



Legal aspects of relevant EU legislation related to contaminants and veterinary medicinal products

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MRL setting for biocides
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Overview – contaminants & residues of veterinary medicinal products

- *Basic legislation*
- *Definition and scope*
- *Risk assessment*
- *Procedures setting standards*
- *Time frame of procedures*
- *Control and enforcement*
- *Data collection & monitoring*

Scene setting only

Basic legislation on contaminants

- *Regulation (EEC) No. 315/96*
 - ALARA principle following good practices
 - Maximum tolerances for specific contaminants

- *Regulation (EC) No. 1881/2006:*
 - Maximum levels in certain foods for
nitrate, mycotoxins (aflatoxins, ochratoxin A, patulin, deoxynivalenol, zearalenone, fumonisins, T-2 & HT-2), metals (lead, cadmium, mercury, inorganic tin), dioxins and dioxin-like PCBs and polycyclic aromatic hydrocarbons, melamine

Definition and scope contaminants

- *Any substance not intentionally added to food which is **present in such food***
 - **as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food,**
or
 - **as a result of environmental contamination**
- *Extraneous matter is not covered by this definition*
 - **for example, insect fragments, animal hair, etc...**

Risk assessment contaminants

- *EFSA Scientific Opinion & Exposure reports*
 - **Health Based Guidance Value (TDI, TWI...)**
 - **Margin of Exposure approach**

 - **Most important contributors**
 - **More vulnerable consumer groups**

- *Occurrence data generated*
 - **By MSs**
 - **By stakeholders (major contributors)**

Procedures setting maximum levels (MLs) for contaminants

- *Occurrence data*
- *EFSA Opinions and Exposure Reports*
- *Major contributors*
- *Most vulnerable groups*
- *ALARA principle (95th percentile)*

- *Setting of MLs*
- *Consumption advice*

Time frame for contaminant ML

- *EFSA Opinion > 1 year*
- *Data collection 1 – 2 years*
- *Discussions at expert levels < 1 → 3 years*
- *SPS notification (60 days)*
- *Vote in Standing Committee*
- *Scrutiny for Council and European Parliament (3 months)*

- *Total estimated time:*
 - **1 (→ 3) year for opinion**
 - **1 (→ 3) years for setting of ML**

Data collection & monitoring for contaminants

- *"Emerging" contaminants*
 - **Monitoring recommendations → occurrence data collection (MSs & interested/affected stakeholders) → exposure assessment → MLs**
- *Contaminants in 1881/2006*
 - **Article 9 → occurrence data to EFSA (mostly MSs) → exposure reports → review of MLs?**

Basic legislation on veterinary medicinal products

- *Directive 96/22/EC and Decision 1999/879/EC – "Hormone ban" and "rbST ban"*
- *Directive 2001/82/EC "veterinary code"*
- *Regulation (EC) No 470/2009 – procedure related to establishment of MRLs and RPAs*
- *Regulation (EU) No 37/2010 – List of MRLs*

- *Directive 96/23/EC & Decision 97/747/EC – "residue monitoring"*

Definition and scope residues

- *residue of substances having a pharmacological action, of their metabolites and of other substances **transmitted to animal products** and likely to be harmful to human health*
 - **MRL – maximum residue limit – maximum concentration of residue in food of animal origin for allowed substances**
 - **RPA – reference point for action – level of residue established for control reasons for non-allowed substances in food of animal origin**

Risk assessment VMPs

- *EMA (CVMP) Opinion*
 - **Based on ADI approach**
 - **(Alternative approaches)**
 - **(Monitoring or exposure data)**
- *MRLs proposed if needed*
 - **Will be used to calculate withdrawal time needed for authorisation of VMP**
- *Four possible outcomes (→ listing in R 37/2010)*
 - **No MRL needed, (provisional) MRL, prohibited substance**
- *MRLs only for "target tissues"*
 - **Muscle, liver, kidney, fat, milk, eggs, honey**

Procedures setting MRLs for VMPs

- *Data submission by applicant / producer of the substance*
- *EMA evaluation of active substance*
 - **Metabolism and depletion in relevant animal species**
 - **Type and amount of residue considered not to present a safety concern for human health**
 - **Risk of toxicological, pharmacological or microbiological effects in human beings**
 - **Residues that occur in food of plant origin or that come from the environment**

MRLs for biocidal substances used in animal husbandry

Article 10 R 470/2009 contains specific provisions

- *on procedures*
 - **referring to EMA**
- *on classification*
 - **in specific act**
- *on costs of evaluation*
 - **fee to be decided**
 - EMA part on EMA budget**
 - rapporteur not on EMA budget**

Time frame establishment of MRLs

- *Evaluation 225 – 360 days*
 - **EMA evaluation < 210 days ("stop the clock" mechanism)**
 - **15d + 60d for applicant to request re-examination**
 - **60d for EMA to adopt final evaluation**
 - **15d to inform COMM**
- *Legislative drafting*
 - **Approx. 4 – 6 months**

Procedures setting RPAs

- *Based on methodological principles & scientific methods*
 - **EFSA opinion available**
 - **Toxicological screening/subdivision**
- *Lowest residue concentration which can be quantified with a validated analytical method*
 - **Analytically driven, CC_{α} (\approx LOD)**
 - **\approx practical implementation of zero tolerance**
- *Where appropriate, request to EFSA for a risk assessment as to whether the RPAs are adequate to protect human health*

Procedures setting RPAs: all non-allowed substances → RPA?

- When it is deemed necessary in order to ensure the functioning of controls of food of animal origin imported or placed on the market → RPA
- Substance is authorised for use in VMP in a third country and no MRL in EU legislation (e.g. therapy for a disease / condition not occurring in the EU) → MRL is possible (Article 9(1)(a) of R 470/2009)

Time frame establishment of RPAs

- *If substance covered by EFSA generic RPA opinion*
 - → **discussion in expert committee and vote in Standing Committee**
 - → **depending on the urgency, (very) fast**
- *If substance excluded from generic RPA opinion*
 - → **specific RPA opinion needed (1 year)**
 - → **discussion in expert committee and vote in Standing Committee**

Control and enforcement for VMPs

- *Controls allowed substances → target tissues*
 - **No MRL required: little relevance**
 - **(Provisional) MRL: compliance against MRL**
- *Controls prohibited substances / banned uses → all matrices*
 - **Zero tolerance**
- *Not recommended to apply MRLs on processed products, even less on composite products*
- *Enforcement:*
 - **Very prescriptive follow-up measures aiming at prevention of repetition of non-compliance**

Data collection & monitoring for VMPs

- *Residue monitoring plans*
 - **Very prescriptive species / sampling ratios**
 - **Substance groups to be included**
 - **Emphasis on detection of abuse**
 - **Targeted (& suspect) sampling**
- *live animals, their excrement and body fluids and in tissue, animal products, animal feed and drinking water*
- *production process of animals and primary products of animal origin*

Thank you for your attention

Questions?

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