

Exposure modelling: generating robust exposure data to increase confidence in safety decision-making

Perspectives from the agrochemical sector

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Introduction – the importance of exposure data

Risk is a function of hazard and exposure.

- The intrinsic hazard of an [agro]chemical cannot be altered.
- Exposure to the [agro]chemical can be mitigated once it is understood. Knowledge of potential exposure can become more realistic through monitoring under representative conditions using science-based approaches.

Introduction

Why generate exposure data for agrochemical registrations?

- Refine risk assessments – to increase confidence in presented assessments.
- Provide data on a specific exposure scenario not covered by existing approaches.

What is robust exposure data?

- Data that can be used to support regulatory decisions and positions.
- Data that is scientifically robust.

Key considerations when generating robust data

- The exposure scenario being monitored is reflective of reality.
- Studies using human volunteers are ethically sound.
- The data is generated according to international quality criteria (GLP) and guidance on methodology (OECD).
- The data will meet regulatory requirements for acceptability.

Case studies from the agrochemical sector

- Agricultural Operator Exposure Model (AOEM)
- AOEM greenhouse model
- The updated SEEDTROPEX model
- The Bystander, Resident, Orchard and Vineyard (BROV) project
- Dermal absorption project



The AOEM & greenhouse model

The projects were a partnership between the BfR, CtgB, ANSES, CRD, JKI, BVL, IVA and CLE. EFSA and TNO were observers.

CLE provided 34 field exposure studies and BfR provided statistical and modelling experts. The project team sought to address questions/issues raised.

CLE were able to provide detailed technical knowledge regarding the individual studies.

Once the project team had completed creating a model all the data were submitted to EFSA for independent review and interpretation.

The AOEM formed the basis of the 2014 EFSA Model and the greenhouse data was incorporated into the EFSA 2022 model.



SEEDTROPEX Model

Seed Treatment Taskforce model

The original SEEDTROPEX Models were published in the 1990s.

The data and model were initially proprietary but were generally accepted by Member States. However, the original model could not be incorporated into the EFSA 2014 Guidance and associated Model.

In 2016 the taskforce was re-launched with the aim of gathering additional seed treatment data and produce an updated model that would be publicly available. The working group consisted of taskforce members and regulators including CtgB, CRD, ANSES, BfR and EFSA as observers. BfR conducted an independent technical evaluation, including statistical analysis, of the project.

In 2023 the data and study reports were submitted to EFSA for review.



Bystander, Resident, Orchard, Vineyard (BROV) Project

The project consisted of two phases.

- Worker re-entry project measuring worker exposure during standard work practices in vineyards.
- Measuring resident/bystander exposure associated with drift from airblast applications in orchards and vineyards during early and late growth stages.

The project team was made up with representatives from CRD, BVL, TNO, JKI, SSAU (Silsoe Spray Applications Unit), CLE and EFSA as an observer.

BROV Project continued

Re-entry worker in vineyard project

- The aim of the project was to refine the Transfer Coefficient (TC) currently used by EFSA. The TC value is a key parameter in the re-entry worker exposure assessment.
- Studies were conducted between 2015 – 2017. An additional study from 2004 was added to the database. The database contained a total of 73 workers.
- Work tasks included hand harvest, pruning, training and shoot lifting in vineyards.
- CRD was the leader of the project and managed the interpretation of the data. A report was published in February 2020.
- The data was not considered in the 2022 update of the Guidance Document but was submitted to EFSA. It is likely to be considered in the next update.



BROV Project continued

Resident/bystander exposure in orchards project

- The aim of the project was to generate drift exposure data to residents/bystanders in orchards and vineyards at early and late growth stages to refine the current EFSA approaches.
- A total of 16 trials were conducted between 2016 – 2017 (8 in orchards and 8 in vineyards).
- CRD was the leader of the project and managed the interpretation of the data. A report was published in September 2021.
- The data was not considered in the 2022 update of the Guidance Document but was submitted to EFSA. It is likely to be considered in the next update.



Dermal absorption

- Due to the conservative approaches taken by EFSA in its 2012 Guidance Document (default values of 25% for concentrates and 75% for spray dilutions), industry (CLE) undertook a project to refine the default values contained in the EFSA guidance.
- Two papers were published as a result of the CLE project (Aggarwal et al., 2014 & 2015).
- Proposed refined default values were 2%, 6% and 30% for solid concentrates, liquid concentrates and all spray dilutions, respectively.
- EFSA reviewed the CLE data and additional data from BfR. In 2017 it published its revised guidance supporting default values of 10% and 50% for water-based formulations and 25% and 70% for solvent-based formulations.

Lessons learned

- The generation and/or sharing of relevant, robust and scientifically sound data forms the basis for working with regulators to refine risk assessment approaches.
- When dealing with EFSA all the raw data and reports need to be fully available.
- A working group position can be reached but EFSA will conduct their own assessment and reach a conclusion that may be very different.
- Timelines can be extended until official adoption (2 – 7 years in the examples given).
- Statistics can be used to interpret the same data set very differently.

Summary

- The generation and sharing of relevant, robust, scientifically sound exposure data is a good way of engaging with regulators.
- In the agrochemical sector data is usually required to be validated at the EU level before member states are willing to accept it.
- Working with key regulatory authorities who are prepared to take the lead in data interpretation and manipulation is a tried and tested way of getting data/approaches to be considered by EFSA.
- However, data review and interpretation at the EU level may be very different from the original project team assessment.
- Trust, communication and transparency are key when working with regulators.

Thank you for your attention