CODEX ALIMENTARIUS COMMISSION

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 **CRD 13**

Original language only

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Twentieth Session

San Juan, Puerto Rico, 7-11 May 2012

RISK MANAGEMENT RECOMMENDATIONS FOR THE VETERINARY DRUGS FOR WHICH NO ADI AND/OR MRL HAS BEEN RECOMMENDED BY JECFA DUE TO SPECIFIC HUMAN HEALTH CONCERNS

Comments of Egypt, European Union, Kenya, Nigeria, Philippines and IACFO

EGYPT

Egypt recommended that:

Carbadox, Chloramphenicol, Chlorpromazine, Malachite green, Nitrofurans Nitroimidazoles, Olaquindox, Stilbenes (diethylstilbestrol)

To be completely prohibited to be used in food producing animals with exception of metronidazale from nitroimidazoles as used in Egypt for poultry and large animals and exception of nitrofurans which is banned in Egypt since 10 years for its mutagenic and query carcinogenic actions.

Egypt also like to assure its opinion in relation to Ractopamine and bovine somatoropin to be stopped completely at Step 8.

EUROPEAN UNION

The European Union (EU) would like to thank the participants of the electronic working group for the active participation in developing the document on the risk management recommendations for veterinary drugs where JECFA identified specific human health concerns.

The EU welcomes the initiative of CCRVDF to develop risk management recommendations for the drugs where JECFA identified health risks.

The EU strongly supports the widely accepted principle that substances which are both genotoxic and carcinogenic should not be intentionally added to the food chain. They should not be used as veterinary drugs in food producing animals because risks for human health cannot be ruled out even at very low concentrations. The same policy should be applied to drugs where JECFA has identified other significant health risks. Therefore, the EU supports option A for risk management recommendations for all the substances in the Annex of the document.

Option B would not be suitable for a Codex risk management recommendation for the following reasons:

- It fails to give clear and harmonised risk management recommendations to national authorities but instead invites them to take any measure they see fit. In this way, it goes against the basic Codex objective which is to introduce harmonised international standards protecting the health of consumers and ensuring fair practices in the food trade.
- It does not recognise JECFA's role as the primary source of scientific advice to CCRVDF by referring to national risk assessments on equal footing. Governments which have conducted risk assessments which allow the use of these substances under some circumstances, should bring those risk assessments to CCRVDF, together with any underlying scientific data which may not have been available to JECFA. It would then be for CCRVDF to decide whether JECFA should be asked to review the new information.

KENYA

Issues and observations

i. The risk management options provided by the JEFCA under ‘’option B’’ for Carbadox, Chloramphenicol, Chlorpromazine, Malachite Green, Nitrofurans, Nitroimidazoles, Olaquindox, Stillbenes may not be fully complied with in the context of developing countries

Option B

- Basing the risk management conclusion on results of the existing JECFA risk assessment(s); or
- Basing the risk management conclusion on risk assessments conducted by other government/competent authorities; or
- Basing the risk management conclusion on approaches to determine an acceptable level of risk and residue concentrations that result in consumers not exceeding that level of risk (such as an acceptable margin of exposure or extrapolation of the dose response curve to a specified risk level); or
- Basing the risk management conclusion on development of scientific data to address the concerns identified in the JECFA risk assessment; or

Basing the risk management conclusion on establishment of conditions of use that limit exposure of the consumer to residues of concern (such as limiting use to a very early life stage or establishing a long withdrawal time).

Comments

i. Option A is recommended

Option A

- In view of the health risks identified by JECFA, CCRVDF recommends that Carbadox, Chloramphenicol, Chlorpromazine, Malachite Green, Nitrofurans, Nitroimidazoles, Olaquindox, Stillbenes should not be used in food producing animals.

In addition there are new and safer alternative drugs in the market.

NIGERIA

Nigeria commends the e-Working Group led by the European Union for the good work done on the document.

Nigeria supports option A in view of the health risks identified by JECFA and agrees that Carbadox, Chloramphenicol, Chlorpromazine, Malachite Green, Nitrofurans, Nitroimidazoles, Olaquindox and Stillbenes should not be used in food producing animals.

Justification

When health concerns identified by JECFA on the use of substances are based on genotoxicity and carcinogenicity, it is logical that such substances should not get into the food chain because health risks cannot be ruled out, even at very low concentrations

Enforcement of compliance with withdrawal periods (WP) for Veterinary drugs is a major challenge under the prevailing circumstances in some developing countries. More so, there are safer alternative drugs in the market that can replace the ones in the priority lists.

PHILIPPINES

Background

In the 19th Session of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) in Burlington, USA, the committee agreed to establish an electronic working group (eWG), led by the European Union with the following terms of reference:

- To develop risk management recommendations for the following veterinary drugs for which no ADI and/or MRL has been recommended by JECFA due to specific human health concerns: carbadox, chloramphenicol, chlorpromazine, malachite green, nitrofurans, nitroimidazoles, olaquindox, stilbenes (diethylstilbestrol);
- The risk management recommendations should be based on evaluation of the information available through the JECFA reports and monographs and through dialogue with the JECFA secretariats; and
- The risk management recommendations should incorporate the decisions of the 18th Session of CCRVDF that chloramphenicol should not be used in food producing animals.

Options

The electronic working group came up with two risk management options:

- Option A. The listed veterinary drugs should not be used in food producing animals

- Option B. To manage the risk, the competent authorities should base its decision on risk assessment done by JECFA, other government/competent authorities, margin of exposure, scientific data or establishment of conditions of use.

Country Position

The Philippines has banned the use of chloramphenicol (DA-AO No. 60 s 1990/ DOH-AO No. 91 s 1991), carbadox and olaquindox (DA-AO No. 1 s 2000/ DOH-AO No. 4, s 2000) and nitrofurans (Joint AO No. 2 s 2000) in food animals.

The Philippines strongly supports Option A with the following justifications:

1. The Philippine government decision to ban a drug for use in food animals is triggered by human health concern. It is based on genotoxicity, carcinogenicity and other significant health risks that the drug may cause to humans. Human safety is always a top priority. In addition, the Philippines recognizes and supports the scientific advice of JECFA.
2. It is a strong belief of the Philippines that genotoxicity, carcinogenicity and other significant health risks cannot be compromised and are independent of geographic region. The country does not support the use of alternative approaches like long withdrawal period and margin of exposure.
3. These banned drugs are not unique and there are other available effective alternatives. The use of these drugs will not provide additional benefit to the food industry. There are other drugs currently available which are proven safe and equally effective.

IACFO - The International Association of Consumer Food Organizations

Recommended risk management measures

IACFO strongly supports Option A for each drug because it is the management measure that best protects public health. In reference to Option B, should it be adopted, IACFO proposes that for all drugs under review in this agenda item that the Committee remove the 3rd and 4th bullet points.

- *Basing the risk management conclusion on results of the existing JECFA risk assessment(s); or*
- *Basing the risk management conclusion on risk assessments conducted by other government/competent authorities; or*
- ~~***Basing the risk management conclusion on approaches to determine an acceptable level of risk and residue concentrations that result in consumers not exceeding the level of risk (such as an acceptable margin of exposure or extrapolation of the dose response curve to the specified risk level); or***~~
- ~~***Basing the risk management conclusion on development of scientific data to address the concerns identified in the JECFA risk assessment; or***~~
- *Basing the risk management conclusion on establishment of conditions of use that limit exposure of the consumer to residues of concern (such as limiting use to a very early life stage or establishing a long withdrawal time).*

Rationale: The term "approaches" used in the 3rd bullet has no context or clear guidance. Additionally, the terms "development of scientific data" in the 4th bullet is vague and does not require that the data be at a scientifically comparable level to JECFA. These segments of Option B should be removed because consumer protection requires clear and understandable tools to be used by nations, and these bullets do not provide guidance on identifying those tools. Furthermore, with regard to the 3rd bullet, allowing governments/competent authorities to use undefined "approaches to determine an acceptable level of risk" runs counter to treaty obligations that require use of a science-based risk assessment that applies techniques developed by relevant international organizations. Regarding the 4th bullet, risk management decisions that lower health protections based on unqualified scientific data are not comparable and therefore should not be allowed to become part of a WTO challenge. Again, IACFO recommends that the 3rd and 4th bullet points be removed due to inconsistencies with international treaty obligations.

ANNEX

Risk management recommendations for substances for which JECFA could not establish ADI/MRL due to specific health concerns

IACFO proposes that information on the classification of drugs by the World Health Organization (WHO) as important antimicrobial (IA), highly important antimicrobial (HIA), or critically important antimicrobial (CIA) to human medicine be included in this agenda item. IACFO offers the following format for including this information:

CHLORAMPHENICOL

Chloramphenicol is a broad-spectrum antibiotic ***that is classified as HIA**** *with historical veterinary uses in all major food-producing animals and with current uses in companion animals.*

[…]

NITROFURANS

Nitrofurans are antimicrobial substances which have been used in the past therapeutically and prophylactically in a number of food producing species including pigs, poultry and cattle. ***The nitrofuran, furazolidone, is classified as IA.****

[…]

NITROIMIDAZOLES

Nitroimidazoles are active against protozoal parasites and anaerobic bacteria. In veterinary medicine, the most important indication is the prevention of histomoniasis in turkeys with dimetridazole. ***The nitroimidzole, metronidazole, is classified as IA.****

[…]

****WHO has defined antimicrobials as Critically Important (CIA), highly important (HIA) and important (IA) to human medicine.***

Rationale: The WHO classifies chloramphenicol, furazolidone, and nitroimidazole as highly important and important drugs to human medicine – meaning that these drugs require the most urgent development of risk management strategies in order to preserve its effectiveness in human medicine.[1] This Committee focuses on veterinary drug residues, but the Committee should not overlook additional public health considerations, including antibiotic resistance (ABR). ABR that develops through the use of veterinary drugs is a significant cross-cutting issue for the Committee to consider and it is well within the expertise of the members. When making decisions on the use and allowable levels of veterinary drug residues in food products, issues surrounding the potential to promote the spread and development of ABR pathogens should be noted.

[1] Critically Important Antimicrobials for Human Medicine: http://www.who.int/foodsafety/foodborne_disease/CIA_2nd_rev_2009.pdf