

22/04/2005

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

COMMENTS FROM THE EUROPEAN COMMUNITY ON VETERINARY DRUGS WITHOUT ADI/MRL

(CL 2004/50-RVDF)

PART C: Request for Comments and Information

5. Information on veterinary drugs without ADI/MRL

The 15th CCRVDF agreed to establish a Working Group to develop recommendations on how to deal with compounds without an ADI or MRL. The EC provides the following information as requested in order to assist the Working Group to carry out its tasks:

i) All compounds with no Codex MRLs used at national level for food animals

In the European Community substances intended for use in food producing animals, as pharmacologically active substances in veterinary medicinal products or as feed additives, are submitted to a scientific evaluation with regard to the safety of residues to the consumer. However there are different legislations regarding veterinary medicinal products and feed additives in the EC.

a) Veterinary medicinal products

The legislation concerning veterinary medicinal products requires that all pharmacologically active substances used in veterinary medicinal products intended for food producing animals are evaluated with regard to the safety of residues prior to the granting of the marketing authorisation for the product. The veterinary medicinal product can only be authorised if:

- definitive MRLs have been established (listed in Annex I of Regulation 2377/90).
or
- temporary MRLs have been established (listed in Annex III of Regulation 2377/90).
or
- a conclusion is reached that it is not necessary for the protection of the consumer to establish a maximum residue limit (listed in Annex II of Regulation 2377/90).

Substances for which no Codex MRLs exist and for which definitive MRLs have been established for use in veterinary medicinal products in the EC (Annex I of Regulation No 2377/90):

Acetylisovaleryltylosin, Albendazole oxide, Alpha-cypermethrin, Altrenogest, Amitraz, Amoxicillin, Ampicillin, Apramycin (bovine), Bacitracin (milk and rabbits), Baquiloprim, Betamethasone, Carprofen, Cefacetrile (milk), Cefalexin, Cefalonium (milk), Cefazolin (milk), Cefoperazone (milk), Cefquinome (bovine, porcine, Equidae), Cefapirin, Chlormadinone acetate, Clavulanic acid, Clorsulon, Cloxacillin, Colistin, Coumafos,

Cyhalothrin, Cypermethrin, Cyromazine, Deltamethrin, Dexamethasone, Diazinon, Diclofenac, Dicloxacin, Dicyclanil, Difloxacin, Diflubenzuron, Doxycycline, Emamectin, Enrofloxacin, Erythromycin, Florfenicol, Flugestone acetate (sheep milk), Flumequine, Flumethrin (bovine, ovine), Flunixin, Halofuginone, Kanamycin, Marbofloxacin, Mebendazole, Meloxicam, Metamizole, Methylprednisolone, Morantel, Moxidectin, Nafcillin, (including framycetin) , Netobimin, Nitroxynil, Novobiocin (milk), Oxacillin, Oxfendazole, Oxibendazole, Oxolinic acid, Oxytocan, Paromomycin, Aminocyclitol, Penethamate, Permethrin, Phenoxymethyl penicillin, Piperazine (porcine, chicken eggs), Pirlimycin, Prednisolone, Rafoxanide, Rifaximin (milk), Sulfonamide group, Teflubenzuron, Thiamphenicol, Tiamulin, Tolfenamic acid, Toltrazuril, Trimethoprim, Tulathromycin, Tylosin, Valnemulin, Vedaprofen

Substances for which no Codex MRLs exist and for which temporary MRLs have been established for use in veterinary medicinal products in the EC (Annex III of Regulation No 2377/90):

Fenvalerate, Flugestone acetate (meat/muscle), Norgestomet, Oxolinic acid, Acetyl-isovaleryltylosin, Phoxim, Toltrazuril (for details see list 1 attached)

Substances for which no Codex MRLs exist and that have been evaluated for use in veterinary medicinal products in the EC and the establishment of MRLs was not considered necessary for the protection of human health (Annex II of Regulation (EEC) No 2377/90):

538 substances are listed in Annex II of the Regulation (see list 2 attached).

b) Feed additives

The legislation on feed additives requires that maximum residue limits are established for all feed additives unless as a result of the evaluation it is considered that the establishment of MRLs is not necessary for the protection of consumers or MRLs have already been established for the use of the substance in veterinary medicinal products. This legislation however entered into force only in October 2004 and therefore the evaluation of the authorised feed additives is currently ongoing.

Substances authorised for use as feed additives intended to have an effect on treated animals under Council Directive (EEC) No 70/524 and for which no MRLs were established: Avilamycin; Canthaxanthin; Diclazuril; Halofuginone hydrobromide; Lasalocid A sodium; Lecithin; Lignosulfonate; Maduramicin ammonium alpha; Monensin sodium; Narasin; Nicarbazine; Potassium diformate; Robenidine hydrochloride; Salinomycin sodium; Semduramicin sodium

The antibiotics, currently authorised under feed category “antibiotics”, among these substances, i.e. Salinomycin sodium, Avilamycin, Monensin sodium and Flavophospholipol will be phased out from 1 January 2006.

ii) Compounds in use that raise health concerns

In the European Community substances intended for use in food producing animals have to be evaluated with regard to the safety of residues. If the assessment indicates that residues of the substance concerned constitute a hazard to the health of the consumer, that substance will be prohibited or its use restricted in food producing animals.

Substances prohibited because available data suggest that their use in food producing animals is generally unsafe:

Aristolochia spp, Carbadox, Chloramphenicol, Chloroform, Chlorpromazine, Colchicines, Dapsone, Dimetridazole, Ronidazole, Malachite Green, Metronidazole, Nitrofurans (including Furazolidone) and Ronidazole, Olaquinox, Stilbenes including stilbene derivatives their salts and esters, Thyrostatic substances

Substances that are restricted to specific treatments due to consumer exposure concerns:
Substances having oestrogenic (other than oestradiol 17 β and its ester-like derivatives), androgenic or gestagenic action, Oestradiol 17 β and its ester-like derivatives, Beta-agonists.

Substances whose use as feed additives has been restricted or prohibited due to concerns related to antimicrobial resistance:

Avoparcin, Zinc-Bacitracin, Tylosin, Spiramycin, Virginiamycin.

Zinc bacitacin, Tylosin and Spiramycin however, have been assessed for use in veterinary medicinal products and MRLs established. The therapeutic use of these substances as veterinary medicinal products is therefore authorised in the EC.

iii) Compounds in use that create trade problems; compounds recommended for inclusion in a negative list and the reason for the inclusion in that list

1. Substances under ii) above in particular:

Carbadox, Chloramphenicol, Dimetridazole, Malachite green, Metronidazole, Nitrofurans Phenylbutazone, Stilbenes, Thyrostatic substances.

iv) National or regional MRLs (if any)

See list 1 attached

v) Other tolerances or application of an analytical limit of detection or determination

The EC uses harmonised analytical performance limits as reference points for action (MRPLs = minimum required performance limits). MRPLs are control tools based on expert advice on feasibility of controls. They have so far been established for: Chloramphenicol, Medroxyprogesterone acetate, Nitrofurans metabolites (Furazolidone, Furaldone, Nitrofurantoin, Nitrofurazone), the sum of Malachite green and Leucomalachite green.

MRPLs are not tolerances. They are not tantamount to tolerating the use of prohibited substances in third countries in the products destined for the EC market. The EC still requires from its trading partners to prohibit the use of substances banned in the EC or to establish split systems and ask third countries to provide respective guarantees.

Annexes

List 1: MRLs established in the EC

List 2: Substances for which no Codex MRL evaluation exist have been evaluated as safe for use as pharmacologically active substances in veterinary medicinal products intended for use in food producing animals.