Zonal assessments of the PPP – Austrian view on the harmonised approach in toxicology and exposure assessment

Dr. Tamara Coja, MSc Toxicology
Institute for Plant Protection Products, Department for Toxicology

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Overview

- national specifics of the central zone Member States in exposure assessment (ECPA questionnaire 2010)
- experiences in exposure assessment from the zonal evaluations – overview of the comments by cMS
- additional topics for harmonisation
- benefits of the harmonised approach

National specifics – operator exposure (ECPA questionnaire 2010)

- AT: no national specifics

- BE: for seed treatment SEEDTROPEX model, for application of granules PHED model. For assessment of amateur exposure the new UK POEM "Home garden sprayer (5 L tank)", the French model "Expo Jardin v 3.3" or the UK amateur use model 2. The only PPE we consider for amateurs are gloves. For application in greenhouses, we use the results of a study performed in Germany under the sponsorship of Industrieverband Agar (ECON, Bayer, 1996) if the notifier has access to these data or the NL model. Belgium welcomes an EU harmonized approach and therefore is awaiting the adoption of the EFSA PPR Panel proposed GD.

- CZ: no national specifics

National specifics – operator exposure (ECPA questionnaire 2010)

- DE: For intended uses not covered by the German model the following models are applied: SEEDTROPEX for seed treatment, PHED model for granules, a study performed in Germany under the sponsorship of Industrieverband Agar (ECON, 1996) for greenhouse applications, Amateur exposure is assessed based on the German model (high crop hand held equipment adjusted to 500 m²)

- HU: In the case of certain crops (e.g. Wheat, barley, maize, sunflower and rapeseed) Hungary would require an operator exposure assessment with the German model prepared with a work rate of 50 ha/day

- LU: no feedback

National specifics – operator exposure (ECPA questionnaire 2010)

- NL: specific requirements indicated in the Dutch Plant Protection Products and Biocides Regulations. Use specific models (e.g. EUROPOEM, Dutch model) for different types of uses and types of formulations, have different assessments for amateur/professional products, the prescription of PPE is one of the last refinement-steps (tiered approach: first unprotected operator, then if not yet available may ask for dermal absorption data and finally PPE can be prescribed), might use the NL-AOEL, based on allometric extrapolation (caloric demand) as a refinement, and derive a chronic AOEL if necessary

- PL: applies 20 ha of treated area in both models

National specifics – operator exposure (ECPA questionnaire 2010)

- IE: no feedback

- RO: Use specific models for different types of uses and types of formulations, have different assessment for professional and amateur products

- SK: no national specifics

- SI: For national registration German model (geometric mean), body weight of 70 kg, UK POEM for hand-held application to low targets only. For zonal registration German model (geom. mean) and UK POEM. For seed treatment we use the SEEDTROPEX model. For application of granules we use the PHED model. For indoor use EUROPOEM data can be applied for handlance and knapsack sprayers

National specifics – operator exposure (ECPA questionnaire 2010)

- UK: There are instances when these models are not appropriate, e.g. Indoor use, where EUROPOEM data can be applied for handlance and knapsack sprayers. There are also a number of specialist applications for which Health and Safety Executive data (to be found on ECB website) can be used, such as paint brush application and dipping treatment. For amateurs, HSE data is used to predict exposure when using trigger spray packs, shaker pack dust and granule packs and aerosols. The UK approach is that amateur products should not require PPE, as availability and compliance are not guaranteed

National specifics – bystander and worker exposure (ECPA questionnaire 2010)

- AT: Ganzelmeier et al. model for bystander exposure and Hoernicke et al. model for worker re-entry exposure. Austria welcomes an EU harmonised approach

- BE: Both bystander and worker exposures are estimated according to German BBA methods using some data from EUROPOEM II or data provided by Industry. For workers, dermal absorption usually taken from the diluted preparation and a default DFRO of 3 µg/cm2/kg a.s./ha

- CZ: no national specifics

National specifics – bystander and worker exposure (ECPA questionnaire 2010)

- DE: National guidance on bystander and resident, Martin et al. (2008), J. Verbr. Lebensm. 3, 272 - 281; National guidance on worker re-entry, Krebs et al. (2000), Nachrichtenbl. Deut. Pflanzenschutzd., 52, S. 5 - 9 (In addition to national guidance, TCs for worker exposure are used from EUROPOEM II or from US EPA (2000) Policy No. 3.1.)

- HU: no national specifics

- LU: no feedback

- NL: Use additional NL default values in addition to EUROPOEM II

- PL: no national specifics

National specifics – bystander and worker exposure (ECPA questionnaire 2010)

- IE: no feedback
- RO: no national specifics
- SK: no national specifics
- SI: Worker and bystander exposure assessment accepted when performed according to the UK approach (bystanders: Lloyd et al, 1983 and 1987, workers: values from EUROPOEM project. Re-entry Report, risk assessed for single application)

National specifics – bystander and worker exposure (ECPA questionnaire 2010)

- UK: UK uses data collected from direct measurements of bystander exposure (Lloyd et al, 1983 and 1987). Also, exposure due to volatilisation is assessed in comparison with surrogate data for chlorpyrifos (US) and other insecticides (Siebers). Exposure due to drift fallout is assessed using Rautmann drift data and US EPA data for exposure of children playing on lawns. Worker exposure is evaluated with the EUROPOEM II re-entry model, using the indicative TC values (2500 – 5000 cm2/h) and a default DFR0 of 3 µg/cm2/kg a.s./ha

Necessity of national specifics in toxicology?

- field size certainly depends on national geographic conditions….
- level of technical equipment might differ (even within each single country) …
- reasonableness of PPE might differ based on climatic conditions….

Source: NASA/Goddard Space Flight Center/Bill Hrybyk

Zonal assessments and comments of cMS (exposure assessments)

- misunderstandings on national specifics – these should be dealt with in national addenda but not in the core evaluation

- frequently comments on:
- applied buffer strips for bystanders (either too narrow or to broad …)
- work rate (ha/d) for non-professionals
- applicability of PPE for non-professionals
- appropriate MAF and degradation rate on foliage

- new EFSA GD with the calculator is highly appreciated and will be hopefully further developed for currently not addressed or data poor scenarios

However, the most different opinions are by far related to another topic …..

Some further topics for harmonisation…

- dermal absorption (will be discussed at the conference)

- comparability/bridging of formulations (animal welfare (Article 62 of Regulation (EC) 1107/2009) *versus* level of human protection)

- guidance document on relevance of metabolites in groundwater *versus* relevance of metabolites in food and feed commodities / hazard *versus* risk assessment

- classification and labelling of products based on inherent properties of active substance(s)/co-formulants in formulation:

  latest knowledge *versus* legally binding timelines

  classification and labelling by authority *versus* self-classification

- combined exposure to multiple active substances in one plant protection product / the missing tool *versus* public need

Benefits of the harmonised approach

- better quality of applications and evaluations
- better predictability for applicants and Member States
- time and resource savings for all concerned parties
- improved confidence of cMSs in the evaluation of zRMS
- an easier start for acceding Member States
- less stress ☺ …

Thank you very much for your attention