



JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS
Twentieth Session
San Juan, Puerto Rico, United States of America, 7 –11 May 2012

REPORT OF THE *AD HOC* WORKING GROUP ON PRIORTIES

The *ad hoc* Working Group on Priorities (WGP) met on Sunday 6 May 2012 from 9.00 am until 10.30 am. The meeting was attended by representatives from a large number of delegations.

Introduction

The delegation of Australia (Dr Robert Munro) welcomed everyone to the working group and made some introductory remarks. He clarified that the task of the WG is to prepare recommendations to the plenary on agenda items 9a and 9b.

Agenda item 9a: Priority list for of veterinary drugs for evaluation by JECFA – new nominations

The chair noted that requests for seven compounds have been received, details are found in documents CX/RVDF 12/10/11 and CX/RVDF 12/10/11 Add.1, and discussions on each compound are summarized below.

Gentian Violet requested by Canada. A complete form with all relevant information was provided, toxicological and residue data are available and can be submitted to JECFA following a call for data. It was noted that the data package does not constitute a standard regulatory data package. Based on this the WG agreed to include this compound in the priority list, for establishment of an ADI and recommend MRLs considering topical use in cattle, swine, sheep, goats and horses, as well as potential environmental contamination.

Flumequine, Emamectin Benzoate and Oxolinic acid were requested by Chile for use in salmon and trout. Information gaps for this request were identified. Chile provided no information on data availability, also the exact nature of the request requires clarification. The WG agreed to include these compounds on the priority list on a conditional basis, pending clarification of the open questions from the country and the availability of data.

Questions that need to be clarified:

- Exact application of these compounds, either alone or in combination
- Data availability: type of data and time frame of availability

Lasalocid was requested by the USA. A complete form with all relevant information was provided, toxicological and residue data are available and can be submitted to JECFA following a call for data. Based on this the WG agreed to include this compound in the priority list, for request of establishment of an ADI and recommendation of MRLs for poultry (chickens, turkey, duck, quail, pheasants) tissues and eggs, taking into account use patterns in all regions where the product is registered.

Phenylpyrazole was requested by the USA. A complete form with all relevant information was provided, toxicological and residue data are available and can be submitted to JECFA by July 2013, following a call for data. Based on this the WG agreed to include this compound in the priority list, for request of establishment of an ADI and recommendation of MRLs for cattle tissues (liver, kidney, muscle, fat).

Zilpaterol hydrochloride was requested by the USA, with a complete form submitted. Several delegations strongly objected to the inclusion of this compound on the priority list, since it is a beta-agonist and such compounds are not allowed in their countries, so there will not be a consensus in CCRVDF on the establishment of MRLs subsequent to the JECFA assessment, thereby not fulfilling basic requirements for Codex work.

This compound is similar to ractopamine for which proposed MRLs have been retained at step 8 for many years and including this compound will create the same situation. Other delegations strongly supported inclusion of the compound, since it fulfills the CCRVDF criteria for inclusion in the priority list, and is considered a safe and effective tool for food production, so improves people's access to food. Moreover, the product has been registered in several countries. It was also mentioned that there is a need for a scientific assessment, irrespective of what CCRVDF will then do, since this evaluation in itself has an important international value. One delegation raised strong objections based on ethical and animal welfare concerns. An observer responded that there were no known animal welfare issues associated with the approved use of the compound. Another delegation raised concern in light of very limited financial resources for JECFA to request a priority evaluation of such a controversial compound, and suggested to put it on a 'waiting' list until the ractopamine issue is solved. One observer supported the view of countries objecting to the inclusion in the priority list, whereas one other organization supported its inclusion, since it fulfills the criteria, and a scientific assessment in itself is of value, until Codex finds a way to deal with policy differences.

The Chair reminded the meeting of the criteria for referring compounds to JECFA as laid down in Section 3.1.2 "Establishment of Priority List".

The Chair also reminded delegations that the WG was evaluating proposals against criteria, which are fulfilled in this case. Hence he recommended the compound to be included, since scientific evaluation in itself is an important step and may help with further discussion. One delegation replied that Codex works on the basis of consensus, which is not reached in this case. The Chair repeated that the compound fulfills the requirement for inclusion in the priority list, and the final decision on inclusion on the priority list will have to be made by the plenary.

Data submissions

The JECFA Secretariat emphasized that when countries respond to a JECFA call for data it is important to submit all registered use information (i.e., label information including species, route of administration, dose, withdrawal periods and other instructions for use).

Recommendations

1. To forward the priority list (Annex 1) to the CAC for approval, noting that the WG was unable to achieve consensus concerning zilpaterol hydrochloride
2. To recommend that Members submit all requested information when proposing compounds for consideration for inclusion in the priority list

Agenda item 9b: Database on the need for MRLs for Developing Countries

The USA, as Chair of the Working Group reported on this initiative. The task of the eWG was to clarify the existing list of needs of developing countries and progress has been achieved. The group was unsuccessful in clarifying data availability on many compounds, so overall further work is necessary. However the group was successful in identifying three compounds of common interest to many developing countries. The compounds are bacitracin, enrofloxacin and florfenicol. The group can now try to identify relevant available data required to recommend additional MRLs.

Recommendation:

That the e-WG continues its work and clearly identifies developing country requirements, taking into account what has been done by JECFA already, and in particular for these three compounds identify data needs and define the exact request (i.e. MRLs species and tissues).

Any other matters:**Ivermectin:**

Brazil requested consideration of the pending request for re-evaluation of ivermectin, in reference to the outcome of the 75th JECFA meeting, requesting further data relating to the ADI. The IFAH representative noted that at this point in time there is no interest by industry to submit further data.

Uruguay repeated its previous request for the need for MRLs for ivermectin in cattle (muscle). The Chair noted that these requests will be dealt with under Agenda Item 3a in plenary. The Chair then thanked the delegates for active participation and closed the meeting.

Annex 1**PRIORITY LIST OF VETERINARY DRUGS FOR EVALUATION OR RE-EVALUATION BY JECFA**

Name of the Compound	Questions(s) to be answered	Data Availability/Time	Proposed by	Comments
Gentian Violet	Can an ADI be established? Is the continued use in food producing animals safe for humans? (MRLs considering topical use in cattle, swine, sheep, goats and horses, and potential environmental contamination)	Data package is available and can be submitted to JECFA following a call for data.	Canada	For details see CX/RVDF 12/20/11
Flumequin		Not known	Chile	Conditional pending clarification of nature of request and data availability
Emamectin Benzoate		Not known	Chile	Conditional pending clarification of nature of request and data availability
Oxalinic acid		Not known	Chile	Conditional pending clarification of nature of request and data availability
Lasalocid	Request to establish ADI and recommend MRLs in poultry (tissues and eggs) use patterns in all regions where it is registered. Chickens, turkey, duck, quail, pheasant	Data available, can be submitted in response to call for data	USA	For details see CX/RVDF 12/20/11 Add.1 EU: registered and willing to provide all data possible
Phenylpyrazole	Request to establish ADI and recommend MRLs in cattle (tissues) use patterns in all regions where it is registered. Beef cattle liver, kidney, muscle	Data available, can be submitted in response to call for data	USA	For details see CX/RVDF 12/20/11 Add.1

	and fat			
Zilpaterol hydrochloride	ADI; MRLs for cattle muscle, liver, kidney and fat	Data available, can be submitted in response to call for data	USA	For details see CX/RVDF 12/20/11 Add.1