

# codex alimentarius commission

FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD HEALTH  
ORGANIZATION

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**Agenda item 8**

**CX/RVDF 00/7-Add.1**

March 2000

## **JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

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

**Twelfth Session**

**Washington, D.C., 28 - 31 March 2000**

### **CONSIDERATION OF MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS AT STEPS 7 AND 4**

#### **HARMONIZATION OF MRL SETTING FOR COMPOUNDS USED BOTH AS PESTICIDES AND AS VETERINARY DRUGS**

#### **BACKGROUND**

Subsequent to the publication of the document CX/RVDF 00/7, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) at its 54th meeting (15-24 February 2000) considered the relevant recommendations of the informal JECFA/JMPR Harmonization Meeting (Rome, February 1999).

The conclusions of the 54th JECFA on this issue are shown below along with other recommendations of the JECFA/JMPR Meeting pertinent to the work of the CCRVDF. New or revised definitions of certain tissues/products proposed by the 54th JECFA are contained in Annex 1 of this paper.

#### **CONSIDERATION BY THE 54TH JECFA OF THE RECOMMENDATIONS OF THE JECFA/JMPR INFORMAL HARMONIZATION MEETING**

#### **TISSUE**

2. Clarification of the definition of muscle tissue (Volume 3 of Codex Alimentarius) is needed to establish the portion of the commodity to which the MRL applies. Muscle tissue (JECFA/CCRVDF) shall include interstitial fat and exclude trimmable fat. It is recognized that other minor components, e.g., connective tissue, may be present in muscle tissue. Muscle tissue includes skeletal muscle tissue and all other edible muscle tissues. For muscle tissues other than skeletal muscle, the MRLs for skeletal muscle tissue shall apply, unless studies show greater residues in the other types of tissue. Sponsors may submit data for consideration for other muscle tissues, such as tongue, etc.

**54th JECFA:** The Committee agreed with the recommendation to clarify the portion of the commodity to which the MRL applies and will provide a recommendation on a revised definition for inclusion in Volume 3.

3. For the determination of fat-soluble pesticide/veterinary drug residues in meat/muscle for enforcement or monitoring purposes, laboratories are advised to collect and to analyse trimmable fat and to report the residue on a lipid basis, i.e. meat (fat) for JMPR and fat for JECFA. For meat without trimmable fat, the entire commodity should be analysed as meat/muscle, but only where the MRL has been set on a meat/muscle basis.

**54th JECFA:** The Committee agreed that guidance should be provided to laboratories based on the proposed definitions of muscle and fat that were drafted by the present Committee (attached) for consideration by the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF). However, guidance is, in general, the responsibility of national authorities.

4. For determination of non-fat soluble pesticides/veterinary drug residues in meat/muscle, laboratories are advised to analyse meat/muscle with trimmable fat removed, as far as practical.

**54th JECFA:** The Committee agreed that laboratories should analyse samples based on the proposed draft definitions of muscle and fat for consideration by CCRVDF. However, guidance is, in general, a responsibility of national authorities.

5. Where JECFA and JMPR have recommended MRLs for the same chemical with the same residue marker definition on the same commodity, the higher MRL shall prevail.

**54th JECFA:** The Committee agreed that where different MRLs may occur, the higher MRL should prevail, provided intake of residues does not exceed the ADI. With the risk assessment procedures used by JECFA and JMPR, no adverse public health effects would be expected to occur.

6. *CCRVDF* should consider describing fat as the trimmable lipid-based tissue (eg., subcutaneous, perirenal, etc) from food producing animals.

## **MILK**

7. For the determination of fat-soluble pesticide/veterinary drug residues in milk, the milk fat portion of fresh milk should be analysed and results expressed on a whole weight basis using 4% as the nominal fat content.

**54th JECFA:** The Committee agreed with this recommendation.

8. For the determination of non-fat soluble pesticide/veterinary drug residues in milk, laboratories should analyse the whole milk and should report results on a whole milk basis.

**54th JECFA:** The Committee agreed with this recommendation.

9. JECFA should consider expressing MRLs for milk on a weight (kg) basis rather than the current volume (L) basis.

**54th JECFA:** The Committee agreed with the recommendation and has implemented this approach. Reporting residue concentrations on a weight-per-weight basis is consistent with international recommended analytical protocols.

**Secretariat's Note:** The 52nd JECFA already recommended MRLs in milk on a weight basis. The Committee is invited to consider the amendments of all Codex MRLs and draft/proposed draft MRLs in milk as recommended above to be expressed on a weight basis ( $\mu\text{g}/\text{kg}$ ).

The CCRVDF is invited to consider the following new definition (contained in the General Standard for the Use of Dairy Terms adopted by the Commission in 1999) to replace the existing one:

“2.1 Milk is the normal mammary secretion of milking animals obtained from one or more milkings without either addition to it or extraction from it, intended for consumption as liquid milk or for further processing.”

## **EGGS**

10. JECFA should specify that the portion of the raw commodity “egg” (in shell) to be analysed is the whole egg white and yolk combined after removal of the shell.

**54th JECFA:** The Committee agreed with the recommendation to add wording to the current definition to clarify any ambiguity on the portion of egg to be analysed for residues.

11. The description of eggs should not be limited to chicken, and sampling size should be a minimum of 500 grams. *CCRVDF* and CCPR are invited to modify the appropriate sections of Volumes 2 and 3 on sampling, accordingly.
12. *CCRVDF* establishes MRLs on raw meat and poultry products only. *CCRVDF* should consider deletion of the sampling guidelines for the processed products for Class E (types 16 - 19).

#### **HARMONIZATION**

- 13 The working group noted disparate residue definitions by CCPR and *CCRVDF* for abamectin and recommended that *CCRVDF*/JECFA consider expansion of its residue definition to include other isomers, such as the photodegradation isomer of B1a. CCPR/JMPR should consider its need to include the various isomers as part of the periodic review of abamectin.

**54th JECFA:** The Committee carefully considered the toxicological and chemical assessments of abamectin by JMPR and has concluded that inclusion of the photodegradation isomer in the residue definition would not be consistent with the JECFA assessment of abamectin as a veterinary drug. Inclusion of other possible residues of abamectin will be reviewed at a future meeting of the Committee.

14. Cypermethin and alpha-cypermethrin should remain as the marker residue definitions for their use as veterinary drugs for cypermethrin and alpha-cypermethrin, respectively, and cypermethrin (sum of isomers) should remain as the residue definition for the pesticide cypermethrin. Guidance should be supplied to laboratories on the designation of the measured residue as cypermethrin or alpha-cypermethrin based on the chromatography of the test substance.

**54th JECFA:** The Committee agreed with the recommendation on marker residue definition for the different uses. The Committee recognized that the current analytical methods have the capability to measure all isomers of interest. Accordingly, guidance should be provided to Member States so that they may develop their specific guidance for residue control authorities.

15. Harmonization efforts should be undertaken on a case-by-case basis where marker residue definition/residue definition differences occur between JECFA and JMPR.

**54th JECFA:** The Committee agreed with the recommendation and will co-ordinate liaison with the JMPR Secretariat when necessary.

16. JECFA should review the apparent anomaly of MRLs for both fat and muscle for the fat-soluble drugs alpha-cypermethrin and cypermethrin. JECFA should consider which sample tissues are to be analyzed by the enforcement laboratory.

**54th JECFA:** The Committee agreed in principle with the recommendation. However, it should be noted that, because the required data were not provided, the temporary MRLs for alpha-cypermethrin and cypermethrin were not extended at the present meeting. The Committee has indicated that in some instances the recommendations for MRLs are for guidance purposes only (e.g., MRL in muscle tissue for the synthetic pyrethroids where there are no measurable residues). These guidance MRLs should not be considered in theoretical maximum residue intake calculations and are not intended for residue control purposes.

18. For compounds that are common to both, JMPR and JECFA should use the more specific animal commodity descriptions to enhance harmonization. For example, separate MRLs for cattle muscle, goat muscle, horse muscle, pig muscle, and sheep muscle are preferable to meat of cattle, horses, pigs and sheep.

**54th JECFA:** The Committee agreed with the recommendation and has routinely noted the specific animal commodity descriptions in its recommendations on MRLs for residues of veterinary drugs in food. These commodity descriptions provide clarity to JMPR for their assessment of risk for pesticides.

19. Each expert panel needs a better understanding of the other's procedures for food safety assessments for estimating MRLs and dietary exposure, for example. JECFA will provide JMPR its guidance document describing the JECFA evaluation procedures when the draft version is finalized. The JMPR FAO Manual (1997) will be distributed to the JECFA members at the February 1999 meeting.

**54th JECFA:** The Committee agreed with the recommendation and has provided the guidance document<sup>1</sup> to the JMPR Secretariat. The document will also be provided to delegates attending the Twelfth Session of CCRVDF in March 2000.

20. The JECFA/JMPR Group acknowledged the very different approaches used for dietary exposure determinations. JMPR will provide JECFA with detailed reports of its assessments, dietary intake calculations and % ADI determinations for compounds of interest to JECFA. When the data are available, JECFA will provide JMPR with median and upper limit animal commodity residue values and dietary intake calculations/% ADI determinations for compounds of interest to JMPR.

**54th JECFA:** The Committee acknowledged that its dietary intake calculations are very different from those performed by JMPR. To facilitate the JMPR intake assessments, JECFA will provide veterinary residue data on compounds of interest when they are available.

21. JECFA and JMPR should consider the exchange of one panel member each for a portion of the expert panel meetings to facilitate the harmonization of MRLs and risk assessment for substances used as veterinary drugs and pesticides.

**54th JECFA:** The Committee agreed with the recommendation. JMPR experts participated in the present meeting.

22. The Joint Secretary for JMPR will attend the JECFA meeting, and the Joint Secretary for JECFA will attend the JMPR meeting, particularly when MRLs and risk assessments of substances used as veterinary drugs and as pesticides are being considered.

**54th JECFA:** The Committee agreed that both FAO Joint Secretaries should participate in the meeting when a substance used both as a veterinary drug and as a pesticide is being considered.

23. Joint meetings of JMPR and JECFA should be held on an *ad hoc* basis to address issues of a mutual interest, for example, how to address MRL and ADI issues for classes of compounds with common modes of action, e.g., organophosphorus compounds.

**54th JECFA:** The Committee agreed with the recommendation. *Ad hoc* meetings of members of the expert group/committee and the Joint Secretaries are appropriate to resolve potential issues that might impede the risk assessment of a compound or class of compounds, particularly on matters of general principles for risk assessments.

24. For compounds of mutual interest, JMPR and JECFA should have each other's recommendations/reports available when conducting evaluations. The Joint Secretaries will have responsibility for obtaining and distributing the documents and information, as appropriate.

**54th JECFA:** The Committee agreed with the recommendation. The Joint Secretaries should ensure that reports of the other committee are provided to the expert reviewing the compound so that it will be considered when the substance is evaluated.

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<sup>1</sup> *Procedures for recommending maximum residue limits – residues of veterinary drugs in food (1987-1999)*. Food and Agriculture Organization of the United Nations and World Health Organization. Rome, 2000 (available on the internet at <http://www.fao.org/WAICENT/FAOINFO/ECONOMIC/ESN/NUTRI.HTM> or from the FAO Joint Secretary of JECFA on request).

## ANNEX 1: DEFINITIONS PROPOSED BY THE 54TH JECFA

**Meat:** Meat is the skeletal muscular tissue of an animal carcass or cuts of these tissues from an animal carcass that contains interstitial and intramuscular fat. The muscular tissue may also include bone, connective tissue, tendons as well as nerves and lymph nodes in natural portions. It does not include edible offal or trimmable fat.

Portion of the commodity to which the MRL applies: The whole commodity without bones.

*Present definition:* **Meat:** The edible part of any mammal.

**Fat:** The lipid-based tissue that is trimmable from an animal carcass or cuts from an animal carcass. It may include subcutaneous, omental or perirenal fat. It does not include interstitial or intramuscular carcass fat or milk fat.

Portion of the commodity to which the MRL applies: The whole commodity. For fat-soluble compounds the fat is analysed and MRLs apply to the fat. For those compounds where the trimmable fat is insufficient to provide a suitable test sample, the whole commodity (muscle and fat but without bone) is analysed and the MRL applies to the whole commodity (e.g., rabbit meat).

*Present definition:* **None.**

**Milk:** No change from current definition in Volume 3.

Portion of the commodity to which the MRL applies: Codex MRLs for fat-soluble compounds in milk are expressed on a whole commodity basis. Milk is considered to have an average composition of 4% fat content.

**Egg:** The fresh edible portion of the spheroid body produced by female birds, especially domestic fowl.

Portion of the commodity to which the MRL applies: The edible portion of the egg including the yolk and egg white after removal of the shell.

*Present definition:* **Egg** (in shell) of domesticated chickens (hens).