DRAFT – MARCH 2011

CCRVDF ELECTRONIC WORKING GROUP ON HONEY

Introduction

1. At the 19th session of the Codex Committee on Residues of Veterinary Drugs in Food (CCRVDF) in Burlington, USA (30 August – 3 September 2010), the Committee agreed to establish a working group under the chairmanship of the United Kingdom. The purpose of the group is to:-

- Develop a policy for the establishment of MRLs or other limits in honey for consideration by the 20th session of the CCRVDF.

Proceedings of the Electronic Working Group

2. The Working Group worked primarily by email and comment and document exchange was facilitated by an electronic forum established by the United Kingdom. The Working Group sought to:-

    i. collate data from national authorities which have authorised veterinary drugs for use in bees from which honey is harvested for human consumption;
    ii. consider the criteria used by national competent authorities and identify common or related parameters used when authorising these treatments; and
    iii. propose a risk assessment policy for JECFA when the Committee would require its advice for setting appropriate limits in honey.

3. This document reflects the input and views of the following countries and organisations:-

- Australia, Austria, Belgium, Canada, Cyprus, Czech Republic, Denmark, European Commission, France, Germany, Hungary, Japan, Libya, Lithuania, the Netherlands, Portugal, Switzerland, United Kingdom, and Uruguay. (NOTE: FURTHER NAMES WILL BE INCLUDED IF INPUT TO THIS DOCUMENT IS RECEIVED)

Response to initial call for data

4. In response to a call for data, responses were received from a total of 19 countries and organisations. Of these, one response was received from the European Commission and 12 from Member States of the European Union (EU). Six responses were received from non-EU countries.

Data dossiers

5. All respondents require submission of substantial data dossiers prior to authorisation of treatments for honey producing bees. These dossiers must support the quality, efficacy and safety of the treatment and they are subject to independent review by a range of technical assessors in each of the responding countries. However, in some countries, treatments can be considered as veterinary drugs and/or pesticides and thus require co-ordinated consideration in cases of overlap.

Withdrawal periods after bee treatment and acceptable residue limits

6. The majority of countries and organisations agree that it is not practical to set withdrawal periods for bee treatments and therefore apply a “zero days” withdrawal period after bee treatment. However, Japan has established a withdrawal period for “Apiten” (active ingredient mirosamycin) of 14 days (COULD COLLEAGUES IN JAPAN PLEASE EXPLAIN HOW THIS TIME PERIOD IS SET?).

7. Whilst a “zero days” withdrawal period may be applied by many authorities, Maximum Residue Limits (MRLs) or other limits (such as “working residue limits” [WRLs] in Canada) may be applied to honey. These limits are derived from consideration of the detailed data dossiers submitted, or are derived from a risk based approach by extrapolation where no residue data are available.

Recommendations

8. A draft policy for the establishment of MRLs or other limits in honey has been prepared for consideration by the Committee and is attached at Annex 1.

ANNEX 1: DRAFT POLICY FOR THE ESTABLISHMENT OF MRLs OR OTHER LIMITS IN HONEY

Introduction

1. The purpose of this document is to provide guidance on the data to be provided to permit risk assessors to propose Maximum Residue Limits (MRLs) or other limits in honey following the treatment of bees with veterinary medicines.

Data to be provided

2. All applications for consideration and proposal of MRLs or other limits of veterinary drug residues in honey shall follow existing JECFA requirements in the data to be provided and the quality which is expected. The data provided shall include, but not necessarily be restricted to:-

- origin and history of development;
- physical, chemical and biological properties;
- manufacturing process;
- indications, effects and potency;
- administration and dosage;
- stability;
- toxicity;
- target animal safety;
- pharmacological action;
- absorption, distribution, metabolism and excretion;
- clinical trials; and
- residue study data

3. All studies above, except the residue study data should follow existing JECFA guidance. Due to the unique nature of residue depletion in honey, particular guidance is required on conducting residue studies. Published data suggest that there can be very significant variation in residue concentrations within and between hives. This is compounded by variable effects due to seasonality of treatment. Therefore, a specific residue study protocol is required for bee treatments if honey is to be harvested for human consumption.

Residue study data

4. For the purposes of establishing a safe residue limit for honey, the following protocol should be followed.

- Residue studies should be conducted over a minimum of two treatment seasons.
- A minimum of 40 hives in the same geographical location should be used in each treatment study.
- Five hives should be used per time point. As there can be considerable variation within and between hives, all honey produced in the five hives should be collected at the same time point post treatment, filtered to remove extraneous materials and homogenised in bulk. No less than five aliquots of a minimum of 100g each must be taken from random points in the bulk honey. Each aliquot must be analysed in replicate.
- A control group of five hives should be maintained in the vicinity of the treatment hives but not treated. All honey from these five control hives will be collected at the end of the study (i.e. the last time point sampled after treatment) and dealt with as in the paragraph above. This will indicate if significant transfer of honey between hives has taken place. If the residue concentrations in the control honey exceed the concentrations determined in the honey from the final post-treatment hives the overall study must be considered unreliable and repeated.
- The results from the residue studies above, together with the other data provided, will assist risk assessors in proposing a MRL for honey, assuming a daily consumption of 50g per adult.

Data submitted without a satisfactory residue study

5. If no residue data is submitted or the residue data is unsatisfactory, it may still be possible for risk assessors to propose temporary limits for honey. For veterinary drug residues with an existing Acceptable Daily Intake, extrapolation to assume that all sugar in the human diet is honey should enable calculation of a safe temporary limit in honey. Applying a further safety factor, if necessary, should then provide a conservatively based concentration appropriate for human health protection until detailed residue studies permit a reconsideration of the data.