CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 10 **CX/RVDF 13/21/12**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Twenty-first Session

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DISCUSSION PAPER ON GUIDELINES ON THE ESTABLISHMENT OF MRLS OR OTHER LIMITS IN HONEY

(Report of the CCRVDF Electronic Working Group on Honey)

Introduction

1. At the 20th session of the Codex Committee on Residues of Veterinary Drugs in Food (CCRVDF) in San Juan, Puerto Rico, (7 – 11 May 2012), the Committee agreed to establish an electronic working group. The purpose of the group is:

- To prepare a discussion paper giving consideration to appropriate forms of guidelines for the establishment of MRLs or other limits for residues of veterinary drugs in honey, and if necessary
- To prepare a project document for new work.

Proceedings of the Electronic Working Group

2. The electronic Working Group (eWG) worked primarily by email and comment and document exchange was facilitated by an electronic forum established by the United Kingdom. This document reflects the input and views of the following countries: Argentina, Belgium, Brazil, Canada, European Union, France, Italy, New Zealand, Sweden, United kingdom and United States of America.

Discussion

3. Honey is a unique food of animal origin as there is no real metabolism and pharmacokinetic depletion of residues following treatment of bees as is found, for example, after treatment of mammals. When present in honey, residues deplete mainly by dilution as more honey is produced and possibly by thermal degradation or acidic hydrolysis.

4. Drug use in honey bee production is a minor use in minor species in most jurisdictions. The majority of countries agree that it is not practical to set withdrawal periods for bee treatments and therefore consider that only drugs with a “zero days” withdrawal period after bee treatment before honey flow commences should be permitted.

5. “Zero days” withdrawal may not be applicable or possible, such as when treatment during the honey flow period is essential to maintain bee health if there is an epidemic outbreak. In these cases, conditions under which the drug use is permitted and conditions that need to be met for the honey to enter the food chain should be specified and supported with evidence. For example, it may be considered appropriate to exclude honey from the brood area of the colonies treated with this drug from human consumption.

6. Maximum Residue Limits (MRLs) or other limits (such as “working residue levels” [WRLs] in Canada) may be established by national authorities in honey to establish a suitable withdrawal period (which should ideally be zero days) and allow for residue control. MRLs are derived from consideration of the detailed data (toxicological and residue depletion) dossiers submitted. On the other hand, WRLs are derived using a risk based approach and is based on the existing assessment of the toxicological data dossiers associated with other food animal species and by consideration of residue data from these species. Only drugs which have been approved for use in other food producing species, have an established Acceptable Daily Intake (ADI), and have the parent compound as the marker residue could be considered for determining WRLs. Other limits, such as WRLs should only be used for risk management purposes when no MRL is available.

7. A further possible approach to consider for setting limits for veterinary drug residues in honey is to follow the approach of the Codex Committee on Pesticide Residues (CCPR) for setting pesticide MRLs in spices. As there is a lack of residue data in this area because spices are considered a minor commodity, the CCPR has agreed that limits can be established from consideration of monitoring data. This policy has been set out in the Codex Alimentarius Procedural Manual (20th Edition, page 137, paragraph 12). If agreed, MRLs for honey could be established on the basis of monitoring data in accordance with guidelines established by JECFA. For extension to honey, it is suggested that the following criteria should be met:-

- An ADI for the substance is required;
- The substance monitored should be the marker residue; and
- The proportion of marker residue to total residues should be taken into account when proposing the MRL.

8. Veterinary medicines are clearly needed to protect bee health and welfare. Established MRLs or other limits are needed for these drugs to protect consumers of bee products (e.g. honey), and facilitate international trade in these commodities. However, there is a lack of internationally accepted guidance on how the human food risks associated with using bee treatments might best be managed.

9. The CCRVDF is awaiting the consideration by JECFA of the proposed risk assessment document at Annex 2 of CX/RVDF 12/20/14 on veterinary drugs used to treat honey producing bees. When JECFA has agreed upon the risk assessment document, the CCRVDF will be able to submit veterinary drugs for use in bees to JECFA for consideration. At that time the CCRVDF will need to consider if there is a need for a policy on how to consider the recommendations made by JECFA or whether the existing provisions in the Risk Analysis Principles by CCRVDF are sufficient for this purpose.

10. The eWG considered the need for developing guidance on setting MRLs or other limits for residues of veterinary drugs in honey. It was considered that there was a need to develop guidelines suitable for use particularly by national authorities which rely on Codex guidance when setting their legislative controls. The guidelines would be best placed as an appendix to existing guidance on sampling and analysis in CAC/GL 71-2009, which already contains guidance on good beekeeping practice as regards the selection of suitable drugs for the treatment of bee diseases.

11. One delegation dissented and considered that a case for new work had not been made nor did it agree that the rightful place for any new work in this area should be as an appendix to CAC/GL 71-2009. It further considered that the proposed progression of work is both premature and inappropriate in its current form.

Recommendations

12. Guidelines are necessary to allow national authorities to recommend MRLs or other limits for residues of veterinary drugs in honey and other edible bee products for control purposes. These guidelines could be prepared as an appendix to CAC/GL 71-2009.

13. If the Committee agrees to the preparation of the guidelines above, a project document for new work will be required and an initial draft of this is at Annex 1 for consideration.

ANNEX 1

PROJECT DOCUMENT FORNEW WORK ON

THE REVISION OF THE "*GUIDELINES FOR THE DESIGN AND IMPLEMENTATION OF NATIONAL REGULATORY FOOD SAFETY ASSURANCE PROGRAMME ASSOCIATED WITH THE USE OF VETERINARY DRUGS IN FOOD PRODUCING ANIMALS*" (CAC/GL 71-2009) TO INCLUDE GUIDELINES FOR NATIONAL AUTHORITIES ON THE ESTABLISHMENT OF MRLs OR OTHER LIMITS FOR RESIDUES OF VETERINARY DRUGS IN HONEY FOR CONTROL PURPOSES

1. PURPOSE AND SCOPE OF THE NEW WORK

The purpose of the new work is to prepare a guidance document on the establishment of MRLs or other limits for residues of veterinary drugs in honey for national authorities. This will allow bee treatments whilst assuring consumers of the safety of honey produced.

The scope of new work will involve:

- Reviewing existing guidance on setting MRLs and other limits (including related areas such as pesticides), bee husbandry and honey production to prepare consolidated guidance on setting MRLs or other limits on veterinary medicines for use in honey production following treatment of bees to minimise and control residues of veterinary drugs. This will bring international guidance in line with the latest knowledge and practices.
- Consideration of the risk management issues involved in using veterinary medicines in bees producing honey and the harvesting of honey to ensure consumer safety.

2. RELEVANCE AND TIMELINESS

Testing honey for residues of veterinary drugs is routinely used by competent authorities and business operators to evaluate the safety of food.

Whilst there is an existing Codex *Standard for Honey* (CODEX STAN 12-1981), this relates to the composition of honey. The overall Codex principles of establishing MRLs in other food animal tissues and products can also be applied to honey in a limited way. No international guidance exists on setting MRLs or other limits for the unique situation related to honey production, but limited national and regional guidance exists.

New work is proposed to reflect on the range of information and experience available from various sources. It is proposed that a guidance document is prepared to cover the establishment of MRLs or other limits in honey to minimise and control residues of veterinary medicines which might adversely affect human health and give rise to trade issues.

3. MAIN ASPECTS TO BE COVERED

Guidance will be introduced in the document to reflect current best practice regarding setting MRLs or other limits and how these might be applied to bee husbandry and honey production. Existing guidance on setting limits on residues of veterinary medicines used in bee husbandry and honey production should be considered to determine the most appropriate practices in this area. To do so, the following aspects require attention:

- Consideration of honey sampling guidance in the existing *Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programme Associated with the Use of Veterinary Drugs in Food Producing Animals* (CAC/GL 71-2009) to ensure that the variability of residue concentrations within and between hives, and also between seasons is reflected in the guidelines to be produced,
- Recognition of local practices in bee husbandry, where this does not compromise the integrity of the overall aim of the guidance to ensure good bee health,
- The appropriate roles of bee health maintenance and control of honey production for verification of process control within the context of HACCP and validation of control measures.

4. ASSESSMENT AGAINST THE CRITERIA FOR THE ESTABLISHMENT OF WORK PRIORITIES

General criterion

This work is directed towards consumer protection from the point of view of food safety, quality and ensuring fair practices in food trade while taking into account the identified needs of developing countries. This new work will strengthen other guidance provided in general support of consumer protection in developing and developed countries. On a global scale, it will contribute to a reduction of human health issues arising from exposure to veterinary drug residues. This new work also supports the general goal of Codex Alimentarius to continually review and update its standards and guidance.

Criteria applicable to general subjects

(a) Diversification of national legislations and apparent resultant or potential impediments to international trade: this new work aims to provide general best practice guidance on the establishment of MRLs or other limits of residues of veterinary drugs in honey for control purposes and update on new scientific and technical developments that are relevant for all countries and enable them to further refine their own risk management strategies.

(b) Scope of work and establishment of priorities between the various sections of the work: the most important parts of the work may be the review of existing guidance on setting MRLs and other limits in honey leading to the update on the benefits of maintaining good bee health to minimise the potential for veterinary drug residues in honey and the relationship with risk management.

(c) Work already undertaken by other international organisations in this field and/or suggested by the relevant international intergovernmental bodies: VICH is currently drafting a technical paper to become a guideline on residue studies in honey. This new work does not duplicate any current or proposed work undertaken by other (inter)national governmental organisations.

5. RELEVANCE TO CODEX STRATEGIC GOALS

The proposed work falls under all five goals of the Codex Strategic Plan 2008-2013.

Goal 1: Promoting Sound Regulatory Frameworks.

The results of this new work will further contribute to the development of sound food control and regulatory infrastructures and consequently will promote assurance of the safety of foods in general.

Goal 2: Promoting Widest and Consistent Application of Scientific Principles and Risk Analysis.

The new work updates the existing general guidance document with the latest thinking on the application of scientific principles and risk analysis and thus is essential to meeting this objective.

Goal 3: Strengthening Codex work-management capabilities

The new work strengthens an important aspect of Codex regarding the risk-based approach to food safety management and makes links to operational practice that are key to implementing the risk-based approach in day-to-day food industry practice.

Goal 4: Promoting cooperation between Codex and other relevant international organisations.

This work requires a close coordination between FAO, WHO and Codex, as well as competent authorities in countries and organisations representing bee keepers/honey producers.

Goal 5: Promoting Maximum and effective Participation of members.

The new work affects all members of Codex and may trigger further participation of both developing and developed countries with general interests in global trade of food and food ingredients.

6. INFORMATION ON THE RELATION BETWEEN THE PROPOSAL AND OTHER EXISTING CODEX DOCUMENTS

The proposed work concerns several general guidance documents (see above), specifically CAC/GL 71-2009, the Codex *Standard for Honey* (CODEX STAN 12-1981) and in general to other general guidance on risk management, such as the *Working Principles for Risk Analysis for Safety for Application by Governments* (CAC/GL 62-2007).

7. IDENTIFICATION OF ANY REQUIREMENT FOR AND AVAILABILITY OF EXPERT SCIENTIFIC ADVICE

There is adequate existing documentation available to allow this new work to be undertaken and no need for expert scientific advice is foreseen at this time.

8. IDENTIFICATION OF ANY NEED FOR TECHNICAL INPUT TO THE STANDARD FROM EXTERNAL BODIES SO THAT THIS CAN BE PLANNED FOR

None identified.

9. PROPOSED TIMELINE FOR COMPLETION OF THE NEW WORK

The following timeline is proposed for the completion of the work, preferably for final adoption in 2016/2017. The timeline should not exceed four years (2017).

Date	Meeting	Progress
August 2013	21st session CCRVDF	Agree on project documents and submit to 36th CAC for approval of new work.
July 2014	37th CAC	Approval of new work.
2014	22nd session CCRVDF	Consideration of the proposed draft guidelines at Step 4 and advance to 38th CAC for adoption at Step 5/8.
July 2015	38th CAC	Adoption at Step 5/8.
		Circulation for comments at Step 5/8.
2016	23rd session CCRVDF	Consideration of the proposed draft guidelines at Step 5/8 and advance to Step 8.
July 2017	39th / 40th CAC (depending on the schedules)	Final adoption.