codex alimentarius commission E

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00153 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 9 **CX/RVDF 07/17/12 Add.1**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Seventeenth Session

Breckenridge, Colorado, United States of America, 3 -7 September 2007

REPORT OF THE PHYSICAL WORKING GROUP ON RESIDUES OF VETERINARY DRUGS WITHOUT ADI/MRL

Comments submitted by Brazil, Canada, Ghana, United States of America and IFAH

BRAZIL

Brazil thanks the opportunity to comment the document and presents the following remarks:

SUMMARY CONCLUSIONS ON PROPOSALS FOR SOLUTIONS

*36. The working group agreed that the adoption of **specific reference methods** would not solve trade problems (potential effect low, feasibility low), while setting **default limits** would potentially solve trade problems (potential effect high) but would not be a solution because it would be very unlikely that Codex members could agree on one or more default limits (feasibility low).*

Brazil considers that "default limits" should not be a solution because there are not based on scientific risk assessment.

REPORT OF THE PHYSICAL WORKING GROUP ON RESIDUES OF VETERINARY DRUGS WITHOUT ADI/MRL

Paragraph 4

4. Further input by Codex members is needed in order to identify which veterinary drugs should be considered next. To this end it is necessary to identify these veterinary drugs and to provide sufficient detailed information on the veterinary drug and in particular on use, the consumer health concerns, trade problems and data availability. This is important as questions for the risk assessors (JECFA) by the risk managers (Codex) need to clearly and fully express the needs and desired end product(s). This is particularly true in those cases where it may be recognized that an ADI or MRL cannot be established, and the Codex is seeking additional risk assessment guidance from the JECFA.

Brazil considers needed include at final the sentence: "strictly based on scientific studies" as follow:

This is particularly true in those cases where it may be recognized that an ADI or MRL cannot be established, and the Codex is seeking additional risk assessment guidance from the JECFA, ***strictly based on scientific studies***

Paragraphs 16, 17 e 18

16. Export/import checks may include analytical tests for residues of veterinary drugs in order to verify whether the consignments fulfil the requirements of the importing country. Validated confirmatory analytical methods should be employed to confirm that apparently non compliant residues have been correctly identified.

Validation may use the performance criteria approach, which combines a single laboratory validation model with a requirement that methods meet specific performance specifications as described in a guideline currently under discussion in the CCRVDF.

17. In cases where MRLs have not been established, national or regional authorities responsible for food control frequently consider any amount of the veterinary drugs found in food consignment non-compliant ("zero tolerance").

18. In practice zero tolerance means not determined with the confirmation method employed. The tolerance is therefore determined by the capability of the laboratory in charge (i.e. the individual laboratory's detection limit). Thus the tolerance limit employed in practice may vary considerably between Codex members and from region to region. Moreover, detection limits may change over time. This may result in legal uncertainty and difficulties in trade.

Brazil understands that this procedure can not be legitimated to meet the SPS agreement, because it lacks of scientific background, and in most cases, does not address concerns toward consumer health.

In such cases, the use of administrative MRLs would be a fair option toward the adoption of procedures related to food safety and fair commercial practices.

Paragraphs 44, 46,

44. The summary should list all veterinary drugs that have been evaluated, a very brief summary of the JECFA evaluation and conclusion (i.e., ADI and recommended MRL), and the Codex evaluation and conclusion (i.e. MRLs). In instances where an ADI or MRL could not be established there should be a brief explanation to inform national/regional risk managers.

B Recommendation on specific veterinary drugs

46. The Working Group on Veterinary Drugs Without ADI/MRL recommends that on the basis of the JECFA conclusions established for the veterinary drugs listed below, the CCRDVF develop risk management decisions. In this it should also consider the results of the Working Group led by France asked to prepare a Discussion Paper to identify risk management topics and options to be considered at the 17th CCRVDF (see para 113 of ALINORM 06/29/31, Report of the16th CCRVDF). The CCRVDF may for example provide risk management advice to national and regional authorities that acceptable daily intakes and maximum residue limits cannot be recommended for the following veterinary drugs:

- Carbadox

  Evaluated: 38th and 60th JECFA

- Chloramphenicol

  Evaluated: 42nd and 62nd JECFA

- Nitrofurans including furazolidone, nitrofurazone

  Evaluated: 40th JECFA

- Nitroimidazoles including

  - Ronidazole, evaluated: 34th, 42nd JECFA

  - Ipronidazole, Dimetridazole, Evaluated: 34th JECFA

  - Metronidazole Evaluated: 34th JECFA

- Olaquindox

  Evaluated: 36th and 42nd JECFA:

- Stilbenes, Diethylstilbestrol

  Evaluated: 5th JECFA

Brazil will support the item 46, only if the list is strictly for information purposes and if the recommendations of item 44 are taken into account, in order that national or regional authorities can use information provided by the JECFA for risk management without the need generating a negative list.

47. A respective recommendation may read: *"The Codex Alimentarius Commission has evaluated the use of […] for use in food producing animals and cannot recommend either an MRL or extra label/off label use due to concern for toxicity to the human consumer."*

Paragraph 47 Brazil does not agree with this proposal for understanding that: national and regional authorities are capable and hold the exclusive authority for establishing their own information procedures, based on the results of risk assessment with recommendations from the JECFA, and after taking into account, specific characteristics of the production and control processes of their Country.

Paragraph 53 bullet 6- However, where there is insufficient data to support the safe use of a particular veterinary drug in food producing animals, consideration could be given to a recommendation not to use the veterinary drug and the establishment of an appropriate action limits for the veterinary drug residues.

Paragraph 53 bullet 6- This criterion must be restricted to substances with scientific evidence of public health problems.

CANADA

- Canada supports the JECFA recommendations to convene an expert group to develop a decision-tree approach for the evaluation of veterinary drugs, including different options for hazard identification and characterization and exposure assessment.
- Canada would support setting up procedures (outside of CCRVDF) to commit potential sponsors to join forces in order to share cost and efforts to enhance the generation of safety data for all veterinary drugs.
- Canada would support the organization of an expert working group and the development of alternative methods for the scientific evaluation of veterinary drugs. However, Canada would not support the inclusion of drugs on the priority list that have been previously evaluated by JECFA in which an ADI/MRL could not either be established and/or an ADI/MRL has been withdrawn.
- Canada would recommend that if a veterinary drug has been banned for use in food producing animals based on JECEA evaluation then the importing country should be able to monitor the level of residue for this product in the imported food using the best analytical methodology available to protect public health in the respective country.
- Canada would support the establishment of new criteria being suggested by the working group for the compounds to be listed on the priority list of CCRVDF in Annex III for evaluation by JECFA.

GHANA

On the issue of limits based on alternative methods of scientific evaluation, Ghana recommends that for developing countries to meet international standards regarding the requirement of MRLs, National and Regional Laboratories capacities need to be enhanced so as to enable them to conform to the acceptable performance of analytical methods.

In line with recommendation to be taken by the 17th CCRVDF on the provision of a complete list of evaluation to be made publicly available, Ghana supports the recommendations that Codex develops a more global approach for veterinary drugs used in food producing animals and also supports that evaluations and decisions made on veterinary drugs since CCRVDF was instated be made publicly available.

UNITED STATES OF AMERICA

The United States wishes to offer the following comments in response to CXRVDF 07/17/12.

1. The US generally believes this to be a very well written report and commends the Working Group on the work accomplished.
2. The US believes that the remaining issues are minor and can readily be resolved, allowing for acceptance of the Working Group's final report by the Codex Committee on Residues of Veterinary Drugs in Foods. To that end, the US has the following comments.

3. Paragraph 14. It is suggested that this recommended language be modified for clarity and brevity. The recommended language would read:

   "The Codex Alimentarius Commission has evaluated the use of chloramphenicol for use in food producing animals and does not recommend either an ADI or MRL, or its use in food producing animals."

   The recommended changes include the important endpoint of the acceptable daily intake (ADI) in addition to the MRL. Also, because chloramphenicol does not appear to be approved for use in food animals in any member countries, AND because neither an ADI nor MRL have been determined, it is appropriate for the Codex to provide the risk management suggestion that it (chloramphenicol) is not recommended for use in food producing animals.

4. Paragraph 41. Care must be taken that the assessment of risk, derived from the alternative ways of scientific evaluation, drive the action limit rather than allowing this endpoint to be driven by the performance capabilities of the analytical method. It is appropriate for the performance of the analytical method to modify the action limit that has been established based on risk to the human consumer.

5. Paragraph 46, last sentence before the box. The sentence should be edited to change "cannot be" to "are not" so that the entire sentence reads:

   "The CCRVDF may for example provide risk management advice to national and regional authorities that acceptable daily intakes and maximum residue limits are not recommended for the following veterinary drugs."

6. Paragraph 47. The sentence should be edited to be more closely in alignment with paragraph 46, to read:

   "A respective recommendation may read: "The Codex Alimentarius Commission has evaluated the use of (…) for use in food producing animals and does not recommend either an ADI or MRL."

   While it may be possible for Codex to do so, it seems more in the realm of national authorities to address potential extra-label/off-label use. Since the focus of the Codex is entirely on safety to the human consumer, the phrase "due to concern for toxicity to the human consumer" is superfluous.

7. Paragraph 48. The US is in agreement with the comment by Australia. While the US does not believe the table in paragraph 46 constitutes a negative list, it concurs with the concern expressed by Australia that the table may be misinterpreted.

8. Annex 1, page 29, carbadox. The column "consumer health protection concerns" should be edited to read:

   "Genetic carcinogen, no threshold for carcinogenesis is available."

   The US disagrees with the existing language. The US believes that a dose that presents an acceptable risk to consumers is determinable based on linear low dose extrapolation techniques and cannot agree with the existing statement. However, the suggested edited statement is factually correct and acceptable.

9. Annex 1, page 29, carbadox. The column "necessity for treatment/prevention of disease in animals" should be edited to read:

   "Control of dysentery and enteritis in swine, growth promoter."

   The existing text does not acknowledge the approved therapeutic claims for carbadox.

INTERNATIONAL FEDERATION FOR ANIMAL HEALTH (IFAH)

The International Federation for Animal Health (IFAH) submits these comments in response to CX/RVDF 07/17/12 (Report of the Physical Working Group on Residues of Veterinary Drugs without ADI/MRL). IFAH congratulates the EU as chair of the working group for developing the list of veterinary drugs in Annex 1 of the document. This list is appropriately called "Starting Point for a Priority List of Veterinary Drugs for Discussion at the 17th CCRVDF." This list will be valuable for the Working Group on Priorities to develop future lists requesting risk assessments from JECFA. The list is of particular value to the animal health industry to identify those veterinary drugs where safety data is required. The list will further help identify those risk management issues that may be preventing sponsors from submitting safety data to JECFA. IFAH offers several specific comments regarding CX/RVDF 07/17/12 for consideration by the 17th Session of CCRVDF:

1. The document makes frequent reference to drugs which should not be used / approved for use in food producing animals. The related concept of a “negative list”is also raised. Under Point 8 (marketing authorization issues) it is noted that approval of veterinary drugs is the role of national / regional regulatory programs. IFAH supports Point 48 attributed to Australia which completely opposes the concept of negative listing recommendations by the CODEX. IFAH endorses the exclusive role of national / regional government agencies in the establishment of marketing approvals for veterinary drugs.
2. IFAH acknowledges the role of the WG chaired by Australia on Priorities and notes that the material presented in Annex 1 should be transferred to the Priorities WG which should determine matters of priority. Marketing approval is the role of national governments; accordingly IFAH opposes the making of recommendations that some Annex 1 listed drugs should not be used in food producing animals. Further evaluation of positive risk management options should be addressed by the WG on risk management chaired by France.
3. IFAH strongly endorses the content of Point 27 and Point 28, noting that in 2006 Japan adopted a positive default limit principle for a wide range of veterinary and other chemical residues in food commodities to facilitate trade. The use of a “limit of toxicological concern” is referenced and supported by IFAH as one of the possible ways forward. IFAH notes it is most unlikely that the establishment of default limits for compounds currently without ADI/MRL can be achieved through the current JECFA framework as recommended in Point 28. Nonetheless, if JECFA is able to participate in the establishment of default limits based on limited data the involvement of this Expert Committee is endorsed. Risk management pathways to achieve progress in the setting of default limits should be now be taken up by the WG chaired by France on this subject. IFAH endorses the consideration of the use of the “old drug policy” options referenced in Point 40. Point 51 (expert working group) is also supported.
4. Point 33: IFAH believes caution should apply to the use of analytical limit of detection based “action limits”. The use of analytical performance limits tends to create disharmony when trading partners may have differing levels of analytical capability. In general this approach may become the most restrictive version of an absence of established Codex MRL, under this scenario trading partners may choose to adopt the analytical LOD, but often do not deem this appropriate or necessary. A Codex endorsement of the LOD as an action limit may be counterproductive relative to existing alternatives.
5. Section D: Points 52-54. These items can be taken up by the Priorities WG as the appropriate forum for this matter.