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

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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
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, $CC_\alpha (\approx \text{LOD})$
  - $\approx$ 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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