



**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS**

Twenty-second Session

San José, Costa Rica, 27 April – 1 May 2015

**THE DRAFT PROVISIONS ON ESTABLISHMENT OF MRLS FOR HONEY
(FOR INCLUSION ON THE RISK ANALYSIS PRINCIPLES APPLIED BY THE CCRVDF)**

Comments of Argentina, El Salvador, India, Kenya, Peru, Philippines, African Union

ARGENTINA

Argentina strongly discourages the inclusion of the proposed additions in Appendix IX of REP14/RVDF.

Rationale:

Argentina disagrees with the proposal to obtain MRLs for honey from data of national monitoring programs, similar to the approach taken by JMPR for spices.

First, honey consumption per person per day is at least 10 times higher than the consumption of spices (taken together). While the estimated consumption is 1 to 7 g/person/day for spices¹, the 21st CCRVDF Session assumed an estimated consumption of 50 g/person/day for honey. It does not seem appropriate to apply similar criteria against substantially higher consumption data for honey.

Moreover, “JECFA bases MRLs recommendations on residue data produced under good veterinary practices (GVP) conditions of use in one or more member states. A critical consideration in the establishment of MRLs for honey is that the MRL must be consistent with good beekeeping practice”.² On the contrary, the values obtained from monitoring programs of national governments do not accurately reflect the GVP but rather the modalities of honey commercialization, i.e. the values expected to be found in bulk honey from multiple producers. With this approach, two negative consequences are possible. One: setting low values of MRLs may be unnecessarily inconsistent with the approved GVP usage and therefore not practical. This could have a negative impact on the approval of new veterinary products for honey production, resulting in the lack of tools to control pests, which is just the opposite of what is desired. The other consequence: using these sampling criteria, the traceability of the primary production of honey would be threatened, making the detection of deviations from good practices and their correction impossible.

The main argument to support the alternative of MRLs for honey based on monitoring data is the difficulty in obtaining reliable data from field trials. This seems to be grounded on the paradigm or model of traditional studies of the depletion of residues in animal tissues, which involves numerous sampling time points multiplied by the need to include studies in different geographical areas. In this sense, Argentina suggests waiting for the progress of the VICH guideline for residue studies in honey hoping that a more flexible type of testing is required, reducing the number of samples to be processed and thus allowing study development at a lower cost.

Finally, with regard to the decision tree for the establishment of MRLs for veterinary drugs in honey recommended by JECFA (WHO Technical Report Series 988), Argentina outlines that the term “depletion studies” in the third box on the left and in the fourth box on the right is inappropriate. Since there is not a real depletion of residues in the honey matrix but a dilution as more honey is produced within the hive, Argentina suggest using the phrase “residue studies”.

EL SALVADOR

El Salvador supports the incorporation into the Codex Procedures Manual of the recommendation included in REP14/RVDF APPENDIX XI.

¹ GEMS/Food, http://www.who.int/nutrition/landscape_analysis/nlis_gem_food/en/

² JECFA's Response to nine questions posed by CCRVDF 20, Question 8.

INDIA**General Comment:-**

India Appreciate the work initiated by an eWG.

Specific Comment:-**Section IV: Risk Analysis****CCRVDF**i) 3.3 *Evaluation of Risk Management Options*

Paragraph 26. CCRVDF may: (insert before the second bullet point)

- Consider recommending MRLs for honey using alternative approaches in accordance with the guidance established by JECFA.

and

ii) ***Risk Assessment Policy for the Setting of MRLs of Veterinary Drugs in Food*****Role of JECFA** (page 137)

Paragraph 2. (insert just before 2 h)

- JECFA may consider alternative ways such as using residue monitoring data to derive MRLs in honey.

1. With respect to point i) said above, India suggest not to include this provision.

Rationale:-

The para 3.3 related to *Evaluation of Risk Management Options* describes the mandate of the CCRVDF where there is no reference for specific food has been mentioned. Hence, it seems that there is no need to include commodity specific provision under para 3.3.

2. With respect to point ii) said above, India support the inclusion of the provisions ii) in the Procedural Manual as proposed above.

Rationale:

3. As JECFA is a scientific body which performs risk assessments and provides scientific advice to FAO, WHO and the member countries of both organizations and the recommendations of the JECFA will also be endorsed by the concerned committee.

Further, Para 2(g) of 'Role of JECFA' describes the specific food commodities eg eggs, milk, honey. Hence, it will be more appropriate to add provision ii) related to MRLs in honey under para 2 of the Role of JECFA.

KENYA**COMMENT:**

Kenya supports the proposed additions, as presented in REP 14/RVDF Appendix XI, for inclusion in the Risk Analysis Principles Applied by CCRVDF. These additions should facilitate establishing Codex MRLs for honey. Therefore JECFA may consider alternative ways such as using residue monitoring data to derive MRLs in honey.

General Comment

We appreciate the comments submitted by **Brazil, Chile, Costa Rica, European Union, Iran and FoodDrink Europe.**

Kenya is of the opinion that it is not prudent to specify a food commodity in the procedural manual. This will be restrictive and will require further amendment of the procedural manual to accommodate other food commodities when need for MRLs arise.

PERU**GENERAL OBSERVATIONS:**

As a result of the meetings to review this document, the collegial decision of the Technical Committee on Residues of Veterinary Drugs in Foods was to approve the information that was circulated; basically regarding the alternative approach to determine MRLs for honey and the use of the information collected by the National Residue Programs developed by the sanitary authorities.

SPECIFIC OBSERVATIONS:

The Technical Committee on Residues of Veterinary Drugs in Food agrees with the information that was circulated.

PHILIPPINES

The Philippines with the Beekeepers’ Network Philippines Foundation and the University of the Philippines Bee Program show its support to address the establishment of MRLs for honey using an alternative approach in accordance with the guidance established by JECFA. The provisions are consistent with the objectives of the Philippines to produce honey that is safe to human health.

AFRICAN UNION

<p>3.3 Evaluation of Risk Management Options Paragraph 26. CCRVDF may: (insert before the second bullet point)</p> <p>AU is of the opinion that it is not prudent to specify a food commodity in the procedural manual. This will be restrictive and will require further amendment of the procedural manual to accommodate other food commodities when need for MRLs arise.</p> <p>Risk Assessment Policy for the Setting of MRLs of Veterinary Drugs in Food</p> <p>Role of JECFA (page 137) Paragraph 2. (insert just before 2h)</p> <p>AU opinion is that it is not prudent to specify a food commodity in the procedural manual. This will be restrictive and will require further amendment of the procedural manual to accommodate other food commodities when need for MRLs arise.</p>	<p>AU recommends amendment to the statement by deleting the words <i>..”for honey”</i> immediately after the word <i>”MRLs”</i> and before the word <i>”using”</i>...to read as follows... <i>”Consider recommending MRLs using alternative approaches in accordance with the guidance established by JECFA”</i>.</p> <p>AU recommends supporting inclusion of the statement with amendment.</p> <p>AU recommends amendment to the statement by deleting the words <i>....”in honey”</i>...at the end of the statement that is after the word <i>...”MRLs”</i>..in order to read <i>.....”JECFA may consider alternative ways such as using residue monitoring data to derive MRLs”</i>.</p> <p>AU recommends supporting inclusion of the statement with amendment.</p>
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