EMERGENCY REGISTRATION REPORT

Product name: Cruiser SB

Active substance:

thiamethoxam 600 g/l

United Kingdom

Applicant: NFU sugar and British Sugar

Submission date: 29 June 2021

Finalisation date (post ECP): 29 Oct 2021

HSE Ref Number: COP 2021/01344

Version history

When	What

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	**Health and Safety Executive, UK**
Reviewer's comments	HSE input is contained within these green boxes all other text is written by the applicant.

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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 Level
HC5	Hazardous concentration for 5% of species
SSD	species sensitivity distribution
ETR	Exposure Toxicity Ratio
TER	Toxicity/exposure ratio

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	**Health and Safety Executive, UK – approach to Article 53**
Reviewer's comments	This Emergency registration report (eRR) is for the evaluation of an application for emergency authorisation for the use of the plant protection product "Cruiser SB" in England. An emergency authorisation may be granted under Article 53 of Regulation 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 and Department for Environment, Food and Rural Affairs (Defra). 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 of this eRR), 'danger' (section 2.2.1) 'any other reasonable means' (sections 2.2.2), 'limited and controlled use' (section 2.2.4) and 'appears 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 eRR will be presented to members of the Expert Committee on Pesticides (ECP) who will be asked questions relating to the HSE assessment for honey bees. The ECP will produce independent scientific advice to Government which will be presented to Defra and the Devolved Administrations in Scotland, Wales and Northern Ireland. Should HSE issue an authorisation under Article 53, it will permit the product to be placed on the market for a maximum of 120 days. Users of the product must only apply the product in line with the conditions laid out in the authorisation notice as published on the HSE website. A draft is presented at Appendix 1 of this eRR. Failure to comply with these conditions may result in enforcement action being taken. The applicant and users must monitor and record any use of the product under this Article 53 authorisation. HSE may request additional information to be generated during the period/season of use.

1 Details of the application

1.1 Background of Application

Evaluation, Summary and Conclusion by The Health and Safety Executive.

1.1.1 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 authorised 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 requiring treated seed to remain under protection for the entirety of the plant life-cycle. Following implementation of this restriction, the applicant withdrew support for the renewal process and the EU approval for the active substance thiamethoxam expired.

1.1.2 Situation

This is a repeat of the application for an Article 53 authorisation that was made and granted in 2020 for treatment of sugar beet seed to be planted in the Eastern counties of England in spring 2021. Due to the cold weather in January and February 2021, the virus yellows forecast run on 1 March indicated that virus infection in 2021 was relatively low and below the threshold at which the treatment was permitted under the authorisation.

Therefore 'Cruiser SB' was not used on sugar beet crops planted in 2021.

1.1.3 Application History

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 authorisation for the use of 'Cruiser SB' as a seed treatment on sugar beet seed planted in 2022, for the control of peach potato aphid (*Myzus persicae* (MYZUPE)), which is the main vector of Beet Virus Yellows (BYV). The Yellows Virus complex consists of three viruses; Beet Yellows Virus (BYV), Beet mild yellowing virus (BMYV) and Beet Chlorosis virus (BChV).

The applicant has proposed that, if authorised, seed will only be treated if predicted virus infection is above an economic treatment threshold. The forecast for virus infection is run in late February, based on a long-standing validated model which predicts virus levels in untreated sugar beet in August (details below). The treatment threshold is then established based on predicted yield losses from BYV in comparison with the sugar beet commodity price and the cost of treatment with 'Cruiser SB'. At the time of writing, and submission of the application, 2021 prices have not been finalised and therefore the actual proposed threshold figure is unknown. An update with the proposed figure will be provided by the applicant as soon as possible, although early indications are it will be at a similar level to last year.

Thiamethoxam was included in Annex I to Directive 91/414/EEC on 1 February 2007 by Commission Directive 2007/6/EC, and was subsequently deemed to be approved under

Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011

Use of thiamethoxam as a seed treatment on sugar beet seed was first authorised in UK on 27 June 2006, following consideration via the Committee Procedure (COP 2006/00175 PP) and was subsequently re-registered following the Annex I inclusion of thiamethoxam under EU Directive 91/414/EEC (UK application reference, COP 2008/00049). The use was subsequently withdrawn in 2018 as a result of Commission Implementing Regulation (EU) 2018/785 which restricted use of thiamethoxam to plants where the entire life cycle was inside.

An Article 53 application (at a higher rate under COP 2018/01509) was previously considered at the July 2018 ECP (for the 2019 season) when ultimately an authorisation was refused by HSE.

Following exceptionally large numbers of aphids in 2020 along with the highest virus levels for over 40 years (38% National crop infected) and significant yield losses, a further Article 53 application was submitted for use in 2021. The concern being a further mild winter would lead to a repeat of the 2020 situation. The applicant proposed a reduced application dose on the seed, and an economic treatment threshold (as described above). Additional data to further the assessment of the risk to bees was also provided by the manufacturer. Ultimately authorisation was granted (as detailed in the Defra statement) and included a number of conditions, most notably:

> Sugar beet seed must only be treated in accordance with this authorisation under the direction of British Sugar, if the agreed 9% threshold of virus levels is met based on the British Beet Research Organisation (BBRO) 2021 virus yellows forecast

The forecast (run on 1 March 2021) predicted that 8.3% of sugar beet crops would be infected with virus in August without intervention measures. Consequently, the conditions for use of 'Cruiser SB' were not met and seed was not treated for the 2021 season. Foliar treatments were still necessary for a proportion of the national crop, consisting of 1-2 sprays (where needed/), using the authorised product 'Teppeki' (MAPP 12402, containing flonicamid), and an Article 53 authorisation for 'Insyst' (MAPP 13414, containing acetamiprid).

Part D of the applicant's application form (pages 6 and 7) is copied below and includes details of the background on the current and previous applications.

1.1.4 Consideration of Special circumstances

For over 25 years *Myzus persicae* vectors and the Yellows Virus complex was controlled by the neonicotinoid seed treatments (most recently 'Cruiser SB' (MAPP 12958) and 'Poncho Beta' (MAPP 12076) (beta-cyfluthrin + clothianidin) and prior to that 'Gaucho FS' containing imidacloprid) which also controlled the range of other sugar beet insect/soil pests. Consequently, few if any other insecticides were required during the season. Since their withdrawal in 2018, there have been only 3 seasons experience for the industry to understand and develop new strategies (largely without sufficient available insecticides) to manage aphid/virus yellows complex. There are no recent reference baselines or comparable situations, and each season has been different. 2019 was a moderate year with 57% of crop surveyed sprayed with one or two foliar sprays against aphids (using either Teppeki (flonicamid) or an Article 53 authorisation for Biscaya (thiacloprid), and little impact on national yield. This was followed by the 2020 epidemic with unprecedented aphid numbers caught. 78% of surveyed crop receiving two-four foliar sprays (using either Teppeki or Article 53 authorisations for Biscaya, Gazelle (acetamiprid) or Insyst (acetamiprid)), and very significant yield losses occurred. In 2021, it has been a very different situation again, with the cold winter reducing aphid populations and delaying migration. Only localised areas needed a second foliar spray.

However, virus levels remain high and the general trend as evidenced by the applicant (see Section 2.2.1.1 b) is for the continued build up in background *M. persicae* populations, which can then cause significant problems in seasons with favourable conditions. This general trend reflects the wider lack of control options on other *Myzus* host crops. In addition, the range of other foliar and soil sugar beet pests now need additional insecticide sprays, which is dependent on use of pyrethroids which themselves 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. Whilst research is on-going to develop a more integrated approach, this will take time. In particular, one of the central strategies in developing commercial resistant varieties is proving challenging because the complex consists of three viruses and there is no one single trait conferring resistance/tolerance to the virus. And during years of high epidemics, as in 2020, the testing of commercial varieties is impaired because they were also affected by virus infection.

All of this uncertainty, and growing threat to crop yields, is reflected in British Sugar and NFU Sugar supporting growers through the new virus yellows assurance scheme (funded by British Sugar) to compensate for yield losses. However, the applicant has noted the 2021 contracted area has decreased by 12% due to the yield losses of 2020.

The applicant had already made a significant investment in long term research to develop commercial resistant varieties, which was initiated before neonicotinoids were withdrawn, recognizing the need to find alternatives (full details in section 2.2.5 ‘repeat applications’).

Taking into account the above points HSE consider that there are special circumstances supporting this proposed Article 53 Authorisation.

Response to data requirements or request for supporting information

The following data requirements were set as part of the authorisation for use in 2021:

(1) By the end of February 2021, the following must be submitted to HSE:

(a) The details of the grower and agronomist facing stewardship document as indicated in the stewardship information outlined in Annex B.

Draft stewardship was provided 22 February for comment, and an agreement was made that the final stewardship could be submitted on 2 March, after the forecast was run. Since the forecast meant that there would be no use in 2021, the finalised stewardship document was not required.

(b) Proposals for the monitoring programme of residues in soil and plants for HSE consideration.

Draft protocols were provided on 19 February, but since there was no use, no monitoring was undertaken.

(c) Details of whether the threshold for treatment was met and the quantity of 'Cruiser SB' treated seed ordered.

HSE and Defra were informed on 1 March (w 002007449) that "*The VY infection is forecast to be 8.37%. Given it is under the 9% threshold in our EA application 'Cruiser SB' will not be applied on sugar beet seed in the UK this spring.*"

(2) **By end of October 2021 (and ideally earlier)**

All the crop monitoring information and evidence that the stewardship plan has been implemented and followed by all users, must be submitted to HSE. This must include an assessment of how successful the stewardship plan was in achieving its aims and recommendations for improvement as necessary.

Since there was no use in 2021, the above data requirement did not apply.

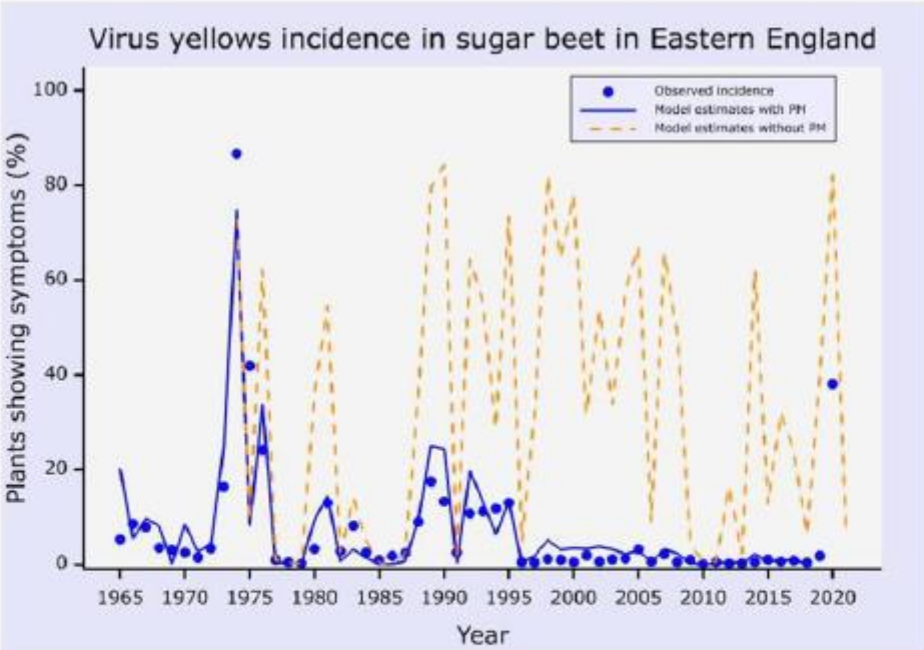
Part D – Repeat applications			
16	Has HSE authorised a previous emergency use for the proposed crop/situation and pest?*.		
	Yes (This is a repeat please complete Part D section 17 to 21 and Parts E to H) ☒		No (Please go to Part E) ☐
17	COP number(s) and Notice of Authorisation number(s)(NANUMS) of previous authorisation(s)	COP2020/01677	
18	If this application request is not identical to the use given above outline any differences	In 2020, the UK sugar beet sector experienced its worst virus yellows epidemic since the mid-1970s. In 2020, two years since the EU withdrawal of the neonicotinoid seed treatments on sugar beet, 38.1% of the national crop became infected with virus yellows. Many growers in Cambridgeshire, Norfolk, Suffolk and South Lincolnshire experienced up to 100% infection even with the use of up to four aphicide sprays applied at the BBRO recommended aphid spray threshold. 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. A similar situation was experienced across Europe, especially France. The UK sugar beet industry, in light of this ongoing pressure, was granted a short term, limited and controlled emergency authorisation for the use of Cruiser SB on seed. Unlike anywhere else in Europe, our application included the long-standing virus yellows forecast (issued by Rothamsted Research) to determine if conditions triggered the application of Cruiser SB to sugar beet seed. **The 1st of March forecast predicted that 8.37% of the national sugar beet area will be affected by virus yellows by the end of August 2021. Under the terms of the emergency authorisation from HSE and DEFRA this meant that the use of Cruiser SB was not triggered and was not applied to seed in 2021.**	

* A pest is defined as 'Any organism harmful to plants or to wood or other plant products, any undesired plant and any harmful creature.'

19	Justification for repeat authorisation

You must provide justification why a repeat authorisation is required.

Following the very cold January and early February, the well-established Rothamsted model predicted low levels of Virus Yellows in the crop for 2021. The model outcomes predicted around 1/10th of the virus levels of last year and below economic trigger level of 9%; first aphid flights were predicted to be 6 weeks later. With a predication of 8.3% (without any controls), the trigger was not met and therefore the seed was not treated with Cruiser SB in 2021.



It is to be welcomed that the emergency situation our industry faced in 2020 is not likely to be repeated in 2021. The application for emergency use of the seed treatment was just that – we committed to only treating the seed if the risk to the crop was significant. We have followed the science, using a proven model that has been in place for over 55 years, and minimised impact where possible. We will also continue to work to progress our plans to tackle Virus Yellows with an integrated crop management approach without the need for neonicotinoid seed treatments in future years, but for now the need for Cruiser SB remains.

1.2 Proposed uses

The proposed use as provided by the applicant is set out in the tables below. This is supplemented by the draft Stewardship scheme (appendix 3). This will be updated to reflect conclusions of the assessment if an Article 53 authorisation is recommended.

Of critical importance to the risk assessment is the seed drilling rate. A consideration of drilling rate is presented in section 2.6 Environmental Fate and behaviour but a maximum drilling rate of 115,000 seeds/ha has been used in the risk assessment. If authorisation is granted a restriction limiting the maximum number of seeds per hectare to 115,000 will be imposed. This gives a maximum active substance application rate of 51.75 g a.s./ha.

12 Product	Proposed emergency use/situation	Comparison product
On-label/Extension of Use/ Previous Emergency authorisation		
Product	Cruiser SB	Cruiser SB
MAPP number	15012	15012
Active substance(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 (e.g. fungicide)	Professional – seed treatment	Professional – seed treatment

13	Uses	Proposed emergency situation		Current authorised use or previous Emergency authorisation	
Crop details	Identity of crop or situation of use[1]	Sugar beet (seed)		Sugar beet and fodder beet (seed)	
	Situation of crop[2]	indoor (non crop production)	☐	indoor (non crop production)	☐
		outdoor	☒	outdoor	☒
		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 target	n/a applied as seed treatment		n/a applied as 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 leaf miner fly complex (e.g. *Pegomya hyoscyami* and related sub-species) e.g. PEGOHY
Max. individual dose	75 ml product / 100 000 seeds	75 ml product / 100 000 seeds
Max. total dose	75 ml product / 100 000 seeds	75 ml product / 100 000 seeds
Max. number of treatments	1	1
Earliest time of application (estimated date and BBCH code[5])	BBCH 00 – seed treatment before drilling	BBCH 00 – seed treatment before drilling
Latest time of application (estimated date and BBCH code[5])	BBCH 00 – seed treatment before drilling	BBCH 00 – seed treatment before drilling
Interval between applications	Not applicable	Not applicable
Proposed period of use (Dates)	March 2021	March 2021 (however, seed not treated as model was not triggered)

14	**Application**	**Proposed emergency situation**	**Current authorised use or previous Emergency authorisation**
Total amount of crop grown in the UK	**Hectares**	approx 100,000 hectares	105,000 hectares
	Tonnage where applicable	Approx. 7.5 million tonnes	Approx. 8 million tonnes

Total amount of crop treated	**Hectares**	0--100,000 hectares depending on 2022 virus yellows forecast			0-105,000 hectares depending on virus yellows forecast		
	Tonnage where applicable						
% Area of UK crop to be treated		0-99% depending on 2022 virus yellows forecast			0-99% depending on virus yellows forecast		
Geographical locations of proposed uses		Eastern counties of England surrounding four sugar factories in Norfolk, Suffolk and Nottinghamshire			Eastern counties of England surrounding four sugar factories in Norfolk, Suffolk and Nottinghamshire		
Application method(s) to be used			Protected/(PPFE)	Outdoor		Protected/(PPFE)	Outdoor
		Horizontal boom sprayer	☐	☐	Horizontal boom sprayer	☐	☐
		Broadcast sprayer with air assistance / variable geometry boom sprayer	☐	☐	Broadcast sprayer with air assistance / variable geometry boom sprayer	☐	☐
		Hand-held application – rotary atomiser	☐	☐	Hand-held application – rotary atomiser	☐	☐
		Hand-held application – hydraulic nozzle	☐	☐	Hand-held application – hydraulic nozzle	☐	☐
		Drip irrigation	☐	☐	Drip irrigation	☐	☐
		Soil drench	☐	☐	Soil drench	☐	☐
		Other – please provide details and provide photographs if possible	☐	☒ seed treatment	Other – please provide details and provide photographs if possible	☐	☒ seed treatment
Water volumes (range)		N/A			N/A		

15 Restrictions	Proposed emergency situation	Current authorised use or previous Emergency authorisation
Operator protection	a) Operators must wear suitable protective clothing (coveralls) and suitable protective gloves when handling the concentrate, handling contaminated surfaces or handling treated seed. (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 FFP2 or equivalent.	(a) Operators must wear suitable protective clothing (coveralls) and suitable protective gloves when handling the concentrate, handling contaminated surfaces or handling treated seed. (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 FFP2 or equivalent.
Environmental protection	1) To protect birds and mammals treated seed should not be left on the soil surface. Bury or remove spillages. (2) 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. (3) 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 SURFACE WATERS OR DITCHES with chemical or used container.	1) To protect birds and mammals treated seed should not be left on the soil surface. Bury or remove spillages. (2) 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. (3) 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 SURFACE WATERS OR DITCHES with chemical or used container.

15	Restrictions	Proposed emergency situation	Current authorised use or previous Emergency authorisation
Other specific restrictions		1) Returnable containers must not be re-used for any other purpose. (2) Returnable containers must be returned to the supplier. (3) Treated seed must not be used for food or feed. (4) Sacks containing treated seed must not be re-used for food or feed. (5) Treated seed must not be applied from the air.	(1) Returnable containers must not be re-used for any other purpose. (2) Returnable containers must be returned to the supplier. (3) Treated seed must not be used for food or feed. (4) Sacks containing treated seed must not be re-used for food or feed. (5) Treated seed must not be applied from the air.

Notes	
1	For ornamental plant production give details of whether all ornamentals or specific types e.g. pot grown, soil grown, cut flowers, shrubs etc List individual crops. Do not list crop groups. Use the basic crop terms as set out in the current crop definitions list. Do not use the parent or primary group terms. For renewal and re-registration applications update the crop terms to those currently in the crop definitions list.' crop definitions list.
2	For protected crops describe whether permanent protection, grown in soil or substrate, pots on hard surfaces, bench systems etc. Further information on crop situations can be found on the crop definitions list.
3	This may be a specific number e.g. 1 or a range such as 1-3
4	Individual crops and pests are given an EPPO code for harmonised identification. Please use the following link to obtain the required EPPO code https://gd.eppo.int/
5	The growth stages of crops are categorised using a scale. The following link provides a PDF document containing the growth stages for multiple crops BBCH scale.
6	Novel methods of application must be described in full and include pictures of how they are filled and operated (this can be provided in a separate document).

2 Risk Assessment

2.1 Physical and chemical properties

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	**Health and Safety Executive, UK**
Reviewer's comments	No new assessment has been undertaken. The physical and chemical properties of the formulation were considered acceptable in the original assessment for 'Cruiser SB' which was 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. Syngenta has confirmed (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).

2.2 Efficacy

The following efficacy sections discuss the requested Emergency authorisation use in relation to the Article 53 requirements to consider; 'a danger', 'any other reasonable means' (both chemical and non-chemical control) and 'limited and controlled'.

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	**Health and Safety Executive, UK**
2.2.1 The danger	a) Danger - Background (Sections 25, 26 and 27 of the application form). Previous Article 53 applications have described and evidenced 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 application also includes information on the development and historical review of the model predicting virus incidence (with and without control measures). HSE recognises that the virus yellows/aphid vectors represent a threat and danger to the yield production of sugar beet and therefore the production of sugar. The danger could lead to economic impacts as a result.

25	Details of pest problem

Please provide details of the pest (specific danger to be controlled) including life cycle, mode of action and severity of the threat posed to the crop/situation. Include details of relevant pest threshold levels, where known, and the results of any recent or ongoing relevant monitoring or surveys of pest numbers. Please indicate whether this is a new problem.

Overview

In the UK, neonicotinoid seed treatments have been used to control up to 15 different pests (and associated virus diseases) that can be found across all the sugar beet growing area in Eastern England (**Foster and Dewar, 2013**). These treatments control similar or additional pests across north-west Europe too (**Hauer et al., 2016**). The pests can be divided into three key sub-groups:

1. the critical **virus yellows-carrying aphids**, principally the peach-potato aphid (*Myzus persicae*);

2. the **leaf miner fly complex** (e.g. *Pegomya hyoscyami* and related sub-species);

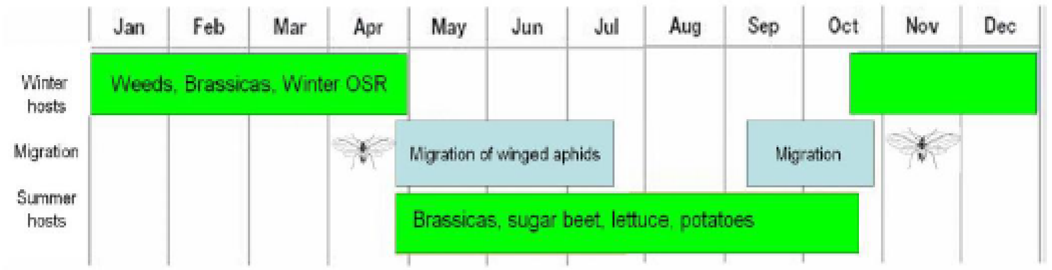
3. the **soil pest complex** (e.g. springtails, symphylids and millipedes) that cause generalist root grazing, damage and/or plant loss (reviewed by **Dewar, 2000**) but can be reasonably controlled in low/medium pest pressure situations by ongoing use of tefluthrin (Force) as previously used in the late 1980s/early 1990s prior to the first registration of the neonicotinoids in the UK in 1994.

We set out details of pest thresholds and ongoing monitoring results for aphids and virus yellows.

Virus yellows transmitted by aphids

The peach-potato aphid (*M. persicae*) is regarded as a major pest on a range of crop species including potatoes, brassicas, legumes and sugar beet. It is the most important pest and virus vector aphid in the UK due to its wide host range and proficiency in transmitting more than 120 plant viruses. Most peach-potato aphids overwinter as winged and wingless forms on weeds and brassicas. Winged individuals then migrate from winter hosts to summer hosts from late April and numbers usually peak in July. This aphid species does not form dense colonies and rarely reaches levels that cause direct feeding damage. However, its tendency to move short distances when crowded enhances its importance as an aphid vector.

Virus yellows is an aphid-transmitted virus 'complex' of three different viruses that includes the poleroviruses *Beet mild yellowing virus* (BMYV) and *Beet chlorosis virus* (BChV), and the closterovirus *Beet yellows virus* (BYV). *M. persicae* is regarded as the principle aphid vector, although the potato aphid (*Macrosiphum euphorbiae*) can transmit all three viruses to sugar beet too; the viruses are transmitted via persistent (BMYV and BChV) or semi-persistent (BYV) transmission mechanisms by both aphid species. Therefore, once an aphid has acquired BMYV and BChV it remains infective for the rest of its life, although the adult cannot pass this virus directly onto its progeny. Aphids carrying BYV remain infective for up to three days.



The two aphid species can overwinter on weeds (e.g. *Capsella bursa-pastoris* and *Senecio vulgaris*), oilseed rape, brassica cover crops or on beet 'volunteers' or spoilage heaps of root remnants following harvest (see timeline above). Although brassica species are not hosts for the sugar beet yellowing viruses, many common arable weed species associated with these crops and surrounding margins are hosts for these viruses. If aphids infect and/or acquire the viruses from these and migrate into spring crops such as sugar beet, then primary virus infection and secondary spread can occur.

Infection of sugar beet plants with the yellowing viruses causes chlorosis of leaves which in turn disrupts photosynthetic, respiratory and other metabolic processes. These changes increase the levels of amino nitrogen, sodium and potassium in roots which adversely affects extractability of sugar during factory processing. Also, yellow leaves are susceptible to attack by secondary fungi such as *Alternaria alternata*, which may destroy the leaf, further exacerbating yield loss.

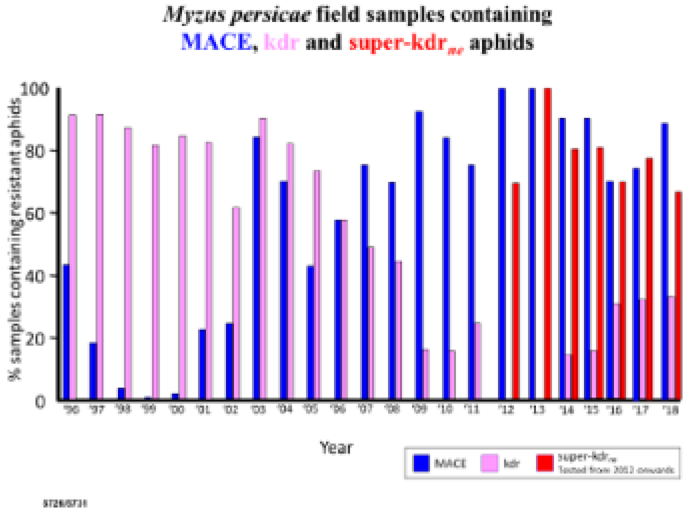
As the UK sugar beet crop is grown under contract by growers for British Sugar plc, each grower has access to a Contract Manager (22 in total across the four factory areas) who provide support and advise on agronomic factors such as aphid control. Each year the industry is provided by the BBRO with pre-season forecasts, produced by Rothamsted Research, of the incidence and abundance of aphids and Virus Yellows. These forecasts are issued at the beginning March and are 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 (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).** These annual forecasts are then supplemented by season-long real-time information on the incidence of the virus vectors, their resistance status and infectivity from both the Rothamsted suction trap and BBRO-managed yellow water pan networks run in association with British Sugar staff, growers and agronomists at approximately 30 sites from the end April/early May until the end of July each year. Both networks have been working in tandem since 1990 and currently this information assists growers who have not used seed treatments or treatments have been compromised by specific weather conditions (e.g. too dry or too wet as occurred in 2007 and 2012 respectively) allowing the aphids to build up above threshold levels for the need for subsequent foliar aphicide application (if available).

From historical aphid monitoring and infectivity testing by the BBRO (between 1994-2004), when the neonicotinoid seed treatments were first introduced into UK sugar beet production, a total of 20,255 *M. persicae* were caught in the yellow water pan network across the UK sugar beet growing area; 222 BMYV-infective aphids were identified using diagnostic tests. Therefore, the proportion of viruliferous aphids was approximately 1% of the population of winged aphids. Although the total number of aphids can differ significantly from one factory region to another, and between years depending on winter weather, the proportion of viruliferous aphids has remained constant and has not significantly differed from one percent, although at several sites in certain weeks and years up to 5% of aphids have been found to carry BMYV.

The industry has continued to support the BBRO aphid monitoring programme and 8109, 5029 and 4970 *M. persicae* were caught in yellow water traps at the 30 locations in 2015, 2016 and 2017, respectively. Equivalent virus testing showed that none of the individuals caught in 2015 or 2016 contained BMYV. Three *M. persicae,* all caught in Cambridgeshire, were viruliferous in 2017. Although these recent data suggest the infectivity of aphids has decreased over time since the late 1990s/early 2000s, and this decline in infectivity might well be linked to neonicotinoid seed treatment use, it must be stressed that there were cases of high levels of virus yellows infection in UK fodder beet in 2017, particularly in the west Midlands, south-west England and in the borders of Scotland. Neonicotinoid seed treatments were not used on these crops, although the seed was treated with tefluthrin, and clearly demonstrates that virus yellows has remained in the UK and would rapidly return into the sugar beet areas if not controlled. In addition, in 2017, several commercial sugar beet crops in Normandy, France, where neonicotinoid seed treatments were not used or partly used in fields by growers (although up to three pyrethroid sprays were applied), showed levels of virus infection of up to 40%. Assessments made by ITB (the French equivalent of BBRO) showed yield losses of around 32% on average in the French crop in 2020 (picture below).

New molecular (qPCR) diagnostics have now been developed at Rothamsted Research for BBRO enabling aphids to be tested for all yellowing viruses simultaneously (rather than just BMYV), further refining the data collected and improving the understanding of the risk associated with virus yellows infection in the future.

The current UK model for seed variety procurement by the British Sugar and NFU seed committee is that varieties are ordered, alongside seed treatments, six to eight months before drilling commences the following spring. Therefore, the decision by growers to order seed treatments (if successful in this application) has been based on previous risk analysis and on-farm experiences. If necessary, foliar sprays are then applied (if available) following the recognised aphid threshold. Historically, sprays have been important if crops were left untreated at drilling, if weather compromised plant uptake of the seed treatment, or if the main aphid migration is later in the season. However, it must be emphasised that there is only one product currently registered for aphid control in the UK (Teppeki) due to widespread MACE and/or kdr/super kdr resistance in *M. persicae* populations to pyrethroids and carbamates respectively, as monitored annually across the UK by Rothamsted Research (see figure below).



When foliar insecticides are available for aphid control then the existing threshold for application is one green wingless aphid per four plants (Hull, 1968). This threshold was revised to consider the reduced susceptibility of plants to both aphids and virus infection with plant maturity. Therefore, after the 12-14 leaf stage the threshold for aphicide sprays decreases to one aphid per plant and after the 16-leaf stage no further control measures are necessary as plants become unpalatable to aphids (Kift et al., 1997). At this stage of the season the black bean aphid (*Aphis fabae*) can become an issue. However, this species can only transmit BYV and is usually controlled by the large number of predators and parasitoids found in the crop at this time of the year and usually control measures are not recommended by the industry.

Our industry is working hard to develop long-term solutions through a sustainable pathway to virus yellows control. (See section 34 for details of the industry's Virus Yellows Pathway). At present, there are no virus yellows tolerant or resistant sugar beet varieties commercially available to any of the yellowing viruses. In 2022, there is one partially resistant sugar beet variety (Maruscha KWS) commercially available which has mild resistance to one of the three yellowing viruses that form the virus yellows complex (BMYV, BChV or BYV). The yield potential in the absence of virus is 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.

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26	Potential pest risk

Please give details on the estimated risk to public health and/or economic impact of the pest should no authorisation be granted, for the proposed use for the crop/crop group.

The maritime climate of the UK has favoured the growth and increasing yield potential of sugar beet. Sugar beet is a non-flowering crop grown, almost exclusively, across the eastern counties of England. The current crop area is approximately 92,000 hectares, grown to supply the four British Sugar factories at Bury St Edmunds, Cantley, Newark and Wissington, supporting over 9,000 jobs within the sector. Sugar beet provides key ecosystem services (e.g. habitats for stone curlew, skylark and lapwing and food for almost 90% of the world's population of overwintering pink-footed geese) as well as rotational benefits as a spring break crop to limit other important arable issues such as blackgrass. However, in many years, the climate is also highly favourable for the build-up and development of damaging pest and disease threats. Consequently, the beet industry has developed and adopted a range of methods and thresholds wherever necessary. These include plant protection products and the use of neonicotinoid seed treatments between 1994 and 2018. The seed treatments were the only option to control and limit the impact of aphid pests and associated virus diseases on establishment, growth and yield, reducing the need for follow-up secondary applications of insecticides, when these treatments were available in the past.

Neonicotinoid seed treatments, combined with valuable foliar sprays when needed, remain the only viable method to successfully control for virus yellows in the short term. 2020 showed that there are currently limited effective alternative chemical or non-chemical treatments available to protect the UK industry from virus yellows. As happened in 2020, the economic (yield loss) and environmental risks (further active ingredient being applied as sprays) should no authorisation be granted, could be very significant if no authorisation is granted.

Using the virus yellows model we can estimate that between 2011-2016, the losses from growing beet without neonicotinoid seed treatments, as a result of virus yellows, would have been conservatively estimated as costing from £0.11M in 2011 to £51.55M in 2014, with an average of £17.30M annual loss over that period (the table below sets out this analysis). These losses are conservative because they are specifically due to the effect of virus yellows, and exclude:

1) any consequences of leaf miner damage, which we believe nationally to have been small, although would have produced significant local losses in affected fields (BBRO trials in 2015 showed losses of up to 9% specifically due to the second and third generation of this pest); and

2) the effect of the soil pest complex, which can be reasonably controlled in many cases using the pyrethroid element of the seed treatments (e.g. Force, active ingredient tefluthrin).

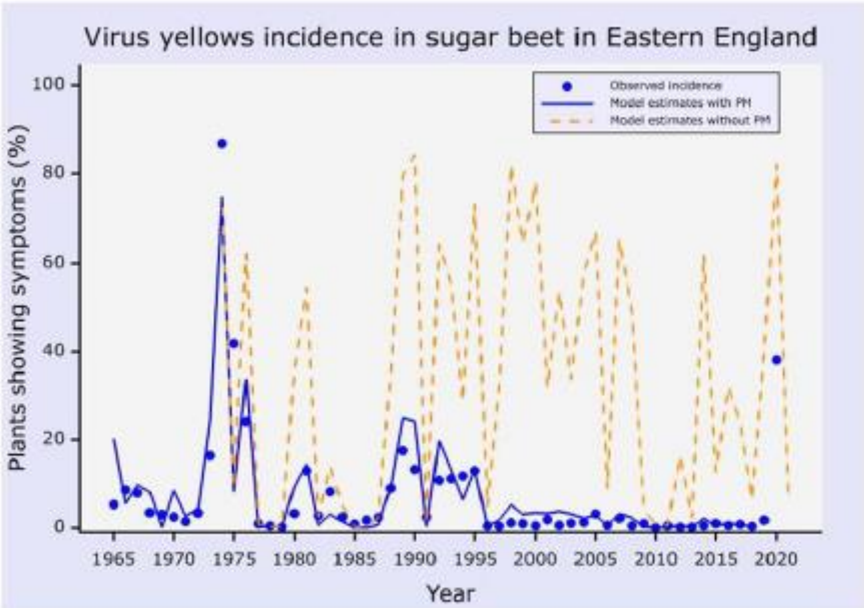
It is estimated that the costs to growers in the 2020 season was approximately £43m and subsequent impact to the processor of a further £24m.

As previously highlighted, the extent of disease and hence potential losses is determined by winter and early spring weather prior to the sowing of the crop.

30th March drill date							
Virus Prediction %	2011	2012	2013	2014	2015	2016	
Bury	0.6%	19.50%	2.16%	62.10%	12.70%	32.10%	
Cantley	0.50%	10.30%	1.38%	65.50%	29.40%	39.80%	
Wissington	0.60%	19.50%	2.16%	62.10%	12.70%	32.10%	
Newark	1.10%	19.70%	2.92%	74.20%	32.10%	48.90%	
Average % infection	0.70%	17.25%	2.16%	65.98%	21.73%	38.23%	
Infection with treated	0.52%	0.25%	0.18%	0.52%	1.03%	1.00%	
Potential Impact	0.18%	17.00%	1.98%	65.46%	20.70%	37.23%	
Assuming 25% yield loss per affected plant and 1% infected on treated							
Total Crop Volume	8504100	7291418	8431600	9309184	6217431	600000	Est
DEFRA Crop Value £M	£251	£231	£266	£315	£173	£160	Est
Potential Loss £M	£0.11	£9.82	£1.31	£51.55	£8.95	£14.89	Est
5 year Average	£17.30						

Virus yellows prediction using the Virus Yellows Model for a crop drilled on 30 March for 2011 – 2016 and associated potential losses

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 forecast is validated by the assessment of the UK sugar beet crop each year by the British Sugar Contract Managers at up to 500 geographically diverse sites each year (represented by the blue dot in the diagram below). The model can be used to give an overall level of virus yellows infection at the end of August each year for the UK crop (see below), either without any pest management (PM) intervention or with the best pest management practice available at that time. Over the decades, pest management practices have evolved and changed due to many different reasons. These have included the use of specific organophosphate, carbamate or pyrethroid insecticides, neonicotinoid seed treatments, and cultural control methods. This clearly indicates the potential consequences of virus yellows infection if not controlled and the clear benefits provided by the neonicotinoid seed treatments.



Local versus national virus yellows forecasts

It is not currently possible to localise the virus yellows forecast, as there are only two suction traps in the sugar beet growing region. However, the BBRO is working closely with Rothamsted Research to explore options, via the yellow water pan network, for regionalisation of the forecast in future years.

27	Control of pest problem and benefit of proposed product

Please provide a detailed reasoned case, with reference to any available supporting data, justifying how the proposed emergency authorisation will provide a sufficient level of benefit (pest control, reduction in damage etc.) to warrant the use. Where applicable, please provide historical information.

The UK maritime climate favours overwintering survival of aphids more so than any other EU country. Monitoring shows that the UK sugar beet crop, primarily grown across the eastern counties, would have experienced nine virus epidemics of over 50% infection since 2000 without effective control options such as the neonicotinoid seed treatments (see chart and table in section 26). In 13 years between 2000 and 2017 these treatments prevented economically significant crop losses due to virus yellows alone. Between 1994 and 2018, neonicotinoid seed treatments ensured that virus yellows levels remained at around just one percent of the national crop being affected.

The consequences and economic impact of a ban on neonicotinoid seed treatments on the EU sugar beet sector have been studied by LMC International in 2017 (a report commissioned by Syngenta AG). The authors conclude that a ban on neonicotinoid seed treatments will decrease farm incomes through loss of yield and increase yield volatility. Also, losses will be greater in milder maritime areas, such as the UK, regions that currently produce some of the highest yields across Europe. We have now experienced the damaging impact of this emergency situation with the author's predictions demonstrated across the growing area in 2020. *The full report has been previously provided to HSE for reference.*

Previous studies and grower experiences have shown that neonicotinoid seed treatments are highly effective to protect sugar beet from the significant impact of pests and viruses on yield. Studies have shown that the earlier the infection with virus yellows the greater the yield loss, therefore protecting the plants from aphids from emergence until the 12-leaf stage (before the phenomenon of mature plant resistance develops) is crucial. We note in particular:

• Without control, the poleroviruses BMYV and BChV cause the greatest yield loss when the plants are infected at an early growth stage with infection reducing light interception by up to 40% (**De koeijer and van der Werf, 1995**) and final yields decreased by up to 30% (**Smith and Hallsworth, 1990; Stevens *et al.*, 2004**). Later infection, when the plants have more than 20 leaves, is currently thought to have little effect on yield. For example, previous neonicotinoid seed treatment trials (**Tait et al., 2012**) showed significant yield responses when virus-carrying *M.persicae* were introduced and then controlled by seed treatments after 7 weeks post sowing. Control of later infections produced positive yield responses, but these were not always significant.

• As with BMYV, without control, sugar yield losses due to BYV depend on the time of infection; late infection (i.e. after mid-July in northern Europe) has little effect, whereas early infection can decrease yield by up to 47% as well as increasing the level of impurities (**Heijbroek, 1988; Smith and Hallsworth, 1990; Clover *et al.*, 1999**). Plants infected with BYV show a reduced formation of leaf area compared to healthy or BMYV-infected plants. Also, leaves developing after infection are smaller than healthy or BMYV-infected sugar beet (**De Koeijer and van der Werf, 1999**).

Infection with virus yellows decreases the overall weight of sugar beet plants. **Clover et al. (1999)** concluded that infection with BYV reduced total dry matter yield of sugar beet by 20% from 18.7 to 15.1 t/ha. The decrease was primarily due to the reduction in the yield of storage roots (3.3 t/ha; 25%) rather than foliage (0.4 t/ha; 7%). It is the reduction in the size of storage roots in diseased plants which is the main cause of yield loss in BYV-infected sugar beet. In field experiments five cultivars in the UK, **Smith and Hallsworth (1990)** observed decreases in fresh storage root and sugar yield of 13-47% and 16-47%, respectively.

• A minor component in the loss of sugar yield in BYV-infected sugar beet results from the decrease in the concentration of sugar in infected storage roots. The size of the decrease in sugar concentration in infected sugar beet is very dependent on cultivar and the time of infection and Smith and Hallsworth (1990) observed a reduction in the sugar concentrations of fresh storage roots of between 0 and 0.5 percentage points. There was no reduction in sugar concentration in plants infected after the end of July. Clover et al. (1999) reported similar reductions (0-0.3 percentage points) in sugar concentration in three field experiments on one cultivar infected with BYV in the UK.

• Sugar is extracted from the storage root of sugar beet by a complex industrial process that involves clarification using lime, evaporation and crystallization. The pH value is critical during each of these stages and the presence of impurities such as sodium and potassium that increase pH during lime clarification, and amino-nitrogen which decreases pH during evaporation, affects extractability. Without controlling the aphid vectors, virus infection will significantly increase the concentration of sodium, potassium and amino-nitrogen impurities in the storage roots of sugar beet (Smith and Hallsworth, 1990). In common with other components of yield loss, the extent of this loss in quality is determined by the time of infection and sugar beet cultivar (Smith and Hallsworth 1990; Clover et al., 1999).

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2.2.1.1 The danger (cont'd)	b) 'Danger' – Experience since neonicotinoids withdrawn (section 24 of application) Following the withdrawal of the neonicotinoid seed treatments in 2018 ('Cruiser SB' (MAPP 12958) and 'Poncho Beta' (MAPP 12076) (beta-cyfluthrin + clothianidin), the only authorised effective use for control of peach potato aphid (*Myzus persicae*) (main vector of beet virus yellows complex) has been one foliar application of 'Teppeki' (MAPP 12402), 500 g/kg WG flonicamid. Teppeki has a persistence of up to three weeks and is insufficient under sustained pest pressure to provide protection for the 12 – 16 week period when sugar beet seedlings remain most susceptible to virus yellows (and subsequent yield losses). At around 16 weeks plants reach the 12-16 true leaf stage maturity when natural plant resistance starts to develop and further control of the virus vectors is not required.

This has resulted in a series of Article 53 applications: 'Cruiser SB' has been considered for an Article 53 authorisation on two occasions: in 2018 (refused) and 2020 when a decision to authorise was granted, but the treatment threshold to allow use was not met. Following the initial 2018 refusal, a series of Article 53 applications for foliar sprays were submitted and ultimately authorised: thiacloprid (Biscaya) in 2019 and 2020 season; and foliar sprays for acetamiprid (Gazelle/Insyst) in 2020 and 2021.

In addition, generally foliar sprays are inherently not as effective as a seed treatment under all circumstances. This is because there are practical challenges in targeting the emerging seedlings with sufficient contact on the leaves and growers are reliant on favourable weather conditions at point of germination to be able to spray. In contrast, a seed treatment provides available active as the seed germinates and moves systemically through the plant including to new growth areas. In the specific case of 'Cruiser SB', when authorised it provided protection for the full period of susceptibility. However, the longevity of the control period at the proposed lower rate is not fully evidenced (refer to section 2.2.6, Effectiveness of 'Cruiser SB').

The applicant has provided a summary of the three seasons since the 'Cruiser SB' authorisation was withdrawn (2019-2021) (Section 24 of application form below). This includes results from the British Sugar national survey which is conducted on nearly 500 randomly selected sites and includes an assessment of virus incidence. This provided figures of virus incidence of 1.8% in 2019 and 38.1% in 2020 where there was the worst virus epidemic since the 1970's and significant yield losses. The developing problems have been illustrated by the accompanying maps of virus incidence from the BBRO monitoring sites for 2018 (the last year that neonicotinoids were authorised), through 2019 and 2020.

The difference in the seasons is reflected in the National survey of foliar sprays used for 2019 and 2020 (and also what is known for 2021 season – see below). The survey also provides strong evidence that growers are monitoring crops actively and adhering to thresholds:

Spray Programme (% of area surveyed)

	2020	**2019**
No Spray	3.67	16
1 Spray	18.59	41
2 Sprays	57.65	39
3 Sprays	19.10	3
4 Sprays	0.99	N/A (4 sprays were not available)

The review of aphid numbers caught each year in the Broom's Barn trap up to mid-June provides a very strong illustration of the continuing build-up of *M. persicae* populations if not controlled, with the five highest migrations occurring in the last seven years, and 2020 reaching unprecedented levels (4000 caught). There are a number of reasons for this, through a combination of increasing frequency of mild winters, and the withdrawal of neonicotinoids and other insecticides not only on sugar beet but other important host crops including oilseed rape. Against such high levels in 2020, the spray programmes employed provided some control, sufficient in some areas, but not able to prevent significant yield losses in others.

	The situation in 2021 is significantly different, as predicted by the model which suggested a figure of 8.37% incidence (below the treatment threshold for 'Cruiser SB'. This is due to the cold January/February impacting on population numbers and delaying migration into the crop. (It also illustrates how successive mild winters currently allow *M.persicae* populations to build each year, in the absence of fully effective combined control measures). At the time of submission, the figures for the 2021 season from the national survey are not available, for either national incidence of virus or use of foliar sprays. The available collated information until the end of June was provided, showing that only 190 aphids had been caught at Broom's barn trap (compared to the 4000 caught in 2020). Although the treatment threshold for 'Cruiser SB' was not met in 2021, some foliar sprays have been required (reflecting the balance in costs between treating seed, or using foliar sprays, and likely yield losses). At the BBRO monitoring sites, only half of the 51 sites had received one spray, and none received two sprays. Although at some other more localised areas two sprays ('Teppeki' followed by the Article 53 'Insyst') have been used (pers.com BBRO). It is also noted that the area of sugar beet grown in 2021 has reduced to around 92,000 hectares, compared to 100,000 ha in 2020. Unless cold weather develops at the critical early part of the year, there remains a significant and growing threat to sugar beet crop most years. Even in seasons with low aphid numbers, virus incidence remains high (indicated by infections on other host plants). As explained above, alternative foliar sprays provide useful levels of control particularly against moderate pest pressures, but are inherently not as effective as a seed treatment, with the latter available to the seedling on germination and moving through new growth to provide protection for the whole plant. If the treatment threshold is met for 'Cruiser SB', this would indicate a sufficiently high degree of risk to the crop in terms of predicted economic yield losses which would warrant application of the seed treatment rather than reliance on foliar sprays and integrated measures (which are important but not by themselves sufficient (see 2.2.2). In conclusion, the test of danger is considered met should the predicted virus level for the 2022 season exceed the threshold.

Part F - Emergency Situation		
24	**Summary of available pest control options and nature of Emergency**	
A typical realistic spray programme showing any current available products, and timings and targets (which includes the requested emergency use) is attached in a separate document.		☒
Please summarise the nature of the emergency situation and why an emergency authorisation is required. As part of this you must explain why the pest cannot be treated by any other means, explaining, where possible, whether previously authorised products were used.		

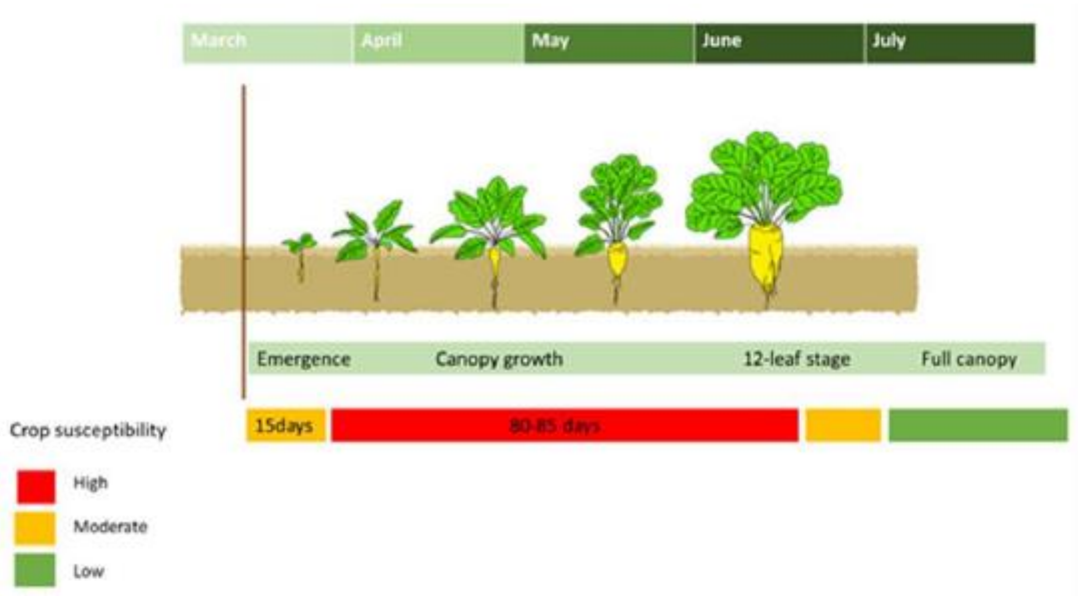
Last year, the UK sugar beet sector experienced its worst virus yellows epidemic since the mid-1970s. In 2020, two years since the EU withdrawal of the neonicotinoid seed treatments on sugar beet, 38.1% of the national crop was infected with virus yellows. Many growers in Cambridgeshire, Norfolk, Suffolk and South Lincolnshire experienced up to 100% infection despite the use of up to 4 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. A similar situation was experienced across Europe, especially France.

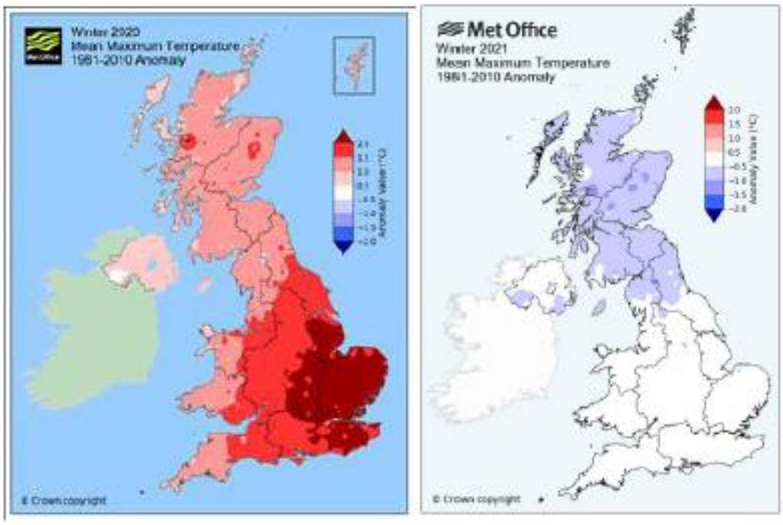
In September 2020, a new Virus Yellows Taskforce was established between British Sugar, NFU Sugar and the BBRO to accelerate and develop ongoing and novel pathways of research to limit the future impact of this disease across the UK industry. British Sugar and NFU Sugar have also introduced a new virus yellows assurance scheme, funded by British Sugar, for the next three years to mitigate a proportion of future losses incurred by growers from virus yellows. However, in 2021 the contracted areas reduced by around 12% 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.

Why a seed treatment emergency authorisation is requested for 2022 to avert another virus yellows epidemic.

Without additional protection from sowing until the 12-leaf stage (the period when beet are most susceptible to colonisation by aphids and virus infection) there currently remain limited alternative control options for 2022 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.



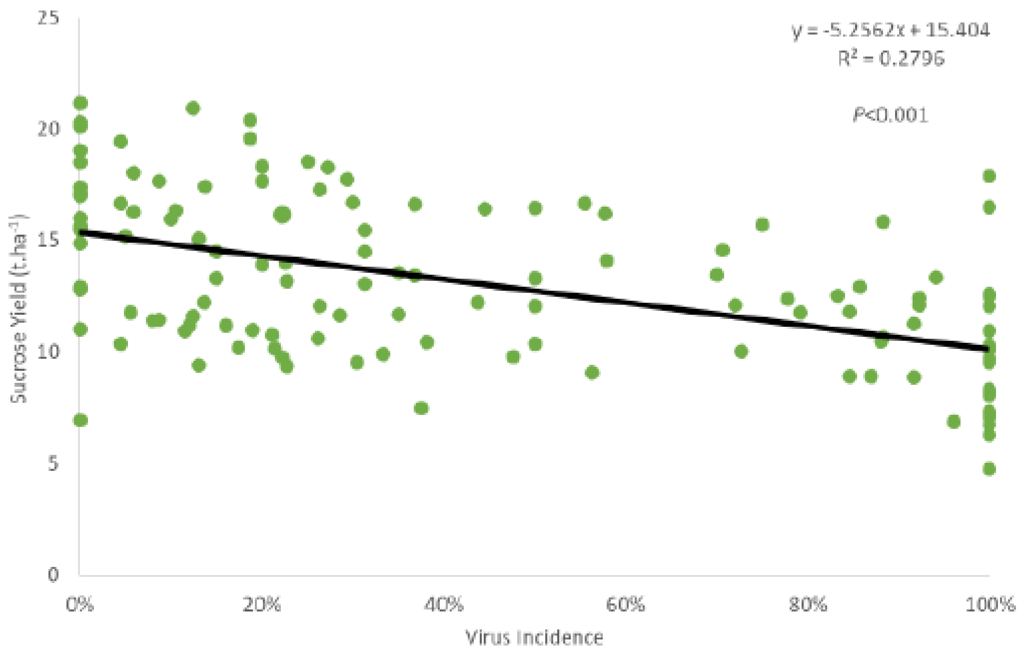
Without a cold winter and additional insecticidal seed treatment protection for 2022 the UK sugar beet sector will again be at high risk of widespread virus yellows infection. Previously, seed treatments provided effective and targeted aphid control, for up to 12 weeks from sowing, until the onset of mature plant resistance.

In 2020 and 2021, growers and agronomists have had valuable, but not always complete success (especially in 2020), in controlling aphids when 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 and to a more limited extent in 2021).

Following the 2019 season (first season without neonicotinoid seed treatments), 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 is expected to be observed in 8.3% of the crop (without any pest management). However, following the last two years, there are now numerous sources of infection available from which aphids could acquire virus and infect the 2022 crop.

Detailed analysis by the BBRO of the impact of virus infection at 16 commercial aphid and virus monitoring sites in September 2020 has shown highly significant yield losses from virus yellows infection (data below).



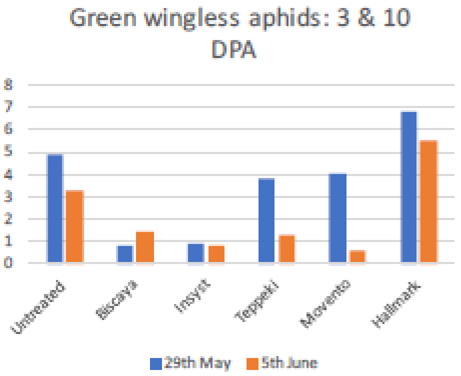
As highlighted, in 2021 the trigger for the use of thiamethoxam was not reached due to the impact of the previous cold winter.

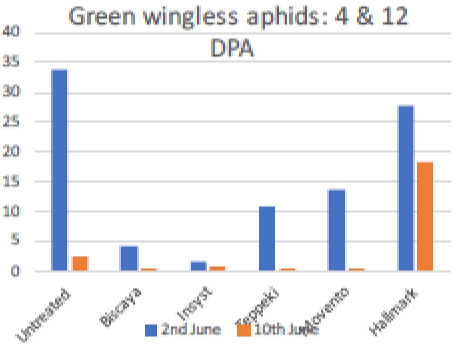
Regardless of the availability of seed treatments (if approved), aphicide sprays are required and justified if conditions result in aphid numbers exceeding recognised treatment thresholds. In 2007 for example, drought conditions affected the efficacy of seed treatments and necessitated the later use of sprays.

Currently for 2021, one spray of Teppeki, followed by one spray of InSyst is permitted for growers to control virus-carrying aphids (at the time of submitting this application we are awaiting the formal approval for our Emergency Authorisation application for use of 'Movento' in 2021).

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.

BBRO Aphicide trials:Rougham & Bracebridge





DPA = days post applicatio

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.

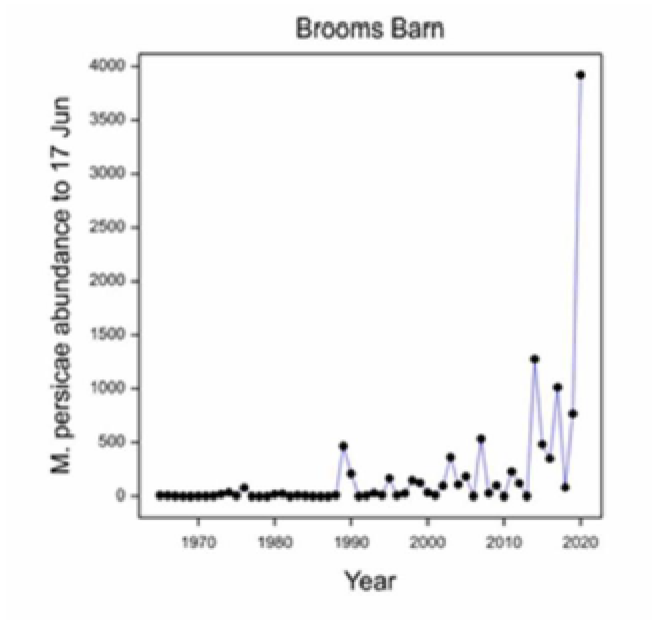
Some progress is being made with the development of virus tolerant sugar beet varieties and there will be one partially tolerant BMYV sugar beet variety (Maruscha KWS) commercially available for 2022. BMYV is one of the three yellowing viruses that form the virus yellows complex (BMYV, BChV and BYV). 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.

Sources of infection and the number of virus yellows carrying aphids will continue to increase each year and is expected to do so unless there is significant cold weather (as seen in 2021) and 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.

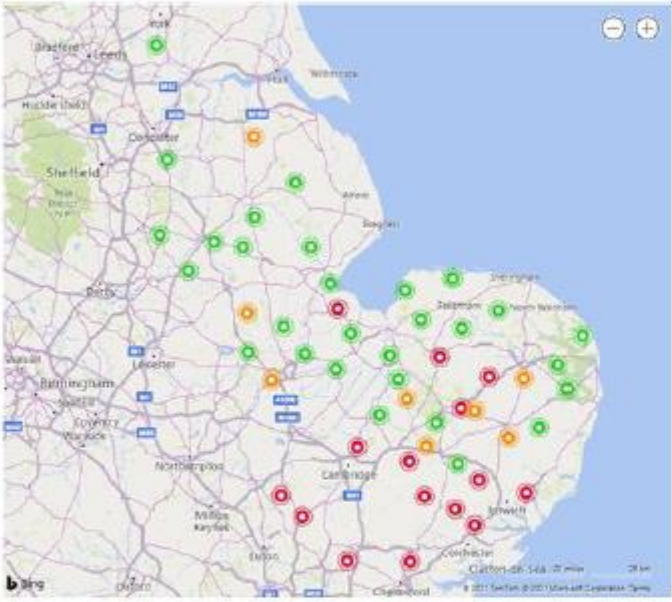
The 2020 season clearly highlighted the limitations of current control strategies without an effective replacement for the neonicotinoid seed treatments. The 2020 virus situation was unprecedented, following the exceptionally mild January and February. Initially, this was reflected in the virus yellows 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, have 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 55 years. Almost 4,000 *M. persicae* were trapped by the reference date of 17 June 2020.

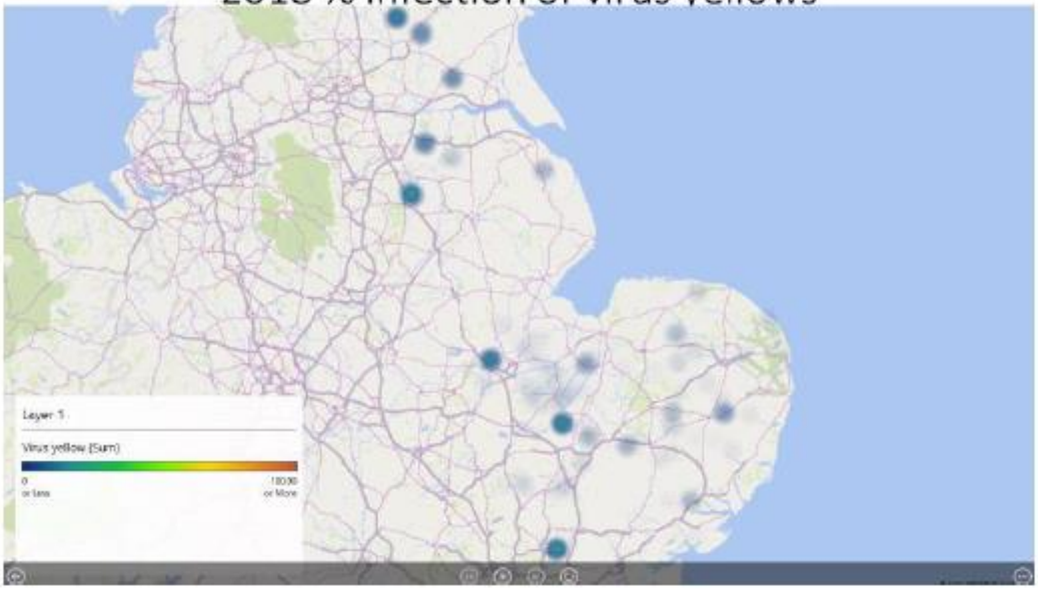


BBRO selected 51 sites across the sugar beet growing region for the 2020 yellow water pan and aphid monitoring survey. Although COVID-19 affected the ability to collect some of these data, sites were visited by British Sugar Contract Managers or agronomists twice a week (April to July), to photograph 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.

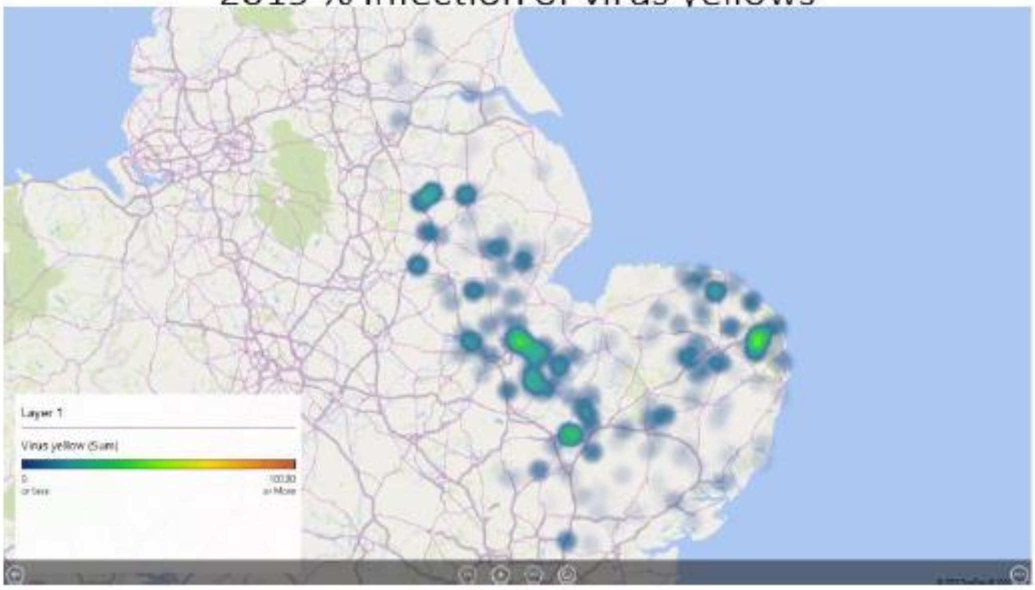


Due to the early and sustained aphid pressure in 2020, the first virus symptoms were observed by mid-June 2020. Widespread symptom development continued throughout the summer. British Sugar undertook the annual virus yellows survey at the end of August/early September 2020 across 484 sites (the annual 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 2018 to 2020 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.

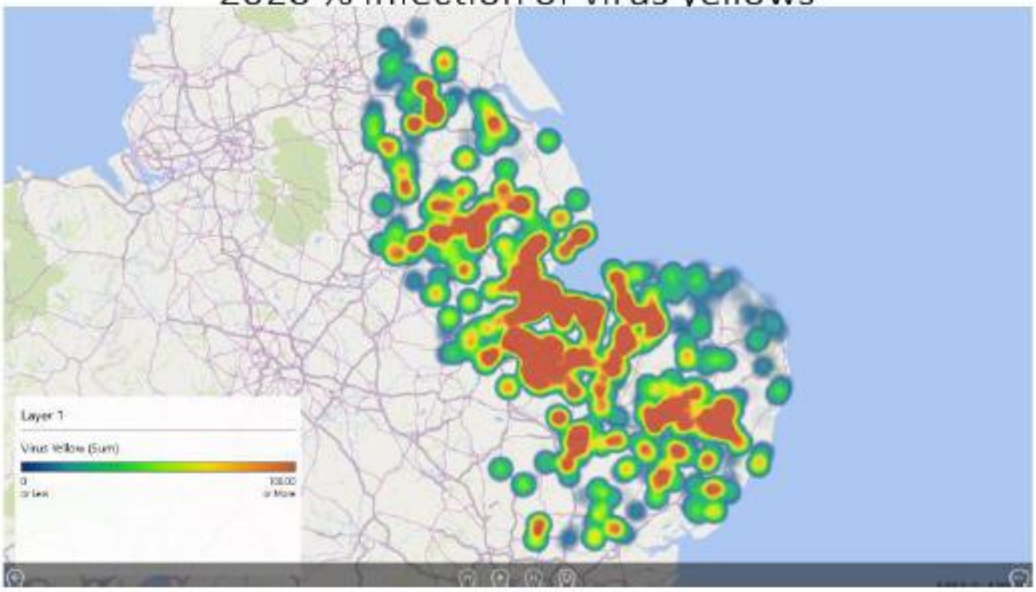
2018 % infection of virus yellows



2019 % infection of virus yellows



2020 % infection of virus yellows



Currently, for 2022, the UK industry only has one foliar spray of Teppeki available for aphid control, without the approval of further emergency authorisations for insecticides. Sprays are valuable, but not completely successful, in controlling unprecedented numbers of aphids as seen in 2020. Grower vigilance, good on-farm hygiene, monitoring and targeted treatments will all be key to protecting the 2022 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 emergency authorisation application as a limited, short-term solution, to ensure the sector can 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 2022, as well as the need to protect the BBRO R&D and Recommended List trials programme (approximately 20 hectares) that was heavily affected by virus yellows in 2020.

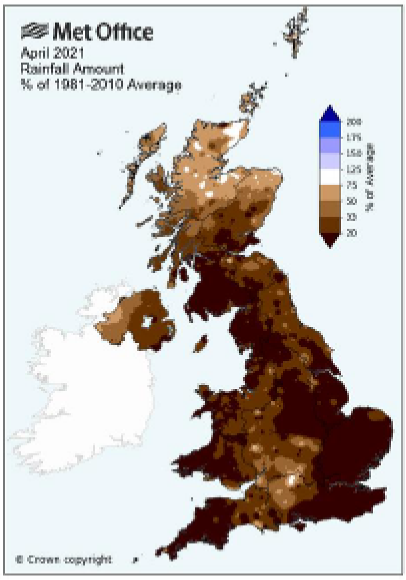
2021 sugar beet crop and aphid update (end June 2021)

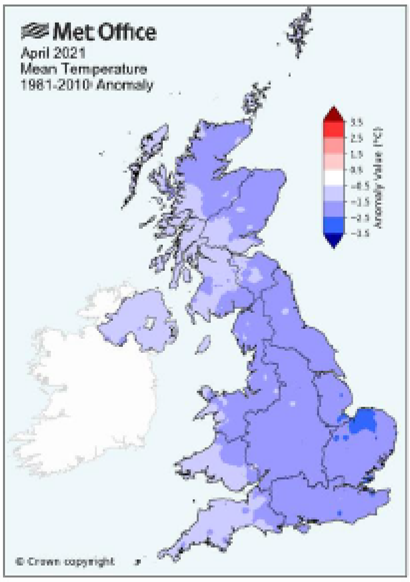
The Crop

In spring 2021, around 92,000 hectares of sugar beet were sown in the UK. Seed was delivered later onto farm for those growers who had requested the use of Cruiser SB (compared to previous years) as the Industry anticipated the outcome of the Rothamsted virus yellows forecast (1st March). The use of Cruiser SB treated seed was conditional on the 9% economical threshold for its emergency authorisation. Due to the previous cold winter this trigger point was not reached and hence none of the UK seed was treated with thiamethoxam. However, the impact of this decision meant that seed processing could not be completed until after 1st March.

Following the dry conditions experienced at the end of March, good drilling progress was made and 75% of the UK crop was sown by the week beginning 5th April and 99% by week beginning 26th April.

However, the crop has experienced one of the coldest and driest Aprils on record (see Met Office April charts below) which has been followed by a cool, but wetter, May. As a consequence, sugar beet germination and growth has been slow and protracted, and some of the crop area has been affected by frost and seedling pests; approximately 400ha has had to be resown.



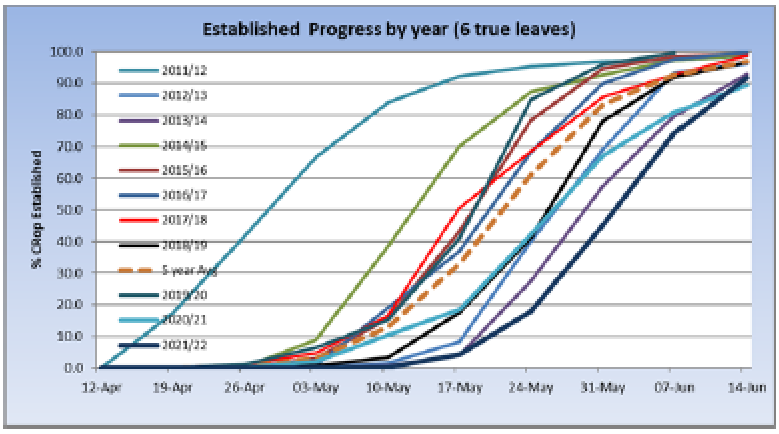


At the end of May the crop was at a wide range of growth stages from cotyledon to 8 true leaves across the four factory areas, with British Sugar estimating that only 18% of the crop had reached establishment (6 true leaves) by 24th May (see chart below); this was the slowest development of the crop for the last 10 years.

However, as the chart below shows, throughout June crops have improved due to the warmer weather following the May rainfall, with many plants now at or beyond the 10-12 leaf stage. However, growers remain vigilant in checking slower developing and gappy areas of the crop for aphids as these remain attractive to aphids.

From the 12th-leaf stage, sugar beet becomes an increasingly poor host for aphids and the number of progeny/young produced by winged adults declines. This reduces secondary spread and infection with virus within the field.

Aphid numbers have continued to increase through June, and growers are able to track this on the BBRO yellow water pan network which shows the migration moving northwards across the beet area. Many crops in Suffolk, Cambridgeshire and Norfolk have now exceeded the threshold and been sprayed with Teppeki, with some receiving a second spray of InSyst.



The Aphids

Rothamsted Research originally predicted *M. persicae* flight in eastern England from the third week of May 2021 (six weeks later than 2020). In reality, the first *M. persicae* was caught in the Broom's Barn suction trap (near Bury St Edmunds) on the 27 April, followed by a second on 11th May. Up until the 20th June (latest available data at time of submission) the Rothamsted suction trap data showed that 190 *M. persicae* had been recorded at the Broom's Barn suction trap (compared to almost 4,000 in 2020).

The BBRO yellow water pan and aphid monitoring sites were established on the 30th April. Aphid numbers recorded at sites have been much lower than last year, although a north-south split has been observed with higher numbers of aphids being recorded in Essex, Hertfordshire, south Suffolk and Cambridgeshire. Up until 20th June only 50% of sites had received an aphicide spray and none of the 51 sites had received two sprays. The first symptoms of virus yellows were recorded in the 3rd week of June in Cambridgeshire and Suffolk.

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.

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Qi, A., Dewar, A., Harrington, R. (2004). Decision making in controlling virus yellows in sugar beet in the UK. Pest Management Science 60, 727-732.

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2.2.2 **Consideration of other reasonable means of control**

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	**Health and Safety Executive, UK**
2.2.2.1 Alternative pesticide product control options	Alternative pesticide product control options (extract from section 24 below) There are no alternative authorised PPP seed treatments. 'Teppeki' (MAPP 1204), 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. One foliar spray is less than the total number of applications required in a treatment period where there is sustained aphid pressure which will lead to foliar treatment thresholds being met (1 aphid per 4 plants up to 12 true leaves; 1 aphid per plant between 12 and 16 true leaves) to prevent significant yield losses. 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 detrimental impact on natural predators. (Refer to resistance section 2.2.3 for additional information)

Please provide details of any current authorised products with relevant claims explaining why these products are not providing sufficient control options for this season. You must provide details on why these products are not sufficient to control the pest (e.g. any practical limitations on use; resistance; sustained pest pressure; maximum number of applications already applied)
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. Biscaya has now been withdrawn and the only foliar spray currently available to growers in 2022 is Teppeki, subject to further emergency authorisation applications. BBRO received many questions from growers and agronomists regarding this difficult situation and a number of these are highlighted below to reflect the challenges experienced and to show why additional protection

has been required in 2021 (with in season BBRO responses included), especially as the only product currently approved without emergency authorisation is Teppeki.

For the 2021 crop it was encouraging for growers to have the emergency authorisation approved for the Cruiser SB seed treatment. However, we were also pleased that, following a very cold January and February, the well-established Rothamsted model predicted low levels of Virus Yellows in the crop for 2021. With a prediction of 8.3% virus yellows infection (without any controls), the trigger was not met and as a result we did not treat any sugar beet seed with Cruiser SB this year.

Q: Why did the foliar insecticides appear not to be controlling aphids effectively in 2020?

A: Part of the problem in 2020 was the sheer number of aphids. The ongoing warm conditions resulted in a continual movement of large numbers of winged aphids and their subsequent progeny moving into and through crops which insecticides struggled to control, particularly when plants were small. Additionally, dry conditions may have reduced the systemic action of insecticides. However, in most situations insecticides were giving some level of control. Foliar sprays remain a vital part of a holistic approach to infection control.

Q: Are all the aphids being recorded *Myzus persicae*, or are there other non-virus aphid vectors being found?

A: The vast majority of aphids being found on sugar beet in both 2020 and 2021 were peach-potato aphids (*Myzus persicae*) with some potato aphids (*Macrosiphum euphorbiae*). Several other species were identified such as the sycamore aphid and the willow carrot aphid and the black bean aphid (especially in 2021), but we believe that at least 95% of aphids counted in fields were peach-potato aphids, the main virus yellows vectors, and therefore this warrants control when above threshold. Aphid numbers, so far, are much lower in 2021 compared to 2020.

Q: Why can I find live aphids on leaves shortly after spraying?

A: Teppeki works by affecting the mouthparts of the aphids ultimately preventing them from feeding. Aphids may still be present for up to 72 hours post application although they should not be spreading the virus further. Insyst should have a more direct and faster effect on aphid mortality.

Q: Can I stop applying insecticides at the 12-leaf stage and what if I have part of a field at the 6-leaf stage and the rest at the 12-leaf stage?

A: Sprays should be applied up until the 16-leaf stage when aphids are found at threshold, although the threshold changes to one green wingless per plant above the 12-leaf stage. However, with variable plant sizes being reported in some fields, keep monitoring, and in such fields treat at the lower threshold value until all plants are 12 leaves and above, i.e. one green wingless per four plants.

Q: Why were the numbers of ladybirds and other beneficial insects so low in the 2020 season?

A: 2020 saw far fewer early ladybirds present in crops compared to 2019, although numbers did build from June onwards, although this was after the main peak of aphid activity. It is not clear why this was the case, but the wet winter may have had an impact and/or their lifecycle was out of synchronisation with the rapid build-up of aphids this year. The 2021 aphid flight is both lower in number and delayed and as a result there have been significantly more beneficial insects present on crop when the aphids arrived.

Q: Does Tefluthrin (Force) provide aphid control?

A: Use of the seed applied pyrethroid tefluthrin (Force), to limit the impact of the sugar beet soil pest complex will remain available in 2022 and provides an ongoing option for control of these pests, but when used as a standalone treatment it is not as effective as when it is used in combination with the neonicotinoid. Tefluthrin is not systemic and relies on vapour phase activity. Also, the combined use of the neonicotinoid and pyrethroid on the seed is more effective in controlling the soil pest complex on those soils with a high pest pressure (**Hauer et al., 2016; Dewar et al., 2000**). Tefluthrin has no efficacy against foliar pests in sugar beet such as aphids or leaf miner, so will not provide any protection against these pests.

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	**Health and Safety Executive, UK**
2.2.2.2 Alternative non-chemical control options	Alternative non-chemical control options The application provides an update on the ongoing work looking at more integrated approaches (see extract from section 24 of the application form below), and BBRO actively promote a variety of measures to reduce virus presence. (These are included in the draft stewardship plan which is copied at Appendix 3). The main strategy remains the research into developing resistant varieties (discussed in 2.2.5). 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 to reduce wind damage. This also appears to have reduced virus levels and 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 manipulating drilling date to sow as near as 1st March (taking care to avoid bolters and early flowering), so plants are older and less attractive when winged aphid migration starts. However, the virus does have other host plants which could remain as a source. Due to the fact that *Myzus* has 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.

2.2.2.3 Conclus-ion on alternat-ive means	There are insufficient alternative means which individually or collectively provide sufficient control for the most susceptible growth stages (up to 12 true leaves).

Please provide details of any available non-chemical alternative control options.
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 investigating this concept further in 2021 but crop growth stage is critical for success. 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.

References

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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.

2.2.3 Resistance	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 occurrence high level of pyrethroid resistance at the target site (kdr and super-kdr forms, see above under 'danger', 2.2.1). The authorised pyrethroid products used 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*' (2021 Sugar Beet: Weeds, Pests & Diseases' supplement to the 2019 sugar beet reference book). 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 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)). 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. All 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 at present UK clones remain fully susceptible and therefore use of thiamethoxam under an Article 53 authorisation would remain effective.

2.2.4 Limited and controlled	<u>2.2.4 a) Limited</u> The use of 'Cruiser SB' will, as in 2021, be limited by using an agreed treatment threshold, reflecting the costs of seed treatment, the agreed price for sugar, and predicted virus incidence/yield losses provided by the long-established model. The area of sugar beet grown in 2021 was around 92,000 hectares located in Eastern counties of England close to the 4 sugar beet processing plants. In 2021, prior to the winter cold snap 94% of growers had chosen to order treated seed in the event that the treatment threshold was met. The pre-season forecast is provided by Rothamsted Research and 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 model provided predictions for virus incidence both with and without 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. A graphical presentation shows the close correlation between prediction of virus incidence with pest measures, and the actual incidence observed over the last 50+ years. The prediction is based on assuming no control measures (it is no longer possible to include a figure with pest measures since the withdrawal of neonicotinoids). For 2021, the proposed threshold was 9% virus infection by August, The predicted first flight was given as third week in May. The first aphid was actually trapped in last week in April, and Rothamsted are investigating further and believe this may have been an individual transported by prevailing winds from the continent (BBRO pers com). The next aphids were caught in the second week of May. The threshold figure proposed for 2022 will be provided as soon as the sugar price for this season (and costs of treating seed) have been finalized. But it has been indicated it is likely to be at a similar level to 2021. If the criteria for treatment were met, then the proposal would be for the capacity to treat up to 99% of the crop, although untreated seed would still be available to growers. For 2021, prior to the winter cold snap 94% of growers had chosen to order treated seed in the event that the threshold was met. However British Sugar and NFU did contact growers again during early 2021 to confirm choices given the developing cold weather). There is also still an intention to apply for Article 53 foliar sprays, which would provide an alternative strategy to using 'Cruiser SB'. Overall any area treated would be lower than last year, because the national area grown has reduced by 12%.

	As proposed last time, 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 usual. 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, it is recognised that the use of this treatment threshold does provide an appropriate mechanism to limit the use (of 'Cruiser SB' if authorised) 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 such a model that allows this limitation. The experience of the last three years does indicate that it might be possible in the future to further refine the model to a more regional basis, and BBRO and Rothamsted are researching how this might be achieved. It may also be possible to compare virus incidence and spraying from each season to identify those areas at highest risk and potentially use this as a basis to request a more limited proportion of the crop to treat even if the threshold is met (and use in combination with other measures). But at this point, it is accepted that this requires more experience and data, given how different each season has been and the fact that there are no other relevant past comparisons (because neonicotinoids were authorised for so many years and effectively controlled aphids). The development of diagnostic tests which now allow monitoring of each individual virus within the complex may also help. For example, this year unusually Beet Yellows Virus (BYV) was the dominant virus (and caused the largest yield losses). But this is not typically the case, and again illustrates it is a learning process in understanding how the yellows virus complex will develop each year. If an authorisation is granted, HSE 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). The applicant would be required to amend the stewardship plan accordingly. 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. <u>2.2.4 b) Controlled</u> As described in previous applications (and in this one), sugar 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) using an exact process which leads to minimal dust emission. The application indicates that in 2017, the level of dust produced at Germains was 0.02g/100,000 seeds (below the industry standard of 0.25g/100,000 seeds).

	Grower orders are made six to eight months before drilling commences and determine the variety and the different seed dressings applied. The decision to order seed treatments (where available) will depend on growers' own risk analysis and previous on farm experience. If the use is authorised only sufficient seed to fulfil these 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'. Once treated, seed will be packaged and delivered to growers. Supply of the treated seed will be managed as part of the contract with British Sugar. The applicant has advised that the pelleting process ensures 100% traceability of the product. 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 (Appendix 3) has been submitted which identifies the range of communication that will be undertaken, reinforcing the messaging at timely points in the season. Specific guidelines will be produced for drill operators, various IPM measures will be reinforced specifically 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 limited and controlled use.

28	Limitation and Control

Please provide details of how the use of the product will be limited and controlled. Include details of the decision process governing the use of the product (e.g. agronomic factors, pest thresholds and monitoring); a reasoned case justifying the scale of use (% crop that may be required to be treated, including geographical location); or other limitations on use (e.g. period of use); bespoke product stewardship arrangements, and the rationale underlying these proposals.

Overview

As in 2020, to address a potential emergency facing the UK industry in 2022, the UK sugar beet sector is prepared to commit to the following proposed limitations and controls on use, should the authorisation for Cruiser SB be granted. These limitations will result in the UK sugar sector incurring significant costs and modifying existing procurement and seed processing timelines. The industry is committed to the responsible use of plant protection products. For a summary of the stewardship programme refer to the attached document entitled '2022 Cruiser SB Neonicotinoid Stewardship Document'.

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 sustain the reduced rate of thiamethoxam applied from (the normal) 60g to 45g per 100,000 plants to lower potential risks.**

Our approach highlighted below is substantially more prescriptive than any other European country currently applying for emergency authorisations for seed treatments for 2021 ([redacted] BBRO personal communication via the International Institute of Sugar Beet Research) as the UK approach 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 by either the UK seed processor Germains in Norfolk; by KWS in either Einbeck, Germany, Buzet-Sur-Baise, France, or Holeby, Denmark; or a proportion may be applied by SES Vanderhave in Tienen, Belgium, or Cappelle-en-Pévèle, France. This is a significant undertaking by the sugar sector, as the neonicotinoid seed treatment would be purchased by the companies but only 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 neonicotinoid seed treatments were not required, due to a low risk of virus infection from the 2022 forecast, product would be returned to the supplier as per the 2021 season.

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 2021. This is anticipated to be over 90% of the crop (based on previous usage data) 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 2022 due to poor weather conditions affecting germination and/or crop establishment.

Once treated and packaged, seed would be delivered to growers from March 2022 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 Reference book). However, the industry is prepared to accept this yield penalty to ensure the crop is protected against the more damaging virus yellows infection.

As in 2020, to determine whether neonicotinoid seed treatments would need to be used on the 2022 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 2022. 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 regional models usually predict, when conditions are favourable, that all the cropping area would be at an economic risk from virus infection. Therefore, the value of current regional models is valid. Also, the current virus yellows forecast is being refined and regionalised by Rothamsted Research via a four-year BBRO-funded project that started in autumn 2019 to target and rationalise, as well as localise, insecticide usage in sugar beet and to support any future emergency authorisations. With a limited number of suctions traps available (there are only two in the main sugar beet growing region) to cross correlate the data and the analysis of using yellow water pan from the 50 sites we will retain the current single national threshold for the 2022 season.

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 2022 and the virus yellows forecast **is below the economic threshold of the cost of the seed treatment** then these treatments will **not** be applied. **Therefore, under these conditions, neonicotinoids would not be used under the emergency authorisation in 2022 by the sugar beet Industry, even if approved by DEFRA.**

Calculations of the economic threshold are 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 2021 economic threshold for use of neonicotinoid seed treatments for virus yellows was 9%. ***The same formula will be used to calculate the economic threshold for 2022 once the 2022 sugar beet contract price and Cruiser SB price is known.***

In addition, following the virus yellows impact in 2020, British Sugar and the NFU have agreed a new virus yellows compensation scheme for all growers. This started for the current (2021) year and will last for three years. Individual growers who are eligible for compensation will be able to claim for up to 35% yield loss. The first 10% of lost yield acts as an excess and is deducted from the total yield loss.

British Sugar will pay 45% of the remaining loss of yield at the agreed contract price. For a grower to be able to claim they will have to:

- Plant enough area to fill their total contract tonnage (CTE) when multiplied by the growers 5-year average yield (at the current level before the 2020 crop).

- Deliver all the beet contracted and grown on the fields declared to British Sugar.

- Be contracted to grow beet for the following year and not in breach of contract obligations.

- Inform British Sugar in the annual crop declaration if crop damage results in a plant population falling below 80,000 plants per hectare.

- Register the presence of Virus Yellows in crops by a specified date.

- If requested, provide evidence (e.g. invoices or spray records) of the aphicide sprays applied if aphid thresholds reached in accordance with BBRO recommended practice.

Steps involved in determination of use

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 the 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 2022 seed contract offer letter, jointly agreed by British Sugar and the 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 buy treated seed on the seed offer letter described above, but it will be stipulated that neonicotinoid treatments will only be available if the economic threshold for treatment is triggered in March 2022.

- Growers will always have the option to buy untreated seed.

- Autumn/early winter 2021, seed and neonicotinoid seed dressing will be purchased by and delivered to the ESTA accredited and the UK processing facility at [redacted] and other European seed producers as highlighted above.

- 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 2017, the average dust level at the Germains factory was well below this minimum dust level at 0.02g/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 2022.

- Below **X%** infection for national crop at mid-point forecast (30th March) – no neonicotinoid treatment to be applied. The 2021 economic threshold for use of neonicotinoid seed treatments for virus yellows was 9%. ***The same formula will be used to calculate the economic threshold for 2022 once the 2022 sugar beet contract price and Cruiser SB price is known.***

Above **X%** infection - treat seed as requested by growers via ordering process. The 2021 economic threshold for use of neonicotinoid seed treatments for virus yellows was 9%. ***The same formula will be used to calculate the economic threshold for 2022 once the 2022sugar beet contract price and Cruiser SB price is known.***

- BBRO to monitor winter aphid and virus levels on weeds, cover crops and unharvested beet (e.g. for anaerobic digestion) in January to April 2022.

- March 2022 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 British Sugar CRM database and monitored by their team of 22 agricultural contract managers.

- 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.

- We propose the introduction of a new following crop restriction clause 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 are as follows:

	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

Any crop excluded from the above table should be considered 'restricted' i.e. a minimum of 32 months from drilling of Sugar Beet.

Cover crops (including mixes) must follow the above restrictions.

We have strived to address the concerns raised by HSE in response to the 2021 application by moving crops that are bee-attractive before harvest, such as mustard and linseed, into the restricted category meaning that they may only be planted a minimum of 32 months from the drilling of sugar beet.

- No further use of thiamethoxam seed treatments (including any re-drilling of treated sugar beet if crop lost due to wind blow or capping) on the same field area for 46 months from the date of sowing treated sugar beet seed in 2022. This is to minimise the risk of any residues being acquired by succeeding flowering crops or weeds and hence exposing bees and/or other pollinators to neonicotinoids.
- 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 within treated sugar beet crops and reduce the risk of indirect exposure of pollinators to neonicotinoids. This is standard best practice and only applies in field, not next to or around the field, i.e. field margins.
- 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 in 2022 onwards 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 2022.

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.

2.2.5 **Repeat applications**	A range of research is being undertaken to find integrated long-term solutions and is described in the application (see table in section 32 below). A key strategy is to continue to build on the five-year, £1.13 million project with sugar beet breeders (described in section 33 below). 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 applicant has stated that the first generation of BMYV partially resistant sugar beet varieties (Marushka KWS) will become available in 2022. However, it is noted their yield potential in the absence of virus is low compared to existing, elite susceptible varieties. BBRO has 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. This is in addition to other development work (summarised in the application form sections below) being done in conjunction with other significant European sugar beet breeding companies. 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 a new task force to identify a number of strategies around conventional and possible (gene editing) breeding solutions, identifying alternatives including garlic based products and jasmonic acid. The outputs from the current AHDB SCEPTRE plus programme, which is looking at identifying alternative products including biopesticides, are also being monitored to identify other solutions for the control of Myzus persicae in sugar beet. In addition, a range of integrated approaches including encouraging beneficials and boosting sugar beet resistance are being researched. 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.

Part G – Permanent solution	
31	**Proposed permanent solution**
Please outline the steps that will be taken by you or the authorisation holder to transfer this emergency authorisation to an on-label recommendation or extension of authorisation of minor use. Please outline the most likely time frame for a permanent solution to be available (See guidance in Part G).	
Not applicable. Alternative permanent solutions to neonicotinoid seed treatments for sugar beet are being sought as a matter of priority.	

32	Alternative product(s)
Please provide details of ongoing work aimed at developing alternative products to address this pest problem. Include information on the active substance and anticipated timelines for availability of the data or application for the alternative solution.	
There remains significant research and trial work being undertaken on an accelerated basis to develop alternative, sustainable solutions to the use of neonicotinoids and the Industry has established a new Virus Yellows taskforce in 2020 to identify pathways to provide new and integrated aphid and virus mitigation strategies for the future. The timeline is highlighted below:	

Area of Development	2021	2022	2023	2024	2025	2026	2027	2028 onwards
VY assurance fund	Established fund to assure the worst hit growers for VY (£12m BS investment)			Possible extension for "early years" post derogation				
Improved grower practices	Improved husbandry Increased hygiene measures Cover crops Increase beneficial insects	Alternative spray trials programme (e.g. raffinate) Improved husbandry Increase beneficial insects Increased hygiene measures Cover crops						Potential for bio plastics Improved husbandry Increase beneficial insects Increased hygiene measures Cover crops
Improved seed germination	Improved pellet coatings to establish crop and earlier sowing to reach 12- leaf stage							
Traditional Seed Breeding	First partially resistant variety launched "Maruscha" (yield penalty compared to standard varieties)	Potential further varieties available	ID Aphid/ Mature plant resistance genes	More varieties with partial BMYV/BYV tolerance/resistance, but with continued yield drag relative to the susceptible alternatives.				More varieties with partial BMYV/BYV tolerance/resistance
Sustainable spray programme	EAs for current sprays + Teppeki	3 - 4 established sustainable sprays (not requiring EAs) InSyst, Movento + x + x						3 - 4 established sustainable sprays
Gene Editing	Gene mapping Identification of potential genetic changes	Regeneration into viable plants		Multiplication into sufficient volumes to trial Lab trials to ensure VY resistance expresses in practice Lab trials to screen other detrimental traits Field trials to ensure performance in field conditions National Listing trials			Multiplication into commercial volumes Recommended List 3rd year	Continued multiplication Commercial availability
					EU food/feed approval process for products derived from specific GE sugar beet event Approval for products to enter EU market through international supply chains (from 2030)			
Neonics Derogation	3-year derogation to allow for development of practices / seed varieties / sustainable sprays							

In 2022, growers will have access to the first generation of virus tolerant sugar beet. Maruscha KWS is partially tolerant to BMYV. 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.

The industry continues to use advanced seed technology for enhance germination/establishment to ensure plants reach the 12-leaf stage as quickly as possible and currently Enrich 200 (Germains) and EPD 2 (KWS) treatments are available to growers when they purchase their seed. In addition, BBRO are 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 continue 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. garlic-based products and jasmonic acid) 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 seed treatments. The outputs from ongoing aphid projects within the current AHDB SCEPTREplus programme are also being closely monitored for outcomes that could be beneficial for *M. persicae* control in sugar beet.

33	Non-chemical solutions

Please provide details of any alternative non-chemical methods of control that are under development and whether any of these measures have already been implemented or when they will be implemented.

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).

The BBRO recently completed 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) and is exploiting and developing the genetic diversity found in beet relatives and identifying candidates exhibiting resistance and tolerance to virus yellows (see picture below). From this, we have developed a novel phenotyping approach to quantify resistance/tolerance traits and have worked to identify genes which protect against virus yellows foliar damage. Using this toolkit, we have undertaken a two-tier pre-breeding strategy. Firstly, tolerance quantitative trait loci (QTL) are currently being introgressed into modern breeding material, with hybrids being assessed for foliar health and yield. Secondly, new resistant candidates are being characterised, QTL identified, and molecular markers developed for future breeding. The outputs from this pre-breeding project are currently being consolidated by the breeders and will enable future production of new virus resistant or tolerant commercial varieties, bringing significant economic and environmental benefits.

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 and 2021, the BBRO produced sufficient viruliferous aphids to inoculate over 90,000 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. The concept of using gene editing to accelerate the development of virus yellows resistant sugar beet varieties is currently being discussed and we await the outcome of the recent government consultation on this technology.

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 integrated approached for the future as highlighted in the 2021 BBRO Annual Report BBRO Annual Report - BBRO. 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). • 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. • We continue to look at the use of biofilms to protect crops against aphids. Whilst this presents challenges on several other fronts, its value for virus control is being investigated. • 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 are involved in two PhD projects, which have started at the University of East Anglia and Wageningen University 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. 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.

34	Progress from previous authorisation
Where this is a repeat application, please explain the progress towards a permanent solution that has been made since the previous application. Include timelines and projections for data/application for the permanent solution.	
See Virus Yellows Pathway table in section 32. The industry engaged in the Government's genetic technologies consultation and is committed to finding breeding solutions to virus yellows disease. Commercial discussions are ongoing with breeding companies to find solutions.	
Where this is the 3rd or more repeat, please provide justification why no permanent solution is available.	

2.2.6 Effectiveness of 'Cruiser SB'	'Cruiser SB' (600 g/l thiamethoxam) was first authorised in 2006, under a Uniform Principles assessment, for use on sugar beet and fodder beet against the beet soil pest complex, and a range of foliar pests including aphid vectors with peach-potato aphid (*M. persicae,* MYZUPE*)* being the principle aphid species. The authorised dose was 100 ml (60 g a.s.) per 100,000 seed. The proposed use under this application is for a reduced dose of 75 ml (45 g a.s.) per 100,000 seed. In re-examining the original Efficacy regulatory studies, no data were provided at lower doses, with dose justification based on the soil pest complex. The applicant did provide evidence to support effectiveness under the previous Article 53 request for 'Cruiser SB' (HSE ref: 2020/01677 (W001978798). There were 5 trials: 2 x 2014, 3 x 2015 comparing 60, 45 and 30 g a.s./100,000 seed. Assessments of aphid populations (including *Myzus* – 'green' aphids) were made 10 weeks after sowing. Populations in the untreated 2014 trials ranged from 10-14 aphids per plant; with the 45 g a.s. dose indicating around 90% control. In the 2015 trials, two had higher populations (23 or 55 per plant), with the 45 g a.s. dose retaining 70-90% control. There was also an indicative trend of a dose response in these trials, although there was a marginal difference between the 60 and 45 g a.s. dose. One other 2015 trial had a population of 12 aphids per plant and indicated reduced levels of control, to around 50% control for 45 g a.s. dose. All treatments including the other neonicotinoid, 'Poncho Beta', also giving moderate control levels. This indicates there may have been local conditions affecting the uptake and availability of active in the germinating seedlings. The evidence provided confirms a sufficient level of effectiveness at the proposed lower dose, for up to 10 weeks and against challenging aphid populations. There is no evidence beyond this period until the end of the 12-week susceptible phase, and therefore it is not possible to confirm any possible decrease in effectiveness/level of persistence compared with the previously authorised dose.

2.2.7 Efficacy Summary	The Article 53 request for 'Cruiser SB' is considered to meet the relevant criteria relating to danger, no other reasonable means, limited, and controlled use. Beet yellows virus complex and the main aphid vector, *Myzus persicae*, are a major danger to sugar beet and the sugar industry, with a potential to cause major yield losses. In the current absence of a sufficient range of fully effective control measures, and regular winter conditions with prolonged cold periods, background levels of *M. persicae* populations and the underlying virus continue to increase. Whilst there may be seasonal fluctuations, the review of aphid numbers over many years illustrated that the five highest *M. persicae* migrations occurred in the last seven years, and 2020 reached unprecedented levels. This trend indicates the potential for epidemic episodes in seasons following generally mild winters. The foliar spray programme is reliant on the authorised 'Teppeki' being supported by a series of 'Article 53' authorisations to ensure sufficient available foliar sprays. Whilst of clear benefit, a foliar programme inherently struggles to be as effective as a seed treatment when protecting germinating seedlings and particularly where a significant aphid migration occurs. The use of the trigger threshold for treating with 'Cruiser SB' is a critical determinant in targeting and limiting when any seed treatment authorisation will be used. This does mean accepting potential practical difficulties in delaying drilling until later in March (with potential yield penalties). The use of the model and threshold as an effective measure to limit use was demonstrated in 2021, when the Article 53 authorisation for 'Cruiser SB' was not used because the treatment threshold was not met. This provision is possible because of over 50 years research by the industry in developing, validating, and adapting the model, with the UK being unique amongst European countries in having such a model. Any authorisation would be controlled through the extensive support and communication by BBRO and British Sugar (including their contract managers) throughout the relevant period. A draft stewardship plan has been submitted, and includes key elements of crop management in order to take an integrated approach to reducing any risks. Importantly, growers will also have the opportunity to make their own choice and buy untreated seed (and therefore chose a strategy of foliar sprays). In future, with further experience and evidence, the industry should consider further defining and limiting of any seed treatment authorisation to a smaller proportion of the crop. This could be based on a combination of refining the model further (and research is already under way to do this), as well as reflecting on experience to identify where possible those areas of the cropping area most at risk. Through investment, the industry now has a new diagnostic tool to monitor each of the three viruses individually. Considerable investment and research has been undertaken to identify long term integrated strategies. A key component of this is developing commercial resistant varieties, and although there is some success, it is very challenging because the virus complex consists of three individual viruses and there is no one main trait conferring resistance. It is also acknowledged that this programme started in 2015, three years before neonicotinoids were withdrawn, illustrating that the industry was already

	aware of the need to move away from complete reliance on neonicotinoids.

2.3 Mammalian Toxicology

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	**Health and Safety Executive, UK**
Reviewer's comments	No updated assessment is presented. 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. 'CRUISER SB' is therefore unclassified. 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.

Summary

	Value	Study	Safety factor
ADI:	0.026 mg/kg bw/day	18-month study mice	100
AOEL systemic:	0.08 mg/kg bw/day	90-days dog study	100
AOEL inhalation:	No required		
AOEL dermal:	No required		
ARfD (acute reference dose):	0.5 mg/kg bw	Rabbit developmental toxidity study	100

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

Evaluation, Summary and Conclusion by The Health and Safety Executive.

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

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".

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 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 below for completeness:

<u>Operators</u>

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.

Bystanders

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.

Workers

Predicted exposure levels (geometric mean) when drilling treated seed

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.

Operator, Worker, Bystander/Resident Exposure (Predictive operator exposure models can be submitted)
Fully supported by the extant authorisation for Cruiser SB, COP 2013_02236

2.5 Residues and consumer exposure

Evaluation, Summary and Conclusion by The Health and Safety.
Residues and consumer exposure ***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".***
This application is for an emergency authorisation of 'Cruiser SB' under Article 53 of 1107/2009. This is a GB application. '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 GB. 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' data requirements as laid down in Commission Regulation (EU) No. 544/2011 have been applied. 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). Some of the 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 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**

The predicted consumer exposure falls within the agreed safe levels and no health effects are anticipated from the use of 'Cruiser SB' as proposed.

Summary of the evaluation

The preparation 'Cruiser SB' is composed of thiamethoxam.

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

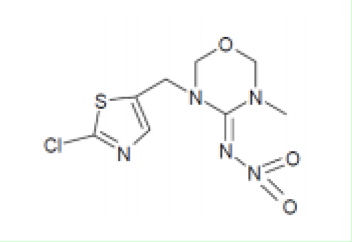
* Purpose of withholding period to be specified

** 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 Regulation (EC) No 671/2017. EU (NI) Regulation (EU) No 671/2017.
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

* Notifier in the EU process to whom the a.s. belong(s)

** If yes: EFSA, YYYY - see list of references

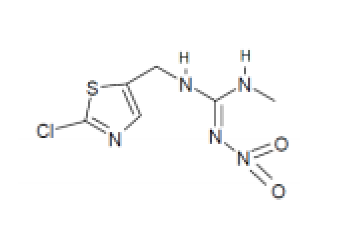
† If the EFSA RO relates to MRL decisions delivered after 31/12/2020, then it will be applicable to NI only. In this case the MRL review has been addressed for NI but is pending for GB. This will need

to be recorded separately. In addition, if a specific MRL review for GB has been undertaken this will need to be stated. This relates to a review of all the MRLs under Article 12 of Regulation (EC) No 396/2005. If for GB MRLs only a focused MRL review under article 6 (3) of Regulation (EC) No 396/2005 has been conducted then the MRL review is still pending.

‡ The EFSA PR assessment would only be directly relevant to GB if it relates to a decision delivered prior to 01/01/2021. EFSA PR assessments after 31/12/20 are only directly relevant to NI

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 Regulation (EC) No 671/2017. EU (NI) Regulation (EC) No 671/2017.
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

* Notifier in the EU process to whom the a.s. belong(s)

** If yes: EFSA, YYYY - see list of references

† If the EFSA RO relates to MRL decisions delivered after 31/12/2020, then it will be applicable to NI only. In this case the MRL review has been addressed for NI but is pending for GB. This will need

to be recorded separately. In addition, if a specific MRL review for GB has been undertaken this will need to be stated. This relates to a review of all the MRLs under Article 12 of Regulation (EC) No 396/2005. If for GB MRLs only a focused MRL review under article 6 (3) of Regulation (EC) No 396/2005 has been conducted then the MRL review is still pending.

‡ The EFSA PR assessment would only be directly relevant to GB if it relates to a decision delivered prior to 01/01/2021. EFSA PR assessments after 31/12/20 are only directly relevant to NI

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 clo-thianidin 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 thia-methoxam 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.

Stability of residues in sample extracts

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.

Nature of residue in primary crops

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 enough to support use on sugar beet from this group. Seed treatment was tested in these studies, which is the same as the 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 monitoring in plants 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 monitoring 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.

Nature of residue in rotational crops

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.

Thiamethoxam:

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 PBIs. On this basis no further consideration of rotational crops is required.

Clothianidin:

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 PBIs. On this basis no further consideration of rotational crops is required.

Nature of residues in processed commodities

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 Reg. (EU) 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) *(Reg. (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 monitoring 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 monitoring 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.

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

Magnitude of residues in plants

CROP: Sugar beet

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 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
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 to 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 (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 544/2011.

Under the previous 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', and supporting method validation data were evaluated to support the ecotoxicological assessment. These data have not been reconsidered as part of this application (2021):

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] 2020
Study/Report No.: SPK-17-29052

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 CG322704 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 °[redacted]. 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]; 2020
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 CGA332204 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. 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).

PRIMo

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.

Thiamethoxam

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.

Clothianidin

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

Combined exposure and risk assessment

As the active substance thiamethoxam has a metabolite which is also an active substance (clothianidin), a combined risk assessment is considered necessary.

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.

Consumer exposure (supporting data or case must address UK specific requirements)
Fully supported by the extant authorisation for Cruiser SB, COP 2013_02236

2.5.1 Maximum Residue Levels

Evaluation, Summary and Conclusion by The Health and Safety Executive.

MRLs

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 (as outlined in the GB MRL statutory Register and Commission Regulation 671/2017†) (mg/kg)	Potential future GB MRL (mg/kg)‡
0900010	Sugar beet roots	0.02*	0.02*	N/A

† Only relevant for MRLs set prior to 01/01/2021.
‡ 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 (as outlined in the GB MRL statutory Register and Commission Regulation 671/2017†) (mg/kg)	Potential future GB MRL (mg/kg)‡
0900010	Sugar beet roots	0.02*	0.02*	N/A

† Only relevant for MRLs set prior to 01/01/2021.
‡ Agreed future MRLs outlined in the Register or proposed MRLs outlined in the Published MRL reviews List

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 (July 2021), the MRLs in NI (EU) are the same as those currently in force in GB for sugar beet roots.

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.

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

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	Exposure (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				
	DE child			Grapefruits		Grapefruits				
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	DE child			Grapefruits		Grapefruits				
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	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): ---

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

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.

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	VEGETAR-IAN	ELDERLY (OWN HOME)	ELDERLY (RESIDEN-TIAL)
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**	**VEGETAR-IAN**	**ELDERLY (OWN HOME)**	**ELDERLY (RESIDEN-TIAL)**
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

COMBINED RISK ASSESSMENTS

See estimates presented above.

2.6 Environmental Fate and Behaviour

Evaluation, Summary and Conclusion by The 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".***

No new data or information has been provided that would require assessment, and the guidance and exposure models remain unchanged from the versions used in considering the Article 53 application for 'Cruiser SB' in 2020.

When this application was considered in 2020, ECP advised that HSEs 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.

Therefore, the previous assessment from 2020 remains largely unchanged and for completeness is reproduced below. Minor changes have been made to the soil exposure section, to reflect changes firstly to the restrictions on planting following flowering crops (proposed as 32 months from drilling sugar beet), and secondly to changes to restrictions on planting treated sugar beet seed in the same field (restricted to 46 months from the date of first sowing treated seed).

Since no use of 'Cruiser SB' treated seed occurred in 2020, the surface water monitoring information has not been updated at this time.

2020 Assessment (blue text has been added in 2021)

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.

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.

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
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 Commission Implementing Decision (EU) 2015/495 (notified under document C(2018) 3362) (legislation.gov.uk)

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

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.

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

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) (no change from 2020)

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.

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 1st March and latest sowing date of 1st 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 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) degradation does not vary across soil types and thiamethoxam is not converted to clothianidin in surface water (Pickford et al 2018)*[2]*.*

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

[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

[2] 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

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 principle 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, 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 (Ford 2016)[3] 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

[3] Thiamethoxam - A FOCUS Surface Water Exposure Assessment at Step 3 for Parent and Metabolite CGA322704 Following Seed Treatment Applications. SYN/28/08-SW08

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[4] resulted in a maximum PEC_{sw} of 0.222 µg thiamethoxam /L and 0.001 µg clothianidin /L.

Environment Agency surface water monitoring

The final part of the applicant's submission in 2020 included a brief summary of Environment Agency monitoring data from 2016. The HSE evaluator noted that 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[5], 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*

[4] 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

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

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 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).

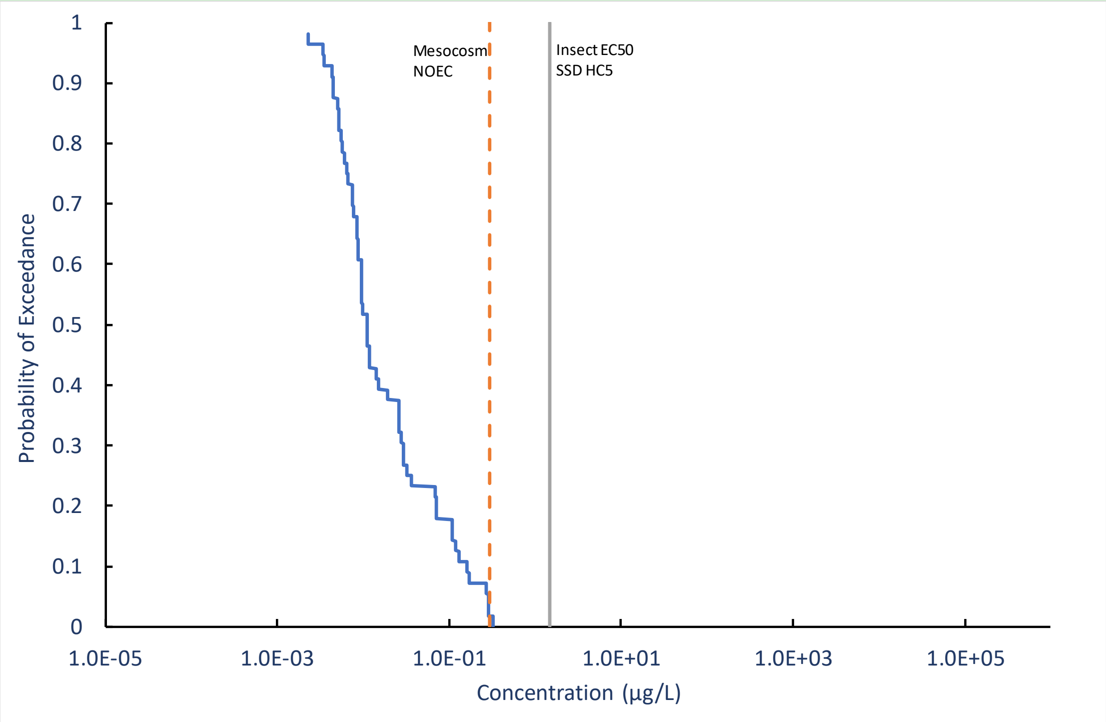

Figure 1 Distribution curve for thiamethoxam detection in daily samples collected from the River Waveney (Watchlist 1 data) compared with the mesocosm NOEC from continuous thiamethoxam exposure (Pickford et al. (2018) and the insect EC50 SSD HC5 from Finneghan et al (2017) (note these effect concentrations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

<u>Groundwater exposure – PECgw</u>

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 groundwater resources was identified as part of the previous assessments and no further assessment is required.

RECOMMENDATIONS

For soil and groundwater, 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. 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.

A brief review of Environment Agency surface monitoring data for England from 2016 showed that concentrations were being detected above the Water Framework Directive 1st Watch List PNEC of 0.14 µg/l, as well as the revised PNEC of 0.042 µg/l proposed under the 2nd Watch List. Therefore, although the standard regulatory risk assessment under Regulation 1107/2009 demonstrates an acceptable risk based on higher tier effects endpoints for thiamethoxam, use of the product may be expected to result in thiamethoxam surface water concentrations above PNEC values set by the Water Framework Directive.

29	Additional risk(s)
Please provide details of any additional risk mitigation measures proposed to protect humans, the environment and wildlife and the rationale for these proposals.	
The proposed modelling and monitoring-based approach for targeted seed treatment use in 2022 has been taken as the UK sugar beet sector is fully aware of the recent published papers that suggest that neonicotinoid residues can be found within soils/water following a neonicotinoid seed-treated crop.	

The proposals made in this application to limit seed treatment use are assisted by the nature of the UK sugar beet crop itself. For example, compared to winter cereals and oilseed rape grown across the British Isles, the UK sugar beet is regarded as a 'niche' non-flowering crop with around 100,000 hectares grown each year. Sugar beet is an important rotational spring break crop, grown, on average, one year in four, across eastern England, primarily around the four processing factories.

Sugar beet seed is precision drilled, usually at 18cm apart and 50cm between rows to achieve a final BBRO-recommended field population of 100,000 plants per hectare, with the neonicotinoid treatments being incorporated into the seed pellet and then sealed via film coating (unlike cereals) at the processing factory such as Germains following ESTA guidelines (http://esta.euroseeds.eu/Standard/Dust). Consequently, dust is not regarded as an issue and seed is not left on the soil surface.

To mitigate risks to soil, water and pollinators the Industry will undertake the following:

• Decrease the rate of thiamethoxam on seed by 25% from 60g to 45g/100,000 plants. This would result in 1,130kg less neonicotinoid active being introduced into the environment (based on 2018 Pesticide Use Statistics)

• Only use treatments when the virus yellows forecast is above the economic threshold

• Monitor all treated crops and associated field-areas

• To continue the following crop restriction clause into grower agreements

• No further use of thiamethoxam seed treatments (including any re-drilling of treated sugar beet from crop loss due to wind blow or capping) on the same field area for 46 months from the date of sowing treated sugar beet seed in 2022. This is to minimise the risk of residues being acquired by succeeding flowering crops or weeds and hence exposing bees and/or other pollinators to neonicotinoids.

• Follow industry recommended herbicide programmes to minimise the number of flowering weeds within treated sugar beet crops and reduce the risk of indirect exposure of pollinators to neonicotinoids. This is standard best practice and only applies within field, **not** next to or around the field, i.e. field margins.

• Monitor neonicotinoid-treated sugar beet fields post-harvest to determine any neonicotinoid seed treatment residue levels in soil and plants.

Clearly, there is a paucity of relevant residue data for sugar beet; limited studies have been conducted by FERA and in the sugar beet growing region in northern Spain. **Jones et al** (2014) undertook a preliminary study at FERA to evaluate neonicotinoid concentrations in UK arable soils following seed treatments and included one field (of the 18), 'Norfolk 2', that had previously included thiamethoxam-treated sugar beet and clothianidin-treated winter wheat in 2012.

These FERA studies demonstrated that neonicotinoids could be detected in soils following previous usage but imidacloprid (no longer used in beet) tended to show the highest levels. Also, previously the

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clothianidin soil half-life had been estimated at between 148 and 1,155 days in aerobic soil and for imidacloprid between 1268-1233 days. Jones et al found the DT_{50} values (half-life) for the UK soils studied were lower than previously reported; for clothianidin between 277-1386 days and thiamethoxam 75-109 days. They concluded that thiamethoxam levels were below 2ug/kg and saw no appreciable build-up of this chemical in the fields studied and both clothianidin and thiamethoxam were less persistent than imidacloprid. It was unclear what concentration would arise in succeeding pollen/nectar but speculated that less than 1.5ug/kg soil would need to accumulate to impact the succeeding flowering crop.

More recently, in 2016/17, a soil study was conducted by the Instituto Tecnológico Agrario de Castilla y León (ITACyL) in Spain to meet the Castile and León beet sector's demand for scientific and impartial information on the persistence of neonicotinoid insecticides after use of such products on sugar beet crops. The reasons for this report were based on the sector's concern about the possible loss of use of such insecticides due to their negative impact on pollinators. In the farmers' view, this loss will have an extremely negative impact on the viability of beet crops in Spain.

The objective of this Spanish study was to evaluate the persistence of the insecticides clothianidin, imidacloprid and thiamethoxam in soils in which sugar beet crops treated with these insecticides were grown in 2016 and then crops not treated with insecticides and not attractive to pollinators were grown in 2017. Based on the early results obtained (the full report is attached within the additional papers submitted with this application), the following conclusions were made by the authors:

- There is no persistence of neonicotinoids in soils in a rotation of treated sugar beet followed by an untreated non-flowering crop that is not attractive to pollinators.
- Following the crop sequence described above, since there is no persistence of neonicotinoids in soils, crops that are attractive to pollinators may be grown with no risk to the pollinator population.
- Considering the significant importance of pollinators, it would be appropriate to conduct a systematic evaluation of the potential presence of neonicotinoids in soil before planting species that are attractive to pollinators. Testing methods with lower limits of quantitation should be used for this purpose.
- Likewise, evaluations should be conducted to assess the potential presence of neonicotinoids in nectar and pollen samples from the following pollinator-attracting crop after the described crop rotation to categorically ensure there is no persistence of these insecticides.

Additional supplementary data from Syngenta, addressing some of the concerns raised by ECP in 2018, were submitted as part of the 2020 CRD9 application for Cruiser SB.

References

Jones, A., Harrington, P., Turnbull, G. (2014). Neonicotinoid concentrations in arable soils after seed treatment applications in preceding years. Pest management Science 70 (12) 1780-84.

Instituto Tecnológico Agrario de Castilla y León (2017). Persistence of clothianidin, imidacloprid and thiamethoxam in soils after sugar beet crops and subsequent crops that are not attractive to pollinators. 1-8.

Environmental fate (supporting data or case must address UK specific requirements)
Fully supported by the extant authorisation for Cruiser SB, COP 2013_02236

2.7 Ecotoxicology

Evaluation, Summary and Conclusion by The 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".

Background

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.[6]/100000 seeds.

The weight of sugar beet seeds is assumed to be 6 g per 100 seeds equivalent to one seed weighing 60 mg.

Content of a.s. in product (g a.s./L)	Seed loading (g a.s./100000 seeds)	Seeds/ha	Seed loading (mg/kg seed)	Application Rate (g a.s./ha)
600	45	115000	7500	51.75

The following ecotoxicology assessment has used existing agreed endpoints from the Review Report for thiamethoxam (European Commission 2006[7]) 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.

This eRR provides an update to the previous (2005) evaluation for 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).

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[8], however the toxicity endpoints have not changed. In light

[6] a.s. = active substance
[7] European Commission (2006) Review report for the active substance thiamethoxam SANCO/10390/2002 - rev. 2
[8] Guidance has changed from SANCO 4145/2001 to EFSA (2009)

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)[9] using the EU agreed endpoints (European Commission (2006)[1]).

Toxicity

Toxicity endpoints have been taken from the latest EU review (European Commission (2006)):

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 beer 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.

[9] 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.

Acute exposure:

$$DGritD_{acute}(\text{large granules})^{44} = 2453 \times \frac{G_{density}}{(71+G_{density})} \times G_{loading}$$

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

<u>Exposure to birds and mammals from eating sugar beet seedlings</u>

According to EFSA (2009)[10], the risk assessment scheme for seedlings grown from treated seed considers the following generic focal species:

- Small omnivorous bird (FIR/bw[11] = 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

[10] In addition to EFSA (2009), further details are provided in https://www.hse.gov.uk/pesticides/pesticides-registration/data-requirements-handbook/birds.htm.
[11] FIR/bw = food intake rate/body weight

		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 beer 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

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 (Thompson 2007a, primarily considering acute effects on birds) and a wood mouse monitoring study (Thompson 2007b). 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[12], 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)[13]).

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	

[12] Changed from SANCO/3268/2001/rev.4 – Guidance Document on Aquatic Ecotoxicology, to EFSA (2013).
[13] 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.

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.)

<u>Clothianidin</u>

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)[14]):

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

[14] 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.

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

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.

Combined risk

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.

Consideration of the RAC used for thiamethoxam and the Water Framework Directive (WFD) PNEC

Two sets of PNECs are available (JRC Technical Report 2018[15]):

- 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.

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

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 a 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.

Effects on bees

The risk to bees from the use of thiamethoxam has been considered in detail by EFSA (2013a[16], 2015[17] and 2018[18]) 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[19]). 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);

[16] 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.

[17] 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

[18] 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

[19] 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

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:

> *Treated crop scenario*
>
> *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.*
>
> *Succeeding crop scenario*
>
> *A high risk at the Tier-1 was concluded for all crops and all bee groups.*

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[20]), 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[21]) and confirmed during the expert meeting related to this assessment.*

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[20] 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.

[21] 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

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:

"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). This endpoint will be considered further below.

Additional data

A new study of residues in following crops was submitted for the previous application (HSE internal ref: COP202001677). This study was evaluated for that application; however, the evaluation is presented below for information.

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]/; 2020
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] (2020)
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.

Available guidance

The current guidance document being applied is SANCO/10329/2002[22]. 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.

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

It should be noted that 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.

[22] SANCO/10329/2002[22] rev 2 final 17 October 2002 DRAFT Working Document Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC

Associated with 283/2013 and 284/2013 are "Commission Communications" which specify the test methods and the associated guidance[23, 24].

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)).

Risk assessment

First-tier

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 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

[23] 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)

[24] 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)

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

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. For adult foragers, there is a margin of safety[25] between the exposure estimate and the toxicity endpoint for all scenarios except the succeeding crop scenario. As for larvae, there is a margin of safety 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.

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**

[25] Due to the lack of agreed protection goals and hence trigger values for honey bees, a margin of safety approach has been adopted whereby the effects endpoint is compared to the exposure endpoint. It should be noted that there is no agreed level of acceptability in terms of margin of safety, however from the above comparison, it is apparent that there are several orders of magnitude between the toxicity endpoint and the exposure estimate.

risk to adult forager honeybees foraging on succeeding crops is unacceptable, i.e., the exposure estimate is greater than the toxicity endpoint, similarly **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. All other scenarios, i.e., risk to bees foraging in field either adjacent crops or field margins, are acceptable. It should be noted that due to the lack of an agreed chronic toxicity endpoint, that the chronic risk could not be determined; this is considered further below.

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[26] 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.

Refined risk 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)

[26] The risk from dust drift is acceptable with and without a deflector.

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 [redacted] (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

	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.

As stated above, the toxicity endpoints from the EFSA conclusion on thiamethoxam (EFSA 2018) are:

Acute oral LD50 = 0.005 µg a.s./bee
Larvae NOEL = 0.0217 µg a.s./larvae/developmental period

An ETR calculation has not been performed as outlined in EFSA (2013b) as protection goals and associated trigger values for a standard risk assessment have not been agreed.

The toxicity values have instead been compared to the exposure predictions to determine the factor between the two (how much higher is the toxicity endpoint than the exposure prediction). This is shown below:

			Factor between exposure and effects	
		Toxicity	$RI_{forager}$	RI_{larvae}
		(µg a.s./bee/d or µg a.s./larvae/d)	0.000512	0.0002428
Acute oral LD50		0.005	10	-
Larvae NOEL		0.0217	-	~100

(red)	Exposure higher than toxicity
(orange)	Exposure similar to toxicity
(green)	Exposure an order of magnitude or more lower than toxicity

There is a least an order of magnitude between the predicted exposure and the acute oral LD50 and the larvae NOEL. However, there has been no consideration of the chronic risk to adult foragers, this is considered further below.

Consideration of the lack of an adult forager chronic toxicity endpoint

As was flagged up above, there is currently no agreed adult chronic oral toxicity endpoint for forager honey bees. Conventionally, this would be addressed via OECD 245[27], noting that this study was adopted by the OECD after the Regulations 283/2013 and 284/2013 were agreed.

EFSA (2013a) stated the following regarding chronic and sub-lethal effects:

> *1.2. Chronic toxicity*
>
> *A subchronic feeding study with thiamethoxam and metabolite clothianidin (CGA322704) was available ([redacted] (2002), see Study evaluation notes; EFSA 2012e). After 10 days of exposure (10 hours per day) a mortality of less than 7 % was observed. The cumulative dose ingested over a 10-day period was approximately 2 ng/bee. For the purposes of risk assessment a 10-day LC50 > 0.2 ng a.s./bee per day is assumed.*
>
> *1.3. Sublethal effects*
>
> *In the data submitted for the purpose of this assessment, there were two studies which specifically considered the sublethal effects of thiamethoxam or the metabolite clothianidin (CGA322704) to bees. The two return-flight ability studies conducted by [redacted] (2001) (see Study evaluation notes; EFSA 2012e) were of reasonable scientific quality but were not performed according to GLP. The methodology used to determine the return-flight ability (using colour coding of the bees) was not as sophisticated as the recent studies by [redacted] et al (2012a) where the use of RFID (radio-frequency identification) was employed. In the study of [redacted] (2001) with thiamethoxam the study author proposed that the NOEL for return-flight ability was 25 µg/kg sucrose solution (equivalent to 3.03 ng a.s./bee). However, it is noted that, at 25 µg/kg sucrose solution, 2 out of 11 bees had not returned within 24-hours compared to 100 % of control bees. It is therefore questionable whether the NOEL was 25 µg/kg sucrose solution. All bees returned at 0.1, 1 and 10 µg/kg sucrose solution and therefore the NOEL is considered to be 10 µg/kg sucrose solution (equivalent to 1.13 ng a.s./bee). It is noted that very few bees were used*

[27] OECD 245: Guideline for the testing of chemicals Honey bee (*Apis mellifera* L.) Chronic oral toxicity test (10-day feeding)

during the study which creates some uncertainty with regard to the robustness of the results.

In the study of [redacted]*, (2012a) (considered in EFSA, 2012b) sublethal effects on return-flight ability were observed at 1.34 ng/bee.*

It is interesting to see that the results of the two studies, although conducted using different methodologies, both indicate an adverse effect on the return-flight ability of honey bees. For the purposes of risk assessment a sublethal dose of 1.34 ng a.s./bee will be considered.

EFSA (2015) summarised several studies, including those referenced above in EFSA (2013), however they concluded the following:

No first-tier chronic risk assessment for honey bees (including an assessment of the HPG), bumble bees or solitary bees could be performed as no suitable chronic toxicity endpoints were available.

The following was also stated in EFSA (2015):

Two chronic oral toxicity studies with thiamethoxam were available in the dossiers, [redacted] *(2002) (see study evaluation notes in EFSA, 2013a) and Kling (2012) (see study evaluation notes; EFSA, 2015a). Neither of the studies included an assessment of the HPG nor an assessment of accumulative effects. Both studies followed similar methodology whereby the honey bees were offered contaminated food for 10 hours per day for 10 days. During the remaining 14 hours the honey bees were offered uncontaminated food. In order to perform a risk assessment according to EFSA, 2013b, a chronic toxicity endpoint, where the honey bees were offered contaminated food continuously for 10 days, is needed. Consequently, the available chronic toxicity endpoints are not considered suitable for risk assessment in accordance with EFSA, 2013b.*

EFSA (2018) stated the following:

No reliable data were available to derive a chronic lethal dietary dose (LDD50) for honey bees.

In the previous assessment of ‘Cruiser SB’ (HSE Internal ref: COP2020/01677), the value of 1.34 ng a.s./bee has been used, along with a value of >0.2 ng a.s./bee/day from EFSA (2013). It is noted that neither is stated to be reliable in subsequent assessments (e.g., EFSA (2018)), however it is considered that they provide a potentially illustrative indication of the chronic/sub-lethal effect of thiamethoxam on honey bees.

Using the information presented above regarding the intake of thiamethoxam and the factor between exposure and effects, the following comparison is determined:

			Factor between exposure and effects	
		Toxicity	$RI_{forager}$	RI_{nurse}
		(ng a.s./bee/d)	0.512	0.2312
Chronic LC50	>	0.2	0.4	0.9
Sublethal dose	<	1.34	2.6	5.8

(red)	Exposure higher than toxicity
(orange)	Exposure similar to toxicity
(green)	Exposure an order of magnitude or more lower than toxicity

On the basis of the above, it is seen that the exposure is higher than the toxicity, however the chronic toxicity endpoint LC50 is a greater than value, and as a result, the “true” toxicity is not known. Further consideration of the chronic risk to bees from exposure via a following crop is therefore required.

For the sublethal effects, noting that this is not a standard study, or part of the routine risk assessment, the toxicity endpoint is between 2.6 and 5.8 times higher than the exposure, but 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 a following crop of oilseed rape is required.

Overall, on the basis of the above assessment, it is not possible to conclude regarding the chronic or sub-lethal effect on honey bees due to the lack of toxicity data. No assessment has been done for the field-margin and adjacent crops scenarios, it is considered that due to the lack of robust chronic endpoints, that it would not be able to conclude regarding the chronic risk for these scenarios.

Further consideration of the potential chronic risk to honey bees from thiamethoxam

A published paper was submitted with an earlier application[28] that involved a study designed to investigate long-term effects following honey bee colony-level exposure to thiamethoxam and the resulting implications for risk assessment (Thompson *et al* 2019[29])

This paper was based on two colony studies conducted in in Orange, Caswell or Alamance Counties, in central North Carolina, USA. Over 100 colonies were assessed to determine the numbers of adult bees and numbers of cells containing brood, pollen/bee-bread and nectar/honey in early June (4 weeks before the start of exposure) and of these, 96 colonies were selected for the study based on general health. Colonies had all stages of brood, a queen, and some food stores but no visible symptoms of Varroa mites (*Varroa destructor*), Nosema or other bee diseases. Each study had 6 weeks of continuous dosing of 12 colonies per treatment (24 control) to 12.5, 25, 37.5, 50 or 100 ng thiamethoxam/g sucrose solution.

The results from the study showed that, compared to control, the highest dose treatment group (100 ng a.s./ g) had significant reductions in adult bees (first assessment after dosing to the last assessment before over-wintering). The 50 ng a.s./g treatment group also has significantly fewer adult bees at the end of dosing. Brood levels were also reduced at 100 ng a.s./g and 50 ng a.s./g. There was significant reduction in pupal cell numbers compared to control for the 25 ng a.s./g dose group at one time point, which the study author concluded was not dose related. Effects on the amount of stored bee-bread were seen at 37.5 ng a.s./g, 50 ng a.s./g and 100 ng a.s./g. There were effects on nectar storage at 12.5 ng a.s./g and 25 ng a.s./g, but not at the higher dose levels except at a single time point at 100 ng a.s./g, so the study author concluded this was not treatment related.

Based on the published paper there were no dose related effects on the colony at 25 ng a.s./g and below. The study authors proposed 37.5 ng a.s./g as the NOEC based on the effect seen at 37.5 ng a.s./g being reversed by 10 weeks after the start of exposure, however HSE considers that a no effect level should be based on no effects, rather than reversible effects, therefore HSE considers the potential NOEC from this study to be 25 ng a.s./g.

Compared to a regulatory study there is a lack of detail provided in a publication, so this is a tentative conclusion.

In the paper the residue of thiamethoxam in nectar was compared to the colony NOEC based on the amount of thiamethoxam in a 50% sucrose solution fed to bees. When considering the risk assessment proposed by EFSA the two were not considered equivalent because a bee

[28] HSE internal reference: COP202001677

[29] Thompson, H, Overmyer, J, Feken, M, Ruddle, N, Vaughan, S, Scordie, E, Bocksch, S and M Hill (2019) Thiamethoxam: Long term effects following honey bee colony-level exposure and implications for risk assessment. Science of the Total Environment 654, 60-71.

would need to consume more nectar than sugar in order to obtain its requirement for sugar. The use of the 15% sugar content in nectar of oilseed rape by EFSA was questioned by the study authors, as it was claimed that this leads to a bee consuming 5 times its body weight in nectar, compared to 3 times its body weight assumed by the USEPA (based on a 30% sugar content).

If the proposed no effect concentration was corrected based on a 15% sugar content, compared to the 50% sugar content in the tested solution the result would be 7.5 ng a.s./g. the maximum residue in nectar in the residue study is 0.6 µg a.s./kg, which is 0.6 ng a.s./g, which is approximately an order of magnitude lower than the suggested no effect level in the colony study provided.

There are a number of uncertainties that need to be taken into account, for example:

- The representativeness of the small, low disease colonies in the USA for UK colonies.
- Relevant of the prevailing weather conditions to UK conditions.
- Residues of thiamethoxam in pollen were not taken into account in the colony study, so there would be an additional source of thiamethoxam.
- The study was a colony feeding study and not a foraging study, therefore there is uncertainty as to what the exposure of honey bees were.

Overall, whilst the study appears to indicate that the residues found in oilseed rape in the following crop study would not be likely to have an adverse effect on bee colonies, due to the above uncertainties and lack of details in the published paper, it does not address the concerns raised at the lower tiers of the risk assessment.

Risk from metabolites

Clothianidin is a soil metabolite of thiamethoxam and requires consideration. Data from the above following crop study (see [redacted] 2020), 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:

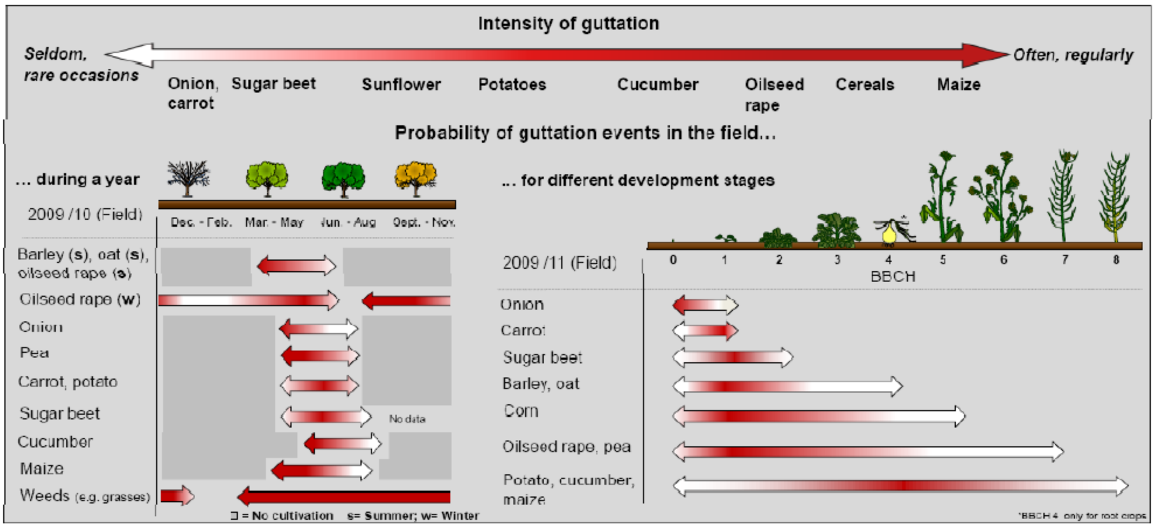
- the intrinsic conservativeness of the Tier-1 assessment;
- the very similar toxicity profiles expressed by the two compounds;
- the available information on plant metabolites, which suggest that the formation fraction of metabolite clothianidin is likely to be well below 100%.

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) [30] which shows the intensity and frequency of guttation observed in the field trials.

[30] Joachimsmeier I, Pistorius J, Heimbach U, Schenke D, Zwerger P and Kirchner W, 2011. Details on



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)”[31].

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 [redacted] (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.

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[32]. These can be converted to µg/µL and

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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.

[31] 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.

[32] 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

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 LC50	>	0.0002	0.4
Sublethal dose	<	0.00134	2.8
Larvae			
			0.004662 µg/period[a]
Larvae		0.0217	4.65

Clothianidin[33]		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[34]	4.32

[a] The exposure value is, according to EFSA (2013b), meant to be a 5-day time-weighted average value. Whilst data in [redacted] (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.

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 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

[33] 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

[34] Endpoint stated to be “provisional endpoint because of 3 days exposure and nominal food consumption”.

The result is less clear cut for the chronic risk from thiamethoxam (noting the comments above regarding the reliability of these endpoints), where the exposure is higher than the toxicity, but the chronic LC50 is a greater than value, so the true toxicity is not known. Further consideration of the chronic risk to bees from exposure via guttation is required. 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. [redacted] (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] (2020) 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)[35] 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 EU moratorium on neonicotinoid use. The residues in honey were then

[35] 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

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[36]; 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.

[36] 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.

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 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 conclusion

The **acute contact risk** from dust drift is considered to be acceptable, providing that the read across from the spray-based hazard quotient approach and the associated trigger value is accepted.

As regards the **oral routes** of exposure the risk from honey bees foraging on the treated crop is deemed not be relevant and hence is acceptable. As regards honey bees foraging on **flowering plants in the field margin**, **adjacent crops** and **succeeding crops**, the acute oral route for adult bees as well as the risk to larvae have been assessed, and as a result of the assessment there is at least an order of magnitude between the predicted exposure and either the acute oral LD50 or the larvae NOEL.

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 for adult honeybees 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 (for further details see "Effects on bees – Consideration of the lack of an adult forager chronic endpoint" (page no. 135 above)). 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.

The risk from guttation was considered and it was noted that the risk from the initial use on sugar beet seed was considered to be acceptable by EFSA (2018); HSE agrees with this conclusion. However, the risk from guttation formed in succeeding crops was not assessed in EFSA (2018). HSE has assessed the risk using data on the levels of thiamethoxam in guttation fluid formed on maize (see [redacted] (2020)) with the available toxicity data, with the outcome indicating potential concern, especially with regard to chronic risk to adult forager honey bees. It should be noted that data on the likely levels of the active substance in guttation fluid on other plants were not available, nor were data on the likely frequency of occurrence of guttation fluid. Due to the lack of information regarding the likelihood of occurrence of guttation including which crops it may occur in, it is not possible to determine which crops could pose an acceptable risk.

Other areas of the risk assessment

The following assessments (presented on a blue background) are taken from the original assessment of 'Cruiser SB' (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 other 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] 1998a
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] 1998b
'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] 1998a
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] 1998b

[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] 2001a)

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] 2001b)

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] 2005)

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] 2000)

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 cu preus* 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 betwee seeds in the row) at a depth of 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 ar 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' plots had died compared to 7.5% in untreated plots (corrected mortality = 18.9%). In addition, 33% of surviving beetles in the 'Cruiser' plots showed co-ordination problems while all beetle in untreated plots appeared normal. No effects on mean food consumption/beetle/da were seen.

This study was performed according to Barrett *et al* (1994), Dohmen (1998) and Heimbach *et al* (1992) and in accordance with GLP.

([redacted] 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' 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' 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.

([redacted] 1998b)

B.9.5.4 Field studies

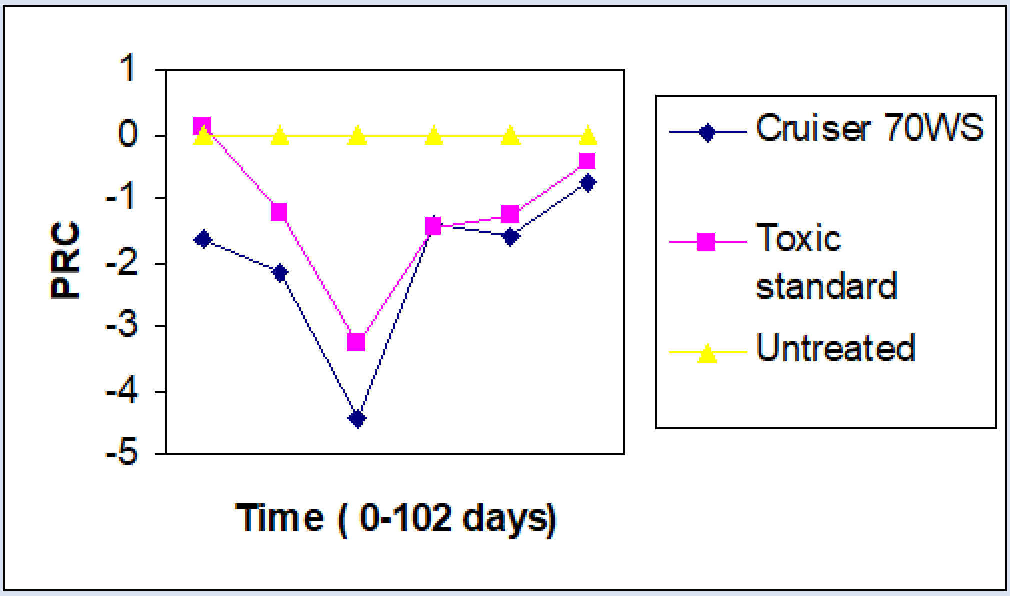
No field studies were conducted with the proposed formulation 'Cruiser 350FS' but a range of other formulations were used in four field studies.

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. <u>Principal response curve for non-target invertebrates</u>



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' 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' 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' 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.

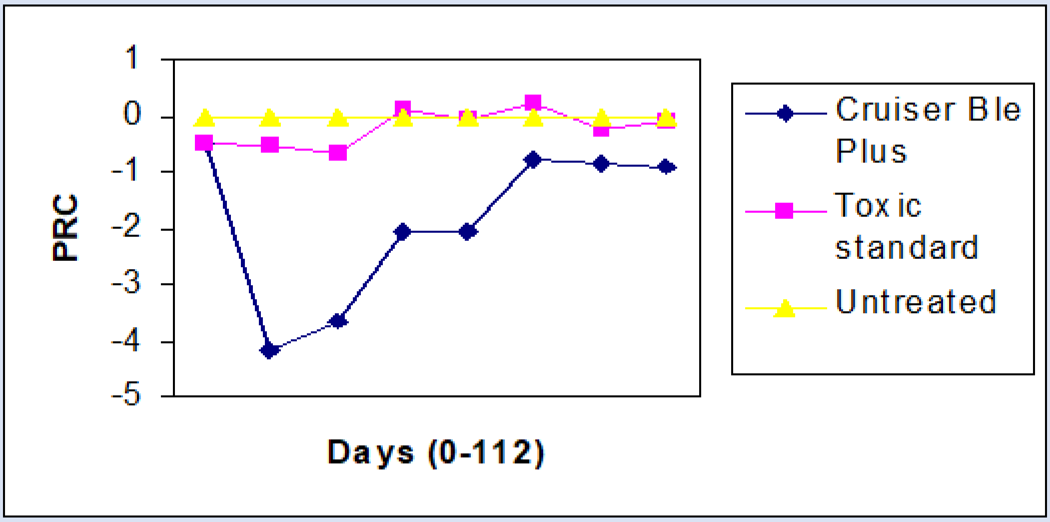
([redacted] 2001)

b) In a field study near Mulhouse in France, the effects of 'Cruiser Ble Plus' applied to spring 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 of 400 ml/100kg seed. Sowing rate was 175 kg seed/ha (equivalent to a nomina rate of 92 g 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 <u>Principal response curve for non-target invertebrates</u>



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.

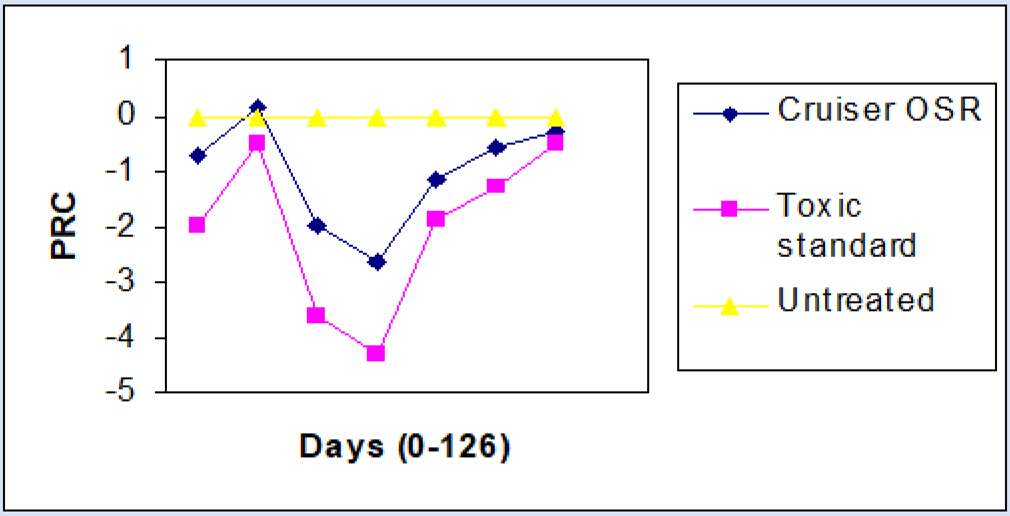
([redacted] 2002a)

c) The effects of 'Cruiser OSR' (containing 28% w/w thiamethoxam plus 3% w/w metalaxyl-m 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 1.5 litres/100kg seed. Sowing rate was 8 kg seed/ha (equivalent to 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.

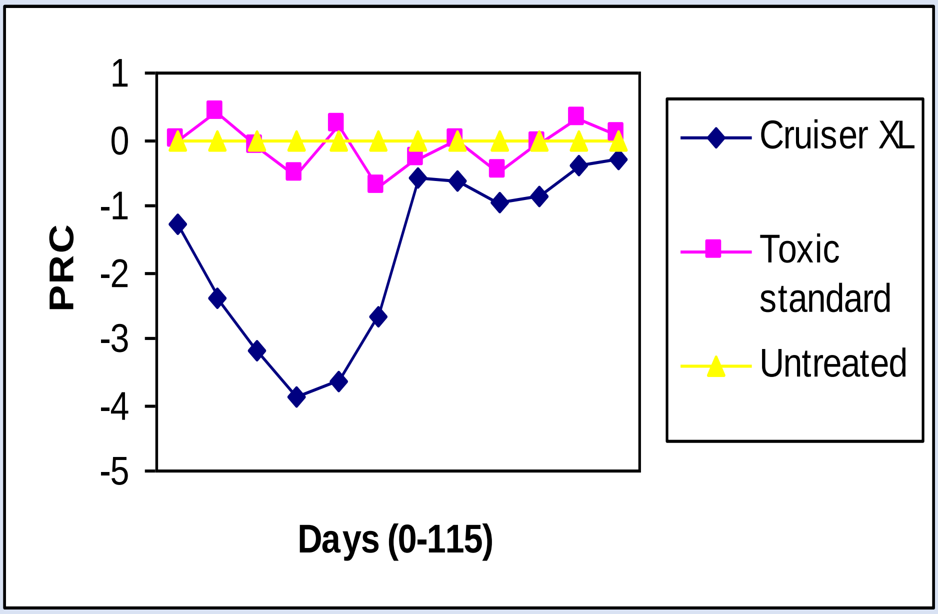
([redacted] 2002b)

d) The effects of 'Cruiser XL 424.6FS' (containing 417 g/l thiamethoxam plus 4 g/l fludioxonil 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 o 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] 2002c)

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 <u>Results of screening tests on four metabolites against insects and mites</u>

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 litto-ralis L-1	feeding contact	0	0	0	100
Spodoptera litto-ralis 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] 1998)

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] 2001a)

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] 2001b)

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 [redacted] 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 [redacted] 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 ([redacted] 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 ([redacted] 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 ([redacted] 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 [redacted] 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[37], 2001[38]). 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 [redacted] 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.

[37] 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.

[38] 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.

			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 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[39], however, outlined below is the evaluator's assessment.

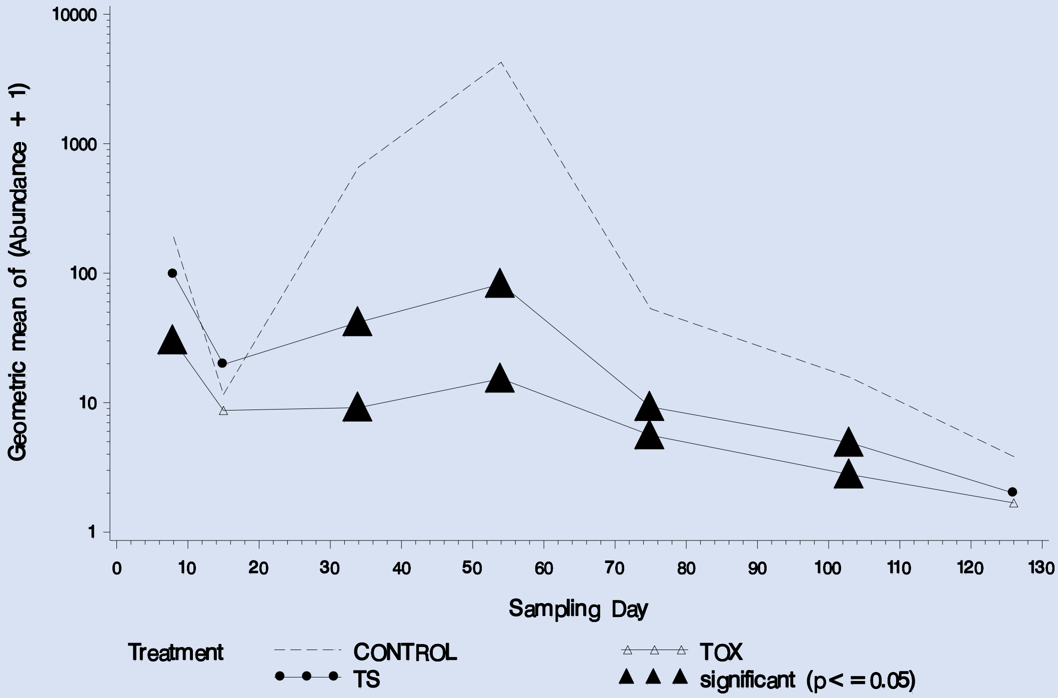
a) Effects on collembolan populations

[39] Appendix 8 has not be included, but is available if required.

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.

Figure B.9.18 Population density of *Sminthuridae* (Collembola) in pitfall traps in the oilseed rape study ([redacted]002b).

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] 2005); 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] 2001b).

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 (on a blue background) 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.

([redacted] 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] 1999a)

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] 1999b)

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] 2000)

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] 2000)

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] 2002)

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] 1997)

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 off-spring/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] 1999)

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] 1997d)

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	527	12	179
0.06	2.5	552	19	71
0.18	0	536	19	104
0.3				

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] 2000)

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)

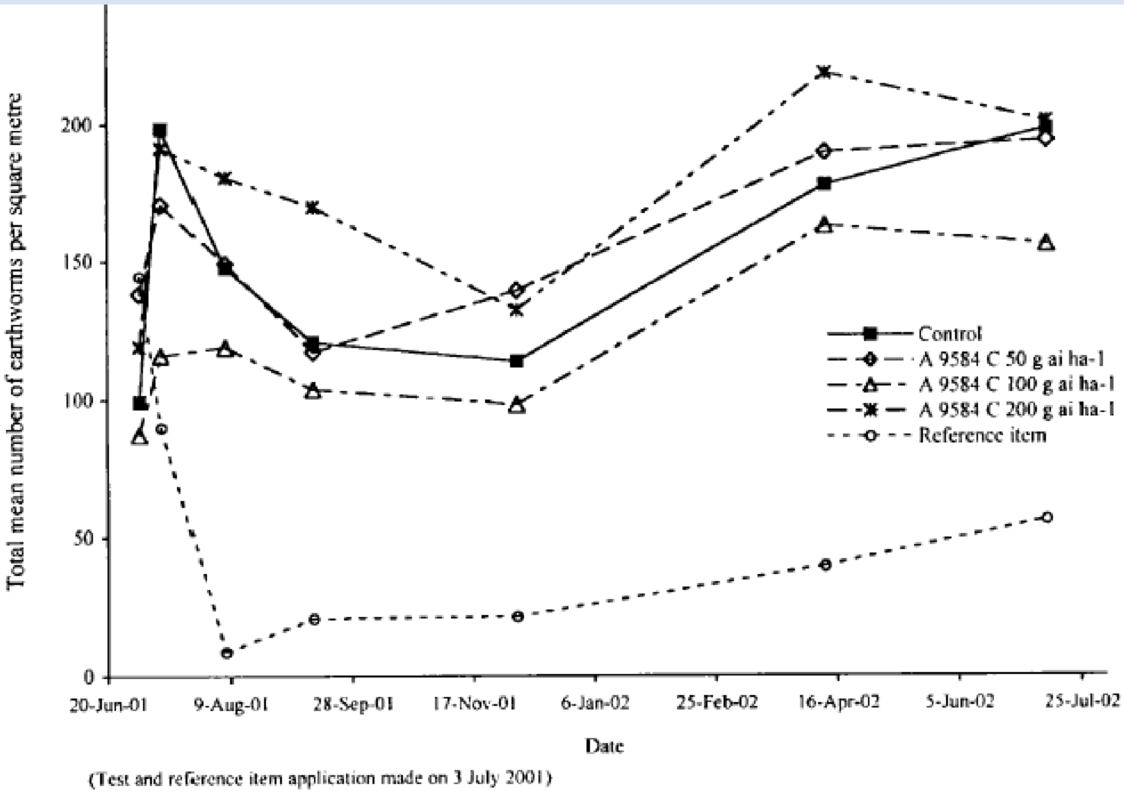
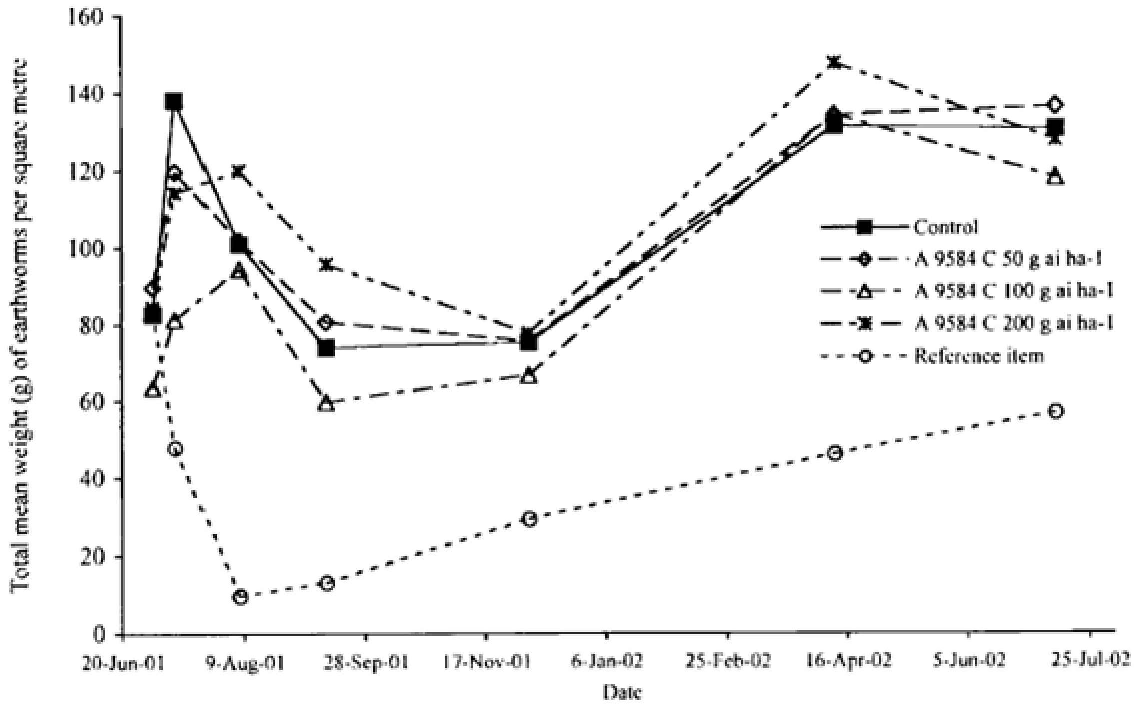


Figure B.9.21 Trend graph for mean total earthworm weights (g) per treatment collected during the study (earthworms/m^2)



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] 2003)

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 Total mean number of earthworms collected on each sampling occasion following application of CGA 322704 in the field ([redacted] 2004)

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 ([redacted] 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 ≤ 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], D. 2004)

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[40]. 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

[40] 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.

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[41]	>9615	-	10	[redacted] 1995
	LC50: >1000 mg formn/kg soil [>700 mg a.s./kg soil] ('Cruiser WS70')	0.104	>6730	-	10	[redacted] 1997
	NOEC (repro)* 0.3 kg formn/ha [0.14 mg a.s./kg] # ('Cruiser 350FS')	0.104	-	**1.35**	5	[redacted], 1999
	NOEC (repro)* 4.6 kg formn/ha [3.05 mg a.s./kg soil] ('Actara'')	0.104	-	29.3	5	[redacted], 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 [redacted] (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] (1997d), 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 [redacted] 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:

[41] 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.

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] 2001)

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] 2001)

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 [redacted] 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 [redacted] 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] 2005)

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[42] (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] study 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.

The [redacted] (2005) study was done on bare soil and there was also analytical verification of thiamethoxam, therefore the study is considered to be acceptable. This

[42] 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.

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 [redacted] 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 [redacted] 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 (see [redacted] 2001). 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 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 [redacted] 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 [redacted] study and therefore as there were no adverse effects on litter degradation in the [redacted] 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] 1998)

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] 1999)

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.

2.8 Relevance of metabolites

Evaluation, Summary and Conclusion by The Health and Safety Executive
Reviewer's comments
No consideration has been undertaken. The original UK assessment (for the higher rate) concluded that thiamethoxam or its metabolite CGA 322704 are unlikely to occur in groundwater at or above 0.1 µg/ L.

3 Conclusion of Article 53 Application

3.1 Regulatory Approach

Evaluation, Summary and Conclusion by The Health and Safety Executive
'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, that risks to bees cannot be excluded without imposing further restrictions. As a result Commission Implementing Regulation (EU) 2018/785 prohibited all outdoor uses and resulted in the withdrawal of the 'Cruiser SB' authorisation. 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. This latest HSE evaluation for 'Cruiser SB', relies in part on assessments supporting the previous authorisation and in part on new assessments.

3.2 Conclusion

Evaluation, Summary and Conclusion by The Health and Safety Executive
Summary of the risk assessment based on the uniform principles for commercial authorisation[43] The predicted exposure of humans (dietary and non-dietary) falls within the agreed safe levels (ADI/ ARfD/ AOEL) and no health effects are anticipated.

[43] 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, whilst (for example) reference to unacceptable risks in the conclusion 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.

Sufficient data are available to enable the risk to birds, mammals, aquatic life, non-target arthropods, soil macro-invertebrates, soil process and non-target terrestrial plants, to be determined. The assessment concludes that exposure to these wildlife groups is within that which would be deemed acceptable for a commercial authorisation.

Although not part of the standard pesticides risk assessment, it should be noted that exposure above the PNEC established under the Water Framework Directive (WFD) would potentially be expected in edge of field water bodies (as demonstrated by the outputs of the standard regulatory modelling). At the larger catchment scale, concentrations above the WFD PNEC may also be expected as demonstrated by previous monitoring data. The HSE risk assessment has used the standard aquatic dataset along with any appropriate higher tier data to derive a regulatory acceptable approach. HSE has not reviewed the derivation of the WFD PNEC and therefore is unable to determine what the practical effect of exceedance of the PNEC would be. (Consideration of the purpose of setting PNECs, real life monitoring (prior to the EU moratorium on use of thiamethoxam) and consideration of the RAC used is given in sections 2.6 fate and behaviour and section 2.7 Ecotoxicology). This does not change the conclusion with respect to the risk to aquatic life as set out in the previous paragraph.

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.

Article 53 tests

An emergency authorisation may be granted under Article 53 of Regulation 1107/2009 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. If an emergency authorisation is granted the product may be placed on the market for a period not exceeding 120 days. A judgement on whether an authorisation appears necessary to address the danger involves a consideration as to whether the likely benefits of granting the authorisation to address the identified danger outweigh the potential adverse impacts of granting it.

Four of these tests are considered within the body of this eRR above and summarised below 'special circumstances' (section 1.1), 'danger' (section 2.2.1), 'any other reasonable means' (sections 2.2.2), 'limited and controlled use' (section 2.2.4). The test of necessity is considered below:

Special Circumstances

For over 25 years *Myzus persicae* vectors and the Yellows Virus complex were controlled by the neonicotinoid seed treatments. Since their withdrawal in 2018, there have been only 3 seasons experience for the industry to understand and develop new strategies (largely without sufficient available insecticides) to manage aphid/virus yellows complex. There are no recent reference baselines or comparable situations, and each season has been different. The management of virus yellows also needs to be considered in the wider challenges for the whole insect/soil pest complex, which neonicotinoids also effectively controlled. The applicant had recognised the need to find alternatives and initiated significant investment in long term research to develop commercial resistant varieties, before neonicotinoids were withdrawn. This is proving challenging because the complex consists of three viruses and there is no one single trait conferring resistance/tolerance to the virus. All of this uncertainty, and growing threat to crop yields, is reflected in British Sugar and NFU sugar supporting growers through the new virus yellows assurance scheme (funded by British Sugar) to compensate for yield losses. However, the applicant has noted the 2021 contracted area has decreased by 12% due to the yield losses of 2020.

This test is considered met.

Danger

The biology of the yellows virus complex and principle aphid vector, peach-potato aphid (*Myzus persicae*, MYZUPE), economic impacts and control measures in sugar beet has been well described, evidenced and addressed in the series of Article 53 applications. The impact in seasons when conditions are favourable to high population development was illustrated by the 2020 season, with the worst virus epidemic since the 1970's and significant yield losses. It is also notable that the review of aphid numbers caught each year in the Broom's Barn trap up to mid-June provides a very strong illustration of the continuing build-up of *M. persicae* populations, with the five highest migrations occurring in the last seven years. populations, and the limitations of existing control measures.

This test is considered met.

Which cannot be contained by any other reasonable means

The only available authorised effective PPP option is one foliar application of 'Teppeki' (flonicamid), which is insufficient under sustained pest pressure to provide protection for around 12 – 16 week period when sugar beet seedlings remain most susceptible to virus yellows (and subsequent yield losses). Whilst pyrethroids are also authorised, widespread established resistance in Myzus populations means they are not effective. Integrated measures to reduce aphid populations and virus incidence are also extremely important, but not in themselves sufficient. HSE has therefore also issued Article 53 authorisations to provide further foliar sprays, and these combined measures have provided useful control, particularly in seasons with moderate/low pest pressure. But there are practical challenges in using foliar sprays to target the emerging seedlings with sufficient contact on the leaves, and additionally reliant on favourable weather conditions at point of germination to be able to spray. In contrast, a seed treatment provides available active as the seed germinates and moves systemically through the plant including to new growth areas. In conclusion, unless cold weather develops at the critical early part of the year, there remains a significant and growing threat to sugar beet crop most years. If the treatment threshold is met for 'Cruiser', this indicates a high degree of risk to the crop in terms of predicted economic yield losses which would warrant application of the seed treatment rather than reliance on foliar sprays and integrated measures.

This test is considered met

Limited

The use of ‘Cruiser SB’ will, as in 2021, be limited by using an agreed treatment threshold, reflecting the costs of seed treatment, the agreed price for sugar, and predicted virus incidence/yield losses provided by the long established, validated model. The pre-season forecast is provided by Rothamsted Research and 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 model provided predictions for virus incidence both with and without 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. A graphical presentation shows the close correlation between prediction of virus incidence with pest measures, and the actual observed over the last 50+ years. The prediction is based on assuming no control measures (it is no longer possible to include a figure with pest measures since the withdrawal of neonicotinoids). The threshold figure proposed for 2022 will be provided as soon as the sugar price for this season (and costs of treating seed) have been finalized. But it has been indicated it is likely to be at a similar level to 2021.

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, it is recognized that the use of this treatment threshold does provide an appropriate mechanism to limit the use. And no other European country, including those issuing Article 53 authorisations for sugar beet neonicotinoid treatments in the last few years, has such a model that allows this limitation.

This test is considered met.

<u>Controlled</u>

Sugar is grown under contract to British Sugar. BBRO provide detailed and extensive advice on all aspects of sugar beet growing and provide exhaustive information on crop management, IPM measures, monitoring aphid populations/virus incidence throughout the season, as well as technical advice and plant clinics. This includes season-long real-time information on; the incidence of the virus vectors, their resistance status and infectivity from both the Rothamsted suction trap and BBRO-managed yellow water pan networks (run in association with British Sugar staff, growers and agronomists). There are various measures discussed in the application relating to advice, and included within a draft stewardship plan (at appendix 3).
If an authorisation is granted, this will include an additional restriction limiting the planting density to a maximum of 115,000 seeds/ha. The applicant would be required to amend the stewardship plan accordingly. All of these combined measures, are considered robust in supporting growers and meet the test for limited and controlled use.

This test is considered met.

<u>Necessity</u>

A judgement on whether an authorisation appears necessary to address the danger involves consideration of whether the likely benefits of granting the authorisation in terms of addressing the identified danger outweigh the potential adverse impacts of granting it.

HSE agrees that the proposed use would bring significant benefits to UK sugar beet production if high virus levels are predicted in 2022.

In relation to the potential adverse effects of an authorisation, the studies that were available to assess the chronic risk to honey bees were not ideal but indicated that there is an unacceptable risk under the standard criteria for a commercial authorization. These studies indicated 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. The available data do not permit an assessment of the likely consequences at the colony level. It is also noted that a risk management decision was made in 2021 by the Secretary of State for Environment, Food and Rural Affairs regarding the risk to honey bees from thiamethoxam residues in succeeding crops. It should be noted that adverse consequences to bees and other pollinators were the basis for the EU restrictions on certain neonicotinoids including thiamethoxam (Commission Implementing Regulation (EU) 2018/785) which prohibited all outdoor uses.

Given this context, and taking into account the precautionary principle, HSE considers the potential adverse effects to honey bees (and other pollinators) which could arise if an authorisation was to be granted outweigh the likely benefits of granting the authorisation, so on the basis of the information available the authorisation cannot be supported.

This test is not considered to be met

HSE conclusion

Assessments of the benefits from the proposed use, the risks from that use and whether the necessary Article 53 tests are met, are presented above. On balance and as described in the test of ‘necessity’ HSE does not support authorisation.

Post ECP further considerations and conclusion

This application was considered by the Expert Committee on Pesticides (ECP) on 28 September 2021. A copy of the ECP advice is included at Appendix 4 of this document.

Although the ECP did not support the proposed use, they advised that if authorisation is granted further consideration should be given to how the use could impact on growers involved in agri-environment schemes which involved planting flowering margins.

The applicant proposed a stewardship scheme (Appendix 3), which 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 is not possible to determine if this is an appropriate interval. However, a list of non-flowering and flowering crops was included in the stewardship scheme by the applicant. Modifications to this list are proposed to better accommodate agri-environment schemes (see Appendix 3). 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 have been 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). Section 8 of the proposed 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 2022, 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.

The ECP also advised that the threshold at which 'Cruiser SB' treatment is triggered should be recalibrated to take account of the compensation scheme offered by British Sugar. The HSE assessor considered that whilst both of these relate to the economics of the crop, the threshold and the compensation scheme serve different functions. If a decision is taken to authorise the proposed use, further consideration of this issue may be required.

Overall the ECP advice does not change the HSE conclusions set out above, including HSE's conclusion that the test for necessity is not met. HSE considers the potential risks from using 'Cruiser SB' in the event that 2022 presents a high virus risk outweigh the crop protection benefits.

3.2.1 Assessed GAP

Use-No.	Crop and/ or situation	Pests or Group of pests controlled	Situation	Application method	Timing / Growth stage of crop or season	Maximum individual dose	Maximum total dose	Maximum number of treatments	Latest time of application:	Pre-harvest interval
1.	Sugar beet seed	*Myzus persicae*	Outdoor	Seed treatment	Before drilling	75 ml product (45 g a.s) / 100000 seeds	N/A	1	Before drilling	N/A

3.2.2 Risk Mitigation Measures

Those restrictions considered necessary following the evaluation by HSE of the requested use.

Operator protection:
Wear suitable protective clothing (coveralls) and suitable protective gloves when handling the concentrate or handling contaminated surfaces. 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. Wear suitable protective clothing (coveralls) when bagging treated seed.
Worker protection:
wear suitable protective clothing (coveralls) and suitable protective gloves when handling treated seed and contaminated seed sowing equipment.

Environmental protection
To protect birds and mammals treated seed must be en-tirely incorporated in the soil; ensure that the product is also fully incorporated at the end of rows. To protect birds and mammals treated seed should not be left on the soil surface. Bury or remove spillages. To minimise the number of flowering weeds in treated sugar beet crops and reduce the risk of indirect expo-sure of pollinators to neonicotinoids BASIS recom-mended herbicide programmes must be adopted by growers and their agronomists. This applies in treated fields only (NOT next to or around sugar beet field drilled with 'Cruiser SB' treated seed). In order to reduce the risk of exposure to pollinators a minimum 32 month interval must be observed be-tween drilling 'Cruiser SB' treated sugar beet seed and planting any flowering crop*. *Refer to agreed stewardship programme for details of flowering/ non-flowering crops. A minimum 46 month interval must be observed be-tween drilling 'Cruiser SB' treated sugar beet seed and planting any other seed treated with thiamethoxam.
Other specific restrictions
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 re-lease of dust during application to the seed, storage and transport can be minimised. Treated seed must be labelled with the appropriate pre-cautions using printed sacks, labels or bag tags (refer to label for agreed text). Treated seed must not be used for food or feed. Sacks containing treated seed must not be re-used for food or feed. Treated seed must be drilled (broadcasting and aerial spreading of coated seed is forbidden). Adequate seed drilling equipment shall be used to en-sure a high degree of incorporation in soil, minimisa-tion of spillage and minimisation of dust emission. The drilling rate for 'Cruiser SB'' treated sugar beet seed must not exceed 115,000 seeds/ha. Returnable containers must not be re-used for any other purpose. Returnable containers must be returned to the supplier. Records must be kept of the fields sown with 'Cruiser SB' treated seed and monitoring in accordance with any agreed stewardship plan.

3.3 Data Requirements for Repeat Applications

Evaluation, Summary and Conclusion by The Health and Safety Executive (Chemicals Regulation Division).
Data required supporting a returning application.
Since no authorisation is recommended, no data requirements have been set. If an authorisation is granted it will at the very least be necessary to formalise the proposed stewardship and for growers and the applicant to provide clear evidence that this and the conditions of authorisation were complied with. This issue will be revisited if a decision to authorise is taken.

Appendix 1 Authorisation Notice

No authorisation is recommended, however for completeness a draft version of an authorisation has been prepared and is copied below:

Emergency Authorisation Number: XXXX of 2021

EMERGENCY AUTHORISATION 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 (a flowable concentrate for seed treatment formulation as detailed in the application form dated 24 June 2010 (HSE ref.: W001349407).
MAPP number*:*	00000
Product authorisation holder*:*	Syngenta UK Limited, CPC4, Capital Park, Fulbourn, Cambridge, Cambridgeshire, CB21 5XE. (Registered company number: 849037)
Marketing company*:*	Syngenta UK Limited

This Emergency use ends:

(a) XXXX for sale and distribution of stocks

(b) XXXX for disposal, storage and use of stocks

This emergency authorisation will be withdrawn or amended before its end date if a decision is taken to withdraw or amend this emergency authorisation under Regulation (EC) No 1107/2009 on any other grounds.

HSE Digital Signature

This and the attached Appendices 1 and 2 are signed by the Health and Safety Executive (“HSE”) for and on behalf of the Secretary of State.

Date of issue: XXXX

EXPLANATORY NOTES

(1) This is emergency authorisation number XXXXX.

(2) This emergency authorisation will be published on the website of the Chemicals Regulation Division of the HSE.

(3) Application reference number: COP XXXXXX.

(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, including the duty on the holder of any emergency authorisation to notify information on potentially dangerous effects, a contravention of which is a criminal offence under those Regulations.

(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.

Application is as a seed coating and 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.

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 any of the pests listed on this label. 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.

In the event of any authorisation any additional requirements would be included

The Emergency Authorisation will expire on XXXXX for use.

APPENDIX 1: CONDITIONS OF EMERGENCY AUTHORISATION

The conditions below are obligatory. They must be complied with when the emergency use occurs. Failure to comply with the following conditions will 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 authorisation holder must only place this product on the market 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 authorisation holder must only sell and supply the product with the agreed labels (for product and seed bag), which were the labels submitted on 26 October 2020 (HSE ref.: W001980922) and label amendments as specified in Annex A to HSE's letter dated XXXXX sent to the authorisation holder.

Use:

Field of use: **ONLY AS A SEED TREATMENT**

User: Professional

Crops/situations:	Maximum individual dose: (ml product / 100000 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) Workers must wear suitable protective clothing (coveralls) and suitable protective gloves when handling treated seed and contaminated seed sowing equipment.

(c) 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.

(d) Operators must wear suitable protective clothing (coveralls) when bagging treated seed.

(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:

- 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.

- To protect birds and mammals treated seed should not be left on the soil surface. Bury or remove spillages.

- 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 next to or around sugar beet field drilled with Cruiser SB seed).

- In order to reduce the risk of exposure to pollinators a minimum 32 month interval must be observed between drilling 'Cruiser SB' treated sugar beet seed and planting any flowering crop*.

*Refer to agreed stewardship programme for details of flowering/ non-flowering crops.

(5) A minimum 46 month interval must be observed between drilling 'Cruiser SB' treated sugar beet seed and planting any other seed treated with thiamethoxam.

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 scheme.

2. Sugar beet seed must only be treated in accordance with this authorisation under the direction of British Sugar, if the agreed X% threshold of virus levels is met based on the British Beet Research Organisation (BBRO) 2022 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 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. Returnable containers must not be re-used for any other purpose.

11. Returnable containers must be returned to the supplier.

12. Records must be kept of the fields sown with ‘Cruiser SB’ treated seed and monitoring in accordance with any agreed stewardship plan.

APPENDIX 2: GENERAL CONDITIONS FOR AN EMERGENCY AUTHORISATION

Failure to comply with the following conditions will 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 emergency 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 Product Label

The 1000 L IBC draft label is presented below, similar labels were supplied for the different packaging but are not reproduced below.

If authorised the following label amendments would be required:

(i) All reference to 'MAPP 15012' must be deleted. [This is because the label relates to an emergency derogation rather than an authorised product].

(ii) All references to 'fodder beet' must be deleted.

(iii) The biological use phrase must be amended to read '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, if the agreed X% threshold of virus levels is met based on the British Beet Research Organisation 2022 virus yellows forecast.

(iv) Under 'Operator Protection', the phrase 'WEAR SUITABLE PROTECTIVE CLOTHING…when handling the concentrate, calibrating or cleaning machinery and when handling contaminated surfaces or dealing with spillages' must be amended to read 'WEAR SUITABLE PROTECTIVE CLOTHING…when handling the concentrate or handling contaminated surfaces'.

(v) Under the heading 'Environmental protection' the following must appear:

(a) In order to reduce the risk of exposure to pollinators the following restrictions apply to following crops planted in the same area of land:

A minimum 32 month interval must be observed between drilling 'Cruiser SB' treated sugar beet seed and planting any flowering crop*.
A minimum 46 month interval must be observed between drilling 'Cruiser SB' treated sugar beet seed and planting any other seed treated with thiamethoxam.

(b) Treated seed must be drilled (Broadcasting and aerial spreading of coated seed is forbidden).

(c) The drilling rate for Cruiser SB treated sugar beet seed must not exceed 115,000 seeds/ha.

(d) Records must be kept of the fields sown with 'Cruiser SB' treated seed and monitoring carried out and recorded in accordance with any agreed stewardship plan.

(vi) Under 'Resistance management', the paragraph 'CRUISER SB' must be amended as follows:

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 any of the pests listed on this label. 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.

(vii) Under ‘PESTS CONTROLLED’:

(a) The paragraph: CRUISER SB is a broad spectrum treatment, containing the neonicotinoid insecticide thiamethoxam, for the control of aphid vectors of virus yellows ………’ must be amended to read ‘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’.

(b) the phrase ‘In situations where very high populations of soil pests are present, the level of protection given by CRUISER SB may be inadequate to achieve an optimum plant stand’ must be deleted.

(c) the following must be added ‘control of aphid vectors’ may decline after 10 weeks’.

(viii) Under the heading ‘Storage after treatment’ the phrase ‘Seed should be … longer than 18 months’ must be amended to read ‘‘Seed should be stored in a cool, dry, ventilated building. Treated seed must be used in the season of use only’.

(ix) The following must appear under the heading ‘Herbicides’:

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 next to or around sugar beet field drilled with Cruiser SB seed).

(x) The following amendments are required for the SEED BAG label text:

(a) ‘This seed has been treated with CRUISER SB’ must be amended to read ‘This seed has been treated with CRUISER SB 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 plan’

(b) The phrase ‘In situations where very high populations of soil pests are present, the level of protection given by CRUISER SB may be inadequate to achieve an optimum plant stand’ must be deleted.

(c) All reference to fodder beet must be deleted

(d) The following phrases must appear:

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 next to or around sugar beet field drilled with Cruiser SB seed).

In order to reduce the risk of exposure to pollinators the following restrictions apply to following crops planted in the same area of land:

A minimum 32 month interval must be observed between drilling 'Cruiser SB' treated sugar beet seed and planting any flowering crop.
A minimum 46 month interval must be observed between drilling 'Cruiser SB' treated sugar beet seed and planting any other seed treated with thiamethoxam.

WEAR SUITABLE PROTECTIVE CLOTHING (COVERALLS) AND SUITABLE PROTECTIVE GLOVES when handling treated seed and contaminated seed sowing equipment.

(e) The phrase 'HARMFUL TO GAME…. Remove spillages' must be amended to read '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 should not be left on the soil surface. Bury or remove spillages.'

(f) The mode of action group (Group 4A) may be added to the label.

(g) The phrase 'Consider resistance………' must be deleted and replaced with 'Subsequent foliar sprays against peach-potato aphid (Myzus persicae) should be made with a product from a different mode of action class.

(h) Under NOTES, under Storage, the paragraph 'Seed should be stored … longer than 18 months' must be amended to read ''Seed should be stored in a cool, dry, ventilated building. Treated seed must be used in the season of use only'

CRUISER SB

DRAFT LABEL TEXT

1000 litre Intermediate Bulk Container (IBC)

October 2020

CRUISER SB

Product registration number: MAPP 15012

A flowable concentrate for seed treatment containing 600g/litre thiamethoxam.

CRUISER SB is a broad spectrum seed treatment, containing the neo-nicotinoid insecticide thiamethoxam, for the control of aphid vectors of virus yellows and a range of foliar and soil pests attacking sugar beet and fodder beet seedlings.

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.

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
MIX THOROUGHLY BEFORE USE

This container should be handled only by mechanical means

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, calibrating or cleaning machinery, and when handling contaminated surfaces or dealing with spillages
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.

(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

For returnable containers
KEEP IN ORIGINAL CONTAINER, tightly closed in a safe place.
DO NOT RINSE OUT CONTAINER.
RETURN EMPTY CONTAINER TO SUPPLIER
DO NOT RE-USE CONTAINER FOR ANY OTHER PURPOSE
OPEN THE CONTAINER ONLY AS DIRECTED
LABEL TREATED SEED with the appropriate precautions using printed sacks, labels or bag tags.
Do not use treated seed as food or feed.

ADDITIONAL PRECAUTIONS SPECIFIC TO 1000 LITRE INTERMEDIATE BULK CONTAINERS (IBC)

FOLLOW THE OPERATING INSTRUCTIONS SUPPLIED WITH EACH IBC AT ALL TIMES.
(REF. "SAFE OPERATION OF CRUISER OSR DISPENSING SYSTEM USING IBC")
OPEN THE CONTAINER ONLY AS DIRECTED
EMPTY IBC'S SHOULD BE TREATED AS FULL CONTAINERS WITH RESPECT TO STORAGE, TRANSPORT AND HANDLING AS THEY WILL STILL BE CONTAMINATED INTERNALLY.
DO NOT RINSE OUT THE CONTAINER
DO NOT RE-USE THE CONTAINER FOR ANY OTHER PURPOSE
ENSURE THAT VALVES ARE CLOSED, ALL CAPS ARE SECURED AND THAT THE PRODUCT LABEL IS LEGIBLE.

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.

MAPP 15012

IMPORTANT INFORMATION

FOR USE ONLY AS AN AGRICULTURAL SEED TREATMENT

For use on:

Crops:	Sugar beet (seed) and fodder 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.

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 neo-nicotinoid insecticide. There are no known cases of resistance to thiamethoxam or other neo-nicotinoid insecticides in the UK to date for any of the pests listed on this label. 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 neo-nicotinoids develop.

Use of this product should form part of a resistance management strategy. Subsequent foliar sprays should be made with a product containing a different active substance and from a different mode of action class.
Consult the IRAG website for further information on a particular management strategy for the targets in question.

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 broad spectrum seed treatment, containing the neo-nicotinoid insecticide thiamethoxam, for the control of aphid vectors of virus yellows and a range of foliar and soil pests attacking sugar beet and fodder beet seedlings (including springtails, millipedes, symphylids, beet leaf miner/mangold fly, pygmy beetle and flea beetle) and improves crop establishment by reducing damage by wireworms.

In situations where very high populations of soil pests are present, the level of protection given by CRUISER SB may be inadequate to achieve an optimum plant stand.

CROP SPECIFIC INFORMATION

Crops
Sugar beet and fodder 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 and fodder beet seed as part of the normal commercial pelleting process using special treatment machinery.

Re-circulate contents of the IBC before use to ensure homogeneity. Containers of greater than 20 litres capacity should be handled only with mechanical assistance.

The container should be connected to the seed treater suction hose using the dry break coupling provided.

Storage after treatment

Seed should be stored in a cool, dry, ventilated building. Ideally treated seed should be used in the season of treatment. It is not recommended to store CRUISER SB treated seed for longer than 18 months.

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.

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
The empty container should not be rinsed out but should be stored in a purpose built chemical store and subsequently returned to the supplier. The empty container should be treated as if containing product and transported in accordance with the advice in the Code of Practise for the Safe Use of Pesticides on Farms and Holdings.

SEED BAG LABEL TEXT

This seed has been treated with CRUISER SB

CRUISER SB contains thiamethoxam a broad spectrum neo-nicotinoid insecticide seed treatment for the control of a range of foliar and soil pests attacking sugar beet and fodder beet seedlings.

In situations where very high populations of soil pests are present, the level of protection given by CRUISER SB may be inadequate to achieve an optimum plant stand.

Consider resistance management when using subsequent foliar applications. Consult the IRAG website for further information.

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 should 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, well ventilated building. Ideally treated seed should be used in the season of treatment. It is not recommended to store CRUISER SB treated seed for longer than 18 months.

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 3 Proposed Stewardship

If a decision is taken to authorise the requested use, the stewardship scheme below will need to be revisited and finalised.

The changes required include those listed below, although upon finalization other changes may be required:

(i) In section 9, the following should appear immediately above the table relating to restricted and non-restricted crops (this should replace the text in bold currently immediately below the table):

*Any crop excluded from the table below should be considered 'restricted' i.e. subject to a minimum of 32 month interval from drilling Sugar Beet. Agri-environment (e.g. Environmental Stewardship, Countryside Stewardship, Sustainable Farming Incentive, and catchment / voluntary schemes) options including low input (restricted herbicide) cereals, mixes (sown or natural regeneration), and cultivated areas (nesting or plant plots) must follow the 32 month restriction.

Cover crops (including mixes) must also follow the 32 month restrictions

(ii) Borage, Sainfoin, Nyger, Lupins should be added to the list of restricted crops.

(ii) The seed rate and optimum plant populations section must be amended to reflect a maximum drilling density of 115,000 seeds/hectare.

2022 Cruiser SB Neonicotinoid Stewardship Document

For Growers/Operators/Agronomists

Purpose

This document is prepared in accordance with the **APPLICATION FOR EMERGENCY AUTHORISATION OF 'CRUISER SB'** and is targeted to those individuals in the sugar beet industry that will grow Cruiser SB treated sugar beet in 2022, subject to an emergency authorisation being granted.

Outcome

Effective stewardship to clearly explain the conditions of the emergency authorisation to ensure understanding and compliance. A specific stewardship group was set-up to manage this.

Structure

The document is broken down into specific sections starting with the Virus Yellows forecast in 2022 through to drilling the crop and subsequent sugar beet agronomy and production. It also highlights other stewardship activities that will be covered by BBRO outside of the grower/operator/agronomist base.

Timing

This Stewardship Document is submitted as part of the Cruiser SB Emergency Authorisation for 2022.

Contents

1. The 2022 Virus Yellows Forecast

The Cruiser SB EA requires the submission of the 2022 Virus Yellows forecast to HSE at the beginning of March 2022.

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 2021 economic threshold for use of noenicitinoid seed treatments for virus yellows was 9%. This will be updated with the new sugar beet price and Cruiser SB price once negotiations and contracting are completed.

The forecast is issued at the beginning of March and 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 (as recorded by the suction traps managed by the Insect Survey group at Rothamsted Research) and crop emergence date.

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.

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. As soon as conditions allow, growers will be reminded to remove, or manage sources of potential virus-infected material.

Good farm hygiene is key, follow these top tips:

- Monitor harvesting closely in order to minimise the number of roots left in the soil
- Regularly re-check fields and remove any groundkeepers
- Carefully dispose of all crop debris under cleaner loaders and around clamps
- Clear and destroy any remaining spoil heaps before the new crop emerges
- Control any leaf growth on beet clamps
- Keep crop volunteers and weed species under control with well-timed, comprehensive herbicide programmes. This standard best practice applies in field, not next to or around sugar beet fields, i.e. field margins.
- Be aware of energy/AD beet or unharvested sugar beet still in the ground on neighbouring fields/farms

Overwintered cover crops can also be a source of VY infection for following sugar beet crops and should be destroyed ahead of sugar beet being drilled as opposed to cover crops which are under-sown in sugar beet crops for managing wind-blow. A pragmatic approach is to reduce the use of brassica-based cover crops to help reduce the potential build-up of aphid numbers. Ensure that cover crops are destroyed thoroughly, so no green material is left, on which aphids can survive. Target to destroy cover crops a minimum of 5-6 weeks ahead of drilling sugar beet. Where possible, timing cover crop destruction, particularly mechanical destruction and grazing to coincide with predicted spells of cold weather as this will help reduce aphid numbers even further.

Additional information can be found at:

- Controlling the Green Bridge, June 2020
- Brilliant Basic 5: Don't keep virus yellows alive
- Sugar Beet Review, Feb 2021, Vol 89, No.1, P 11-15 – Virus Feature

3. Drill Operator guidance and seed rates

The sugar beet industry is committed to targeting Cruiser SB stewardship information to all growers and drill operators therefore we have created a drill operator guidance document.

BBRO is aware that farm operators do not always receive the information that is sent directly to growers as the contract decision maker (this is the contact person on the database for receipt of emails etc.). Therefore, in recognition of this, the stewardship group has developed a specific and targeted guidance document for drill operators (see Annex 1) to be distributed on farm. This explains the importance of efficient drilling, 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. It is also critical that drills are checked and set up accurately to ensure 100,000 plants per hectare are achieved as expected. A drill set-up check list and maintenance information can be found in the BBRO Sugar Beet Drill Maintenance Guide.

4. Pesticide spill kits

The use of Cruiser SB treated seed requires growers to have access to a spill kit.

As part of the industry due diligence spill kits will be provided to all growers (to be passed onto the drill operator) in case of any accidental spillage of Cruiser SB treated seed. The kits will be sent to growers directly by the company providing them to ensure speedy delivery as soon as the Cruiser SB trigger is reached and seed processing begins.

Each spill kit includes the following items:

- 25kg polythene sack (450 x 650mm OT Welded base 90mu)
- Cable tie (300mm x 3.6mm)

In addition to the spill kits drill operators are advised to ensure they have appropriate PPE (e.g. face mask & gloves) and a small shovel/scoop in their drill cab to clean up any spilled seed. All spillages should be cleaned up using the spill kit provided, bags should be tied up appropriately and taken to an approved disposal contractor. Whilst this should be standard practice for operators the importance of this will be highlighted for Cruiser SB seed as its use is only allowed under the derogation.

5. Late drilling/re-drilling of sugar beet

No Cruiser SB may be used on the same field area for 46 months from the date of sowing treated sugar beet seed in 2022.

No Cruiser SB treated will be used after the date specified in the derogation. This is regardless of any unfavourable weather conditions, e.g. extreme wet, that may result in a delay to drilling and also includes any re-drilling of treated sugar beet from crop loss (due to wind blow or capping) on the same field area for 46 months from the date of sowing treated sugar beet seed in 2022. This is to minimise the risk of residues being acquired by succeeding flowering crops or weeds and hence exposing bees and/or other pollinators to neonicotinoid seed treatments. This will be communicated by British Sugar to all growers in February 2022, ahead of Cruiser SB seed being available on-farm. Information will also be sent out directly to all British Sugar Contract Managers reiterating the 120-approval period, crop restrictions and redrilling restrictions and it is also covered in the Drill Operators Guidance, ensuring that the stewardship information is received by drill operators, growers and individuals speaking to growers.

6. Weed control in sugar beet fields

Alongside the use of Cruiser SB treated seed, usual 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).

BBRO will issue Advisory Bulletins to all growers clarifying the herbicide condition, particularly emphasising that this requirement does not include areas outside or next to the crop such as field margins. This will also be re-emphasised in the BBRO winter technical events for agronomists and growers in February/March 2022.

As is standard practice in the sugar beet sector weed control must be done in accordance with recommendations from a BASIS qualified agronomist. Guidelines and further information are also provided in the grower facing BBRO Reference Book. The 2021 Reference Book supplement had an expanded section on weed control to provide further information. This was sent out to all growers spring 2021 in hard copy and is also available on the BBRO website. Recognising weed control can be challenging in sugar beet, with the loss of some key herbicides in recent years, BBRO commissioned a 6-page technical feature in the February 2021 Beet Review, pulling in expertise from three industry experts on weed control to help growers. Sugar Beet Review, Feb 2021, Vol 89, No.1, P 16-21 – Weeds Feature

The key basics of weed control are also covered in Brilliant Basic 3: Keep your plants growing strong, don't get your spray mix or timing wrong, growers will be reminded of this again in 2022.

Here are the 10 top tips for weed control in sugar beet which will be communicated to growers by BBRO in the spring, they will also be reminded of these during the season:

1. Greater monitoring of weeds and weed growth stages
2. First spray timing is critical
3. Consider a pre-emergence herbicide where conditions allow
4. Monitor the crop carefully for growth stage and stress levels to minimise herbicide damage. Be wary of large diurnal fluctuations in temperatures
5. Be flexible on your approach to the choice of actives and rates of use
6. Consider 'tailoring' your herbicides to 'problem' fields
7. Don't delay in controlling fat hen
8. Select rates of phenmedipham carefully in relation to weeds and conditions
9. Consider use of adjuvants, but be mindful of conditions of use

10. Mechanical hoeing may be an option – be prepared!

7. Aphid monitoring, thresholds and subsequent aphicide applications

Product use Monitoring

The Cruiser SB EA requires all treated crops and associated field-areas to be recorded. All treated crops and associated field-areas will be recorded via the British Sugar CRM database and monitored by their team of 22 agricultural contract managers.

Aphid Monitoring

BBRO runs an annual yellow water pan network to provide a large amount of data across numerous sites in order to provide UK sugar beet growers with a clearer view to aphid activity in their area. Monitoring is done in the field by BBRO, British Sugar and a range of agronomists and growers. Aphid numbers are recorded in an annual survey and also a representative sample of aphids are tested in the laboratory to confirm the presence/absence of virus yellows throughout the season.

Growers and agronomists are also encouraged to regularly check their crops for aphids from crop emergence and for the following 10-week period, when the crop is at its most susceptible to aphid attack. Previous scientific research has identified an aphid threshold, above which foliar insecticides should be applied to protect the crop – the thresholds are explained below, Cruiser SB will run out of residual activity around 10-weeks after drilling so following this time monitoring becomes even more crucial.

Spray Thresholds

- The threshold for foliar insecticide applications is **1 green wingless aphid per 4 plants up to the 12-leaf stage (or 5 aphids per 20 plants)**. *Cruiser SB should provide good efficacy up to 10 weeks after drilling reducing the need for foliar spray at the stage.*
- Between 12-16 leaves the treatment threshold is **1 green wingless aphid per plant**. *During this period Cruiser SB will have run out of efficacy and additional insecticide treatment will be required.*

Foliar Insecticide Applications

Foliar sprays should be applied as soon as the above thresholds are met and not delayed. High temperatures and drought stress can reduce efficacy of insecticides. Where Cruiser SB seed treatment has been used then any additional foliar insecticides must not include a neonicotinoid active ingredient. Teppeki is currently the only foliar approved insecticide for aphid control, however, additional Emergency Authorisations will be submitted for 2022 if required but additional foliar products could also be available for 2022 if full approval is granted. If the Virus Yellows pressure is low further spray applications should not be necessary but every field/farm is different and hence the importance of crop monitoring at the field level.

A detailed article on crop monitoring can be found in the Sugar Beet Review, Feb 2021, Vol 89, No.1, P 11-15 – Virus Feature. Magnifying glasses were provided to all growers in 2021 with the Beet Review publication to help growers identify aphids in the crop during regular checks. An aphid identification clinic will also be provided to agronomists and growers in the BBRO BeetTech22 winter technical events (planned for February/March). Any ground-truth data provided by growers and agronomists will be double checked by BBRO.

8. Integrated crop management to boost beneficial insects

Although not a complete solution, the industry is committed to maximising beneficial insects as part of our commitment to integrated pest management.

Hedgerows and field margins have been shown to support beneficials and to contribute to reducing aphid numbers in crops. Beneficial insects can increase when prey numbers e.g. aphids are high. There are a number of different things growers can do to encourage beneficial insects into their crops and the following points are key:

- Consider establishing field margins or drill strips with plant species which encourage beneficial insects such as ladybirds, ground beetles, lacewings, hover flies and parasitic wasps.
- Early establishment of field margins will help build beneficial numbers earlier in the season and have more impact.
- Use a mix of grasses and wild flowers in field margins to provide ground cover and sources of pollen and nectar. Mixes including some of the following flowering species are considered to be effective – oxeye daisy, buckwheat, bird's foot trefoil, yarrow, common knapweed, wild carrot, chamomile, sainfoin, wild red clover, selfheal, phacelia and borage.
- Some growers have released beneficial insects into crops to predate on aphids but the number and the timing of release is critical to success. BBRO continues to look into this approach further in 2021.
- It is essential to avoid using pyrethroid foliar insecticides for aphid control as aphids are widely resistant to these insecticides and they can reduce the number of beneficials which is counter productive, leading to an increase in aphids in the longer-term.

This was reported in the Sugar Beet Review, Feb 2021, Vol 89, No.1, P 11-15 – Virus Feature and further information can be found in Sugar Beet Review, May 2020, Vol 88, No. 2, P16-23 – The Good, The Bad and The Ugly and the Sugar Beet Review, May 2021, Vol 89, No. 2, P26-29 – What's in your crop? These messages will be reiterated during the growing season via BBRO Bulletins issued regularly to growers and agronomists.

9. Following crop restrictions

The Cruiser SB EA requires growers to follow strict rotational requirements.

The Inter Professional Agreement (IPA) is an extensive document governing the relationship between NFU Sugar (growers) and British Sugar (processor), the terms of the IPA are incorporated into each grower's contract. A grower may not sell sugar beet to British Sugar without a contract and complying with the accompanying IPA agreement. Growers must follow the following crop restrictions stated in the table below. If a grower is in non-compliance, then they are breaking the law and in breach of their contract.

Table 5 will be shared with growers, operators and agronomists on multiple occasions by British Sugar, NFU Sugar and BBRO. Growers will place their seed orders, plan future rotations and evaluated their future growing sugar beet in response to the information contained in the table below.

The following-crop restrictions apply for Cruiser SB sugar beet drilled in 2022.

	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

Any crop excluded from the above table should be considered 'restricted' i.e. a minimum of 32 months from drilling of Sugar Beet.

Cover crops (including mixes) must follow the above restrictions.

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) on the same field area for 46 months from the date of sowing treated sugar beet seed in 2022 – 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.

10. BBRO soil and plant residue monitoring

A programme of sampling of neonicotinoid-treated sugar beet fields in 2022 onwards to determine any neonicotinoid seed treatment residue levels in soil and plants will be established.

Annex 2 details the 2022 Neonicotinoid Residue Monitoring Protocol that has been proposed.

11. BBRO liaison with relevant water companies/organisations

As part of the industry due diligence contact will be made with relevant water companies to understand what monitoring they are doing and review any data they hold regarding neonicotinoids in water. Companies that will be contacted are: Anglia Water, Cambridge Water, Yorkshire Water, Severn Trent, Suffolk & Essex Water, Affinity Water, and the Environment Agency.

Alongside water companies operating in the sugar beet growing areas, we will also liaise with other relevant organisations e.g. Norfolk Rivers Trust, who operate in these areas and often have grower groups/meetings.

12. Knowledge Exchange (KE) activities

BBRO, NFU Sugar and British Sugar are all jointly involved in communicating the importance of good stewardship to the sugar beet industry, with BBRO taking the lead on KE technical information to the grower and agronomy base. Many different KE channels are used, this list below highlights BBRO's regular activities carried out every year.

Activity	Format	Audience	Frequency
Advisory Bulletin	Electronic	Growers/Operators/ Agronomists	Every 2-3 weeks during growing key season
Beet Review	Hard copy & electronic	Growers/Operators/ Agronomists	3 times p.a.
BBRO Reference Book	Hard copy & electronic	Growers/Operators/ Agronomists	Annual update *c.* Feb
News & Opinions pieces	Electronic	Growers/Operators/ Agronomists	When topical
BeetTech	Webinar/face2face	Growers/Operators/ Agronomists	Annual update *c.* Feb
BeetField	Webinar/face2face	Growers/Operators/ Agronomists	Annual update *c.* July
Agronomist Conferences	webinar	Agronomists	Annual update *c.* Feb
Demonstration Farms	Face2face	Growers/Operators/ Agronomists	When topical
YouTube videos	online	Growers/Operators/ Agronomists	When topical
BeetCast	audio	Growers/Operators/ Agronomists	Monthly topical updates
Brilliant Basics	Variety of different channels per topic	Growers/Operators/ Agronomists	*c.* 4-5 times p.a.
Breakfast meetings	Webinar Q&A	British Sugar Contract Managers	Every 2 weeks during growing key season
NFU Regional meetings	Webinar/face2face	Growers	Every 2-3 months or as invited
Ad hoc technical requests	Webinar/face2face	Growers/Operators/ Agronomists	As requested
Training events	Webinar/face2face	Growers/Operators	2-3 times p.a.

In addition, BBRO will respond to any requests to provide technical information outside of its routine activities highlighted above. BBRO will proactively and reactively communicate with growers and agronomists to respond to any issues that arise during the season.

A draft KE plan for 2022 (it will evolve) is presented in Annex 3 highlighting different channel and timelines.

Annex 1 - Cruiser SB Drill Operator Guidance

In accordance with the requirements of the Cruiser SB Emergency Authorisation for the 2022 sugar beet crop, the industry is required to follow strict conditions. This card outlines the on-farm requirements that must be followed when using Cruiser SB treated sugar beet seed – please ensure it is seen by drill operators.

Conditions of the Cruiser SB Emergency Authorisation

- **Cruiser SB is available for use under Emergency Authorisation for 120 days – *dates to be inserted if or when derogation is approved.* All treated seed must be drilled within these dates.**
- If a field is drilled with Cruiser SB treated seed, any re-drilled beet in that field must not be treated with Cruiser SB due to loading limits on any given area. There can be no further use of thiamethoxam seed treatments on the same field within 46 months. If you need to plant sugar beet in the same field *within* 46 months, it would have to be a non-neonicotinoid treated seed. This is important if any future Cruiser SB derogations are granted.
- **There are strict following crop rules attached to the Emergency Authorisation. Refer to table overleaf.**
- **Only sugar beet contracted with British Sugar plc is included in the Emergency Authorisation. Fodder, energy and red beet are not included.**

Drilling

- Handle seed carefully and wear PPE such as gloves and a mask
- Store seed securely in a dry and frost-free area
- Ensure the drill has been checked and tested
- Set the drill for the desired spacing and depth using an appropriate seed rate to achieve a maximum final field population of 100,000 plants/ha (see below)
- All spillages should be cleaned up using the spillage kit provided. Label and tie up bags appropriately and use an approved disposal contractor to destroy the treated seed (Details can be found at the Environment Agency website https://www.wastedirectory.org.uk if you do not know an approved disposal contractor)
- Ensure that all seed is well covered with soil including the drill row ends
- Empty all units at the end of the drilling season
- Records must be kept of the fields sown with 'Cruiser SB' treated seed

Herbicides

As part of the Emergency Authorisation growers and industry partners must observe standard best practice, industry-recommended herbicide programmes, applicable only to **in field** weeds. Please adopt the programme recommended by your BASIS-qualified agronomist/adviser and BBRO guidance contained in Advisory Bulletins and the BBRO Reference Book.

Seed rate and optimum plant populations

The crop is referred to as established once it reaches the 6-leaf stage. Most sugar beet is drilled using 50cm or 45cm row widths.

The ideal row spacing is 16cm but use your predicted establishment together with the tables below to choose the required seed spacing for your establishment conditions.

Plants/20m	50	60	70	80	90	100
Average plant population (Plants/ha x 1,000)						
50cm row	50	60	70	80	90	100
45cm row	56	67	78	89	100	111
Below optimum	Optimum		Above optimum			

Establishment – 000's plant/ha based on 50cm row widths							
Seed spacing cm	14	15	16	17	18	19	20
Seed units/ha (one unit = 100,000 seeds)	1.43	1.33	**1.25**	1.18	1.11	1.05	1.00
90%	129	120	113	106	100	95	90
80%	114	107	100	94	89	84	80
70%	100	93	88	82	78	74	70
60%	86	80	75	71	67	63	60
50%	71	67	63	59	56	53	50
40%	57	53	50	47	44	42	40

Establishment – 000's plant/ha based on 45cm row widths								
Seed spacing cm	14	15	16	17	18	19	20	21
Seed units/ha (one unit = 100,000 seeds)	1.59	1.48	1.39	**1.31**	1.23	1.17	1.11	1.06
90%	143	133	125	118	110	105	100	95
80%	127	118	111	105	98	94	89	85
70%	111	104	97	92	86	82	78	74
60%	95	88	83	79	74	70	67	64
50%	79	74	69	65	61	58	55	53
40%	64	59	56	52	49	47	44	42

Plant populations above optimal requirements that can still produce maximum yields but not maximum profit.

Optimum plant populations (within 5% of 100,000 plants/ha).

Plant populations below optimal requirements that may not produce maximum yields.

The following-crop restrictions apply for Cruiser SB sugar beet drilled in 2022.

	Non-restricted		Restricted	
Rules	No restrictions following Sugar Beet		A minimum of 32 months from drilling of Sugar Beet	
Crops	38.	*Wheat (including Durum Wheat)*	60.	*Oilseed Rape*
	39.	*Barley*	61.	*Linseed*
	40.	*Millet*	62.	*Mustard*
	41.	*Sorghum*	63.	*Soya Bean*
	42.	*Oat*	64.	*Pea*
	43.	*Maize / Corn*	65.	*Bean*
	44.	*Rye*	66.	*Buckwheat*
	45.	*Triticale*	67.	*Clover*
	46.	*Canary seed*	68.	*Phacelia*
	47.	*Spelt*	69.	Chicory
	48.	*Potato*	70.	Radish
	49.	*Cabbage*	71.	Vetch
	50.	*Kale*	72.	False flax
	51.	*Swede*	73.	Lucerne
	52.	*Lettuce/ Babyleaf/ Spinach*	74.	Sunflower
	53.	*Onions*		
	54.	*Leeks*		
	55.	*Carrots*		
	56.	*Parsnips*		
	57.	*Cauliflower*		
	58.	*Broccoli*		
	59.	*Turnip*		

Any crop excluded from the above table should be considered 'restricted' i.e. a minimum of 32 months from drilling of Sugar Beet.

Cover crops (including mixes) must follow the above restrictions.

No further use of thiamethoxam seed treatments (including any re-drilling of treated sugar beet if crop lost due to wind blow or capping) on the same field area for 46 months from the date of sowing treated sugar beet seed in 2022 – 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.

More information

https://bbro.co.uk/our-news-opinions/our-news/news-2021/emergency-authorisation/

Annex 2 - 2021 Neonicotinoid Residue Monitoring Protocol

Background

If the sugar beet industry is granted an Emergency Authorisation for the use of a neonicotinoid seed treatment (Formulated product 'Cruiser', containing the active ingredient thiamethoxam) on sugar beet grown in the UK under contract to British Sugar in 2022, treated seed will only available for use where the Rothamsted Virus Yellows Risk Forecast model predicts a high risk and the economic threshold being met. Once treated seed is drilled several other criteria must be met including a programme of monitoring in soil and vegetation for neonicotinoid residues. Potential issues include the build-up of residues in the soil profile as a result of the relative persistence of the compounds, migration of residues from the area of use, and translocation to non-target flowering plants that could be a source of food for bees.

Objectives of the study

To provide robust data on thiamethoxam residues in soil and non-crop vegetation to support the continued use of neonicotinoid seed treatments if required by the sugar beet industry until more sustainable solutions are available.

A targeted soil monitoring programme would need to establish a baseline preceding drilling of treated sugar beet seed, with monitoring extending to post harvest, and through the following crop due to the reported persistence of neonicotinoids. Vegetation sampling should also be conducted e.g. from field margins.

The OECD guidance document for conducting pesticide terrestrial field dissipation studies and for determination of vegetative residues (applicable to studies destined for submission to regulatory authorities) suggest the number of individual trials to be undertaken (per region) for determination of soil residues should be 4 to 6, and in vegetation 6 to 10.

Considerations

- Six sites will be selected for monitoring
- Representative of soil type (BBRO data suggests roughly 60% cropping occurs on sandy soils, 30% on clay soils, and 10% on silty soils)
- Geographical location
- Climatic conditions e.g. low/high rainfall areas
- Number of repeat samples
- A full pesticide use history (5 years) of the selected sites must be available

Sampling

- The OECD guidance for TFD studies mentioned above will be followed to ensure sufficient replication in sampling. For each site, and on each sampling occasion, 15 soil cores will be taken in-field and edge of field (outside of the cropped area) to give replicated bulk samples (N=3) at each of 2 depths (0-20, 20-40 cm). This regime will generate 12 samples (6 in-field, 6 edge of field) for each trial site, and a total of 72 soil samples per sampling occasion.
- It is suggested that a minimum of 3 sampling occasions be considered, e.g., before drilling (baseline), during the growing season, and post-harvest. This would generate a total of 216 soil samples for analysis.

- In addition to the soil sampling regime, samples of field margin vegetation (outside of the cropped area) will be taken from each of the field sites on two occasions, firstly when the majority of plants are in flower, and secondly in the Autumn in advance of harvest. At each site/sampling occasion three samples will be taken and analysed for neonicotinoid residues (whole of plant), giving a total of 36 samples. In advance of analysis, plant species and abundance within the sample will be identified and documented.
- The sampling, as described, will be carried out following Good laboratory Practice (GLP) practices and principles, although GLP will not be claimed for this phase.

Analysis

- Soil and vegetation residue analysis will be carried out by an appropriate laboratory operating to GLP.

Reporting

- Interim data will be provided to the Stewardship Group after each sampling occasion.
- A final report will be provided to the Stewardship Group following analysis of the final set of samples, with a target date of 30 November 2022.

Annex 3 – A DRAFT BBRO Knowledge Exchange Plan for 2022

Activity	Jan	Jan	Feb	Feb	Mar	Mar	Apr	May	June
Advisory Bulletin		Hygiene – clear up spoil	Hygiene	Beneficials/ under sown					
Beet Review			Key virus article/ supporting articles					TBC	
BeetCast			Seedbed prep Beneficials/ under sown b	Post 14th seed trmt decision					
Agronomist conf				Virus/ weeds/ establishment/ Cercospora					
BeetTec Live Grower					Virus/weed establish/ Cercospora				
Text/tweet B.Basic prog									
Website		Virus 21 plan		Beneficials					
Ref Book Supplement									

Without fail you must:

Remove/destroy cover crops/strips/clamps/ energy & fodder beet

Additional things you can do to protect your crop:

Use under sown barley
Encourage beneficials on to farm

You must do the basics brilliantly:

Good seed bed prep, select seed rates to optimise, plant populations, drill as soon as conditions are right, drill accuracy, ensure optimise nutrition, avoid herbicide damage

Checking your crops for aphids at an early stage:

- Keep in touch with all the latest info on aphids from BBRO
- Cruiser SB will help protect your crop for 10 weeks following drilling?
- Keep checking crops for aphids from emergence and especially toward the end of this period

Does your crops need a foliar insecticide?

Check your crops daily to assess whether the threshold of 1 green wingless to 4 plants triggers the need for additional foliar insecticides

Appendix 4 Copy of ECP advice

ECP ADVICE TO GOVERNMENT: USE OF 'CRUISER SB' ON SUGAR BEET

Issue

- 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

- The Committee is requested to advise:
    - If there is any additional relevant evidence on the chronic risk to adult honeybees that should have been taken into account
    - If there is any relevant evidence on the potential risk to adult honeybees from guttation that should have been taken into account
    - If authorisation is granted, can members suggest any suitable monitoring that could be conducted by growers and the sugar industry which would further governments' understanding of the risk to honeybees
- The Committee is requested to provide a view on:
    - The likelihood of impacts at the colony level from proposed use
    - The appropriateness of these risk mitigation measures in reducing the risk to honeybees
    - Whether there are any additional measures that could be implemented to mitigate the risk to honeybees

Discussion

- The Committee *noted* that:
    1. This is the second consecutive application for this proposed use.
    2. The applicant has not provided any new data to government since the previous emergency authorisation application for which the Committee provided advice in November 2020.
    3. The risk from non-dietary exposure is acceptable if suitable PPE is worn.
    4. The dietary exposure assessments indicated that the use would result in produce complying with maximum residue levels and acceptable risks to those consuming treated produce.
    5. The environmental risk assessment indicated an acceptable risk to birds, mammals, aquatic life, non-target arthropods, soil macro-invertebrates, soil processes and non-target terrestrial plants

6. The risks to birds from consuming treated seeds had not been demonstrated to be acceptable. However, consumption of pelleted seeds is considered an unlikely route of exposure

7. The chronic risk for adult honeybees from a sugar beet crop could not be assessed. Therefore, no conclusion could be drawn on what the potential effects of exposure to thiamethoxam could be from the proposed use and resulting exposure.

8. The opinion of Natural England is that the potential off-crop contamination of flowering plants could jeopardise payments under agri-environmental schemes.

9. The proposed mitigation measures acted through reducing the food sources of the wildlife groups which the mitigation aimed to preserve.

10. The latest contracts between growers and British Sugar included an insurance scheme to offset possible losses due to the occurrence of the virus and this needs to be considered in the context of the case for need.

- The Committee *agreed* with HSE's evaluation that:

1. Surface water concentrations may exceed PNEC values established under water quality legislation.

2. There was a case for need based on the impact that failure to control aphids transmitting Beet Virus Yellows can have on yields, though the magnitude of financial loss to growers could not be predicted because of the contract changes.

3. The requirements for emergency authorisation have not been met.

- The Committee *advised* that:

1. There is new evidence regarding the risk from neonicotinoids globally which adds to the weight of evidence of adverse impact on honeybee behaviour and demonstrated negative impacts on bee colonies.

2. Further evidence has been published on the occurrence of thiamethoxam in honey and of adverse effects on other bee species, and these effects should be considered in addition to chronic effects on honeybees.

3. There is a lot of literature on the adverse impact of neonicotinoids on aquatic organisms. Members noted sugar beet production is concentrated into certain areas of the country and therefore regional effects are more likely than if the proposed usage was spread more widely across the country. The HSE assessment indicates that an acceptable risk had been demonstrated for application in March utilising the higher tier RACs for thiamethoxam and clothianidin. However, the predicted levels exceeded the PNECs set under the Water Framework Directive.

4. The data provided indicated that the potential risk to adult honeybees from guttation in sugar beet was low.

5. None of the suggested mitigation measures protected off-crop areas and, if the authorisation is granted, further consideration needs to be given to how this could impact on growers involved in agri-environmental schemes which involved planting flowering margins.

6. The proposed trigger threshold for the authorisation of the treatment of seed was derived when there was no compensation scheme available to growers and needs to be re-calibrated to take into account the terms of the new contracts.

Conclusion

On the basis of the evidence presented to ECP, the Committee agreed that it is unable to support an emergency authorisation under Article 53 of Regulation 1107/2009 because of the reasons laid out by HSE, the expected off-crop environmental effects and the impact of grower contract changes on the trigger threshold for use.