# The UK Expert Committee on Pesticides (ECP)

# Full Minutes of the meeting of the UK Expert Committee on Pesticides (ECP) held 14 March 2023

The meeting was held as a virtual meeting.

# Those present:

#### Chairman:

Prof W Cushley

#### Members:

Prof R Blackshaw; Mr J Clarke; Prof M Eddleston; Dr J Garratt; Mr M Glynn; Dr I Katsiadaki; Prof T Lock; Dr R Mann; Dr M Rose; Prof D Spurgeon; Prof M Whelan and Prof M Wright

### Assessors:

Mr B MacDonald (Welsh Government); Ms C McCartney-Collard (FSA); Ms G Reay (Scottish Government) and Mr D Williams (Defra)

### Advisors:

Dr S Brescia (HSE); Mr A Dixon (HSE); Mr D Flynn (HSE); Ms S Hugo (Defra); Ms S Mattock (HSE); Mr B Maycock (HSE); Dr J Newman (Environment Agency); Ms A Porter (Defra); Dr S Qassim (Natural England); Ms O Sepai (UKHSA); Mr G Stark (HSE); Mr P Shannon-Hughes (Natural England); Dr C Snaith (HSE) and Ms M Wade (HSE)

#### Others:

Mr S Bradley (HSE); Mr P Brian (HSE); Ms H Bennet (HSE); Mr T Carter (HSE); Mr J Chambers (HSE); Ms P Croft (HSE); Ms A Faulkner (HSE); Mr T Fisher (HSE); Ms S Goodchild (HSE); Mr N Graham (HSE); Ms S Mason (HSE); Ms J O'Leary Quinn (HSE); Mr D Roberts-Clark (HSE); Mr J Smith (HSE); Ms V Swaine (HSE) and Mr A Tucker (HSE)

### Apologies:

Dr C Harris; Mr P Stephenson; Ms H Nakeeb (UKHSA) and Dr S Jess (DAEREA)

# Agenda Item 1: Introduction

1.1 The Chair reminded the meeting of the confidentiality of the papers and their discussions. If Members believed that they had a commercial or financial interest in any of the items being discussed, they were required to declare their interest to the Chair and Secretariat prior to the meeting. They may then either be invited to absent themselves from the discussions, not participate and/or not be involved in any discussions and decision-making, unless invited to do so.

1.2 No Members identified potential conflicts of interest.

1.3 The Chair welcomed Dr Qassim and Mr P Shannon-Hughes who will be representing Natural England on the Committee.

1.4 The Committee noted a member and an advisor had both suffered recent bereavements. They offered their sincerest condolences to the individuals and their families.

# Agenda Item 2: Full Minutes of the previous meeting [ECP 1 (57/2023)]

2.1 The Committee noted the draft Full Minutes of the December 2022 meeting had been agreed by correspondence to avoid unnecessary delays in publication due to the January meeting not being held.

# Agenda Item 3: Matters Arising and Forward Business Plan [ECP 2 (57/2023)]

3.1 The Secretariat provided an update on matters arising from previous meetings and invited Members to suggest any additions/amendments to the forward business plan which would be incorporated before the next meeting.

3.2 The Committee noted the advice notes for pydiflumetofen and isoflucypram were amended and agreed following the December meeting and have been submitted to HSE. The Committee will be informed when a decision on the outcome of these applications is made.

### Action: HSE

# Agenda Item 4: Emergency Authorisation: 'Tutavir on tomatoes frown in glasshouses [ECP 3 – 3-12 (57/2023)]

4.1 The Government has received an application for emergency authorisation under Article 53 of Regulation 1107/2009 for the use of 'Tutavir' (a suspension concentrate

containing 2 x 10<sup>13</sup> occlusion bodies of *Phthorimaea operculella* granulovirus per litre) for control of Tomato leaf miner.

- 4.2 The Committee was asked to advise on:
  - If it is appropriate to conclude that the qPCR method is sufficient to quantify microbial contaminants within the five-batch analysis study
  - If the ECP consider the level of variability within the formulated product to be acceptable for a virus-based plant product
  - If the ECP consider sufficient information is present to provide an acceptable level of confidence in the strain identity
  - How early intervention through the use of Tutavir would support tomato growers to maintain crops under IPM programmes

4.3 Members discussed the application, and their advice can be found in Annex 1 of these minutes.

# Agenda Item 5: KMD Approach in pesticide assessments [ECP 4 (57/2023)]

5.1 HSE presented on the Kinetically-derived Maximum Dose (KMD) approach. They noted this approach is an alternative to the traditional Maximum Tolerates Dose (MTD) approach. There has been significant interest in the KMD approach, though there is currently no guidance at an OECD level. HSE noted as the KMD approach is likely to be increasingly applied in studies supporting active substance submissions it is important HSE develops a consistent position that is in line with the most up to date science.

5.2 The Committee was asked to advise on:

- If the KMD approach is a scientifically valid tool for setting top doses in toxicity tests within a hazard-based regulatory regime
- Possible criteria to increase the utility of the KMD approach in toxicity testing in a hazard-based regime
- What degree of inflection from linear kinetics could be considered acceptable when selecting the top dose or if the top dose should be set a level where a clear plateau of systemic exposure (100% saturation) has been observed.

- If the kinetic data should be generated for the ultimate toxic entity or are the kinetic data produced on the active substance sufficient to set appropriate top does on toxicity testing
- If top doses should be determined using a weight-of-evidence approach which considers saturation of kinetic mechanisms, hazard information from short-term and rage finding studies and human exposure information
- If there are any other recommendations which could be useful in determining and selecting top does in toxicity testing within a hazard-based regulatory system.
- 5.3 Members noted:
  - They were supportive of efforts to reduce the need for animal testing within the regulatory regime and the development of novel analysis methods.
  - They had specific concerns over the KMD approach and scientific literature had raised notable concerns over the method. They felt there was a lack of consensus in the scientific community and aspects of risk such as immunological responses were not adequately addressed in the KMD approach.
  - The paper would be of interest to the Committee on Toxicity of Chemicals in Food, Consumer products and the Environment (CoT) and the Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment (COC). They felt there was wider interest in alternative methods and could represent an area for joint working.
  - Their concern over bias in the creation of graphs, noting how the data points are interpreted could significantly change the inflection point. They discussed the need for a large number of data points and the use of tools such as joint point analysis to reduce bias.
  - That it would not always be possible to determine the ultimate toxic entity, and would support determining top-doses through a weight of evidence approach.
  - They required further information on adverse outcomes pathway outcomes to safely conclude on the toxicity of any given product and the KMD approach does not provide information on toxicity, hence is not suitable for this purpose.

• They were unable to support the use of the KMD approach in its current form within a hazard-based regulatory regime.

# Agenda Item 6: Outcome of habitat protection/buffer zone and UKspecific restriction reviews

6.1 HSE updated the Committee on the ongoing review to create a 'tool-box' approach to risk mitigation, noting work had been commissioned to review the current spray drift curves and data had been received to work towards having only one drift curve. HSE is currently assessing the recommendations.

6.2 HSE further noted they would bring a paper on the outcome of this review to the ECP for consideration. Members expressed support for reforms noting the current system led to confusion and clearer guidance was needed.

# Agenda Item 7: Update from other government departments

# 7.1 Northern Irish Government

7.1.1 DAERA continues to monitor divergence with Great Britain (GB) and provides relevant information to Northern Ireland (NI) growers through contacts in the Ulster Farm's Union (UFU) and the College of Agriculture, Food and Rural Enterprise (CAFRE). HSE continue to provide significant support in this activity.

7.1.2 The final phase of the registration portal to compile a list of pesticide operators in NI is now complete, allowing professional users to register online. The number of operators registered is currently considered low in relation to both the supply chain operators and professional users. UFU and CAFRE are assisting DAERA in encouraging users to register through grower groups and business development groups.

7.1.3 DAERA plan to further supplement this final phase of the registration portal with a more targeted approach through letters and emails to specific groups of amenity users and retailers to advertise the registration portal and the operator's legal obligation.

7.1.4 The Laboratorie de Paris was formally designated as the Official Laboratory for Pesticide Residues in NI. HSE is working towards getting a National Reference Laboratory in place.

### 7.2 Scottish Government

7.2.1 The Scottish Government along with other UK administration are currently seeking views from their respective Minsters on an agreed official-level draft of the UK National Action Plan on the Sustainable use of Pesticides (NAP) ahead of a possible cross-UK Ministerial meeting to discuss and reach consensus on the NAP.

7.2.2 The Scottish Government have commissioned a review intended to understand the implications of not controlling bracken with asulam in Scotland on biodiversity, rural productivity and public health, in the short, medium and long term, for rough grazing, upland/moorland, amenity grassland and native and commercial woodlands. This work will be conducted by the James Hutton Institute. It is expected to highlight evidence gaps and provide a starting point for action required going forward.

7.2.3 The Agri-Environment Climate Scheme (AECS) is the Scottish Government's single largest funding mechanism for environmental and sustainable land management. It is the only scheme providing targeted support to land managers to undertake specific actions on environmental management. The 2023 round will target agri-environment support, organics and slurry storage options, and will support the ambition to double the amount of land under organic management by 2026.

7.2.4 To maximise the benefits of the scheme, in the face of budgetary pressures the Scottish Government have reluctantly had to suspend or restrict some capital elements in the 2023 round, including chemical and mechanised treatment of bracken. Manual treatment of bracken will continue to be offered. Those with existing AECS contracts or new contracts, following the 2022 AECS awards, which contain bracken control through chemical and mechanised to be supported.

7.2.5 The Scottish Government noted a survey of rodenticide use on farms growing grassland and fodder crops in 2021 was conducted. The report was published by the Pesticide Survey Unit at SASA on the 22 February. This dataset is the second in this series to be conducted since an industry led rodenticide stewardship scheme was introduced in 2015. This survey, and the previous survey in 2017, display a trend of decreased rodenticide usage, increased baiting by PCPs rather than farmers, and increased uptake of best practice. This is likely to have been influenced by the introduction of stewardship and associated regulatory changes aimed to reduce risk of rodenticide use to non-target species.

# 7.3 Welsh Government

7.3.1 The Welsh Government noted the number of registrations from pesticide operators received is lower than expected. They are currently reviewing their initial expectations to ensure they were correct and assessing how they could encourage further registrations.

7.3.2 Work on the NAP is continuing, with Minsters considering the NAP in the context of the 2022 UN Biodiversity Conference (COP 15) and the commitment to biodiversity.

7.3.3 The Welsh Government continue to work closely with colleagues in Defra on the Active Substance Review Programme (ASRP) to promote the sustainable use of pesticides. During the First Minster's Questions the First Minster noted the policy of the Welsh Government was to reduce pesticide usage, particularly in the amenity sphere.

# 7.4 Defra

7.4.1 Defra noted they have started planning for the delivery of the draft NAP commitments, including the ASRP and bio-pesticide regulatory reform.

7.4.2 Work on ASRP is progressing and Defra have almost reached agreement on a draft Target Operating Model. The biopesticide reform is currently in the initial scoping stage, with the project due to launch later in the year.

7.4.3 Defra are working with HSE to establish a more developed framework for measuring the impact of loss of active substances. Further work includes finalising the Pesticide Load Indicator project in co-operation with FERA and contrasting the model with the Total Applied Toxicity model.

# 7.5 Environment Agency

7.5.1 The Environment agency (EA) noted they monitor residues of thiamethoxam and clothianidin at weekly intervals and report back to Defra and the ECP on any significant concentrations. The EA has started a two-year passive sampling program to understand ecological exposure profiles of various pesticides at 21 sites. Data will be published when the final report is complete in 2025.

7.5.2 Additional project work to determine sub-lethal effects of chemicals in the environment will start this year, with the aim of informing the EA priorities and Defra policies. They continue to report trend information on pesticide exposure in the Outcome Indicator Framework of the Defra 25 Year Environment Plan.

# 7.6 Natural England

7.6.1 Natural England noted they had been working with the Environment Agency, Defra and other project partners to develop 25 year environment plan indicators of chemical exposure and effects (Exposure and adverse effects of chemicals on wildlife in the environment: interim H4 indicator - GOV.UK (www.gov.uk).

7.6.2 Natural England commissioned a report on <u>Second generation anticoagulant</u> <u>rodenticide residues in red kites 2020</u>, which has been published by the UK Centre of Ecology and Hydrology on the Predatory Bird Monitoring Scheme website in 2022.

7.6.3 Natural England also noted they were recruiting for a Senior Specialist in Agrochemicals and Ecotoxicology

# 7.7 UK Health Security Agency

7.7.1 The UK Health Security Agency (UKHSA) noted the COC held a workshop on developments in cancer assessment in the UK. The workshop that was intended to determine what steps could be undertaken to make progress on chemical risk assessments and regulatory requirements based on modern research. UKHSA will provide the full report to the Committee once formalised.

7.7.2 They noted UKHSA was working with a range of partners to develop data on human exposure to pesticides and prioritised chemicals.

# Agenda Item 8: Date of next meeting

8.1 18 April 2023 – To be held in a hybrid manner.

# Agenda Item 9: Any other business

#### 9.1 PUS reports 2021

9.1.1 The Committee noted the publication of the 2021 Pesticide Usage Survey reports on 'Grassland and fodder crops in the UK' and 'Outdoor vegetable crops in the UK'

9.1.2 Members discussed changes in the active substances used within the UK and how the regulatory regime monitors the impact of withdrawn products. The Secretariat agreed to find an appropriate point to schedule a more detailed discussion.

#### **Action: Secretariat**

### 9.2 ECP Annual report 2022 [ECP 5 (57/2023)]

9.2.1 The Committee noted the second draft of the 2022 Annual Report. Members agreed to provide final comments by 28 March 2023.

#### **Action: Members**

#### 9.3 Update from other Committees

9.3.1 Members noted updates from the Expert Committee on Pesticide Residues in Food (PRiF) and the Pesticide Forum.

9.3.2 HSE discussed the work of the residue monitoring programme to facilitate both a GB and NI monitoring programme.

#### 9.4 Chair's report

9.4.1 The Chair noted the Committee was currently reviewing the way in which the Devolved Governments and wider government departments could seek advice from the Committee. They aim was to develop a clear procedure that ensured the ECP was able to provide advice on questions of science relating to their remit to interested parties across government.

9.4.2 The Chair noted they had discussed recruitment with the Secretariat, including succession planning for a number of posts, the process of establishing a bio-pesticides cloud and recruitment for a new Chair. The Committee once again noted their strong preference for having ECP member on the recruitment panel for the Chair post.

Ethan Clabby ECP Secretariat

April 2022

# ECP ADVICE TO GOVERNMENT: USE OF 'TUTAVIR' ON GLASSHOUSE GROWN TOMATO CROPS

#### Issue

1. The Government has received an application for an emergency authorisation for the use of 'Tutavir' (containing *Phthorimaea operculella* granulovirus (PhopGV)) for use as an insecticide to control Tomato leaf minor (*Tuta absoluta*) on glasshouse grown tomato crops.

#### Action required

- 2. The Committee is requested to advise on:
  - whether it is appropriate to conclude that the qPCR method is sufficient to quantify microbial contaminants within the five-batch analysis study?
  - whether the level of variability within the formulated product is acceptable for a virusbased plant protection product?
  - whether sufficient information is present to provide an acceptable level of confidence in the strain identity ('PhopGV strain V65')?
  - how early intervention, using 'Tutavir', could support tomato growers to maintain crops under IPM programmes?

#### Discussion

- 3. The Committee *noted* that:
  - This is the first time the Committee have seen an application for this use. A previous application for this proposed use had been rejected by HSE.
  - HSE consider a safe use has been demonstrated for this emergency scenario in the areas of physical and chemical properties, mammalian toxicology, non-dietary human exposure, residues and consumer exposure, environmental fate and behaviour and ecotoxicology.
  - HSE have utilised draft guidance and considered a weight of evidence approach in some areas of the risk assessment to ensure consideration was to the most recent scientific understanding.
  - Baculoviruses are enveloped viruses and therefore would not be predicted to have a high level or persistence.
  - There is a high degree of specificity and a limited range of moths in the target family *Gelechiidae* (not all of whom would feed on tomatoes). This and the enclosed nature of the use in glasshouse tomato crops, would serve to limit the risk and wider exposure is likely to be negligible.

- 4. The Committee dis*agreed* with HSE's evaluation that:
  - Other alternative products and bio-controls were not appropriate. Members understood arguments made by the applicant and HSE that the alternative bio-controls could be expensive and their efficacy may compare unfavourably to 'Tutavir'. However, no evidence had been provided by the applicant to confirm either that approved biocontrol agents were too expensive to use or that they were less efficacious than 'Tutavir'. Members could not, therefore, conclude other alternatives were not viable.
- 5. The Committee *advised* that:
  - A qPCR method is sufficient to quantify the contaminants. ECP recommended extracting RNA to verify the presence of viable, living contaminants.
  - Variability could have a significant impact on the efficacy of the product. If a full authorisation were to be considered, data requirements should be put in place to evidence the efficacy of the product to control, rather than eliminate, the pest, in order to optimise predator populations which would manage pests.
  - There is sufficient information to provide an acceptable level of confidence in the strain identity. However, data on the mutation rate of the baculovirus should also be collected.
  - The introduction of new IPM tools is always welcome in the industry. The use of the emergency application, if authorised, could provide an opportunity to collect practical efficacy and resistance monitoring data.
  - The use of biopesticides, such as this, could help reduce the reliance on conventional chemistry and extend the longevity of conventional chemical control options in tomato crops.

#### Conclusion

On the basis of the evidence presented to ECP, the Committee agreed, on balance, it supports the CRD assessment and that it is able to support an emergency authorisation under Article 53 of Regulation 1107/2009.