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WORLD HEALTH ORGANIZATION

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Agenda Item 11

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

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CODEX WORK ON ANTIMICROBIAL RESISTANCE

Comments submitted in reply to CL 2005/33-CAC, Part A

by: Australia, Canada, Cuba, European Community, Japan, Norway, Paraguay, Republic of Korea, United States, Venezuela, Consumers International, IDF and OIE

AUSTRALIA

Australia is pleased to provide the following comments in response to CL 2005/33-CAC: Request for Comments on Codex work on Antimicrobial Resistance.

PART A: REQUEST FOR COMMENTS

(a) Comments on the proposal attached in Annex I for new Codex work on antimicrobial resistance

GENERAL COMMENTS:

The Task Force, in performing its work, should bear in mind that the major contributing factor to the risk of developing antimicrobial resistance in humans is the use and overuse of antimicrobials in human medicine. The use and overuse of antimicrobials in animals is a minor, but nonetheless, potentially important contributing factor to antimicrobial resistance in humans.

Although it is acknowledged that the issue of antimicrobial residues will not be the focus of the Task Force, the terms of reference should specify whether antimicrobial residues will be considered. One of the findings of Australia's Joint Expert Technical Advisory Committee on Antibiotic Resistance (JETACAR) was that it is highly unlikely that the consumption of antibiotic residues in food would lead to the development of resistance. This is because antibiotic residue levels in food are very low and are likely to be further reduced by cooking and other food processing and also by metabolism in the gut.

The Task Force should address antimicrobial resistance issues of international relevance. For example, there is a need to define the extent to which the movement of food across borders will increase the spread of resistance around the world. There is also a need to define the nature and cost of any future surveillance activities to meet requirements of trade, and national and international public health. Australia considers it more efficient for this work to be done by Codex rather than individual nations.

Reliance on risk profiles is a sensible approach and suits the model of international collaboration developed through the Joint FAO/WHO Meetings on Microbiological Risk Assessment (JEMRA).

FAO and WHO have, through the JEMRA process gained experience at managing similar issues and Codex work on antimicrobial resistance will benefit from this. Nevertheless, care needs to be taken to avoid initiating protracted studies of a quantitative nature that do not at the outset recognise the enormous scientific uncertainty likely to be encountered.

The Task Force should avoid costly processes that cover what has already been comprehensively reviewed and critiqued by member countries and in the scientific literature. The Task Force should therefore rely heavily on the processes and experiences of other countries (e.g. JETACAR and equivalent reports).

The Task Force should be made aware of the difficulties and costs that would be involved in implementing any of their recommendations, particularly for developing economies. Without commitment from member countries, the initiative may suffer considerable delays and frustrations.

Therefore, Australia would like to see the work of the Task Force avoid replication, address international trade and developing country needs, and keep risk assessment and risk priority activities as simple as possible.

SPECIFIC COMMENTS:

A. Purpose

Australia agrees with the overall purpose of the Task Force proposed in Annex I, however, the sentence as currently written is broad. Therefore, Australia considers it prudent that further guidance is provided.

To ensure the work of the Task Force is achievable within a limited timeframe, the focus on feed and antimicrobials must be consistent with work underway and already completed by Codex in these areas. Any focus on animal feed should be complementary to the work achieved by the *Ad hoc* Intergovernmental Task Force on Animal Feeding and therefore should not create any new work on animal feeding.

The term 'Veterinary Antimicrobial Drug' is well-defined by the Codex Committee on Residues of Veterinary Drugs in Food. The term 'antimicrobial' has been established in the two joint workshops held by the FAO, WHO and OIE in 2003 and 2004, on risk management and risk assessment, respectively. Therefore, the work of the Task Force should focus on those antimicrobial drugs of critical importance to human and animal health where there is the potential to impact on international trade and should not seek to broaden the types of antimicrobials to include pesticides. This is also consistent with work on antimicrobial resistance being undertaken at the national level.

The sentence as it is written gives the impression of capturing antimicrobial resistance genes present in foods and has the potential to also capture genetically modified (GM) plants that contain antimicrobial resistance genes. Often to assist in the transformation process, antimicrobial resistance genes are used as marker genes to identify transformed plants.

Australia considers that GM organisms that are used as food sources should not be captured under the purpose of this Task Force, for the following reasons:

- The presence of antimicrobial resistance genes in GM foods has been assessed scientifically and is considered to effectively have no impact on human health.
- The transfer of antimicrobial resistance genes from GM foods to bacteria in the human digestive tract is unlikely because of the many complex and improbable steps that would have to occur for this to happen.
- In food, it is the microorganisms carrying antimicrobial resistance genes that may be harmful to human health, not the antimicrobial resistance genes themselves. Guidance for effective control and minimisation of microorganisms is considered by the Codex Committee on Food Hygiene.
- Antimicrobial resistance genes present in GM plants and food derived from those plants are unlikely to be transferred to microorganisms. The genes are not expressed in plants and therefore do not present selective pressure.

B. Scope

Australia agrees with the scope of the work of the Task Force outlined in Annex I, however, Australia considers the second dot point of the scope should be amended to provide greater clarity. Suggested wording is as follows:

- The prioritization of this work with a particular emphasis on the public health and animal health significance of the antimicrobials under consideration, with reference to the *WHO Critically Important Antibacterial Agents for Human Medicine* and the *OIE List of Critically Important Antimicrobials in Veterinary Medicine* (once developed).

C. Activities

Australia is in broad agreement with the proposed activities of the Task Force outlined in Annex I.

Points ii) and iii) as currently written emphasise feed production. It is important that it be noted that this is only one factor that impacts on antimicrobial resistance at the level of primary production. Australia suggests that the wording 'animals intended for food and in feed production' be returned to the original Codex wording of 'primary food production (animals and crops)' to reflect a wider application.

Point vi) should highlight that specific risk management advice will focus on human health aspects.

(b) Suggestions for the title of a new ad hoc Intergovernmental Codex Task Force to deal with antimicrobial resistance and for the length of its mandate

Australia proposes the following title for consideration:

Ad hoc Codex Intergovernmental Taskforce on Minimising Antimicrobial Resistance in Primary Food Production.

Time frame:

The Taskforce shall complete its work within four years.

CANADA

Canada supports the establishment of an *Ad Hoc* Task Force on Antimicrobial Resistance mandated to develop guidance on methodologies and processes to reduce risks to human health associated with the presence of antimicrobial resistant microorganisms and genes in food and feed. An appropriate name would be the *"Codex ad hoc Intergovernmental Task Force on Antimicrobial Resistance"*.

Canada believes there is a need for a structured approach and defined timelines for Codex work in this area. We suggest that, once the Commission approves the establishment of a Task Force on Antimicrobial Resistance and endorses its Terms of Reference, a first step would be the issuance of a Circular Letter (CL) soliciting specific proposals for new work including proposed priorities. Comments received in response to this CL would be circulated as a working document for consideration by the first session of the Task Force which, based on the comments, would select two or three specific topics as the focus of its work.

We support the activities identified in Annex I of CL 2005/33-CAC, and believe they are important to the success of the Task Force. However, we are of the view these reflect how the Task Force would actually go about doing its work and should, therefore, be the subject of discussion by the Task Force. Canada agrees that the process by which the Task Force will undertake its work needs to be clearly understood, but we do not believe that the process should be specifically defined in the Terms of Reference, noting that such processes have not been included in the Terms of Reference of other Task Forces established by the Commission. We suggest that the activities identified in Annex I could be incorporated into the above referenced CL, with a request for the identification of additional activities members believe to be relevant, including, as appropriate, project documents.

We suggest, therefore, that Annex I be restructured for consistency with the guidance in the Codex Procedural Manual, 15th Edition, page 69, Terms of Reference for subsidiary bodies created under Rule XI(b)(i). In this respect, we believe that elements of the "purpose" and "scope" statements can form the basis of the Task Force "objectives" and that other elements of "scope" and "activities" can form the basis of the "Terms of Reference". We further note there is a requirement to identify timelines for the Task Force. In view of the above considerations, Canada proposes the following as the Terms of Reference for the Codex *ad hoc* Task Force on Antimicrobial Resistance:

Objective

To develop standards, guidelines or recommendations, as appropriate, taking full account of the Working Principles for Risk Analysis, to reduce the risks to human health associated with the presence in food and feed, and the transmission through food, of antimicrobial resistant microorganisms and antimicrobial resistant genes.

Timeframe

The Task Force shall complete its work within five years. The Task Force should submit a full report to the Commission in 2011.

Terms of Reference

(a) To establish risk profiles with respect to the antimicrobial resistance potential of different antimicrobials used in animals intended for food (including with respect to aquaculture), and in feed production.

(b) To develop a prioritized list of antimicrobials used in animals intended for food and in feed production, with a particular emphasis on the public health significance of the antimicrobials under consideration, taking into account relevant animal health issues.

(c) To provide specific risk management advice in relation to reducing risk to human health associated with the transmission through food of antimicrobial resistance, taking into consideration the prioritized list of antimicrobials.

(d) To work in close collaboration with appropriate Codex Committees (e.g. CCFH, CCRVDF) and the OIE, taking into account relevant work carried out by national authorities, FAO, WHO, other international organizations and other relevant international fora.

CUBA

The widespread increase of antimicrobial resistance in pathogenic bacteria has given rise to worldwide concern over the indiscriminate use of antimicrobials in animal production that can facilitate the development of resistant bacteria or resistance genes that can be transmitted to bacteria causing illness in humans. This is an important issue for the safety of consumers.

The fundamental problem is the relationship between resistance to antimicrobials in bacteria responsible for food-borne infections in humans and the use of antimicrobials in food-producing animals. Some pathogens, notably *Salmonella*, do not transfer easily between persons, which suggests that foods are the main and most likely source of human exposure to such bacteria.

The surveillance of resistance in isolations of bacteria in foods should apply not only to zoonotic bacteria and human pathogens such as *Campylobacter coli/jejuni*, S*almonella*, *Stapylococcus aureus*, *Listeria monocytogenes*, etc, which are the usual cause of food-borne infections, but also to indicator bacteria such as *Escherichia coli*, which are part of the microflora of many types of food and are often used as parameters of food hygiene. We suggest an emphasis on the monitoring of *E.coli* because of its noted propensity to transmit resistance genes, because it is one of the bacteria that have developed the greatest resistance to antimicrobials and because of its ecological distribution.

Raw foods should also be controlled, especially those that, with the development of trade, can now be imported within a matter of hours from very distant and different locations that often lack appropriate food surveillance programmes. The selection of antimicrobial drugs in human and veterinary medicine is also very important.

The name for the new task force

We suggest: **Codex *Ad Hoc* Intergovernmental Task Force on Antimicrobial Resistance.**

The contents of Annex 1

We recommend the following:

In A.Purpose

- including after science-based [guidance]: …"on antimicrobial resistance"…

In B. Scope:

- We suggest including in the first indent an analysis of all antimicrobials used both internationally and in the resource-poor developing countries.
- Also within the first indent, the inclusion of **beekeeping** within the parentheses.
- Emphasis on the monitoring of *E. coli* because of its noted propensity to transmit resistance genes, because it is one of the bacteria that have developed the greatest resistance to antimicrobials and because of its ecological distribution.
- We consider that there should be emphasis on the antimicrobial control of raw foods (beef, pigmeat, poultry, eggs, dairy products, fish, fruit and vegetables, **honey**).

In C. Activities

- We suggest the inclusion that each year each country should determine the possible changes in resistance that could have occurred in pathogenic bacteria (*Campylobacter coli/jejuni*, S*almonella*, *Stapylococcus aureus*, *Listeria monocytogenes* and others) responsible for food-borne diseases in humans, for which monitoring should be programmed together with exchanges between countries, with FAO/WHO collaboration.
- We suggest including in iii) **beekeeping** as this item only refers to animals intended for food and feed, while there are products intended as food (**honey)** that cannot be cooked or processed to reduce microbial load.

EUROPEAN COMMUNITY

In response to Codex Circular Letter 2005/33-CAC *"Request for comments on Codex work on antimicrobial resistance"*, the European Community and its 25 Member States are pleased to offer the following comments.

(a) Comments on the proposal attached in Annex I (to CL 2005/33-CAC) for new Codex work on antimicrobial resistance

General Comments

- The European Community and its Member States support the establishment of an *ad hoc* Intergovernmental Task Force on Antimicrobial Resistance.
- This new work should begin as soon as possible.

Specific Comments

- **B. Scope:**
  - The European Community and its Member States would like to include the option of taking into account the work carried out by regional economic integration organisations. This could be addressed with the following change at the end of the first paragraph under "B. Scope":

    *"The outcome of Codex work in this area would be guidance on methodology and processes, including specific risk management options for risk reduction, based on risk assessment as provided by FAO/WHO through JEMRA and in close collaboration with OIE, taking into account work undertaken in this field at national/**regional** and international level."*
  - The European Community and its Member States strongly support activities aimed at preventing the development of antimicrobial resistance in a balanced way in all relevant areas: human medicine, veterinary medicine related in particular to animal and food productions, and plant protection.

In this context, the first indent of the second paragraph should cover all food and not only "antimicrobials used in animals intended for food (including aquaculture) and in feed production". As indicated in the first paragraph of the Circular Letter *("It was however suggested that Codex future work should (…) address antimicrobials in general so as to cover the use of pesticides and additives and not be restricted solely to antimicrobial drugs, and should also include animal feed.")* and in order to cover pesticides and other antimicrobials used in plant production and at different steps of the food processing chain, the European Community and its Member States would propose the following changes:

"To achieve this outcome, elements would include:

– *The establishment of risk profiles with respect to the* ***development of*** *antimicrobial resistance* ***arising from the use*** ~~*potential*~~ *of different antimicrobials* ~~*used*~~ *in* ***the food chain, i.e. in feed production and processing, in food production and processing, including in food producing*** *animals* ~~*intended for food (including aquaculture) and in feed production*~~*."*

Same version (without "track changes"):

"- The establishment of risk profiles with respect to the development of antimicrobial resistance arising from the use of different antimicrobials in the food chain, i.e. in feed production and processing, in food production and processing, including in food producing animals."

- **C. Activities:**

– As a consequential change, paragraph iii) under C should be changed accordingly:

"iii) Establish risk profiles with respect to the antimicrobial resistance potential of different antimicrobials used in ***food producing*** *animals*, ~~*intended for*~~ *food and* ~~*in*~~ *feed production* ***and processing****, including identification of additional data needed for scientific advice."*

– The European Community and its Member States believe that the phrase "**food producing animals**" could be used throughout the document and replace the phrase *"animals intended for food"*, this would lead to the following additional changes to paragraphs *ii)* and *vi)* under C:

"*ii)Prioritize the antimicrobials used in* ***food producing*** *animals* ~~*intended for food*~~ *and in feed production, with a particular emphasis on their public health and animal health significance, taking into consideration ongoing FAO, WHO and OIE work to define antimicrobials critically important to human and animal health.*

(…)

vi) Develop specific risk management advice based on the identified priorities, the risk profiles, the results of the risk assessments, as well as existing documents/guidelines from FAO, WHO and OIE related to the containment of antimicrobial resistance in ***food producing*** *animals* ~~*for food*~~ *and ongoing work from FAO, WHO and OIE on critically important antimicrobials."*

– In addition, the European Community and its Member States believe that in accordance with the provision of the Procedural Manual of the *Codex Alimentarius* Commission relating to the Procedures for the Elaboration of Codex Standards and Related Texts, all relevant Codex subsidiary bodies (CCFH, CCRVDF, etc.) should be invited to comment on the draft documents when appropriate.

(b) Suggestions for the title of a new ad hoc Intergovernmental Codex Task Force to deal with antimicrobial resistance and for the length of its mandate

- The European Community and its Member States would suggest naming the new task force as follows:

  "Codex *Ad Hoc* Intergovernmental Task Force on Antimicrobial Resistance"

- Bearing in mind that it was agreed in July 2005 that a final decision as to the establishment of this task force would only be taken at the next session of the *Codex Alimentarius* Commission, the European Community and its Member States believe that the Intergovernmental Task Force on Antimicrobial Resistance could be invited to submit its **final report to the Commission by 2010 at the latest.**

JAPAN

The Government of Japan would like to thank for the opportunity to submit comments in reply to CL 2005/33-CAC (A) Request for Comments).

(a) Comments on "Proposed Terms of Reference for Codex work on Antimicrobial Resistance"

First, Japan would like to express our support for the establishment of a new task force and appreciate the Republic of Korea for taking initiative in this work.

Since much work has already been done on the issue of antimicrobial resistance nationally and internationally including the work of Codex, WHO, FAO and OIE, duplication of work should be avoided. For example, CCRVDF, since its 12th session in 2000, developed the Code of Practice for the Containment of Antimicrobial Resistance, which was subsequently adopted at the 28th Session of the Commission. In order to produce expected outcomes within a limited time frame, future work should focus on high priority issues which have not been fully addressed or resolved, taking into consideration all of these accomplishment.

As antimicrobials applied and purposes/modes of their application are different among various food production activities, risk analysis of antimicrobial resistance needs multidisciplinary contribution. The future Codex work on this subject should be proceeded with in a coordinated manner. Therefore, it may be desirable for this new task force to integrate all the relevant work including past, ongoing and future work (not only on veterinary drugs but also on pesticides, food additives, feed additives and risks arising from ingesting resistant microbes), and to develop a strategy/guidance document for the future Codex work to be conducted by the relevant Codex subsidiary bodies. During its work, the task force should take into consideration the weight of food production relative to the other relevant activities in terms of the emergence of antimicrobial resistance.

(b) Suggestions for the title of a new task force and for the length of its mandate

We would like to propose the "***Codex ad hoc Intergovernmental Task Force on Antimicrobial Resistance Associated with Food and Feed***" for the title of the new task force. Regarding the length of the new task force, 4 year time frame seems appropriate in order that the task force accomplishes its work promptly and efficiently.

The Government of Japan would like to thank for the opportunity to submit comments in reply to CL 2005/33-CAC (A) Request for Comments.

NORWAY

Referring to the Circular Letter of July 2005 (CL 2005/33-CAC) from the Codex Secretariat, Norway would like to submit the following comments:

Norway acknowledges that antimicrobial resistance is an emerging public health problem of international dimension and that, due to the complexity of the problem, a multidisciplinary and holistic approach is needed in order to contain antimicrobial resistance, including in animals/the food chain.

Norway expressed in its response to CL 2004/32-EXEC full support to the urgent establishment of a Codex Task Force on Antimicrobial Resistance to develop risk management options on antimicrobial resistance related to non-human antimicrobial use, to be used at both national as well as the international level. Furthermore, Norway expressed full support to the Republic of Korea as a host country of a future Task Force. Norway has strong confidence in that Korea will execute its role as a host for the Task Force both excellently and efficiently. In addition, Norway sees the importance in the fact that a country outside Europe and North-America be the host of the Task Force as this will help increase the recognition of non-human antimicrobial use as a problem affecting the whole world.

In its Circular Letter, the Codex Secretariat asks for:

1. Comments on the proposal attached in annex 1 for new Codex work on antimicrobial resistance
2. Suggestions for the title of a new *ad hoc* Intergovernmental Codex Task Force to deal with antimicrobial resistance and for the length of its mandate

Norway would initially like to congratulate the Codex Secretariat, FAO and WHO for drafting a very good proposal.

As regards question 1:

A. Purpose:

Norway agrees fully with the proposed Purpose, as its captures what Norway thinks should be the ultimate aim of the work of the Task Force.

B. Scope:

Norway agrees with the content of the proposed Scope. However, we suggest rewording the first paragraph to read: "The outcome of Codex work in this area would be **guidance on specific risk management options, including methods and processes, for reduction of risk to human health associated with antimicrobial resistance transmission through food. The guidance should be based on**……etc …".

We suggest rewording the first sub-point to read: "The development of risk profiles regarding use of different antimicrobials **in animals (including aquaculture), feed production and horticulture**".

The rationale for this proposal:

a) We believe that the use of antimicrobials in horticulture also should be addressed, as recognized in the report from the Joint FAO/WHO/OIE workshop, held in Geneva in December 2003.

b) We believe use in animals should not be limited to food animals. It is the opinion of Norway that the Task Force should take a holistic approach when developing risk profiles, acknowledging all relevant sources of resistance, but bearing in mind that the ultimate goal is to reduce the risk to public health associated with antimicrobial resistant bacteria and antimicrobial resistance genes in the food to consumers. Food animals, including aquaculture, are most relevant in relation to food safety and Codex work. However, it should be acknowledged that also other animals than traditional food animals may impact indirectly the occurrence of antimicrobial resistant bacteria in the food. Even use of antimicrobials in pets can represent a public health risk, and antimicrobial resistance can spread from pets to humans also via the food chain by cross-contamination. Indeed, the use of antimicrobials regarded as critically important in humans is usually more widespread in pets as compared to food animals. Also potential spread of antimicrobial resistance to the food chain via the environment needs to be addressed when relevant. Thus, Norway believes that it is important that the Task Force have an open mind and holistic approach to the issue of public risk related to antimicrobial resistance in the food chain.

Norway also suggests rewording the third sub-point to read: "**A qualitative assessment of the risk to human health, including the clear identification and characterization of the hazard, associated with antimicrobial resistance transmission through food**".

C. Activities

ii) Norway suggests deleting "intended for food" and inserting "including aquaculture" to cover animals in general (including aquaculture), when relevant.

iii) Norway suggests rewording to read: "Develop risk profiles regarding use of different antimicrobials **in animals (including aquaculture), feed production and horticulture**, including the identification of additional data needed for scientific advice".

vi) Norway suggests deleting "for food" in the third line.

The rationale for the above proposals is that although food animals are most important, also other animals than traditional food animals may impact indirectly the occurrence of antimicrobial resistant bacteria in the food. Norway believes that the Task Force should take a holistic approach when prioritizing the various antimicrobials and developing risk profiles, acknowledging all relevant sources of resistance, but bearing in mind that the ultimate goal is to reduce the risk to public health associated with antimicrobial resistant bacteria and antimicrobial resistance genes in the food to consumers.

As regard 2:

Norway suggests the following name for the new *ad hoc* Intergovernmental Codex Task Force; Codex Task Force on Antimicrobial Resistance (abbreviated AMR Task Force). We propose that the length of the mandate should be 4 years (2007-2010).

Other issues:

Norway believes it is important that there is collaboration between the Task Force and OIE, e.g. by actively encouraging OIE to participate in the Task Force.

Furthermore, it is important that the Task Force draws upon the expertise and risk assessment advices provided by JEMRA.

Norway would like to reiterate the conclusions from the response to CL 2004/32-EXEC:

Norway supports the urgent establishment of a Codex Task Force on Antimicrobial Resistance to develop risk management options on antimicrobial resistance related to non-human antimicrobial use. Norway hopes that it can be decided at the next CAC meeting that a Task Force will be established. Finally, Norway fully supports that the Republic of Korea be the host of the Task Force.

PARAGUAY

General comments

PARAGUAY considers that antimicrobial resistance is an important topic that needs to be addressed because of its potential impact on human health. However, we stress that the developing countries need technical assistance, cooperation and guidance if they are apply methodologies and processes to reduce the level of risk of antimicrobial resistance in foods.

Reply to the two questions

a) PARAGUAY agrees with the content of ANNEX I.

However, it suggests the following editorial amendment in Section A. Purpose to make the Spanish clearer: *Codex should develop science-based guidance, taking full account of its risk analysis principles, to reduce the risks to human health associated with the presence in food and feed and the transmission ~~through food~~ of antimicrobial resistant microorganisms and antimicrobial resistant genes, through food.*

b) We propose the following name for the new Task Force: ***"Codex Task Force on Antimicrobial Resistance in Feeds for Animal Consumption and in Foods for Human Consumption".***

With regard to the duration of the mandate, we suggest a period of 4 (four) years.

REPUBLIC OF KOREA

In response to Codex Circular Letter 2005/33-CAC "Request for comments on Codex work on Antimicrobial Resistance," the Republic of Korea is very pleased to submit the following comments, fully and strongly supporting the establishment of an *ad hoc* Intergovernmental Task Force on Antimicrobial Resistance.

(a) Comments on the proposal attached in Annex I for new Codex work on antimicrobial resistance.

Comments on the Scope:

- The risks associated with non-human antimicrobials use and antimicrobial resistance should be part of the human safety assessment and management for regulatory decision.

- Antimicrobial resistance is a multi-factorial problem and thus requires a multidisciplinary approach, and all the relevant issues of antimicrobials should be carefully considered for food producing animals including aquaculture, feed production, and horticulture.

- Task Force should review and consolidate existing all relative documents on antimicrobial resistance. Task Force should develop "Codex guideline on antimicrobial resistance risk assessment and management."

- The Codex guideline should include all the elements, i.e. the risk profiles, the prioritization of the new work, the identification and characterization of the hazard and risk, and risk management advice, at national, regional, and international level.

Comments on the Activities:

ii) Prioritize the antimicrobials used in animals intended for food **including aquaculture** and in feed production, with a particular emphasis on their public health and animal health significance, taking into consideration ongoing FAO, WHO, and OIE work to define antimicrobials critically important to human and animal health.

iii) Establish risk profiles with respect to the antimicrobial resistance potential of different antimicrobials used in animals intended for food **including aquaculture** and in feed production, including identification of additional data needed for scientific advice.

iv) Define risk assessment **methodology and** policy for use by FAO and WHO(JEMRA) in this area taking account of all the relevant work undertaken in this area.

(b) Suggestions for the title of a new *ad hoc* Intergovernmental Codex Task Force to deal with antimicrobial resistance and the length of its mandate.

The Title of Task Force

- The Republic of Korea would suggest the title of the new Task Force as **"Codex *ad hoc* Intergovernmental Task Force on Antimicrobial Resistance."**

Timeframe

- The suggested timeframe for the Task Force is four years, **commencing in 2007 and ending in 2010. Thus, the final report should be submitted to the Codex in 2011.**

UNITED STATES

GENERAL COMMENTS

The United States recognizes the importance of the issue of antimicrobial resistance and the need for countries and Codex to consider how scientifically-sound risk assessment and risk management can minimize the development of antimicrobial resistant microorganisms in foods at levels that represent a risk to human health. The U.S. supports the establishment of a Codex Task Force and supports the Republic of Korea as the host government.

The United States believes that the Task Force must focus on food safety. The use of antimicrobials in human medicine is a major contributing factor to antimicrobial resistance in humans; however the mandate of Codex relates to food. Therefore, the Task Force should address the issue of minimizing the development of antimicrobial resistant food borne pathogens. Additionally, the U.S. believes that the Task Force should take into account the positive aspects, as well as the risks, associated with the use of antimicrobials. The U.S. has provided language in the Scope and Activities sections to take these aspects into account.

It is important that the previous work undertaken in Codex (e.g. in the Codex Committees on Residues of Veterinary Drugs in Foods (CCRVDF)and on Food Hygiene (CCFH)) as well as work by WHO and FAO, including earlier Joint WHO and FAO Expert Consultations, and work by other international organizations and countries be used to inform the Task Force. In this regard, there must be close communication and cooperation between the Task Force and CCRVDF and CCFH, over and above the usual “matters Referred” mechanism. The U.S. also encourages close communication between the Chairperson of the Task Force and the Chairpersons of CCRVDF and CCFH.

The Proposed Terms of Reference as given in CL 2005/33-CAC differ somewhat from those resulting from the informal meeting of delegations during the 28th Session of the Codex Alimentarius Commission and recorded in CAC/28 LIM/32, "Summary of the informal sharing of ideas regarding proposed terms of reference for future Codex work on antimicrobial resistance". It is our opinion that some important points in LIM/32 were not incorporated into the Terms of Reference proposed in CL 2005/33-CAC. We will re-emphasize these points in our comments below.

In the "Purpose" Section of the proposed Terms of Reference antimicrobial resistance incurred through the transmission of antimicrobial resistance genes is included within the proposed work of the Task Force. While we support this inclusion, we believe that it does not apply to the use of antimicrobial resistance genes used as markers within the field of food derived from modern biotechnology. The U.S. notes that the potential for antimicrobial resistance arising from a biotechnology event is an appropriate component of a food safety assessment, to ensure that inadvertent development of antimicrobial resistance in an organism does not occur.

SPECIFIC COMMENTS

Title of the Task Force

The U.S. recommends the title: Codex Ad-Hoc Intergovernmental Task Force on Antimicrobial Resistance with respect to Food Safety.

Length of the Mandate

The U.S. believes that four sessions of the Task Force may be necessary to carry out its work, but suggests the mandate of the Task Force be five (5) years recognizing that it may require some time to complete risk assessments recommended by the Task Force. It is quite possible that the Task Force may skip a year of meeting in order to carry out these risk assessments.

Comments on the Proposed Terms of Reference

The U.S. generally supports the Terms of Reference contained in Annex I to CL 2005/33-CAC. However, we submit the following specific comments that, among other things, better align the Terms of Reference (TOR) to the discussions summarized in LIM 32.

Purpose

The purpose of the Task Force, as reflected in the scope and activities of the TOR, is to provide risk assessment and risk management guidance with respect to the impact of antimicrobial resistance on food safety. Accordingly, we suggest the following modifications to the statement of purpose (changes shown in bolded and strikeout text).

"To ~~Codex should~~ develop science based guidance, taking full account of ~~its~~ risk analysis principles, to assess ~~reduce~~ the risks to human health associated with the presence and

transmission of antimicrobial resistant microorganisms and antimicrobial resistant genes in food and feed ~~and the transmission through food of antimicrobial resistant microorganisms and antimicrobial resistance genes,~~ and, based on that assessment, develop appropriate risk management guidance.

Scope

The U.S. suggests certain wording that better reflects the summary in LIM 32. The revised Scope should read as follows (changes shown in bolded and strikeout text):

"The work outcome ~~of Codex work in this area~~ would be guidance on methodology and processes, including specific risk management options for risk reduction, based on risk assessment as provided by FAO/WHO through JEMRA and in ~~close~~ cooperation with OIE, taking into account work undertaken in this field at both national and international levels.

To achieve this outcome, elements would include:

- The establishment of risk profiles with respect to the development of antimicrobial resistance ~~potential~~ appropriately balanced with consideration of the possible positive aspects to food safety of different antimicrobials used in ~~animals intended for~~ food ~~(including aquaculture)~~ production and processing and in feed production.

- The prioritization of this work with a particular emphasis on the public health and animal health significance of the antimicrobials under consideration.
- A clear identification and characterization of the hazard and risk presented by antimicrobial resistance transmission through food and feed. This should be done on an individual animal/drug/bacterial species combination basis.
- The provision of specific risk management advice in relation to reducing risk to human health associated with the transmission through food of antimicrobial resistance.

Activities

The U.S. suggests wording changes to better align the text with the activity elements presented in LIM 32. We note that the specified activities are, in fact, the "process" noted in item (i). Therefore, item (i) can be become a "chapeau" statement for the section. We also believe that it would be appropriate to include in this section the importance of cross-communication with other Codex committees and task forces as appropriate, particularly CCRVDF and CCFH. The revised Activities should read as follows (changes shown in bolded and strikeout text):

The following process will be followed in undertaking the work of the Task Force, subject to review at the first session to assure its appropriateness and completeness.

i. ~~Define the process by which this work would be undertaken~~.

ii. Prioritize the antimicrobials used in animals intended for food and in feed production and processing, with a particular emphasis on their public health and animal health significance, taking into consideration ongoing FAO, WHO and OIE work to define antimicrobials critically important to human and animal health.

iii. Identify data available concerning antimicrobial-resistant microorganisms in food production.

iv. Establish risk profiles with respect to antimicrobial resistance potential appropriately balanced with consideration of the possible positive aspects to food safety of different antimicrobials used ~~in animals intended~~ for food and feed production, including identification of additional data needed for scientific advice. This should be done on an individual food/drug/bacterial species combination basis.

v. Define risk assessment methodology and policy for use by FAO and WHO (JEMRA) in this area taking account of relevant work undertaken in this area.

vi. Seek scientific advice from FAO/WHO/OIE as required. This could include requests for risk assessments to be performed by FAO/WHO (JEMRA) in coordination with OIE, after a clear definition of scope and purpose of the work to be done is developed.

vii. Develop specific risk management advice, if needed, based on the identified priorities, the risk profiles, the results of the risk assessments, as well as existing documents/guidelines from FAO/WHO and OIE related to the containment of antimicrobial resistance in animals for food, Codex codes of practice and codes of hygienic practice (especially those from CCRVDF and CCFH) and ongoing work from FAO, WHO and OIE on critically important antimicrobials.

viii. Implement a dialogue between other Codex committees or task forces that have responsibility for developing guidance that impacts on antimicrobial resistance, particularly the Codex Committee on Residues of Veterinary Drugs in Foods and the Codex Committee on Food Hygiene.

Thank you for the opportunity to provide these comments.

VENEZUELA

Background

- Part of the first paragraph of this section reads: **"It was however suggested that Codex future work should have a clear focus on public health and ensure a holistic approach to solving the question at hand, should address antimicrobials in general so as to cover the use of pesticides and additives and not be restricted solely to antimicrobial drugs, and should also include animal feed**".
- **Venezuela requests clarification as to why this is not reflected** in points A. Purpose, B. Scope or C. Activities of the suggested terms of reference for Codex work on antimicrobial resistance**.**

Purpose

- We recommend replacing the end of point A. Purpose "**and antimicrobial resistance genes" with "antimicrobial residues and mobile genetic elements responsible for transmitting antimicrobial resistance".**

Scope

- Include in point B. Scope: "**the experts on food additives and veterinary drug residues in foods (JECFA**)";
- Add under point B. Scope**: a paragraph on the "communication of risk" relating to the reduction of risk to human health from the transmission of antimicrobial resistance though foods.**

Activities

- Include in point C. Activities iv) and v**): the experts of the JECFA;**
- Add under point C**: a new activity on the "comunication of risk" relating to the reduction of risk to human health from the transmission of antimicrobial resistance through foods.**

Note: **Venezuela considers it essential that Codex initiate the study of risk profiles on the "Transmission of antimicrobial resistance through plant-based foods".**

CONSUMERS INTERNATIONAL

General Comments

Consumers International (CI) strongly supports Codex work on antimicrobial resistance. In our view such work is long overdue, as it has been discussed within Codex for many years, and should be a high priority due to the significant impact of antimicrobial resistance on public health. We strongly support the formation of a new *ad hoc* Intergovernmental Codex Task Force to deal with this issue, in recognition of the cross-cutting nature of the issue (covering not only animal drugs used in meat (including poultry) production and aquaculture, but also pesticides and additives, and feed as well as food) and the need for a holistic approach.

Title of Task Force

The title of the new task force could be the *Ad Hoc* Intergovernmental Task Force for the Prevention and Management of Antimicrobial Resistance Related to Food and Feed Systems.

Length of Mandate

The length of mandate for *Ad Hoc* Intergovernmental Task Forces is typically set at four years, with a preliminary and/or mid-term report to the Commission and/or Executive Committee. This would seem a reasonable approach for an *ad hoc* intergovernmental task force on antimicrobial resistance as well. We recommend that the work be undertaken with a tight timeframe since important public health issues are involved, while recognizing that the option exists to extend the time frame if deemed necessary.

Purpose/Objectives

In light of the need for a holistic approach to effectively address the issue of antimicrobial resistance, the Task Force should consider not only food itself but all aspects related to the production and processing of food and feed. Research indicates that various pathways "from feed to farm to fork" can play an important role in transmitting antimicrobial resistance, and all relevant pathways must be taken into account in order to address the issue in a comprehensive manner. It is also important to not wait until resistance has emerged, but to prevent the emergence of antimicrobial resistance whenever possible. We therefore suggest that the Purpose in Annex I be modified as follows:

> Codex should develop science-based guidance, taking full account of its risk analysis principles, to PREVENT AND/OR reduce the risks to human health FROM ANTIMICROBIAL RESISTANCE THAT ARISES IN OR IS TRANSMITED THROUGH FOOD ~~associated with the presence, in food and feed,~~ OR FEED PRODUCTION AND PROCESSING SYSTEMS. ~~and the transmission through food of antimicrobial resistant microorganisms and antimicrobial resistance genes~~.

Activities/Terms of Reference

Annex I lists six activities that could be undertaken by the task force. Consumers International believes that the primary activity of the Task Force should be to develop an over-arching risk management framework that would utilize and build upon existing work, such as the Code of Practice to Minimize and Contain Antimicrobial Resistance. Such a framework should consider both existing antimicrobials and antimicrobial resistance genes, and new compounds that could contribute to antimicrobial resistance, by focusing upon selection for antibiotic resistance determinants and increases in microbial resistance reservoirs. It would help to guide the work of other Codex committees as they dealt with aspects within their scope that related to the presence, development, or transmission of antimicrobial resistance through food and feed. Such a document might also prove useful to national governments. In CI's view, this activity is especially appropriate to the time-limited status of a Task Force. Such a framework would also clarify the process by which Codex would accomplish work related to antimicrobial resistance over the long-term.

Therefore, CI suggests that an activity (i)(bis) be added as follows:

> i)(bis) Develop an antimicrobial resistance risk management framework document, building upon existing work such as the Code of Practice to Minimize and Contain Antimicrobial Resistance, that would provide risk management guidance and strategies for use by other Codex bodies (and national governments where appropriate) for the prevention and/or mitigation of antimicrobial resistance determinants that arise in or are transmitted through, food and feed systems, covering both existing and proposed new uses of antimicrobials (both existing and new compounds) that could give rise to antimicrobial resistance concerns.

We note that Annex I does not clearly indicate how Codex will obtain scientific advice pertaining to antimicrobial resistance. This is a critically important and fundamental question, in our view, and it is essential that adequate resources be provided for this purpose. One possibility is that all scientific advice relating to antimicrobial resistance should be provided by one expert body, such as JEMRA. While JEMRA could address issues related to resistant pathogens, it should be noted that antimicrobial resistance issues go beyond microbiological risk assessment, and that none of the present expert bodies are set up to address the full scope of scientific issues related to antimicrobial resistance. However, if this is the approach to be taken, it should be stated clearly, and the appropriate experts would need to be assembled. Depending on the work of the Task Force and its need for scientific advice, it will likely be necessary to convene one or more special, targeted sessions of experts to provide the necessary expertise in and advice on antimicrobial resistance.

On a related point, Annex I also does not indicate how the Task Force will relate to the work currently undertaken by CCRVDF, as well as the Codex Committee on Pesticide Residues (CCPR), to establish MRLs for compounds that have antimicrobial activity, including antimicrobials critically important to human health. Currently, antimicrobial resistance is only considered at best in an extremely limited way by JECFA and JMPR (e.g., the impact of the compound on gut flora) and AMR issues are largely outside the remit and expertise of these two overworked expert bodies. A more comprehensive approach, as well as an effective strategy for obtaining risk assessments and other scientific advice when required, is needed.

CI strongly supports activity iv, defining risk assessment policy, although as explained above, JEMRA might not be the only user of such risk assessment policy. In our view, general as well as specific risk assessment policies and approaches for assessing antimicrobial resistance risks are required, particularly with a focus on reducing the reservoir of antimicrobial resistance within microbial communities, rather than focusing solely on specific pathogens with specific resistance traits. Risk assessment policies are essential to ensuring the scientific integrity and transparency of the process. To provide just one example, risk assessment policy should define the attributes of new compounds (e.g., antimicrobial, biocidal) that would trigger the need for an assessment of antimicrobial resistance developing, along with the effectiveness of different strategies for preventing and/or minimizing it.

CI also notes that the activities listed in Annex I need not be undertaken in the sequence listed. In particular, given the large amount of scientific advice that has already been provided through expert consultations and other similar fora convened by WHO, FAO, OIE, and member countries, it should be possible to develop prudent risk management advice prior to commissioning risk assessments. Indeed, further delay in providing practical risk management advice in accordance with the conclusions of expert groups convened by WHO, FAO, and OIE, cannot be justified. At the same time, it is recognized that in certain instances specific types of scientific advice will need to be sought and that risk profiles may need to be developed. However, every effort should be made to make use of the range of scientific advice that has already been provided, particularly by WHO but from other scientific bodies as well, in order to avoid delay. Also, risk management advice should not be limited to containment but should also include prevention, since containment is practically impossible as experience has shown for all antimicrobials introduced in either agriculture or clinical medicine. Similarly, the Task Force should address all antimicrobial resistance issues relating to food and feed systems, not just those that relate to feed production and the production of animals for food (e.g., some antimicrobials are used as pesticides). Therefore, activity vi should be revised as follows:

> Develop specific risk management advice based on the identified priorities, AND TAKING INTO ACCOUNT, AS NECESSARY AND APPROPRIATE, ~~the~~ risk profiles~~, the~~ results of ~~the~~ risk assessments, AND OTHER ~~as well as~~ AVAILABLE RELEVANT INFORMATION, INCLUDING ~~existing documents/guidelines from~~ ~~related to the containment of antimicrobial resistance~~ ~~in animals for food~~ ~~and ongoing~~ work from FAO, WHO and OIE on critically important antimicrobials.

IDF

IDF notes the Proposed Terms of Reference for Codex Work on antimicrobial resistance.

Although antimicrobial resistance due to the presence of antimicrobials in food has not been shown to be a major problem in international trade in food IDF recognises that it is a consumer concern that need to be addressed.

In recognition of the fact that there are different international organizations currently undertaking work in the area of antimicrobial resistance IDF would like to suggest to establish a joint Codex/OIE consultation to determine which Codex Committee or other international organization should take leadership for the development of principles and guidelines for specific aspects of the management of antibiotic resistance related to the non-human use of antimicrobials.

IDF also notes that the recently released Codex document "Proposed Draft Revised Guidelines for the Establishment of a Regulatory Program for the Control of Veterinary Drugs Residues in Foods" (CX/RVDF 06/16/8) seems to preempt some of the work proposed by Circular Letter CL 2005/33-CAC."

OIE

A) REQUEST FOR COMMENTS

As an observer Organisation, the World Organisation for Animal Health (OIE) would like to thank the *Codex Alimentarius* Commission (CAC) for the opportunity to contribute to its work on antimicrobial resistance.

The OIE would like to draw the CAC's attention to the document CAC/28 INF/3 distributed during the 28th CAC in Rome. This document provides an overview, notably on antimicrobial resistance, of OIE activities relevant to the CAC.

As far as the new CAC work on antimicrobial resistance is concerned, OIE would like to stress the importance and usefulness of the initiative. Developing science based guidance, structured on risk analysis principles to help conduct relevant risk management activities, is considered by OIE to be essential.

In fact, that is similar to the OIE's approach to the establishment of specific guidelines since recent years.

The outcomes of the Oslo workshop in February 2004 also tackled this need. On this basis, OIE supports in general the proposal, but has reservations regarding the following aspects.

We regret that the expected work which arose from the tripartite Oslo workshop, has not been developed through a joint tripartite task force, as proposed by the group of experts. This remains a necessity if we are to gain the strict confidence of members countries. Beyond general efficiency, we consider this is a necessity for some technical aspects. For instance, we can't consider that Codex has the competence at the international level to take on board some issues such as the prioritisation of antimicrobials used in animals.

As a consequence, the OIE supports the establishment of a task force, but again strongly prefers to establish a tripartite taskforce with FAO/WHO/OIE as full members. Additionally the OIE reiterates its offer to share the costs of this issue.

We would appreciate feedback on that issue before contributing in more detail to the improvement of the documents, and if necessary to the name of the group.

B) REQUEST FOR INFORMATION

The OIE has already started (in 1998) to address the matter through an expert meeting (an *ad hoc* group) and an international conference in Paris in October 2001. Four guidelines were adopted by the OIE International Committee in May 2003. Three of them were incorporated into the Terrestrial Animal Health Code and another into the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals.

Guidelines on Risk Analysis for Antimicrobial Resistance, a companion appendix for the three adopted in 2003 were unanimously adopted in May 2004 by OIE Member Countries.

During 2004 the OIE convened two meeting of the *ad hoc* group on Antimicrobial Resistance. Two of the invited experts were officials from FAO and WHO. The *ad hoc* group revised and updated the OIE standards on antimicrobial resistance (Appendixes 3.9.4. and 3.9.3.) taking into account the latest scientific knowledge and the work done during the October 2004 CCRVDF meeting in Washington. The updates proposed by the *ad hoc* group were endorsed by the OIE Animal Production Food Safety Working Group first and subsequently by the OIE International Committee in May 2005.

To address the outcomes of the Oslo Workshop on Non-Human Antimicrobial Usage, the same *ad hoc* group is currently preparing a list of Critical Antimicrobials for animals, based on information requested from OIE Member Countries.

The current *Terrestrial Code* Appendixes are:

- Appendix 3.9.1. : Guidelines for the harmonisation of antimicrobial resistance surveillance and monitoring programmes.
- Appendix 3.9.2.: Guidelines for the monitoring of the quantities of antimicrobials used in animal husbandry.
- Appendix 3.9.3. : Guidelines for the responsible and prudent use of antimicrobial agents in veterinary medicine.
- Appendix 3.9.4. : Risk assessment for antimicrobial resistance arising from the use of antimicrobials in animals.

The current Chapter in the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals is:

- Chapter I.1.10: Laboratory methodologies for bacterial antimicrobial susceptibility testing.