codex alimentarius commission E

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 6 **CX/RVDF 09/18/6**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Eighteenth Session

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DRAFT GUIDELINES FOR THE DESIGN AND IMPLEMENTATION OF NATIONAL REGULATORY FOOD SAFETY ASSURANCE PROGRAMMES ASSOCIATED WITH THE USE OF VETERINARY DRUGS IN FOOD PRODUCING ANIMALS

Comments at Step 6 (CL 2007/37-RVDF) of Comments of Argentina, Egypt, Iran (Islamic Republic of), Paraguay and United States of America

ARGENTINA

Argentina appreciates the opportunity to comment on the Draft Guidelines.

We present the following comments regarding the text in Spanish.

Specific comments

In **paragraph 11**, where the final example enclosed in parenthesis is mentioned, "(e.g. ISO 17025)", we suggest deleting this example since its interpretation could be a source of confusion because there are other validation methods / systems internationally accepted. Otherwise, there should be a list of all the methods / systems accepted, as recognized by the CCMAS.

As to the **Definitions**' section (page 43), we don't consider the definition given for the "Production system" appropriate. In this regard, we suggest deleting the last part of the definition, so that its application may be of a more general nature.

Specifically, the text should read as follows:

"Production system means the methods or activities used to produce food for human consumption.~~ for which the residue control programme of a Competent Authority has been designed.~~"

In **paragraph 27**, the use of the term "law" is not considered appropriate, since the decision of what type of standard will be used for regulation will depend on the internal code and legal practice of each country. We suggest replacing this term with "appropriate national regulations".

Specifically, the text should read as follows:

*"The conditions for the approval of veterinary drugs should be specified in **the appropriate national regulations**~~ law~~."*

In **paragraph 28, item (c)**, we suggest clarifying the term by adding the phrase "***for therapeutic use***" to the text.

Specifically, the text should read as follows:

"28. To mitigate potential risk, restrictions may be imposed on:

(a) formulations;

(b) criteria of use (e.g. time, species);

*(c) indications **for therapeutic use**;*

(d) withdrawal time/withholding time/food harvest restriction."

In **paragraph 33, item (d)**, we suggest changing the term "central database" to "unified database", since the significance lies in that there should be only ONE database and not a central one. As such, even when instances of operational decentralization were to take place, the idea of a unified database could be maintained, whereas the term "central" could give the wrong idea regarding the pursued objective.

Specifically, the text should read as follows:

*"(d) Requiring all uses to be recorded and/or notified to a ~~central~~ **unified** database."*

Paragraph 176 refers to the criterion used to determine the concentration of substances for which ADIs and MRLs have not been established by Codex. In this regard, the application of the "detection limit" as a criterion for this type of substances will be discussed in the framework of new work in the CCRVDF, which should be adopted as such by the CAC in its 32nd Session (2009). Therefore, Argentina considers that no criteria for this type of substances should be established before the discussion of this new work of the Committee is finalized.

EGYPT

We confirm Egyptian keenness to revise precisely all of what was mentioned in the appendix VI especially about:

- General principles about programmes for the control of residues of vet. drugs in food.
- The approach which is based on risk applied across the entire production chain and all food groups.
- The regulatory framework of sales, criteria, approved restrictions and responsibilities of business operators.
- Verification programmers purpose and design principles, system and targeted verification for our country and/or production system.
- Sample taking with appropriate mechanisms to prevent possible bias accruing in both the selection and taking of samples.
- Regulatory action in investigation of non compliances results to ascertain the contributing factors which lead to its occurrence and measures to fit for human consumption.
- Statistical considerations on sampling population size and sampling confidence reporting (table 1, 2).
- Sampling procedures and specific sample preparation instructions for honey.
- Preparing laboratory samples, shipment, interpretation and records.
- Instructions for collection of minimum quantity required for different commodities:

  (table A: meat and poultry products)

  (table B: milk, eggs, dairy products and aquatic animal products).
- General considerations on analytical methods for Residue control, integration and validation of methods.
- Analytical methods for residues of vet. drugs in food, methods of development considerations and performance characteristics of quantitative methods criteria in table 3.
- Confirmatory methods performance characteristics and performance required for relative in intensities mentioned in table 4.
- Recommendations of Miskolc consultation for confirmatory analysis of substances (table 5).
- Validation considerations for residue control methods, selection of appropriate test material, uncertainty of measurements and use of internal standards and choice of validation model.
- Quality control and quality assurance measures to be consistent with the principles published by IUPAC recommended for regulatory control laboratories.

- We recommend holding thorough discussions especially by developing countries including Egypt to be adopted by the 31st session of the Codex Alimentarius Commission.

IRAN (ISLAMIC REPUBLIC OF)

Iran, is not agreed with the use of EDI and full ADI. Although use of full ADI is scientifically justifiable within the current bases for Risk assessment however due to the possible extra-label use of veterinary drugs and possible uses in minor species it is recommended not to use full ADI to provide an extra safety margin.

Finally, it is suggested to extend establish MRLs for routine veterinary drugs in cattle, goat and sheep edible's offal such as rumen, abomasums and brain.

PARAGUAY

Paraguay presents the following information:

a) Paraguay is in general agreement with the content of the document.

b) With respect to paragraph 94 specifically (Port of entry testing programmes), the nature of its content is not clearly understood. After reading both the Spanish and English versions of the text, it is not clear what extension of the result attained from the sample unit applies, on consignments of either homogenous or non-homogeneous products.

Paraguay requests that this paragraph be drafted again, in a way that leaves no room for doubt in its interpretation.

UNITED STATES OF AMERICA

The United States is in broad agreement with the principles of this document. Below we provide comments which we believe are "house keeping," editorial in nature. The United States would like to see the following edits, but is also fine with the document as it stands should these comments not be taken up.

The document uses "sample size" for two different meanings. The first usage, found in para 53(c), 78, 87, 136, 137, 139,140 and 143 is based on the statistical definition of sample size, the number of samples taken from a population. We would suggest that "sample size" should be changed to more precisely, "number of samples" in the paragraphs listed above, because in Appendix B of the guidelines, Para 152 (b) and tables A and B (many locations), sample size is used to mean the amount (volume, weight, etc.) to be sampled of a commodity.

Quality Assurance and Quality Control:

At the meeting of the 17th CCRVDF, it was requested that the term "Quality Management Systems" be used instead of "Quality Assurance and Quality Control" as "Quality Management Systems" is now the preferred usage in ISO 17025. In reviewing the document, the old terms still appear in several locations in the document. However, in several places where the older terminology is used, it may still be appropriate. We have identified each location below where quality control or quality assurance is used with our thoughts on whether the term should be changed.

Para 49 (e) we would recommend changing to Quality Management Systems.

Para 85, refers to on farm sampling program so quality assurance may still be appropriate.

Para 188 (a) references a peer reviewed publication which uses the term so the current use is appropriate.

Para 189 The first reference to laboratory quality assurance system should be changed to Quality Management Systems. The usage of Quality control refers to the publication mentioned in the previous paragraph so use is appropriate. The third reference quality assurance and quality control should be changed to Quality Management System.

Para 194 refers to Quality Control Data, as not the total system, usage is fine.

Para 196 (b) refers to Quality Assurance in conjunction with ISO 17025 so should be changed to Quality Management System.

Para 227 change from Quality System to Quality Management System.

Para 234 usage of Quality Control within the context of the paragraph appears fine.

Para 236 The header should be changed to Quality Management Systems (and in the table of contents) The first line should read "A Quality Management System is an . . ." The second sentence will need to be rewritten. One suggestion would be "A Quality Management System both monitors those factors associated with the analysis of a sample by a

tester and provides the oversight by independent reviewers to ensure that the analytical programme is performing in an acceptable manner." I would suggest that the third sentence start "The use of a well-founded Quality Management System is invaluable to support . . ."

Para 88 a) It is difficult to follow the meaning of the sentence. A suggested revision (if we read the original intent of the sentence correctly) would be "immediate action, such as product recall, is indicated by a non-compliant finding; or"

Para 113. If this paragraph is taken to a literal conclusion, a laboratory would have to report any unexplained peak seen in a chromatogram. Because of differences in diet etc., seeing extra peaks in chromatogram in residue analysis is a common occurrence. We would recommend the sentence be removed. If the intent was that labs report suspect samples that are likely contain residues, but cannot fully meet confirmation criteria (such as a low intensity ion is missing in the MS analysis), then the sentence needs to be reworked.