EFSA WG on effect models in Environmental Risk Assessment (ERA)

Working Group meeting n. 17

14th November 2025 (14:00-18:00)

Minutes agreed on the 5th of December

Location: EFSA

Attendees (virtual participation):

- Chair
  Ivana Teodorović (IT).
- Working Group Members:
  Jon Haselman (JH); Andreas Focks (AF); Sandrine Charles (SC).
- Hearing Experts:
  Leonhard U. Bürger (LB); Ella Rothe (ER)
- EFSA:
  Alberto Linguadoca (AL); Alessio Ippolito (AI), Edith Padilla Suarez (EPS).

Welcome and apologies for absence

The Chair welcomed the participants.

Adoption of agenda

The agenda was adopted without changes.

Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2,] EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

Agreement of the minutes of the 16th Working Group meeting held on the 6th of November 2025

The minutes of the 16th Working Group meeting were agreed by written procedure on the 6st of November 2025.

Scientific topic(s) for discussion

- **A scenario-based analysis using an ecotoxicological population model for solitary bees: exploring impacts of foraging activity, floral composition, and pesticide exposure in agroecosystems on simulated abundances**

The invited hearing expert ER was requested to give a presentation on unpublished experimental work on the scenario development for the model $SolBeePop_{ecotox}$. This study used a set of biologically informed hypotheses to design and test environmental scenarios for $SolBeePop_{ecotox}$ for

[1] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

use in the Environmental Risk Assessment (ERA) of pesticides. This work was also presented as proof-of-concept, illustrating how the binary input list of SolBeePop can support the development of realistic scenarios that reflect environmental complexity of agro-ecosystems.

The experimental work focused on two model species: *Osmia bicornis* and *Megachile rotundata*. Key aspects of the scenario definition included weather conditions and floral quality (both crop and non-crop). Simulations of population dynamics for the two species were presented and discussed under combinations of:

i) contrasting weather conditions affecting bee foraging; and
ii) floral quality/composition scenarios representing a gradient of environmental complexity.

The potential impact of pesticide exposure on bee population dynamics was explored by integrating exposure modification factors (EMFs). Complexity in the modelling results was restrained by making use of risk matrixes combining simulations from the abovementioned scenarios with increasing EMFs, in line with recommendations provided in EFSA (2023)[3].

- **The assessment of the parameter estimation and the relevant underlying literature of SolbeePop and SolbeePop$_{ecotox}$**

The invited hearing expert LB was requested to give a presentation on the parameter estimation for the SolBeePop model species. Initial focus concerned species-specific parameters, parameters common across species, and generic parameters applied in case of limited data availability. Key literature references were reviewed and discussed by the experts regarding their suitability for supporting robust parametrisation.

The model assumes that female nesting bee age and resource abundance are linked to brood cell production, sex ratio, and female offspring provision size through linear relationships. The experts examined the extent to which these assumptions are supported by the available literature. Outstanding questions from the previous meeting were also addressed.

[3] https://doi.org/10.2903%2Fsp.efsa.2023.EN-8535

EFSA WG on effect models in Environmental Risk Assessment (ERA)

Working Group meeting n. 16

17th October 2025 (14:00-18:00)

Minutes agreed on the 7th of November

Location: EFSA

Attendees (virtual participation):

- Chair
  Ivana Teodorović (IT).
- Working Group Members:
  Jon Haselman (JH); Andreas Focks (AF); Sandrine Charles (SC).
- Hearing Experts:
  Leonhard U. Bürger (LB).
- EFSA:
  Alberto Linguadoca (AL); Alessio Ippolito (AI).

Welcome and apologies for absence

The Chair welcomed the participants.

Adoption of agenda

The agenda was adopted without changes.

Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2,] EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

Agreement of the minutes of the 15th Working Group meeting held on the 19th of September 2025

The minutes of the 15th Working Group meeting were agreed by written procedure on the 1st of October 2025.

Scientific topic(s) for discussion

The conceptual, formal and computer model of SolbeePop and SolbeePop$_{ecotox}$

An EFSA negotiated procedure to purchase services for the scientific and technical support on the assessment of a mechanistic effect model was awarded to LB. Therefore, LB was invited as hearing expert to the meeting and was asked to summarise and present the conceptual, formal and computer model of SolbeePop and SolbeePop$_{ecotox}$. His presentation was used to guide the assessment by the WG experts, who identified possible sources of uncertainty, open questions and

[1] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

aspects requiring further discussion. The experts agreed to dedicate WG meeting n. 17 (scheduled on the 14th of November 2025) to the parameter estimation and the relevant underlying literature to the model.

The WG committed to the evaluation of SolbeePop and SolbeePop$_{ecotox}$, pending the need to prioritise any upcoming regulatory submission. Should a dossier submission require assessment, the evaluation of SolbeePop and SolbeePop$_{ecotox}$ will be put temporarily on hold.

AoB

The experts were given a brief presentation summarizing the former evaluation of the BeeGUTS model (see minutes of the 5th and 6th WG meetings) and discussed to consolidate a written advice on this model separate from the assessment of SolbeePop and SolbeePop$_{ecotox}$.

The WG members were informed about the endorsement (hence upcoming adoption and publication) of the latest version of the statement on FAIR principles for MEMs in ERA by the EFSA PPR panel. This version incorporates modifications triggered by the public consultation.

EFSA WG on effect models in Environmental Risk Assessment (ERA)

Working Group meeting n. 15

19th September 2025 (14:00-18:00)

Minutes agreed on September 25th, 2025

Location: EFSA

Attendees (virtual participation):

- Chair
  Ivana Teodorović (IT).
- Working Group Members:
  Jon Haselman (JH); Andreas Focks (AF); Sandrine Charles (SC).
- Hearing Experts:
  None.
- EFSA:
  Alberto Linguadoca (AL); Alessio Ippolito (AI).
- Observers:
  Leonhard U. Bürger.

Welcome and apologies for absence

The Chair welcomed the participants.

Adoption of agenda

The agenda was adopted without changes.

Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2,] EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

Agreement of the minutes of the 14th Working Group meeting held on the 31st of February 2025

The minutes of the 14th Working Group meeting were agreed by written procedure on the 22nd of April 2025.

Scientific topic(s) for discussion

Overview of SolBeePop and SolBeePop$_{ecotox}$[3]

The solitary bee population model 'SolBeePop' and its update including an ecotoxicological effect module 'SolBeePop$_{ecotox}$' were presented as potential candidates for assessment. The reasons

[1] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf
[3] https://doi.org/10.1111/1365-2664.14541; https://doi.org/10.1002/etc.5990

behind this choice include consideration of its recent publication and the availability of rich and publicly available documentation, as well as of a published computer model implementation. Furthermore, the model was designed for use in the prospective regulatory risk assessment of plant protection products. As such, its relevance for Regulation n. 1107/2009 was considered high. Consequently, the experts agreed to self-task the assessment of this model with the main goal of gaining experience (hence, ensuring preparedness) on the assessment of ecologically complex models in the peer review process and in the implementation of the revised bee guidance document[4].

The WG members were given a presentation on the available documentation SolBeePop and SolBeePop$_{ecotox}$. The conceptual model, formal model, sensitivity analysis, calibration and output verification were preliminarily discussed and aspects of the model design and use requiring further consideration were identified.

[4] https://doi.org/10.2903/j.efsa.2023.7989

EFSA WG on effect models in Environmental Risk Assessment (ERA)

Working Group meeting n. 14

31st March 2025 (15:30-18:00)

Location: EFSA

Attendees (virtual participation):

- Chair
  Ivana Teodorović (IT).
- Working Group Members:
  Jon Haselman (JH); Andreas Focks (AF); Sandrine Charles (SC).
- Hearing Experts:
  None
- EFSA:
  Alberto Linguadoca (AL); Alessio Ippolito (AI), Davide Gibin (DG).

Welcome and apologies for absence

The Chair welcomed the participants.

Adoption of agenda

The agenda was adopted without changes.

Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2,] EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

Agreement of the minutes of the 13th Working Group meeting held on the 18th of February 2025

The minutes of the 13th Working Group meeting were agreed by written procedure on the 10th of March 2025.

[1] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

Scientific topic(s) for discussion

EFSA Statement titled: 'Interpretation of FAIR principles for mechanistic effect models in regulatory environmental risk assessment of pesticides' (EFSA-Q-2025-00205)

The WG members discussed the latest version of the EFSA statement on the interpretation of FAIR principles for the regulatory use of mechanistic effect models in ERA, which was reviewed by the EFSA PPR Panel. Specifically, the WG experts and EFSA gathered to agree on how to address the comments by the PPR Panel in a revised, final version of the document. The revised statement is scheduled for endorsement by the PPR on the plenary of the 29th and 30th of April 2025.

EFSA WG on effect models in Environmental Risk Assessment (ERA)

Working Group meeting n. 13

18th February 2025 (14:00-18:00)

Location: EFSA

Attendees (virtual participation):

- Chair
  Ivana Teodorović (IT).
- Working Group Members:
  Jon Haselman (JH); Andreas Focks (AF); Sandrine Charles (SC).
- Hearing Experts:
  None
- EFSA:
  Alberto Linguadoca (AL); Alessio Ippolito (AI).

Welcome and apologies for absence

The Chair welcomed the participants.

Adoption of agenda

The agenda was adopted without changes.

Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2,] EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

Agreement of the minutes of the 12th Working Group meeting held on the 24th January 2024

The minutes of the 12th Working Group meeting were agreed by written procedure on the 12th of February 2025.

[1] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

Scientific topic(s) for discussion

The WG members discussed the latest version of the document on the interpretation of FAIR principles for the regulatory use of mechanistic effect models in ERA. Particularly, the experts agreed on the drafting of the i) abstract, ii) summary, iii) interpretation of FAIR principles for the computer model and iv) concluding remarks. The experts were informed that the process of endorsement by the EFSA panel on Plant Protection Products and their Residues (PPR) was confirmed. A presentation of the FAIR document to the PPR panel members was scheduled on the 27th of February at the 130th panel plenary meeting, where three reviewers should be formally appointed.

EFSA WG on effect models in Environmental Risk Assessment (ERA)

Working Group meeting n. 12

24th January 2025 (15:00-18:00)

Location: EFSA

Attendees (virtual participation):

- Chair
  Ivana Teodorović (IT).
- Working Group Members:
  Jon Haselman (JH); Andreas Focks (AF); Sandrine Charles (SC).
- Hearing Experts:
  None
- EFSA:
  Alberto Linguadoca (AL); Alessio Ippolito (AI), Clarissa Cantore (CC).

Welcome and apologies for absence

The Chair welcomed the participants.

Adoption of agenda

The agenda was adopted without changes.

Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2,] EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

Agreement of the minutes of the 11th Working Group meeting held on the 26th of November 2024

The minutes of the 11th Working Group meeting were agreed by written procedure on the 5th of December 2024.

[1] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

Scientific topic(s) for discussion

The WG members discussed the latest version of the document on the interpretation of FAIR principles for the regulatory use of mechanistic effect models in ERA. Specifically, the title, structure and new sections were discussed and agreed upon and new tasks were identified for the drafting of a consolidated version. A possible timeline for the endorsement of this document by the EFSA PPR Panel was finally discussed.

EFSA WG on effect models in Environmental Risk Assessment (ERA)

Working Group meeting n. 11

26th November 2024
(14:00-18:00)

Location: EFSA

Attendees (virtual participation):

- Chair
  Ivana Teodorović (IT).
- Working Group Members:
  Jon Haselman (JH); Andreas Focks (AF); Sandrine Charles (SC).
- Hearing Experts:
  Volker Grimm
- EFSA:
  Alberto Linguadoca (AL); Alessio Ippolito (AI).

Welcome and apologies for absence

The Chair welcomed the participants.

Adoption of agenda

The agenda was adopted without changes.

Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2,] EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

Agreement of the minutes of the 10th Working Group meeting held on the 19th November 2024

The minutes of the 10th Working Group meeting were agreed by written procedure on the 5th of December 2024.

[1] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

Scientific topic(s) for discussion

- **FAIR principles**

The WG members gathered to continue the discussion initiated during the "restricted workshop" held on the 19th of November 2024. The aim of this discussion was to agree on a consolidated proposal on the FAIR principles for mechanistic effect models in regulatory ERA regarding: i) data, ii) computer models and iii) model assessment documentation. A consolidated version of the document on FAIR principles for mechanistic effect models in EFA was discussed and agreed upon, and the experts were tasked with including it in a revised draft of the document, along with an explanation section.

More general issues related to the path to publication of the FAIR principle document were also discussed, such as the type of publication, the possibility to seek for the endorsement of the PPR panel and to carry out a public consultation on the final draft.

Finally the possibility of performing a prioritisation exercise was discussed, identifying which of the FAIR principles would be most important for the regulatory assessment of mechanistic effect models in ERA.

It was finally agreed that this exercise might need to await for an implementation phase of the FAIR principles. The implementation will likely be voluntary, as the FAIR document was seen as a starting point to draw a roadmap towards the use of FAIR principles in regulatory ERA, using mechanistic effect models as case study.

EFSA WG on effect models in Environmental Risk Assessment (ERA)

Working Group meeting n. 10

19th November 2024
(14:00-18:00)

Location: EFSA

Attendees (virtual participation):

- Chair
  Ivana Teodorović (IT).
- Working Group Members:
  Jon Haselman (JH); Andreas Focks (AF); Sandrine Charles (SC).
- Hearing Experts:
  Volker Grimm
- EFSA:
  Alberto Linguadoca (AL); Alessio Ippolito (AI).

Welcome and apologies for absence

The Chair welcomed the participants.

Adoption of agenda

The agenda was adopted without changes.

Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2,] EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

Agreement of the minutes of the 9th Working Group meeting held on the 30th October 2024

The minutes of the 9th Working Group meeting were agreed by written procedure on the 19th of November 2024.

[1] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

Scientific topic for discussion

- **Conceptualisation/implementation of FAIR principles to data, computer model and model assessment documentation**

The experts discussed the latest draft of the document on FAIR principles for mechanistic effect models in regulatory ERA, which was edited by all WG members prior to the 19th of November. Outstanding comments were briefly reviewed and addressed. The second part of the meeting was structured as a "restricted workshop" (i.e., open to WG member and EFSA staff only) on the online platform miro[3]. This "restricted workshop" was organised into small breakout groups for i) data, ii) computer model and iii) model assessment documentation. The aim of this workshop was to finalise a proposal for the FAIR principle implementation in areas i to iii. Finally, experts were tasked with identifying outstanding points for discussion on the conceptualisation of FAIR principles for mechanistic effect models in regulatory ERA.

3 https://miro.com/

EFSA WG on effect models in Environmental Risk Assessment (ERA)

9th Working Group meeting

30th October 2024
(14:00-18:00)

Location: EFSA

Attendees (virtual participation):

- Chair
  Ivana Teodorović (IT).
- Working Group Members:
  Jon Haselman (JH); Andreas Focks (AF); Sandrine Charles (SC).
- Hearing Experts:
  Volker Grimm
- EFSA:
  Alberto Linguadoca (AL); Alessio Ippolito (AI).

Welcome and apologies for absence

The Chair welcomed the participants.

Adoption of agenda

The agenda was adopted without changes.

Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2,] EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

Agreement of the minutes of the 8th Working Group meeting held on the 17th September 2024

The minutes of the 8th Working Group meeting were agreed by written procedure on the 3rd of October 2024.

[1] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

Scientific topic(s) for discussion

1.1. Body Burden Models (BBMs)

Following meeting n. 8 the WG members had a follow up discussion on the possibility to draft a statement on the use of BBMs in the ecological (regulatory) risk assessment of pesticides for birds and wild mammals. Specifically, the scope of this document was clarified and the interest to follow up on this activity in future general working group meetings was confirmed.

- **FAIR principles**

The WG followed up on the activity on FAIR principles (see minutes of the WG meeting n. 7) by inviting Prof. Volker Grimm, as hearing expert and representative from the Open Modeling Foundation (OMF). The OMF started as a continuation of COMSES.net from an initiative of the Arizona state initiative (in 2008, hence being older than FAIR). Currently the OMF comprises ~ 44 organisations spanning diverse fields of model use/development, divided in working groups with voluntary, open participation (i.e., OMF WGs on 'standards', 'certification', 'education and outreach', 'cyberinfrastructure' and 'early career scholars'). The EFSA WG was given a presentation on the scope and activities of the OMF, with particular emphasis on the role, composition and tasks of the OMF WG on standards. As such the OMF was noted to have broad scope, going far beyond the remit of the regulatory ERA of pesticides. The activities related to the OMF WG on standards – noted to be established relatively recently – were discussed more in detail. Several projects were discussed and considered relevant for the regulatory ERA, such as the "white paper", "fit-for-purpose" and "lingua franca" projects. Through the development and (voluntary) implementation of these standards, the OMF aims to improve model reusability, reproducibility, and interoperability. As such OMF also showed interest in- and highlighted the importance of implementing FAIR principles to model development, albeit under a much larger remit than the regulatory ERA of PPPs. The aim behind the development of a document on FAIR principles by the EFSA WG on effect models in ERA were discussed and the importance of pursuing this activity was confirmed. Therefore, the EFSA WG agreed on a timeline task allocation for the drafting the document on FAIR principles (see minutes of the WG meeting n. 7).

PESTICIDES PEER REVIEW UNIT

8th Working Group meeting on effect models in Environmental Risk Assessment (ERA)

17th Sept 2024
14:00-18:00

EUROPEAN FOOD SAFETY AUTHORITY

Location: Webconference

Attendees (virtual participation):

- Chair
  Ivana Teodorović (IT).
- Working Group Members:
  Jon Haselman (JH); Andreas Focks (AF); Sandrine Charles (SC).
- Hearing Experts:
  None
- EFSA:
  Alberto Linguadoca (AL); Alessio Ippolito (AI), Jochem Louisse (JL).

Welcome and apologies for absence

The Chair welcomed the participants.

Adoption of agenda

The agenda was adopted without changes.

Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2,] EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

Agreement of the minutes of the 7th Working Group meeting held on the 6th and 7th June 2024

The minutes of the 7th Working Group meeting were agreed by written procedure on 21st June 2024.

[1] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

Scientific topic(s) for discussion

The WG gathered to discuss general aspects of the use of Boby Burden Models (BBMs) in the ecological risk assessment of pesticide use for birds and wild mammals.

- **Physiologically based kinetic (PBK) models and Absorption, Distribution, Metabolism, Elimination (ADME) data in human toxicology**

A presentation was given by JL explaining the details of ADME data and their use in PBK modelling for human toxicology with the aim of identifying potential parallelism with the use of toxicokinetic (TK) models in ERA.

The presentation initially covered the following aspects of the ADME dataset in pesticide dossiers: i) the data requirements outlined in regulation 283/2013, their interpretation and implementation into the OECD testing battery and the key EFSA (PPR) outputs on ADME; ii) the study designs used for the investigation of ADME in rodents; their current use and some key limitations for their use in PBK modelling; iii) the study design and use of comparative in-vitro metabolism studies; iv) the dermal adsorption studies with the Plant Protection Product (PPP).

Then, relevant use examples of PBK models in human toxicology were presented: i) route-to-route extrapolations; ii) the inter- and intra-specific (e.g. adults and child) extrapolation; iii) the quantitative interpretation of human biomonitoring data ; iv) the quantitative interpretation of effect concentrations obtained *in vitro*, with the notable example of QIVIVE, self-mandate for developmental neurotoxicity (DNT) *in vitro* testing battery (IVB) on this topic for the EFSA PPR Panel. The scope of the EFSA WG on QIVIVE DNT IVB was discussed in more detail. Finally, the use of ADME data in the risk assessment for birds and wild mammals was discussed in relation to inter-specific extrapolations and the possible approaches for the estimation of elimination kinetics.

- **US EPA Terrestrial Investigation Model (TIM)**

Aspects of previous WG 'advices' on the regulatory use of specific avian BBMs were considered generally in line with the problem formulation, species and endpoint selection and use of ecological information by the US EPA's TIM model. Therefore, as follow up of previous assessments of BBMs by the working group, JH gave a presentation on the TIM model as an example of use of pesticide regulatory data for the extrapolation of individual level observations to avian populations. The presentation covered the following topics:

- The regulatory question to be addressed. Specifically, the current place of the TIM model in the tiered avian environmental risk assessment was explained, including consideration of aspects which might have limited its routine implementation in a regulatory context.
- The problem formulation, considering the hazard endpoint selection, the species selection.
- The model implementation in C++ and the graphical user interface in Matlab.
- The conceptual and formal model, considering: i) routes of exposure (oral, dermal, inhalation and their combination); spatial scale (in-field and edge-of-field); the use of Monte-Carlo simulations for the extrapolation of individual effects to populations.
- General aspects of the estimation of key model parameters: e.g., i) diet composition; ii) proportion of active time spent in the focal crop; iii) injestion and inhalation rates iv) dermal residue transfer rates; v) behavioural data and, specifically, the assumption of a bimodal daily feeding behaviour pattern

Questions were raised for clarification purpose on the parameter estimation, model equations, hazard characterisation and the estimation of the 'internal' exposure dose. There was general agreement that several conceptual aspects of the model could provide a solid basis for the

conceptualisation of BBMs, e.g., building upon published examples previously assessed by the WG[3].

- **General use and assessment of BBMs in ERA (+ document drafting)**

A summary of two WG advice on the regulatory assessment of avian BBMs was given to the members, highlighting conceptualisation aspects and key drawbacks of the two model submissions. Given the knowledge gathered during the two assessments by the WG members it was suggested that the WG could start working towards the drafting of a document on the (general) use and assessment of BBM in the ERA of PPPs for wild avian and mammalian species. It was suggested that the goals of this document could be to: 1) highlight the state-of-the-art of TK models for the RA of B&M; 2) to understand the best use of the information that is available in regulatory assessment; 3) to work towards general recommendations on how BBMs might be used in regulatory risk assessment. The drafting of such a document could, ideally, aim at an EFSA publication (e.g., a 'statement') targeted to regulators and risk assessors from industry. For practical reasons, any publication would not be aimed at providing guidance for risk assessors, but rather, general reflections on the use of BBMs in ERA (e.g., building upon published examples).

The WG members reflected on the need to discuss: i) harmonization of terminology (e.g., internal exposure estimation); ii) The use of pointwise estimations of toxicity from standardised study design (e.g., LD50s from gavage/bolus administration studies) in comparison with the time-course of the internal dose (body burden); iii) the use of ADME studies for the derivation of elimination rate constants.

A draft outline of the document (i.e., table of contents) was briefly discussed and suggestions were made to simplify the proposed structure.

[3] E.g., a) Ducrot, V., Ashauer, R., Bednarska, A. J., Hinarejos, S., Thorbek, P., & Weyman, G. (2016). Using toxicokinetic-toxicodynamic modeling as an acute risk assessment refinement approach in vertebrate ecological risk assessment. *Integrated environmental assessment and management*, *12*(1), 32-45; b) EFSA PPR panel (2005) Opinion of the Scientific Panel on Plant protection products and their residues (PPR) on a request from EFSA related to the evaluation of pirimicarb. *EFSA Journal*.

PESTICIDE PEER REVIEW UNIT

7th Working Group meeting on effect models in Environmental Risk Assessment (ERA)

6th June 2024 (09:00-18:00)
7th June 2024 (09:00-13:00)

EUROPEAN FOOD SAFETY AUTHORITY

Location: EFSA

Attendees (in-presence or virtual participation):

- Chair
  Ivana Teodorović (IT).
- Working Group Members:
  Jon Haselman (JH); Andreas Focks (AF); Sandrine Charles (SC).
- Hearing Experts:
  Jeremias Becker (JB); Devdutt Kulkarni (DK)
- EFSA:
  Alberto Linguadoca (AL); Alessio Ippolito (AI); Kehinde Olajide (KO); Elena Zioga (EZ); Jean-Lou Dorne (JLD); Davide Gibin (DG) and Edoardo Carnesecchi (EC).

Welcome and apologies for absence

The Chair welcomed the participants.

Adoption of agenda

The agenda was adopted without changes.

Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2,] EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

Agreement of the minutes of the 6th Working Group meeting held on the 9th of April and 22nd of May 2024, via web-conference

The minutes of the 6th Working Group meeting were agreed by written procedure on the 14th of June 2024.

Scientific topic(s) for discussion

- **Short introduction of the Working Group (WG)**

A short presentation was given to the new attendees on the terms of references and the composition of the WG.

[1] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

- **Status of the WG**

The aim of this presentation was to foster discussion on the i) achievements; ii) ongoing activities; iii) challenges and iv) areas of future work by the WG.

i) achievements:

- 8 model assessments were finalised, mainly covering individual-based models. The WG produced 2 advices and 1 data requirement during 13 teleconferences.

ii) The ongoing activities included:

- the conceptualisation of FAIR principles for mechanistic effect models in ERA and the uses of body burden models in the ERA of birds and mammals.

iii) The challenges encountered by the WG were also discussed, with a focus on practical organisational aspects.

iv) Finally, the WG brainstormed on potential areas of work for the future. Proposals included:

- template standardisation;
- a reflection on the TKTD quantitative criteria of the EFSA opinion on TKTD models (EFSA, 2018)[3], given the experience gained by the experts since their publication;
- the evaluation of other model types than TKTD
- the evaluation of models of communal interest by EFSA and the US EPA;
- the identification of screening (i.e., cut-off) criteria for the assessment of MEMs in regulatory ERA;
- ways for EFSA to efficiently guide WG members to navigate across background documents relevant to each assessment;
- ways to make assessments transparent and more immediately available to the public.

The proposals above were translated into an action plan to be discussed at the next meetings.

MAD book

A presentation was given by AF on a book drafted by a WG of the Society of Environmental Toxicology and Chemistry (SETAC) named Model Acceptability criteria and scenario Development (MAD). The book titled 'mechanistic effect models in the environmental risk assessment of chemicals, special focus on plant protection products' is currently under review (second round). An introduction to the MAD working group composition, scope and to the structure of the publication was given by AF, before presenting each chapter in detail. Key aspects of the presentation were discussed by the experts, with a focus on the framework for modelling and environmental scenarios and the separation between mechanistic effect models and their specific application. Overall, it was commented that the book will likely provide a solid basis for the assessment of mechanistic models by regulatory scientists.

Short intro on the activities of EFSA related to data stewardship, quality, transparency

A brief induction was given by EFSA on in-house data quality and stewardship initiatives at EFSA. The first part of the presentation focussed on definitions, dimensions, roles, and processes related to data quality. In the second part the OpenFoodTox database was presented as an example of application of FAIR principles at EFSA. Special focus was given to the ongoing effort to improve the interoperability of this database with IUCLID 6 and the EU Common Data Platform on Chemicals. Finally, the process and status of the OpenFoodTox migration into IUCLID was briefly

[3] EFSA Panel on Plant Protection Products and their Residues (PPR), Ockleford, C., Adriaanse, P., Berny, P., Brock, T., Duquesne, S., ... & Teodorovic, I. (2018). Scientific Opinion on the state of the art of Toxicokinetic/Toxicodynamic (TKTD) effect models for regulatory risk assessment of pesticides for aquatic organisms. *EFSA journal*, *16*(8), e05377.

explained. The presentation was followed by an open discussion, which mainly aimed to clarify aspects of the structure and functionalities of OpenFoodTox and IUCLID.

FAIR principles

A first draft of a working document on the conceptualisation of FAIR principles for MEMs in ERA was shared by EFSA and reviewed by the experts prior to the meeting. A presentation on the scope and domain of applicability of this document was shared at the meeting, where the following conclusions were drawn:

- There was a provisional agreement on the current structure (i.e., table of contents) of the document. Yet modifications might be required in relation to the actions reported below.
- Experts agreed that the conceptualisation exercise should cover i) data; ii) model implementation (i.e., software and code) and iii) model assessment documentation. Furthermore, it was considered key to explicitly address model documentation in the conceptualisation exercise (strategy to be defined).
    - Concerning the conceptualisation of the FAIR principles for the underlying data used in modelling: there was agreement that the interpretation by Wilkinson et al., (2016)[4] may provide a good basis.
    - Concerning the conceptualisation exercise for the model and software implementation: it was considered that the work of the open modelling foundation[5] on 'Accessibility, Documentation, Interoperability and Reusability (ADIR)' should be further explored (together with the FAIR4research software)[6] to understand its potential to inform the conceptualisation by the WG.
    - Concerning the conceptualisation exercise for the model assessment documentation, further discussion by the WG is required to translate what is currently available into proposals. For such purpose it was considered important to comprehensively collect information on the available standards (e.g., data, metadata and reporting, libraries, standards and templates)
- The document should be explicit on the need of a separation between a model and its specific use. There should be further reflections on the potential implications on the conceptualisation of the FAIR princples.
- It was suggested that a revision of the FAIR document should report agreed definitions by the WG in a glossary (e.g., data; quality; stewardship; software etc)
- A set of actions will be shared by the WG considering the possibility to invite ad hoc hearing experts in dedicated meetings and to foresee an open consultation on a final draft of the document.

Report on the "Critical Evaluation of Effect Models for the Risk Assessment of Plant Protection Products"

The hearing expert JB was invited to present a recent publication by the German Environment Agency UBA on the "critical evaluation of effect models for the risk assessment of plant protection products" (Becker et al., 2024[7]). The publication is the outcome of a project founded by the UBA on the evaluation of MEMs and their uses in the ERA of plant protection products, based on EFSA

[4] Wilkinson, M. D., Dumontier, M., Aalbersberg, I. J., Appleton, G., Axton, M., Baak, A., ... & Mons, B. (2016). The FAIR Guiding Principles for scientific data management and stewardship. *Scientific data*, *3*(1), 1-9.
[5] https://www.openmodelingfoundation.org/
[6] Katz, D. S., Gruenpeter, M., & Honeyman, T. (2021). Taking a fresh look at FAIR for research software. *Patterns*, *2*(3).
[7] https://www.umweltbundesamt.de/en/publikationen/critical-evaluation-of-effect-models-for-the-risk (last access: June 20204)

scientific opinion on Good Modeling Practice (EFSA, 2014[8]). The consortium members, their expertise and the timeline of activities was presented before discussing the individual chapters in detail.

Overall, the evaluation effort was considered solid and providing very useful information/tools for the risk assessment community (i.e., a potential steppingstone towards guidance for the evaluation and use of models in ERA). Furthermore, aspects such as the separation of the model assessment from its application or the use of the GMP modelling cycle were particularly appreciated by the WG.

The following aspects fostered discussion among the experts:

- It was noted that the timeline did not allow using the guideline of the TKTD opinion (EFSA, 2018). Furthermore, there was a time lag between the project initiation and the publication, so that newer models, even if available, could not be assessed.
- Some experts wished for higher representation of community models. However, it was acknowledged that the final choice was a result of a prioritisation effort by the consortium and UBA.
- Given the constraint imposed by the consortium composition and owing to the prioritisation exercise mentioned above, it was not always possible to completely avoid that scientists played a role in the assessment of models they coauthored or co-developed. However, this practice was avoided whenever possible.
- While studies were generally assessed, the available resources did not always allow for a systematic assessment of the model code and the underlying data, especially not for the models of high complexity, where the amount of information was too high. It was often necessary to make reasoned decisions on the type of information to assess. Yet this may be an area where future assessments of the same models by regulatory scientist could complement the existing assessment by Becker et al. (2024).
- Incorporating species competition (e.g., trophic interation) in population models designed for the assessment of chemical stress may lead to complex systems analysis and unpredictable model behaviour. In principle, despite the complexity, it may be reasonable to assess extreme cases of species competition. Yet, it may also be possible to addess similar questions via a reasoned definition of environmental scenarios.

SETAC (Europe) special session on the regulatory use of MEMS in the ERA of PPPs

The SETAC EU meeting 2024 in Seville included a special session titled "are we there yet? Ways forward for mechanistic effect modelling in Environmental Risk Assessment", which was chaired by DK. Therefore, DK was invited as hearing expert to share the main outcomes of this special session with the WG.

DK initially presented the session schedule, scope and the composition of room invitees. He then proceeded presenting the views by industry, regulators, academia and contract research organisations on the key challenges and solutions to the regulatory use and acceptance of models in ERA. Finally, key topics of the panel discussion were brought to the attention of the WG experts.

There was a general feeling that past and recent initiatives by EFSA and EU member states had an overall positive impact on the perception of the role of models in ERA: i.e., we are a few steps forward, yet still time away from the routine implementation of MEMs in ERA.

Overall, it was suggested that some of the ongoing and future[9] activities by EFSA may effectively provide solutions to some of the key recurring challenges behind the model acceptance in ERA.

[8] EFSA Panel on Plant Protection Products and their Residues (PPR). (2014). Scientific Opinion on good modelling practice in the context of mechanistic effect models for risk assessment of plant protection products. *EFSA Journal*, *12*(3), 3589.
[9] https://www.efsa.europa.eu/en/art36grants/article36/euba-efsa-prev-2023-01-pera-advancing-era-plant-protection-products-towards

These include: i) the conceptualisation of FAIR principles for MEMs in ERA (see discussion above); ii) the environmental scenario[10] development and iii) efforts in training and model assessment[11]

[10] https://www.efsa.europa.eu/en/events/webinar-ocefsaprev202302-call-tender-eu-environmental-scenarios-era-non-target-organisms
[11] https://www.efsa.europa.eu/en/art36grants/article36/euba-efsa-prev-2023-01-pera-advancing-era-plant-protection-products-towards

PESTICIDE PEER REVIEW UNIT

6th Working Group meeting on effect models in Environmental Risk Assessment (ERA)

9th April and 22nd May 2024
14:00-18:00

EUROPEAN FOOD SAFETY AUTHORITY

Location: Webconference

Attendees:

- Chair
  Ivana Teodorović (IT).
- Working Group Members:
  Jon Haselman (JH); Andreas Focks (AF); Sandrine Charles (SC).
- Hearing Experts:
  None
- EFSA:
  Alberto Linguadoca (AL); Alessio Ippolito (AI); Kehinde Olajide (KO).

Welcome and apologies for absence

The Chair welcomed the participants.

Adoption of agenda

The agenda was adopted without changes.

Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2,] EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

Agreement of the minutes of the 5th Working Group meeting held on 6th and 7th of March 2024, via web-conference

The minutes of the 5th Working Group meeting were agreed by written procedure on the 27th of March 2024.

Scientific topic(s) for discussion

Follow up on the use of GUTS in terrestrial ecotoxicology: a case-study for bees

During the previous meeting (i.e., n. 5) the WG discussed an application of GUTS models from a recent open literature publication. This exercise was aimed to gain experience in the application of regulatory criteria for the assessment of TKTD models in terrestrial ecotoxicology.

[1] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

During meeting n. 6, the WG assessed a case study where the same GUTS model was used in the risk assessment for bees. Such an exercise was not aimed to conclude on a specific regulatory submission, but rather to gain experience and ensure preparedness for upcoming regulatory assessment of pesticide active substances.

The assessment by the WG covered: i) the problem definition; ii) the supporting experimental data; iii) the conceptual, formal and computer model; iv) the environmental scenarios; v) the parameter estimation; vi) the sensitivity analysis; vii) the model validation and viii) the model documentation. Several critical aspects were identified, which would require particular attention, should similar models be used in regulatory peer review of pesticide active substances. First and foremost, it was remarked that a clear, detailed problem formulation about the regulatory question to be addressed is essential to the successful assessment of mechanistic effect models (MEMs) in ERA. Furthermore, particular attention should be given to the following aspects of the assessment:

- model conceptualisation and formalisation, with particular reference to the exposure conceptualisation;
- quality of the supporting experimental data and their unbiased retrieval;
- estimation of GUTS-related and physiological parameters;
- calibration and validation steps (including consideration of the underlying data);
- sensitivity and uncertainty analysis;
- model use.

The experts concluded that the interpretation of the assessment criteria of the EFSA opinion on TKTD models for aquatic ecotoxicology (EFSA 2018[3]), would require careful interpretation for their suitability for non-aquatic ecotoxicology.

Outstanding issues: assessment of the avian body burden for metam (EFSA-Q-2019-00482)

Concerning the assessment of the avian body burden model submitted in the context of the renewal dossier of the active substance metam, the WG finalised the drafting of the 'data requirements' (the requests of additional data to the applicant) to be included in the column 4 of the peer review 'reporting table'.

Outstanding issues: the use of body burden models in the acute dietary risk assessment for birds and wild mammals

In view of the experience gained during the assessment of chlorotoluron and metam, the WG initiated a discussion aimed to identify potentially acceptable uses of body burden models in the risk assessment for birds and mammals. A proposal by EFSA was used as a starting point for an initial assessment covering: i) the problem definition; ii) conceptualisation, formalisation and implementation; iii) the 'ecological' scenario and iv) the parameter estimation.

Outstanding issues: WG outputs

It was discussed that the outputs of the WG (i.e., the advice on the model assessment) are currently published as background to the EFSA conclusions. However, for generic assessments such as the ones above other output types may be considered.

[3] EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2018. Scientific Opinion on the state of the art of Toxicokinetic/Toxicodynamic (TKTD)effect models for regulatory risk assessment of pesticides for aquatic organisms. EFSA Journal 2018;16(8):5377, 188 pp.https://doi.org/10.2903/j.efsa.2018.5377

PESTICIDE PEER REVIEW UNIT

5th Working Group meeting on Effect Models in Environmental Risk Assessment

6th – 7th March 2024
14:00-18:00

EUROPEAN FOOD SAFETY AUTHORITY

Location: Webconference

Attendees:

- Chair
  Ivana Teodorović (IT).
- Working Group Members:
  Jon Haselman (JH); Andreas Focks (AF) present during agenda points 1-5; Sandrine Charles (SC).
- Hearing Experts (6th March 2024):
  Brecht Ingels (RMS); Elena Alonso Prados (co-RMS).
- EFSA:
  Alberto Linguadoca (AL); Alessio Ippolito (AI); Franco Ferilli (FF); Kehinde Olajide (KO).

Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from the RMS.

Adoption of agenda

The agenda was adopted without changes.

Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2], EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

Scientific topic(s) for discussion

a. Avian body burden model for metam

The meeting discussed the aspects of the model evaluation which were not covered in the previous assessment.

The WG discussed the following aspects: i) model description; ii) problem definition; iii) quality of underlying data and their search; iv) conceptual and formal model; v) model implementation; vi) model parameters; vii) environmental scenario; viii) sensitivity and uncertainty analysis.

Several concerns were identified following the model assessment for regulatory ERA purpose including some fundamental issues related to i) the lack of clarity on the model use in risk assessment; ii) uncertainties around the model assumption of a first order decay, given the available data on the ADME in rat. The concerns by the WG were translated into requests and

[1] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

indications for the applicants on how the model(ling) could be improved. These requests will be reflected in a 'data requirement' in the written peer review process. Following the stop of the clock and pending the submission of additional data by the applicant, the assessment by the WG will be reflected in an advice document for consideration by the peer review experts' meeting.

b. Use of GUTS in terrestrial ecotoxicology

An application of a GUTS model to bees from a recent open literature peer-reviewed publication was discussed by the WG, to ensure preparedness in future assessments.

It was highlighted that the purpose of this evaluation was not to assess the quality and robustness of this research *per se*. Additionally, the value of this research application was not questioned by the experts.

With the aim of gaining experience on the application of GUTS in terrestrial ecotoxicology, the WG assessed the applicability of the same evaluation criteria normally applied for regulatory assessments of pesticide risks in aquatic ecotoxicology. For this purpose, models are used to prospectively quantify risks of pesticide use (i.e., to inform risk management decisions on the approval of plant protection products or their active substances).

The assessment by the WG covered the following points: i) the problem definition; ii) the supporting experimental data; iii) the conceptual, formal and computer model; iv) the environmental scenarios; v) the parameter estimation; vi) the sensitivity analysis; vii) the model validation and viii) the model documentation. Because the model was not actually presented for a specific risk assessment application (e.g., by quantifying risks for a specific pesticide use), some of the previous criteria could not be fully assessed.

Where possible, the checklists of the EFSA opinions on good modelling practices (EFSA, 2014[3]) and TKTD models (EFSA 2018[4]) were used. The WG recognized that the EFSA opinion did not specifically cover terrestrial organisms. Owing to the inherent differences of the terrestrial compartment relative to the surface water ecosystems it was recognized that several aspects of the application of GUTS to terrestrial organisms require particular attention. These include the conceptualization of exposure; its relationship with the scaled damage and the evaluation of model performances (e.g., use of quantitative criteria originally conceptualized for aquatic organisms).

[3] EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2014. Scientific Opinion on good modelling practice in the context of mechanistic effect models for risk assessment of plant protection products. EFSA Journal 2014;12(3):3589, 92 pp. doi:10.2903/j.efsa.2014.3589

[4] EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2018. Scientific Opinion on the state of the art of Toxicokinetic/Toxicodynamic (TKTD)effect models for regulatory risk assessment of pesticides for aquatic organisms. EFSA Journal 2018;16(8):5377, 188 pp.https://doi.org/10.2903/j.efsa.2018.5377

PESTICIDE PEER REVIEW UNIT

4th Working Group meeting on Effect Models in Environmental Risk Assessment

14th February 2024
14:00-18:00
MINUTES - Agreed on 26th February 2024

Location: Webconference

Attendees:

- Chair
Ivana Teodorović (IT).
- Working Group Members:
Jon Haselman (JH); Andreas Focks (AF) present during agenda points 1-5; Sandrine Charles (SC).
- Hearing Experts:
Elena Alonso Prados (co-RMS).
- EFSA:
Alberto Linguadoca (AL); Alessio Ippolito (AI); Franco Ferilli (FF); Kehinde Olajide (KO).

Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from the RMS.

Adoption of agenda

The agenda was adopted without changes.

Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2], EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

Scientific topic(s) for discussion

Avian body burden model for Metam

The pesticide active substance Metam in undergoing EU-level risk assessment in the framework of its renewal under Commission Regulation (EC) 1107/2009 (AIR III). For this process, Belgium and Spain have been appointed as Rapporteur Member State (RMS) and Co-Rapporteur Member State (Co-RMS) respectively. In this framework, a Renewal Assessment Report (RAR) of the supplementary dossier has been submitted by the applicant, forming the basis of the ongoing peer-review process of metam. The supplementary dossier includes Mechanistic Effect Models (MEMs) for use in ERA, which fall under the remit of the EFSA Working Group (WG) on effect models in Environmental Risk Assessment (ERA). Specifically, a body burden was proposed for

[1] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

use in the higher-tier risk assessment of the acute dietary risk for birds of (a subset of) the representative uses.

The Tier-1 hazard and risk assessment of the representative uses was briefly discussed, before carrying out a preliminary assessment following the structure of the EFSA modelling cycle[3]. Specifically, the WG discussed the following:

- the problem formulation (with reference to the species and endpoint selection)
- the model formulation and formalisation, considering the EFSA PPR panel opinion on Pirimicarb[4]
- a subset of the parameter set proposed by the applicant.

A follow-up meeting was deemed necessary before identifying any data requirement for the applicant.

Next assessments

As mentioned above, the need of a follow-up discussion on the avian body burden model was identified.

Additionally, the WG discussed the need to ensure preparedness for the evaluation of TKTD and population models in the area of terrestrial ecotoxicology. Therefore, a proposal was made to initially focus on a case-study covering the use of GUTS beyond the remit of the EFSA PPR Panel TKTD opinion[5] (i.e., application to terrestrial organisms). It was considered that this work will likely directly feed into upcoming peer reviews of pesticide active substances.

A general remark was made that future assessments should aim, where possible, to separate the model assessment from the model use assessment. It was acknowledged that such a separation may not always be straightforward, considering that there are aspects of the design of a model which are inherently linked to the model use in risk assessment. However, it was finally suggested that – regardless of the model type – some aspects of the model assessment (e.g., evaluation of the conceptual and formal model; sensitivity analysis etc.) may be easily 'decoupled' from the evaluation of the model use. Overall, there was agreement that future 'advices' by the WG aim, where possible, to ensure a separation between model assessment and model use assessment.

[3] EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2014. Scientific Opinion on good modelling practice in the context of mechanistic effect models for risk assessment of plant protection products. EFSA Journal 2014;12(3):3589, 92 pp. doi:10.2903/j.efsa.2014.3589

[4] EFSA Panel on Plant Protection Products and their Residues, 2005. Opinion of the Scientific Panel on Plant protection products and their residues (PPR) on a request from EFSA related to the evaluation of pirimicarb, *EFSA Journal* 2005; 3(8):240, 21 pp. doi:10.2903/j.efsa.2005.240

[5] EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues),Ockleford C, Adriaanse P, Berny P, Brock T, Duquesne S, Grilli S, Hernandez-Jerez AF, Bennekou SH,Klein M, Kuhl T, Laskowski R, Machera K, Pelkonen O, Pieper S, Smith RH, Stemmer M, Sundh I, Tiktak A,Topping CJ, Wolterink G, Cedergreen N, Charles S, Focks A, Reed M, Arena M, Ippolito A, Byers H andTeodorovic I, 2018. Scientific Opinion on the state of the art of Toxicokinetic/Toxicodynamic (TKTD)effect models for regulatory risk assessment of pesticides for aquatic organisms. EFSA Journal 2018;16(8):5377, 188 pp.https://doi.org/10.2903/j.efsa.2018.5377

PESTICIDE PEER REVIEW UNIT

3rd Working Group meeting on Effect Models in Environmental Risk Assessment

09 November 2023
14:00-18:00
MINUTES - Agreed on 28 November 2023

Location: Teleconference

Attendees:

Chair: Ivana Teodorović (IT)
Members: Jon Haselman (JH); Andreas Focks (AF); Sandrine Charles (SC)
EFSA: Alberto Linguadoca (AL); Alessio Ippolito (AI), Kehinde Olajide (KO), Elena Zioga (EZ)
Hearing experts: Not applicable

I. Welcome and apologies for absence

The Chair welcomed the participants. All WG members attended the meeting.

II. Adoption of the agenda

The agenda was adopted without changes.

III. Declaration of Interest

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2,] EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

IV. Scientific topic for discussion

The WG discussed possible strategies for working towards the definition of a framework for the assessment of MEMs.

An initial discussion aimed to reflect on the "lesson learned" from the previous evaluation of General Unified Threshold models of Survival (GUTS) by the WG. A key outcome of this exchange was a proposal to draft a document summarising the practical aspects of the implementation of quantitative assessment criteria in GUTS modelling. The WG discussed the criteria in the Toxicokinetic/Toxicodynamic (TKTD) opinion[3] in addition to others encountered during the assessments of chlorotoluron and deltamethrin. While an initial reflection on their

[1] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf
[3] EFSA PPR, 2018. Scientific Opinion on the state of the art of Toxicokinetic/Toxicodynamic (TKTD) effect models for regulatory risk assessment of pesticides for aquatic organisms. EFSA Journal 2018;16(8):5377

implementation was possible, further discussion and additional experience in a second general meeting was considered necessary before producing a written output.

Another discussion point aimed to reflect on the possibility to take inspiration from the Findability, Accessibility, Interoperability, and Reusability (FAIR)[4] guiding principles to promote best practices on the (re)use of data, models and model assessment in a regulatory context. Specifically, a short-term goal was identified to work towards the application of FAIR principles *sensu lato* to: i) the reporting and use of data; ii) model implementation, including coding practices and iii) the model assessment. A first step in this direction would be a reflection how and which of the FAIR principles could be readapted for application to the abovementioned steps.

Another short-term goal identified was to work towards the drafting of a checklist specific to TKTD models to be used in the regulatory assessment. This could serve as basis to ensure harmonised definition of data requirements in the peer review process of pesticide active ingredients in the framework of the reg. (EC) 1107/2009. It was acknowledged that guidance is already available in the TKTD[3] and Good Modelling Practice (GMP)[5] EFSA opinions, which could be used as basis for the drafting of such a checklist. Additional sources which may be considered preliminarily to the drafting of such checklists are the TRAnsparent and Comprehensive Ecological modelling documentation (TRACE)[6] and Overview, Design concepts, Details (ODD)[7] protocols.

Finally, the WG was given a presentation of the software implementation of a one compartment avian toxicokinetic model in a 'shiny'[8] application.

[4] Wilkinson et al. 2016. The FAIR Guiding Principles for scientific data management and stewardship. Scientific data, 3(1), 1-9.

[5] EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2014. Scientific Opinion on good modelling practice in the context of mechanistic effect models for risk assessment of plant protection products. EFSA Journal 2014;12(3):3589, 92 pp. doi:10.2903/j.efsa.2014.3589

[6] Grimm et al., 2014. Towards better modelling and decision support: Documenting model development, testing, and analysis using TRACE. Ecological modelling, 280, 129-139.

[7] Grimm et al., 2020. The ODD protocol for describing agent-based and other simulation models: A second update to improve clarity, replication, and structural realism. Journal of Artificial Societies and Social Simulation, 23(2).

[8] Chang et al., 2023. shiny: web application framework for R. R package version 1.8.0.9000, https://github.com/rstudio/shiny, https://shiny.posit.co/.

PESTICIDE PEER REVIEW UNIT

2nd Working Group meeting on Effect Models in Environmental Risk Assessment

18-19 July 2023 / 12 September 2023 / 10-11 October 2023
14:00-18:00
MINUTES - Agreed on 31 October 2023

Location: Teleconference

Attendees:

Day 1:

Date (time): 18/July/2023 (14:00 – 18-00 CEST)
Chair: Ivana Teodorović (IT)
Members: Jon Haselman (JH); Andreas Focks (AF); Sandrine Charles (SC)
EFSA: Alberto Linguadoca (AL); Alessio Ippolito (AI)
Hearing experts: Desislava Delikirova (RMS, BG) and Harry Byers (co-RMS, FR)

Day 2:

Date (time): 19/July/2023 (14:00 – 18-00 CEST)
Chair: Ivana Teodorović (IT)
Members: Jon Haselman (JH); Andreas Focks (AF); Sandrine Charles (SC)
EFSA: Alberto Linguadoca (AL); Alessio Ippolito (AI)
Hearing experts: Desislava Delikirova (RMS, BG) and Harry Byers (co-RMS, FR)

Day 3:

Date (time): 12/September/2023 (14:00 – 18-00 CEST)
Chair: Ivana Teodorović (IT)
Members: Jon Haselman (JH); Andreas Focks (AF); Sandrine Charles (SC)
EFSA: Alberto Linguadoca (AL); Alessio Ippolito (AI); Rachel Sharp (RS)
Hearing experts: Desislava Delikirova (RMS, BG) and Harry Byers (co-RMS, FR)

Day 4:

Date (time): 10/October/2023 (14:00 – 18-00 CEST)
Chair: Ivana Teodorović (IT)
Members: Jon Haselman (JH); Andreas Focks (AF); Sandrine Charles (SC)
EFSA: Alberto Linguadoca (AL); Alessio Ippolito (AI)
Hearing experts: Desislava Delikirova (RMS, BG) and Harry Byers (co-RMS, FR)

Day 5:

Date (time): 11/October/2023 (14:00 – 18-00 CEST)
Chair: Ivana Teodorović (IT)
Members: Jon Haselman (JH); Andreas Focks (AF); Sandrine Charles (SC)
EFSA: Alberto Linguadoca (AL); Alessio Ippolito (AI)
Hearing experts: Desislava Delikirova (RMS, BG) and Harry Byers (co-RMS, FR)

I. Welcome and apologies for absence

The Chair welcomed the participants.
A quick round of table was done on day 1, for introducing all the participants, their backgrounds and the scope of the WG.
Apologies were received from the co-RMS (Harry Byers FR) on the 12th of September 2023.

II. Adoption of the agenda

The agenda was adopted without changes.

III. Declaration of Interest

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2,] EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

IV. Scientific topic for discussion

The pesticide active substance Chlorotoluron in undergoing EU-level risk assessment in the framework of its renewal under Commission Regulation (EC) 1107/2009 (AIR III). For this process, Bulgaria and France have been appointed as Rapporteur Member State (RMS) and Co-Rapporteur Member State (Co-RMS) respectively. In this framework, a Renewal Assessment Report (RAR) of the supplementary dossier has been submitted by the applicant, forming the basis of the ongoing peer-review process of chlorotoluron. The supplementary dossier includes Mechanistic Effect Models (MEMs) for use in ERA, which fall under the remit of the EFSA Working Group (WG) on effect models in Environmental Risk Assessment (ERA).

These include i) a body burden model for use in the acute avian risk assessment; ii) an algae population model and iii) an aquatic macrophyte TKTD model for *Lemna*.

The WG was therefore tasked to assess these MEMs and their use in the ERA of chlorotoluron considering its representative uses. Hence, to produce a written "advice" summarising their assessment, for consideration of the upcoming peer review meeting.

[1] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

PESTICIDE PEER REVIEW UNIT

1st Working Group meeting on Effect Models in Environmental Risk Assessment

12 May 2023 / 01 June 2023 / 14 June 2023
14:00-18:00
MINUTES - Agreed on 29 June 2023

Location: Webconference

Attendees:

Day 1:

Date: 12/05/2023

Chair: Ivana Teodorovic (IT)

Members: Jon Haselman (JH); Andreas Focks (AF); Sandrine Charles (SC)
EFSA: Alberto Linguadoca (AL); Alessio Ippolito (AI); Aude Kienzler (AK); Rachel Sharp (RS); Csaba Szentes (CS); Simone Rizzuto (SR); Maria Arena (MA)

Hearing experts: None

Day 2:

Date: 01/06/2023

Chair: Ivana Teodorovic (IT)

Members: Jon Haselman (JH); Andreas Focks (AF); Sandrine Charles (SC)
EFSA: Alberto Linguadoca (AL); Alessio Ippolito (AI);
Hearing experts: Matthias Fürst, representing the Rapporteur Member State (RMS)

Day 3:

Date: 14/06/2023

Chair: Ivana Teodorovic (IT)

Members: Jon Haselman (JH); Andreas Focks (AF); Sandrine Charles (SC)
EFSA: Alberto Linguadoca (AL); Alessio Ippolito (AI)

Hearing experts: None

I. Welcome and apologies for absence

The Chair welcomed the participants. A quick round of table was done on day 1, for introducing all the partecipants and their backgrounds. Apologies were received from the RMS on day 3.

II. Adoption of the agenda

The agenda was adopted without changes on 12/05/2023; 1/06/2023 and 14/06/2023.

III. Declaration of Interest

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2], EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the

[1] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

IV. Approval of the last meeting minutes

Not relevant.

V. Scientific topic for discussion

The WG discussed the need to harmonise of the evaluation of models in the context of the peer-review process of pesticides.

The terms of reference of the working group were introduced. It was clarified that the main goal is to establish a framework for the assessment of mechanistic effect models (MEMs) in the context of the peer-review of pesticide active substance (i.e., in the framework of regulation (EC) 1107/2009).

The WG discussed the possibility to expand the current set of expertise in view of future model assessment.

It was agreed that the WG could initially work towards assessing specific cases related to the EU peer-review activities. Consequently, sufficient experience may be gathered in order to generalize the principles of individual evaluations into rules and guidance that could later be followed at the MS level.

A set of targeted discussions covered the following topics:

- The history, scope and key written outputs of the working group on Model Acceptability criteria and scenario Development of the Society of Environmental Toxicology and Chemistry (SETAC MAD WG), in relation to the possible use for the EFSA working group
- The use of MEMs in the US-EPA, in relation to the similarities and differences with EFSA
- The application of MEMs in the context of the EU regulatory environmental risk assessment of plant protection products[3]; their use i) across non target organism groups (i.e., links between model types and biological groups) ii) over time and iii) across chemical groups. Finally, key limitations of the application of complex models in risk assessment were highlighted.
- The EFSA scientific opinions on "good modelling practice in the context of MEMS for the risk assessment of plant protection products"[4] and on "the state of the art of Toxicokinetic/Toxicodynamic (TKTD) effect models for regulatory risk assessment of pesticides for aquatic organisms"[5]

The MEMs submitted in the framework of the peer review of deltamethrin were discussed by the WG.

The RAR for deltamethrin included TKTD (GUTS) modelling on the following non-standard species:

[3] Larras et al. (2022). A meta-analysis of ecotoxicological models used for plant protection product risk assessment before their placing on the market. *Science of the Total Environment*, 157003.
[4] EFSA PPR (2014). Scientific Opinion on good modelling practice in the context of mechanistic effect models for risk assessment of plant protection products. EFSA Journal, 12(3), 3589.
[5] EFSA PPR (2018). Scientific Opinion on the state of the art of Toxicokinetic/Toxicodynamic (TKTD) effect models for regulatory risk assessment of pesticides for aquatic organisms. EFSA journal, 16(8), e05377.

- *Asellus aquaticus*
- *Cloeon dipterum*
- *Gammarus pulex*

The WG discussed these models, based on a preliminary assessment of the data conducted by EFSA. The assessment of the abovementioned models covered the following topics:

1. Consideration of the most appropriate assessment endpoint (i.e., if mortality/immobility as modelled by GUTS would cover for the likelihood of sublethal effects) to address the RA for aquatic invertebrates at tier 2c.
2. Problem formulation, including the:
    - Selection of the most appropriate species for addressing the risk assessment for deltamethrin
    - Consideration of the quality of the experimental data
3. Parameter estimation
4. Model validation

The assessment by the WG was summarised in a written advice for consideration by the pesticide peer review meeting Pesticide Peer Review TC 113 Ecotoxicology (27-30 June 2023).