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

Frank Swartenbroux, European Commission
DG Health and Consumers, Unit E.3

BfR Workshop on MRL setting for biocides
17 & 18 March 2014

Health and Consumers

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**

Control and enforcement for contaminants

- *Only MLs for the important contributors*
- *Levels detected in other commodities?*
  - **Processing factor – Art. 2 of R 1881/2006**

    Dried, diluted, processed and compound foodstuffs

    FBO info, if not → competent authority
  - **Commodities for which no MLs are set – Art. 14 of R 178/2002**

    Injurious to health, unfit for human consumption
  - **Composite products**

    Depending on the composition

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, CCα (≈ LOD)**
  - **≈ 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?

Contact:
frank.swartenbroux@ec.europa.eu

European Commission