NEW REGULATION FOR VETERINARY DRUGS – IMPACT FOR THE PESTICIDE NETWORK?

European Commission

EURL-AO

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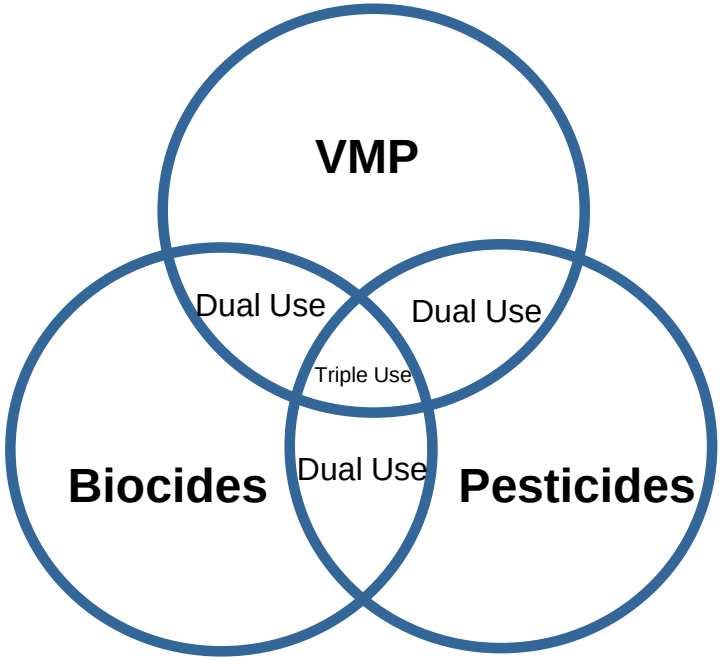
INTRODUCTION

- Veterinary Medical Products (VMP)
- Pesticides
- Biocides

- Different Regulations
- Different validation requirements
- Most MRLs harmonized



INTRODUCTION

- Some veterinary drugs are also used as pesticides or biocides

- Validation concepts
  - Veterinary Medical Products Residues:
    - Commission Implementing Regulation (EU) 2021/808 of 22 March 2021 repealing Decisions 2002/657/EC and 98/179/EC
  - Pesticide Residues:
    - Analytical Quality Control and Method Validation Procedures for Pesticide Residues Analysis in Food and Feed (SANTE 11312/2021)

- Different requirements for validation
  - Requirements of SANTE document are simpler comparing to the veterinary drugs requirements (eg. cc alpha and cc beta!)
  - SANTE document has more focus on quality control routine

QUESTION

- So what can laboratories do when analysing pesticides in official control and in national residue control plans (NRCP) for veterinary drugs?

- Situation so far:

  Agreement, that validation following AQC guidelines is accepted.

- Is this agreement from 2010 still in place?

FORMER SITUATION

- **Former rules:**
  - **Council directive 96/23/EC**
    - **Requirements to monitor certain substances and resides thereof in live animals and animal products**
    - **Annex I**
      - **Group A (zero tolerance)**
      - **and B (Veterinary drugs and contaminants)**

FORMER SITUATION

- **Former rules:**
  - **Council directive 96/23/EC**

GROUP B — **Veterinary drugs** (1) **and contaminants**

(1) Antibacterial substances, including sulphonomides, quinolones

(2) Other veterinary drugs

(a) Anthelmintics

(b) Anticoccidials, including nitroimidazoles

(c) Carbamates and pyrethroids

(d) Sedatives

(e) Non-steroidal anti-inflammatory drugs (NSAIDs)

(f) Other pharmacologically active substances

(3) Other substances and environmental contaminants

(a) Organochlorine compounds including PcBs

(b) Organophosphorus compounds

(d) Chemical elements

(d) Mycotoxins

(e) Dyes

(f) Others

Cut off values and MRLs available
→ Validation according to SANTE doc.

SITUATION?

- **New rules from 15 Dec 2022:**
  - **Commission Delegated Regulation (EU) 2022/1644 of 7 July 2022**
    - **specific requirements for the performance of official controls on the use of pharmacologically active substances authorised as veterinary medicinal products or as feed additives and of prohibited or unauthorised pharmacologically active substances and residues thereof**
    - **Annex I Group A (Prohibited or unauthorised pharmacologically active substances in food-producing animals)**

3. Pharmacologically active substances, not listed in Table 1 of the Annex to Regulation (EU) No 37/2010 ([2]) or substances not authorised for use in feed for food-producing animals in the Union according to Regulation (EU) No 1831/2003 of the European Parliament and of the Council ([3]):

(a) Dyes;

(b) Plant protection products as defined in Regulation (EU) No 1107/2009 of the European Parliament and of the Council ([4]) and biocides as defined in Regulation (EU) No 528/2012 of the European Parliament and of the Council ([5]) which may be used in animal husbandry of food-producing animals;

(c) Antimicrobial substances;

(d) Coccidiostats, histomonostats and other antiparasitic agents;

(e) Protein and peptide hormones;

(f) Anti-inflammatory substances, sedatives and any other pharmacologically active substances;

(g) Antiviral substances.

Zero tolerance for all substances in group A: samples non-compliant in case of detection (concentration > cc alpha)

SITUATION?

- **New rules from 15 Dec 2022:**
  - **Commission Delegated Regulation (EU) 2022/1644 of 7 July 2022**
    - **Annex I Group B (Pharmacologically active substances authorised in food-producing animals)**

Group B – Pharmacologically active substances authorised for use in food-producing animals

1. Pharmacologically active substances listed in Table 1 of the Annex to Regulation (EU) No 37/2010:
   (a) Antimicrobial substances;
   (b) Insecticides, fungicides, anthelmintics and other antiparasitic agents;
   (c) Sedatives;
   (d) Non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids and glucocorticoids;
   (e) Other pharmacologically active substances.

2. Coccidiostats and histomonostats authorised according to Union legislation, for which maximum levels and maximum residue limits are set under Union legislation

Cut off values and MRLs available
→ Validation according to SANTE doc.

SITUATION?

- **New rules from 15 Dec 2022:**
  - **Commission Delegated Regulation (EU) 2022/1644 of 7 July 2022**
    - **Annex I Group A (Prohibited or unauthorised pharmacologically active substances in food-producing animals)**

3. Pharmacologically active substances, not listed in Table 1 of the Annex to Regulation (EU) No 37/2010 ([2]) or substances not authorised for use in feed for food-producing animals in the Union according to Regulation (EU) No 1831/2003 of the European Parliament and of the Council ([3]):

(a) Dyes;

(b) Plant protection products as defined in Regulation (EU) No 1107/2009 of the European Parliament and of the Council ([4]) and biocides as defined in Regulation (EU) No 528/2012 of the European Parliament and of the Council ([5]) which may be used in animal husbandry of food-producing animals;

(c) Antimicrobial substances;

(d) Coccidiostats, histomonostats and other antiparasitic agents;

(e) Protein and peptide hormones;

(f) Anti-inflammatory substances, sedatives and any other pharmacologically active substances;

(g) Antiviral substances.

Zero tolerance for all substances in group A: samples non-compliant in case of any detection of a pesticide not authorized as/in a VMP (concentration > cc alpha)

SITUATION?

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SITUATION

- **New rules from 15 Dec 2022:**
  - **Commission Delegated Regulation (EU) 2022/1644 of 7 July 2022**
    - **Is there a gap in interpretation of detected pesticides?**

Pesticides or biocides not authorized as VMP detected and confirmed at any concentration in food of animal origin result in non-compliance, even if MRLs or *MRL for pesticides or biocides exist.

Examples are fipronil in egg or pyrethroides in meat.

- unauthorized as VMP
- *MRL for pesticides (Fipronil in egg): 0.005 mg/kg
- detected @ 0.003 mg/kg, cc alpha = 0.002 mg/kg -> sample non-compliant

For pesticides or biocides not authorized as VMP, pesticides or biocides the “default *MRL” of 0.010 mg/kg according Regulation (EC) 396/2005 will be ignored. Thus, detected and confirmed concentrations (≥ cc alpha) in food of animal origin even far below 0.01 mg/kg result in non-compliance.

QUESTIONS AND CONCERNS

- What about validation rules?
- Is the agreement from 2010 still valid?
- What about interpretation of results for pesticides and biocides in group A?
  - Is zero tolerance used in case of findings of unauthorised pesticides?
- EURL AO contacted the Commission and the EURL for Veterinary Drugs (group A3b) in Berlin
- Clarification from Commission as follows

CLARIFICATIONS

- **Clarification regarding validation**

- **A3b unauthorized substances (plant protection products and biocides)**

- **Validation procedures for pesticide residues as well as for VMPR could be used (as decided by a Member State)**

Both validation concepts accepted!

CLARIFICATIONS

- **Existing MRLs of pesticide residues are considered!**
- **Enforcement level for A3b substances not authorized as VMP, but with established MRL or default MRL of 0.01 mg/kg as pesticide residue**
- **Validation according to SANTE guidelines, level for enforcement is MRL or default MRL considering measurement uncertainty (±50%)**
- **Results are reported under the pesticide domain (→ to EFSA)**

CLARIFICATIONS

- **Existing MRLs of pesticide residues are considered!**

- **Number of samples taken in the frame of VMPR control plan have to be reported under the VMPR control plan with indication that analytical results are reported to EFSA (pesticide domain)**

CLARIFICATIONS

- **Existing MRLs of pesticide residues are considered!**
- **In case of MRL exceedances the food shall not be placed on the market or shall be withdrawn from it**
- **Findings of a pesticide that may be used a veterinary medicinal product not authorised may be investigated by a Member State and can lead to penalties for unauthorized use of that substance**
- **As long as no pesticide MRL is exceeded, the food should remain on the market and no withdrawl is performed**

SUSPICIOUS OBSERVATIONS

- **Findings of a pesticide that may be used a veterinary medicinal product (VMP) not authorised may be investigated by a Member State and can lead to sanctions for unauthorized use of that substance**
  - **List of EURL Vet drugs (Berlin) with potential use as veterinary drugs (not complete)**

Malathion
Metaflumizone
Pyriproxyfen
Spinetoram
Spinosad
Chlorpyrifos
Dichlorvos
Dinotefuran
Dioxathion
Fenoxycarb
Fenthion
Fipronil
Flucythrinate
Indoxacarb
Methoprene
Methoxychlor
Nitenpyram
Propoxur
Rotenone
Tetrachlorvinphos
Tetramethrin
Triflumuron
Pyriprol

CONCLUSIONS

Pesticide - Veterinary Drug – Biocide

- Both validation concepts are accepted for A3b substances
- Results validated under SANTE guidelines (pesticides) reported to EFSA (pesticides domain), but number of samples under VMPR control plan
- In case of pesticide MRL compliance the food should remain on the market
- Unauthorised use can be investigated by Member States

THANKS TO…

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Thank You
for Your Attention

EURL EUROPEAN UNION REFERENCE LABORATORY