NL view on biocide MRLs

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Contents

1. NL history on biocide MRLs
2. Enforcement
3. Dietary risk assessment
4. Legislation
NL History on Biocide MRLs (I)

Prior to 2008

After 2008

NL Regulation MRLs for PPP and BP

EU harmonisation PPP MRLs

NL Regulation BP MRLs
- PTSA
- ICA
- CC
- BrAc
- QAC
NL History on Biocide MRLs (II)

- **ALARA principle:**
  Minimize biocide residues in/on food, feed, water or livestock

- **Label:** risk mitigation measures
  - Remove or cover food/feed before treatment
  - Obligatory rinsing
  - Treatment out of reach of livestock

- **Biocide use should not result in residues in food:**
  MRL = LOQ of analytical method
MRL setting?

- No MRLs
  - residues identified by coincidence
  - problematic food areas and trends not easily identified
  - if identified, ad hoc dietary risk assessments necessary
  - food safety authority too late to act

- MRLs
  - monitoring program is obligatory
  - problematic food areas and trends easily identified
  - food safety authorities can act directly when MRL is exceeded
  - food producing industries and food retailers are triggered
  - ensures risk mitigation measures are followed
Enforcement/monitoring in NL

- **PT 4 disinfectants**
  - QAC - 0.5* mg/kg
  - PTSA - 0.1* mg/kg
  - ICA - 1* mg/kg

- **2000-2012: QAC & PTSA > MRL:**
  - (soft) ice cream, milkshakes, whipped cream, cream cake, minced meat/beef/steak, sausages

- **PT19 repellent**
  - DEET – 0.01* mg/kg

- **2013: DEET > MRL:**
  - hand picked rosemary, wild mushrooms, glasswort
Dietary risk assessment (I)

- Residue concentration: MRLs
- Consumption
  - Toxicological reference value (hazard)
  - Residue intake (exposure)
  - MRLs safe?
Dietary risk assessment (II)

- VMP
- PPP
- Raw commodities
- BP
- Food additives
- Contaminants
- FCM
- Processed foods
Dietary risk assessment (III)

- **Screening**
  - FCM: 1 kg food packaged
  - FA budget method: 1.5 kg solids and 6 L liquids
  - VMP – food basket 0.5 kg meat + 1.5 L milk + 0.1 kg eggs

- **Survey based**
  - FAIM: 18 food/drink groups
  - PPP: EFSA PRIMo
  - CONTAM: EFSA comprehensive database

- **Level of refinement**
Dietary risk assessment (IV)

Biocide product types identified by DRAWG (now ARTfood)

| Disinfectants, Preservatives, Pest control, Antifouling | PT3, PT4, PT5 PT6, PT8, PT12 PT18, PT19 PT 21 | raw, processed and mixed foods of plant and animal origin, packaged foods, drinks, water, raw fish and shellfish |

Similarity with consumption model for food additives

<table>
<thead>
<tr>
<th>Food additives</th>
<th>Screening</th>
<th>Budget method: 1.5 kg solid foods + 6 L drinks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Survey based</td>
<td>FAIM: 18 groups covering all foods: raw foods of plant and animal origin (incl fish), processed foods, drinks, sweets, mixed foods, water</td>
</tr>
</tbody>
</table>
Possible estimation biocide MRLs

- **ALARA** – risk mitigation measures
  - default biocide MRL
    - 0.01 mg/kg food (as in PPP) or
    - LOQ of analytical method (as in PPP)
- **MRLs, MLs already set** for VMP, PPP, FA (in specified foods only) or SMLs set for FCM can be taken over by biocides, assuming biocide use will result in lower residues
- **Actual levels** in specified foods
  Proposal by Applicant
  - Show biocide use is necessary
  - Show risk mitigation measures are insufficient
  - Substantiate levels in (specified) foods by studies
  Assessment by CA
Possible biocide MRL setting procedure

MRLs – default, from VMP, PPP, or actual levels in food

Consumption Screening model or Survey based model

Toxicological reference value (hazard) (ADI, TDI, ARfD)

Residue intake (exposure)

MRLs safe?

yes → MRLs set

yes
Legislation

- **VMP** – biocides no veterinary claim, biocide residues may occur post-slaughter during/after processing
- **PPP** – biocides no use on living plants, biocide residues may occur post-harvest during/after processing
- **FA** – biocides no efficacy in final foods
- **CONTAM** – biocide use intended/regulated
- **FCM** – biocide use not limited to use in packaging materials
Legislation

Options for biocides

● Prepare amended legislation for biocide residues describing dietary risk methodology and biocide MRL setting procedures
● Merge MRLs in Reg 396/2005 (PPP) with Reg 37/2010 (VMP), if necessary, add additional food groups for biocides
● Committee/Procedure to coordinate VMP, PPP, BP proposals for MRLs
Pyrethr ine/Pyrethrum example

- **VMP** - MRLs not necessary: 1998 TMDI < ADI
- **PPP** - Reg EC 149/2008
  - MRLs 0.5-3 mg/kg for all plant commodities
  - MRLs 0.05* mg/kg for all animal commodities
  - TMDI - PRIMO rev 2 – 330% ADI (3.3 x exceedance)
- **BP** - PT18 treatment in livestock housing
  - residues > 0.05* mg/kg in raw animal commodities

- BP MRLs cannot be taken from VMP or PPP
- VMP MRLs <> PPP MRLs;
- 45% ADI for VMP, 55% ADI for PPP ??
- ADI is exceeded, who decides which MRLs go?
Recommendations/summary

- Biocide residues are not zero
- ALARA principle – risk mitigation, MRL setting, monitoring
- MRL set at default level of 0.01* mg/kg or LOQ
  MRL taken over from VMP/PPP
  MRL at actual levels (no alternative & risk mitigation difficult)
- Amend existing legislation – dietary risk model – MRL procedure
- Merge MRL list for VMP and PPP and add biocide MRLs
- Coordination for VMP – PPP – BP MRLs