codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 7 **CX/RVDF 04/15/5-Add. 1**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Fifteenth Session

Washington, DC (metro area), (United States of America), 26- 29 October 2004

PROPOSED DRAFT CODE OF PRACTICE TO MINIMIZE AND CONTAIN ANTIMICROBIAL RESISTANCE

COMMENTS AT STEP 3

Comments submitted by Cuba and United States in response to CL 2003/40-RVDF

CUBA

In response to CL 2003/40-RVDF, regarding the Proposed Draft Code of Practice to Minimize and Contain Antimicrobial Resistance, we inform you that the Republic of Cuba approves the Proposed Draft presented, with the inclusion of the following comments:

- It would be necessary to implement a method to carry out the study of the antimicrobial resistance of commensal microorganisms.
- Among the responsibilities of the pharmaceutical industry, the methodology for the destruction of antimicrobials and containers should also be included.

UNITED STATES

This responds to CL 2003/40-RVDF which requested comments on the Proposed Draft Code of Practice to Minimize and contain Antimicrobial Resistance. The United States appreciates the opportunity to provide the following comments for consideration at the forthcoming 15th Session of the Codex Committee on Residues of Veterinary Drugs in Foods.

The U.S. delegation thanks the Working Group chaired by the United States and all its contributors for the extensive work on developing this complex issue document. We appreciate the opportunity to provide some general comments and brief specific comments on the individual sections of the draft document. The intent of our comments is to help the Working Group and the CCRVDF quickly move this document through Codex so that it might be adopted by the CAC as soon as possible.

General Comments

Recognizing that the draft code of practice is to contain antimicrobial resistance, the term "antimicrobial veterinary drug" should be used in place of "veterinary medicinal products" in this document. This replacement should be made with the understanding that a definition of a veterinary drug has already been provided by Codex. While the inclusion of anticoccidial drugs as antimicrobials is technically correct, there are many anticoccidial products, such as polyether ionophores, with no recognized genetic mechanisms of resistance and no human use. Therefore, they are not a recognized issue with respect to antimicrobial resistance. In this regard, the U.S. Delegation also wishes that the Glossary and Definitions of Terms be amended to more clearly specify the anticoccidial products that do not pertain to antimicrobial resistance.

The document should be very explicit about the use of the term antimicrobial resistance with respect to disease prevention or prophylaxis. In this document risk assessments are only recommended for growth promoters. This should be made in accordance with FDA Guidance #152 which states that all antimicrobial drugs require a risk assessment.

At every juncture, the drafting committee has reaffirmed the proposed code's focus on the risks to human health from antimicrobial resistance. Throughout the revision process, every effort should be made to remain consistent with the original aim identified in the draft code of practice. Secondly, this document should also recognize that antimicrobial

veterinary medicines, when used prudently, can result in a safer food supply. Finally, the document should always remain cognizant to the terms of reference of CCRVDF, forming its topics and recommendations accordingly.

Specific Comments

Aims and Objectives

Without minimizing environmental impact, paragraph 7 addressing environmental concerns remains outside the terms of reference of CCRVDF. CCRVDF is guided by the Codex second principle concerning the role of science in the decision-making process which states "When elaborating and deciding upon food standards, Codex will have regard, where *appropriate*, to other legitimate factors relevant to the health protection of consumer and for the promotion of fair practices in food trade."

Due to the lengthy nature of this text, potential overlaps and contradictory statements may occur. There is general consensus that there are some points of contradiction in paragraphs 8 and 51 with their attending bullet points. In addition, there may also be a conflict between the bulleted points of paragraphs 8 and 9. It is recommended that the drafting group review the latter paragraph to determine conformance with the WHO document *Principle for the Containment of Antimicrobial Resistance in Animals Intended for Food.*

Responsibilities of the Regulatory Authorities

The U.S. delegation is of the opinion that paragraph 11 does not duly recognize the safety and well-being of animals and the associated benefits to the safety of consumers from the prudent use of antimicrobial veterinary products. Secondly, as it is generally agreed that antimicrobial resistance is mechanism based rather than product based, it is neither necessary nor prudent to ignore entire classes of drugs at the expense of individual drugs.

In paragraph 14 it should clarify how expediting approvals for antimicrobial drugs will reduce the development of resistance. This paragraph should be edited with the following perspectives in mind (1) limiting off-label use to those antimicrobial drugs that may select for resistance and are of importance for human medicine unless there is an appropriate evaluation for such use by the relevant authorities and/or veterinarian; and (2) better define the listing of antimicrobials that are of critical importance for human medicine needs. A second option (as suggested by the recent FAO/WHO meeting in Oslo, Norway) is to simply delete this phrasing until such time when a generally agreed upon definition can be provided. At this same meeting, there was also a recommendation made that bears striking similarity with paragraph 33. This paragraph implies that a "bright-line" standard or a threshold could be established through the use of surveillance data from a government operated programme designed to re-evaluate the conditions of use of an antimicrobial agent. For the sake of consistency with the Oslo recommendation, this paragraph should be reviewed accordingly.

The U.S. delegation believes that paragraph 35 addressing the control of advertising should be deleted. This matter does not fall within the terms of reference for Codex as there is currently no recognized guidance for advertising. In acknowledging the inherent inconsistencies in national legislation among Codex members, this absence of guidance was instituted to prevent incongruous measures between any two member countries. In addition, there is a similar statement about advertising found in paragraph 42 that also deserves attention.

Veterinarians need research support to be successful in fulfilling their responsibility to prevent or treat infectious diseases in food producing animals. In this regard, paragraph 37 should be strengthened to encourage relevant authorities to support and promote public and private research to develop alternative methods and treatment regimes to prevent and treat infectious diseases.

Responsibilities of the Veterinary Pharmaceutical Industry

The first bullet point in paragraph 41 needs to be strengthened. Manufacturers of veterinary products have the primary responsibility of producing veterinary products that meet the quality and effectiveness standards of both the country of manufacture and the importing country.

Responsibilities of the Pharmacists and/or Distributors

The U.S. delegation believes that paragraphs 45-47 are too narrow in their scope and would be more appropriate if they referred more generically to authorized disciplines and/or specialists rather than provide the potential to be limited to a specific class of professionals. The reality is that pharmacists are not or may not be relevant sources of veterinary medical products in many countries. Secondly, where pharmacists do actually operate, they may be too few in number to effectively provide a timely and readily available source of antimicrobials for animal needs.

Responsibilities of the Veterinarians

The U.S. delegation wishes to address concerns with the limited professional roles found in prophylactic treatment of individual animals, located in paragraph 52. The first bullet in paragraph 51 should be deleted because much of the information required on the prescription would be stated on the product label. In paragraph 53, the sixth sub-bullet under the second bullet should be revised to make it consistent with that paragraph's leading statement. In paragraph 54, the rationale in the draft text regarding limitations for using products in combination where appropriate treatment cannot be readily accomplished by the administration of a single product needs to be clarified. Paragraph 57 should be edited so that it is more consistent with the U.S. FDA regulations in addition to regulations set by other member governments regarding any off-label use of an antimicrobial agent being permitted in agreement with national legislation in force.

Responsibilities of the Producers

In paragraph 62, the U.S. delegation believes that in order to assist relevant authorities in surveillance programs related to antimicrobial resistance, the role of producers in surveillance should receive greater emphasis.