0.0003 **Adjacent crop** Sugar beet with deflector = 0.0000115 Sugar beet without a deflector = 0.00015 **Shortcut values** Shortcut values for the **treated crop** and **succeeding crop** are presented in Table Jxx of EFSA (2013b) and are as follows: Honey bee forager acute = 0.70 (NB this is for succeeding crops) Honey bee forager acute = 3.7 (NB this is for plants in the field margin) Honey bee larva = 0.40 (NB this is for succeeding crops) Honey bee larva = 2.2 (NB this is for plants in the field margin) As regards the shortcut value for **adjacent crops**, this is presented in Table Jyy of EFSA (2013b) and are as follows: Honey bee forager – crop attractive for pollen and nectar = 7.6 Honey bee larva – crop attractive for pollen and nectar = 4.4 Presented below are the exposure estimates for the scenarios of honey bee adult forager in field margin, adjacent crop and succeeding crop as well the honey bee larva in the field margin, adjacent crop and succeeding crop.

Scenario	AR kg a.s.ha	Ef	SV	Exposure estimate (µg a.s./bee/day)
		Adult		
Succeeding crops	0.05175	-	0.70	0.036225
Field margin – with a deflector		0.00003	3.7	0.000006
Field margin – without a deflector		0.0003	3.7	0.000057
Adjacent crops – with a deflector		0.000015	7.6	0.000006
Adjacent crops – without a deflector		0.00015	7.6	0.000059
		Larvae		
Succeeding crops		-	0.4	0.020700
Field margin – with a deflector		0.00003	2.2	0.000003
Field margin – without a deflector		0.0003	2.2	0.000034
Adjacent crops – with a deflector		0.000015	4.4	0.000003
Adjacent crops – with a deflector		0.00015	4.4	0.000034

Refined exposure assessment for succeeding crops

As stated above, whilst there is not agreed guidance available to determine the risk to honey bees from foraging on succeeding crops, the method used by EFSA to determine the exposure can be

	used to convert the residues in pollen and nectar into dietary doses, which can be compared to the toxicity data to give an indication of risk. Presented below is information from EFSA (2013b), which outlines how a residue value in pollen or nectar can be converted into a daily dose. As the effect endpoints are expressed as daily doses, it is then possible to compare one with the other, in much the same way as was done for the first-tier assessment above. Information from Appendix N of EFSA (2013b) states that the following equations were used to calculate the residue intakes for forager and nurse bees: $$RI_{forager} = \frac{Rn \times Cn}{1000}$$ $$RI_{nurse} = \frac{(Rn \times Cn) + (Rp \times Cp)}{1000}$$ Where: $RI_{forager}$ is the residue intake by a forager bee expressed in µg a.s./bee/day RI_{nurse} is the residue intake by a nurse bee expressed in µg a.s./bee/day *Rn* is the residue level in nectar in mg a.s./kg *Rp* is the residue level in pollen in mg a.s./kg *Cn* is the consumption of nectar in mg (mg/bee/day) *Cp* is the consumption of pollen in mg (mg/bee/day) According to Table J6 of Appendix L of EFSA (2013b), the amount of sugar consumed by bees is assumed to be: 80-120 mg sugar/day for a forager (acute) 32 - 128 mg sugar/day for a forager bee (chronic) 34 - 50 mg sugar/day and 6.5 - 12 mg pollen/day for a nurse bee 59.4 mg sugar/day for larvae The sugar content of oilseed nectar is assumed by EFSA (2013b) to be 15% as a realistic worst case. As regards the exposure estimate for larvae, details were taken from Table J6 in Appendix L of EFSA (2013b), where it is indicated that larva consume 2 mg/larvae pollen, and 59.4 mg sugar /larvae and that the sugar content of nectar is 15%. The residue values in pollen and nectar in the succeeding crop study (see Peterek (2020) evaluated above for details) for oilseed rape are: Oilseed rape pollen <0.0010 – 0.0026 mg/kg Oilseed rape nectar <0.0005 – 0.0006 mg/kg The lower value is the LOQ and it can be seen that it is not much lower than the maximum values measured, so the maximum values will be used for the risk assessment. Therefore, the calculation of the residue intakes for forager and nurse bees are shown below: Food consumption

Food consumption

	Min	Max	
Forager bee	32	128	mg sugar/d
Larvae	59.4		mg/larvae

Sugar content in OSR	15	%	

Nectar consumption

	Min	Max	
Forager bee (Cn)	213.3	853.3	mg nectar/d
Larvae	396		mg larvae

Pollen consumption

	Min	Max	
Larvae	2		Mg/larvae

RIforager	0.512	ng a.s./bee/d
Larvae	0.2428	ng a.s./larvae/d

Please note that nurse bees have not been included in the above assessment; it is likely that the risk to nurse bees will be less than that for adult forager bees.

Risk assessment

As stated above, the acute oral toxicity value for adult foragers is 0.005 µg a.s./bee, whilst the NOEL for larvae is 0.0217 µg a.s./larvae/developmental period.

The margins of safety for acute oral, larvae and chronic adult risk are shown in the two tables below:

Comparison of exposure and effects for acute oral adult honeybee toxicity using EFSA endpoints

Scenario	Exposure estimate (ng a.s./bee/day)	LDD50 (ng a.s./bee/day)	Factor between exposure and effects
First tier			
Succeeding crops	36.225	5	0.138
Field margin – with a deflector	0.006	5	833.3
Field margin – without a deflector	0.057	5	87.7
Adjacent crops – with a deflector	0.006	5	833.3
Adjacent crops – without a deflector	0.059	5	84.7
Higher tier			
Succeeding crops – refined residues (Peterek, 2020)	0.512	5	9.8

Comparison of exposure and effects for larval honeybee toxicity using EFSA endpoints

Scenario	Exposure estimate (ng a.s./bee/day)	LDD50 (ng a.s./bee/day)	Factor between exposure and effects
First tier			
Succeeding crops	20.7	21.7	1.05

Field margin – with a deflector	0.003	21.7	7233.3
Field margin – without a deflector	0.034	21.7	638.2
Adjacent crops – with a deflector	0.003	21.7	7233.3
Adjacent crops – without a deflector	0.034	21.7	638.2
Higher tier			
Succeeding crops – refined residues (Peterek, 2020)	0.512	21.7	42.4

Comparison of exposure and effects for chronic adult honeybee toxicity using [redacted]

Scenario	**Exposure estimate (ng a.s./bee/day)**	**LDD50 (ng a.s./bee/day)**	**Factor between exposure and effects**
First tier			
Succeeding crops	36.225	3.816	0.105
Field margin – with a deflector	0.006	3.816	636
Field margin – without a deflector	0.057	3.816	66.9
Adjacent crops – with a deflector	0.006	3.816	636
Adjacent crops – without a deflector	0.059	3.816	64.7
Higher tier			
Succeeding crops – refined residues (Peterek, 2020)	0.512	3.816	7.45

(red)	Exposure higher than toxicity
(amber)	Exposure similar to toxicity
(green)	Exposure an order of magnitude or more lower than toxicity

Due to the lack of agreed protection goals and hence trigger values for honeybees, a margin of safety approach has been adopted whereby the effects endpoint is compared to the exposure estimate. It should be noted that there is no agreed level of acceptability in terms of margin of safety.

Acute oral risk
For adult foragers, there is a margin of safety of at leave an order of magnitude between the exposure estimate and the toxicity endpoint for all scenarios except the succeeding crop scenario. For succeeding crops the margin of safety is just below an order of magnitude based on measured residue data as a higher tier refinement.

On the basis of the above first-tier worst-case assumptions, it is concluded that the acute contact risk from the proposed used is acceptable. As for the acute oral risk, the acute risk to adult forager honeybees foraging on succeeding crops is unacceptable, i.e., the exposure estimate is greater than the toxicity endpoint, Based on the higher tier residue data it is less clear whether

	there is a sufficient margin of safety for acute oral risk. All other scenarios, i.e., risk to bees foraging in field either adjacent crops or field margins, are acceptable. *Larval risk* As for larvae, there is a margin of safety of at least an order of magnitude between the toxicity endpoint and the exposure estimate for all scenarios except the succeeding crop scenario where the exposure estimate is more or less equivalent to the NOEL. When the higher tier data are used to refine the risk from succeeding crops there is more than an order of magnitude margin of safety. On the basis of the above first-tier worst-case assumptions, it is concluded that the risk to larva being fed from pollen and nectar from succeeding crops is also unacceptable as the exposure estimate and the toxicity endpoint are more or less equivalent. Based on the higher tier residue data the risk to larvae is acceptable. All other scenarios, i.e., risk to bees foraging in field either adjacent crops or field margins, are acceptable. *Chronic risk* For bees foraging in field margins and adjacent crops the estimated exposure levels are below the LDD50 by at least an order of magnitude. Given the magnitude of difference between the predicted exposure and effect levels, it is considered reasonable to conclude that mortality resulting from chronic exposure is unlikely to occur in adult honeybees foraging in field margins and adjacent crops. For bees foraging in succeeding crops, the first tier exposure estimate exceeds the LDD50. The refined higher tier exposure estimate (taking into account measured residue values) is below the LDD50 by a factor of >7. It is therefore less clear that there is a sufficient margin of safety between the exposure estimate and LDD50 for bees exposed foraging on succeeding crops. The exposure estimate considering uptake via guttation fluid is below the LDD50 by around a factor of 8. It is not clear that there is a sufficient margin of safety between the exposure estimate and LDD50 for bees exposed via consumption of guttation fluid. This concern does not relate to guttation fluids produced by sugar beet plants but was identified using data derived using maize as a succeeding crop. The applicability of the maize residue data for other crops is unknown, as is the extent to which guttation occurs in different crops. It is feasible that guttation fluid with residues of thiamethoxam (and clothianidin) could occur with other crops that follow sugar beet in rotation. However, it is not possible to say to what extent or concentration. It is noted that the above consideration for succeeding crops does not account for a time period between drilling of treated sugar beet seeds and planting of bee-attractive crops of more than 1 year. In previous applications for the emergency use of ‘Cruiser SB’ on sugar beet a risk management decision was taken to require a 32 month period between drilling treated sugar beet seed and drilling a crop that is attractive to honeybees. In the absence of data on residues in pollen/nectar in flowering crops following a 32 month gap post-drilling of sugar beet, the impact of this difference in timing has not been quantitatively assessed. It is expected that a longer period before drilling of succeeding crops would reduce exposure but whether exposure would be sufficiently reduced not to cause concern remains unknown. It is not possible on the basis of first-tier data and the lack of an agreed risk assessment scheme with associated protection goals to determine what the impact could be on honey bees at the colony level from the exceedances of the toxicity endpoints highlighted above. As the above first-tier assessment has highlighted concern, then it is necessary to try to either refine or mitigate the risk.

It should be noted that the above risk assessment only considers the potential risk from succeeding crops, dust drift[27] on to adjacent crops and field margins; the risk from other routes of exposure is considered further below. In addition, due to the lack of an agreed adult chronic oral toxicity endpoint, it is not possible to conclude on the chronic risk to forager honey bees.

Sublethal effects:

The [redacted] study included observations of sublethal effects on adult honeybees. Abnormal behaviours were noted pre-mortality and included bees stumbling, agitated and uncoordinated ('affected') and bees knocked down ('moribund'). These symptoms were noted only in bees that subsequently died. Therefore, the sublethal effects data from this study are not considered to indicate any additional concern beyond the key toxicity endpoints determined based on the mortality data.

However, the design of chronic adult honeybee laboratory toxicity studies is primarily intended to investigate mortality and the enclosed nature of these studies limits their ability to fully detect effects on bee behaviour and the implications of any such effects on survival in the field. In the EU review of thiamethoxam results from studies investigating effects on bee homing flight ability were considered – [redacted] These studies indicated that exposure to thiamethoxam could negatively impact the return flight ability of forager honeybees.

In the study by [redacted] honeybees were marked, exposed to thiamethoxam in sucrose solution or a control, released at a 500 m distance from their hives and it was monitored whether they returned to the hive. None of the bees exposed to 50 or 100 µg/kg sucrose solution returned to their hives. In contrast all control group bees returned to their hives. At 25 µg/kg sucrose solution (equivalent to 3 ng a.s./bee), 11% of bees did not return to their hives. On this basis a NOEC of 10 µg/kg sucrose solution was determined (equivalent to 1.13 ng a.s./bee).

The [redacted] study followed a similar design except bees were released at up to a 1 km from their hives and their flight activity was radio-tracked. Bees were exposed to 1.85 µg/kg sucrose solution, which equated to a consumed dose of 1.34 ng a.s./bee. There was a statistically significant difference in the proportion of released bees returning to their hives in thiamethoxam group relative to the control. Across several experiments run by [redacted] there was a maximum 31.6% of honeybees exposed to thiamethoxam failing to return to their hives. It is noted that in this study bees would have consumed the offered diet quickly, rather feeding at a slower, more realistic rate over a longer period.

In the previous UK emergency consideration for use of 'Cruiser SB' in 2021 and 2022, a toxicity endpoint for sublethal effects of 1.34 ng a.s./bee was identified, though it was noted that this was an exposure level resulting in effects, rather than a no effect level.

Due to the absence of new information regarding potential effects of thiamethoxam on bee flight ability, the previously conducted risk assessment for such effects has not been updated and the key finding are summarised below.

Comparison of exposure and sublethal effects endpoint for honeybees [redacted]

Scenario	Exposure estimate (ng a.s./bee/day)	Sublethal LOED (ng a.s./bee)	Factor between exposure and effects
First tier			
Succeeding crops	36.225	1.34	0.04
Field margin – with a deflector	0.006	1.34	223

[27] The risk from dust drift is acceptable with and without a deflector.

Field margin – without a deflector	0.057	1.34	23.5
Adjacent crops – with a deflector	0.006	1.34	223
Adjacent crops – without a deflector	0.059	1.34	22.7
Guttation fluid	0.4788	1.34	2.80
Higher tier			
Succeeding crops – refined residues [redacted]	0.512	1.34	2.62

As for the chronic risk, due to the lack of agreed protection goals and hence trigger values for honeybees, a margin of safety approach has been adopted whereby the effects endpoint is compared to the exposure estimate. It should be noted that there is no agreed level of acceptability in terms of margin of safety.

For the field margin and adjacent crop scenarios the margin of difference between the exposure and effects estimates exceeds an order of magnitude. For the succeeding crops and guttation fluid scenarios the exposure estimate is also below the toxicity endpoint, though the margin of difference between the toxicity and exposure values is less than an order of magnitude. Ultimately, given the sublethal toxicity endpoint is an unbound 'less than' value it cannot be confirmed that exposure is below a level where effects could occur. For the succeeding crop and guttation fluid scenarios the comparison indicates that exposure in the field can potentially be at a similar level where effects on honeybee return flight ability were seen in published studies.

It is important to note that the [redacted] studies were bespoke in design and did not follow a standard protocol that is routinely assessed as part of the regulatory risk assessment process for UK pesticide active substances. There is currently no standard regulatory requirement for the conduct of such studies.

Risk from metabolites

Clothianidin is a soil metabolite of thiamethoxam and requires consideration. Data from the above following crop study (see [redacted]), indicates that residues are either less than the level of quantification (LOQ) of 0.0010 mg/kg or slightly above, with a maximum residue value detected in maize of 0.0012 mg/kg. It is noted that EFSA (2018) stated the following regarding clothianidin:

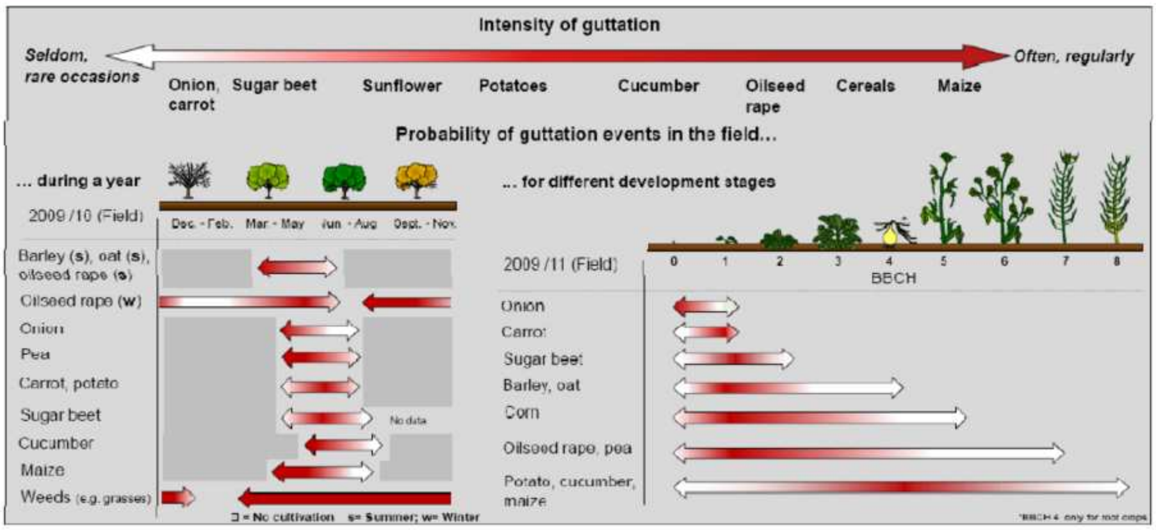
No specific Tier-1 risk assessment was carried out for thiamethoxam metabolite clothianidin. Indeed, it was concluded that the Tier-1 risk assessment for the parent substance (thiamethoxam) covers the risk due to the exposure of the metabolite clothianidin. Such decision was taken considering:

- the intrinsic conservativeness of the Tier-1 assessment;
- the very similar toxicity profiles expressed by the two compounds;
- the available information on plant metabolites, which suggest that the formation fraction of metabolite clothianidin is likely to be well below 100%.

In light of the above, it is not considered necessary to assess the risk from the metabolite, clothianidin.

Risk to honey bees from exposure via guttation fluid

According to EFSA (2012) “some crops show guttation more frequently than others, and the intensity of guttation also varies. Whereas some crops show guttation only at younger growth stages, some may show guttation up to inflorescence.” EFSA (2012) includes the following diagram, taken from Joachimsmeier *et al* (2011) [28] which shows the intensity and frequency of guttation observed in the field trials.



EFSA (2013b) states that “in some crops, such as onions, carrots and sugar beet, guttation (JKI13 personal communication) is rarely observed, while in others (e.g., maize) guttation occurs frequently. It is not possible on the basis of the available information to rule out exposure to guttation droplets from certain crops or under certain conditions”. On the basis of this, EFSA (2013b) states that due to the potentially high residues that can occur in guttation fluid, that the assessment should be carried out for all crops and uses. EFSA (2013a) states that the “risk assessment for the treated crop is worst case and the risk from other plants is considered to be covered (e.g., weeds or adjacent crops)”[29].

EFSA (2013b) also flags up that “further work should be conducted to identify crops for which exposure to residues in guttation droplets is not relevant”.

Presented below is an assessment of the potential risk to honey bees from guttation fluid from maize (see Peterek (2020) for details) as a succeeding crop. The following assessment assumes that bees will consume guttation fluid as water; it is also assumed that foragers collect guttation fluid and take it to the colony, where it is incorporated into brood food (e.g., royal jelly) and then fed to larvae.

[28] Joachimsmeier I, Pistorius J, Heimbach U, Schenke D, Zwerger P and Kirchner W, 2011. Details on occurrence and frequency of guttation in different crops in Germany. Poster presentation on the 11th ICPBR Symposium Hazards of Pesticides to Bees, Wageningen, The Netherlands.

[29] Appendix T of EFSA (2013a) states the following: “The vast majority of the measurements were carried out with maize seeds treated with imidacloprid, clothiadin (sic) and thiamethoxam at rates ranging from 0.5 to 1.25 mg per seed. The few measurements of concentrations in guttation water available for other crops (winter oilseed rape, winter barley, sugar beet and wheat; see Figure H7 of the opinion of the EFSA Panel on Plant Protection Products and their Residues (PPR) (2012a), and (Reetz et al., 2011)) show concentrations that are considerably lower than those found for maize. The estimated values have been based on the results for maize as this is expected to result in conservative estimates for all crops.” Whilst, this conclusion is based on a limited dataset, it could be interpreted that maize is worst-case, however it is on a limited dataset and a limited range of compounds. Furthermore, the overarching guidance states that the assessment should be done for all crops and uses and assumes in the absence of data that the concentration in guttation fluid is equivalent to the water solubility (see Section 3.5.1 of EFSA (2013a). Overall, it is considered that it is not, currently, possible, to derive a worst-case crop/situation.

	The maximum concentrations in guttation fluid from maize plants in the residue study were 42 µg/L for thiamethoxam and 11 µg/L for clothianidin[30]. These can be converted to µg/µL and multiplied by the water uptake per bee according to EFSA (2013b) to give an intake of residue per day. The water uptake of adult bees is 11.4 µL/bee per day for adult bees and 111 µL/5 day period for larvae. The EFSA guidance then calculates an ETR and compares to a trigger but since this guidance has not been noted this step will not be conducted. Instead, the predicted exposure will be compared directly to the toxicity endpoints to give an indication of the level of risk. The toxicity values have, as above, been compared to the exposure predictions to determine the factor between the two (i.e., how much higher is the toxicity endpoint than the exposure prediction).

Thiamethoxam		Toxicity	Factor between exposure and effects
		(µg a.s./bee/day)	
Adult			
			0.0004788 µg/µL/bee/day
Acute oral LD50		0.005	10.4
Chronic LDD50		0.003816	7.9
Sublethal LOED	<	0.00134	2.8
Larvae			
			0.004662 µg/period[a]
Larvae		0.0217	4.65

Clothianidin[31]		Toxicity	Factor between exposure and effects
		(µg a.s./bee/d)	
Adult			
			0.0001254 µg/period[a]
Acute oral LD50		0.00379	30.2
Chronic LC50		0.00138	11
Larvae			
			0.001221 µg/µL/bee/day [a]
Larvae NOEL		0.00528[32]	4.32

[a] The exposure value is, according to EFSA (2013b), meant to be a 5-day time-weighted average value. Whilst data in Peterek (2020) cover several time points, it is noted that the samples were only taken every 7 days and more importantly, the data did not show a simple decline. In some of the trials, (e.g., page 416 of the study report), the concentration in the guttation fluid increased to a peak/plateau and then declined. It is noted that the 5-day time-weighted concentration either side of the peak is probably very similar to the peak, hence by taking the peak concentration as above, is not overly precautionary.

[30] It should be noted that there was background contamination within the study. No residues of thiamethoxam >LOQ (0.001 mg/kg) were detected in control soil samples, but residues of clothianidin >LOQ (0.0001 mg/kg), up to 0.0039 mg/kg were detected in soil control samples from 6 of the 8 trials. Whilst these were at low levels, they were within the range of residues identified in the actual test samples. Residues of thiamethoxam and CGA322704 were found in guttation fluid in some of the control samples analysed from the trials. These were as high as 1.9 mg/kg for CGA322704 in one trial and 1.0 mg/kg for thiamethoxam in the same trial. The presence of these is not explained. The analytical results reported in the table above have not been corrected for the residues in the control samples and the levels found in the control samples are generally well below the maximum levels found in the test samples. Hence, they can still be considered to represent the worst-case situation

[31] Endpoints taken from EFSA (European Food Safety Authority), 2016. Conclusion on the peer review of the pesticide risk assessment for the active substance clothianidin in light of confirmatory data submitted. EFSA Journal 2016;14(11):4606, 34 pp. doi:10.2903/j.efsa.2016.4606

[32] Endpoint stated to be “provisional endpoint because of 3 days exposure and nominal food consumption”.

	There is a least an order of magnitude between the predicted exposure and the acute LD50 for both active substances, so the acute risk from exposure via guttation is likely to be low as there is a margin of safety of at least ten between the acute oral endpoint and the exposure values. The result is less clear cut for the chronic risk from thiamethoxam, where the margin of safety is less than an order of magnitude. There is a margin of safety of at least ten between the chronic endpoint and the exposure value for clothianidin. For the sublethal effects (thiamethoxam only) the toxicity endpoint is 2.8 times higher than the exposure, however, it should be noted that this is an effect level rather than a no effect level. Therefore, it is not possible to conclude whether there would be effects on return flight ability with this level of exposure so further consideration of the sub lethal risk to bees from exposure via guttation is required As regards the risk to larvae, the above assessment indicates that the exposure is similar to the effects endpoint, indicating a potential risk from the active substance and the metabolite. EFSA (2013b) indicates that there are uncertainties associated with the approach to the assessment of the risk from guttation fluid, for example: 1. The degree to which guttation occurs. The risk assessment scheme in EFSA (2013b) assumes that guttation occurs in every crop albeit within the guttation period. The likely occurrence of guttation occurring has not been considered in the above assessment; this is due to the lack of information on the likelihood of occurrence. 2. The degree to which honey bees forage guttation fluid. EFSA (2013b) assumes that in the lower tiers that honey bees will forage on and collect/consume guttation fluid. 3. The use of guttation fluid in royal jelly and other brood food. EFSA (2013b) assumes that guttation fluid is used in brood food. It is unknown to what extent this may occur. In addition to the above, EFSA (2012) stated the following: *Plants offering nectar and pollen will attract bees from further away, whereas water is collected in closer proximity of the hive. Thus, in contrast to nectar and pollen, collection of guttation liquid does not appear to be a regular exposure scenario. The possible uptake of guttation water may be highly variable and is determined by, for example, climate conditions, time of bee activity, seasonal activity and the seasonal water needs of colonies and the occurrence of guttation droplets containing high residue levels. The water need of a colony is highest during spring and summer. As water foragers will preferably choose water sources in the proximity of the hive and avoid long distance flights for energetic reasons, the position of the bee hive in relation to the treated crop and the availability of alternative water sources are most important factors. Furthermore, if guttation occurs, it also occurs in untreated plants like grasses and weeds.* Furthermore, EFSA (2013b) states the following: *The few measurements of concentrations in guttation water available for other crops (winter oilseed rape, winter barley, sugar beet and wheat; see Figure H7 of the opinion of the EFSA Panel on Plant Protection Products and their Residues (PPR) (2012a), and (Reetz* et al*., 2011)) show concentrations that are considerably lower than those found for maize. The estimated values have been based on the results for maize as this is expected to result in conservative estimates for all crops*. The above points regarding the uncertainties related to the assessment of guttation are considered relevant to the assessment carried out by HSE and hence indicate that approach taken by HSE is potentially precautionary.

According to EFSA (2018), "a low risk to honey bees was concluded for residues in guttation fluid for the uses in sugar beet", however it further states that "a high risk was concluded for all other uses". On the basis of the available evidence, HSE agrees regarding the risk to honey bees from foraging on guttation fluid from treated sugar beet.

It should, however, be noted that EFSA (2018) assessed, and hence concluded on, the risk from the seed treatment use, and not, as has been considered above, the risk from succeeding crops growing in soil where thiamethoxam treated seed has previously been drilled. Peterek (2020) indicates that residues of thiamethoxam can occur in a succeeding crop, albeit only maize was considered, hence it is considered appropriate to assess the risk.

Given what is stated above regarding the likelihood of occurrence, it is feasible that guttation fluid with residues of thiamethoxam (and clothianidin) could occur with other crops that follow sugar beet in rotation. However, it is not possible to say to what extent or concentration.

Consideration of the interval between planting the treated seed and planting a bee attractive following crop

The above study by [redacted] provided information on residues in a range of crops approximately 1 year following drilling of a sugar beet crop. The current application proposes a 32 month gap between drilling treated sugar beet seed and drilling a crop that is attractive to honey bees.

Environmental Fate provided initial predicted environmental concentrations in soil (PECsoil) values as well as PECsoil values for 13 months, 22 months and 32 months following drilling of the sugar beet crop, so the effect of additional years in delaying planting a flowering crop that is an attractive crop.

The PECs from Environmental Fate are:

PEC	Concentration (mg/kg)
Initial PEC soil	0.069
13 month PEC (20cm)	0.0035
32 month PEC (20 cm)	0.00035

It should be noted that due to a lack of a reliable chronic toxicity endpoint for adult forager honey bees, it is not possible to use the above information in a quantitative risk assessment. It is only possible to say that the risk will reduce with time, but it is not possible to quantify the risk, or even indicate whether the level is sufficiently low not to cause concern.

When the previous application was considered (HSE Internal reference COP 2020/01677), a risk management decision was made by Defra that the risk was deemed to be acceptable after 32 months to drill oilseed rape seed. It should be noted that that this recommendation was not supported by an HSE assessment indicating what the potential risk to bees is at this time interval.

Residues in honey

In September 2018, HSE presented an assessment of Woodcock *et al* (2018)[33] to the Expert Committee on Pesticides (ECP), see ECP 5 (24/2018). Woodcock *et al* sampled honey samples sourced from amateur beekeepers both before (2014) and after (2015) the implementation of the

[33] Neonicotinoid residues in UK honey despite European Union moratorium Woodcock BA, Ridding L, Freeman SN, Pereira MG, Sleep D, Redhead J, et al. (2018). PLoS ONE 13(1):e0189681. https://doi.org/10.1371/journal.pone.0189681

EU moratorium on neonicotinoid use. The residues in honey were then related to the areas of oilseed rape, winter sown cereals and total arable cover that surrounded the sampled apiaries.

Over 130 honey samples were analysed (N_{2014} = 21; N_{2015} = 109). Concentrations of clothianidin, thiamethoxam and imidacloprid residues within honey were low and did not exceed 1.69 ng/g for any given product. The combined residues of all three products did not exceed 1.99 ng/g in a honey sample in 2015. However, across the three active substances there was little difference in the maximum residue concentration in the post moratorium period, with the values ranging from 1.41 ± 1.69 ng/g. The likelihood of honey containing neonicotinoid residues was higher before the moratorium than after it, with 52.3% of samples from 2014 containing residues of either clothianidin, thiamethoxam or imidacloprid, compared to the 22.9% in 2015. The most frequently identified neonicotinoid was clothianidin, which was in 72.0% of samples testing positive for neonicotinoids in 2014 (pre-moratorium) and 38.1% of samples in 2015 (post-moratorium). Thiamethoxam and imidacloprid were less common, occurring in 14±28% of neonicotinoid-contaminated honey samples in either year.

HSE reviewed this paper and compared the concentrations of the active substances in honey with those measured in nectar and considered by EFSA. The results of the comparison for thiamethoxam are presented below:

Comparison of thiamethoxam residue levels in honey and nectar

Maximum residue measured in 2015 honey – Thiamethoxam (mg/Kg)	**Range of measured values in winter OSR nectar – Thiamethoxam (mg/Kg) Thiamethoxam EFSA conclusion (2018) Appendix D**	**Range of measured values in nectar from succeeding crops (sum of thiamethoxam + clothianidin) mg/Kg (3 trials – considered insufficient for refining exposure) Thiamethoxam EFSA conclusion (2018)**
0.00141	<LOQ-0.003	OSR 0.0022-0.0077 *Phacelia* 0.001-0.0021 *Alfalfa* 0.0005-0.0022

Note: for succeeding crops data was only available for thiamethoxam and clothianidin combined.

In addition to the above, HSE also compared the residues in honey with the toxicity endpoints for thiamethoxam (see EFSA (2018)) for honey bees; this is presented below:
Comparison of thiamethoxam residues measured in honey with toxicity endpoints for honey bees

		Daily consumption of residues (using max residue measured in 2015 honey)	**Margin of safety**
Acute oral toxicity	0.005 µg a.s./bee	0.001203 µg/bee/day	~4 fold
Larval toxicity	0.0217 µg a.s./larva per developmental period	0.0005203 µg/larvae	~42 fold

Note: No chronic toxicity data is available for thiamethoxam

It is worth noting that the above assessment is based on using maximum residues in honey as a surrogate for nectar. If the bees were only consuming the honey then the exposure would be lower – due to the much higher sugar content of honey compared with nectar (calculations have assumed sugar content of nectar of 15%, whereas honey is likely to be around 80%). As a consequence, the margin of safety would be greater.

Defra has recently funded further work on the likely levels of pesticides in honey[34]; part of this work focused on the occurrence of neonicotinoids, including thiamethoxam, in samples of honey. Although not yet finalized and published, it was considered important to include a consideration of this work in this eRR.

This work indicated that "following the cessation of use in oilseed rape, by 2015 there was a significant reduction in the detection frequency of all three compounds in honey samples. By 2019 both IMI and TMX were largely absent from honey (3% of samples). This reduction is concurrent with their almost (IMI) or complete (TMX) cessation of use from 2015 onwards. However, CTD while reducing in frequency from 2014-2015, continued to be found in on average between 10.9 to 21.0 % of honey samples. It is likely this reflects the continued use of this product on winter wheat and sugar beet from 2015-2018". Presented below is a summary table outlining the residues of clothianidin, thiamethoxam and imidacloprid in honey samples.

Summary statistics for the residues of clothianidin (CTD), thiamethoxam (TMX) and imidacloprid (IMI) identified from honey samples from 2014-19. Where: LoD= residue limit of detection set at 0.38 ng / g ww; N= number of samples with residues above the limit of detection.

		2014 (pre-moratorium)	2015	2016	2017	2019 (NHMS data)
Number of honey samples		21	109	92	101	100
Percentage of Residues > LoD	***CTD***	38.1% (N=8)	16.6% (N=18)	10.9% (N=10)	11.9% (N=12)	21.0% (N=21)
	TMX	14.3% (N=3)	6.5% (N=7)	5.5% (N=5)	0.0% (N=0)	1.0% (N=1)
	IMI	9.6% (N=2)	5.6% (N=6)	2.2% (N=2)	1.0% (N=1)	0.0% (N=0)
Mean concentration in honey (ng g^{-1})	***CTD***	0.29 (SE 0.09)	0.12 (SE 0.03)	0.07 (SE 0.03)	0.10 (SE 0.04)	0.16 (SE 0.04)
	TMX	0.11 (SE 0.08)	0.05 (SE 0.02)	0.03 (SE 0.01)	0.00 (SE 0.00)	0.01 (SE 0.01)
	IMI	0.05 (SE 0.04)	0.04 (SE 0.02)	0.02 (SE 0.01)	0.01 (SE 0.01)	0.00 (SE 0.00)
Maximum recorded concentration	***CTD***	1.02 ng g^{-1}	1.69 ng g^{-1}	1.94 ng g^{-1}	2.78 ng g^{-1}	1.94 ng g^{-1}
	TMX	1.41 ng g^{-1}	1.41 ng g^{-1}	0.82 ng g^{-1}	0 ng g^{-1}	0.96 ng g^{-1}
	IMI	0.64 ng g^{-1}	1.61 ng g^{-1}	0.98 ng g^{-1}	0.78 ng g^{-1}	0.00 ng g^{-1}

According to the above table, the maximum concentration of thiamethoxam in 2019 was 0.96 ng a.s./g, in the 2015 data previously considered by HSE and the ECP, the maximum figure was 1.41 ng a.s/g (see above). The resulting risk will be slightly less than that outlined above.

Additional consideration of the risk to bees foraging in field margins

Data from a Defra funded project (PS2372 - Quantifying exposure of bumblebees to neonicotinoids and mixtures of agrochemicals – see Defra, UK - Science Search) indicated that residues of thiamethoxam could occur in the pollen and nectar of flowers in field margins.
In this study, the crops being studied were oilseed rape and wheat, both of these seed treatments have higher dust drift factors than for sugar beet, i.e., default deposition percentages for sugar beet (as used above) are 0.003 and 0.03 with and without a deflector, whereas for oilseed rape with and without a deflector the range is 0.66 and 6.6 respectively, whilst for cereals the range is

[34] Defra research project – PN 0806: Analysis of samples from National Honey Monitoring Scheme for pesticide residues to quantify pesticide exposure risk to honey bees. Draft report accessed August 2021.

0.99 and 9.9 with and without a deflector, respectively (see Table H1b of EFSA (2013a) for further details). Therefore, exposure and hence risk resulting from dust drift should be less for sugar beet seed than for either cereals or oilseed rape. Further details regarding the risk from dust drift is outlined above.

It was further noted in PS2372, that the concentrations in plants in field margins could be greater than those in the field. It was postulated by the study authors that the “differential presence of these compounds in OSR flowers and field margin wildflowers was related to the route of contamination in each case (i.e., root uptake from the residues in soil and soil water, spray drift or contaminated dust emissions during coated-seeds sowing)”. It should be noted that at this point in time, the routine honey bee risk assessment focuses on the risk to honey bees foraging the treated crop and not the off-field habitat, however an assessment has been done for the use of ‘Cruiser SB’ due to the concerns associated with the a.s., metabolite and use of the product. Furthermore, the reasons why residues in pollen and nectar in the off-field habitat were greater than in-field is unclear and warrants further consideration.

Overall consideration of the risks to bees from use of ‘Cruiser SB’ on sugar beet

The regulatory risk assessment situation for bees, in light of the new data submitted to HSE in November 2022, is summarised in the following table.

Table HSE 2.6-12: Summary of bee risk assessment outcomes for ‘Cruiser SB’

<table>
<tr><th rowspan="2">Foraging scenario</th><th colspan="4">Honeybees</th><th rowspan="2">Other bee species (bumble bees, wild bees)</th></tr>
<tr><th>Acute risk to adults</th><th>Chronic risk to adults</th><th>Sublethal effects on adults</th><th>Risks to larvae</th></tr>
<tr><td>Treated crop</td><td colspan="5">Low risks due to crop being harvested before flowering</td></tr>
<tr><td>Flowering weeds within treated field</td><td colspan="5">Low risks where weeds are controlled through herbicide use programme</td></tr>
<tr><td>Flowering weeds in field margins</td><td>Low risk indicated</td><td>Low risk indicated</td><td>Low risk likely but toxicity endpoint is unbound*</td><td>Low risk indicated</td><td rowspan="4">No assessment performed due to insufficient toxicity data and lack of suitable risk assessment methodology</td></tr>
<tr><td>Adjacent crops</td><td>Low risk indicated</td><td>Low risk indicated</td><td>Low risk likely but toxicity endpoint is unbound*</td><td>Low risk indicated</td></tr>
<tr><td>Succeeding crops</td><td>Low risk indicated</td><td>Insufficient margin to conclude low risk</td><td>Insufficient margin to conclude low risk</td><td>Low risk indicated</td></tr>
<tr><td>Guttation fluid</td><td>Low risk indicated</td><td>Insufficient margin to conclude low risk for succeeding crops</td><td>Insufficient margin to conclude low risk for succeeding crops</td><td>Insufficient margin to conclude low risk for thiamethoxam and the metabolite clothianidin from succeeding crops</td></tr>
</table>

* There were effects at the lowest concentration tested, hence effectively the endpoint is a 'less than' value

	Section 3.8.3 of Regulation 1107/2009 specifies the following regarding risks to bees: '*An active substance, safener or synergist shall be approved only if it is established following an appropriate risk assessment on the basis of Community or internationally agreed test guidelines, that the use under the proposed conditions of use of plant protection products containing this active substance, safener or synergist:* *— will result in a negligible exposure of honeybees, or* *— has no unacceptable acute or chronic effects on colony survival and development, taking into account effects on honeybee larvae and honeybee behaviour*.' Section 2.5.2.3 of Regulation 546/2011 goes on to state that evaluation of the risk to honeybees is required and this shall include: *(i) the ratio between the maximum application rate expressed in grams of active substance per hectare and the contact and oral LD 50 expressed in µg of active substance per bee (hazard quotients) and where necessary the persistence of residues on or, where relevant, in the treated plants;* *(ii) where relevant, the effects on honeybee larvae, honeybee behaviour, colony survival and development after use of the plant protection product in accordance with the proposed conditions of use.* The following decision criteria are also specified for honeybees: '*Where there is a possibility of honeybees being exposed, no authorisation shall be granted if the hazard quotients for oral or contact exposure of honeybees are greater than 50, unless it is clearly established through an appropriate risk assessment that under field conditions there are no unacceptable effects on honeybee larvae, honeybee behaviour, or colony survival and development after use of the plant protection product in accordance with the proposed conditions of use.*' In order to conclude on the acceptability of risk to bees from the proposed emergency use of 'Cruiser SB' on sugar beet, the following key regulatory questions are addressed. **1. <u>Will use result in negligible exposure to honeybees?</u>** Residues of thiamethoxam and the metabolite clothianidin above detection/quantification limits were found in pollen, nectar and guttation fluid from succeeding crops, which could lead to exposure of bees. Exposure could also occur via flowering plants in field margins/neighbouring fields and currently no robust data are available to quantify exposure via these pathways. **Therefore, it is concluded that use of 'Cruiser SB' on sugar beet will not result in negligible exposure to honeybees.** **2. <u>Are oral and contact hazard quotients ≤ 50?</u>** The acute contact hazard quotients are 0.13 and 1.3 for use with and without a deflector respectively. Oral hazard quotients have not been calculated. However, the decision-making criteria related to hazard quotient and the trigger value of 50 were developed with respect to applications made via a spray and not solid formulations like seed treatments.

	It is concluded that the available hazard quotients do not exceed 50. However, this criterion was not developed for assessing risks from products applied as seed treatments and does not account for effects from chronic exposure. **3. <u>Has it been clearly established that under field conditions there are no unacceptable effects on honeybee larvae, honeybee behaviour, or colony survival and development after use of the plant protection product in accordance with the proposed conditions of use?</u>** HSE considers that in order for it to be "clearly established" that there will be no unacceptable effects on honeybees from use of the product, it needs to be transparently demonstrated that there are no unacceptable impacts and a high level of certainty is required. The term "unacceptable effects" is not further defined in the regulation. The current risk assessment framework for bees is outlined in the SANCO terrestrial guidance document (EC 2002). Section 2.1 states: *'There is a common understanding that the ecological risk assessment aims not at individuals but at the protection of populations. In general the continuance of populations of non-target organisms should be ensured. Structural and functional endpoints should be regarded of equal importance.'* And Section 4.3 (relating to risks to bees) states: *'It is important to consider any effects observed [in field trials] in relation to the overall survival and productivity of the hive'* On this basis effects that would negatively impact the hive/colony, in terms of its survival, development or productivity would be considered unacceptable. HSE has compared predicted (or measured) exposure levels with toxicity endpoints for honeybees to determine the likelihood of impacts occurring under field conditions. Exposure has been calculated for succeeding crops, flowering weeds in field margins, adjacent crops and guttation fluid scenarios. There is an insufficient margin of safety in the succeeding crop and guttation fluid (succeeding crop) exposure scenarios in order to be able to conclude with high certainty that there will be no unacceptable impacts on individual adult honeybees or honeybee larvae under field conditions. From the available data it is not possible to determine what the impact could be on honeybees at the colony level from the exceedances of the toxicity endpoints highlighted above. This is due to: • the lack of an agreed risk assessment scheme with associated protection goals; • the absence of suitable higher tier data investigating effects on honeybee colonies under field conditions; • and the absence of suitable models that could use the output from lower tier studies to determine effects at the colony level. **Therefore, HSE remains of the view that it has not been clearly established that there will be no unacceptable effects on adult or larval honeybee survival and behaviour after use of the plant protection product in accordance with the proposed conditions of use. It has also not been clearly established that any such effects would not negatively impact the survival, development or productivity of the colony.** **4. <u>Can the risk to bees be reduced via risk mitigation measures?</u>**

	Ensuring treated fields are free of flowering weeds will limit one pathway of potential exposure for bees, though it is recognised that removal of flowering plants may also impact the health of bee colonies. This mitigation measure has already been taken into account in the risk assessment. Stipulating a 32 month period between drilling treated sugar beet seed and drilling a crop that is attractive to honeybees could reduce exposure of bees to thiamethoxam and clothianidin. However, due to the high persistence of these substances in soil, it is unclear to what extent (if any) this would impact the risk assessment. Further discussion of the persistence of the active substance and metabolite can be found in section 2.5 of this document. **Therefore, the proposed mitigation measures could reduce exposure of bees but the magnitude of any reduction is unknown and it has not been shown that this would be sufficient to reduce impacts to an acceptable level.** **5. What impacts on honeybees could result from the proposed emergency use of 'Cruiser SB' on sugar beet?** As discussed above, for the succeeding crop and guttation fluid scenarios, predicted exposure levels are close to levels where mortality from chronic exposure and sublethal effects were observed in toxicity studies with thiamethoxam. In terms of sublethal effects, homing flight activity was impaired in the [redacted] studies, with affected bees not returning to the hive and presumed dead. Assuming a 6.5 day lifespan for foragers, the authors estimated that in the experiment where the greatest effect was seen, exposure to thiamethoxam resulted in approximately doubling the normal mortality rate for foragers. Effects at the individual level may go on to impact the survival/development/productivity of the colony/hive. The magnitude of any impact will depend on the ability of the hive to compensate for this loss. As explained above, the available data don't currently allow for a robust estimate of the effect of use of 'Cruiser SB' at a colony level to be determined. It is noted that [redacted] included limited discussion of results from some population modelling, suggesting that based on the homing flight effects observed, colony size decreased during the exposure period but was able to recover after exposure stopped. However, very little information has been provided on the modelling performed by [redacted] meaning that it cannot be checked and it is not clear what assumptions underlie the modelling, e.g. was a particular landscape modelled, were other stressors considered? Therefore, HSE does not have a sound basis to rely on the modelling referred to in [redacted] It remains unknown whether honeybee colonies situated in the vicinity of treated sugar beet fields would be able to recover from any reduction in colony size. This would likely depend on the prior health of the colony, disease status and availability of other flowering plants in the locality. While honeybee maximum foraging distances can vary in relation to colony size, significant exposure of any colonies located 4 km or more from treated fields is unlikely to occur. **6. What are the risks to bee species other than honeybees?** As with honeybees, bumblebees, solitary bees and other wild bees would not be exposed directly via the treated crop but could be exposed to residues of thiamethoxam and/or clothianidin when foraging on flowering plants in field margins, surrounding fields and/or succeeding crops (if allowed to flower). Due to the lack of suitable information on sensitivity and the lack of an agreed risk assessment scheme with associated protection goals, it is not currently possible to perform an assessment of the risks to bees other than honeybees from the proposed use of 'Cruiser SB'. Therefore, in the absence of information to the contrary, it cannot be excluded that effects on such species could occur. Maximum foraging distances for bumblebees are generally lower than

	for honeybees, though for solitary bees the figure is highly variable between species and can be similar to honeybees.

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY

Summary of data and monitoring previously considered under emergency applications

Section 2.6-1 - Study authors' summary – [redacted]

Study title:	Thiamethoxam: 10 Day chronic oral toxicity test (repeated dose) for adult honeybees (*Apis mellifera* L.)
Objective:	The objective of the study was to assess the chronic toxicity of thiamethoxam to adult honeybees (*Apis mellifera* L.) in a 10-day continuous feeding test. The honeybee is chosen as the test organism, being representative of the pollinating insects likely to be at risk of exposure if flowering crops or weeds are sprayed with plant protection products. Honeybees may be exposed to plant protection products from foraging on sprayed plants leading to the oral uptake of contaminated food (pollen, nectar etc.). These data are required for the registration of new plant protection products and continued registration of existing products in accordance with Regulation (EC) No. 1107/2009.
Guideline:	OECD 245: Guideline for the Testing of Chemicals: Honeybee (*Apis Mellifera* L.), chronic oral toxicity test (10 Day Feeding Test in the Laboratory) 2017.
Fera study number:	FR/002785-10
Test item:	Thiamethoxam
Toxic reference item:	Dimethoate (Pestanal analytical grade)
Test species:	Honeybee (*Apis mellifera* L.)
Stage:	Newly emerged adult workers (< 48 hours old)
Source:	Home apiary, FERA National Bee Unit
Test system:	Newly emerged honeybees (*Apis mellifera* L.), no more than 48 hours old were used in the chronic test. They were allowed continual access to a 50% (w/v) aqueous sucrose solution, either with or without the test/reference item, via a feeder inserted into the side of the plastic housing cage. This feeder was changed and weighed in and out every day, allowing the amount of sucrose and dose consumed to be calculated.
Temperature: (Except during observations)	33 ± 2 °C
Humidity: (Except during observations)	60 ± 10% RH

Photoperiod & lighting: (Except during observations)	Test units were held in darkness	
Treatments, dose calculation and expression:	The test item dose rates were based on the results of separate non-GLP range finding and solubility/suspensibility studies and in discussion with the Sponsor's monitor. The main test was run as a dose response test at five nominal concentrations: 0.01, 0.02, 0.04, 0.08, and 0.16 mg thiamethoxam/kg feed solution. Following analysis of the dosed feed samples it was seen that the difference between expected concentration and analysed content was greater than 20%. Therefore, the results have been expressed in terms of analysed a.s. content rather than nominal. Doses based on mean analysed thiamethoxam content of the dosed feed were 0.0149, 0.0304, 0.0660, 0.131, and 0.267 mg thiamethoxam/kg feed solution. Each cage of bees was offered approximately 1.5 mL of treated or control diet each day. The mean measured doses consumed by the bees in the test item treated groups were calculated to be 0.577, 1.199, 2.055, 3.733, and 6.714 ng a.s./bee/day. The toxic reference item was offered at a rate of 1 mg a.s./kg 50% (w/v) aqueous sucrose solution. The mean measured dose consumed by the bees in the reference item treated group was calculated to be 0.023 µg a.s./bee/day. The untreated control group was fed untreated 50% (w/v) aqueous sucrose solution.	
Dosing solution analysis:	Sub-samples of the initial stock solution, control feed and all 5 dosed feed solutions were taken on day 0, and day 9. All dosed feed samples were analysed by liquid chromatography with Mass Spectrometry (LC-MS) to assess the concentration, homogeneity, and stability of the a.s. thiamethoxam. The method used, FR/002785-10-A, (see Appendix 4) was validated to SANTE 2020/12830 rev1 and found to be suitable (see Appendix 5). Analysis of the A samples showed a greater than 20% deviation from expected concentrations of thiamethoxam and contamination in one of the undosed controls (day 6-9 feed batch). The samples were rerun with fresh stocks which confirmed the results. The B samples were analysed which confirmed the deviation in sample concentration but demonstrated that both control samples were free of contamination. It is the B sample analysis that is reported here.	

	Triplicate dosed feed samples taken on day 0 all showed less than 10% relative standard deviation (RSD), confirming the homogeneity of the solutions. Comparison of day 0 and day 9 sample results (taken on the first and last days of dosing) demonstrated that the test item was stable in the dosed feed over the dosing period. Based on the results of the analysis; as samples showed a greater than 20% deviation from expected concentrations of thiamethoxam, the results are reported in terms of analysed content of thiamethoxam in the dosing solutions.
Replicates:	3 cages of 10 bees were used for each treatment group
Test duration:	10 days with continuous exposure
Toxicity endpoints:	The toxicity endpoint is the mortality after 10 days.
Repeat of Main Test:	The Initial Main Test failed the validity criterion for control mortality ($\leq$15% control mortality) with mean control mortality on day 10 of 23% (7 / 30 bees). The test was, therefore, repeated and it is the results of this second Main Test which are reported here.

Results

The results of the definitive test are summarised in the table below. The was no abnormal behaviour noted in the test other than some agitated and affected (uncoordinated but not stumbling) bees that later died.

Table HSE 2.6- 1: Mean percentage mortality in the control, reference and test item treated groups over 10 days

Treatment group	Analysed Concentration (mg a.s.kg)	Mean dose ng a.s./ bee/day	Mean Percentage Mortality									
			Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10
Water control	0	-	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	10.0
Thiamethoxam	0.0149	0.577	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	0.0304	1.199	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	0.0660	2.055	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	0.131	3.733	0.0	0.0	0.0	0.0	3.33	6.67	10.0	16.7	23.3	33.3
	0.267	6.714	13.3	60.0	86.7	86.7	90.0	90.0	93.3	96.7	96.7	96.7
Toxic reference	1.0	23.0 µg a.s./bee/day	0.0	3.33	53.3	73.3	96.7	100	100	100	100	100

Conclusion

There was 10.0 % mortality in the water control, meeting the validity criterion of ≤15% control mortality. In the toxic reference group 100% mortality was observed, meeting the validity criterion of ≥ 50% mortality at day 10.

There was a clear dose response which allowed for the estimation of LC_{10}, LC_{20} and LC_{50} as well as values LDD_{10}, LDD_{20} and LDD_{50}. It was also possible to estimate the NOEC/LOEC and NOEDD and LOEDD values

Table HSE 2.6-2: LOEC/NOEC and LOEDD/NOEDD Values for Day 10

NOEC (mg a.s./kg)	NOEDD (ng/a.s./bee/day)
0.0660	2.055
LOEC	**LOEDD**
0.131	3.733

Table HSE 2.6-3: LCx values

LC_{10} (95% CI levels)	**LC_{20} (95% CI levels)**	**LC_{50} (95% CI levels)**
(mg a.s./kg)		
0.1039 (0.08586 – 0.1257)	0.1185 (0.1013 – 0.1387)	0.1525 (0.1343 – 0.1732)

Table HSE 2.6-4: LDDx values

LDD_{10} (95% CI levels)	**LDD_{20} (95% CI levels)**	**LDD_{50} (95% CI levels)**
(ng/a.s./bee/day)		
2.553 (2.139 – 3.048)	2.931 (2.551 – 3.368)	3.816 (3.416 – 4.263)

Section 2.6-2 - HSE ecotoxicology comments on new chronic adult honeybee toxicity study (Wilkins, 2022)

The following study report has been submitted to inform the consideration of potential risks to bees associated with use of the product 'Cruiser SB':

[redacted] *Thiamethoxam: 10 Day chronic oral toxicity test (repeated dose) for adult honeybees (Apis mellifera L.).* Fera Study Number: FR/002785-10. Final QA version (audited).

The report has been reviewed by HSE, with the Study Summary copied above. The study follows Good Laboratory Practice (GLP), with signed statement of compliance. The Study also follows the relevant guidance OECD 245 (2017) in terms of the following (with deviations underlined):

- Visually healthy, honeybees (*Apis mellifera*) were used, with source detailed, no varrocide treatment in over a month and obtained from queen-right colonies. The number of different colonies used was not reported, nor was the bee race. The bees were free from statutory notifiable disease (American and European Foulbrood), however there were low incidences of adult diseases. These minor deviations are unlikely to have adversely affected the study conclusions as the bees were randomly allocated to the test units and the mortality in the control was below guideline requirements, along with no mortality occurring in three of the treatments;
- Three replicates of 10 female (worker) bees were used per treatment, collected as brood combs in early August with hatched bees being less than 48 hours old and acclimatised on 50% w/v aqueous sucrose solution for less than 24 hours (overnight) until test start date. Although the bees were taken from the colony at a less favourable time of year (as the colony is winding down for winter) collection in August is acceptable in this instance as the control group met the validity criteria;
- Use of appropriate toxic reference substance – dimethoate, offered at 1 mg/kg in 50% w/v aqueous sucrose solution;
- Appropriate test conditions with 10 bees per replicate, kept in suitable containers (volume = 1710.6 cm^3 so > 200 cm^3 minimum required by the guidelines), in the dark, except for feeding and checking. Suitable temperature range (mean: 33.0ºC, range: 32.5 – 33.1ºC) and appropriate humidity (mean 66.7%, range 36.3 – 68.8%) was maintained at all times bar one occasion where low humidity (the single 36.6% reading) was recorded, linked to handling. Brief exposures to low temperatures or humidity are acceptable during handling according to the guidelines, and is unlikely to have adversely impacted the study as control validity criteria were met;
- Appropriate feeding with 50% (w/v) sucrose solution, product and toxic reference, provided fresh daily and continually accessible, taking into account evaporation. Although only 1.5 mL of fresh feeding solution was offered daily (the guidelines stipulate minimum of 2 mL), this was sufficient to provide *ad libitum* feeding based on past experience of the laboratory. As such, this minor deviation is unlikely to have impacted the study conclusions;
- The dosed feed solutions were refrigerated between 2 - 6ºC, however the guidelines state they should be stored at 6±2ºC. This deviation is acceptable as all feeds, including the control, were stored at these temperatures, and the recovery of the active substance has been verified analytically.
- Analysis of the active substance concentrations in all solutions and control on days 0 and 9 to confirm appropriate solution concentrations of active substance. However, mean recovery was unexpectedly high in the first set of samples taken (A samples) and there was evidence of contamination of the control, so the B samples were run. The recovery was between 149.0% and 166.9% for each concentration over the two time periods combined, with no contamination in the control in the B run. As such, mean measured concentrations are used in the final calculations; and
- The use of an appropriate regression analysis to determine LDD_x and LC_x values and a step-down test, equivalent to a Cochrane-Armitage Test, for determining LOEC/LOEDD and NOEDD/NOEC. Correction for control mortality was not undertaken and is optional according to the guidelines. This is acceptable given that mortality in the controls was higher than that of three of the test item treatments. Not correcting for mortality also results in more conservative endpoints, which is acceptable, and can be taken into account in the risk assessment if required.

Control

Daily evaporation ranged between 31.0 – 40.9 mg in the sucrose control and has been taken into account within the calculations. The food intake in the controls was 44.62 mg/bee/day. Data on behavioural abnormalities in the control groups was not provided. Mortality in the control group by day 10 was 10.0%, which is below the 15% allowed in the OECD guideline confirming the bees used were healthy and the study conditions appropriate.

Reference Item

The toxic reference Dimethoate (99.4% purity) was provided at 1 mg a.s./kg food, which is within the concentration range recommended by the guidelines, with 23 ng a.s./bee/day consumed. No data on behavioural abnormalities was provided for the reference item. Mortality was noted by day 2, with 100% mortality after 6 days of exposure, meaning the reference test criteria were met (i.e., > 50% mortality required when using one concentration of between 0.5 and 1.0 mg a.s./kg food). The daily food intake rate of Dimethoate was 23.22 mg solution/bee/day, which is below the daily intake of sucrose solutions by control bees (44.62 mg/bee/day). This suggests there may be some avoidance of Dimethoate by bees, although statistical analysis was not undertaken to confirm this.

Product

Test item concentrations of 0.01, 0.02, 0.04, 0.08 and 0.016 mg a.s./kg were used. As the analytical determination of active substance concentrations in the solutions were outside the acceptable 20% range of expected, mean measured concentrations were used, equating to 0.0149, 0.0304, 0.0660, 0.131 and 0.267 mg a.s./kg.

Daily evaporation ranged between 31.7 – 42.9 mg in tubes set up in empty test units at the lowest and highest concentration of test item (evaporation averaged between the two concentrations). This evaporation has been taken into account within the calculations for all concentrations. The mean product food intake rate was 24.90 - 39.44 mg solution/bee/day, with decreasing food uptake as product concentration increased, notable from concentrations of 0.0660 mg a.s./kg and above, This pattern of decreased uptake with increased product concentration was more evident when assessing mean total uptake of solution over the 10 days, with a notable decline in uptake relative to active substance concentration from 394.5 mg/bee (at 0.0304 mg a.s./kg) to 174.3 mg/bee (at 0.267 mg a.s./kg). This implies there is likely some avoidance of the product solutions by bees, however no statistics were run to confirm this. Nevertheless, there was incremental uptake in thiamethoxam relative to the concentration of active substances in the solutions supplied, with total uptake increasing from 5.77 ng/bee to 47 ng/bee as test item concentration increased. Therefore, bees were exposed to sufficient levels of active substance for the results to be of relevance to the risk assessment.

Abnormal behaviours were noted pre-mortality and included bees stumbling, agitated and uncoordinated ('affected') and bees knocked down ('moribund'). These symptoms were noted only in bees that subsequently died[35], mainly in the 0.131 mg a.s./kg treatment (with bees in all replicates 'affected' on day 1), with the only other treatment where behavioural effects were noted being the 0.267 mg a.s./kg treatment (1 bee 'stumbling' on day 5).

Mortality in the samples treated with product was first noted on day 1 in the 0.267 mg a.s./kg concentration (6.714 ng a.s./bee/day), with mortality occurring from day 5 in the 0.131 mg a.s./kg treatment (3.733 ng a.s./bee/day). The three lower test item concentrations had no mortality. By day 2 there was more than 50% mortality in the highest treatment concentration. By day 10, there was 33.3% mortality (10 bees) in the second highest concentration treatment, and 96.7% mortality in the highest concentration treatment. It is also noted that all bees had died in one replicate of the highest treatment concentration by day 3, with all bees having died in a second replicate of this treatment by day 8. The death rate of bees as a result of ingestion of 'Cruiser SB' at 0.267 mg a.s./kg, is similar to that of the toxic reference (where the >50% mortality level was reached a day later, by day 3).

The dose-response curve of dose per bee per day against mortality is copied below from Appendix 11 of the report (Figure 1 below). The data points do not fit the curve well, with a wide range recorded at the second highest uptake rate (data derived from the three replicates of treatment concentration 0.131 mg a.s./kg and one from the 0.267 mg a.s./kg treatment where uptake was lower in one replicate than in the other two). The curve is also steep due to lack of mortality in the three lower uptake rates. The statistical package has also not included 95% confidence intervals on the figure, so it is not immediately clear how statistically reliable the calculated endpoints are, although 95% confidence limits are provided as ranges later in the statistical outputs. Given these limitations there is some uncertainty in the final calculated LDD_x endpoints and this will need to be taken into account at the risk assessment stage.

[35] Whilst this is specified by the study authors, the way the data is presented does not allow for this point to be confirmed.

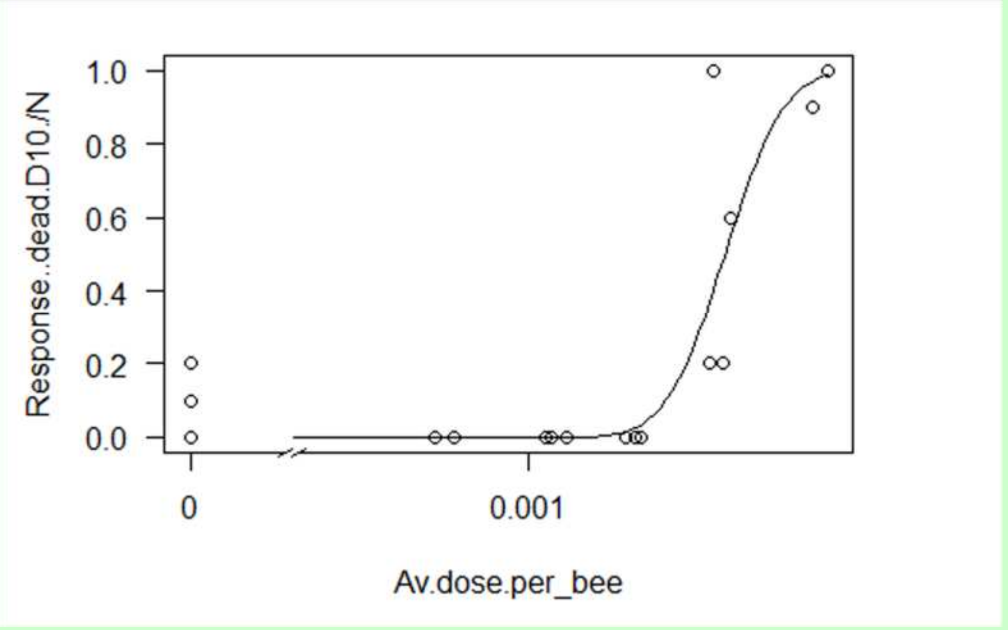


Figure HSE 2.6-1: Statistically derived dose-response curve showing average dose of thiamethoxam in µg/bee/day from measured uptake against mortality used to determine LDD_x.

The dose-response curve of treatment concentration (mean measured) against mortality is copied below from Appendix 11 of the report (Figure 2 below). The data points fit this curve better, although the curve is still steep and there are no 95% confidence intervals. This curve, however, provides more certainty in the derived LC_x endpoints than the LDD_x endpoints derived from the thiamethoxam uptake curve above.

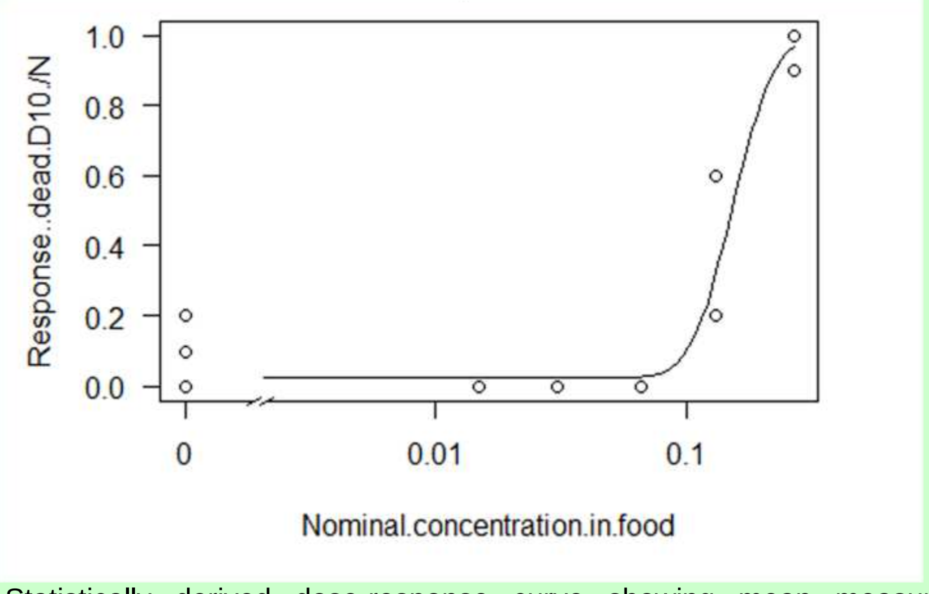


Figure HSE 2.6-2: Statistically derived dose-response curve showing mean measured concentration of thiamethoxam provided as mg/kg feed against mortality, used to determine LC_x.

There is some uncertainty in values derived from the curves. The dosing factor used was 2. Given the steep dose-response curves, derived from effects noted in only two of the five does, a lower dosing factor may have been more appropriate, and may have provided more precise endpoints. Nevertheless, the key endpoints (including 95% confidence limits) for consideration in the risk assessment are as follows:

- LDD_{50} **3.816** ng a.s./bee/day (3.416 – 4.263);
- LDD_{10} **2.553** ng a.s./bee/day (2.139 – 3.048);
- LOEED **3.733** ng a.s./bee/day;
- NOEED **2.055** ng a.s./bee/day;
- LC_{50} **0.1525** mg a.s./kg (0.1343 – 0.1732);

- LC_{10} **0.1039** mg a.s./kg (0.08586 – 0.1257);
- LOEC **0.131** mg a.s./kg;
- NOEC **0.0660** mg a.s./kg.

In Summary:
Study Acceptable: **Yes**
Deficiencies: **None**
Corrections: **None**
Recent Guidelines: **Yes OECD 245 (2017) and Good Laboratory Practice**
Evaluation use or Additional info only: **Evaluation**

Section 2.6-3 - HSE chemistry comments on new chronic adult honeybee toxicity study [redacted]

Thiamethoxam: 10 Day chronic oral toxicity test (repeated dose) for adult honeybees (*Apis mellifera* L.)
Study Number: FR/002785-10
GLP Status: Yes

The objective of the analytical part of the study was to determine the content of thiamethoxam in feeding solutions in the context of a 10-day chronic oral toxicity test (repeated exposure) for adult honeybees (*Apis mellifera* L.). The test was run as a dose repeat test at the following concentrations:

Nominal Concentration (mg thiamethoxam/kg feed solution)	Mean measured concentration (mg thiamethoxam/kg feed solution)*
0.01	0.0149
0.02	0.0304
0.04	0.0660
0.08	0.131
0.16	0.267

*The mean measured concentration is used for the dose level instead of the nominal concentration in the study as samples showed a greater than 20% deviation from expected concentrations of thiamethoxam.

Analytical samples of the initial stock solution, control feed and all 5 dosed feed solutions were taken on day 0 and day 9. Samples were analysed using method FR/002785-10-A.

Principle of the method
Samples are stored in the freezer until analysis. To the supplied 1 mL aliquots of control and dosing samples, add 1 mL of methanol. Vortex mix for a few seconds and ultrasonicate for approximately 5 minutes. Filter a portion through a 0.2 µm PVDF filter into a vial for analysis. Analyse with matrix matched standards by LC-MS.

Chromatographic Conditions

Instrument	LC-MS
Analytical column	Kinetex XB C18, 50 x 2.1 mm, 2.6 µm particle size with a guard column or filter
Injection volume	1 µL
Mobile phase	Solvent A: 1 mM ammonium acetate (aq) Solvent B: methanol
Flow rate	0.4 mL/minute
Gradient	(see below)

Time (mins)	%A	%B
0	90	10
3	10	90
7	10	90

	7.1	90	10
	10	90	10
Retention time	Approximately 1.43 minutes		
MS system	AB Sciex ATRAP 5500+ Mass spectrometer		
Ionisation type	Turbospray positive ion		
Detection	MS/MS		
Source temperature	300°C		
Ion spray voltage	3500 volts		
MS transitions	Thiamethoxam: *m/z* 292 → 211 *m/z 292* → 181		

Analytical validation data for the determination of thiamethoxam in feeding solutions (50% w/v sucrose solution)

Matrix	Analyte	LOQ (mg/kg feed solution)	Fortification level (mg/kg feed solution)	Recoveries %			Linearity
					mean	% RSD (n)	
Feeding solution: 50% w/v sucrose solution	thiamethoxam	0.006	0.006 (corresponding to approximately 0.0036 µg/mL)	99.0, 99.4, 99.7, 97.4, 95.5	98.2	1.8 (5)	Linearity 1 0.001-0.01 µg/mL (n = 4*2)
			0.25 (corresponding to approximately 0.15 µg/mL)	93.3, 98.0, 94.8, 97.4, 94.6	95.6	2.1 (5)	Linearity 2 0.001-0.22 µg/mL (n = 9*2) R^2 = 0.9924 y = 12,592,381x+13,247

Specificity:
Specificity was demonstrated by retention time match with thiamethoxam analytical standard. The following chromatograms were presented for both mass transitions:

- Matrix matched calibration solutions (0.001 and 0.22 µg/mL)
- Control sample
- Fortified sample at 0.3 mg/kg
- Dosed feed samples at 0.01 mg/kg on day 0 and day 9

Analysis of unfortified control sample demonstrated no significant interference (> 30% of the LOQ) at the retention time of interest. It is noted a product ion spectrum has not been provided to justify the selection of ions used for the determination. However, this is not a critical concern for a risk assessment method.

Matrix Effects:

Significant matrix effects were observed. Therefore, matrix matched standards were used for quantification.

Linearity:
Two linear ranges have been presented: the first to cover the LOQ level and the second to cover the higher fortification level and B sample analysis.

Linearity 1: linearity was demonstrated by the analysis of four matrix matched standards in increasing concentration in duplicate. The range of standard concentrations used was 0.001-0.01 µg/mL. No calibration plot was presented for this linear range. However, this is acceptable as additional linearity data including a calibration plot has been provided (see below).

Linearity 2: linearity was demonstrated by the analysis of nine matrix matched standards in increasing concentration in duplicate. The range of standard concentrations used was 0.001-0.22 µg/mL. This covers from at least 30% of the LOQ to 20% above the highest level. The response was linear with a coefficient of determination (R^2) of 0.9924. SANTE/2020/12830 rev. 1 states the suitability of the chosen function should be demonstrated, which should preferably be accomplished by a residual analysis using the residuals. However, as the use of residuals is only preferable, it is considered that the coefficient of determination is sufficient to assess the acceptability of the linearity.

Accuracy:
Recovery samples were prepared by spiking the control (50% aqueous sucrose solution) with thiamethoxam and analysing them by the method described. The spike concentrations were 0.006 and 0.25 mg of a.s./kg, equivalent to approximately 0.0036 and 0.15 µg a.s./L in the final diluted solution. The fortification levels are appropriate to the dose rates in the study. Five samples were prepared at each fortification level. Mean recovery levels were within the range 95.6-98.2%, which is within the acceptable limits.

Procedural recoveries are reported below on day 0 and day 9:

Matrix	Analyte	Nominal Concentration (mg thiamethoxam/kg feed solution)	Sample interval	Recoveries %		
					mean	% RSD (n)
Feeding solution	thiamethoxam	0.01	Day 0	153, 144, 155	151	4 (3)
			Day 9	147	-	-
		0.02	Day 0	151, 148, 159	152	4 (3)
			Day 9	152	-	-
		0.04	Day 0	167, 168, 167	167	0.1 (3)
			Day 9	163	-	-
		0.08	Day 0	166, 160, 159	162	2 (3)
			Day 9	165	-	-
		0.016	Day 0	164, 166, 172	167	2 (3)
			Day 9	166	-	-

For sample analysis in the test, two sets of samples (A samples and B samples) were used. The A samples showed higher recoveries than expected and one of the controls was contaminated. Therefore, the B samples were analysed which confirmed the deviation in sample concentration but demonstrated both control samples were free of contamination. The procedural recoveries shown above are outside of the acceptable limit (70-120%). The applicant has accounted for this by using the mean analysed thiamethoxam content of the dosed feed instead of the nominal concentration for the dose level. It is also noted the recoveries from the method validation data are acceptable.

Precision:
Precision was determined from the accuracy recovery data. Five samples were prepared at each fortification level in line with SANTE/2020/12830 rev. 1. The % RSD at each fortification level was less than 20%.

LOQ:
The LOQ is 0.006 mg/kg, which is the lowest fortification level with acceptable accuracy and precision.

LOD:
The LOD is 0.00167 mg/kg, which is the lowest calibration standard.

Confirmation of identity:
In line with SANTE/2020/12830 rev. 1, confirmation of analyte identity is not required as this is a method for risk assessment.

Storage stability:
The stock solution used for each analysis run was made up fresh on the day so no assessment was required for the stability of the stock solution. Stability of the final extract solutions was demonstrated by the acceptable recoveries of the fortified samples when measured against freshly prepared standards. It is noted only one recovery per dosing level was reported on day 9, but the day 9 recoveries were comparable to the day 0 recoveries. This indicates there are no issues with stability of the final extract solutions.

Storage stability data has also been submitted as samples were stored for 33 days prior to analysis. The mean recovery of samples at 0.2 mg/kg feed solution is 99% on day 0 and after storage for 34 days the mean recovery is 106%. It is noted the study doesn't state how many samples were analysed at each time point. Nevertheless, the recoveries are within the acceptable range and the data presented demonstrates the active is stable under the storage conditions and period used in the study.

Conclusion
The method is sufficiently validated in accordance with SANTE/2020/12830 rev. 1 for the determination of thiamethoxam in feeding solutions. It is noted mean procedural recoveries in the test were in the range 151-167%, which is outside of the acceptable limit (70-120%). However, this has been accounted for by using the mean analysed thiamethoxam content of the dosed feed instead of the nominal concentration for the dose level.

Thiamethoxam – Residue Study on Pollen, Nectar, and Guttation Fluid from Crops Succeeding Sugar Beet Treated with A9765R in Germany, the United Kingdom, Poland, Austria and Italy in 2017-2018

Author/Year [redacted]
Study/Report No.: SPK-17-29052

This is a GLP residues study which consists of 8 field trials conducted in Europe (2 DE, 2 UK, 2 PL, 1 AT, 1 IT) in 2017-18.

Eight residue field trials were conducted to investigate the magnitude of residues of thiamethoxam and its metabolite CGA322704 in rotated crops in Germany, the United Kingdom, Poland, Austria and Italy during 2017 – 2018.

Thiamethoxam was applied to pelleted sugar beet seed as A9765R, a flowable concentrate (FS) formulation for seed treatment containing nominally 600 g thiamethoxam per litre. The seeds were treated at a nominal rate of 0.45 mg thiamethoxam/seed and were drilled in spring 2017 at a rate of 1.24 - 1.34 seed units/ha (1 seed unit = 100000 seeds; equivalent to 57 - 64 g a.s./ha).

Additionally, at each trial site, an additional plot was drilled with untreated pelleted sugar beet seed in spring 2017 according to normal commercial practice at a rate of 1.24 - 1.34 seed units/ha (1 seed unit = 100 000 seeds; equivalent to 57 - 64 g ai/ha).

The sugar beet was grown to maturity and harvested according to normal commercial practice. In trials GB03 and GB04, as a result of adverse weather conditions, normal commercial harvest occurred slightly later than intended. This is not considered to impact the integrity of the trials as the samples taken were still considered to be representative of commercially harvested samples.

The sugar beet crop was sown on 5th April 2017 and the succeeding crops were sown on the following dates:

- Maize – 3rd May 2018
- Potato – 3rd May 2018
- Oilseed rape – 30th April 2018
- Phacelia – 30th April 2018

In the following spring (i.e., spring 2018), four representative succeeding crops (maize, potato, oilseed rape and phacelia) were drilled into the site previously used to grow the sugar beet, and cultivated according to normal commercial practice, thus affording four side-by-side subplots at each trial site for each treatment scenario (i.e., the untreated and treated plots).

Three insect-proof tunnels, approximately 108 m² in area per tunnel, were placed on each of the subplots of oilseed rape and phacelia prior to flowering (BBCH 61-65). Honey bee (*Apis mellifera mellifera*) colonies (one per tunnel) were placed into each of the oilseed rape and phacelia tunnels at the start of flowering (BBCH 61-65). These tunnels were treated as replicates.

Untreated and treated soil samples were collected from the entire plot at 0-3 days before drilling of the sugar beet seed (DBD1) and at 0-1 days before drilling of the succeeding crops (DBD2). Additionally, treated samples of soil were collected from the maize subplot at 0-16 days after emergence (DAE; BBCH 11-16), and from all subplots at 1-8 days after flowering (DAF; BBCH 59-67).

Treated samples of maize guttation fluid were collected at 0 days after emergence (DAE; BBCH 11-14), 5-8 DAE (BBCH 13-18), 12-15 DAE (BBCH 15-32), 19-22 DAE (BBCH 16- 35), 27-29 DAE (BBCH 16-33), 33-35 DAE (BBCH 16-34) and 40-42 DAE (BBCH 19-51). Additionally, untreated samples of maize guttation fluid were collected at 40-42 DAE (BBCH 19-51).

Treated samples of maize pollen were collected at 0 days after flowering (DAF; BBCH 61- 65), 3-4 DAF (BBCH 63-67) and 6-9 DAF (BBCH 65-69). Additionally, untreated samples of maize pollen were collected at 0-2 DAF (BBCH 61-65) and 6-9 DAF (BBCH 65-69).

Treated samples of potato anthers were collected at 0 DAF (BBCH 59-69), 2-4 DAF (BBCH 62-67) and 7-9 DAF (BBCH 65-69). Additionally, untreated samples of potato anthers were collected at 0-1 DAF (BBCH 62-69) and 7-9 DAF (BBCH 65-69).

Treated samples of oilseed rape pollen were collected at 0-1 DAF (BBCH 63-65), 3-4 DAF (BBCH 64-69) and 6-8 DAF (BBCH 67-69). Additionally, untreated samples of oilseed rape pollen were collected at 0-1 DAF (BBCH 63-65) and 6-8 DAF (BBCH 67-69).

Treated samples of phacelia pollen were collected at 0 DAF (BBCH 61-65), 7-15 DAF (BBCH 65-69), and 12-21 DAF (BBCH 65-69). Additionally, untreated samples of phacelia pollen were collected at 0-1 DAF (BBCH 61-65) and 12-21 DAF (BBCH 65-69).

Treated samples of oilseed rape nectar were collected at 0 DAF (BBCH 63-65), 3 DAF (BBCH 64-69) and 6-8 DAF (BBCH 67-69). Additionally, untreated samples of oilseed rape nectar were collected at 6-7 DAF (BBCH 67-69).

Treated samples of phacelia nectar were collected at 0 DAF (BBCH 61-65), 7-15 DAF (BBCH 65-69) and 12-21 DAF (BBCH 65-69). Additionally, untreated samples of phacelia nectar were collected at 11-21 DAF (BBCH 65-69).

Samples were analysed for thiamethoxam and its metabolite CGA322704.

Results:

Residues of thiamethoxam and its metabolite CGA322704 in pollen and nectar from the 8 plots are summarised in the table below.

Sampling Interval (days)	Thiamethoxam Residues in the Range (mg/kg)	CGA322704 Residues in the Range (mg/kg)
Treated Plot (P2): at a rate of 57 – 64 g ai/ha		
Maize Pollen		
0 DAF	< 0.0010	< 0.0010 – 0.0011
3-4 DAF	< 0.0010	< 0.0010 – 0.0012
6-9 DAF	< 0.0010	< 0.0010
Oilseed Rape Pollen		
0-1 DAF	< 0.0010 – 0.0026	< 0.0010
3-4 DAF	< 0.0010 – 0.0024	< 0.0010
6-8 DAF	< 0.0010 – 0.0015	< 0.0010
***Phacelia* Pollen**		
0 DAF	< 0.0010	< 0.0010
7–15 DAF	< 0.0010	< 0.0010
12–21 DAF	< 0.0010	< 0.0010
Oilseed Rape Nectar		
0 DAF	< 0.0005	< 0.0010
3 DAF	< 0.0005 – 0.0006	< 0.0010
6-8 DAF	< 0.0005	< 0.0010
***Phacelia* Nectar**		
0 DAF	< 0.0005	< 0.0010
7–15 DAF	< 0.0005	< 0.0010
12–21 DAF	< 0.0005	< 0.0010

DAF = days after start of flowering

Residues of thiamethoxam and its metabolite CGA322704 in guttation fluid are summarised in the table below.

Sampling Interval (days)	Thiamethoxam Residues in the Range (µg/L)	CGA322704 Residues in the Range (µg/L)
Treated Plot (P2): at a rate of 57 – 64 g ai/ha		
Guttation Fluid		
0 DAE	< 0.01 – 17	0.042 – 3.6
5-8 DAE	< 0.01 – 20	0.13 – 3.7
12-15 DAE	< 0.01 – 32	0.14 – 3.2
19-22 DAE	0.025 – 34	0.31 – 5.9
27-29 DAE	0.010 – 42	0.38 – 9.0
33-35 DAE	0.023 – 33	0.97 – 8.5
40-42 DAE	0.011 – 18	0.48 – 11

DAE = days after emergence

Residues of thiamethoxam and CGA322704 were found in guttation in some of the control samples analysed from the trials. These were as high as 1.9 mg/kg for CGA322704 in one trial and 1.0 mg/kg for thiamethoxam in the same trial. The presence of these is not explained. The analytical results reported in the table above have not been corrected for the residues in the control samples, hence, they can still be considered to represent the worst-case situation.

Residues of thiamethoxam and its metabolite CGA322704 in soil are summarised in the table below.

Sampling Interval (days)	Thiamethoxam Residues in the Range (mg/kg)	CGA322704 Residues in the Range (mg/kg)
Treated Plot (P2): at a rate of 57 – 64 g ai/ha		
Soil – Total Plot		
0-3 DBD1	< 0.0010 – 0.0033	< 0.0001 – 0.0039
0-1 DBD2	< 0.0010 – 0.0034	<0.0010 – 0.0040
Maize Soil		
0-16 DAE	< 0.0010 – 0.0029	0.00019 – 0.0039
0-8 DAF	< 0.0010 – 0.0070	0.00067 – 0.0043
Oilseed Rape Soil		
-1-0 DAF	< 0.0010 – 0.0023	0.00078 – 0.0037
Phacelia Soil		
-1-7 DAF	< 0.0010 – 0.0061	0.00043 – 0.0056
Potato Soil		
0 DAF	< 0.0010 – 0.0024	0.00052 – 0.0035

DBD = days before drilling
DAE = days after emergence
DAF = days after start of flowering

Results were also provided for residues in potato anthers, but these have not been used in the current assessment and have not been presented here.

Extract from evaluation by residues specialist:

This is a GLP residues study which consists of 8 field trials conducted in Europe (2 DE, 2 UK, 2 PL, 1 AT, 1 IT) in 2017-18.

In each trial, sugar beet seeds were treated with thiamethoxam at the nominal rate of 0.450 mg a.s./seed (actual: 0.462 mg a.s./seed) using 'A9765R', a 600 g a.s./L flowable concentrate (FS) formulation – this matches the application rate being proposed for the use and the formulation type is the same.

Samples were analysed for thiamethoxam and its CGA332204 metabolite using the following analytical methods. See Section 5 for details of the acceptable validation of the method for pollen and nectar and water (representing guttation fluid). The study claims that the methods for soil and anther are also appropriately validated, but this has not been confirmed):

Analytical methods:

Pollen and nectar: Method GRM009.13A for both analytes.

LOQ:

Thiamethoxam:	0.0010 mg/kg for pollen
	0.0005 mg/kg for nectar
CGA322704:	0.0010 mg/kg for pollen and nectar

Guttation fluid: Method GRM009.10A for both analytes.

LOQ:

Thiamethoxam:	0.01 µg/L
CGA322704:	0.01 µg/L

Soil: Method GRM009.09A for both analytes.

LOQ:

Thiamethoxam:	0.001 mg/kg
CGA322704:	0.0001 mg/kg

Pollen and nectar:

NB: In 3 of the trials, the oilseed rape crop did not produce sufficient viable flowers for pollen or nectar samples to be collected. The number of trials on which the ranges are based are highlighted in the table below.

Number of trials which produced results:

- 8 for maize pollen
- 5 for oilseed rape pollen and nectar
- 8 for phacelia pollen and nectar

The study is acceptable from a residue's perspective.

HSE conclusion:

This study is suitable for use in the risk assessment of bee attractive crops planted the year following a sugar beet crop grown from seeds treated with 'Cruiser SB' at up to 0.45 mg a.s./seed, equivalent to 57 - 64 g a.s./ha.
EFSA (2013a) uses the concept of "residue per unit dose" or RUD and in deriving RUD data from field studies where pollen and nectar are collected and converted to RUD values for use in the first-tier assessment (see Appendix F of EFSA (2013a) for further details.)
Presented below is a comparison of the residues in the above succeeding crop study with those predicted using the RUD values in EFSA (2013b). It should be noted that RUD values are presented in Table F2 of Appendix F of EFSA (2013b) and relate to crops grown from treated seed, whereas the above study relates to pollen and nectar from oilseed rape grown the following season after sugar beet treated with thiamethoxam. In addition, the maximum RUD values have been chosen.

	Lowest 'maximum application rate' authorised for oilseed rape in the EU	Highest 'maximum application rate' authorised for oilseed rape in the EU	Residue trial on oilseed rape as a succeeding crop (max values) from [redacted]
Application rate g a.s./ha	8	42	-
Maximum RUD nectar mg a.s./kg from Table F2 of Appendix F of EFSA (2013b)	0.081	0.081	-
Residue level in nectar for application rate	0.000648 mg a.s./kg (=0.648 µg a.s./kg)	0.003402 mg a.s./kg (=3.402 µg a.s./kg)	0.0006 mg a.s./kg (0.6 µg a.s./kg)
Maximum RUD pollen mg a.s./kg from Table F2 of Appendix F of EFSA (2013b)	0.574	0.574	
Residue level in pollen for application rate	0.004592 mg a.s./kg (=4.592 µg a.s./kg)	0.024108 mg a.s./kg (=24.108 µg a.s./kg)	0.0026 mg a.s./kg (2.6 µg a.s./kg)

From the table above it can be seen that the residue level found in nectar of a succeeding crop of oilseed rape is very similar to the residue that would be found in a treated oilseed rape crop at the minimum rate used in the EU. For residues in pollen the residue found was just over half what would be expected in a treated oilseed rape crop at the minimum rate used in the EU.

2022 monitoring data on thiamethoxam and clothianidin residues

Final reports of the whole plant and pollen monitoring referred to below were submitted in support of the application for use in 2024. These are assessed in the Environmental Fate section above. Due to the limitations of the LOQ and LOD in the methods of analysis (as reported in the fate section) it was not possible to use these to update the assessment.

New monitoring data were provided in 2024 (to support use in 2025), these are reported in the Environmental fate section and used an improved method of analysis with lower LOQ and LOD, the full results are not replicated in this section as they are reported in the Environmental Fate section. The discussion of the preliminary results (stage 1) is retained below as a record. The new results (stage 2 and phase III) do not change the risk assessment presented above. Given the very low levels detected and the difficulties in using these in any risk assessment on the potential impact on bees, future monitoring is likely to focus on soils only.

Preliminary results from monitoring of vegetation samples collected in 2022 have been submitted. Residues of thiamethoxan and clothianidin have been determined from plants sampled in the field margins of drilled sugar beet fields. Only summary results are available, with no detail regarding how the data were generated or interpretation of study results presented. Therefore it is not currently possible to validate the reliability or sufficiency of these data. The plant residue monitoring results are summarised, as submitted to HSE, in the following tables.

Summary of initial whole plant monitoring results – full growth (sampling 2)

Site number	Site location	Sample location	Sample matrix	Collection Date	Sample weight (g)	Thiamethoxam calculated concentration (µg/kg)	Clothianidin calculated concentration (µg/kg)
1	Bilsthorpe	edge of field	vegetation	08/08/2022	1100	< 0	No Peak
1	Bilsthorpe	edge of field	vegetation	08/08/2022	1070	< 0	No Peak
1	Bilsthorpe	edge of field	vegetation	08/08/2022	1080	No Peak	No Peak
2	Attleborough	edge of field	vegetation	22/06/2022	1035	No Peak	< 0
2	Attleborough	edge of field	vegetation	22/06/2022	1150	< 0	No Peak
2	Attleborough	edge of field	vegetation	22/06/2022	1085	< 0	*1.57*
3	Weybourne	edge of field	vegetation	10/08/2022	1110	No Peak	No Peak
3	Weybourne	edge of field	vegetation	10/08/2022	1130	< 0	No Peak
3	Weybourne	edge of field	vegetation	10/08/2022	1070	< 0	No Peak
4	Holbeach	edge of field	vegetation	04/08/2022	1060	< 0	No Peak
4	Holbeach	edge of field	vegetation	04/08/2022	1055	< 0	*0.321*
4	Holbeach	edge of field	vegetation	04/08/2022	1055	< 0	No Peak
5	Bury	edge of field	vegetation	01/08/2022	1020	No Peak	No Peak
5	Bury	edge of field	vegetation	01/08/2022	1065	< 0	No Peak
5	Bury	edge of field	vegetation	01/08/2022	1020	No Peak	No Peak
6	Thorney	edge of field	vegetation	03/08/2022	1170	< 0	No Peak
6	Thorney	edge of field	vegetation	03/08/2022	1085	< 0	No Peak
6	Thorney	edge of field	vegetation	03/08/2022	1130	< 0	No Peak

LOD = 3 µg/kg
LOQ = 10 µg/kg
Values in italics are below the LOD

Summary of initial whole plant monitoring results – pre-harvest (sampling 3)

Site number	Site location	Sample location	Sample matrix	Collection Date	Sample weight (g)	Thiamethoxam calculated concentration (µg/kg)	Clothianidin calculated concentration (µg/kg)
1	Bilsthorpe	edge of field	vegetation	12/09/2022	1090	< 0	*2.34*
1	Bilsthorpe	edge of field	vegetation	12/09/2022	1130	< 0	*2.43*

1	Bilsthorpe	edge of field	vegetation	12/09/2022	1070	< 0	*1.95*
2	Attleborough	edge of field	vegetation	19/09/2022	1160	< 0	**3.27**
2	Attleborough	edge of field	vegetation	19/09/2022	1035	< 0	*2.03*
2	Attleborough	edge of field	vegetation	19/09/2022	1080	< 0	No peak
3	Weybourne	edge of field	vegetation	14/09/2022	1005	< 0	< 0
3	Weybourne	edge of field	vegetation	14/09/2022	1110	*0.0798*	< 0
3	Weybourne	edge of field	vegetation	14/09/2022	1185	< 0	< 0
4	Holbeach	edge of field	vegetation	22/09/2022	1145	< 0	< 0
4	Holbeach	edge of field	vegetation	22/09/2022	1235	< 0	No Peak
4	Holbeach	edge of field	vegetation	22/09/2022	1100	*1.42*	< 0
5	Bury	edge of field	vegetation	15/09/2022	1095	**3.35**	< 0
5	Bury	edge of field	vegetation	15/09/2022	1170	< 0	< 0
5	Bury	edge of field	vegetation	15/09/2022	1185	*1.65*	< 0
6	Thorney	edge of field	vegetation	21/09/2022	1280	*0.616*	< 0
6	Thorney	edge of field	vegetation	21/09/2022	1335	< 0	*0.42*
6	Thorney	edge of field	vegetation	21/09/2022	1110	< 0	< 0

LOD = 3 µg/kg
LOQ = 10 µg/kg
Values in italics are below the LOD

Summary of initial pollen monitoring results – full growth (sampling 2)

Site number	Site location	Sample location	Sample matrix	Collection Date	Sample weight (g)	Thiamethoxam calculated concentration (µg/kg)	Clothianidin calculated concentration (µg/kg)
1	Bilsthorpe	edge of field	pollen	08/08/2022	165	*0.303*	< 0
2	Attleborough	edge of field	pollen	23/06/2022	170	*0.607*	< 0
3	Weybourne	edge of field	pollen	10/08/2022	555	*0.470*	No Peak
4	Holbeach	edge of field	pollen	04/08/2022	1005	< 0	< 0
5	Bury	edge of field	pollen	01/08/2022	1035	*0.0128*	< 0
6	Thorney	edge of field	pollen	03/08/2022	1095	< 0	< 0

LOD = 3 µg/kg
LOQ = 10 µg/kg
Values in italics are below the LOD

Summary of initial pollen monitoring results – pre-harvest (sampling 3)

Site number	Site location	Sample location	Sample matrix	Collection Date	Sample weight (g)	Thiamethoxam calculated concentration (µg/kg)	Clothianidin calculated concentration (µg/kg)
1	Bilsthorpe	edge of field	pollen	08/08/2022	135	No Peak	No Peak
2	Attleborough	edge of field	pollen	23/06/2022	140	No Peak	*1.18*
3	Weybourne	edge of field	pollen	10/08/2022	1007	No Peak	No Peak
4	Holbeach	edge of field	pollen	04/08/2022	840	**4.88**	*1.80*
5	Bury	edge of field	pollen	01/08/2022	260	No Peak	No Peak
6	Thorney	edge of field	pollen	03/08/2022	1020	No Peak	No Peak

LOD = 3 µg/kg

LOQ = 10 µg/kg
Values in italics are below the LOD

Whole plant data:

The data on residues in whole plants are not directly usable in the bee risk assessment but can potentially inform on the importance of different exposure pathways.

In the full growth samples (sampling 2) thiamethoxam levels were determined to be '< 0' or 'no peak'. These categories are not clearly defined but it is apparent that residues were below the LOD. While numerical concentrations of clothianidin are presented for 2 samples, all clothianidin concentrations are also below the LOD.

In the pre-harvest period (sampling 3) the maximum thiamethoxam concentration calculated in whole field margin plants across all sites was 3.35 µg/kg. This is above the LOD but below the LOQ. All other thiamethoxam concentrations were below the LOD. Clothianidin concentrations were also below the LOD, except in one sample from the Attleborough site, where a residue of 3.27 µg was determined (above the LOD but below the LOQ).

Therefore, while the reliability and sufficiency of this dataset has yet to be determined, the presented results suggest that residues of both thiamethoxam and the metabolite clothianidin in field margin plants were relatively low in the full growth stage of the crop. These results, if confirmed, would suggest that any lateral movement of thiamethoxam and clothianidin from the treated field through the soil and uptake into neighbouring plants was limited. However, it must be considered that while all residues of thiamethoxam and clothianidin were below the LOQ, in this case the LOQ of the analytical method used is relatively high (10 µg/kg).

Pollen data:

Residues of thiamethoxam and clothianidin in pollen are available for the full growth stage (sampling 2) and pre-harvest (sampling 3) periods. For the full growth stage (sampling 2), the maximum concentration of thiamethoxam determined is 0.607 µg/kg, though since this value is below the LOD, it is not considered a reliable estimate. For the pre-harvest period (sampling 3), the maximum thiamethoxam concentration in pollen was 4.88 µg/kg (above the LOD but below the LOQ), with concentrations from all other sites being below the LOD. For clothianidin, residues in pollen were below the LOD for both the full growth stage and pre-harvest periods. Therefore, the results suggest relatively low levels of thiamethoxam and clothianidin in the pollen of field margin plants. However, the reliability and sufficiency of these data are still to be confirmed and the LOD and LOQ are considered to be relatively high.

In the previous assessment of the risk to bees for the 2021/22 uses of 'Cruiser SB' on sugar beet (re-presented in the green box below), a measured residue value for thiamethoxam in the pollen from flowering plants in field margins or adjacent crops was not used, in the absence of available supporting data to derive such a value. Instead, a default first tier exposure estimate was determined using the methodology described in EFSA (2013). As a result, a simple comparison between residues in pollen assumed in the previous risk assessment and measured residues in pollen from the new monitoring data is not possible. In future, the risk assessment could be updated to incorporate measured residues in pollen from flowering plants in field margins, replacing the generic default values used. However, it will be first necessary to confirm the sufficiency and reliability of the new pollen residue dataset, and this will likely be impacted by the relatively high LOD and LOQ. Additionally, adult bees and larvae can be exposed to thiamethoxam (and clothianidin) via residues in nectar as well as pollen. No information is available on residues of these substances in nectar from flowering plants in field margins, following drilling of treated sugar beet seed. Therefore, the exposure assessment could only be partially updated.

Data on residues of thiamethoxam in the pollen (and nectar) of flowers in field margins is also available from a Defra funded project (PS2372 - Quantifying exposure of bumblebees to neonicotinoids and mixtures of agrochemicals – see Defra, UK - Science Search). It is noted though that in this study the crops studied were oilseed rape and wheat, with both of these seed treatments having higher dust drift factors than for sugar beet in the EFSA guidance (EFSA, 2013). Thiamethoxam was detected in 58% of pollen samples collected from wildflowers in OSR field margins, with a maximum residue of 86 µg/kg. Clothianidin was detected in 14% of pollen samples from wildflowers in OSR field margins, with a maximum residue of 0.36 µg/kg. For pollen collected from wildflowers in winter wheat margins, thiamethoxam was detected in only 1.8% of samples (maximum = 7.47 µg/kg) and clothianidin was not detected in any samples. Therefore, the new data on thiamethoxam in flowers from sugar beet margins suggest lower residues when compared to residues found in pollen from OSR field margins in PS2372. However, it is noted that monitoring data on thiamethoxam residues in pollen from field margins are not available for sugar beet fields at the time of drilling, where exposure via dust drift may occur, potentially leading to higher residues. As a result, meaningful comparison of the new monitoring data and PS2372 results is limited.

Comparison of the new pollen residue data from flowers in field margins with pollen residue data from succeeding crops in fields previously planted with treated sugar beet is possible. Concentrations of thiamethoxam in the pollen of succeeding crops were up to 2.6 µg/kg for oilseed rape and <1 µg/kg for maize and *Phacelia* [redacted]. The maximum concentration of clothianidin in pollen from succeeding crops in [redacted] was 1.2 µg/kg for maize. Therefore the maximum residues of both substances in pollen from succeeding crops appear similar to the residues found in pollen from flowers in sugar beet field margins. However, as the residues in pollen from field margins are to be confirmed and are below the reported LOQ (and the LOD in most cases), again this comparison is limited.

Honey data:

Information on residues of thiamethoxan and clothianidin in honey is collected under the National Honey Monitoring Scheme (NHMS - link). In the previous bee risk assessment conducted by HSE for the 2022 emergency use of 'Cruiser SB' on sugar beet seeds (see green box below), there was some consideration of reported residues in honey from NHMS 2019 data and comparison to equivalent data from 2014-2017. While the 2020 data has not yet been published, the summary data have been made available to HSE and are summarised in the following table.

Average residue levels (ng/g w/w) of neonicotinoid seed treatments found within honey for 2020

N	Statistic	Clothianidin	Thiamethoxam	Imidacloprid
80 (total arable)	Mean	0.153	0.017	0.012
	SE	0.045	0.010	0.005
	Max	2.868	0.787	0.249
61 (non-sugar beet areas)	Mean	0.11	0	0.007
	SE	0.037	0	0.005
	Max	1.84	0	0.25
19 (sugar beet areas)	Mean	0.292	0.07	0.027
	SE	0.149	0.043	0.015
	Max	2.868	0.787	0.23
20 (urban and semi-natural)	Mean	0	0	0.009 (1 sample)

The arable data has been subdivided, comparing those honey samples originating from hives with or without sugar beet grown within 2 km of hives (assessed using the 2020 CEH Land Cover® plus Crop Map).

For thiamethoxam, the 2019 data shows a mean concentration in honey of 0.01 ng/g and maximum concentration of 0.96 ng/g. Therefore, the 2020 maximum residue (0.79 ng/g) is slightly lower than the 2019 figure, while the 2020 average arable residue (0.017 ng/g) is similar to the average residue from 2019.

For clothianidin, the 2019 data shows a mean concentration in honey of 0.16 ng/g and maximum concentration of 1.94 ng/g. Therefore the maximum residue from 2020 is higher than 2019 (2.87 ng/g), though the difference is less than a factor of 2. The 2020 average arable residue (0.153 ng/g) are similar to the average residue from 2019.

In the previous bee risk assessment conducted by HSE for the 2022 emergency use of 'Cruiser SB' on sugar beet seeds, data on residues in honey was not directly relied upon in the risk assessment. There was some comparison

between maximum residue levels of thiamethoxam in honey and available toxicity endpoints. Since the maximum residue in 2020 samples is lower, the previous consideration still represents a worst-case. Additionally, it is noted that data on residues in honey is of limited use for assessing risks to foraging bees, since oral exposure will be from consumption of nectar and extrapolating data on residues in honey to residues in nectar is uncertain. Residues in honey could potentially be used to assess the risk to in-hive bees over winter, where feeding on honey is expected, but there is currently a lack of appropriate assessment methodology for evaluating such risks.

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Other areas of the risk assessment	The following assessments are taken from the original assessment of 'Cruiser SB' supporting the original commercial authorisation (previously circulated with the 2020 application for 'Cruiser SB', see ECP 4-7 (39/2020), HSE internal reference WIS 001072834). As the rate is within that being proposed for 'Cruiser SB' and the guidance has not changed, the risk assessment has not been revisited. It should however be noted that PEC values are greater in the following assessment than for the proposed use. It should also be noted that since this application was undertaken, there have been changes to the DT50 and the DT90. The key impact of the change in the DT90 is that this triggers the need to consider the issue of accumulation. However, with the proposed restriction not to apply sugar beet treated seed to the same field for 46 months, the risk of accumulation of residues of thiamethoxam in soil from repeated use is effectively mitigated by the restriction not to plant sugar beet treated on the same field for 46 months.
Effects on arthropod species other than bees	**B.9.5 Effects on other arthropod species (IIA 8.3.2, IIIA 10.5)** **It should be noted that the risk to non-target arthropods from a plant protection product is usually assessed using ESCORT 2 (see Candolfi *et al* 2001). According to Candolfi *et al* when a seed treatment is being considered, data on species such as spiders and ground dwelling beetles should be considered. Outlined below is a summary of all the toxicity data that has been submitted including ground dwelling and leaf dwelling non-target arthropods. Data on the effects of thiamethoxam as well as the metabolite CGA 322704 on the soil mite are also included below. (The effects of thiamethoxam and the metabolite CGA 322704 on soil *function* are considered in Section B.9.7.)** **B.9.5.1 Laboratory toxicity studies** Studies have been submitted on the toxicity of the formulated products 'Cruiser 350FS' and 'Actara 25WG' to non-target terrestrial arthropods. These data have been summarised in Table B.9.66. All tests were conducted in accordance with GLP. No data were submitted from laboratory studies with technical thiamethoxam but it is acceptable to address the risk to non-target arthropods using formulation studies. Table B.9.66 Effects of formulations of thiamethoxam on non-target terrestrial arthropods

Species	Test type, substrate & duration	Appln. (g a.s./ha) [1]	Effect(s)	Test guideline	Ref
'Cruiser 350FS'					
Poecilus cupreus	laboratory sand substrate, treated wheat seed placed on surface to equate to 140 g a.s./ha. Equivalent to 70 g a.s./100 kg seed, or 0.035 mg a.s./seed assuming 20000 seeds/kg.	control 140	Adult mortality after 4 days (%): 0 100 Food consumption in treated was reduced compared to untreated from start	Heimbach (1992)	[redacted]
Aleochara bilineata	laboratory sand substrate, treated wheat seed placed on surface to equate to 140 g a.s./ha. Four days exposure followed by 10 days egg viability assessment. Equivalent to 70 g a.s./ha or 0.035 mg a.s./seed assuming 20000 seeds/kg.	control 140	Adult mortality after 4 days (%): 0 90 79% reduction in food consumption relative to untreated (days 1-4) No eggs laid in treated compared to 54 eggs/beetle in untreated (93% hatch)	Samsoe-Petersen (1992)	[redacted]
'Actara 25WG'					
Aphidius rhopalosiphi	exposure of adults to dry residues on glass plates for 48 hrs followed by fecundity assessment	control 200	Adult mortality (%): 5 100 Parasitisation not assessed due to 100% mortality	IOBC (Mead-Briggs 1992) Hassan (1992)	[redacted]
Typhlodromus pyri	exposure of nymphs to dry residues on glass plates for 7 days followed by fecundity assessment	control 200 control 200	Adult mortality after one day (%): 0 87 after 3 days (%): 8 100 Fecundity not assessed due to 100% mortality	Overmeer (1988) Hassan (1992)	[redacted]

[1] proposed max. application rate equates to 61.25 g a.s./ha on cereals and 147 g a.s./ha on peas

a) The chronic toxicity of technical thiamethoxam (purity 98.7%) to *Folsomia candida* (Collembola) was investigated in a 4-week laboratory study. Juveniles (10-12 days old at start) were exposed to thiamethoxam at 0.36, 0.72, 4.44, 2.88, 5.76, 11.52, 23.04 and 46.08 mg a.s./kg dry soil in glass vessels of 100 ml capacity (5 cm diameter) containing 30 g of artificial soil (10% peat). The collembola were fed moist yeast every 7 days. Results are summarised in Table B.9.67.

Table B.9.67 Toxicity of technical thiamethoxam to collembola

Treatment	Nominal conc.n (mg a.s./kg)]	Mean adult mortality after 4 weeks (%)	juveniles/ replicate after 4 weeks	
			mean	% of control
Control	-	4	735	-
Thiamethoxam	0.36	3	756	103
	0.72	20*	802	109
	1.44	8	707	96
	2.88	15	713	97
	5.76	43*	385	52*
	11.52	68*	20	3*
	23.04	80*	4	1*
	46.08	98*	0	0*
Toxic standard	30.3	12	384	52

* significantly different to control

A clear concentration-dependent effect on the survival of collembola was observed after 4 weeks exposure to thiamethoxam. The relatively high adult mortality at 0.72 mg a.s./kg was not considered to be treatment related. The level of reproduction observed in this treatment was greater than the control. Surviving collembola exhibited normal behaviour in all treatments. Reproduction of collembola was unaffected at concentrations of thiamethoxam up to and including 2.88 mg/kg dry weight soil. At concentrations of 5.76 mg/kg dry weight soil and higher the reproductive performance of collembola was negatively affected. The validity criteria for the control reproduction were accomplished, with > 100 juveniles/replicate and a coefficient of variation of reproduction of 11.6% (i.e. < 30%).

The 28-day EC50 (based on reproduction) of collembola following exposure to thiamethoxam was determined to be 5.61 mg/kg dry soil and the 28-day NOEC to be 2.88 mg/kg dry soil.

This study was conducted according to ISO 11267 (1999) and in compliance with GLP. [redacted]

b) The chronic toxicity of the thiamethoxam metabolite CGA 322704 (purity 99%) to *Folsomia candida* (Collembola) was investigated in a 4-week laboratory study. Juveniles (10-12 days old at start) were exposed to CGA 322704 at 0.15, 0.3, 0.6, 1.2, 2.4, 4.8, 9.6 and 19.2 mg/kg soil in glass vessels of 100 ml capacity (5 cm diameter) containing 30 g of artificial soil (10% peat). The collembola were fed moist yeast every 7 days. Results are summarised in Table B.9.68.

Table B.9.68 Toxicity of CGA 322704 (metabolite) to collembola

Treatment	Nominal conc.n (mg a.s./kg)]	Mean adult mortality after 4 weeks (%)	juveniles/ replicate after 4 weeks	
			mean	% of control
Control	-	20	1267	-
Thiamethoxam	0.15	50*	671	53*
	0.3	100*	2	0*
	0.6	98*	2	0*
	1.2	100*	1	0*

	2.4	100*	0	0*
	4.8	100*	0	0*
	9.6	100*	0	0*
	19.2	100*	0	0*
Toxic standard	30.3	50*	305	24*

* significantly different to control

Significant mortality in comparison to the control, as well as a significant decrease in reproduction was observed at 0.15 mg CGA 322704/kg dry weight soil. Surviving collembola exhibited normal behaviour. The validity criteria for the control reproduction were accomplished, with > 100 juveniles/replicate and a coefficient of variation of reproduction of 23.2% (i.e. < 30%). The EC50 for reproduction was not calculated but the 28-day NOEC (based on reproduction) of collembola following exposure to CGA 322704 was < 0.15 mg/kg dry weight soil. This study was conducted according to ISO 11267 (1999) and in compliance with GLP.

[redacted]

c) The chronic toxicity of the metabolite CGA 322704 applied to artificial soil to *Hypoaspis* (*Geolaelaps*) *aculeifer* was determined using the OECD Guideline Proposal for the Testing of Chemicals "Predatory mite reproduction test in soil (*Hypoaspis* (*Geolaelaps*) *aculeifer*)", Fifth Draft March 06, 2005. The study was conducted to GLP and there were no deviations.

Adult mated female mites of similar age (approx. 7 - 14 days after reaching the adult stage) from a synchronised culture taken between the 28th and 35th day after starting the respective culture were kept in a precisely defined artificial soil to which the test item had been applied.

On the day of test initiation, the test item was dissolved in an amount of deionised water sufficient to prepare a stock solution. This stock solution was used to produce the various dosage solutions of the test item. An appropriate amount of the stock and the dosage solutions respectively served to prepare the different concentrations of the test item in the artificial soil.

The control substrate contained the corresponding amount of water only. The test item was incorporated into the soil. Each test vessel was then filled with the treated soil (approximately 30 g dry weight).

Ten adult mated female mites were placed on the soil substrate of each test vessel (4 control vessels and 4 replicates per treatment rate).

At test start three spatula tips of *Tyrophagus putrescentiae* were added as a food source to each test vessel. On days 4, 7, 11 and 14 after application, humidity of the test substrate and the amount of food consumed were checked and deionised water and prey mites were added. On day 16 the pH-value and the moisture of the artificial soil were checked for each concentration in additional vessels without mites.

Assessments were performed after an extraction period of 48 hours. The mites of each test vessel were poured into extraction funnels and heat-extracted by a modified infrared extractor. The final number of surviving adult mites and the number of surviving juveniles after 16 days exposure and 2 days heat extraction were recorded.

Results and Discussion

After 16 days of exposure and an additional two days of extraction, 13 to 20 adult mites (females and males) were observed in the control and 8 to 32 adult mites in all concentrations of the test item tested. Since at the end of the test the number of adult mites found was greater than the initial number and furthermore, not only females but males were determined, it can be assumed that an unknown number of individuals of the F1-generation became adult during the test period.

The number of juveniles was statistically significantly reduced compared to the control (Williams test; 1-sided, $p \leq 0.05$) at the highest concentration (500 mg CGA 322704/kg soil (dw)) of the test item tested.

The $NOEC_{Reproduction}$ was determined as 100 mg CGA 322704/kg soil (dw) and the $LOEC_{Reproduction}$ as 500 mg CGA 322704/kg soil (dw).

The EC50 value for reproduction was calculated by Probit analysis using Linear Max. Likelihood Regression as 472.7 mg CGA 322704/kg soil (dw) (95 % confidence limits: 275.2 - 1520.3 mg CGA 322704/kg soil (dw)).

The results are summarised in the tables below in Table B.9.69:

Table B.9.69 Summary of results from the chronic toxicity study on the metabolite CGA 322704 applied to artificial soil to *Hypoaspis* (*Geolaelaps*) *aculeifer*

Concentration (mg CGA 322704/kg soil dw)	**Mean number of adult mites (± standard deviation)**	**Mortality (%)**	**Mean number of juvenile mites (± standard deviation)**	**Number of juvenile mites (% of control)**
Control	16.0 ± 3.0	-60.0	271.4 ± 33.5	-
5	17.8 ± 5.2	-77.5	249.0 ± 25.4	91.8
10	20.8 ± 1.7	-107.5	282.0 ± 47.4	103.9
25	21.0 ± 11.1	-110.0	254.5 ± 55.7	93.8
50	13.5 ± 7.2	-35	266.0 ± 33.3	98.0
100	12.3 ± 2.9	-22.5	245.3 ± 11.1	90.4
500	13.5 ± 4.5	-35.0	130.3 ± 28.0 *	48.0

* significantly different to control (Williams test; 1-sided, $p \leq 0.05$)

Conclusions:
The effects of CGA 322704 on the reproduction of the Predatory Soil Mite *Hypoaspis* (*Geolaelaps*) *aculeifer* were evaluated after incorporating the required quantity of the test item into the artificial soil substrate.

The $NOEC_{Reproduction}$ was determined as 100 mg CGA 322704/kg soil (dw).

The EC50 value for reproduction was calculated as 472.7 mg CGA 322704/kg soil (dw) (95 % confidence limits: 275.2 - 1520.3 mg CGA 322704/kg soil (dw)).

[redacted]

B.9.5.2 Extended laboratory toxicity studies

Larvae of the Carabid beetle *Poecilus cupreus* were exposed to pea seeds treated with 'Cruiser 350FS' at the proposed recommended dose of 150 ml/100 kg seed. Individual larvae were caged in glass tubes (2.2 cm diameter x 7 cm high) containing 5cm of soil, a single treated pea seed and an insect pupa as a food source.

One pea per container was stated to be equivalent to 7143 kg seed/ha, resulting in an application rate of 3750 g a.s./ha. This is approximately 60 times and 26 times the maximum application rate on cereals and peas respectively.

After 3 days, 62.5% of larvae exposed to treated seed had died, and by day 5 all larvae exposed to treated seed had died. No mortality occurred in untreated tubes at this time.

This study was performed according to Heimbach (1998) and in accordance with GLP.

[redacted]

B.9.5.3 Semi-field studies

No semi-field studies were conducted with the proposed formulation 'Cruiser 350FS' but two semi-field studies were conducted with 'Cruiser 70WS'.

a) In a semi-field study in Northern Switzerland, adults of the Carabid beetle *Poecilus cupreus* were exposed to wheat seeds treated with 'Cruiser WS70' to apply 70 g a.s./100 kg seed or 0.035 mg a.s./seed assuming 20000 seeds/kg.

The study used exposure units consisting of 50 cm square metal frames, approximately 25 cm deep, sunk 10-15 cm into the soil with approximately 10 cm protruding. The soil had the following characteristics; 58.29% sand, 17.33% clay and 24.38% silt, the organic carbon was 1.96% and pH was 7.14. Spring wheat was sown at the equivalent of 200 kg/ha to give the equivalent of 140 g a.s./ha. The seeds were equally distributed in rows (distance between rows 7 cm and 2.5 cm distance between seeds in the row) at a depth approximately 1-2 cm. The units were covered with a large mesh netting to avoid disturbance by birds or other large animals yet minimising the influence of the microclimate. Ten beetles (5M, 5F) were placed in each test chamber immediately after seed sowing. Pupae of *Calliphora spp*. were provided as food. Mortality and behaviour were recorded at 1-3 hours after beetle introduction and thereafter at 1, 2, 4, 7, 10 and 14 days after test initiation. In addition, food consumption was recorded on 2, 4, 7, 10 and 14 days after treatment.

By the end of the 14-day study, 25% of the beetles in the 'Cruiser SB' plots had died compared to 7.5% in untreated plots (corrected mortality = 18.9%). In addition, 33% of surviving beetles in the 'Cruiser SB' plots showed co-ordination problems while all beetles in untreated plots appeared normal. No effects on mean food consumption/beetle/day were seen.

This study was performed according to Barrett *et al* (1994), Dohmen (1998) and Heimbach *et al* (1992) and in accordance with GLP.

(Candolfi 1998a)

b) The reproductive performance (parasitism of onion fly pupae) of adult *Aleochara bilineata* exposed to wheat seeds treated with 'Cruiser WS70' was investigated in a 27-day study under semi-field conditions with rain protection. The exposure units were plastic containers (57 cm x 37 cm, approximately 21 cm high) containing approximately 11-12 cm layer of soil. The moisture content of the soil was maintained at approximately 35-40% of the maximum water holding capacity. A wheat seed density of 4.218 g seeds/unit was calculated based on 200 kg seeds/ha (140 g a.s./ha). Seed loading was calculates as 0.035 mg a.s./seed assuming 20000 seeds/kg. The seeds were equally distributed in rows 7 cm apart and planted approximately 1 cm deep. The units were covered with a fine mesh netting to avoid predation and test insect escape. Each test unit held 200 beetles (100M, 100F) and there were four replicates. On days 0, 1, 3, 6, 8, 10, 13, 17 and 20 the beetles were fed with thawed *Chironomus* sp. larvae.

On each of days 6, 13 and 20, approximately 5000 *Delia antiqua* pupae were added to each of the exposure units. The fly pupae being buried in 3 rows (1-3 cm deep). The second and third introductions of fly pupae were placed in new rows, each beside the previous rows. On day 27 all onion fly pupae were carefully removed and set up under laboratory conditions to monitor emergence of adult *Aleochara*. The emergence stage lasted 35 days.

The percentage reduction in parasitism compared to the control was 66.6% for the 'Cruiser SB' treatment and 99.9% for the toxic standard treatment. Both reductions were statistically different. The actual levels of parasitism were 21.2 % in the control, 7.1 % in the 'Cruiser SB' treatment and < 0.1 % in the toxic standard treatment. 'Cruiser WS70' applied at a rate of 70 g a.s./ 100 kg seeds (equivalent to 140 g a.s./ha with a seed density of 200 kg wheat seeds/ha) resulted in a 66.6 % reduction of *A. bilineata* fecundity compared to the control under semi-field conditions.

This study was performed according to Barrett *et al* (1994), Moreth & Naton (1992) and Naton (1988) and in accordance with GLP.

(Candolfi 1998b)

B.9.5.4 Field studies

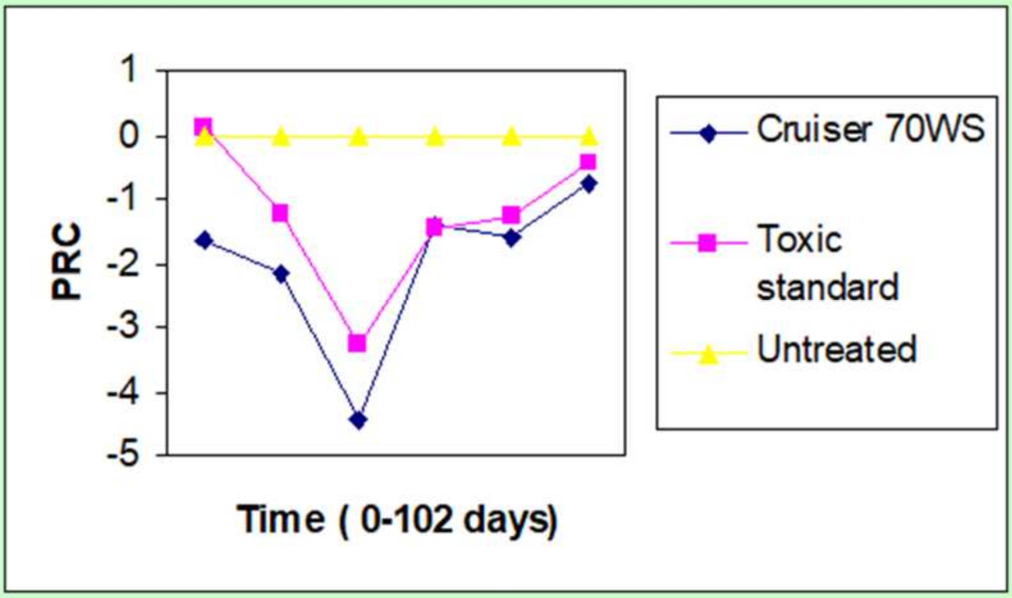
No field studies were conducted with the proposed formulation 'Cruiser 350FS' but a range of other formulations were used in four field studies.

a) In a field study near Leipzig in Germany, the effects of a thiamethoxam seed treatment on non-target arthropods in a spring barley crop was examined. The size of the test field was 12.6 ha, with treatment replicate plot sizes ranging from 0.9 to 1.2 ha. Three treatments were set up, with four replicate plots per treatment: untreated, seed treated with 100 g 'Cruiser 70WS'/100 kg seed, and toxic standard (untreated seed with granular carbofuran at 470 g a.s./ha). Seeds were sown at 150 kg/ha, giving a thiamethoxam equivalent rate of 105 g a.s./ha.

Sampling was carried out over 102 days, covering key crop stages from sowing to shortly before harvest. Pitfall traps (8 per plot) were used to sample surface-active soil dwelling arthropods. Pitfall trapping was carried out continuously from 13 April to 3 August, giving 10 trapping periods, each of one or two week's duration. However during four trapping periods, traps were lost to a variety of causes (flooding, mud, mice). Consequently arthropod taxa were identified from only six sampling periods during the growing season (13 April – 25 May continuously; 1-14 June and 25 June-6 July) Photo-eclectors (5 per plot) were used to sample phototactic arthropods; taxa from four sampling periods performed during the growing season were identified (10 June – 3 August continuously). Aphid counts were also performed four times during the growing season.

The data were analysed for community response to the different treatments using Principle Response Curves (multivariate analysis); and Dunnett-tests on different taxonomic levels for population density dynamics and number of taxa (univariate analysis).

Figure B.9.14. Principal response curve for non-target invertebrates



In the pitfall traps, there was no significant difference in the number of taxa between the test substance treatment and the control from 52 days after sowing. In the photo-eclectors, there was no significant difference in the number of taxa between the test substance treatment and the control from 89 days after sowing.

Univariate population analyses of pitfall trap catches indicated that the 'Cruiser SB' treatment transiently affected a range of soil surface active ground dwelling arthropod taxa. This was followed by recovery of the catches to levels similar to the control. Of 247 species-level taxa identified, 22 showed statistically significant differences between the 'Cruiser SB' treatment and the control at some time during the sampling period. Main taxonomic groupings were also summed for analysis. The most affected taxa were the Collembola ('springtails', families Sminthuridae and Entomobryoidae), the rove beetles Callericerini, Oxypodini, *Gyrohypnus angustatus* and *Oxytelus rugosus* (Coleoptera: Staphylinidae), wolf spiders (Araneae: Lycosidae) and money spiders (Araneae: Linyphiidae). However, by the end of the sampling period, 102 days after sowing, all groups had recovered to control levels, with the exception of the Collembola. Note that population development of Collembola was similar to that in the control from Day 52 onwards, indicating that their populations were recovering. Numbers of Collembola in all treatments were in natural seasonal decline by the end of the sampling period and catch numbers were too low for definitive conclusions to be made. No significant treatment effects were observed in the abundantly caught Hymenoptera (wasps & bees; excluding ants in this analysis), Diptera (flies) and Acari (mites).

Significant differences between treatment and control were observed on some phototactic arthropod populations caught in the photo-eclectors until 89 days after sowing. Of 87 species-level taxa identified, 12 showed statistically significant differences between the 'Cruiser SB' treatment and the control at some time during the sampling period. Main taxonomic groupings were also summed for analysis. The most affected groups included the target pests Aphidiidae ('aphids', Homoptera), Thysanoptera ('thrips') and Ciccadellidae ('leafhoppers', Homoptera). Probably due to a reduction of hosts and prey, some groups of parasitoids and predators were similarly affected for a time period up to 89 days after sowing: Syrphidae ('hover flies', Diptera), Myrmaridae ('fairy flies', Hymenoptera), Ichneumonid wasps (Hymenoptera: Ichneumonidae) and Coccinellidae ('ladybird beetles', Coleoptera). The most abundant insect groups were not affected: the Phoridae ('phorid flies', Diptera), Cecidomyiidae

		('gall midges', Diptera), Drosophilidae ('fruit flies', Diptera) and Muscidae ('house flies', Diptera); none of which are dependent on the pest species as hosts or prey. Results of the multivariate analysis supported results from the univariate analyses. The test treatment generally had little impact on the variation observed in the different communities in the Principle Response Curve (PRC) analysis. Most of the variation was a result of population dynamics due to seasonal or random effects, rather than treatment. In the pitfall trap catch PRC analysis, only 16% of the variance was explained by treatment, whilst 57% was explained by time (seasonal effects). Nevertheless, a high proportion of that variance explained by treatment, 45.7%, could be described by the first component of the PRC. In the photo-eclector catches, again only 16% of the variance was explained by treatment, whilst 48.4% was explained by time. Of that variance explained by treatment, 50.4% could be described by the first component of the PRC. The PRC of the pitfall trap data, which is a more sensitive indicator than the statistical analysis of individual taxa because it incorporates the whole data set, showed significant reductions of arthropod populations up to the end of the sampling period, 102 days after sowing. A marked drop in the PRC of the test treatment was observed until day 32; after day 32 the difference between the treatment and the control gradually decreased, indicating a recovery period. The groups which most influenced the PRC were the Collembola (Sminthuridae and Entomobryoidae), Carabidae and Staphylinidae. The PRC of the photo-eclector samples was also strongly influenced by the reduction of the target pest species, as would be expected from an insecticide treatment. The three aphid genera: *Metoplophium*, *Rhopalosiphum* and *Macrosiphum* contributed most strongly to the curve, which initially dropped from the first sampling on day 61 until day 75 after sowing, and then gradually increased. The observed reduction was significant until day 89. Further pest species that contributed to the difference in the PRC compared to control were thrips (Thysanoptera) and leafhoppers (Homoptera: Cicadellidae). Of the non-pest species, most of the taxa influencing the PRC contained important predators and parasitoids of the above-mentioned pests: Syrphidae (significantly lower than control on day 75), Mymaridae (significant on day 61), Ichneumonidae (significant on day 89) and Coccinellidae (significant on day 102). These are highly mobile arthropod groups which are likely to be attracted by the presence of hosts or prey. Very abundant taxa which are not bound to the phytophagous (herbivorous) species as predators or parasitoids did not show a significant difference from the control on any day in the univariate analyses, e.g. the Phoridae, Cecidomyiidae, Drosophilidae and Muscidae (whereas the Dipteran Syrphidae did show a difference from control). Therefore, it appears that the PRC was also influenced *indirectly* by the effect of the test item on the target pest species. The reference item, carbofuran, resulted in a significant reduction of individuals in the pitfall traps 14 and 32 days after sowing, and a reduction in the number of taxa present 32 days after sowing. A significant effect of the reference item on the number of taxa recorded in the photo-eclector samples was detected on day 61 after sowing. The PRC showed a significant effect of the reference item until day 74. Treatment of barley seeds with the 'Cruiser WS70' at a rate equivalent to 105 g a.s./ha, initially affected a range of soil surface active and phototactic ground dwelling arthropod taxa. Both phytophagous and predatory arthropods were affected. This was followed by recovery to control levels in most cases by the end of the sampling period, 102 days after sowing. Collembola did not fully recover to control levels by the end of the sampling period. However, Collembola populations were in seasonal decline in all treatments at the end of the sampling period, so numbers were too low for definitive

conclusions. Changes in the arthropod community due to treatment were mainly influenced by Collembola and aphids. There were no effects of the test substance on the number of taxa caught (diversity) from 89 days after sowing.

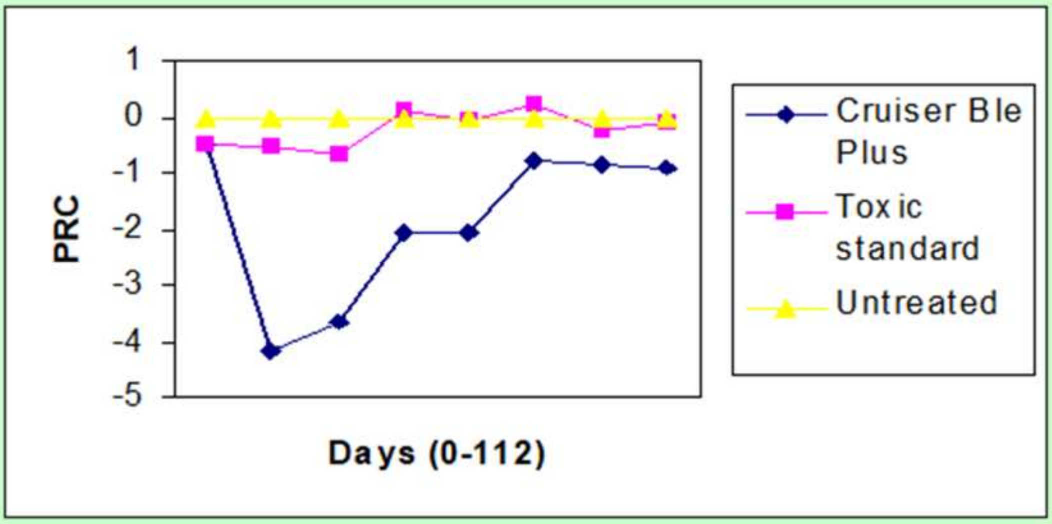
This study was performed according to ESCORT guidelines (Barrett *et al* 1994), MAFF & HSE (1995) and Hassan (1992) and in compliance with GLP. [redacted]

b) In a field study near Mulhouse in France, the effects of 'Cruiser Ble Plus' applied to sprin wheat seed on non-target arthropods was investigated. Note that 'Cruiser Ble Plus' contains 137 g/l thiamethoxam plus 51 g/l of the insecticide tefluthrin, 13.3 g/l difenoconazole and 13.3 g/l fludioxonil. 'Cruiser Ble Plus' was applied to seed at a rate o 400 ml/100kg seed. Sowing rate was 175 kg seed/ha (equivalent to a nominal rate of 92 thiamethoxam/ha).

Three sampling methods were used. Pitfall traps (eight traps per plot) were used to sample surface active, ground dwelling arthropods. Sampling was carried out continuously between 19 April and 18 August (112 days), covering key crop stages from sowing to shortly before harvest. There were 10 individual sampling periods of approximately 10 days each but four were lost to a variety of causes. Arthropods collected in eight sampling periods throughout the growing season were identified. Photo-eclectors (five per plot) were used to sample photo-tactic arthropods emerging from the soil and collected individuals from three sampling periods between 1 July and 16 August were identified. Foliar sweep-net samples were also collected on three occasions (mid-July, late July and mid-August) .

The resulting data were analysed for community response to the different treatments using Principle Response Curves (multivariate analysis); and Dunnett-tests on different taxonomic levels for population density dynamics and number of taxa (univariate analysis).

Figure B.9.15 Principal response curve for non-target invertebrates



For each of the eight sampling periods, the value for the 'Cruiser Ble Plus' plots was statistically significantly different from the untreated (P=0.05).

A total of 181 taxa were observed and identified in the pitfall traps throughout the trial. The number of taxa in test substance treatment was significantly different from the

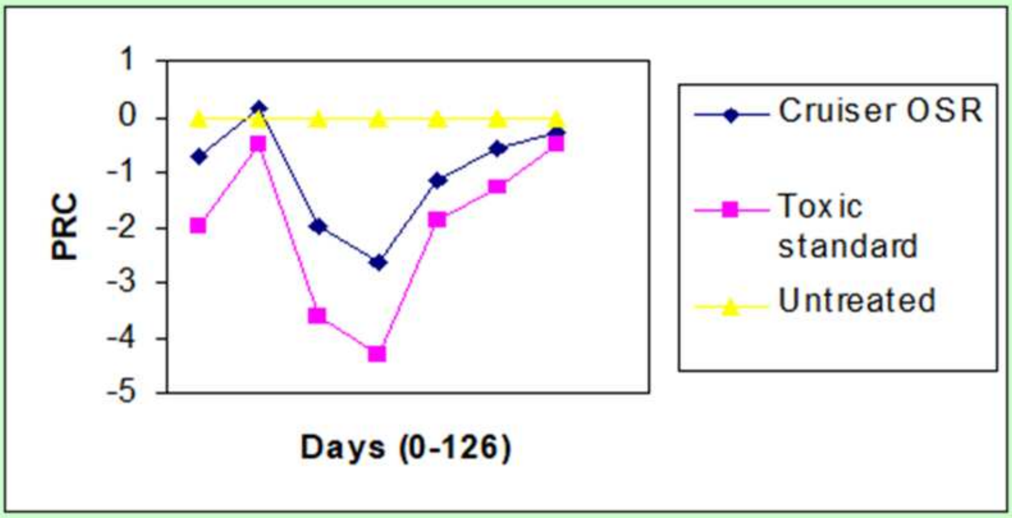
		control only at 44 days after sowing; there were no other significant differences. In the photo-eclectors and sweep-net samples, there were no significant differences in the number of taxa between the test substance treatment and the control on any occasion. In the photo-eclectors, in most cases there was no evidence of a lower abundance of taxa in the test item plots compared to the control. Of the 136 taxa observed throughout the study, 16 showed a significant difference from the control in at least one of the sampling dates; only nine of these indicated a reduction in numbers compared to the control. In the sweep-net samples, in most cases there was no evidence of a real difference in the abundance of taxa in the treatment groups (test item or toxic standard) compared to the untreated control. A detectable difference was found in ten of the 97 observed taxa, in at least one of the treatment groups and sampling dates. The main factors influencing the community response in the test item treatment pitfall trap catches were the numbers of Collembola (family Sminthuridae), and the numbers of aphids. The latter are the main target species; both taxa are potential prey items for a range of non-target predatory arthropods. Some predatory arthropod species also added significant weight to the community response in the pitfall traps. The most influential of these was Coccinellidae larvae ('ladybird beetles'; aphid-specific predators), though it is highly likely that their response was, at least in part, a secondary effect due to the major removal of potential prey causing the predators to relocate. In the photoeclector samples the main community effect drivers were Cicadellidae ('leaf hoppers') and the Collembola family Sminthuridae, both of which taxa contain phytophagous pest species and are prey for non-target predatory arthropods. The Collembola family Entomobryoidea, which consists mainly of fungivorous species, had a significantly 'negative' value compared to the control, i.e. they were more relatively abundant in the treatment community than in the control catches. In the sweep-net samples, again there was a significant community response to the test item treatment on all three sampling occasions. Also again, the main groups influencing the community response were phytophagous potential pest taxa: Ciccadellidae ('leaf hoppers'), Sminthuridae (Collembola) and Heteroptera ('bugs'). All three sampling methods showed significant differences between the toxic standard and control population abundances for some taxa and sampling occasions. Wheat seed treatment with 'Cruiser Ble Plus' (equivalent to 92 g thiamethoxam/ha) caused significant effects on arthropod population and community dynamics. However, the main groups influencing the community response were target or potential secondary pest species. Therefore, the study author considered it likely that effects on the abundances of some predatory non-target arthropod species were indirect effects, caused by relocation of these predators to areas with a higher abundance of prey items. There were no effects of the test substance on the number of taxa caught (diversity) from 44 days after sowing. This study was performed according to ESCORT guidelines (Barrett *et al* 1994), MAFF & HSE (1995) and Hassan (1992) and in compliance with GLP. [redacted]
	c)	The effects of 'Cruiser OSR' (containing 28% w/w thiamethoxam plus 3% w/w metalaxyl- and 0.8% w/w fludioxonil) on non-target arthropods was investigated in a field study near

Leipzig in Germany. 'Cruiser OSR' was applied to spring oilseed rape seed at a rate of 1 litres/100kg seed. Sowing rate was 8 kg seed/ha (equivalent to a nominal rate of 34 g thiamethoxam/ha).

Pitfall traps (8 traps per plot) were used to sample surface active, ground dwelling arthropods. Sampling was carried out continuously between 21 April and 25 August (126 days), covering key crop stages from sowing to shortly before harvest. There were 12 individual sampling periods of approximately 10 days each but five were lost to a variety of causes. Arthropods collected in seven sampling periods throughout the growing season were identified.

The resulting data were analysed for community response to the different treatments using Principle Response Curves (multivariate analysis); and Dunnett-tests on different taxonomic levels for population density dynamics and number of taxa (univariate analysis).

Figure B.9.16 Principal response curve for non-target invertebrates



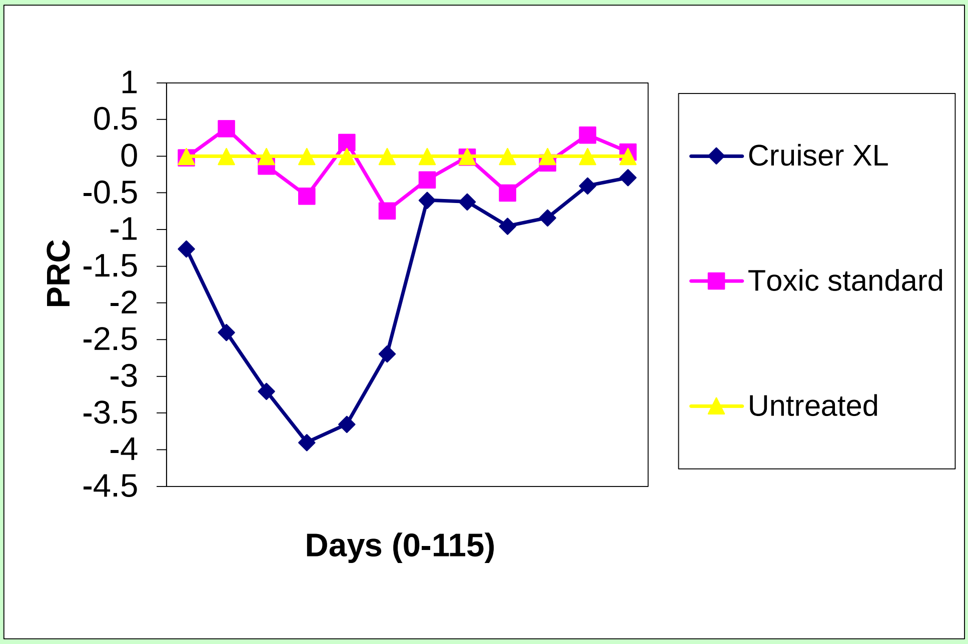
For four of the seven sampling periods, the value for the 'Cruiser OSR' plots was statistically significantly different from the untreated (P=0.05) but the difference was not significant for the last two sampling periods.

Photo-eclectors (5 per plot) were used to sample photo-tactic arthropods emerging from the soil, and individuals collected from six sampling periods were identified. Pest pressure of aphids was assessed by visual inspection of plants on 4 days during the test, and pollen beetles (*Meligethes* spp.) were counted using the beating method on 3 sampling days.

In the pitfall trap samples, 13 of 193 taxa (6.7%) showed a statistically significant reduction in abundance in the test item treatment during at least one sampling period. However only 1 out of 193 taxa revealed statistically significantly lower abundances on the last sampling interval, *Agonum muelleri* (Coleoptera: Carabidae). The lower abundances of *A. muelleri* were considered more likely to be related to an abundance peak due to chance fluctuations in the control than to any treatment effect. Collembola of the family Sminthuridae showed a statistically significant reduction in abundance over a longer time, as recovery by the end of the test period could not be fully demonstrated in this taxon.

		In the photo-eclector samples, 5 of the 80 different taxa (6.3 %) showed a statistically significant reduction in abundance in the 'Cruiser OSR' treatment during one or more sampling periods. Most of the taxa that were collected reliably by this method, as reflected by high numbers in the samples, were not affected by the test treatment during any sampling period. Five taxa had higher abundances in the treatments than in the control during different sampling periods, and none of the abundantly collected Diptera taxa, or Araneae, showed any treatment effect on their population densities throughout the sampling period. The treatment effect on composition of the ground dwelling arthropod community sampled with pitfall traps persisted until day 75. From day 54, recovery occurred rapidly in the treatment plots up until day 75; and from thereon there was no statistically significant difference between the control and the 'Cruiser OSR' treatment up to the end of the sampling period, 126 days after sowing. The main contributor to the PRC was Sminthuridae (Collembola). In the arthropod community collected with photo-eclectors, no statistically significant treatment effects on community composition were detected at any time throughout the sampling period. The reference item carbofuran showed a distinct and statistically significant treatment effect in the ground dwelling arthropod community, from immediately after study initiation until 103 days after sowing. No clear effect was detectable in the reference item community of photo-tactic arthropods. This study was performed according to ESCORT guidelines (Barrett *et al* 1994), Candolfi *et al* (1992) and Hassan (1992) and in compliance with GLP. [redacted]
	d)	The effects of 'Cruiser XL 424.6FS' (containing 417 g/l thiamethoxam plus 4 g/l fludioxon and 1.3 g/l metalaxyl-m) on non-target arthropods was investigated in a field study near Hausgauen in France. 'Cruiser XL' was applied to maize seed at a rate of 0.75 litres/100kg seed. Sowing rate was 33.6 kg seed/ha (equivalent to a nominal rate of 105 g thiamethoxam/ha). Pitfall traps (8 traps per plot) were used to sample surface active, ground dwelling arthropods. Sampling was carried out continuously between 29 May and 20 September (115 days), covering key crop stages from sowing to shortly before harvest. There were 12 individual sampling periods of approximately 10 days each and none were lost. Arthropods collected in 12 sampling periods throughout the growing season were identified. The resulting data were analysed for community response to the different treatments using Principle Response Curves (multivariate analysis); and Dunnett-tests on different taxonomic levels for population density dynamics and number of taxa (univariate analysis).

Figure B.9.17 Principal response curve for non-target invertebrates



For nine of the 12 sampling periods, the value for the 'Cruiser XL' plots was statistically significantly different from the untreated (P=0.05) but the difference was not significant for the last two sampling periods.

Photo-eclectors (5 per plot) were used to sample photo-tactic arthropods emerging from the soil, with samples from three periods identified (late July, mid-August and mid-September). Leaf dwelling arthropods were sampled by a beating method (100 maize plants per plot) on five days during the test (mid and late July, mid and late August and mid September).

In the pitfall traps there were no significant differences in the number of taxa between the 'Cruiser XL' plots and the control on any occasion. In the photo-eclector samples there were significant differences in the number of taxa between the 'Cruiser XL' treatment and the control in the first two sampling periods; in the last photo-eclector sampling period there was no significant difference.

In the univariate analyses, 13 of the 199 taxa collected in pitfall traps showed a statistically significant reduction in abundance compared to the control at some time during the test period. Collembola of the family Sminthuridae showed a statistically significant reduction in abundance in the first half of the sampling period. Recovery of this taxa could not be demonstrated as population densities remained on an extremely low level thereafter in all treatments.

In the photo-eclector samples, 136 taxa were identified and 11 taxa showed significantly lower numbers in the 'Cruiser XL' treatment compared to the control at some time during the sampling period. All affected taxa showed recovery by the last sampling period, or were considered to be chance probability effects, with the exception of the 'fungus gnats' (Diptera: Mycetophilidae) and the Sminthuridae. The 'fungus gnats' were likely to have been indirectly affected by the fungicidal component of the formulation acting on their food supply, as well as by the insecticidal component [though no such significant effect on Mycetophilidae was detected in an oilseed rape study with the same active substances, conducted in a different country]. In the Sminthuridae, statistically significant effects persisted until the end of the sampling period.

	In beating samples, of the 97 taxa identified, seven showed significantly lower catches in the test substance treatment compared to the control. There was a significantly lower population density in various Homopteran taxa in the test item plots, compared to control, and a lower Sminthuridae catch in the last sampling days (though the latter was not statistically significant due to high variability). Both of these taxa include mainly phytophagous groups which may have been feeding on sap of the crop plants, and thus may be considered as pests which had been affected by the systemic test substance. Tetragnathid spiders were also present in lower abundances in the test treatment than in the control on the last sampling date. However, as their abundance generally followed the population curve of the control, the study author considered that this was more likely to be explained by chance than by a true treatment-related response. No other spider taxa found in the beating samples showed any significant treatment effect. Results of the multivariate analysis supported results from the univariate analyses. In the PRC analysis, generally, the test treatment had little impact on the variation observed in the different communities. Most of the variation in abundances was as a result of population dynamics due to seasonal changes, which result in variations in species composition. For all three trapping methods, it was shown in the multivariate PRC analysis that about 90% of the total variation was not related to treatment but was either due to time (seasonal changes) or should be classified as random. Nevertheless, the first component of the PRC was able to explain a relatively high percentage of the remaining treatment-related variation (between 37% and 58%). For the ground dwelling arthropod community that was recorded using pitfall traps, there was a strong treatment-related effect that occurred directly after sowing but which had disappeared by the end of the growing season. The treatment effect on the composition of the ground dwelling arthropod community sampled with pitfall traps persisted until day 94 after sowing, and can be described in three steps: from planting until day 34 after sowing the treatment effect was most pronounced; after day 34 recovery occurred quickly until day 62, and then more slowly until day 94 after sowing. By 94 days after sowing, the arthropod community of the ‘Cruiser XL’ treatment was not significantly different in composition to that in the control. The main community driver in the pitfall traps was the Sminthuridae. Statistically significant treatment effects were observed in the composition of the photo-tactic arthropod community collected with photo-eclectors throughout the sampling period. The test treatment effect on community composition was to a high degree explained by the behaviour of the two taxa Sminthuridae and ‘fungus gnats’ (Mycetophilidae), which were the most abundant groups collected by the photo-eclectors. The leaf dwelling arthropod community, collected by beating, showed a significant treatment effect in the last two samples, days 94 and 112 after sowing. The treatment effect on the community composition could be explained by the decrease in the population density of various Homopteran taxa and a decrease in Sminthuridae catch numbers in the last two sampling days. The study author considered it is likely that many of the Sminthuridae present were phytophagous (herbivores). It was notable that the Entomobryoidea, the other main family of Collembola collected in high numbers, did not show any reduction in abundance. The Entomobryoidea feed almost exclusively on fungi. Therefore, it was considered more likely that the Sminthuridae, a potential secondary pest, were affected by the insecticide in the plants than by the fungicide component of the formulation.

Overall, the observed treatment effects on the total arthropod community in the maize field could be explained by the behaviour of three groups. The 'fungus gnats' (Mycetophilidae) are likely to have been affected indirectly by the fungicidal component of the test substance acting on their food supply, as well as potentially by the insecticidal component. These were among the most abundant taxa in the photo-eclector samples, so the decrease in numbers caught had a strong influence on the community composition of the catches. Secondly, the phytophagous 'aphids' (Homoptera) and 'leaf hoppers' (Cicadellidae) in their various life stages, and other taxa in the Hemiptera ('bugs'), had a great impact on the composition of the communities caught in the photo-eclector and beating samples. Many of these taxa are herbivorous potential pest species. Thirdly, the most influential taxon on community composition, due to the high numbers trapped by all three methods, was the Collembolan family Sminthuridae. The population density of this group was probably affected by the test item because some species feed directly on maize plants. The study author deduced that all phytophagous taxa that feed on the sap of maize plants were affected by the test treatment. The majority of all other arthropod taxa sampled adequately during the study showed full or incipient recovery of numbers trapped within 112 days after sowing. The exceptions were the taxa that decreased in all treatments to an extremely low level, due to natural seasonal population or activity declines, which made it impossible to demonstrate recovery. Effects on some predatory species due to systemic insecticides were considered likely to have been an indirect result of treatment, as sufficiently mobile predators will relocate due to the reductions in prey numbers in the treated plots.

Treatment of maize seeds with the 'Cruiser XL 424.6 FS' (105 g thiamethoxam/ha) initially affected a range of foliar dwelling and soil surface active and phototactic ground dwelling arthropod taxa. This trend was followed by recovery to control levels in most cases by the end of the sampling period, 112 days after sowing. Community effects were largely influenced by the population dynamics of the Sminthuridae. The majority of all other arthropods sampled adequately during the study showed recovery of trapped numbers by the end of the sampling period. Exceptions were a few taxa that decreased in all treatments, due to normal seasonal decline. There were no effects of the test substance on the number of taxa caught (diversity) by the end of the test period.

This study was performed according to ESCORT guidelines (Barrett *et al* 1994), Candolfi *et al* (2000) and Hassan (1992) and in compliance with GLP. [redacted]

B.9.5.5 Metabolites

a) In a non-GLP screening study, four metabolites of thiamethoxam were tested for insecticidal activity against a range of insect and mite pest species. Seven species were exposed to each metabolite, either by contact to dry spray deposits (100 mg/l) on leaf discs or systemically by placing infested plants directly into test solutions. Results are summarised in Table B.9.70.

Table B.9.70 Results of screening tests on four metabolites against insects and mites

Test Species Life stage	Test Method	Mortality [%]			
		CGA 355190	NOA 404617	NOA 407475	CGA 322704
Aphis craccivora mixed population	contact	0	0	0	100
Myzus persicae mixed population	systemic	0	0	0	100

Spodoptera littoralis L-1	feeding contact	0	0	0	100
Spodoptera littoralis L-1	systemic	0	0	0	100
Heliothis virescens egg-larva	egg mortality L-1 mortality L-1 effect	0 0 0	0 0 0	0 0 0	100 - -
Diabrotica balteata L-2	feeding contact	0	0	0	100
Nilaparvata lugens N-3 / F-1	N-3 mortality F-1 reduction	0	0	0 0	0 100
Tetranychus urticae mixed population	egg mortality larval mortality adult mortality	0 0 0	0 0 0	0 0 0	0 0 0

The main metabolite of thiamethoxam, CGA 322704, exhibited broad insecticidal activity but had no effects on mites at the tested rates. The other tested metabolites, CGA 355190, NOA 404617 and NOA 407475 showed no biological activity on any of the tested arthropod species.

No guidelines were cited for this study which was not conducted in accordance with GLP.

[redacted]

b) In a non-GLP screening study, metabolite NOA 459602 was tested for insecticidal activity against a range of insect species. Exposure to NOA 459602 was either to dry spray deposits on leaves, to direct spray or systemically by feeding. A range of doses were tested from 0.4-12.5 mg/l. No mortality was seen to *Myzus persicae* and *Aphis craccivora* (Aphididae), *Spodoptera* larvae (Lepidoptera), *Diabrotica* larvae (Coleoptera, Chrysomelidae) or *Nilaparvata* nymphs (Homoptera). Thiamethoxam was also tested against the same species at identical doses and gave 33-100% mortality (>70% in most cases).

No guidelines were cited for this study which was not conducted in accordance with GLP.

[redacted]

c) In a non-GLP study, metabolite SYN 501406 was tested for insecticidal activity against a range of insect species using the same methodology as Rindlisbacher (2001a) above. No mortality was seen to *Myzus persicae* and *Aphis craccivora* (Aphididae), *Spodoptera* larvae (Lepidoptera), *Diabrotica* larvae (Coleoptera, Chrysomelidae) or *Nilaparvata* nymphs (Homoptera). Thiamethoxam was also tested against the same species at identical doses and gave 95-100% mortality.

No guidelines were cited for this study which was not conducted in accordance with GLP.

[redacted]

B.9.5.6 Risk assessment

It should be noted that the risk to non-target arthropods from a plant protection product is usually assessed using ESCORT 2 (see Candolfi *et al* 2001). According to Candolfi *et al* when a seed treatment is being considered, data on spiders and

ground dwelling beetles should be considered. Outlined below is a summary of all the toxicity data that has been submitted including ground dwelling and leaf dwelling non-target arthropods. Data on the effects of thiamethoxam as well as the metabolite CGA 322704 on the soil mite are also included below. The risk that thiamethoxam poses to these organisms is also assessed. (The effects of thiamethoxam and the metabolite CGA 322704 on soil *function* are considered in Section B.9.7.1)

'Cruiser SB' is to be used as a seed treatment on sugar beet. Exposure to the off-field environment is unlikely and therefore only the risk to non-target arthropods in the cropped area will be considered. The non-target arthropod groups most likely to come into direct contact with treated seed include surface or sub-surface-active polyphagous predators such as carabid or staphylinid beetles and their larvae, as well as other soil-dwelling species (e.g. phytophagus collembolans).

Laboratory tier studies

Laboratory toxicity tests on the ground-dwelling non-target arthropods *Poecilus cupreus* and *Aleochara bilineata* have been carried out with the formulation 'Cruiser 350FS'. 'Cruiser 350FS' was applied to cereal seeds at the rate of approximately 0.035 mg a.s./seed which was calculated to be equivalent to 140 g a.s./ha (see Grimm 1998 (a) and (b)). In these tier I laboratory studies 'Cruiser 350FS' caused 100% and 90% mortality of these species, respectively. The seed loading for sugar beet is 0.6 mg a.s./ha whilst the application rate is equivalent to 78 g a.s./ha. It is clear that these studies were done at significantly greater application rates in terms of g/ha, but the seed loading was significantly less – i.e., 0.035 vs 0.6 mg a.s/seed. This means that should an arthropod encounter a treated seed it will be at greater potential risk from the sugar beet seed, due to the higher seed loading, than the cereal seed. However, what also needs to be considered is the density of seed, it is clear that cereal seeds are sown at approximately 30 times the rate of sugar beet, therefore whilst the concentration per seed is greater on sugar beet, the number of seeds and overall concentration per hectare is greater for cereals. On balance, it is considered that these studies highlight a potentially high risk to soil dwelling beetles from the use of thiamethoxam on sugar beet seed.

In addition, under extended laboratory conditions (natural soil substrate) 'Cruiser 350FS' was harmful (100% mortality) to larvae of *P. cupreus* when applied to pea seeds at a rate equivalent to 3750 g a.s./ha (see Reber 2000).

The above studies indicate a high risk to soil dwelling beetles that requires further consideration – see below for details.

It is customary to considered data on soil mites, eg *Folsomia candida*, under the section on effects on soil macro-invertebrates (see Annex III Section 10.6.2). However, as this particular assessment is concerned with a seed treatment it is considered appropriate to assess the risk to soil mites as part of the non-target arthropod assessment. In a laboratory reproduction study using the collembolan *Folsomia candida*, the EC50 for reproduction was 5.61 mg a.s./kg substrate, whilst the NOEC was 2.88 mg a.s./kg substrate (Meister 2001a). When assessing the risk to soil mites, it is usual to compare the NOEC with the soil PEC, if this is done for above endpoint a TER is determined 27.7. According to the Terrestrial Guidance document as the TER is greater than 5, then the risk is to soil function is low.

Data were submitted on the metabolite CGA 322704 and these indicate that this compound is more toxic to *Folsomia candida* with a NOEC of less than 0.15 mg/kg soil (Meister 2001b). If the NOEC of <0.15 mg/kg is compared to the soil PEC of 0.0312 mg/kg for this metabolite, a TER of less than 4.8 is produced. The mite *Hypoaspis aculeifer* was less sensitive with a NOEC of 100 mg/kg (Moser 2005); comparing this endpoint with the above soil PEC a TER of 3200, indicating a low risk.

The first-tier risk assessment on soil mites indicates that the risk to soil function is low risk, however higher tier data on the structure of soil organisms have been submitted and this is considered below.

Semi-field studies

In a semi-field study on *P. cupreus* using the seed treatment formulation 'Cruiser 70 WS' applied to seed at a rate of 0.035 mg a.s./seed assuming 20000 seeds/kg which was deemed to be equivalent to 140 g a.s./ha, corrected mortality of 18.9% was observed after 14 days of exposure (see Candolfi 1998a). However, it should be noted that at this time 33.3% of the surviving beetles demonstrated co-ordination problems and the mortality was still increasing (8.9 % corrected mortality during the second week of exposure). Therefore, it cannot be ruled out that should the exposure period have been extended further treatment-related mortalities could have occurred. Despite this the percentage of beetles either dead, or demonstrating co-ordination problems, at the end of the test was 46% when corrected for the control treatment. Therefore the effect levels recorded with *P.cupreus* under semi-field conditions were slightly below the 'harmful' trigger value of 50% (Candolfi *et al*, 2000[36], 2001[37]). The Staphylinid beetle *A. bilineata* was more sensitive, as a 66% reduction in parasitism of onion fly pupae was observed in a study with the same formulation and application rate (see Candolfi 1998b).

Based on the above studies 'Cruiser SB' seed treatment is considered to pose a potential risk to non-target arthropods that requires further consideration.

Field studies

Due to the results of the first tier risk assessment, the Notifier has carried out four field trials. These are briefly summarised in Table B.9.71 and discussed in more detail below.

Table B.9.71 Summary of results from four field trials on natural populations of non-target arthropods

Form.n	Crop	g a.s./ha	Summary of results
'Cruiser 70WS'	Spring barley	105	Initially, both phytophagous and predatory arthropods were affected. This was followed by recovery to control levels in most cases by the end of the sampling period, 102 days after sowing. Collembola did not fully recover to control levels by the end of the sampling period but populations were in seasonal decline at this stage. However, population development from day 52 was similar to untreated plots. Changes in the arthropod community due to treatment were mainly

[36] Candolfi M., F. Bigler, P. Campbell, U. Heimbach, R. Schmuck, G. Angeli, F. Bakker, K. Brown, G. Carli, A. Dinter, D. Forti, R. Forster, A. Gathmann, S. Hassan, M. Mead-Briggs, M. Melandri, P. Neumann, E. Pasqualini, W. Powell, J.-N. Reboulet, K. Romijn, B. Sechser, T. Thieme, A. Ufer, C. Vergnet and H. Vogt. 2000. Principles for regulatory testing and interpretation of semi-field and field studies with non-target arthropods. Journal of Pesticide Science 73(6): 141-147.
[37] Candolfi M., K.L., Barrett, P. Campbell, R. Forster, N., Grandy, M.-C, Huet., G. Lewis, P.A. Oomen, R. Schmuck & H. Vogt. 2001. Guidance document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods. Proceedings of the European Standard Characteristics Of non-target arthropod Regulatory Testing workshop ESCORT 2, Wageningen, The Netherlands, 21-23 March 2000.

			influenced by the pest species aphids and phytophagous collembola. There were no effects of the test substance on the number of taxa caught (diversity) from 89 days after sowing.
'Cruiser Ble Plus'	Spring wheat	92	Significant effects on arthropod population and community dynamics were seen. However, the main groups influencing the community response were target or potential secondary pest species. Therefore, it is likely that effects on the abundances of some predatory non-target arthropod species were indirect effects, caused by relocation of these predators to areas with a higher abundance of prey items. There were no effects of the test substance on the number of taxa caught (diversity) from 44 days after sowing. The presence of tefluthrin at 8.75 g a.s./ha does not seem to have affected the magnitude and duration of effects compared with the 2 other studies where thiamethoxam was used at a higher rate.
'Cruiser OSR'	Spring oilseed rape	34	In pitfall trap samples, 13 of 193 taxa (6.7%) showed a statistically significant reduction in abundance in the test item treatment during at least one sampling period. However only 1 out of 193 taxa revealed statistically significantly lower abundance at the last sampling day (126 days after sowing). Collembola of the family Sminthuridae showed a statistically significant reduction in abundance over a longer time period, as recovery by the end of the test period could not be fully demonstrated.
'Cruiser XL 424.6FS'	Maize	105	A range of phototactic foliar dwelling and soil surface active arthropod taxa were initially affected. This was followed by recovery to control levels in most cases by 112 days after sowing. Community effects were largely influenced by the population dynamics of the Sminthuridae. The majority of other arthropods showed recovery of numbers by the end of the sampling period. Exceptions were a few taxa that decreased in all treatments, due to normal seasonal decline, to such low numbers that it was not possible to demonstrate recovery. There were no effects of the test substance on the number of taxa caught (diversity) by the end of the test period. It should be noted that in this trial a few taxa decreased in all treatment groups, due to normal seasonal decline, to such low numbers that it was not possible to demonstrate recovery.

From the detailed summaries, as well as Table B.9.69, it can be seen that a wide range of species were adversely effected, however recovery was noted in most species. The most sensitive group affected were Collembolan, and hence the following assessment will focus on these.

(It should be noted that in the trial using 'Cruiser XL 424.6FS' treated maize seeds a few taxa decreased in all treatment groups, due to normal seasonal decline, to such low numbers that it was not possible to demonstrate recovery.)

The Notifier has submitted a risk assessment, and this is presented in full at Appendix 8[38], however, outlined below is the evaluator's assessment.

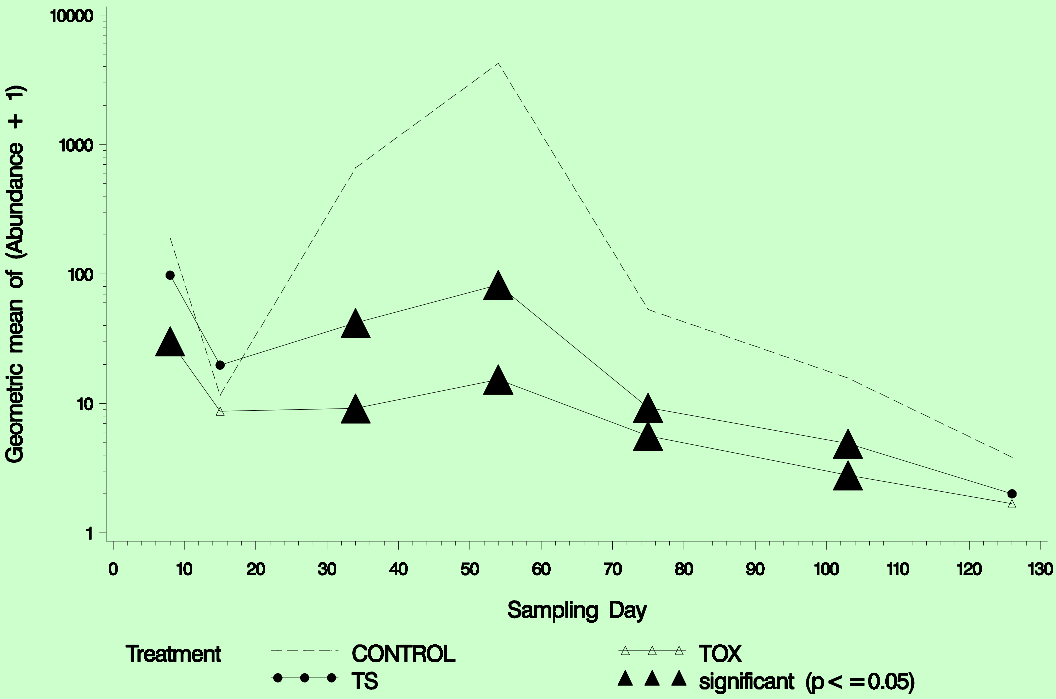
a) Effects on collembolan populations

In the field studies a significant effect was observed in collembolan populations following an application of thiamethoxam treated seeds, which was followed by a period of recovery. The collembolan populations in the treatment groups were generally seen to mimic the pattern seen in the control group (Figure B.9.18). The Notifier s risk assessment is presented in full at Appendix 8, however, outlined below evaluators assessment.

[38] Appendix 8 has not be included, but is available if required.

Figure B.9.18 Population density of *Sminthuridae* (Collembola) in pitfall traps in the oilseed rape study (Grimm 2002b).

Day 0 = sowing, 21 April 1999; Day 126 = end of sampling, 25 August 1999; Day 128 = harvest, 27 August 1999.



b) Recovery

At the end of the field studies the populations of collembolan had recovered to levels which were no longer *statistically* significant in comparison to the control group. However it should be noted that the populations did not fully recover to equal the levels in the control. The Notifier has hypothesised that in-field populations of collembolan will recover by recolonisation from the off-crop habitats as well as reproduction of the surviving in-field populations. The Notifier has also stated that the long-term dynamics of collembolan populations seen in these field studies reflects the normal seasonal pattern, with natural increases seen in spring after soil cultivation, followed by a rapid decline in the hot, dry summer months of July and August. The Notifier proposes that populations of Collembola would be expected to increase again in the damp autumn. The populations in the thiamethoxam treatments at the end of the sampling periods in the field studies were not statistically different to the controls, and hence the population dynamics thereafter would be expected to be similar.

It is considered that the above argument is feasible and hence the studies indicate that the potential for recovery within the treated field.

c) Indirect effects on predatory arthropods

The Notifier has stated that there was a reduction in the number of predatory arthropods observed in the treatment groups compared to the control. The Notifier has proposed that this effect on population is due to the indirect effect of the pesticide and the reduction of potential food for the predatory arthropods and this is to be expected after an application of an insecticide. The Notifier has also suggested that the effect may be exaggerated by the migration of predatory arthropods from the treatment plots to the control plots where there is a higher abundance of food. Whilst it is acknowledged that this is a feasible situation, the evaluator wishes to note that the migration is not quantified. It is therefore impossible to determine whether the population of predatory arthropods in the control plot was amplified by such migration.

d) Effect on taxonomic diversity

There were no reported effects on the taxonomic diversity in the samples taken in any of the field trials.

B.9.5.8 Assessment

On the basis of the first-tier data a potential risk was highlighted, due to this several field studies were conducted.

On the basis of the information provided it is judged that, although collembolan populations did not fully recover to equal the control, the differences were no longer *statistically* significant and therefore indicate that the population dynamics of collembolan have the ability to cope with an application of thiamethoxam treated seeds when sown at the rates tested in the field trials. Therefore, on the basis of the four field studies as well as the above assessment and that provided by the Notifier (see Appendix 8) it is considered that there will be an initial impact on collembolan populations at the rates tested and that these populations should recover and be equivalent to untreated plots.

It should be noted that none of the field studies considered above were conducted using ‘Cruiser SB’, and therefore it is necessary to determine whether these studies provide sufficient information to enable to the risk from the use of ‘Cruiser SB’ to be fully assessed.

Information is presented in Table B.9.72 on the application rates, seed loadings etc for the crops assessed in the field trials summarised above, also presented is the same information for sugar beet.

Table B.9.72 Seed loading number of seeds per hectare

Crop	Concentration of thiamethoxam on seed (mg/kg fresh weight)	Weight of 1 seed (mg)	mg thiamethoxam /seed	Number of seeds/ha (x 10^6)	Dose per ha (g a.s./ha)
Barley	700	45	0.032	3.3	105
Wheat	525	50	0.026	3.5	95
Maize	3150	200	0.63	0.17	105
Sugar beet	**1579**	**38**	**0.6**	**0.11 to 0.13**	**78**

It is clear from Table 9.72 that the trial carried out on maize most closely matches the proposed use on sugar beet both in terms of seed loading and g/ha. The other two studies were done at significantly greater application rates in terms of g/ha, but the seed loading was significantly less – i.e. 0.026 vs 0.6 mg a.s/seed. This means that should an arthropod encounter a treated seed it will be at greater potential risk from the sugar beet seed, due to the higher seed loading, than the cereal seed. However, what

	also needs to be considered is the density of seed, from the above table it is clear that cereal seeds are sown at 20 times the rate of maize and 30 times for sugar beet, therefore whilst the concentration per seed is greater on sugar beet, the number of seeds and overall concentration per hectare is greater for cereals. The four studies give similar results in terms of magnitude and duration of effects. This indicates that whilst exposure differed in terms of seed loading and rates per hectare, the effect on non-target arthropods was similar; indicating that overall exposure in the field is probably equivalent. On the basis of the information provided it is judged that, although collembolan populations did not fully recover to equal the control, the differences were no longer *statistically* significant and therefore indicate the potential for non-target arthropod populations to recovery following exposure to thiamethoxam treated sugar beet seed. **It should be noted that issues related to the *function* of soil macro-organisms are considered below in Section B.9.71.** **B.9.5.9 Metabolites** Based on results from non-GLP studies, the following metabolites showed no insecticidal activity against a range of arthropod species: CGA 355190, NOA 404617, NOA 407475, NOA 459602 and SYN 501406 However, CGA 322704 showed broad-spectrum insecticidal activity. This metabolite has been identified as the major metabolite to occur in soil (Section B.8.1.3) occurring at up to 35% AR after 90 days in laboratory studies and 61.5% AR after 29 days in worst case field studies. Data were submitted on the metabolite CGA 322704 to the mite *Hypoaspis aculeifer* and the NOEC was 100 mg/kg [redacted] data were also submitted on the toxicity of the metabolite to *Folsomia candida*, this organism was considerably more sensitive with a NOEC of less than 0.15 mg/kg soil [redacted]. Thiamethoxam has a worst-case field DT50 in soil of 86 days and is not predicted to accumulate in soil. As the four field studies were of 102-126 days duration, it is likely that CGA 322704 was formed during the studies. On the basis of the field dissipation studies conducted with thiamethoxam (see Section B.8.1.1.2.2) the evaluator considers it likely that significant amounts of CGA 322704 had formed during the NTA field studies and hence there was exposure of non-target arthropods to residues of thiamethoxam. In summary, it is deemed that the risk to non-target arthropods from CGA 322704 has been assessed via the use of laboratory and field studies (using thiamethoxam), therefore the risk is considered to be addressed.
Effects on soil organisms	As stated above, the guidance in place to assess the risk to soil organisms has not changed since the original evaluation of this product and the endpoints have not changed, so the original conclusion that the risk to soil organisms is acceptable remains unchanged. The assessment is presented in the in the document circulated with the 2020 application for 'Cruiser SB', see ECP 4-7 (39/2020), HSE internal reference WIS 001072834)., however, has been presented below for completeness.
	B.9.6 Effects on earthworms (IIA 8.4, IIIA 10.6.1) **B.9.6.1 Acute toxicity** **B.9.6.1.1 Acute toxicity of the active substance**

In an acute toxicity study, earthworms (*Eisenia fetida*) were exposed to technical thiamethoxam (purity 98.6%) for 14 days in artificial soil (70% sand, 20% clay, 10% peat). The test was conducted in 1.5 litre glass beakers with lids, each containing 750 g of moist soil. Nominal soil concentrations of 0 and 1000 mg a.s./kg dry soil were tested in 4 replicates of 10 worms each. By day 14, 7.5% mortality had occurred in the treated soil compared to nil in the untreated. Worms in the treated soil showed a mean 18.6% weight loss during the study compared to a 3.4% weight gain in the untreated. Burrowing time was assessed on day 14. In treated soil, mean burrowing time was 8.3 minutes compared to 4.0 minutes in the untreated.

The LC50 for the earthworm (*Eisenia fetida*) was >1000 mg a.s./kg, the highest concentration tested. The NOEC was <1000 mg a.s./kg (the only concentration tested).

The study was conducted to OECD guideline 207 and GLP.

(Candolfi 1995)

B.9.6.1.2 Acute toxicity of metabolites (IIIA 8.4)

a) In an acute toxicity study, earthworms *(Eisenia fetida)* were exposed to the metabolite NOA 407475 (99.9% pure) for 14 days. The test was performed in glass beakers containing 750 g of moist artificial soil and NOA 407475 was added at nominal concentrations from 62 to 1000 mg/kg. No mortality occurred in any treatment or the untreated. The worms were not fed during the test and worms in all treatments and the untreated lost 31-44% of their starting weight over the 14 days of the study, with no difference between treatments.

The 14 day LC50 was >1000 mg/kg and the NOEC was 125 mg/kg based on some thinning and reduced reaction to external stimuli at higher concentrations.
The study was conducted to OECD 207 and GLP.

[redacted]

b) In an acute toxicity study, earthworms *(Eisenia fetida)* were exposed to the metabolite CGA 355190 (99% pure) for 14 days. The test was performed in glass beakers containing 750 g of moist artificial soil and CGA 355190 was added at nominal concentrations of 62, 125, 250, 500 and 1000 mg/kg. The worms were not fed during the test and worms in all treatments and the untreated lost 28-42% of their starting weight over the 14 days of the study, with no difference between treatments. No mortality occurred at 500 mg/kg soil but 92.5% mortality occurred at 1000 mg/kg.

The 14 day LC50 was 753 mg/kg and the NOEC was 250 mg/kg based on some thinning and reduced reaction to external stimuli at higher concentrations.
The study was conducted to OECD 207 and GLP.

[redacted]

c) In a second acute toxicity study on metabolite CGA 355190, earthworms *(Eisenia fetida)* were exposed to CGA 355190 (99% pure) at nominal concentrations of 95, 171, 309, 556 and 1000 mg/kg. No mortality occurred at 500 mg/kg soil but 5% mortality occurred at 1000 mg/kg by day-14. At the start of the study, worms at all doses had burrowed within 15 minutes. On day-7, worms in the untreated and all doses up to and including 556 mg/kg again burrowed within 15 minutes while worms at 1000 mg/kg took over 2 hours to burrow. On day-14, flaccidity and open wounds were seen at 556 and 1000 mg/kg. A clear dose-related bodyweight loss was seen on day 14 (-5% in untreated increasing to -35% at 1000mg/kg).

		The 14 day LC50 was >1000 mg/kg and the NOEC was 171 mg/kg based on biologically relevant bodyweight reductions (>10%) at higher concentrations. The study was conducted to OECD 207 and GLP. [redacted]
	d)	In an acute toxicity study, earthworms *(Eisenia fetida)* were exposed to the metabolite CGA 322704 (purity 99%) for 14 days in artificial soil at nominal concentrations of 1.25, 2.5, 5, 10, 20 and 40 mg/kg dry soil. All earthworm groups including the control lost weight during the study (range 14-22%) but no dose-related trend was observed. No mortality occurred at 2.5 mg/kg or below but mortality at 5, 10 and 20 mg/kg was 30%, 95% and 100% respectively. The 14 day LC50 was 5.93 mg/kg and the NOEC was 2.5 mg/kg based on mortality at higher concentrations. The study was conducted to OECD 207 and GLP. [redacted]
	e)	In an acute toxicity study, earthworms *(Eisenia fetida)* were exposed to the metabolite NOA 459602 (99% pure) for 14 days in artificial soil at nominal concentrations of 100 and 1000 mg/kg. No mortality occurred in any treatment or the untreated. The worms were not fed during the test and worms in all treatments and the untreated lost 4-6% of their starting weight over the 14 days of the study, with no difference between treatments. The 14 day LC50 was >1000 mg/kg and the NOEC was 1000 mg/kg, the highest dose tested. The study was conducted to OECD 207 and GLP. [redacted]
	B.9.6.1.3	**Acute toxicity of the plant protection product (IIIA 10.6.1)**
		In an acute toxicity study, earthworms *(Eisenia fetida)* were exposed to 'Cruiser WS70' (containing 70% thiamethoxam) for 14 days in artificial soil at nominal concentrations of 12.3, 37, 111, 333 and 1000 mg product/kg dry soil (= 8.6, 25.9, 77.7, 233 and 700 mg a.s./kg respectively). No mortality occurred in any of the treatment groups or the control group. All earthworm groups including the control lost weight during the study. Losses in treated groups were clearly dose-related (7% loss in untreated and 8.6 mg dose, 10%, 12%, 15% and 17% losses at 25.9, 77.7, 233 and 700 mg a.s./kg respectively). The 14 day LC50 was >1000 mg product/kg (>700 mg a.s./kg). The NOEC was 1000 mg product/kg based on the absence of sub-lethal symptoms such as flaccidity at any test concentrations and 10% weight loss at 1000 mg product/kg (>700 mg a.s./kg). The study was conducted to OECD 207 and GLP. [redacted]
	B.9.6.1.4	**Chronic toxicity of the plant protection product**
	a)	A laboratory chronic and reproductive toxicity study was carried our using 4-litre glass vessels (180 cm^2 surface area) containing 10 cm depth of artificial soil (10% peat). 'Cruiser 350FS' was applied to barley seed (70 g a.s./100kg seed) which was then sown in the vessels at a rate equivalent to 150 kg/ha (6 seeds/vessel; 105 g a.s./ha). Twenty adult earthworms (Eisenia fetida) were added to each vessel. The earthworms were fed cattle manure every 7 days. After 4 weeks the barley seedlings were removed and the mortality and weight of adult worms measured. The soil was then returned to the test vessels for a further 4 weeks, after which the number of offspring was assessed. Results are summarised in Table B.9.73.

Table B.9.73 Results of a chronic/reproductive study using the formulated product

	Mean mortality after 4 weeks (%)	Mean weight of adults after 4 weeks (mg)	Mean weight increase after 4 weeks (%)	Number of offspring/test vessel after 8 weeks
Untreated	5	509.8	1.8	331
'Cruiser 350FS' (70 g a.s./100 kg seed)	1.25	506.5	1.0	306

'Cruiser 350FS' used at 70 g a.s./100 kg barley seeds and with a sowing density equivalent to 150 kg seeds/ha (=105 g a.s./ha) had no adverse effects on adult earthworm survival, condition or reproductive ability.

This study was conducted according to BBA VI 2-2 (1994), ISO 11268-2 (1998) and in compliance with GLP.

[redacted]

b) A laboratory chronic and reproductive toxicity study was carried our using 1-litre plastic vessels (198 cm^2 surface area) containing 750 g of artificial soil (10% peat). Ten adult earthworms *(Eisenia fetida)* were added to each vessel and allowed to burrow. 'Actara' (25% thiamethoxam) was applied as a spray to the soil surface at nominal rates equivalent to 931 and 4616 g a.s./ha. The earthworms were fed cattle manure every 7 days. After 4 weeks the adult worms were removed and mortality and weight recorded. The soil was then returned to the test vessels for a further 4 weeks, after which the number of offspring was assessed.

No adverse effects on adult survival, mean live weight of adults or the numbers of offspring were observed. The NOEC was 4616 g formulation/ha.

This study was conducted according to BBA VI 2-2 (1994), draft ISO 11268-2 (1993) and in compliance with GLP.

[redacted]

B.9.6.1.5 Chronic toxicity of metabolites

The chronic and reproductive toxicity effects of CGA 322704 were investigated in a laboratory study using 1-litre glass vessels containing 515 g of artificial soil (10% peat). CGA 322704 was thoroughly mixed into the soil to give concentrations of 0.06, 0.18 and 0.3 mg/kg dry soil prior to the introduction of 10 adult earthworms (Eisenia fetida) per vessel.

The earthworms were fed cattle manure every 7 days. After 4 weeks the adult worms were removed and mortality and weight recorded. The soil was then returned to the test vessels for a further 4 weeks, after which the number of offspring was assessed. Results are summarised in Table B.9.74.

Table B.9.74 Results of a chronic/reproductive study on metabolite CGA 322704

	Mean mortality after 4 weeks (%)	Mean weight of adults after 4 weeks (mg)	Mean weight increase after 4 weeks (%)	Number of offspring/test vessel after 8 weeks

Untreated	5	570	25	165
CGA 322704 0.06	0	527	12	179
0.18	2.5	552	19	71
0.3	0	536	19	104

The survival of adult earthworms was not affected by exposure to CGA 322704 at concentrations up to 0.3 mg/kg. The NOEC was 0.06 mg/kg based on reduced numbers of offspring at higher concentrations. This study was conducted according to BBA VI 2-2 (1994), ISO 11268-2 (1998) and in compliance with GLP. [redacted]

B.9.6.1.6 Field studies

a) Results were presented from a Danish field study which commenced in early July 2001. A single foliar application of 'Actara 25WG' (25.8% w/w thiamethoxam/kg) was applied to a grass sward to deliver three doses of thiamethoxam (50, 100 and 200 g a.s./ha) in a spray volume calibrated to deliver 400 l water/ha. Individual plot size was 16 x 16 m, with a total of 4 plots per replicate and 4 plots each for the untreated control and the toxic standard (carbendazim single application at 4000 g a.s./ha). A few days before application, the grass was cut to approx. 5 cm height and the cuttings left in situ with the aim of providing a worst case exposure for surface-feeding species of earthworms. 5.8 mm of rain fell on the study area during the night following treatment and over the following 48 hrs, 5.6 mm of irrigation was applied and a further 16.2 mm of rain fell. Earthworm numbers were assessed using either the formalin sampling method (pre-treatment samples and three subsequent samples) or by hand sampling (for the final three samples). The efficiency of the recoveries using the formalin method was assessed on each sampling occasion by comparing the numbers recorded by hand digging the formalin treated areas and counting the numbers remaining. The formalin method was considered acceptable where the numbers extracted was greater than 60% of the combined total extracted by digging and formalin extraction. Post-treatment sampling was conducted 8 DAT and at 1, 2.5, 5, 9 and 12 months after treatment (MAT). The total number of earthworms in untreated plots doubled over the course of the study, increasing from 99/m^2 before treatment to 198/m^2 at 12 MAT. Total earthworm biomass in untreated plots increased from 83 g/m^2 before treatment to 130 g/m^2 at 12 MAT. No treatment related differences in total earthworm numbers or total biomass were seen at any assessment.

The soil was described as a sandy loam to loamy sand, with a mean pH of 6.8 and mean organic content of 2.3% and a mean moisture holding capacity of 12.4% w/w. The vegetation cover at the time of application was 100%, with no bare earth.

Four species of the genus Lumbricus were observed on site; L terrestris, L castaneus, L festivus and L rubellus. Numbers of individual species were low. Analysis of the data (ANCOVA) for Lumbricus spp earthworm numbers showed that there were no significant differences between the control and any of the treatments on any of the six post-treatment sampling occasions. Three species of the genus Aporrectodea were observed on site on most sampling occasions; A caliginosa, A rosea and A icterica. All three species were found in good numbers on the first three sampling occasions, but fewer were collected from December 2001, to July 2002. With one exception, analysis of data (ANCOVA) for the numbers of these species, showed that there were no significant differences between treatments. On one occasion only, 20 August 2001, one month after application, there was a significant difference between treatments in (ANCOVA) ($p<0.01$) for A rosea only. This was not significant by Dunnett's test and could not be allocated to treatment. Other species on site were Allobophora chlorotica and Dendrodrilus rubidus. A chlorotica was present in very low numbers and was not

	found on all sampling occasions. D rubidus was not found in pre-treatment of first post treatment samples, but was present on all other sampling occasions in low numbers and with non-homogeneous distribution. Analysis of the data (ANCOVA) for these earthworm numbers, showed that there were no significant differences between the control and the test item. {There were no significant differences between the reference item and the controls for these species} results for juvenile groups (epilobous and tanylobous) and individual species (including Lumbricus terrestris, L. castaneus, L. festivus, L. rubellus, Aporrectodea caliginosa and A. rosea) generally mirror those seen for total earthworm numbers and do not show any adverse effects of the test item treatments. A significant difference ($p<0.05$) was found between weights (but not numbers) of epilobous juveniles in the 100 g a.s./ha treatment compared with the controls on the first post-treatment sampling occasion only (8/9 days after treatment). This is not believed to be a treatment-related effect. The reference substance, carbendazim (applied once at 4000 g a.s./ha), significantly reduced total numbers and biomass of earthworms when compared with controls from the first sample collected one week after application until the final sample was collected one year after application. In comparison with the individual species data, carbendazim reduced numbers and weight for most species (with exceptions of A chlorotica and D rubidus), although not at all time points. The overall response in terms of total earthworm numbers and total earthworm weight in the test item groups, the toxic reference material and the control are provided in the following figures. Representatives of the three major functional groups: litter dwellers such as L castaneus and D rubidus: deep burrowers such as L terrestris and horizontal burrowers such as A caliginosa. The total number of earthworms present at the start and throughout the study was equal to or greater than given in the guideline. The reference material resulted in significant reductions in total earthworm numbers and biomass. Thus, the study is considered to be valid for an assessment of the risk posed by a spray application of thiamethoxam and indicates the absence of any significant impacts on earthworm populations typical of arable ecosystems from a application of up to 200 g thiamethoxam/ha. Figure B.9.20 Trend graph for mean total earthworm numbers per treatment collected during the study (earthworms/m^2)

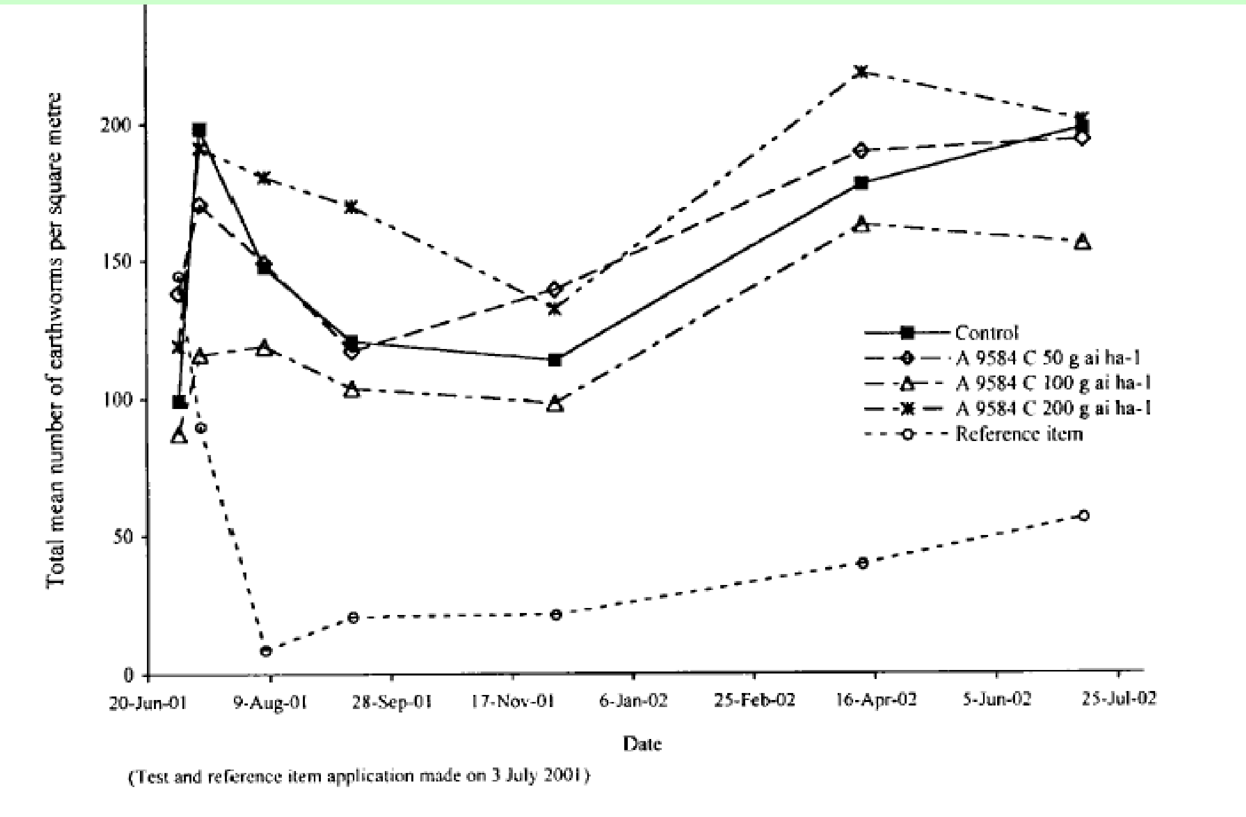
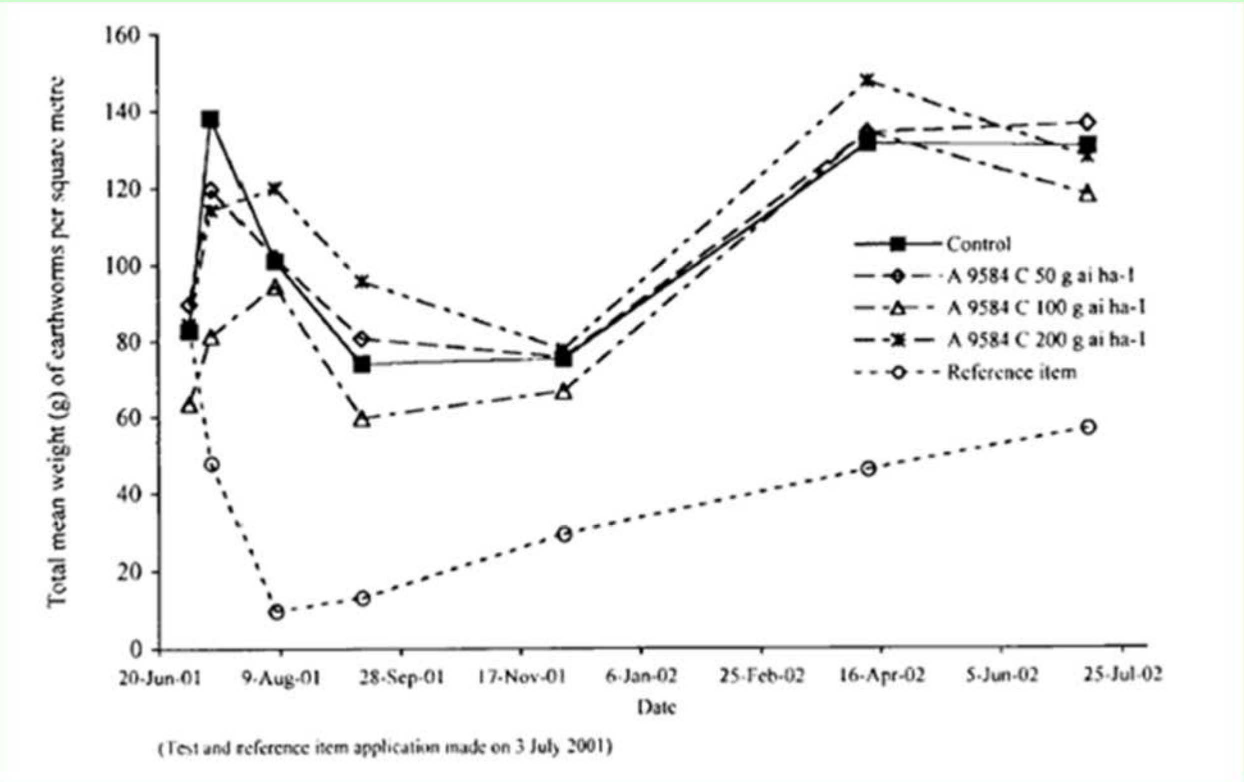


Figure B.9.21 Trend graph for mean total earthworm weights (g) per treatment collected during the study (earthworms/m^2)



No analysis for thiamethoxam or other potential soil metabolites was conducted. This study was conducted according to BBA VI 2-3 and in compliance with GLP.

[redacted]

b) Results were presented from an earthworm field study which commenced in May 2003. A pre-study earthworm sample was conducted to determine whether the site yielded sufficient numbers of earthworms per m^2 (BBA 1994 and ISO 11268-3 1999 guidelines) and included appropriate representative species. Earthworm species representative of the major functional groups were present on the site at the time of the pre-treatment sampling, including *Apporectodea longa*, and *Aporrectodea caliginosa*. epilobous juveniles were the dominant groups in terms of numbers and biomass. Adults of other species, such as *Lumbricus terrestris* and *Allolobophora chlorotica*, were also present. There were fewer occurrences of epigeic species such as *Lumbricus festivus* and *L. castaneus*.

The study was conducted according to BBA Part V1-2-3 (1994) and ISO 11268-3 (1999) guidelines on a bare earth field site in Denmark with a randomised block design of five treatments and four replicates. Treatments were applied on the 16 June 2003 at the following rates:

- Control (water)
- 37.5 g ha^{-1} CGA 322704 test item
- 75 g ha^{-1} CGA 322704 test item
- 150 g ha^{-1} CGA 322704 test item
- 4000 g ai ha^{-1} carbendazim (reference item)

All treatments were applied in a volume of 1000 l ha^{-1} using a tractor mounted Hardi LX MB boom and nozzle sprayer.

Sampling took place within a central 10 m x 10 m area of each plot (12 m x 12 m), using four 0.25 m^2 quadrats in each plot, combined to give a sample of 1m^2. Earthworms were sampled using a digging (to a depth of approximately 30 cm) and hand-sorting method on all occasions. For a period of seven days immediately after application, surface searches were carried out daily and earthworms collected from the same four 1 m^2 areas per plot were identified and counted in the test and reference item treatments.

A permanent Bording Mobil M5 irrigation system at the study site was used both before and after treatment application. Between 4 June 2003 and 15 June 2003 (pre-treatment), approximately 50 mm irrigation was applied to the site. A combination of 22 mm rainfall and irrigation at the site was recorded for the 3-day period following application. In the 5 day period, 8 to 13 July 2003 leading up to the first post-treatment sampling occasion approximately 34 mm irrigation was applied to the site.

Samples of soil were taken for analytical verification and for soil characterisation.

Findings: The soil was analysed and found to be a loamy sand, with a mean pH of 5.7, mean cation exchange capacity of 7.9 meq 100 g^{-1}, mean organic matter content of 1.8 % w/w and mean water holding capacity of 10.98 % w/w.

The results from the sampling of earthworm populations following the application of CGA 322704 in the field are presented in the tables below.

Table B.9.75 <u>Total mean number of earthworms collected on each sampling occasion following application of CGA 322704 in the field (Pease & Webster 2004)</u>

Treatment	Application rate	Mean total number of earthworms collected / m^2

		Pre-treatment	28DAT	92DAT	169DAT	274DAT	386DAT
Control	-	120.25	76.50	85.00	72.25	88.25	63.75
CGA 322704	37.5 g ha^{-1}	106.00	50.75	64.75	65.75	74.00	67.25
	75 g ha^{-1}	123.25	67.00	72.00	61.50	84.00	80.25
	150 g ha^{-1}	112.25	59.75	54.25	65.50	66.75	55.75
Carbendazim	4000 g ai ha^{-1}	105.75	47.50*	40.25*	55.25	47.75*	53.75

DAT – Days after treatment.
*Significantly different from the control in Dunnet test, (p<0.05).

Table B.9.76 Total mean weight (g) of earthworms collected on each sampling occasion following application of CGA 322704 in the field (Pease & Webster 2004)

Treatment	Application rate	Mean total weight (g) of worms collected / m^2					
		Pre-treatment	28DAT	92DAT	169DAT	274DAT	386DAT
Control	-	81.63	55.81	84.42	70.10	87.48	68.75
CGA 322704	37.5 g ha^{-1}	72.04	40.06	59.19	62.79	73.23	71.98
	75 g ha^{-1}	86.73	47.60	60.37*	65.39	89.24	87.62
	150 g ha^{-1}	74.69	49.65	53.42*	59.03	66.78	55.07
Carbendazim	4000 g ai ha^{-1}	71.91	31.99*	40.25*	49.63	51.91*	61.30

DAT – Days after treatment.
*Significantly different from the control in Dunnet test (p<0.05).

Results of the post-treatment surface searches showed that $\leq$ 1 % of the pre-treatment sample population died on the surface during the first week after application in the test and reference item treatments.

There were significant differences between the reference item, carbendazim, applied at 4000 g ai ha^{-1} for total numbers and biomass of earthworms when compared with controls approximately one, four and nine months after treatment. These data confirm the validity of the study. There were no significant differences between the reference item treatment and the controls for any taxa on the final sampling occasion approximately one year after application.

The test item applied at 37.5 g ha^{-1} had no adverse effect on any earthworm group after the first sample collected approximately one month after application.
The test item applied at 75 g ha^{-1} had no adverse effect on any earthworm group after the second post treatment sample collected approximately three months after application.

The test item applied at 150 g ha^{-1} had no adverse effect on abundance or biomass for any earthworm group after the fourth post-treatment sample collected approximately nine months after application. Biomass was more sensitive to effects than abundance in this treatment.

In conclusion; CGA 322704, when applied at three rates of 37.5, 75 and 150 g ha^{-1} showed no adverse effects on earthworm populations for either ecological groups or individual species in samples collected one year after application of the treatments.

[redacted]

B.9.6.2 Risk assessment

Earthworms may be exposed to residues of thiamethoxam in soil following the use of 'Cruiser SB' as a seed treatment on sugar beet.

Acute toxicity studies have been supplied on the active substance and a formulated product called 'Cruiser 350FS'. Chronic toxicity studies have been supplied on 'Cruiser 350FS' and 'Actara 25 WG'.

Section B.8.1.3.5 proposes worst case soil PEC values of 0.104 mg a.s./kg from use on sugar beet[39]. This assumes that all the thiamethoxam applied to treated seed is dislodged and evenly distributed in the top 5 cm of soil (density 1.5 g/cm^3) with no subsequent degradation. These figures will be used in the first tier acute and chronic risk assessments.

B.9.6.2.1 Risk to earthworms from the parent compound

Thiamethoxam has a log P_{ow} of <2 (actually –0.13; see Section B.2.1.13). No adjustment is therefore required to take account of the relatively high organic matter content of the artificial test soils compared with field soil (SANCO/10329/2002, Section 6.3). The acute LC50 and NOEC values are therefore compared directly with the PECs from use in a single year in Table B.8.1.3.5.

Table B.9.77 Acute and long-term risk to earthworms from thiamethoxam

Scenario	LC50/NOEC (test substance)	PEC mg a.s./kg	Acute TER	Long-term TER	Annex VI trigger 91/414 EEC	Reference
Sugar beet	LC50: >1000 mg a.s./kg soil (technical a.s.)	0.104[40]	>9615	-	10	Candolfi, 1995
	LC50: >1000 mg formn/kg soil [>700 mg a.s./kg soil] ('Cruiser WS70')	0.104	>6730	-	10	Rufli, 1997
	NOEC (repro)* 0.3 kg formn/ha [0.14 mg a.s./kg] # ('Cruiser 350FS')	0.104	-	**1.35**	5	Teixeira, 1999
	NOEC (repro)* 4.6 kg formn/ha [3.05 mg a.s./kg soil] ('Actara'')	0.104	-	29.3	5	Rufli, 1997d

Highest concentration tested
* Laboratory studies

The acute TERs are above the Annex VI trigger value of 10 indicating an acceptable acute risk to earthworms from the proposed used of 'Cruiser SB' treated sugar beet seed. No further consideration of the acute risk to earthworms is required.

The long term TER using the NOEC from the Teixeira (1999) study results in a long term TER which breaches the Annex VI trigger value of 5. However, it should be noted that no effect was observed at any of the treatment groups in this study and therefore the NOEC was set at the top dose. Another study has been submitted by [redacted],

[39] Please note that, as stated above, this text is from the original assessment of Cruiser SB, this PEC relates to an application of 78 g /ha which is higher than currently proposed here.
[40] Please note these PECs are for the rate considered in the original assessment of 'Cruiser SB' which was equivalent to 78g a.s./ha. The rate has been reduced for this application.

with a different formulation, 'Actara', which is considered to be comparable to 'Cruiser SB'. No effects were observed in this latter study and again the NOEC was set at the highest dose tested, equivalent to 3.05 mg a.s./ha. If the NOEC from this study is compared to the soil PEC a TER above the Annex VI trigger value of 5 is produced. Therefore, it is concluded that the long-term risk from the active substance is addressed.

An earthworm field study was submitted where thiamethoxam was applied as a spray application at a range of doses up to 200 g a.s./ha (2.5 times that proposed for sugar beet) (see Forster 2003). It was noted that the vegetation cover at the time of application was 100% with no bare ground. Although no treatment-related effects were seen up to 12 MAT (months after treatment), the failure to measure levels of thiamethoxam in the soil raises concern as to whether, and if so, at what concentration, thiamethoxam was present in the study. As this study cannot be fully validated and is not required to identify an acceptable acute risk to earthworms, the study can be regarded as gratuitous.

B.9.6.2.2 Risk to earthworms from metabolites of thiamethoxam

Acute toxicity data were submitted on four metabolites of thiamethoxam and the LC50 and NOEC for each are given in the following table:

Table B.9.78 Summary of acute toxicity of thiamethoxam metabolites to earthworms

Metabolite	LC50	NOEC
NOA 407475	>1000 mg/kg	125 mg/kg
NOA 459602	>1000 mg/kg	1000 mg/kg
CGA 355190 (two studies)	753 mg/kg and >1000 mg/kg	250 mg/kg and 171 mg
CGA 322704	5.93 mg/kg	2.5 mg/kg

The fate and Behaviour Section (Section B.8.1.3.5) identified metabolites NOA 407475, NOA 459602 and CGA 355190 have been identified as being minor soil metabolites (i.e. occurring at less than 10%, SANCO/10329/2002). Metabolite CGA 322704 was identified to occur at 30 % in soil and therefore the risk must be considered further (Section B.8.1.3.5).

Minor metabolites NOA 407475, NOA 459602 and CGA 355190 are of similar low toxicity to thiamethoxam but the major metabolite CGA 322704 is clearly substantially more acutely toxic than the parent substance (Section B.8.1.3.5).

The only metabolite considered major in soil is CGA 322704. Section B.8.1.3.5 indicates that the field DT50 for CGA 322704 is 228 days. The estimated DT_{90} for this metabolite can therefore be assumed to be >365 days, the long term risk must be assessed. In a laboratory study a reproductive NOEC of 0.06 mg a.s./kg soil was established for this metabolite. The maximum accumulated PEC for CGA 322704 is given in Section B.8.1.3.5 as 0.0312 mg/kg.

Table B.9.79 Acute and long-term risk to earthworms from metabolite CGA 322704

Scenario	LC50/NOEC (test substance)	PEC mg/kg[1]	Acute TER	Long-term TER	Annex VI trigger 91/414 EEC
Sugar beet	LC50: 5.93 mg/kg soil	0.0312	190	-	10
	NOEC (repro) 0.06 mg/kg soil	0.0312	-	**1.9**	5

[1] maximum accumulated PEC (See Section B.8.1.3.5)
TERs highlighted in **bold** are below the Annex VI trigger value

The TERs calculated in Table B.9.79 indicate that the acute risk is acceptable. However, based on the laboratory NOEC for CGA 322704 the long term TER is 1.9 which is below the trigger value of 5 indicating a potential long-term risk to earthworm populations.

To address this issue, an earthworm field trial was been submitted using a direct application of the CGA 322704 to bare soil. The study was conducted according to BBA Part V1-2-3 (1994) and ISO 11268-3 (1999) guidelines and is summarised in Section B.9.6.1.6 above.

The findings of this study showed statistical differences in the mean weight of the earthworms between treatment plots and the controls at test concentrations 75 and 150 g /ha 28 days after treatment (DAT). There were no statistical differences 169, 274 or 386 DAT. The study showed that CGA 322704, when applied at three rates of 37.5, 75 and 150 g/ha to bare soil had no adverse effects on earthworm populations in samples collected one year after application of the treatments. The treatment rates used in the study would result in PEC_{soil} in the top 5cm ranging from 0.05 to 0.2 mg/kg. These are at or above the worst case PEC_{soil} of 0.0312 mg/kg for CGA 322704 (B.8.1.3.5) estimated following use of 'Cruiser SB' on sugar beet and indicates an acceptable risk to earthworm populations.

B.9.6.3 Summary

The acute and long term risk of thiamethoxam and the metabolite, CGA 322704 posses an acceptable risk to earthworms when used as proposed on sugar beet.

B.9.7 Effects on soil non-target macro-organisms (IIIA 10.6.2)

Studies on the toxicity of the a.s. and soil metabolite CGA 322704 to collembola were submitted and these have been considered in Section B.9.5.8. It was considered that these studies contributed to an assessment of the effects of thiamethoxam and its associated metabolite on non-target arthropods. Outlined below is a consideration of the effects of thiamethoxam and the metabolite CGA322704 on the function of soil.

B.9.7.1 Effect on litter degradation

a) In a German study, litter bags (10 x 10 cm; mesh size unstated) each containing 5 g of untreated wheat straw were used to study effects of thiamethoxam on the degradation of organic matter. The study field was a grass meadow, which had not received artificial fertiliser or other chemicals in the previous 5 years. The litter bags were placed on the meadow surface and thiamethoxam (as 'Actara 25WG') was applied as an overall spray to deliver 200 g a.s./ha. When spray residues had dried (at least 1 hour), the litterbags were buried 2-5 cm deep in their respective plots. Benomyl was included as a toxic standard (4 kg a.s./ha). There were 4 replicates and 36 bags were buried in each plot. Eight bags were recovered and weighed from each plot at 0, 28, 84, 224 and 364 DAT.

After recovery of the litterbags, soil particles and root material were removed and the straw remnants were dried and weighed before ashing at 530-570°C for 4-5 hours. Results are summarised in Table B.9.80.

Table B.9.80 Results of a litter bag study using thiamethoxam

	% degradation of wheat straw				
	Day 0	Day 28	Day 84	Day 224	Day 364
Control	100	5.8	28.7	53.9	68.0
Actara 25 WG	100	9.3	28.7	42.7	71.4
benomyl toxic standard	100	7.3	34.6	59.6	76.4

There was no significant difference in weight loss of wheat straw between the plots treated with 'Actara' and the untreated at any of the sampling dates.

The study was conducted in accordance with BBA VI 2-3, 'Minutes of a workshop to discuss the data requirements of Annex III point 10.6.2' held in February 2000, and to GLP.

[redacted]

b) In a Swiss study, litter bags (12 x 12 cm; mesh size 6-8 mm) each containing 3-5 g of untreated wheat straw were used to study effects of metabolite CGA 322704 on degradation of organic matter. The study field was a grass meadow, which had not received pesticides in the previous 5 years, though artificial fertilisers had been applied. The litterbags were placed on the meadow surface and CGA 322704 was applied as an overall spray to deliver 70.7 g metabolite/ha. When spray residues had dried (at least 1 hour), the litterbags were buried approximately 5 cm deep in their respective plots. Benomyl was included as a toxic standard (4 kg a.s./ha). There were 4 replicates and 36 bags were buried in each plot. Eight bags were recovered and weighed from each plot at 0, 33, 92, 155 and 275 DAT. After recovery of the litter bags, soil particles and root material were removed and the straw remnants were dried and weighed before ashing at 600°C for 60 minutes to determine the amount of litter remaining. Results are summarised in Table B.9.81.

Table B.9.81 Results of a litter bag study using CGA 322704

	% degradation of wheat straw			
	Day 33	Day 92	Day 155	Day 275
Control	48.5	73.8	78.7	85.6
CGA 322704	44.4	74.2	76.4	81.9
benomyl toxic standard	38.5	69.8	88.7	90.9

No effects on the degradation of organic material in the field were observed during the 275 day test period following the application of CGA 322704 (metabolite of thiamethoxam) at 70.7 g/ha.

The study was conducted in accordance with BBA VI 2-3, 'Minutes of a workshop to discuss the data requirements of Annex III point 10.6.2' held in February 2000, and to GLP.

[redacted]

	c)	The effects of Actara 25WG (A-9584C) on the decomposition of organic material (wheat straw) was evaluated under field conditions. The study was based on the following guidelines: BBA (2000): Minutes of a meeting on the requirement of data according to Annex III, point 10.6.2, organised by the BBA (Braunschweig) 29-30th November, 1999; Minutes edited by C. Kula and S. Guske, February, 2000. BBA (2001): Minutes of a meeting on the requirement of data according to Council Directive 91/414/EEC, Annex III, point 10.6.2, organised by the BBA (Braunschweig) 27-28th November, 12000; Minutes edited by C. Kula and S. Guske, March, 2001. Recommended laboratory testing for assessing the side-effects of pesticides on the soil microflora. From the proceedings of the 3rd International Workshop, Cambridge, September 1985. SETAC-EPFES, 2002. Effects of plant protection products on functional endpoints in soil (EPFES) Workshop recommendations, Lisbon, Portugal, April, 2002 The study was also to GLP with the following exceptions – the soil parameter characterisation, straw drying, litterbag preparation, plot preparation, establishing of plot history, earthworm sampling, set-up of the weather station and collection of weather data before 8th May 2002. To ensure a suitable site was chosen a survey of the field populations of earthworms was conducted before the start of the test. The field site was an arable field in Stein, Switzerland. The soil at the field site was a sandy loam (54.1-57.0% sand, 29.0-31.1% silt, 13.1-15.0% clay) with a pH of 7.19-7.22 and an organic carbon content of 1.55-1.92%. The first application of Actara 25WG (A-9584C) was at rate equivalent to 417.69 g A-9584C/ha (nominally equivalent to 104.4 g a.s./ha) in a water volume of 400 L/ha and was incorporated to a depth of 10 cm. Thirteen days after application of the first spray the litterbags were buried, after a further two days a second spray application of Actara 25WG (A-9584C) at 800g /ha (nominally equivalent to 200 g a.i./ha) was made to the bare soil in a water volume of 800 L/ha (this was achieve by two consecutive applications each at 400 L/ha). Applications of a water control were made on the same occasions as the test substance. After both treatments soil samples to a depth of 10 cm were taken for analytical dose verification. The marked plots of 25 m^2 were 2 metres apart and each had a 1 m margin in which no bags were buried. The litterbags were buried horizontally within the central plot area at a depth of approximately 5 cm and were recovered by the treated soil. The distance between litterbags was 40±10 cm There were thus two treatment groups tested (control and Actara 25WG (A-9584C), with 6 plots assigned to each treatment. Each bag was 13 x 13 cm, made from nylon netting (mesh size 6 x 8 mm). Into each bag was placed approximately 3.4 g (dry weight) of wheat straw, cut into 5-10 cm pieces. The individual weights of the bags were recorded before test start. Since there was no precipitation within 3 days after the second treatment, each plot was irrigated with 10 L of water/m^2. The plots that had previously been arable land were maintained without crop during the course of the test by hand weeding. After the first application, analytical verification of the target plateau concentration of thiamethoxam in the top 10 cm soil layer was conducted. Litterbags were sampled (from a 3 x 3 m sampling area within each plot) 30, 58, 121 and 183 days after burial. For each sampling interval, 8 litterbags per plot were dug out to yield 48 litterbags per treatment. The weight of ash-free dry residues of straw was determined to calculate the percent degradation of the organic material.

Chemical analysis of the soil residues in the top 10 cm depth indicated that after the first application soil residues in the Actara 25WG (A-9584C) treated plots were 0.052-0.084 mg a.i./kg dry soil (mean ± SD of 0.073 mg a.i./kg dry soil ± 0.013 mg a.i./kg dry soil). The mean residue value is equivalent to 104.9% of the target concentration of 0.0696 mg a.i./kg soil).

Chemical analysis of the soil residues in the top 10 cm depth indicated that after the second application soil residues in the Actara 25WG (A-9584C) treated plots were 0.13-0.27 mg a.i./kg dry soil (mean ± SD of 0.185 mg a.i./kg dry soil ± 0.051 mg a.i./kg dry soil).

A summary of the degradation of ash-free residues of straw following exposure to *Actara* 25 WG (A-9584C) is presented in Table B.9.82.

Table B.9.82 Percentage degradation of ash-free residues of straw observed following exposure to Actara 25 WG (A-9584C) under field conditions

Test item	**Percentage decomposition of ash-free residues of straw (Mean ± SD)**			
	Day 30	**Day 58**	**Day 121**	**Day 183**
Control	29.98 ± 2.15	47.46 ± 3.15	69.04 ± 4.01	81.88 ± 5.05
Actara 25 WG (A-9584C)	30.01 ± 2.23	46.93 ± 2.70	70.69 ± 2.82	81.23 ± 3.02
Deviation from control (%)	0.03	-0.52	1.65	-0.64
	Speed of straw decomposition [% decomposition/day] (Mean ± SD)			
	0-30 days	**0-58 days**	**0-121 days**	**0-183 days**
Control	1.00 ± 0.07	0.82 ± 0.05	0.57 ± 0.03	0.45 ± 0.03
Actara 25 WG (A-9584C)	1.00 ± 0.07	0.81 ± 0.05	0.58 ± 0.02	0.44 ± 0.02

There were no significant differences amongst treatments in any of the sampling events. Since after 183 days (i.e. 6 months) in the control plots the litter degradation was > 50% (being 81.88%) no further sampling was required.

The test item Actara 25WG (A-9584C) applied once to bare soil at a rate of 417.69 g A-9584C/ha (nominally equivalent to 104.4 g a.s./ha) and a second spray application 15 days later of Actara 25WG (A-9584C) at 800 g/ha (nominally equivalent to 200 g a.s./ha; mean measured concentration of 0.185 mg a.s./kg dry soil in top 10cm soil depth) had no measurable effect on the decomposition of wheat straw enclosed in litterbags and exposed for up to 6 months in the top soil of an arable field site.

[redacted]

B.9.7.3 Risk assessment to soil organisms involved in the breakdown of organic matter

Studies on the toxicity of the a.s. and soil metabolite CGA 322704 to collembola were submitted and these have been considered in Section B.9.5.8. It was considered that these studies contributed to an assessment of the effects of thiamethoxam and its associated metabolite on non-target arthropods. Outlined below is a consideration of the effects of thiamethoxam and the metabolite CGA322704 on the function of soil.

B.9.7.3.1 Thiamethoxam

The worst case field soil DT_{90} for thiamethoxam is 286 days[41] (Section B.8.1.1.2.2 9g) and therefore according to the Terrestrial Guidance Document, a consideration of the potential effects on soil macro-organisms is required. According to the Terrestrial Guidance Document if the DT90 is between 100 and 365 days there needs to be a consideration of the potential effects on organic matter breakdown. It is recommended as a screening step to assess the long-term risk to earthworms, non-target arthropods, collembolan and mites. If concerns are raised in these areas then a litter bag study is required. From the first tier assessment carried out for non-target arthropods (including soil organisms) it is clear that concern is raised, therefore the Notifier has conducted two litter bag studies.

The [redacted] was conducted at 200 g a.s./ha, however it was carried out on a meadow and there was no analytical verification of the exposure. Due to this it is not possible to determine what soil organisms responsible for organic matter breakdown were exposed to; therefore this study is of supplemental interest.

[redacted] was done on bare soil and there was also analytical verification of thiamethoxam, therefore the study is considered to be acceptable. This study was conducted at 104 g a.s./ha followed by a second application of 200 g a.s./ha which gave a measured concentrations immediately after the second application of 0.13 to 0.27 mg a.s./kg (mean measured on 0.185 mg/kg soil). The predicted rate on sugar beet is stated to be equivalent to 78 g a.s./ha whilst the initial predicted soil concentration for the active substance is 0.104 mg a.s./kg therefore the Zenz study is considered to address the proposed use.

No adverse effects on straw degradation were seen following application of thiamethoxam. On the basis of the Zenz, the risk to organisms involved in organic matter breakdown processes is considered to be acceptable.

The risk to soil macro-invertebrates populations is considered in Section B.9.5.6.

B.9.7.3.2 Metabolite CGA 322704

CGA 322704 is more persistent in soil (DT_{90} greater than 365 days) than the parent thiamethoxam (DT_{90} approx 286 days Section B.8.1.1.2.2), therefore a litter bag study was carried out [redacted] In the field litter bag study provided, no adverse effect on straw degradation was observed following application of CGA 322704 applied at 70.7 g/ha. It should be noted that no analytical confirmation of the metabolite was performed, and therefore as the study was conducted on a grass meadow it is not know what the exposure of the soil organisms was. It has been estimated that the soil PEC was 0.0094 mg/kg soil which has been calculated using a grass interception of 90%. The PEC for CGA 322704 calculated in Section B.8.1.3.5 is 0.0312 mg/kg soil. In the absence of any analytical confirmation of the levels of CGA 322704 to which the litter bags were actually exposed in the soil it is not possible to directly relate the results of this study to the proposed use of 'Cruiser SB' as a seed treatment.

In order to address the above concern regarding the potential effects on organic matter breakdown, the Notifier has put forward an argument which basically highlights that the risk to soil organisms, i.e. non-target arthropods, earthworms and soil microbial processes from the metabolite CGA 322704 is acceptable and hence there is unlikely to

[41] Please note that this text is taken from the original assessment of 'Cruiser SB' and it is noted that the DT90 now quoted is 570 days. This issue is further considered above.

be an adverse effect on organic matter breakdown. This case is plausible; however it is given further weight if the fate and behaviour of thiamethoxam is considered. Thiamethoxam has a worst case field DT50 in soil of 86 days and is not predicted to accumulate in soil. On the basis of the field dissipation studies conducted with thiamethoxam (see Section B.8.1.1.2.2) the evaluator considers it likely that significant amounts of CGA 322704 may had formed during the Zenz litter bag study. This assumption is based on the fact that at several field dissipation sites in Northern Europe (Germany, Northern France, Denmark and Sweden) residues of CGA322704 formed from thiamethoxam had peaked by days 29 to 112. At sites where CGA322704 residues peaked beyond the 120 d sampling point (i.e. peak residues formed at between 180 d and 1 year) CGA322704 residues at the 90 to 120 d time points were between 47 to 70% of the maximum peak level observed at each site. It is therefore considered that CGA 322704 was present in the Zenz study and therefore as there were no adverse effects on litter degradation in the Zenz study, the risk to organisms involved in organic matter breakdown following exposure to CGA 322704 is acceptable.

B.9.7.4 Summary

The risk of thiamethoxam and CGA 322704 to soil organisms involved in organic matter breakdown is acceptable.

B.9.8 Effects on soil non-target micro-organisms (IIA 8.5, IIIA 10.7)

B.9.8.1 Toxicity

B.9.8.1.1 Toxicity of the active substance (IIA 8.5)

Data were submitted from a 28-day laboratory study of the effect of technical thiamethoxam (purity 98.6%) on respiration and nitrification in a loamy sand soil. The soil was treated with thiamethoxam at nominal concentrations of 0.27 and 2.67 mg a.s./kg dry soil (equivalent to 0.2 and 2.0 kg a.s./ha respectively, assuming 5 cm depth of soil and soil bulk density of 1.5 g/cm^3). For the respiration test, soil respiration was stimulated by the addition of glucose (1000 mg/100 g soil). For the mineralisation test, lucerne meal was added at 5g/kg soil.

No meaningful effect on soil respiration was seen at either test concentration after 0, 14 or 28 days of incubation (range – 6.7% to + 1.3% compared to untreated) .
No meaningful effect on soil mineralisation was seen at either test concentration after 0, 14 or 28 days of incubation (range – 1.1% to –11.5% compared to untreated) .

The study was conducted according to BBA VI 1-1, OECD (draft 1996), SETAC (1995) and to GLP.

[redacted]

B.9.8.1.2 Toxicity of the plant protection product (IIIA 10.7)

No studies on the formulated product ‘Cruiser SB’ were submitted.

B.9.8.1.3 Toxicity of metabolites

Data were submitted from a 28-day laboratory study of the combined effect of metabolites CGA 322704 and CGA 355190 (both 99% purity) on respiration and nitrification in a loamy sand soil. The soil was treated with the metabolite mixture at nominal concentrations of 0.1 mg of each/kg dry soil and 0.5 mg of each/kg dry soil (equivalent to 0.15 and 0.75 kg total metabolite/ha respectively, assuming 5 cm depth of soil and soil bulk density of 1.5 g/cm^3). For the respiration test, soil respiration was

	stimulated by the addition of glucose (1000 mg/100 g soil). For the mineralisation test, lucerne meal was added at 5g/kg soil. No meaningful effect on soil respiration was seen at either test concentration after 0, 14 or 28 days of incubation (range –16.8% to + 5.0% compared to untreated) . Total nitrogen content of treated soils over the incubation period (0, 7, 14 and 28 DAT) differed from the untreated by +9.8, -24.5, -9.2 and –7.5% respectively at the lower test concentration and by +11.0, -33.9, -19.2 and –8.0 respectively at the higher test concentration. These results indicate that neither metabolite has a lasting effect on nitrogen metabolism. The study was conducted according to OECD 216 and 217 (draft 1999) and to GLP. [redacted] **B.9.8.2 Risk assessment** As neither respiration nor nitrogen mineralisation of treated soils differed from untreated soils by greater than 25% (the Annex VI trigger) after 28 days there was no need to continue the studies beyond that point. The maximum PEC values for thiamethoxam and the major soil metabolite CGA 322704 based on the use on sugar beet is 0.104 mg a.s./kg soil (see Section B.8.1.3.5). Thus there is a margin of safety between the concentrations observed to give no significant adverse effects (2.67 mg a.s./kg and 0.5 mg CGA 322704/kg) and the maximum respective soil concentrations 0f 0.104 mg a.s./kg soil and 0.0312 mg/kg CGA 322704. There are not expected to be any significant effects on soil microbial function when 'Cruiser SB' is applied at label recommended doses to sugar beet.
Effects on non-target terrestrial plants	The guidance in place to assess the risk to non-target plants has not changed since the original evaluation of this product and the endpoints have not changed, so the original conclusion that the risk to soil organisms is acceptable remains unchanged. The assessment is presented in the document circulated with the 2020 application for 'Cruiser SB', see ECP 4-7 (39/2020), HSE internal reference WIS 001072834)., however, has been presented below for completeness. **B.9.9.1 Effects on non-target flora** No data have been submitted to PSD on the toxicity of technical thiamethoxam or 'Cruiser SB' to non-target plants. However, as thiamethoxam is an insecticide, the risk of adverse effects on plants would be expected to be low. In addition, as 'Cruiser SB' is a seed treatment, exposure of non-target plants to thiamethoxam should be negligible. The only way that exposure could occur would be to residues of thiamethoxam/major metabolites in soil. In Efficacy studies on safety to following crops (Section B.10.8.1), a range of crop species were exposed to soil residues of thiamethoxam applied at 300 g a.s./ha (3.8 times the proposed rate on sugar beet seeds) three weeks before planting/sowing. Barley, lettuce, potato, oilseed rape, sugar beet and onion were unaffected. Germination of carrot may have been slightly retarded but effects were outgrown and plant stand was equal to the untreated by the 6-8 leaf stage. Given the available evidence, the risk to non-target plants is considered to be low. {Additional data summarised in Addendum B-9 (January 2004) to the Rapporteur's DAR indicate little evidence for phytotoxicity in a wide range of weed species. Provided the Notifier can prove that Data requirement 3.5 in the Evaluation Table (SANCO/10389/2002 rev 1-2) has been satisfactorily fulfilled then the UK would not require to see these data.}
Conclusion	The risk to all birds, mammals, aquatic life, non-target arthropods, soil organisms, microbial processes and non-target terrestrial plants is considered to be acceptable when considering standard PPP assessment methodology, noting that existing data have not been re-evaluated.

	The chronic oral risk to adult honey bees could not be assessed due to the lack of data and hence the risk according to para 2.5.2.3 of Annex Part 1, Section C of the Uniform principles for evaluation and authorisation of plant protection products, as provided for in Article 29(6) of Regulation (EC) No 1107/2009 is unacceptable. A detailed consideration of possible chronic endpoints was undertaken, and two endpoints previously considered by EFSA and EU review programme were used. One was from a homing flight study, whilst the other was from a non-ideal laboratory chronic study. As regards the homing study, this is not a standard regulatory study, and hence interpreting what the outcome from the study means is unknown in terms of how it relates to field conditions. The chronic study was not up to modern standards as the exposure was not appropriate (see above for further details). Using these endpoints in an illustrative manner, indicated a potential risk, i.e., either the exposure estimate was greater or more or less equal to the effects endpoints. Whilst it is acknowledged that these data are not ideal, using these data do indicate that the active substance may reach levels in the environment that could cause adverse effects on the survival and/or behaviour of adult forager honey bees. Due to the lack of readily available suitable higher tier data and/or models that could use the output from lower tier studies it is has not been possible to extrapolate the effects seen in these studies to potential colony level effects.

3 Conclusion of Emergency Authorisation

3.1 Regulatory Approach

The HSE evaluation for consideration of use on sugar beet of 'Cruiser SB' in 2025 has been reviewed and updated to reflect currently available information (including updated classification and monitoring data) but relies in part on assessments supporting the previous commercial authorisation and in part on assessments conducted for previous article 53 applications.

3.2 Conclusion

Conclusion by The Health and Safety Executive.

Where the conclusion indicates that the risk is either acceptable or unacceptable, this conclusion is reached within the framework of the standard criteria for a commercial authorisation based on assessment to uniform principles. Article 53 allows a derogation from the standard criteria providing specific tests are met. Therefore, (for example) reference to unacceptable risks in the risk assessment conclusion may highlight the areas of greatest concern and are reflected in the risk assessment conclusion. However this is not the test under Article 53 and may be viewed differently in the overall conclusions for this emergency authorisation application.

Risk Assessment Area	Has a Risk Been Identified that cannot be mitigated?	What is HSE's Assessment of That Risk?
Non-Dietary Human Exposure (operator/ worker/ bystander and resident)	No	The predicted exposure of humans (dietary and non-dietary) falls within the agreed safe levels (ADI (Acceptable daily intake)/ ARfD (Acute reference dose)/ AOEL (Acceptable Operator Exposure Level)) and no health effects are anticipated.
Residues and Consumer Exposure	No	The predicted exposure of humans (dietary and non-dietary) falls within the agreed safe levels (ADI/ ARfD/ AOEL) and no health effects are anticipated. Due to the reclassification of thiamethoxam with effect from 23 October 2023 on the GB Mandatory Classification and Labelling list, one of the metabolites is predicted to occur in groundwater above the regulatory threshold based on standard modelling methods. HSE has conducted a risk assessment and concluded that there are no unacceptable risks to consumers. However, the levels would need to be monitored and may require that water is treated before it can be supplied to consumers. Further information would be

		needed from water supply companies to understand the actual levels of the metabolite present in areas of use and the impact of this on water treatment if this is considered relevant to the decision.
Maximum Residue Levels	No	No changes to current MRLs are required to accommodate the proposed use.
Environmental Fate and Behaviour	No	The standard regulatory exposure assessment in soil and surface water results in acceptable risks (see also Ecotoxicology section below). Due to the presence of a toxicologically relevant metabolite predicted in groundwater above the regulatory threshold of 0.1µg/l a standard regulatory assessment for groundwater would be unacceptable. In order to address this for the purposes of this Article 53 assessment, which allows derogation from the standard requirements for commercial authorisation, as noted above, HSE has conducted a risk assessment and concluded that there are no unacceptable risks to consumers. Monitoring data covering in field and field margin soils, and field margin non-crop vegetation and pollen have been evaluated. Data are only available for three sample points from the 2023 applications using an analytical method with an appropriate limit of detection and quantification, and it is not possible to conclude confidently on the persistence of thiamethoxam or its breakdown product clothianidin at this stage. However, there are indications of the persistence of both substances and the potential for exposure via succeeding crops cannot be excluded. Given there is no agreed method for translating the residues in soil and plants (pollen and nectar) to the exposure for bees and that there are gaps in the toxicity data set, these monitoring data have little impact on the risk assessment and have not been used to update the standard regulatory risk assessments. HSE would propose that monitoring continues at these sites, utilising the analytical method with lower limits of quantification and detection to aid understanding of long-term behaviour.

		Environment Agency surface water monitoring data (up to 1st March 2024) were generally low with a single detection of thiamethoxam above the Water Framework Directive PNEC (Predicted No Effect Concentration) of 0.042 µg/l (at 0.044 µg/l on 1st May 2023 in Waveney catchment). Due to the nature of Environment Agency monitoring in large water bodies, the potential for higher concentrations to occur in smaller, edge of field waterbodies cannot be excluded.
Ecotoxicology	(specific categories covered below)	
Effects on terrestrial vertebrates	No	Acute and long-term/reproductive risks to birds and mammals via consumption of treated seed and germinated seedlings have been assessed and are considered to be low.
Effects on aquatic species	No	Risks to aquatic organisms from exposure to thiamethoxam and the metabolite clothianidin via drainflow are considered acceptable. It is noted that exposure above the PNEC under the Water Framework Directive would be expected in some small, edge of field water bodies.
Effects on bees	**Yes**	Undertaking the risk assessment within the framework of the standard criteria for a commercial authorisation based on assessment to uniform principles, HSE is of the view that it has not been clearly established that there will be no unacceptable effects on adult or larval honeybee survival and behaviour after use of the plant protection product in accordance with the proposed conditions of use. It has also not been clearly established that any such effects would not negatively impact the survival, development or productivity of the colony. See table below.
Effects on other arthropod species other than bees	No	On the basis of the first tier data a potential risk is highlighted. This is considered further using field data; while some initial impact on collembolans is anticipated, recovery of affected populations is expected. On this basis an acceptable risk to non-target arthropods (other than bees) is concluded.
Effects on soil organisms	No	The acute and long term risks of thiamethoxam and the soil metabolite clothianidin to earthworms are considered acceptable when used as proposed on sugar beet. The risk of thiamethoxam and clothianidin to other soil organisms involved in

		organic matter breakdown is also acceptable. Comparison of the available laboratory toxicity data with predicted soil concentrations from sugar beet use indicate there are not expected to be any significant effects on soil microbial function when 'Cruiser SB' is applied to sugar beet at the dose requested by the applicant.
Effects on non-target terrestrial plants	No	Given the seed treatment use, exposure of non-target plants to thiamethoxam should be negligible. Additionally, the available efficacy studies indicate low risks to non-target plants.

The outcome of the bee risk assessment undertaken within the framework of the standard criteria for a commercial authorisation is summarised in the table below (green indicating low risks and yellow indicating inconclusive):

Foraging scenario	**Honeybees**				**Other bee species (bumble bees, wild bees)**
	Acute risk to adults	**Chronic risk to adults**	**Sublethal effects on adults**	**Risks to larvae**	
Treated crop	Low risks due to crop being harvested before flowering				
Flowering weeds within treated field	Low risks where weeds are controlled through herbicide use programme				
Flowering weeds in field margins	Low risk indicated	Low risk indicated	Low risk likely but insufficient difference between predicted exposure and effects to conclude low risk.	Low risk indicated	No assessment performed due to insufficient toxicity data and lack of suitable risk assessment methodology
Adjacent crops	Low risk indicated	Low risk indicated	Low risk likely but insufficient difference between predicted exposure and effects to conclude low risk.	Low risk indicated	
Succeeding crops	Low risk indicated	Insufficient difference between predicted exposure and effects	Insufficient difference between predicted exposure and effects to	Low risk indicated	

		to conclude low risk	conclude low risk		
Guttation fluid#	Low risk indicated	Insufficient difference between predicted exposure and effects to conclude low risk.	Insufficient difference between predicted exposure and effects to conclude low risk.	Insufficient difference between predicted exposure and effects to conclude low risk. ~~s~~	

Guttation is the process of secretion of water droplets from the pores of some vascular plants

Further consideration following advice from the Expert Committee on Pesticides (ECP)

This application was presented to the ECP for independent scientific advice on 10 September 2024. HSE has used the advice to finalise the risk assessment in this document and its assessment below against the tests for an article 53 emergency authorisation. The ECP advice note is presented at Appendix 5

The Tests for an Article 53 application

Assessment Against the Requirements of Article 53	Is the Requirement Met?	Summary of HSE's Assessment
Are there Special circumstances supporting the proposed use?	Yes	The withdrawal of neonicotinoid seed treatments has left only two authorised foliar spray Plant Protection Products, which present challenges to achieve the same level of aphid control, including insufficient number of applications in seasons of high pest pressure. Additionally, mild winters have led to better survival of aphids, exacerbated for *Myzus persicae* which has a variety of alternative crop and non-crop host plants where there are also limited insecticide options. It is only virus-carrying aphids present at the vulnerable plant growth stages that are of concern, and early planting may allow the crop to develop to the resistant growth stages before winged aphids begin to move into the crop. However, seasonal weather conditions are critical in firstly determining how quickly the crop can reach the resistant stages and secondly determining aphid population build up. The sugar industry is considerably investing in research to find alternative strategies. A key part of this is developing commercially tolerant varieties, but this is very challenging because the beet yellows complex consists of a number of individual viruses.

Assessment Against the Requirements of Article 53	Is the Requirement Met?	Summary of HSE's Assessment
If a repeat, are there measures in place to develop long term solutions?	Yes	There have been four previous emergency authorisations granted for this use and three previous years when the specified threshold was met and resulted in the use of 'Cruiser SB'. Considerable research is ongoing, with the industry establishing a multi-million pound research project to develop commercially viable resistant varieties. This was established before neonicotinoids were withdrawn, in recognition of the need for alternative measures. However, this is challenging because the beet yellows virus complex consists of three individual viruses. Progress has been made with new varieties, but it is a long process and full commercialisation of viable resistant varieties is not likely to be before 2030. In the meantime, British Beet Research Organisation has conducted a range of additional research examining a number of other cultural integrated measures that are now recommended to growers. In addition, there are potential new foliar sprays that may be authorised in the medium to longer term. Published UK emergency authorisation guidance indicates that emergency authorisations should be needed for no more than 5 years to allow development of longer-term solutions.
Does the pest/situation present a 'danger'?	Yes	Yes, as demonstrated in 2020, in years of high aphid populations and virus risk, virus yellows can have a significant impact on crop yield and quality.
Are there insufficient reasonable alternative means?	Yes	Whilst there are two commercially available insecticidal foliar sprays for controlling aphids, these may not be sufficient in seasons/areas of high risk. Identifying the risk from virus infection is extremely difficult as it is very geographically localised.
Will the proposed use be limited?	No	British Sugar and NFU sugar propose that the choice whether or not to use 'Cruiser SB' (if available), lies with the individual grower.

		The applicant has not built on the experience of the previous seasons to review the collated data on aphid populations, virus incidence, use of 'Cruiser SB' and foliar sprays to further refine and target the areas of highest risk which may benefit from more limited use of 'Cruiser SB' treated seed. The applicant has proposed a range of mitigation methods, implemented through a stewardship scheme which are expected to reduce the exposure. HSE does not have quantitative information regarding yield reduction when not using Cruiser SB, and the impact on individual growers is unknown. It remains unclear to HSE why growers responsible for 40% of the area of sugar beet used for sugar production chose not to use 'Cruiser SB' treated seed in 2023 and 2024.
Will the proposed use be controlled?	Yes	Sugar beet is grown under contract to British Sugar who arrange the seed treatment in accordance with grower needs and distribute the seed to growers. Were authorisation to be granted, use would be associated with a stewardship scheme and growers would be required to declare that they understood the stewardship requirements and to comply with them. The stewardship scheme specifies: • drilling requirements (seed density, dealing with spillages etc) • requirement to keep the in-crop area free of flowering weeds in accordance with standard practice (to minimise pollinator exposure) • Restrictions on subsequent crops which have the potential to take up any thiamethoxam or clothianidin residues remaining in the soil • A range of knowledge exchange activities including communication/support given to growers by BBRO throughout the season

HSE conclusion of assessment against the requirements of Article 53

Whilst the risk to consumers, including for groundwater are acceptable, the levels of one of the metabolites remain above the regulatory acceptable level according to the Drinking water and Groundwater Directives. This may have implications for water treatment and give rise to potential burdens on water companies.
HSE was unable to determine the level of chronic risk or sub-lethal effects on bees.

From the new monitoring data it is not possible to conclude confidently on the persistence of thiamethoxam or its breakdown product clothianidin at this stage.

However, there are indications of the persistence of both substances and the potential for exposure via succeeding crops cannot be excluded.

Overall, the situation is complex and in the absence of sufficient information on either the risks to bees, or the degree of additional benefit from using ‘Cruiser SB’ compared with other available measures, HSE is unable to conclude on the basis of the information provided that the benefit of the proposed use outweighs the risks.

Having taken into account all the evidence presented, does HSE consider that the necessity of the case supports derogation from Article 28 of Regulation 1107/2009, whereby the benefit of addressing the danger outweighs the potential for harm taking into account any potential mitigations	No

3.3 Data Requirements to support a future Application

Evaluation, Summary and Conclusion by The Health and Safety Executive.
HSE consider that data requirements should be set if authorisation is granted.

Appendix 1 Draft Authorisation Notice plus stewardship proposal (if decision to authorise in 2025)

Emergency Authorisation Number: xxxxxxx

EMERGENCY AUTHORISATION FOR USE OF A PLANT PROTECTION PRODUCT

PLANT PROTECTION PRODUCTS REGULATION (EC) No 1107/2009

Extent of authorisation: England

Product name*:* Cruiser SB

Active ingredient*:* 600 g / l thiamethoxam

Emergency authorisation holders*:* NFU Sugar and British Sugar plc

This Emergency authorisation starts: XXXX

This Emergency authorisation ends: XXXXX for placing the product on the market, use, storage and disposal of unused stocks.

This emergency authorisation can be withdrawn or amended before its end date if the requirements of authorisation under Regulation 1107/2009 are no longer met. The requirements may no longer be met as a result of, for example, new information brought to the attention of the competent authority on the danger necessitating the use of the PPP, the effects of the PPP, or whether use of the PPP is limited and controlled. These examples are not exhaustive.

HSE Digital Signature

This and the attached Appendices 1 and 2 are signed by the Health and Safety Executive for and on behalf of the Secretary of State.

Date of issue: XXXXXXXX

EXPLANATORY NOTES

1. This is Emergency authorisation number XXXXX.

2. This Emergency authorisation will be published on HSE's website.

3. Application reference number: COP 2024/01181.

4. Persons using the product to which this Emergency authorisation applies should acquaint themselves with and observe all requirements contained in the Regulation (EC) No 1107/2009.

5. The efficacy of the product for which this Emergency authorisation has been granted has not been assessed and, as such, the user bears the risk in respect of failures concerning its efficacy.

6. In this notice Regulation (EC) No 1107/2009 means:
   In relation to Great Britain, Regulation (EC) No 1107/2009 as it has effect in Great Britain.

ADVISORY INFORMATION

This Emergency Authorisation relates to the use of 'Cruiser SB' for the control of peach-potato aphid (*Myzus persicae*) to prevent virus yellows infection.

This emergency authorisation relates to use as a seed coating. This use shall only be performed in professional seed treatment facilities. Those facilities must apply the best available techniques in order to ensure that the release of dust during application to the seed, storage and transport is minimised.

IMPORTANT: 'Cruiser SB' contains thiamethoxam a neonicotinoid insecticide (IRAC 4a). There are no known cases of resistance to thiamethoxam or other neonicotinoid insecticides in the UK to date for peach-potato aphid *(Myzus persicae)*. However, the possible development of resistance cannot be excluded or predicted and control may be reduced if strains of the pest resistant to thiamethoxam or other neonicotinoids develop. Total reliance on pesticides of the same mode of action will hasten the development resistance. Pesticides of different modes of action or alternative control measures should be used in the programme. Consecutive applications of two neonicotinoid products are not permitted. Where 'Cruiser SB' treated seed is used, if subsequent foliar sprays are required, the first foliar spray must be a flonicamid (IRAC 29) containing product. It is not permitted to spray 'Insyst' (containing acetamiprid – IRAC 4a) as the first foliar spray.

APPENDIX 1: CONDITIONS OF EMERGENCY AUTHORISATION

The conditions below are obligatory. They must be complied with when the product is placed on the market and used pursuant to this Emergency authorisation. Failure to comply with the following conditions is likely to result in the withdrawal or amendment of the emergency authorisation under Regulation (EC) No 1107/2009 and may result in other enforcement action, including prosecution.

Packaging: The product may only be placed on the market by Syngenta UK Limited in the following containers:

5 to 25 litre high density polyethylene container.

100 to 200 litre high density polyethylene returnable container.

1000 litre high density polyethylene container with a top-mounted discharge valve for use with a closed transfer system (the container must not be fitted with any other type of outlet).

Label: The product may only be sold or supplied with the agreed labels (for product and seed bag), which were the labels submitted on 22 August 2022 (HSE ref.: W002099316) and label amendments as specified in Annex A to HSE's letter dated XX XXXXX XXXXX sent to Syngenta UK Limited.

Use:

Field of use: **ONLY AS A SEED TREATMENT**

User: Professional

Crops/situations:	Maximum individual dose: (ml product / 100,000 seeds)	Maximum total dose:	Maximum number of treatments: (per batch)	Latest time of application:
Sugar beet seed	75	-	1	Before drilling

Operator Protection:

(1) Engineering control of operator exposure must be used where reasonably practicable in addition to the following personal protective equipment:

(a) Operators must wear suitable protective clothing (coveralls) and suitable protective gloves when handling the concentrate or handling contaminated surfaces.

(b) Operators must wear suitable protective clothing (coveralls), suitable protective gloves and suitable respiratory protective equipment* when cleaning machinery. *Disposable filtering facepiece respirator to at least EN149 FFP3 or equivalent.

(c) Operators must wear suitable protective clothing (coveralls) when bagging treated seed.

(d) Workers must wear suitable protective clothing (coveralls) and suitable protective gloves when handling treated seed and contaminated seed sowing equipment.

(2) However, engineering controls may replace personal protective equipment if a COSHH assessment shows that they provide an equal or higher standard of protection.

Environmental protection:

(1) To protect birds and mammals treated seed must be entirely incorporated in the soil; ensure that the product is also fully incorporated at the end of rows.

(2) To protect birds and mammals treated seed should not be left on the soil surface. Bury or remove spillages.

(3) To minimise the number of flowering weeds in treated sugar beet crops and reduce the risk of indirect exposure of pollinators to neonicotinoids BASIS recommended herbicide programmes must be adopted by growers and their agronomists. This applies in treated fields only (not field margins or the surrounding area).

(4) In order to reduce the risk of exposure to pollinators a minimum interval of 32 months must be observed between drilling ‘Cruiser SB’ treated sugar beet seed and planting any restricted crop* on the same field.

*Refer to agreed stewardship document (Appendix 3) for details of restricted/ non-restricted crops.

(5) A minimum interval of 46 months must be observed between drilling ‘Cruiser SB’ treated sugar beet seed and planting any seed (including further sugar beet seed) treated with thiamethoxam on the same area of land.

Other specific restrictions:

(1) This product must only be applied for the control of peach-potato aphid (Myzus persicae) in accordance with the terms of this Emergency Authorisation, the product label and/or leaflet and the agreed stewardship document (see Appendix 3).

(2) Sugar beet seed must only be treated in accordance with this authorisation under the direction of British Sugar, and only if the agreed XX% threshold of virus levels is met as determined on 1 March 2025 by the Rothamsted Research 2025 virus yellows forecast.

(3) Seed coating shall only be performed in professional seed treatment facilities. Those facilities must apply the best available techniques in order to ensure that the release of dust during application to the seed, storage and transport can be minimised.

(4) Treated seed must be labelled with the appropriate precautions using printed sacks, labels or bag tags (refer to product label for agreed text).

(5) Treated seed must not be used for food or feed.

(6) Sacks containing treated seed must not be re-used for food or feed.

(7) Treated seed must be drilled (broadcasting and aerial spreading of coated seed is forbidden).

(8) Adequate seed drilling equipment shall be used to ensure a high degree of incorporation in soil, minimisation of spillage and minimisation of dust emission.

(9) The drilling rate for Cruiser SB treated sugar beet seed must not exceed 115,000 seeds/ha.

(10) Do not apply Insyst' (containing acetamiprid – IRAC 4a) as the first foliar spray on plants grown from 'Cruiser SB treated seed.

(11) Returnable containers must not be re-used for any other purpose.

(12) Returnable containers must be returned to the supplier.

(13) Records must be kept of the fields sown with 'Cruiser SB' treated seed and monitoring in accordance with the agreed stewardship document (Appendix 3).

APPENDIX 2: GENERAL CONDITIONS FOR AN EMERGENCY AUTHORISATION

Failure to comply with the following conditions is likely to result in the withdrawal or amendment of the Emergency authorisation under Regulation (EC) No 1107/2009 and may result in other enforcement action, including prosecution.

Adverse effects:

The authorisation holder must immediately notify the Secretary of State, if they have any new information on the potentially adverse effects of the authorised product, or of residues of an active substance in that product when used in accordance with the conditions of this authorisation. Failure to comply with this requirement is an offence.

Provision of information:

The authorisation holder must comply with all requests for information required by, or on behalf of, the Secretary of State, in accordance with Regulation (EC) No 1107/2009.

Appendix 2: Cruiser SB Neonicotinoid Stewardship Document

2025 Cruiser SB EA
Stewardship Docum

Appendix 3 Draft Product Label (if decision to authorise in 2025)

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY
Label amendments
The below copy of the label was supplied by Syngenta on 22 August 2023 and is filed at w002099316. If a decision is made to authorise use in 2025, required amendments to below will be specified with the authorisation.

APPROVED LABEL TEXT February 2023

CRUISER SB

I

Insecticide Group 4A

A flowable concentrate for seed treatment containing 600g/litre thiamethoxam.

CRUISER SB is a seed treatment containing the neonicotinoid insecticide thiamethoxam, for the control of peach-potato aphid (*Myzus persicae*), an aphid vector of virus yellows attacking sugar beet seedlings. Sugar beet seed must only be treated in accordance with the emergency authorisation, under the direction of British Sugar, and only if the agreed 63% threshold of virus levels is met based on the Rothamsted Research 2023 virus yellows forecast.

The (COSHH) Control of Substances Hazardous to Health Regulations may apply to the use of this product at work.

This product label is compliant with the CPA Voluntary Initiative (VI) guidance.

The Voluntary Initiative

Net contents

Syngenta UK Ltd
CPC4, Capital Park
Fulbourn
Cambridge
CB21 5XE

In case of toxic or transport emergency ring 01484 538444 any time.

PROTECT FROM FROST
SHAKE WELL BEFORE USE
MIX THOROUGHLY BEFORE USE (20 litre containers)

Containers over 20 in size litres should only be handled by mechanical means. (20-25 litre containers)

Product code number/print date/xxxxx

Batch number

SAFETY PRECAUTIONS

(a) Operator protection

Engineering control of operator exposure must be used where reasonably practicable in addition to the following personal protective equipment:

WEAR SUITABLE PROTECTIVE CLOTHING (COVERALLS) AND SUITABLE PROTECTIVE GLOVES when handling the concentrate or handling contaminated surfaces.
WEAR SUITABLE PROTECTIVE CLOTHING (COVERALLS) when bagging treated seed.
WEAR SUITABLE PROTECTIVE CLOTHING (COVERALLS), SUITABLE PROTECTIVE GLOVES AND SUITABLE RESPIRATORY PROTECTIVE EQUIPMENT# when cleaning machinery #i.e. disposable filtering facepiece respirator to EN 149 FFP3(S) or equivalent.

However, engineering controls may replace personal protective equipment if a COSHH assessment shows they provide an equal or higher standard of protection.

WASH HANDS AND EXPOSED SKIN after cleaning and re-calibrating equipment.
WASH HANDS AND EXPOSED SKIN before meals and after work.

(b) Environmental protection

Seed coating shall only be performed in professional seed treatment facilities. Those facilities must apply the best available techniques in order to ensure that the release of dust during application to the seed, storage and transport can be minimised.
Adequate seed drilling equipment shall be used to ensure a high degree of incorporation in soil, minimisation of spillage and minimisation of dust emission.
Do not contaminate water with the product or its container. Do not clean application equipment near surface water. Avoid contamination via drains from farmyards and roads.
HARMFUL TO BIRDS, GAME AND OTHER WILDLIFE. To protect birds and wild mammals the product must be entirely incorporated in the soil; ensure that the product is fully incorporated at the end of rows. Remove spillages.
TREATED SEED MUST NOT BE BROADCAST.

a) In order to reduce the risk of exposure to pollinators a minimum interval of 32 months must be observed between drilling ‘Cruiser SB’ treated sugar beet seed and planting any restricted crop* on the same area of land.

   * Refer to agreed stewardship document for details of restricted/non-restricted crops.

b) A minimum interval of 46 months must be observed between drilling ‘Cruiser SB’ treated sugar beet seed and planting any seed (including further sugar beet seed) treated with thiamethoxam on the same area of land.

c) Treated seed must be drilled (broadcasting and aerial spreading of coated seed is forbidden).

d) The drilling rate for Cruiser SB treated sugar beet seed must not exceed 115,000 seeds/ha.

e) Records must be kept of the fields sown with ‘Cruiser SB’ treated seed and monitoring carried out and recorded in accordance with the agreed stewardship document (Appendix 3 of the authorisation).

(c) Consumer protection

Do not re-use sacks or containers that have been used for treated seed for food or feed.

(d) Storage and disposal

KEEP IN ORIGINAL CONTAINER tightly closed in a safe place.
EMPTY CONTAINER COMPLETELY and dispose of safely.
DO NOT RE-USE CONTAINER for any purpose.

LABEL TREATED SEED with the appropriate precautions using printed sacks, labels or bag tags.
Do not use treated seed as food or feed.

CRUISER SB

A flowable concentrate for seed treatment containing 600g/litre thiamethoxam.

Signal Word	Warning
Hazard Statements	Very toxic to aquatic life with long lasting effects.
Precautions Statements	Avoid release to the environment. Collect spillage Dispose of contents/container to a licensed hazardous-waste disposal contractor or collection site except for empty clean containers which can be disposed of as non-hazardous waste.
Supplemental Information	To avoid risks to human health and the environment comply with the instructions for use.

IMPORTANT INFORMATION

FOR USE ONLY AS AN AGRICULTURAL SEED TREATMENT

For use on:

Crops:	Sugar beet (seed)
Maximum individual dose:	75 ml product per unit of seed
Maximum number of treatments:	One per batch
Latest time of application:	Before drilling

READ THE LABEL BEFORE USE. USING THIS PRODUCT IN A MANNER THAT IS INCONSISTENT WITH THE LABEL MAY BE AN OFFENCE. FOLLOW THE CODE OF PRACTICE FOR USING PLANT PROTECTION PRODUCTS.

‘Cruiser SB’ Link to #Tableofcontents

This leaflet is part of the approved Product Label.

DIRECTIONS FOR USE

IMPORTANT: This information is approved as part of the Product Label. All instructions within this section must be carefully read in order to obtain safe and successful use of this product.

RESISTANCE MANAGEMENT

CRUISER SB contains thiamethoxam a neonicotinoid insecticide (IRAC 4a). There are no known cases of resistance to thiamethoxam or other neonicotinoid insecticides in the UK to date for peach-potato aphid (*Myzus persicae*). However, the possible development of resistance cannot be excluded or predicted and control may be reduced if strains of pest resistant to thiamethoxam or other neonicotinoids develop.

Use of this product should form part of a resistance management strategy. Subsequent foliar sprays against peach-potato aphid (*Myzus persicae*) should be made with a product containing a different active substance and from a different mode of action class.

Consult the UK IRAG website for further information on a particular management strategy.

Since the occurrence of resistance cannot be forecast, neither Syngenta UK Limited nor its distributors can accept responsibility for any loss or damage to crops caused by the failure of CRUISER SB to control resistant strains.

PESTS CONTROLLED

CRUISER SB is a seed treatment, containing the neonicotinoid insecticide thiamethoxam, for the control of peach-potato aphid (*Myzus persicae*) an aphid vector of virus yellows attacking sugar beet seedlings. Control of aphid vectors may decline after 10 weeks.

CROP SPECIFIC INFORMATION

Crops
Sugar beet

Timing
Before drilling

Rate of Use
Apply 75 ml CRUISER SB per unit of seed (1 unit = 100,000seeds)

APPLICATION

CRUISER SB must only be applied to sugar beet seed as part of the normal commercial pelleting process using special treatment machinery.

Agitate container thoroughly before use (For 20 litre containers by rolling containers on a level floor).

<u>For 20 litre 'anti-glug' plug containers</u>

Remove both caps. Pierce the ‘anti-glug’ plug. Add the required amount of CRUISER SB, then replace both caps.

Storage after treatment
Seed should be stored in a cool, dry, ventilated building. Treated seed must be used in the season of use only.

Seedbed Preparation And Drilling
Seed drills must be suitable for use with polymer-coated seeds. If in any doubt, refer to the drill manufacturer. Treatment with CRUISER SB does not alter the physical characteristics of pelleted seed and no change to standard drill settings should be necessary.

Prepare a firm, even seedbed. CRUISER SB is not known to have any adverse effect on seed germination or crop emergence but poor seed quality or seedbed conditions (waterlogged, capped, dry, fluffy or cloddy seedbeds) may result in delayed emergence and/or poor establishment. Similarly, avoid deep or shallow drilling which can adversely affect crop establishment and may reduce the level of pest control.

Herbicides
Herbicides containing the active ingredient lenacil should not be used pre-crop emergence on fields drilled with seed treated with CRUISER SB. Other approved herbicides may be applied pre-emergence of the crop. Approved herbicides may be used as recommended post emergence of the crop.

To minimise the number of flowering weeds in treated sugar beet crops and reduce the risk of indirect exposure of pollinators to neonicotinoids, BASIS recommended herbicide programmes must be adopted by growers and their agronomists. This applies in treated fields only. (Not field margins or the surrounding areas).

Seed Spillages
In case of seed spillage, clean up as much as possible into the related seed sack and re-use the clean seed. Bury or remove the remainder completely.

After Use
Dispose of product concentrate, empty containers and contaminated seed bags according to the “Code of Practice for the Safe Use Of Pesticides on Farms and Holdings” available from HMSO. Do not re-use containers for any purpose.

SEED BAG LABEL TEXT

This seed has been treated with CRUISER SB which contains thiamethoxam a neonicotinoid insecticide for the control of peach-potato aphid (*Myzus persicae*) to prevent virus yellows infection. Records must be kept of the fields sown with ‘Cruiser SB’ treated seed and monitoring in accordance with the agreed stewardship document.

Insecticide Group 4A

Subsequent foliar sprays against peach-potato aphid (*Myzus persicae*) should be made with a product from a different mode of action class. Consult the IRAG website for further information.

Treated seed must be drilled (broadcasting and aerial spreading of coated seed is forbidden).

The drilling rate for Cruiser SB treated sugar beet seed must not exceed 115,000 seeds/ha.

To minimise the number of flowering weeds in treated sugar beet crops and reduce the risk of indirect exposure of pollinators to neonicotinoids, BASIS recommended herbicide programmes must be adopted by growers and their agronomists. This applies in treated fields only. (Not field margins or the surrounding areas).

In order to reduce the risk of exposure to pollinators a minimum interval of 32 months must be observed between drilling 'Cruiser SB' treated sugar beet seed and planting any restricted crop* on the same area of land.

*Refer to agreed stewardship document for details of restricted/non-restricted crops.

A minimum interval of 46 months must be observed between drilling 'Cruiser SB' treated sugar beet seed and planting any seed (including further sugar beet seed) treated with thiamethoxam on the same area of land.

WEAR SUITABLE PROTECTIVE CLOTHING (COVERALLS) AND SUITABLE PROTECTIVE GLOVES when handling treated seed and contaminated seed sowing equipment.

SAFETY PRECAUTIONS

DO NOT HANDLE seed unnecessarily.
DO NOT USE TREATED SEED as food or feed.
KEEP TREATED SEED SECURE from people, domestic stock/pets and wildlife at all times during storage and use.
HARMFUL TO GAME OR OTHER WILDLIFE. Treated seed must be entirely incorporated in the soil; ensure that the product is also fully incorporated at the end of rows. Treated seed must not be left on the soil surface. Bury or remove spillages.
DO NOT RE-USE SACKS OR CONTAINERS THAT HAVE BEEN USED FOR TREATED SEED for food or feed.
TREATED SEED MUST NOT BE USED as food or feed.
TREATED SEED MUST NOT BE BROADCAST.
WASH HANDS AND EXPOSED SKIN before meals and after work.

NOTES

1 Drilling

Seed drills must be suitable for use with polymer-coated seeds. If in any doubt, refer to the drill manufacturer. Treatment with CRUISER SB does not alter the physical characteristics of pelleted seed and no change to standard drill settings should be necessary. Check drill calibration before drilling each batch of seed to ensure an accurate drilling rate.

2 Storage

Seed should be stored in a cool, dry, ventilated building. Treated seed must be used in the season of use only.

3 Seed spillages

In case of seed spillage, clean up as much as possible into the related seed sack and re-use the clean seed. Bury or remove the remainder completely.

Syngenta UK Limited
CPC4, Capital Park
Fulbourn
Cambridge CB21 5XE
Tel: Cambridge (01223) 883400

Section 6 of the Health and Safety at Work Act
Additional Product Safety Information

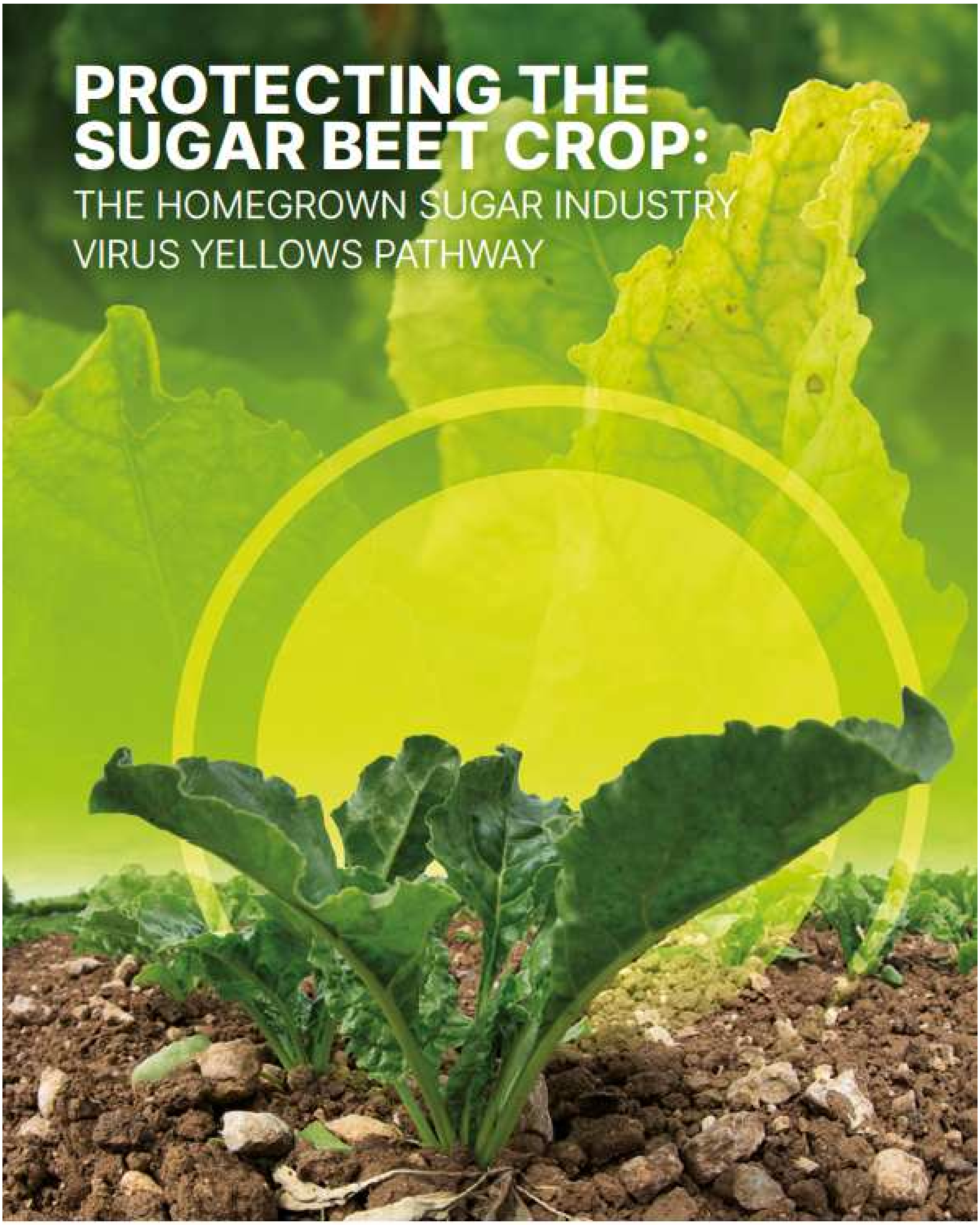
(This section does not form part of the product label under the Plant Protection Product Regulations 1995.)

The product label provides information on a specific pesticidal use of the product; do not use otherwise, unless you have assessed any potential hazard involved, the safety measures required and that the particular use has 'extension of use' approval or is otherwise permitted under the Plant Protection Product Regulations 1995.

The information on this label is based on the best available information including data from test results.

Appendix 4: Virus yellows pathway brochure

Double click the title page to view



'Cruiser SB' Link to #Tableofcontents

Appendix 4: Aphid monitoring 2024 and 2023

BBRO Aphid monitoring summary

Aphid monitoring 2023 summary.pptx

Appendix 5: ECP advice from 10 September 2024 meeting

ECP ADVICE TO GOVERNMENT: USE OF ‘CRUISER SB’ ON SUGAR BEET

Issue

1. The Government has received an application for an emergency authorisation for the use of ‘Cruiser SB’ (containing thiamethoxam) for use as a seed treatment on sugar beet.

Action required

2. The Committee is requested to advise on:

- The approach taken to deviate from guidance and present a drinking water exposure assessment in this emergency authorisation situation, and the risk to consumers resulting from this.

- Whether/how the evidence resulting from monitoring activity could support the regulatory assessment/decision.

- The continuation of soil monitoring and whether/how the evidence could be used to supplement the existing dataset of persistence information on thiamethoxam and clothianidin. Also, whether there is sufficient evidence within the data to indicate lateral movement of residues from the cropped area into field margins or whether monitoring of field margins should be continued.

- Whether there are further additional approaches to appropriately limit the use of ‘Cruiser SB’ to identified higher risk situations, where existing combined control measures may not provide sufficient level of control.

Discussion

3. The Committee *noted* that:

- This is the fifth consecutive application for this proposed use.

- Modelling predicts that one of the metabolites of thiamethoxam (NAO 459602) will exceed the regulatory-based hazard-based cut off for groundwater. In the absence of any further data on the metabolite, HSE have, in accordance with the guidance, assumed it shares the same reproductive toxicity profile as the active substance and therefore that it is a relevant groundwater metabolite. A commercial authorisation is not possible when a relevant metabolite is predicted to occur in groundwater at or above 0.1µg/L. However, since this is for an emergency use, HSE have conducted a risk assessment which shows the risk to consumers from drinking water to be acceptable.

- It would be interesting to understand if water treatment plants tested for clothianidin as well as thiamethoxam and if they would be able to detect the NAO 459602 metabolite at a concentration above the hazard based cut off.

- Six sites sown with 'Cruiser SB' treated seed in 2022 and 2023 were monitored for thiamethoxam and its major metabolite clothianidin. The monitoring was from field soils, field-margins, field margin vegetation and field margin pollen. The method of analysis used in 2022 did not have a sufficiently low LOQ to allow meaningful use of the results in the risk assessment. For the monitoring conducted in 2023 a more sensitive method was used. The difference in methodologies makes comparison between 2022 and 2023 difficult.

- It is HSE's view that the use of a threshold trigger restricting use only to when the predicted virus incidence provided by the virus yellows forecasting model is above the level of this threshold is not sufficient to consider the use limited.

4. The Committee *agreed* with HSE's evaluation that:

- The requirement to ensure that the product will be used in a limited and controlled way has not been met. Members agreed it was unclear why growers responsible for 40% of the area of sugar beet used for sugar production chose not to use 'Cruiser SB' treated seeds in 2023 and 2024.

- The soil, vegetation and pollen monitoring is evidence that, in the field, the persistence of thiamethoxam and clothianidin is greater than expected from the standard regulatory DT_{50} testing.

5. The Committee *advised* that:

- They agreed with HSE's approach to conduct a refined risk assessment to show the risk to consumers from drinking water is acceptable. Due to no toxicology data being available for metabolite NAO 459602, HSE's approach to extrapolate from the parent compound is valid.

- The indications of increases in the concentrations of clothianidin in the water monitoring data for one catchment is in line with what was predicted by modelling members conducted previously, that suggested clothianidin was the main metabolite form that could enter waters. Further, concentrations at the catchment outlet imply higher edge of field concentrations for treated areas. It would be helpful to see additional monitoring from the edge of fields or streams/ditches near fields with a high coverage of sugar beet sown with 'Cruiser SB' treated seeds where concentrations of both thiamethoxam and clothianidin are expected to be higher.

- Reliance on the Rothamsted beet virus yellow forecasting model was not enough. Further research needs to be carried out to understand, for sugar beet grown without the use of seed treated with 'Cruiser SB', what products are being used, where they are being used and why. It is also important to understand yield difference between sugar beet grown from treated seed vs that grown without (with and without later spray treatment).

Conclusion

Based on the evidence presented to ECP, the Committee agreed it supports the HSE assessment and that it is unable to support an emergency authorisation under Article 53 of Regulation 1107/2009.

Appendix 6: Glossary

General

ACP	Advisory Committee on Pesticides
DAR	Draft assessment report
EC	European Commission
ECP	Expert Committee on Pesticides
EFSA	European Food Safety Authority
EU	European Union
GAP	Good Agricultural Practice
MS	Member state

Non-dietary Human Exposure

AOEL	Acceptable Operator Exposure Level
PPE	Personal Protective Equipment

Residues

TTC	Threshold of toxicological concern
NEDI	National estimate of dietary intake
IEDI	International estimated daily intake
ADI	Acceptable daily intake
ARfD	Acute reference dose
MRL	Maximum residue level
RO	EFSA Reasoned Opinion

Environmental Fate and Behaviour

PEC	Predicted Environmental Concentration
PECSOIL	Predicted Environmental Concentration in soil
PNEC	Predicted No Effect Concentration
DT50 /DT90	Degradation time for 50 % or 90 % of substance to degrade.
PECSW	Predicted Environmental Concentration in surface water
PECSED	Predicted Environmental Concentration in sediment
PECGW	Predicted Environmental Concentration in ground water
Pa	Pascal
1/n	Freundlich exponent
LogPow	Octanol/water partition coefficient

Ecotoxicology

EC50	Effect concentration for 50% of the test population
LC50	Lethal concentration for 50% of test population
NOEC	No Observed Effect Concentration
LOEC	Lowest Observed Effect Concentration
NOEDD	No Observed Effect Daily Dose
LOEDD	Lowest Observed Effect Daily Dose
HC5	Hazardous concentration for 5% of species
SSD	species sensitivity distribution
ETR	Exposure Toxicity Ratio
TER	Toxicity/exposure ratio