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MRL setting and intakes for cereals

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Who am I

- Senior adviser at the National Food Institute
- Many years experience from the laboratory
- MRL setting and risk assessment (no laboratory work anymore)
- Responsible for the homepage for cereals and feeds

Legislation

- All MRLs are now harmonised: only set or amend MRLs at the EU level
- Regulation 396/2005
  - MRLs in regulation 149/2008 and 839/2009
  - Commodities in regulation 178/2006
- Regulation 396/2005 covers both food and feed – tomorrow about feed

What is needed to set a MRL

- Residue definition in relevant plants:
  - Which substances are included in the MRLs
  - Which substances shall be determined in the monitoring
  - E.g. residue definition for parathion-methyl is:
    - Sum of parathion-methyl and paraoxon-methyl expressed as parathion-methyl
- Independent validated method for all substances included in the residue definition
  - Two different laboratories have validated the method

What is needed to set a MRL

- MRLs in cereals are set on the background of residue trials conducted according to critical Good Agricultural Practice (GAP):
  - Max. application rate
  - Max. number of treatments
  - Shortest time between treatments
  - Shortest time between treatment and harvest
- IMPORTANT: Setting MRLs in raw agricultural commodity (RAC)
  - e.g. MRL in grain not in flour or bread
  - Calculate back to RAC from flour and bread

What is needed to set a MRL

- At least 8 residue trials for major crops and 4 for minor and very minor crops
- Europe divided in North and South zone (under discussion)
- Major crops in whole Europe Barley, maize, oat, rye, triticale, wheat
- Major in South:
  - Rice and sorghum
- All other cereals are minor or very minor

What is needed to set a MRL

- Enough residue trials from both Northern and Southern countries if uses both places
  - E,g, 8 trials from each if a major crop
- The trials have to be performed
  - Different years
  - Different places/countries

Extrapolation

- Can extrapolate results from residue trials from one commodity to another
  - Not necessary to perform trials for all commodities
  - Only extrapolate if GAPs are similar
  - Same number of treatments, same application rate ± 25 %; E.g. 100 g/ha ≈ 75-125 g/ha
- Dependent on time of treatment
  - Before or after flowering
  - Seed treatment
  - Post-harvest

Extrapolation

- Used close to harvest, after consumable parts are developed (before or after blossom)
  - Barley → oat
  - Wheat → rye and triticale
  - Maize → sorghum and millet
- Used early in growing season
  - Barley, oats, rye, triticale, wheat → each other
  - Maize → sorghum, millet

MRL setting for plants

- Two ways of performing calculations for MRL setting
- $R_{max} = R + k \times s$
  - It is assumed that the residues follow a normal distribution
  - R = mean of residues
  - s = standard deviation of residues
  - k = factor
- Rcal:
  - a non-parametric method (not shown)
  - Rank the residues

MRL setting for plants

- 8 residue trials: 0.2, 0.21, 0.29, 0.36, 0.46, 0.55, 0.66, 1.13 mg/kg
- **Rcal = 1.27**
- **Rmax** = 0.483 + (3.188 x 0.0.308) = **1.46**
  - R = 0.483
  - s = 0.308
  - k (n = 8) = 3.188
- **Proposal: 2 mg/kg**
- Calculate for both for North and South

Risk assessment: Chronic exposure

- Risk assessment performed by comparing the chronic intake with the Acceptable Daily Intake for the pesticide
- Chronic: Whole life
- Use average for consumption and content
- The intake is calculated including all MRLs
- Intake < ADI: no problems
- Intake > ADI: Refinements
- If intake > ADI after refinements:
  - Discussions on what to do
  - What uses should be deleted?

Risk assessment: Chronic exposure

- Refinements:
  - Use median from residue trials in stead of MRL
  - Processing for example:
    - Brewing
    - Baking
    - Peeling (e.g. citrus fruits, pineapple, and banana)

Risk assessment: Acute exposure

- Acute or short term Intake is compared with Acute Reference Dose
- Calculated for each commodity at a time
- Use high intake and MRL
- Different formulas are used depending on commodity
- Acute intake < ARfD: no problems
- Acute intake > ARfD: Refinements
- Acute intake > ARfD after refinements: No approval
- Refinement:
  - Processing
  - Highest residue in stead of MRL

Intake

- European Food Safety Authorisation (EFSA) has collected consumption data from EU Member States
- Database available on the internet
- Put the residue data into the database and both the chronic and acute intake are calculated

EU monitoring programme

- EU monitoring programme also includes cereals
- EFSA has now the responsibility of the monitoring programme
  - Meeting in October about the programme
  - Expect that there will come some changes (reporting the results, what is the results used for)

Thank you for your attention