



JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEx COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS
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RISK ANALYSIS POLICY ON EXTRAPOLATION OF MRL'S OF VETERINARY DRUGS TO ADDITIONAL SPECIES AND TISSUES

(replies to CL 2012/11-RVDF, Part B, Points 7 & 8)

Comments Submitted by:

Kenya, Nigeria and African Union (AU)

KENYA

We support the proposed policy document on extrapolation because the policy is an opportunity of setting MRLs of veterinary drugs in other animal tissues and this will enhance public health protection and safety during implementation.

General Comment

Kenya noted that the development of risk analysis policy for extrapolation is an opportunity for setting MRLs of veterinary drugs in other animal tissues. This will enhance public health protection and safety.

We also noted that the pharmacokinetic and *pharmaco-dynamics* of the drugs are taken into consideration as well as the physiological pattern of the animal species. Consequently, MRL of veterinary drugs in ruminants, monogastric and avian species cannot be extrapolated to either fish or honey.

NIGERIA

General Comments

Nigeria supports that the proposed risk analysis policy on extrapolation of MRLs of Veterinary Drugs in additional species and tissues by CCRVDF be developed. The proposed policy on animals in different classes should also be considered separately. We share the concerns expressed in the general comments made by the USA. However, we deem it necessary to consider honey separately and as such concur with the comments of the EU (on honey).

This is also in accordance to paragraph 6 of REP 12/RVDF Appendix XI which says "Where identical or only slightly different, MRLs have been established for the same tissue matrices in three different animal classes (e.g. ruminant, monogastric and avian) based on separate and complete residue data packages, these MRLs could possibly be extrapolated to all food-producing animals (**except fish and honey**)"

AFRICAN UNION (AU)

African Experts noted that the development of risk analysis policy for extrapolation is an opportunity for setting MRLs of veterinary drugs in other animal tissues. This will enhance public health protection and safety.

African Experts also noted that the pharmacokinetic and pharmaco-dynamics of the drugs are taken into consideration as well as the physiological pattern of the animal species. Consequently, MRL of veterinary drugs in ruminants, monogastric and avian species cannot be extrapolated to either fish or honey.

AU supports the proposed policy document on extrapolation.