Evaluation of active substances in plant protection products – Residues

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Active substances

- (EC) No 1107/2009 of EP & Council concerning the placing of PPP on the market
  - (EU) No 283/2013 setting out data requirements for active substances
  - COM Communication 2013/C 95/01 providing list of test methods and guidance documents for the implementation of (EU) No 283/2013 [OECD and EU Guidance documents, EFSA PRIMo]
MRLs for residues of active substances

Pesticide risk assessment in EFSA

PPR Panel
Scientific Opinions & Guidance documents

Reg. (EC) 396/2005
MRL setting, pesticide monitoring

Reg. (EC) 1107/2009
Evaluation of active substances (representative uses)

Reasoned Opinion

Annual report on pesticide residues

PRAS Unit

Conclusion
Assessment of residues

• Pesticide residues = active substance and pertinent metabolites and/or degradation products in:
  – crops and processed plant commodities used as food or feed items
  – food of animal origin
  – drinking water, if relevant

• Data required and methodologies are the same for residue assessments in the framework of (EC) No.1107/2009 and (EC) No.396/2005
Data required for Residues Overview

- Critical GAPs
- Analytical methods
- Storage stability of the residue
- Metabolism in:
  - primary crops
  - processed commodities
  - rotational crops
  - Livestock
- Toxicological relevance of metabolites
- Residue levels in:
  - primary crops
  - processed commodities
  - rotational crops
  - Livestock
- Dietary exposure calculation
Data required – Part 1

- Primary Crop Metabolism
- Livestock Metabolism
- Succeeding Crop Metabolism
- Nature of the residue
- Food Processing Simulation
Investigation of:

- absorption, translocation, distribution and bioaccumulation processes
- identity of alteration products of a pesticide in food from physical-chemical processes incl. metabolism, photolysis, thermal degradation etc.
- differences and similarities across crop groups / livestock species, when raw or processed, by route of exposure for crops
- composition (proportions) and semi-quantitative estimates of levels of residues
Nature of residue

- reflect representative use pattern and processing conditions
- radiotracer method
- **Primary crops**: categories of fruit, root/tuber, leafy crops, cereals, pulses/oilseeds; post-harvest uses
- **Succeeding crops**: root/tuber crop, leafy crop, cereal or oilseed crop
- **Livestock**: ruminant, chicken, fish
- **Food processing**: hydrolysis simulating most common processes such as pasteurization, baking, boiling, brewing
Residue definition

- Potential for exposure in human diet
- Relative toxicity metabolite vs. parent
- Marker compound simply and cost effective analyses
Residue definition for risk assessment

Residues
- Relative amount % of total residue
- Absolute amount mg/kg food
- Frequency of occurrence in matrices

Toxicity
- Active substance
- Metabolites: higher/equal/lower
- Common or different mechanism

Representative of toxicological burden
Data required – Part 2

- Primary Crop Residue Trials
- Animal Feeding Studies
- Rotational Crop Residue Trials
- Food Processing Studies

Magnitude of the residue
Residue levels

Residue field trials

• Establish residue levels in primary crops and succeeding crops (food and feed) at harvest in accordance with residue definition/s

• Defined minimum number of trials per data set to derive Median & Highest residue, and MRL with sufficient certainty

• Representative of cGAP (crop, geographical zone, application method, rate & timing, formulation type, different seasons, plant back intervals …)
Residue levels

OECD MRL Calculator

- harmonising the calculation of MRLs across the OECD countries
- Excel spreadsheet, simple to use without extensive statistical knowledge
- Outputs: lowest, highest and median residue, MRL estimate
Residue levels

Food processing trials

- Distribution and levels in intermediate and end products, applying representative commercial practices
- Calculation of processing factors (reduction or concentration of residues in processed products)
- Default factors for simple operations possible (drying, pressing …)
- Refining of dietary intake estimates
- Facilitate enforcement of residues in processed food and feed items (MRLs are applicable to processed / composite products)
Livestock feeding studies

- Required if significant residues in food of animal origin are expected
- Investigate different doses of pertinent residues in feed items
- Dosing ($\geq 28$ days) until plateau concentration in animal products reached
- Estimation of residues in muscle, liver, kidney, fat, milk, eggs; derive Median & Highest residue, MRL
Surrogate data - Extrapolations

... can reduce data to be generated

Magnitude of residue

Nature of residue
Dietary exposure assessment

Concentration of pesticide in food (STMR, HR, MRL) \times \text{Food consumption} = \text{Dietary Exposure}
EFSA Model - consumer dietary intake assessment of pesticides

Long term dietary intake data
(average consumption data)

Short term dietary intake data
(97.5th percentile consumption data)

PRIMo Pesticide Residues Intake Model
Dietary Risk Assessment

**Chronic:**
- Lifetime exposure
- All food in a mixed diet is treated with the pesticide according to the authorised or intended uses
- Median residue level, ADI

**Acute:**
- only one food item treated with the pesticide, consumed at a large portion with one meal or during one day
- Highest residue level, variability factor, ARfD

**Cumulative:** *(under development)*
- based on Cumulative Assessment Groups (phenomological effects, Mode of Action), dose addition
Dietary Risk Assessment

Toxicological threshold

Intake (in % of the ADI)

Pesticide A acceptable

Pesticide B not acceptable
MRLs are established...

• on the basis of a GAP,
• if residue data requirements are sufficiently addressed,
• using a statistical-method-based calculation tool (OECD MRL calculator)
• if expected residues do not pose a consumer health risk.
Pesticide MRLs

**Avoiding of trade barriers**
Common market-free movement of goods, WTO agreement

**Consumer protection**
No unacceptable consumer risk

**Guarantee for producers**
Compliance with MRL provisions if pesticides are used according to label (GAP)

**Precautionary principle**
Setting of zero-tolerance in case of missing data or uncertainties

**Minimisation principle**
ALARA (as low as reasonably achievable)
Safety margins for MRLs

Intake in % of ADI

Pesticide A
Pesticide B
Pesticide C
Pesticide D
Pesticide E
Pesticide F
Pesticide G
Pesticide H
Pesticide I
Pesticide J
Pesticide K
Pesticide L
Pesticide M
Pesticide N
Pesticide O
Pesticide P
Pesticide Q
Pesticide MRL is NOT …

Borderline between acceptable residue concentration on food

And

Immediate consumer health risk

Thank you for your attention!

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