BfR Workshop on MRL-Setting for biocides

Legal aspects of relevant EU legislation related to pesticides

Almut Bitterhof, European Commission DG Health and Consumers, Unit E.3
Overview

- Basic legislation on pesticides
- Regulation (EC) No 396/2005 on MRLs
- MRL setting procedures
- International dimension – Codex Alimentarius
- DG SANCO MRL database
- Control and Enforcement
- Coordinated EU multiannual programme
- Future review of Regulation (EC) No 396/2005
Basic legislation on pesticides

*Regulation (EC) No. 1107/2009:*
- Placing of plant protection products on the market
- Authorisation of active substances and plant protection products (PPPs)

*Regulation (EC) No. 396/2005:*
- Maximum residue levels of pesticides in and on food and feed of plant and animal origin
Regulation (EC) No. 396/2005

**Scope:** Regulation applies

- to products of plant and animal origin or parts thereof covered by Annex 1 to be used as fresh, processed and/or composite food or feed in or on which pesticides residues may be present
- and without prejudice to
  - Directive 98/8/EC → Reg. 528/2012 (biocidal products),
  - Directive 2002/32 /EC (undesirable substances in animal feed) and
  - Reg. (EEC) No. 2377/90 (veterinary medicinal products)
Regulation (EC) No. 396/2005

**Definition of "pesticides residues":**

Residues incl. active substances, metabolites and/or breakdown or reaction products of active substances currently or formerly used in PPPs (…), which are present in/on the products covered by Annex 1 to this Regulation, incl. in particular those which may arise as a result of use in PPPs, in veterinary medicine and as a biocide
Regulation (EC) No. 396/2005

**Maximum residue level (MRL)**

- Upper legal level of a concentration for a pesticide residue in or on food or feed..., based on Good Agricultural Practice (GAP) and the lowest consumer exposure necessary to protect vulnerable consumers.

- Where there is more than one GAP for an active substance/product combination the critical GAP is the basis for establishing the MRL (critical GAP gives rise to the highest acceptable level of pesticide residues in a treated crop).
Regulation (EC) No. 396/2005

*General principle:* For any substance not covered by the Annexes of Regulation No. 396/2005 that falls under the definition of "pesticides residues" a default MRL of 0.01 mg/kg applies
Annexes of Reg.(EC) No 396/2005

- Not covered by the Annexes
  - Default MRL 0.01 mg/kg
- Annex I
  - List of commodities
    - 315 commodities
- Annex II
  - Existing EU MRLs
    - 228 substances
- Annex III A
  - Temporary MRLs
    - 225 substances
- Annex IV
  - No MRLs required
    - 59 substances
- Annex V
  - Default value other than 0.01 mg/kg
    - 17 substances
- Annex VI
  - Processing factors
    - Not yet established
- Annex VII
  - Fumigants
    - 4 substances

Health and Consumers
Regulation (EC) No 396/2005

*Setting, modifying or deletion of MRLs: 2 main procedures*

- Routine MRL setting: Evaluation of new applications to set or modify specific MRLs, including import tolerances (Art. 10 of Reg. 396/2005)
- Review of existing MRLs (Art. 12 of Reg. 396/2005)
Routine MRL Setting (1)

- Application to the MS in which authorisation is sought
- Clear data requirements
- MS draws up an Evaluation Report and makes it available to COM, MS and EFSA
- EFSA opinion within 3 months or in exceptional cases 6 months
Routine MRL Setting (2)

- SPS notification, if appropriate (60 days commenting period)
- Legislative proposal of COM (within 3 months)
- Discussion with the MS in the Standing Committee and vote
- Adoption after scrutiny (2 months) by Council and Parliament
- Estimated time: 12 months
Import tolerances

- An import tolerance is an MRL for imported products to meet the needs of international trade where
  - The use of the active substance on a given product is not authorised in the EU for reasons other than public health reasons for the specific product and specific use; or
  - A different level is appropriate because the existing EU MRL was set for reasons other than public health reasons for the specific products and specific use
- Basically same procedure as routine MRL setting.
- Registration in country of origin must be proven.
- Supporting data need to be submitted → EFSA assesses the safety of proposed MRLs

- Review of complete set of existing MRLs for more than 300 substances (Art.12 review)
- For substances approved before 1 September 2008: within 1 year
- For substances approved or non-approved after 1 September 2008: within a period of 12 months from the date of approval or non-approval of an active substance
- Exercise much delayed, also due to deficiencies in Reg. 396/2005
International dimension

Codex Alimentarius

- Codex Committee on pesticides residues (CCPR) → EU coordinated positions on CXLs prepared, based on EFSA scientific report
- Implementation of acceptable CXLs in EU legislation annually (second half of each year)
### EU Pesticides database

#### Fluaizinam (F)

<table>
<thead>
<tr>
<th>Code number</th>
<th>Groups and examples of individual products to which the PNRs apply (a)</th>
<th>Res. (FE) No 251/2013</th>
<th>Res. (EC) No 396/2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td><strong>St▍te of Pesticide</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>01300001</td>
<td><strong>Rust</strong></td>
<td>0.05*</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130020</td>
<td><strong>Citrus</strong></td>
<td>0.05*</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130030</td>
<td><strong>Cherry</strong></td>
<td>0.05*</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130040</td>
<td><strong>Elderberry</strong></td>
<td>0.05*</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130050</td>
<td><strong>Grape</strong></td>
<td>0.05*</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130060</td>
<td><strong>Gooseberry</strong></td>
<td>0.05*</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130070</td>
<td><strong>Horseradish</strong></td>
<td>0.05*</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130080</td>
<td><strong>Macadamia</strong></td>
<td>0.05*</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130090</td>
<td><strong>Peach</strong></td>
<td>0.05*</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130100</td>
<td><strong>Pine nuts</strong></td>
<td>0.05*</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130110</td>
<td><strong>Pitahaya</strong></td>
<td>0.05*</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130120</td>
<td><strong>Walnuts</strong></td>
<td>0.05*</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130130</td>
<td><strong>Olives</strong></td>
<td>0.05*</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130140</td>
<td><strong>Pine nuts</strong></td>
<td>0.05*</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130150</td>
<td><strong>Grape (Cultivar)</strong></td>
<td>0.05*</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130160</td>
<td><strong>Pears</strong></td>
<td>0.05*</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130170</td>
<td><strong>Quince</strong></td>
<td>0.05*</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130180</td>
<td><strong>Medlar</strong></td>
<td>0.05*</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130190</td>
<td><strong>Liqueur</strong></td>
<td>0.05*</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130200</td>
<td><strong>Cigars</strong></td>
<td>0.05*</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130210</td>
<td><strong>Raisins</strong></td>
<td>0.05*</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130220</td>
<td><strong>Cranberries</strong></td>
<td>0.05*</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130230</td>
<td><strong>Grapefruits</strong></td>
<td>0.05*</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130240</td>
<td><strong>Tangerines</strong></td>
<td>0.05*</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130250</td>
<td><strong>Lemons</strong></td>
<td>0.05*</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130260</td>
<td><strong>Oranges</strong></td>
<td>0.05*</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130270</td>
<td><strong>Apricots</strong></td>
<td>0.05*</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130280</td>
<td><strong>Peaches</strong></td>
<td>0.05*</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130290</td>
<td><strong>Plums</strong></td>
<td>0.05*</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130300</td>
<td><strong>Nectarines</strong></td>
<td>0.05*</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130310</td>
<td><strong>Grapes</strong></td>
<td>0.05*</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130320</td>
<td><strong>Scuppernong</strong></td>
<td>0.05*</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130330</td>
<td><strong>Passion fruits and related hybrids</strong></td>
<td>0.05*</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130340</td>
<td><strong>Plums (except Prunus domestica) and Prunus spinosa</strong></td>
<td>0.05*</td>
<td>0.05*</td>
</tr>
</tbody>
</table>

*Pesticide residue and maximum residue levels (mg/kg).*
Control and Enforcement

- Compliance against MRLs is checked by MS authorities
- Unauthorised uses can be controlled through the setting of MRLs at LOD where no authorised uses exist
- Coordinated EU multiannual programme
- Rapid Alert System on Food and Feed
- Art. 15(5) of Regulation 882/2004 – pesticides in food/feed of non-animal origin with increased level of official control at import
- FVO audits in Member States and Third Countries
Coordinated EU multiannual programme

- Dual purpose: a) Check for compliance with MRLs and b) dietary exposure assessment
- Rolling programme with 3 year cycles covering major dietary contributors (3x17 commodities)
- Basis for national monitoring programmes of the MS
- 2015 – 2017 programme voted in February 2014 (166 pesticides)
Review of Reg. 396/2005

- Review should run parallel to planned review of Reg. 1107/2009
- Alignment to Lisbon Treaty
- Addressing legal gaps and clarifications (procedural aspects, dual use substances, etc.)
- Biocides?
Useful links

• **DG SANCO webpage, pesticides:**

• **MRL database:**
Questions?

**Contact:** Almut. Bitterhof@ec.europa.eu