

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
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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: IFAH

IFAH

The International Federation for Animal Health (IFAH) is pleased to provide comment relative to the Codex work on antimicrobial resistance as requested in CL 2005/33-CAC July 2005. As noted the 28th Session of the Codex Alimentarius Commission (CAC) took note of a summary of an “Informal sharing of ideas regarding proposed terms of reference for future Codex work on antimicrobial resistance”, as contained in CAC/28 LIM32.

In general IFAH offers the following comments in developing the task force approach regarding antimicrobial resistance:

- 1) Codex and task force efforts should adhere to the Working Principles for Risk Analysis in the Framework of the Codex Alimentarius. These working principles provide for a balance between risk assessment and risk management. Further, the risk communication component allows for all stakeholders to fully participate in the process.
- 2) The task force needs to operate within the overall mandate of Codex thus focusing on food safety.
- 3) With respect to antimicrobial resistant microbiological hazards, Codex Committees do not now take into account human medical impacts, but rather develops standards to meet stated food safety objectives. Consideration of human medical impact may be beyond the mandate of Codex and Codex should consider that work done on human medical impact in this task force will considerably complicate and expand current Codex Committee on Food Hygiene (CCFH) microbiological risk assessment guidelines.

Note, the following comments are organized via topic area from the circular letter, then lists the Secretariat proposed text, then offers comments by IFAH relative to the topic area and then offers specific text edits, or modifications, for consideration.

Note, edit “additions” are underlined and edit “deletions” are [bracketed].

Topic area: Task Force Name:

Secretariat Proposal: “Codex work on antimicrobial resistance”

IFAH Comment: IFAH suggests that considering the remit of Codex, the task force should be named the “Codex Task Force on Foodborne Antimicrobial Resistance” to reflect the mandate of Codex.

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IFAH Proposed Modified Text: Task Force name: Codex Task Force on Foodborne Antimicrobial Resistance.

Topic area: Purpose:

Secretariat Proposal:

A. Purpose

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 resistance genes.

IFAH Comment: IFAH offers these comments that build upon the informal sharing of ideas as well as the Codex session discussion.

IFAH Proposed Modified Text:

A. Purpose

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 in food [and feed] and the transmission through food of antimicrobial resistant microorganisms and antimicrobial resistance genes, and based on that assessment recommend appropriate risk management steps.

Topic area: Scope:

Secretariat Proposal:

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 and international level.

To achieve this outcome, elements would include:

- The establishment of risk profiles with respect to the antimicrobial resistance potential of different antimicrobials used in animals intended for food (including aquaculture) 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.
- The provision of specific risk management advice in relation to reducing risk to human health associated with the transmission through food of antimicrobial resistance.

IFAH Comment:

IFAH suggests the following edits, based on the discussion at the Commission meeting, as well as noting that certain aspects of the LIM32 document were deleted or modified in the circular document, thus not fully reflecting the discussion. Specifically, we request that the LIM32 taking into account food safety benefits along with the production and processing aspects be incorporated into the document. These points were fully discussed in the informal sharing of ideas and incorporated into LIM32, and thus need to be corrected in the text to accurately reflect the Commission outcome. Also, it needs to be recognized that the hazard and risk need to be determined on an individual food-drug-bacteria species approach.

IFAH Proposed Modified Text:**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, with the support of additional expertise as appropriate, taking into account work undertaken in this field at national and international level.

To achieve this outcome, elements would include:

- A risk analysis methodology and process.
- The establishment of risk profiles with respect to the antimicrobial resistance potential appropriately balanced with consideration of the possible food safety benefit of different antimicrobials used in [animals intended for] food production and processing (including aquaculture) [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)]. Overall, this shall be done on an individual food-drug-bacteria species basis. Consideration for a class of compounds-food-bacteria species may be appropriate for certain drugs when there is no or a limited hazard or risk.
- The provision of specific risk management advice in relation to reducing risk to human health associated with the transmission through food of antimicrobial resistance.

Topic area: Activities**Secretariat Proposal:****C. Activities**

- 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, 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 and in feed production, including identification of additional data needed for scientific advice.
- iv) Define risk assessment policy for use by FAO and WHO (JEMRA) in this area taking account of relevant work undertaken in this area.
- v) 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.
- 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 animals for food and ongoing work from FAO, WHO and OIE on critically important antimicrobials.

IFAH Comment:

IFAH suggests the following edits to reflect the informal sharing and Commission discussion. Again, it is critical to incorporate the full LIM32 reflections including the appropriate balance with the consideration of the possible food safety benefits.

IFAH Proposed Modified Text:**C. Activities**

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

- ii) Define the need for data to be collected and analyzed to carry out risk assessments.
- iii) Prioritize the antimicrobials used in [animals intended for] food [and in feed] production and processing (including aquaculture), 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.
- iv) Establish risk profiles with respect to the antimicrobial resistance potential appropriately balanced with consideration of the possible food safety benefit of different antimicrobials used in [animals intended for] food [and in feed] production and processing, including identification of additional data needed for scientific advice.
- 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 in Codex.
- vi) Seek scientific advice from FAO/WHO/OIE, combined with additional expertise as appropriate, as required. This should [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.
- vii) Consider and define the risk of foodborne bacteria considered within the existing work of Codex by JEMRA and CC Food Hygiene and subsequently consider the relative additional risk due to the subset that are resistant bacteria and offer advice on approaches to collectively advance overall aligned Codex food safety objectives.
- viii) Provide advice relative to the other risks within the Codex mandate, and how microbiological food safety objectives, performance objectives or performance criterion could be applied within the mandate of Codex.
- ix) Develop specific risk management advice, if needed, for specific antimicrobials, 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 and ongoing work from FAO, WHO and OIE on critically important antimicrobials.

Elaborated IFAH Comment:

Timeframe: The suggested timeframe for the project is four years with the understanding that the work would commence in 2007 and thus end in 2011.

Host country: IFAH fully recognizes and supports the gracious offer by Korea to host the task force with the support of government resources.

References: Submitted, also are relevant references to support the Codex task force work, specific to risk assessments.

IFAH notes that the Commission supported the proposal in general, which was considered as providing a good basis for determining future Codex work on antimicrobial resistance. It was noted that the Codex future work must have a clear focus on public health and ensure a holistic approach to solving the question at hand considering antimicrobials in general so as to cover the use of pesticides and additives and include animal feed. Importantly, the scope should take into account ongoing work in other international organizations, in particular OIE (Office International des Epizooties) and should adhere to the Working Principles for Risk Analysis in the Framework of the Codex Alimentarius.

Antimicrobial resistance arising in food producing animals is a complex issue that can have multiple sources one of which can be antimicrobial use in the animal. Foodborne pathogens such as Campylobacter, Salmonella, and E.coli, and enteric commensal organisms such as enterococcus spp. can be present on meat and poultry after slaughter and processing even using current good hygiene practices as elaborated under standards developed by the Codex Committee on Food Hygiene (CCFH) and the Codex Committee on Meat Hygiene (CCMH). Those bacteria that may be resistant to one or more antimicrobial substances, as evidenced from several countries meat safety surveillance systems, represent a small subset of the total microbial load of bacteria on carcasses. Any hygienic measure applied to reduce the presence of foodborne bacteria on raw and processed meat products, and therefore the risk of foodborne illness in humans, will also reduce the risk of foodborne illness with bacteria that may be resistant.

The CCFH has undertaken quantitative risk assessment to assess the overall risk and identify control points where exposures and risks can be reduced from foodborne pathogens. It could be appropriate, under activities proposed, for the CCFH, via a risk assessment, to evaluate any incremental increased risks that may result from the presence of resistance genes. However, the scope of risk assessment that the CCFH would undertake must be clearly delineated by the Task Force for CCFH work. Also, CCFH may need to supplement existing experts as the concern expressed for antimicrobial resistance in food products is their potential to affect treatment of human disease with the same or related antimicrobial substance. This evaluation would need to involve expertise in the medical impact of potential treatment failures. CCFH and JEMRA do not have the kind of expertise to carry out such assessments which extend into human health clinics and hospitals, thus they would need to supplement such expertise.

The Task Force needs to carefully consider the objectives that could address the issue of resistant pathogens beyond what has already been proposed under hygienic food processing standards. As Codex is not a global registration agency, they have no authority to make recommendations on what countries should or should not use in their agricultural production systems. They can only set either specific standards such as residue MRL's, guidelines, objectives, or codes of practice to assure food safety and facilitate fair practices in trade. This is relatively easy for hazards such as animal drug residues, pesticide residues, and food additives, but difficult, if not impossible, for naturally occurring bacteria.

Thus far, Codex has not set specific pathogen standards in raw products since it is recognized that bacteria is naturally occurring in raw meats and therefore heat processing, or other methods such as curing or smoking, are required to render the products safe. Most governments have developed their food safety policies in recognition of the fact that consumers assume their own risks if they choose to consume raw meat or poultry products. What renders raw products safe for sensitive bacteria will also render them safe for any resistant bacteria. In fact, any resulting food borne illness must be the result of mistakes in food hygiene at some point during final product processing.

Codex can also develop Codes of Practice which guide governments on good agricultural or food processing methods. The CCRVDF has developed, and the Commission recently adopted, a code of practice for the containment of antimicrobial resistance. This document was a modification of an earlier guideline developed by the OIE several years ago and adopted into their terrestrial standards. Also, WHO has developed a guideline for the judicious use of antimicrobials in food producing animals. Thus, further work on another such code would clearly be redundant for a new Task Force.

Another option would be a guideline, but the question is what kind of guideline? It would appear that in consideration of the work of the CCFH regarding microbiological risk assessment, a logical effort by Codex relative to antimicrobial resistant pathogens would be to develop a risk assessment guideline for these potential hazards. Development of such a guideline would not be well suited to a Task Force since specific and focused expertise would be more appropriate. For a guideline, the CCFH in consultation with JEMRA would be a far more effective body to proceed with such work. If CCFH and JEMRA would undertake such new work, there should be clear guidance from Task Force on the scope of the activity in the form of risk assessment policy to guide the effort.

Importantly, the Task Force should consider that Codex does not now take into account human medical impact, but rather food safety objectives. With regard to foodborne microbial hazards that may be resistant, the use of particular antimicrobials is a medical decision and not something that can be easily predicted. Most cases of foodborne illness are not treated with antimicrobials because they have either not been shown to affect outcomes or may even be contraindicated in some conditions such as hemorrhagic E. coli infections. Such, considerations may be beyond the mandate of Codex and will considerably complicate and expand current CCFH risk assessment guidelines. Furthermore, it would appear that additional consultants would be necessary to carry out the work if human medical impact is to be considered.

IFAH is pleased to have been provided the opportunity to comment on this important issue. We look forward to working with the Secretariat and Commission as comments are considered and incorporated into the proposed final task force terms of reference.