WTO Workshop on Pesticide MRLs

The EU Policy for Setting Pesticide MRLs

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The regulatory lifecycle of a PPP

Production phase

Regulation (EC) No 1107/2009 on placing of PPP on the market

Use phase

Directive 2009/128/EC on Sustainable Use of Pesticides

Consumption phase

Regulation (EC) No 396/2005 on MRLs of pesticides

Horizontal legislation, esp. Regulation (EC) No 178/2002 General Food Law
General principles

• *Consumer safety vs trade facilitation*
• *Consumer risk assessment*
  • TMDI/ADI
  • IESTI/ARfD
• **ALARA**
  • OECD calculator since 2012
  • default value/LOQ, not zero tolerance
MRLs established based on

- GAPs in EU
- GAPs in Third Countries ("import tolerances"): proof of authorisation and MRL in Third Country
- Codex Alimentarius standards: annual alignment to new CXLs, unless concerns
- Same level of stringency in assessment

MRLs valid for

- Commodities from EU and Third Countries: same MRL for all food and feed on the EU market
MRLs set for

• Raw agricultural commodities, as defined in Annex I to Reg 396/2005

• Processed commodities: MRL(RAC) x PF
• Fish: national standards
• Feed-only: national standards

• See also EU Pesticides database
From application to MRL setting
(MRL applications based on EU uses and import tolerance requests)

APPL \(\xrightarrow{\text{dossier}}\) EMS/RMS \(\xrightarrow{\text{ER}}\) EFSA \(\xrightarrow{\text{RO}}\) COM

- APPL: \(\approx 3\) months
- EMS/RMS: \(\approx 1\) year
- EFSA: \(3-6\) months
- COM: \(< 1\) month

SC PAFF (28 MS) \(\xrightarrow{\text{vote}}\) Council & EP

- SC PAFF: \(1-2\) months
- Council & EP: \(2\) months

COM

- Scrutiny: \(2\) months
- Adoption: \(< 1\) month

MRL

- Draft act: \(\approx 3\) months

Health and Food Safety
Review of existing MRLs

- Full harmonisation of EU-MRLs in 2008
- Based on directives and national MRLs
- Need to review at EU level (RMS => EFSA)
- Delete obsolete MRLs, align to "old" CXLs
- Notification to SPS Committee (draft act)
- Better: early input => see G/SPS/GEN/1494
- Case by case: MRLs maintained with data request
Reasonable period to prepare

- *Time between publication and application*
- *Acts with MRL increases only: 20 days*
- *Acts with MRL decreases: 20 days + 6 months*
- *See EU Pesticides database (hover over MRL)*

- *Transitional measures for products lawfully produced under "old" MRL, unless concerns on consumer protection*
Challenges

- *Interplay PPP and MRL legislation: procedures, timelines, review of legislation*
- *Scope ("currently or formerly used in PPPs")*
  - Dual-use substances: VMPs, biocides, feed additives, biostimulants, fertilisers
  - Use under different legal acts, but residues under Reg 396/2005, and/or need to harmonise
  - Contaminants, naturally occurring substances

- *EU Minor Uses Coordination Facility*  
  => [https://www.minoruses.eu/](https://www.minoruses.eu/)

- *Public perception*
Information (I)

• Guidance document on MRL setting procedure (SANTE/2015/10595 Rev. 4 — June 2016)
• G/SPS/GEN/1494 on MRL review
• Detailed technical and procedural guidance

• http://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines/index_en.htm
Information (II)

- Legal texts:  
  http://eur-lex.europa.eu/homepage.html

- EU Pesticides database:  
  http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public