

VMD Open Meeting

10 January 2008

**Proposed replacement of
Council Regulation 2377/90 on
procedures to establish MRLs**

#201855 – 2377/90 – 08/02



 ASSURING THE SAFETY, QUALITY AND EFFICACY
OF VETERINARY MEDICINES

Purpose of Meeting

- Background
- Proposed changes to 2377/90
 - Extrapolation,
 - Pharmacologically active substances used outside the EU/Codex MRLs,
 - Reference Points for Action,
 - Biocides,
- Directives 96/22 and 96/23



- Commission's "Reflections" consultation exercise in 2004 sought to achieve a balance between:
 - protection of animal health and animal welfare;
 - maintain consumer protection and confidence;
 - facilitate international trade.



- Three pieces of legislation were identified for possible change:
 - **Council Regulation 2377/90** establishing procedures for setting MRLs for veterinary medicinal products;
 - **Council Directive 96/22** on substances prohibited in stock farming;
 - **Council Directive 96/23** requiring Member States to have a residues surveillance programme for national produce.



- **Proposal to replace Council Regulation 2377/90 emerged in April 2007**
- Legal basis to adopt Codex MRLs as EU MRLs where EU agrees the science,
- Create a legal basis for making extrapolation a compulsory part of any assessment of an MRL application,
- To establish Reference Points for Action for substances not authorised for use in the EU for control purposes.



- Initial consultation exercise (one month) held by VMD during September 2007,
- Several Council Working Group Meetings held, particularly mid-September to late November,
- Feedback from consultation and MSs is agreement in principle to Codex MRLs and extrapolation to increase availability of VMPs,
- Scientific basis, supported by guidelines, must be sound.



- No specific concerns expressed about Reference Points for Action during VMD consultation exercise,
- UK and several other MSs expressed concern in CWGs about how they will work,
- Became clear that Commission want to include MRLs for biocides in this legislation.



- No changes to current stringent data requirements and evaluation procedures for VMP applications,
- Applicant for MRL submits dossier to the European Medicines Agency (EMA),
- EMA will carry out scientific risk assessments and draw up risk management recommendations.



Extrapolation (Article 5)

- Proposal will give a legal basis for EMEA to consider extrapolation when assessing applications:
 - using MRLs for substance/foodstuff for another food from same species, *or*
 - using MRL for substance in one/more species for other species, *or*
 - using MRL for substances/foodstuff for another foodstuff derived from other species.



- Commission in consultation with EMEA, will adopt rules specifying circumstances under which scientific data may be used for extrapolation,
- These rules will be adopted in accordance with the regulatory procedure with scrutiny (“Comitology”).



Pharmacologically active substances in VMPs used outside the EU or in biocidal products in EU (Article 9)

- Commission or MS may request an opinion on a substance from the EMEA:
 - Substance is in VMP in a 3C and no company has submitted an EU application for that substance;
 - Substance is in a VMP intended to be used under Article 11 of Directive 2001/82 (“cascade”) but no company has submitted an EU application;
 - P.a.s. in biocidal products used in the EU.



Classification of pharmacologically active substances (Article 13)

- Classification to include p.a.s., therapeutic class, conditions and restrictions where applicable, and establish whether:
 - 2a) needs an MRL
 - 2b) a provisional MRL
 - 2c) no need for MRL
 - 2d) prohibition on administration of a substance



- An MRL shall be laid down and reviewed by EMEA where it appears necessary to protect public health,
- Provision for adopting future Codex MRLs where the EU agrees the science without an additional EMEA assessment,
- Administration prohibited where use of a substance is a risk to human health, or where no final conclusion on risk to human health can be drawn,



Reference Points for Action (Article 15)

- Can be set for substances covered by Article 13(2)(d) – prohibition on administration,
- Reviewed regularly in the light of technical and scientific progress,
- Measures adopted in accordance with the regulatory procedure with scrutiny.



Reference Points for Action (Article 16)

- Could be based on analytical limit recommended by the Community Reference Laboratory,
- If basic scientific data on substance are available, Commission shall forward a request to European Food Safety Authority (EFSA) for assessment on human health risk,
- Rules to be adopted by the Commission in consultation with EFSA.



Reference Points for Action

- Apply to EU and 3C producers,
- Produce below the RPA could enter the food chain in accordance with Commission Decision 2005/34,
- 3C produce in breach of the RPA can be destroyed or re-dispatched (usually back to country of origin) – Council Regulation 882/204.



Reference Points for Action

- How do we deal with an EU producer caught using a prohibited substance with an RPA?
- Council Directive 96/23 requires animals to be slaughtered immediately where illegal treatment is confirmed. Will RPAs affect this?
- Allowing destruction or re-dispatch of imports above the RPA has not produced the consistency requested by 3Cs.



Biocides

- Commission would like to include; biocides used in animal husbandry in this proposal,
- no mechanism currently for setting MRLs for these substances,
- Envisaged that EMEA will take on this role.



In favour of EMEA taking this on;

- no need for a new Agency within EU Chemicals Agency to evaluate on limited number of biocides,
- having EMEA and MS VMP experts assess p.a.s. in biocide products ensure a consistent approach,
- EMEA will be clearer about the quality of data needed.



Biocides

Factors against:

- options for funding EMEA and MS involvement in setting MRLs must be explored first,
- there must be a serious assessment of the predicted workload,
- how prioritise between biocide and VMP applications, since both will have same timescales.



The way forward

- Next Council Working Group on 14 January,
- Presidency (Slovenia) looking to reach a conclusion on RPAs and biocides,
- Difficult to tell how soon CWG will reach agreement,
- European Parliament Committees looking at proposal.



Communication

- Will carry out a full three month consultation as soon as practicable,
- Papers on RPAs and biocides prepared to inform stakeholders and help CWG progress on VMD website,
- Summaries of future CWG meetings and other developments will also go on website,
- Feel free to contact David or myself at any time.



Council Directive 96/22

- Proposal phasing out remaining (therapeutic) used in food producing animals of oestradiol B17 agreed at Council, removes companion animals from the restrictions,
- Removes restrictions on use of beta-agonists in horses,
- Possibility of the ban extending to cover five other hormonal substances relating to food producing animals,
- Proposal has still to clear European Parliament.



Council Directive 96/23

- No proposals for change yet,
- UK seeking move to a more risk-based approach in surveillance, and
- Greater scope for MS to choose substance / foodstuffs combinations they see as domestic problems,
- Better joined-up approach with the Community Reference Laboratories.

