codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel.: +39(06)57051 Telex: 625825-625853 FAO I E-mail: Codex@fao.org Facsimile: +39(06)5705.4593

Agenda Item 3 **CX/PR 99/2**
January 1999

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES
Thirty-first Session
The Hague, The Netherlands, 12 - 17 April 1999

MATTERS REFFERRED TO THE COMMITTEE

A. MATTERS CONSIDERED BY THE 45TH SESSION OF THE EXECUTIVE COMMITTEE (Rome, 3-5 June 1998, ALINORM 99/3)

A.1 REPORT ON MATTERS RELATING TO THE APPLICATION OF THE WTO SPS AND TBT AGREEMENTS (paras 41-44)

1. The 22nd session of the Commission requested the Secretariat to write to the chair of the WTO Committee on the Application of Sanitary and Phytosanitary Measures in order to obtain clarification on how the Committee would "differentiate standards, guidelines and other recommendations" in relation to the SPS Agreement. The response of the Chair of the SPS Committee is provided *verbatim* in the working paper.[1]

2. The 45th Session of the Executive Committee noted[2] the following features in the reply:

- the SPS Committee cannot formally interpret the provisions of the SPS Agreement;
- the Agreement does not differentiate between the terms "standards', "guidelines" or "recommendations";
- there is no legal obligation on WTO Members to apply any of these Codex texts;
- how a text would be applied depended on its substantive content rather than on the category of the text;
- Regional standards are not included in the definition of "international standards" used in the Agreement, but may be applied within a given Region.

3. The Executive Committee also noted that the above points seem to be consistent with the rulings of the Appellate Body in relation to the Panel reports concerning EC Measures Concerning Meat and Meat Products (Hormones)[3]. It also noted that the SPS Committee was of the view that the work of Codex should not be constrained by this question.

4. The Executive Committee agreed that:

- the reply of the SPS Committee should be brought to the attention of all Codex Committees;
- the reply by the SPS Committee seemed to conclude the correspondence on this matter;
- the work of Codex should move forward without concern arising from misunderstandings or misinterpretations as to how Codex standards and related texts might be used;

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1 CX/EXEC 98/45/9
2 ALINORM 99/3, paras. 41-44.
3 WTO Document AB-1997-4, World Trade Organization, Geneva.

- the guidance given by the 22nd Session of the Commission in relation to the status of Codex advisory texts should continue to be adhered to;
- the Committee on General Principles should examine the possibility of developing a set of appropriate preambular statements explaining the intent of different types of Codex texts.

A.2 JUDGEMENT OF EQUIVALENCE (paras 35-36)

5. The Executive Committee discussed in depth the matter of Judgement of Equivalence in relation to the Terms of Reference of the Codex Committee on Food Import and Export Inspection and Certification systems (CCFICS) and the overall work programme of the Commission.

6. The Executive Committee was of the opinion that in the area of determination of equivalence of measures, the mandate of the CCFICS only referred to food inspection and certification systems and that the matter being discussed by the CCFICS involved issues which were also relevant to the responsibilities of other Codex Committees especially those dealing directly with the science-based risk management and the Committee on General Principles.

7. The Executive Committee was of the opinion that the matter was a priority for the work of the Commission, and that the CCFICS was in the best position to deal with the subject with a view to developing concepts for equivalence in food control for import and export. This would require the CCFICS to develop concepts, to identify issues for consideration by the Commission and by other Codex Committees, and to suggest how a systematic approach might be applied. However, the Executive Committee should ensure that the issue was broadened. It suggested that as soon as work proceeded beyond the initial stages, the other relevant Committees (e.g., Food Hygiene, Pesticide Residues, Residues of Veterinary Drugs in Foods, Food Additives and Contaminants, General Principles) should initiate their own work on this matter as appropriate. In order to facilitate understanding of the issues involved, the Executive Committee invited the Secretariat to arrange for a revision of the basic paper and to circulate it to the relevant Committee for their information.

A.3 CODE OF PRACTICE ON GOOD ANIMAL FEEDING (paras 39-40)

8. The 45th Session of the Executive Committee noted[4] that not all of the Codex Committees which had been requested to examine the draft had as yet met. In particular, the opinion of the Codex Committee on Residues of Veterinary Drugs in Foods in the matter of the use of antibiotics in animal feeding would be of special importance. The opinion was expressed that the draft Code as written was too general and too wide to be of use in some of the areas which it intended to cover and that one solution would be to treat specific risks separately.

9. The Executive Committee supported the proposal that once all of the Committees had expressed their opinions, an analysis should be prepared for the further consideration of the Executive Committee and the Commission.

> **Note:** Since the 11th Session of the Codex Committee on Residues of Veterinary Drugs in Foods also considered the Proposed Draft Code in September 1998, all the Codex committees which had been requested to examine the Proposed Draft Code have considered it.

B. MATTERS CONSIDERED BY THE 13TH SESSION OF THE CODEX COMMITTEE ON GENERAL PRINCIPLES (Paris, 7-11 September 1998, ALINORM 99/33)

B.1 CERTAIN DEFINITIONS FOR RISK ANALYSIS TERMS AND WORKING PRINCIPLES FOR RISK ANALYSIS (paras 16-17, 23)

The Committee agreed to propose a definition of *Risk Assessment Policy* to be circulated for further comment and to review the current definitions of *Risk Management* and *Risk Communication*. It also agreed to return to Step 2 the Working Principles for Risk Analysis.

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4 ALINORM 99/3, paras. 39-40.

C. MATTERS REFERRED TO THIS COMMITTEE BY OTHER CODEX COMMITTEES

C.1 MRLs FOR COMPOUNDS USED BOTH AS VETERINARY DRUGS AND PESTICIDES[5] (11th Session of the Codex Committee on Residues of Veterinary Drugs in Foods, Washington, D.C., 15-18 September 1998, ALINORM 99/31, paras 8-9, 60-63)

10. The Committee noted discussions held at the 22nd Session of the Commission, the 29th and 30th Sessions of Codex Committee on Pesticide Residues (CCPR) and the 1997 Joint FAO/WHO Meeting on Pesticide Residues (JMPR)[6] concerning differences in the way the CCRVDF and the CCPR established MRLs. These discussions emphasized the need for harmonization and consistency throughout Codex, particularly in the areas of the consideration of fat solubility of compounds; residue definitions; commodity definitions, especially the definition of "muscle" in relation to fat content; levels recommended for the same commodity/compound combinations; and dietary models used for risk assessment. The Committee further noted the recommendations of the JMPR on harmonization of recommendations from that body and JECFA for MRLs for compounds with both agricultural and veterinary uses.

11. The Committee generally recognized the need for harmonization and requested the FAO Secretaries of the JECFA and JMPR to convene an informal meeting of experts in the areas of residues of veterinary drugs and pesticides to consider these issues. The outcome of this meeting would be reported and considered by the CCRVDF and the CCPR. As a number of issues needing to be addressed depended on the outcome of this meeting, the Committee deferred discussions on this matter until its next session.

Abamectin

12. The Delegation of Germany, speaking on behalf of the European Community, expressed opposition to the basis of the ADI setting of the 1997 JMPR because the NOEL of the most sensitive species, CF1 mouse, had not been used for the ADI setting and no human data were available on abamectin, as opposed to ivermectin. It was also stated that data on a new avermectin was now available. The Committee requested the EC to provide the data to the JMPR.

13. The Committee decided to retain the draft MRLs at Step 7 with the understanding that if no data or information were received by JMPR by the next session of the Committee, the Committee would consider their advancement to Step 8.

Alpha-Cypermethrin and Cypermethrin

14. The Committee noted that there were a number of Codex MRLs adopted for animal products arising from veterinary uses based on the recommendations of the Codex Committee on Pesticide Residues, which had different residue and commodity definitions. The issues raised included, risk assessment policies, different diet patterns and impracticalities in having two different MRLs for substance/commodity combinations. The Committee reaffirmed that there must be only one Codex MRL for a substance/commodity combination. Several delegations stressed that substances used for veterinary purposes must be evaluated by JECFA and MRLs for these uses be elaborated by the CCRVDF.

15. The Committee agreed to advance all draft MRLs to Step 8 with the understanding that if the outcome of the informal meeting between JECFA and JMPR required amendments of these MRLs, it would reconsider them at its next Session.

> **Note:** There will be an informal meeting between the JMPR and JECFA experts scheduled for 1-2 February 1999 to discuss issues related to harmonization of setting MRLs and sampling methods. There will be an oral report on this meeting by the FAO Joint Secretary of the JMPR.

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5 See also Annex 1 of this paper for information.

6 CX/RVDF 98/2 and CX/RVDF 98/2-Add.1.

C.2 RECOMMENDED METHODS OF SAMPLING FOR THE DETERMINATION OF PESTICIDE RESIDUES FOR COMPLIANCE WITH MRLS

16. The CCPR at its 30th Session agreed to advance the Draft Revised Methods of Sampling to Step 8 and to send it to the Codex Committees on Residues of Veterinary Drugs in Foods and on Methods of Analysis and Sampling for consideration.

Codex Committee on Residues of Veterinary Drugs in Foods (11th Session, Washington, D.C., 15-18 September 1998, ALINORM 99/31, paras 10-11)

17. Noting that there were still substantial differences in the way MRLs were derived, defined and analyzed between the two Committees, the Committee agreed that it should be clarified that the revised methods of sampling developed by the CCPR were applicable only to residues of pesticides used for plant protection purposes but not to veterinary uses. It also requested the JECFA and JMPR informal meeting to consider the revised methods of sampling. As the text was forwarded by the 30th CCPR for final adoption by the 23rd Session of the Commission at Step 8, delegations were encouraged to comment on the text for direct consideration by the Commission.

Codex Committee on Methods of Analysis and Sampling (22nd Session, Budapest, 23-27 November 1998, ALINORM 99/23, paras 14-18)

18. It was recognized that the referenced Methods of Sampling and the Guidelines on Sampling being developed by this Committee were based on two different approaches; the former on the practical approach for economic reasons, and the latter on the statistical approach. Therefore, it was felt inappropriate to combine these two documents. However, it was stated that the CCPR Sampling document should not contain any contradiction to the Guidelines on Sampling.

19. A number of delegations stressed the need to harmonize those terms used in the document to internationally agreed ones, such as ISO 7002.

20. Other comments included: (1) Table 2 should be clarified to indicate that for plant products composite samples were prepared whereas for each animal product a single primary sample was taken; (2) Table 2 indicated that where the incidence of violative residues in the lot was below 5%, the number of samples to be taken would be unrealistic; (3) the procedure contained in Section 4.4 for the evaluation of results was too complex.

21. The Committee agreed to forward all written[7] and oral comments to the CCPR for consideration.

C.3 PROPOSED DRAFT REVISED STANDARD FOR PROCESSED CEREALS-BASED FOODS FOR INFANTS AND YOUNG CHILDREN (21st Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses, 21-25 September 1998, Berlin, ALINORM 99/26, para. 74)

22. The Committee recalled that the Committee on Pesticide Residues had asked for clarification on its earlier request for the establishment of MRLs for foods for infants and children, and recognized that justification should be provided. The Committee therefore agreed to request the CCPR to consider the feasibility of establishing specific MRLs for cereal based foods and infant formula. In setting MRLs for each pesticide residue in these foods, the CCPR should describe the general principles for risk assessment that have been taken into account. These principles should include, but not be limited to, consideration of:

- the physiological and developmental characteristics of infants and young children who would be consuming these products;
- the relative contribution of these foods to the total daily intake of these infants and children; and
- the types of ingredients used in these foods.

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[7] Annex 2 of this paper contains the written comments submitted to the Codex Committee on Methods of Analysis along with those submitted by IDF at Step 8.

C.4 REQUEST FOR THE ESTABLISHMENT OF EMRLS FOR FISH[8] (13th Session of the Codex Coordinating Committee for Africa, 3-6 November 1998, Harare, Zimbabwe)

23. In relation to a discussion on the trade of fish, the delegations of Kenya, Tanzania and Uganda expressed their concerns on the difficulties in exporting fish caught in Lake Victoria due to the presence of residues of certain herbicides. The Committee therefore **agreed** to request the CCPR to consider the problem of pesticide residues in fish with a view to establishing EMRLs.

> **Note:** There is no indication of what kinds of pesticide were of their concern and whether data would be available for the JMPR to review. There has been no proposal submitted in response to the circular letter which sought proposals for the Priority List of Pesticides. There will be an oral report by the Codex Secretariat on this issue.

[8] ALINORM 99/28, para. 9.

ANNEX 1

NEED FOR HARMONIZATION IN SETTING MRLS FOR COMPOUNDS USED BOTH AS PESTICIDES AND VETERINARY DRUGS

- **COMMODITY DEFINITIONS**

	Volume 2 of the *Codex Alimentarius*	**Volume 3 of the *Codex Alimentarius***
Muscle/Meat	***Meat:*** *Meats are the muscular tissues, including adhering fatty issues such as intramuscular and subcutaneous fat from animal carcasses or cuts of these as prepared for wholesale or retail distribution in a "fresh" state. The cuts offered to the consumer may include bones, connective tissues and tendons as well as nerves and lymph nodes.* The commodity description of "fresh" meat includes meat which has been quick-frozen or quick-frozen and thawed. This group does not include edible offal. <u>Portion of commodity to which the MRL applies (and which is analyzed):</u> Whole commodity (without bones). For fat-soluble pesticides a portion of adhering fat is analyzed and MRLs apply to the fat. For those commodities where the adhering fat is insufficient to provide a suitable sample, the whole commodity (without bone) is analyzed and the MRL applies to the whole commodity (e.g. rabbit meat)	***Meat:*** *The edible part of any mammal.* ***Muscle:*** *Muscle tissue only* (Definition established and adopted by the JECFA).
Milk	*Milks are the mammary secretions of various species of lactating herbivorous ruminant animals, usually domesticated.* In conformity with the Code of Principles Concerning Milk and Milk Products the term "milk" shall mean exclusively the normal mammary excretion obtained from one or more milkings without either addition thereto or extraction therefrom. Notwithstanding the provisions in the preceding paragraph, "the term 'milk' may be used for milk treated without altering its composition, or for milk, the fat content of which has been standardized under domestic legislation". <u>Portions of the commodity to which the MRL applies (and which is analyzed):</u> Whole commodity Codex MRLs for fat-soluble pesticides in milk and milk products are expressed on a whole products basis. For a "milk product" with a fat content less than 2%, the MRL applied should be half those specified for milk. The MRL for "milk products" with a fat content of 2% or more should be 25 times the maximum residue limits specified for milk, <u>expressed on a fat basis</u>.	*Exclusively the normal mammary secretion obtained from one or more milkings without either addition thereto or extraction therefrom. The term may be used for milk treated without altering its composition, or for milk the fat content of which has been standardized under domestic legislation. The term may also be used in association with a word or words to designate the type, grade, origin and/or intended use of such milk or to describe the physical treatment or the modification of composition to which it has been subjected, provided that the modification is restricted to an addition and/or withdrawal of natural milk constituents. In international trade, the origin of the milk shall be stated if it is not bovine.* (Taken from the Code of Principles Concerning Milk and Milk Products[9], *Codex Alimentarius*, First Edition, Volume XVI)

[9] The Codex Committee on Milk and Milk Products at its 3rd Session agreed to convert it into a form of a standard and to advance the Draft General Standard for the Use of Dairy Terms to Step 8 for adoption by the Commission to replace the existing Code of Principles. In the Draft General Standard, the definition of milk is as follows:
"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."
That Committee also revised the sections on labelling requirements.

	Volume 2 of the *Codex Alimentarius*	Volume 3 of the *Codex Alimentarius*
Egg	Eggs are the fresh edible portion of the body produced by female birds, especially domestic fowl. Portions of the commodity to which the MRL applies (and which is analyzed): Whole egg whites and yolks combined after removal of shell.	Egg (in shell) of domesticated chickens (hens).

- **RESIDUE DEFINITIONS OF COMPOUNDS CONSIDERED BY THE CCRVDF AND CCPR**

	As pesticide	As veterinary drug
Abamectin	Sum of avermectin B_{1a}, avermectin B1b and (Z)-8,9-avermectin B_{1a} and (Z)-8,9-avermectin B_{1b}[10]	Avermectin B_{1a}
Cyfluthrin	Cyfluthrin (fat-soluble)	Cyfluthrin
Cypermethrin	Cypermethrin (sum of isomers) (fat-soluble)	Cypermethrin: Cypermethrin alpha-Cypermethrin: alpha-Cypermethrin
Thiabendazole	Thiabendazole or, in the case of animal products, sum of thiabendazole and 5-hydroxythiabendazole	Sum of thiabendazole and 5-hydroxythiabendazole
Cyhalothrin	Cyhalothrin (sum of all isomers)	(Scheduled for review by JECFA: 1999)
Deltamethrin	Deltamethrin (fat-soluble)	(Scheduled for review by JECFA: 1999)
Permethrin	Permethrin (sum of isomers) (fat-soluble)	(Scheduled for review by JECFA: 1999)
Phoxim	Phoxim (fat-soluble)	(Scheduled for review by JECFA: 1999)

- **MRLS ADOPTED OR BEING ELABORATED FOR COMPOUNDS USED BOTH AS VETERINARY DRUGS AND PESTICIDES (EXPRESSED IN THE SAME MANNER)**

Abamectin

Species	Tissue/ Commodity	MRLP (mg/kg)	Step	MRLVD (µg/kg)	Step
cattle	meat	0.01 (*)[11]	6		
goat	meat	0.01 (*)	6		
cattle	liver	0.1 V 1/	3	100	7
cattle	kidney	0.05 V 1/	3	50	7
cattle	fat	0.1 V 1/	3	100	7
cattle	milk	0.005	6		
goat	milk	0.005	6		
cattle	edible offal	0.05 2/	6		
goat	edible offal	0.1	6		

1/ The 1997 JMPR proposed a harmonized MRL to accommodate the JECFA recommendation arising from veterinary uses of abamectin.
2/ Recommended for withdrawal (1997 JMPR). This recommendation has not yet been considered by the CCPR.

Cyfluthrin

Species	Tissue/ Commodity	MRLP (mg/kg)	Step	MRLVD (µg/kg)	Step
cattle	muscle			20	5
cattle	liver			20	5
cattle	kidney			20	5
cattle	fat			200	5
cattle	milk	0.01 1/	Adopted	40 (µg/l)	5

1/ The CCPR may consider the level of 0.04 mg/kg in milk for the purpose of harmonization at its 31st Session.

[10] The Codex Committee on Pesticide Residues is seeking information on the inclusion of (Z)-8,9-avermectin B_{1b} and its parent compound in the residue definition of abamectin.

[11] (*), the MRL is set at or about the limit of determination; V, the MRL accommodates veterinary uses; MRL without the suffix V means that the residues arise from contaminated feeds.

Cypermethrin (see also residue definitions above)

Species	Tissue/ Commodity	Cypermethrin		Cypermethrin		alpha-Cypermethrin	
		MRLP (mg/kg)	Step	MRLVD (µg/kg)	Step	MRLVD (µg/kg)	Step
cattle	muscle			200 T	8	100 T	8
sheep	muscle			200 T	8	100 T	8
mammals[1/]	meat	0.2 (fat)V	Adopted				
chicken	muscle			200 T	8	100 T	8
poultry	meat	0.05 (*)	Adopted				
cattle	liver			200 T	8	100 T	8
sheep	liver			200 T	8	100 T	8
chicken	liver			200 T	8	100 T	8
cattle	kidney			200 T	8	100 T	8
sheep	kidney			200 T	8	100 T	8
chicken	kidney			200 T	8	100 T	8
mammals [1/]	edible offal	0.05 (*)V	Adopted				
cattle	fat			1000 T	8	500 T	8
sheep	fat			1000 T	8	500 T	8
chicken	fat			1000 T	8	500 T	8
cattle	milk			50 T (µg/l)	8	25 T (µg/l)	8
not specified	milks	0.05 FV	Adopted				
chicken	eggs			100 T	8	50 T	8
not specified	eggs	0.05 (*)	Adopted				

1/ Other than marine mammals.

Thiabendazole

Species	Tissue/ Commodity	MRLP (mg/kg)	Step	MRLVD (µg/kg)	Step
cattle	muscle			100 a/	Adopted
cattle	meat	0.1 [1/ 2/ 4/]	Adopted		
cattle	meat	0.05	3(a)		
pig	muscle			100 a/	Adopted
pig	meat	0.1 [1/ 2/ 4/]	Adopted		
sheep	muscle			100 a/	Adopted
sheep	meat	0.1 [1/ 2/ 4/]	Adopted		
goat	muscle			100 a/	Adopted
goat	meat	0.1 [1/ 2/ 4/]	Adopted		
horse	meat	0.1 [2/ 4/]	Adopted		
poultry	meat	0.05	3(a)		
cattle	liver			100 a/	Adopted
pig	liver			100 a/	Adopted
sheep	liver			100 a/	Adopted
goat	liver			100 a/	Adopted
cattle	kidney			100 a/	Adopted
pig	kidney			100 a/	Adopted
sheep	kidney			100 a/	Adopted
goat	kidney			100 a/	Adopted
cattle	edible offal	0.1 [1/ 3/ 4/]	Adopted		
cattle	edible offal	0.1	3(a)		
goat	edible offal	0.1 [1/ 3/ 4/]	Adopted		
horse	edible offal	0.1 [3/ 4/]	Adopted		

Species	Tissue/ Commodity	MRLP (mg/kg)	Step	MRLVD (µg/kg)	Step
pig	edible offal	0.1 1/ 3/ 4/	Adopted		
sheep	edible offal	0.1 1/ 3/ 4/	Adopted		
cattle	fat			100 a/	Adopted
pig	fat			100 a/	Adopted
sheep	fat			100 a/	Adopted
goat	fat			100 a/	Adopted
cattle	milk	0.05	3(a)	100 a/	Adopted
goat	milk			100 a/	Adopted
not specified	milks	0.1 (*) 1/ 4/	Adopted		

a/ These MRLs also cover residues derived from feed containing the residues resulted from agricultural uses.
1/ The MRL accommodates veterinary uses.
2/ The MRL was adopted for meat of cattle, goats, horses, pigs & sheep.
3/ The MRL was adopted for edible offal of cattle, goats, horses, pigs & sheep.
4/ To be replaced by the MRLs for relevant commodity of cattle (1997 JMPR). It should be noted that these are the MRLs adopted to cover residues arising from both agricultural uses and veterinary uses (horses, only from agricultural uses).

- **DEFINITIONS OF MEASUREMENT LIMITS**

Volume 2 of the *Codex Alimentarius*	**Volume 3 of the *Codex Alimentarius***
Limit of Determination: *Limit of Determination is the lowest concentration of a pesticide residue or contaminants that can be identified and quantitatively measured in a specified food, agricultural commodity, or animal feed with an acceptable degree of certainty by a regulatory method of analysis.*	***Limit of detection:*** *Limit of detection is the smallest measured concentration of an analyte from which it is possible to deduce the presence of the analyte in the test sample with acceptable certainty. This determination should consider matrix related interferences with an instrumental signal to noise (S/N) ratio greater than 5:1 or the concentration determined by a factor of 3 standard deviations of the signal response for blank tissue, whichever is less.* ***Limits of Quantitation:*** *Limit of quantitation corresponds to the smallest measured concentration of residue from endogenously incurred test material above which a determination of the analyte can be made with a specified degree of certainty to its accuracy and precision.* (Extracted from the *Codex Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods*)

- **DIET MODELS USED FOR RISK ASSESSMENT OF RESIDUES OF VETERINARY DRUGS AND PESTICIDES**

Residues of Pesticides	Residues of Veterinary Drugs
- Covers a wide range of food - Theoretical models for regions created using data in the FAO Food Balance Sheet - Total weight of intake/day/caput=1.5 kg.	- Covers only animal products - Theoretical model using conservative values for consumption

ANNEX 2

COMMENTS ON THE DRAFT REVISED RECOMMENDED METHODS OF SAMPLING FOR THE DETERMINATION OF PESTICIDE RESIDUES FOR COMPLIANCE WITH MRLS

ARGENTINA (submitted to the 22nd Session of the CCMAS)

The draft made an extensive description of methods of sampling covering all aspects from sampling through the reporting of the results and its conclusion.

It is observed that the text contains those terms not explicitly defined in Annex I Definitions of Terms, and those terms which are being discussed under Agenda Item 4(a)[12] on this subject; e.g., "Representative sample". It is considered that, if necessary, two documents should be linked in order to avoid contradictions between these two Proposed Draft Directives.

3.5 Sampling Record (Is it similar to a detailed record (Acta in Spanish) of sampling?) It is not clear whether producer or owner of the lot retains one copy of sampling record.

In the section on Criteria for Determining Compliance, in para. 4.1 it is proposed to replace "y deberán ser corroborados por datos aceptables sobre control de calidad" with "y deberán ser respaldados por datos aceptables …" (Spanish only). In the same paragraph, the text shall be extended by indicating the origin of the additional analytical portions and by clarifying whether it corresponds to "a modification of the original sample" or "a new sample".

4.1 When the subject of correction of results for recovery is mentioned, it is suggested that a link be made between this and the conclusions reached on Agenda Item 6 of the Session[12].

Does para. 4.4 refer to measurement uncertainty? What is the criterion proposed for the decision?

In Table 1 (Spanish version) Part a) Meat and Poultry Products – a suspect lot: there is an error in the minimum number of primary sample, where it reads "16-30 aproximadamente", it must read "6-30" and in Annex II Schematic Representation of Sampling, there is another error which reads "6-3".

It is pointed out that minimum size of laboratory sample indicated in Table 3 "Meat and Poultry Products" is substantially bigger than that requested in our sampling plans. We agree with the comments of USA contained in CX/MAS 98/4-Add.1[13].

UNITED STATES OF AMERICA (submitted to the 22nd Session of the CCMAS)

General Comment

There appears to be a large amount of information that is assumed to be common knowledge in the preparation of this document.

Specific Comments

1. The abbreviation "MRL" is used throughout but nowhere is it defined.
2. Sec. 2.2: The MRL is intended to represent the average residue level in a lot as obtained from a composite sample derived from 1-10 primary samples (Sec. 2.3). This may be acceptable for practical purposes, but the uncertainty of the average from such a restricted definition is not included here, but it will probably be very large. Table 2 gives this information in terms of the number of samples required to detect at least 1 non-compliant unit in a lot of various incidence of violation. It shows that for 90-99% probability of detecting at least 1 non-compliant unit in 9-11 primary units, the incidence of violative units must be 20-35%.
3. Although it is not clear, it appears that samples of fat are sufficient to characterize meat and poultry products for the fat-soluble pesticides.

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12 Of the 22nd Session of the CCMAS.

13 Contained in this Annex.

4. Sec. 3.4: Fresh plant products are not to be cut or broken. How are large fruits and vegetables, such as watermelons, melons, squash, celery, broccoli, cauliflower, pineapple, etc. to be handled? Section 3.8 recognizes "segments removed from whole units." There exists some inconsistencies or lack of clarity in the document.

5. Sec. 4.1, page 8, It was indicated that when a residue is found to exceed the MRL, resampling (check analyses) of the lot should be done. It should be noted that this action changes the operating characteristics for the sampling plan that was used to evaluate the compliance status of the lot.

6. Sec. 4.4: This section indicates that prior to taking action on a lot whose sample results exceeds the MRL, the decision should take into account the variability of the results for the sample and the accuracy and precision of the method. However, there is no indication concerning how these requirements will be taken into account in the decision process .

7. Table 1, page 6, For meat and poultry products, non-suspect lots, only one (1) primary sample is to be collected. Though vaguely implied, Section 4. (Criteria for Determining Compliance) and Table 1 do not indicate that the acceptance number associated with the proposed sample sizes is zero (0). Assuming that the acceptance number is zero (0) and using Table 2, for a sample size of one (1), there is 90% confidence that at most 90% of the lot has violative residues. For non-suspect lots, 6-30 samples will be selected and the appropriate number to collect, based on Table 1, note (i), depends on the degree of confidence required. However, there is no indication as to how the "degree of confidence required" shall be determined. For bulk plant, eggs and dairy products, which may not be homogeneous, the sample sizes provided are not very stringent. For example, for samples of 10 units there is 90%, 95% and 99% confidence that the lot weighing 500 kg contains at most the following respective violative percent residues 20.4%, 25.6%, and 36.6%. For cans, cartons or other containers, there is 90%, 95% and 99% confidence that the lot of 100 containers contains at most the following respective violative percent residues 20.0%, 25.0% and 35.0%. This means that the sampling plan for a heterogeneous lot of 500 kg has the same stringency as for a 100 container lot.

8. Table 2, page 7, note (d), it was stated that, "This Table should not be used to determine the probability of detecting a violation in a lot of plant product. As composite samples are prepared for plant products, the statistical distribution of residues in the lot must be known, to determine the probability." At least some assumptions could be made and/or approximate normality for the sample mean (average) be used to provide some information on "the probability."

9. Table 2 Number of randomly selected primary samples required for a given probability of detecting at least one non-compliance in a lot of meat or poultry The title for Table 2 should be changed as follows: "... for a given probability of detecting at least one non-compliant sample in a lot of meat or poultry for a given incidence of violative residues in the lot." Since Table 2 provides sample sizes based on selected incidence of violative residues and confidence levels, it might prove useful to have procedure that permits a wider range of choices for incidence of violative residues and confidence levels. Such procedures are provided in (1) ISO 2859-0; Sampling procedures for inspection by attributes - Part (0), and (2) Schilling, Edward G., "A Lot Sensitive Sampling Plan for Compliance Testing and Acceptance Inspection," Journal of Quarterly Technology, Vol. 10, No. 2, April 1978, pp 47-51.

For the novice user of the document, several examples of how this document would be used might prove beneficial, especially examples demonstrating the combined use of Sec. 4, Tables 1 and 2.

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3.4 Preparation of laboratory sample and 4.4 (Criteria for determining compliance)

It is not clear what is meant: one sample/duplicate analyses or two samples/duplicate analyses. The last sentence of 4.4 must be made clearer.

3.5 Sampling record and 3.6 Packaging and transmission of the laboratory sample

Take into account that documents can be send by computer / on line. It is possible that no paper documents are send with the sample (only a barcode).

3.7 Preparation of the analytical sample

The last sentence is not clear.

Table 5

2.1 Liquid milks…..

The minimum size of each laboratory sample is too much. This has to be a minimum of 0.2 l or 0.2 kg. Use of borer tube can give possible problems with microbiological contamination.

Table 5

For analysis on pesticides it is not necessary to take more than one part from a cheese or from packed butter.

Table 2 (page 7)

Note (d), line 2: Replace "….a plant product. As composite samples are prepared for plant products, the statistical…." by "….a plant, egg or dairy product. As composite samples are prepared for plant, egg and dairy products, the statistical….."

Annex I, Definition of terms

Bulk sample: Replace "For plant products, the combined and well mixed aggregate of the primary samples taken from a lot. For meat, dairy and poultry products, the well mixed primary sample." by "For plant, egg and dairy products, the combined and well mixed aggregate of the primary samples taken from a lot. For meat and poultry products, the well mixed primary sample".

References

Item 4: Replace "International Dairy Federation, 1985. International IDF Standard 50B:" by "International Dairy Federation, 1995. International IDF Standard 50C:"