

EUROPEAN COMMUNITY COMMENTS

on Codex Document CX/RVDF 01/9

Agenda Item 9: Discussion Paper on Risk Analysis Principles and Methodologies in the CCRVDF (prepared by France)

The European Community would like to offer the following comments on the above document – Discussion paper on risk analysis principles and methodologies in CCRVDF.

- (1) The paper on risk analysis and scientific methodology to be developed and implemented in the work of CCRVDF can serve as an excellent basis for future discussions in the Committee and interaction with JECFA. It has, however, to be underlined that the basis of the work undertaken to establish maximum residue limits is the intended use of the substance in veterinary medicine/as feed additive and the documentation requirements. Unless the scientific requirements are fixed and a consistent evaluation method is applied in the risk analysis, any risk management procedures will become arbitrary and variable, which should be avoided as far as possible.
- (2) As JECFA is a separate and independent Committee, the possibilities for CCRVDF to request or impose any risk assessment methodologies have to be further clarified.
- (3) The European Community has since a number of years a developed science based risk assessment methodology for evaluation of dossiers for establishment of maximum residue limits and supports the basic principles of risk analysis. Furthermore, the detailed documentation requirements including advice to applicants/sponsors have recently been updated (EUDRALEX Rules Governing Medicinal Products in the European Union Volume 8) and guidance on the risk analysis approach for residues of veterinary medicinal products in food of animal origin has been put in place.
- (4) Some detailed comments on the discussion paper and Annex I to the discussion paper are provided separately.

Technical comments on the discussion paper including Annex I on risk analysis principles and methodologies in CCRVDF (CX/RVDF 01/9) from EU Commission

Discussion paper

1. Points 25 – 30. The procedure for determining a toxicological ADI is described but the procedure to establish a microbiological ADI should also be outlined.
2. Point 31. It is stated that maximum residue limits can be set for a substance even if it is not possible to establish an ADI. This is in principle not accepted in the European Union. Only for those substances for which it is not necessary to establish quantitative maximum residue limits, i.e. for substances included in Annex II of Council Regulation No 2377/90, this may be acceptable under certain circumstances.
3. Point 39. The standardised daily food intake is discussed and figures for the intakes given. In the European Union these figures apply to mammals. For poultry the figure for fat is 90 g and for kidney 10 g. As regards fish the estimated intake is 300g muscle and skin in natural proportions.

Annex I

4. Point 4. JECFA is requested to take into consideration the procedure followed by JMPR in the establishment of maximum residue limits for pesticides. This should preferably be a reciprocal communication. For substances used both as veterinary drugs and as pesticides, the aim should be a mutual harmonisation of the risk evaluation performed by these expert groups.
5. Point 8. The radio-labeled studies should not be required to be performed in all tissues, but in those tissues which are deemed to be the target tissues. The definition of muscle tissue should be harmonised between CCRVDF and CCPR (muscle vs. meat).
6. Point 9. 1st bullet point. The feasibility of providing general guidance on how to deal with metabolites will be difficult if not impossible, as this will be highly substance dependent, and such data are only important for the choice of marker residue, in cases where the substance is a prodrug or the metabolites have pharmacological activity. It is suggested to modify this point along those lines.
7. Point 9. 2nd bullet point. Such guidance has been put in place in the European Community (Note for Guidance on the risk analysis approach for residues of veterinary medicinal products in food of animal origin adopted by the Committee for Veterinary Medicinal Products under the European Agency for Evaluation of Medicinal Products EMEA/CVMP/187/00-FINAL). In most cases, extrapolation cannot be performed without a minimum set of data.
8. Point 15. Good Laboratory Practice does not assure that the protocols are suitable with respect to endpoints and exposure. It only assures that the trials are carried out to certain standards and which are possible to control retrospectively.

9. Point 16. In the framework of VICH (Veterinary International Conference on Harmonisation), the requirements for assessing the safety of veterinary medicinal products are progressing and it would seem important to take the development of VICH guidelines into consideration. The 3rd bullet point. Immunotoxicity studies are required by European legislation for applications for establishment of MRLs. The second bullet point is not in line with any risk analysis approach, as lack of certain data can only be justified on a case by case basis. The 5th bullet point should also address pharmacological effects.
10. Point 26. A third bullet point may be introduced referring to ADIs already established by e.g. CCPR or by regional bodies with relevant legislation in place.
11. Point 37: should be modified as follows:
Assess the potential overestimate (rest of paragraph unmodified).
Replace infants by relevant sensitive groups of the population.
12. Point 54. The criterion should not be that the method is easily implemented, but that it is suitable for the purpose of residue control.
13. Point 58. It should be pointed out that the establishment of MRLs should also consider the necessity to account for future new species, new tissues and other uses for the substance (such as in plant protection).
14. Point 60. The food commodity honey should be included.
15. Point 67. Last bullet point. This point should be deleted, as this is an impossible task. The eating habits world-wide differ too much to make such distinctions.
16. Point 71. The issue of the withdrawal period can not be explicitly linked to the analytical method for control. It is in the vast majority of cases possible to improve the sensitivity of the analytical control methods. A set of criteria for proposals not to specify numerical MRLs have to be developed and agreed by CCRVDF.