

**European Community comments for the**

**CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS**

**Sixteenth Session**

**Cancun, Quintana Roo, Mexico, 8 -12 May 2006**

**Request for comments on draft and proposed MRLs for Veterinary Drugs  
(at step 6 and step 3 of the Procedure)  
(CX/RVDF 06/16/07)**

**Agenda item 6d**

*European Community Competence  
European Community Vote*

**Colistin:** The EC supports the proposed Codex MRLs for colistin.

**Erythromycin:** The EC cannot support the proposed Codex MRLs for erythromycin at present. In absence of a detailed JECFA report a thorough review of the JECFA assessment was not possible, and it appears that different data were available to JECFA than to the CVMP when the substance was assessed in the EU. The EC will review the JECFA assessment once the report will be made available.

**Flumequine:** The EC supports the proposed Codex MRLs for flumequine in shrimps.

**Melengestrol acetate:** The substance was evaluated by JECFA for use as growth promoters. Such use of hormones with estrogenic, androgenic or gestagenic action is prohibited in the European Union. This provision is permanent for oestradiol 17B and provisional for the other hormonal substances. It is also in line with Article 5.7 of the SPS Agreement. It applies while the Community seeks more complete scientific information. The European Commission (by means of the Scientific Committee on Veterinary Measures relating to Public Health – SCVPH, and now the European Food Safety Authority - EFSA) reviews regularly any additional scientific data from all possible sources that is publicly available. This entails continuing to review, as done in 2000 and 2002, the availability of scientific publications and evaluation reports<sup>1</sup>.

The 2002 review of the Scientific Committee on Veterinary Measures relating to Public Health considered the report on melengestrol acetate prepared by the 54th meeting of JECFA and observed that it provides a comprehensive review of the pharmacokinetic/toxicokinetic parameters (adsorption, distribution, metabolism and excretion) and toxicological properties of MGA in various species. It criticised, however, that no original data are presented in this

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<sup>1</sup> see reports at

[http://europa.eu.int/comm/food/food/chemicalsafety/contaminants/hormones/sci\\_opinion\\_en.htm](http://europa.eu.int/comm/food/food/chemicalsafety/contaminants/hormones/sci_opinion_en.htm)).

review and the majority of the references are to reports that have not been published in the peer-reviewed scientific literature. The 54th JECFA report itself states that “*Most of the studies were conducted before 1979 according to the standards in existence at that time and were not carried out in compliance with GLP*” (page 65, 3<sup>rd</sup> paragraph of 54th JECFA Report) and the 62<sup>nd</sup> JECFA presented only new information regarding the structure and activity of the metabolites of MGA (page 22 of 62nd JECFA Report).

The EU scientific committee considered more recent investigations and summarised (see page 17 to of the SCVPH report of 2002<sup>2</sup>). Preliminary data cited in this report:

- indicated that the metabolism of MGA is more complex than previously assumed, but further experiments should verify the specific metabolite pattern in target animal species as well as man;
- demonstrated that MGA has a very strong potential to bind to bovine progesterone receptors, although these data need further verification;
- suggested that *in utero* or pre- and peripubertal exposure to hormones (including animal evidence on synthetic products) may affect pubertal development and epidemiological studies with opposite sexed twins indicate that prenatal exposure to hormones may be linked to adult cancer risk;
- showed that newer experiments clearly identify a risk for excessive exposure of consumers to residues from misplaced or off-label used implants and incorrect dose regimes. In these cases, levels of oestradiol and its metabolites in muscle, fat, liver and kidney from hormone treated cattle may be 2-fold up to several hundred folds higher as compared to untreated meat. The level of increase depends on the treatment regime and the actual hormone levels in the implants used.

Therefore for melengestrol acetate concerns remain that by excess intake of hormone residues and their metabolites, endocrine, developmental, immunological, neurobiological, immunotoxic, genotoxic and carcinogenic effects could be envisaged, in particular for susceptible risk groups persist. The European Community can therefore not support the adoption of the proposal for maximum residue limits for this substance. The next revision of its scientific opinion by EFSA is to be presented later in 2006. There has been a respective call for data at: [http://www.efsa.eu.int/index\\_de.html](http://www.efsa.eu.int/index_de.html). The European Community suggests that this substance is sent back to JECFA for re-evaluation in the light of the latest information provided in the 2002 and the expected 2006 risk assessments by the scientific committees of the European Community.

**Ractopamine:** The EC cannot support the proposed Codex MRLs as there remain outstanding questions regarding the establishment of an ADI, the determination of a marker residue and the analytical method. A MRL dossier for ractopamine is currently under assessment in the EU and questions have been addressed to the sponsor in relation to the pharmacological NOEL and ADI, the definition of the marker residue and the validation of the analytical method. Before these questions have been satisfactorily answered, no conclusion can be drawn.

**Triclabendazole:** The EC support the proposed Codex MRLs for triclabendazole.

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<sup>2</sup> at see [http://europa.eu.int/comm/food/fs/sc/scv/out50\\_en.pdf](http://europa.eu.int/comm/food/fs/sc/scv/out50_en.pdf):