codex alimentarius commission E

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 6 **CX/AMR 08/2/6**
June 2008

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

***AD HOC* CODEX INTERGOVERNMENTAL TASK FORCE ON ANTIMICROBIAL RESISTANCE**

Second Session

Seoul, Republic of Korea, 20-24 October 2008

PROPOSED DRAFT GUIDANCE TO CONTAIN FOODBORNE ANTIMICROBIAL RESISTANT MICROORGANISMS

At Step 3

(prepared by the physical Working Group led by Denmark and France)

Governments and international organizations in Observer status with the Codex Alimentarius Commission wishing to submit comments at Step 3 on the Proposed Draft Risk Management Guidance to Contain Foodborne Antimicrobial Resistant Microorganisms are invited to do so **no later than 1 September 2008** as follows: Secretariat, *Ad Hoc* Codex Intergovernmental Task Force on Antimicrobial Resistance, Food Microbiology Division, Korea Food and Drug Administration, Eunpyeonggu, Seoul, 122-704, Republic of Korea (Telefax: + 82-2-355-6036, E-mail: kwakhyos@kfda.go.kr ***preferably***), with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00153 Rome, Italy (Telefax: +39 06 5705 4593; E-mail: Codex@fao.org - ***preferably***).

BACKGROUND

1. During its First Session (Seoul, Republic of Korea, from 23 to 26 October 2007), the Codex *ad hoc* Intergovernmental Task Force on Antimicrobial Resistance agreed to undertake new work on the development of Risk Management Guidance to contain foodborne antimicrobial resistant microorganisms, subject to the approval by the 31st Session of the Commission (July 2008).

2. It further agreed to establish a physical Working Group, to be hosted by the European Community and co-chaired by Denmark and France, open to all delegations and observers and working in English, French and Spanish, which would prepare a proposed draft guidance document for circulation at Step 3 and further consideration at Step 4 at the Second Session of the Task Force.

3. The purpose of the proposed work is to develop appropriate risk management guidance for national/regional authorities that may be necessary following risk profiling and/or risk assessments, usually undertaken as described in the Risk Assessment and Risk Profile project documents prepared by the Task Force. Guidance will also be provided on how to measure and monitor the effectiveness of the selected risk management options, including establishing a baseline against which subsequent changes can be measured.[1]

[1] ALINORM 07/31/42 para. 45

PROCEEDING OF THE WORKING GROUPS

4. Written comments were received from several members (Australia, Brazil, Canada, European Community, Finland, Germany, Japan, United States of America) and observers organizations (FAO (Fishery), IFAH, CI, UECBV, IDF) and were used as the basis a first draft circulated by the end of March 2008.

5. The physical working group was held in Brussels from May 29th to 30th, at the kind invitation of the European Commission. It was attended by Australia, Belgium, Brazil, Canada, Czech Republic , Denmark, Estonia, European Community (Member Organization), Finland, France, Germany, Ireland, Japan, Netherlands, New Zealand, Norway, Philippines, Republic of Korea, Spain, Sweden, Thailand, United States of America, FAO, World Health Organization, Consumers International, International Federation For Animal Health (IFAH), European Livestock and Meat Trading Union (UECBV). The Group was co-chaired by Denmark and France and reviewed the initial draft on the basis of all the written comments received before the session.

6. The working group agreed that its work should build on existing texts, published by WHO, OIE and Codex, and, at this stage, did not support the suggestion in the para. 6 of the project document of revoking existing Codex texts upon the adoption of this Guidance[2]. The working group reviewed the draft in order to identify what additional guidance, beyond the existing framework, was provided and agreed to restructure the document to highlight them.

7. The working group also agreed that the scope of its work was limited to the consideration of the risk for human health deriving from the contamination of the food chain by antimicrobial-resistant bacteria and/or antimicrobial resistance determinants and that other issues, such as specific guidelines on the use of antimicrobials or the regulation of the practice of veterinary medicine, although relevant to some extent in this context, were beyond its remit and has already been adequately addressed by other international organizations with competence in these areas.

8. The working group noted that the scope of its work was not limited to food of animal origin, but should address food of plant origin and food processing; a section was inserted to this effect into the document; however, the working group noted that further comments would be required to cover these issues adequately.

9. The revised version of the proposed draft Guidelines (see Appendix 1) has been prepared by the secretariat of the meeting; areas where further comments are required to progress in the elaboration of this paper have been highlighted in Appendix 1. In order to improve readability, the list of possible endpoints (section VIII – para. 33) and the components of the stepwise approach (section VII – para. 27) have been transferred to separate annexes.

10. References to the documents consulted during the drafting are included, for information, as Appendix 2.

RECOMMENDATIONS TO THE 2nd SESSION OF THE TASK FORCE

11. The recommendation of the 3 working groups to the Task Force is that the three working group documents (Guidance on creating a risk profile on risk assessment, on risk management options) could be most usefully read by the intended audiences as an integrated guidance document. With this approach, certain sections such as introduction, definitions, documentation, and risk analysis general principles could be harmonized, resulting in a more consistent and readable guidance document. Furthermore, this approach would allow the inclusion of an overall flowchart that could guide the reader through a range of activities discussed in the three separate but overlapping working group documents. Finally, the integrated document would include a harmonized section on risk communication, which is critical to all activities addressed by the guidance.

12. The Task Force may wish to consider the text of the proposed draft Guidelines on risk management to contain foodborne antimicrobial resistant microorganisms, presented in Appendix 1 and advance it through the step procedure of Codex.

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[2] *"Upon adoption of the proposed document, the Codex Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005) and the Codex Recommended International Code of Hygiene Practice for Control of the Use of Veterinary Drugs (CAC/RCP 38-1993) should be revoked or amended as appropriate, to ensure consistency and avoid duplication within the Codex Alimentarius." (see ALINORM 08/31/42 Appendix IV – section 6).*

Appendix 1

PROPOSED DRAFT GUIDELINES ON RISK MANAGEMENT TO CONTAIN FOODBORNE ANTIMICROBIAL RESISTANT MICROORGANISMS

(At step 3 of the elaboration procedure)

I.- INTRODUCTION

1. (to be harmonized)

II.- PURPOSE AND SCOPE

2. The purpose of the proposed work is to develop appropriate risk management guidance for national/regional authorities that may be necessary following risk profiling and/or risk assessments, usually undertaken as described in the Risk Assessment and Risk Profile project documents prepared by the Task Force. Guidance will also be provided on how to measure and monitor the effectiveness of the selected risk management options, including establishing a baseline against which subsequent changes can be measured.

3. National/regional authorities, in implementing these guidelines, should consider a continuum of possible interventions along the entire food chain, each step of which can reduce risk by minimizing and containing antimicrobial resistant (AMR) microorganisms and resistance determinants.

4. This document should be read in conjunction with the Codex Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC-RCP 61-2005), the relevant sections of the OIE Terrestrial Animal Health Code (2007)[3] and the WHO documents/guidelines on containment of antimicrobial resistance in animals for food[4].

III.- GENERAL PRINCIPLES

PRINCIPLE 1: Protection of human health is the primary objective in antimicrobial resistance risk management.

PRINCIPLE 2: Antimicrobial resistance risk management activities should take into account the emergence and dissemination of both resistant foodborne pathogens and resistance determinants through the whole food chain. ("foodborne pathogens" to be modified based on harmonization of the WGs ("acquired from food"))

PRINCIPLE 3: Antimicrobial resistance risk management activities should focus on clearly defined combinations of food, antimicrobial drug (AM), antimicrobial use and the human pathogens and/or resistance determinants acquired from food.

PRINCIPLE 4: Antimicrobial resistance risk management activities should follow a structured approach[5].

PRINCIPLE 5: The activities conducted in all phases of antimicrobial resistance risk management should be transparent, timely, consistent, fully documented and openly communicated.

PRINCIPLE 6: Risk managers should ensure effective consultations with relevant interested parties[6].

PRINCIPLE 7: Risk managers and risk assessors should ensure effective interaction.

PRINCIPLE 8: Risk managers should take into account risks resulting from regional differences in human exposure to AMR microorganisms & determinants from the food chain and regional differences in available risk management options.

PRINCIPLE 9: Antimicrobial resistance risk management decisions should be subject to monitoring and review and, if necessary, revision.

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[3] http://www.oie.int/eng/normes/Mcode/en_sommaire.htm

[4] http://www.who.int/foodborne_disease/resistance/en/index.html

[5] See para. 7 in GL 62-2007.: "*The risk analysis should follow a structured approach comprising the three distinct but closely linked components of risk analysis (risk assessment, risk management and risk communication) as defined by the Codex Alimentarius Commission2, each component being integral to the overall risk analysis*."

[6] *For the purpose of the present document, the term "interested parties" refers to "risk assessors, risk managers, consumers, industry, the academic community and, as appropriate, other relevant parties and their representative organizations".*

PRINCIPLE 10: Activities of risk management should take into account all work by Codex and work by international organizations on antimicrobial resistance and that Codex Guidelines (GL) and Recommended Code of Practice (RCP) should be fully implemented.

PRINCIPLE 11: Risk Managers should implement additional mitigation steps when Risk Analysis indicates it.

IV.- IDENTIFICATION OF THE AVAILABLE OPTIONS

5. Risk management options should consider the farm to table continuum and could be divided in pre-harvest and post-harvest aspects. Pre-harvest would contain aspects such as responsible use guidelines and codes of practice documents specifically directed to antimicrobial agents and their use in food production, whereas post-harvest would contain such aspects as food hygiene practices which are specifically directed to foodborne contamination.

6. As part of the pre-harvest activities, appropriate emphasis should be laid on evaluation prior to approval, taking due account of the resistance inducing properties of antimicrobials; emphasis should also be placed on defining use conditions of antimicrobials. Countries should pay particular attention to the establishment of the necessary instruments for approval, registration and enforcement of regulations regarding usage.

7. With regard to post-harvest, the aim should be to monitor trends in antimicrobial resistance and prevalence of foodborne bacteria and to apply targeted interventions aimed at reducing antimicrobial resistant bacteria of importance to human and animal health.

8. Risk management options described in the following section may be implemented, at the discretion of national/regional authorities and in a manner that is proportional to the level of risk, based upon the following considerations:

a). as a minimum, the existing Codes of Practice should be followed. These codes of practice describe the respective roles and responsibilities of authorities and groups to minimize and contain antimicrobial resistance:

- Codex Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005),
- Codex Recommended International Code of Hygiene Practice for Control of the Use of Veterinary Drugs (CAC/RCP 38-1993),
- Codex Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007), and
- Food Hygiene Basic Text – Recommended International Code of Practice General Principles of Food Hygiene (CAC/RCP 1-1969) and its annex on Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for Its Application.

b). Implementation of these options is subject to the resources, legislative, and other constraints of the country/region;

c). The selection and implementation of the risk management options should be supported by scientific evidence, be feasible, and reviewable with respect to new scientific information;

d). They are intended to supplement the Codex Codes of Practice and related texts (above) and to provide additional risk management options to risk managers.

9. Examples of potential risk management (RM) options (used either alone or in combination) available for Codex or countries, as appropriate are listed below in the rest of this section:

A.- Pre-harvest options

A.1- General

- Monitoring and surveillance of the use of antimicrobials in animals and horticulture (this set of measures do not contribute to the reduction of foodborne antimicrobial resistance (AMR) risk – Monitoring is essential to establish a baseline for comparing the effectiveness of new MRM activities. It also may provide information which the manager may use to determine what steps may be taken to achieve further improvements in the extent or efficiency of risk mitigation {CAC/GL 63 – 2007, page 9})

a). monitoring should, to the extent possible, include all antimicrobials used in food production

b). monitoring of usage in animals should be at species level and if possible also on category of animal within species & take into account drug/bacteria/animal species relationship;

c). authorities should preferably plan in advance the collection and analysis of data on the dissemination of antimicrobial resistance and on antimicrobial usage.

d). AMR data should be analyzed with AM usage data together with other relevant data to assess possible relationships

- Approval and licensing of antimicrobials used in animals and horticulture

a). Approval and licensing of an Antimicrobial may, whenever possible, be subjected to the monitoring of the use of this AM and of the AM resistance.

b). Approval and licensing of an Antimicrobial may, whenever possible, be subject to the review of existing AMs.

c). AM product should not be authorized if risk assessment indicates unacceptable levels of risk

A.2- Food animal production

- Restrict extra-label use, especially in Critically important antimicrobials (CIA) for human treatment
- Perform a bacterial diagnosis and susceptibility testing prior to treatment for a given AM and bacterial infection.
- Competent authorities and/or professional bodies should elaborate animal (plant & food processing) species-specific prudent use treatment guidelines in consultation with all relevant interested parties
- Recommend on different AM to be used, if several antimicrobials can be used for a given indication in an animal. (more comments required).
- Prophylactic use in healthy animals not considered to be at risk of infection or prior to the onset of clinical infectious disease, should be avoided. (more comments required)
- Prevent the presence and transmission of foodborne bacteria & determinants between animals and from animals to humans by implementing Animal health and infection control programs against the most important zoonotic AMR agents.
- Restrict movement of live animals, carrying a specific AMR foodborne pathogen or a bacteria carrying resistance determinant (more comments required : in/out of scope of Codex? OIE remit?).
- Responsible use in veterinary medicine of antimicrobials of particular importance for human treatment (more comments required : cf. OIE Terrestrial Animal Code).
- If sufficient evidence exists that profit from the sale of antimicrobials negatively impacts on prescribing practices, appropriate countermeasures should be taken to ensure prudent use. (more comments required :in/out of scope of mandate of Codex? but = WHO global principles on containment of AMR)

A.3- Plant production

Controlling the use of antimicrobial agents: more comments required

- Controlling the spread of AMR bacteria through other possible sources of contamination: direct use in agriculture of human and animal waste (manure) should be discontinued, if there is sufficient evidence of risk (practical, feasible and supported by science and to be revised in the light of further knowledge – more comments required).

B.- Post-harvest options

- Target interventions towards those bacteria that are resistant to antimicrobials of critical importance to public and animal health
- Implement of control measures to the extent possible;
- Prevent the food containing an unacceptable level of AMR bacteria & AM determinants, reaching the consumer

- Withdraw food containing an unacceptable level of AMR pathogenic bacteria from the market for reprocessing or destruction (commensals are not included here– to review the inclusion of commensals later on)

V.- EVALUATION OF RISK MANAGEMENT OPTIONS (RMO)

10. Animal health should also be considered when evaluating risk management options, to the extent possible, consistent with the requirement of GENERAL PRINCIPLE 1.

11. Evaluation of the identified Risk management options should be performed at National/ Regional level.

12. Risk management options should be assessed in terms of the scope and purpose of risk analysis and the level of consumer health protection they achieve. The option of not taking any action should also be considered.

13. Risk management options should be assessed taking into account the options' feasibility, effectiveness, economic implications, enforcement and compliance; they should be proportionate to the amount of risk. The level of control or reduction of risk that is necessary, should be specified, when feasible.

VI.- SELECTION OF RISK MANAGEMENT (RM) OPTIONS[7]

14. The selection of RM options should be based on their ability to mitigate the risks effectively and on the practical feasibility and consequences of the options. Where available, a risk assessment can often help in the evaluation and selection of RM options.

15. The selection should be supported by mechanisms to evaluate success to contain and minimize AMR that may be transmitted through the food chain.

16. The various interested parties should be involved when developing regulatory programs.

A.- Identifying a appropriate level of consumer health protection[8]

17. Risk management decisions on appropriate options should be achieved by considering and integrating all evaluation information obtained from preliminary risk management activities and/or the risk assessment.

A.1- Benefit-risk approach

18. Because antimicrobials play a major role in animal health, animal health should be considered when evaluating risk management options, but this must be considered secondary to protecting consumers. When evaluating restrictions on the use of antimicrobial products it is necessary to consider substitutes or alternative practices that would reduce the need for the product. Substitutes could be other less important antimicrobials, non-antimicrobial products, or changes in livestock husbandry that promote animal health. The impact of reduced antimicrobial resistance on animal health should also be considered when evaluating restrictions on antimicrobial use.

A.2- Threshold approach

19. Given the geographic variations in the levels of resistance and the increasing emergence of resistance, it may be necessary to explore the need to develop resistance thresholds for specific antimicrobial-species-pathogen combinations, above which any of a range of risk management options may be triggered. However, this approach needs to be carefully assessed as it should be put in perspective with the current use of antimicrobials and the current level of resistance.

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[7] CAC/GL 63 – 2007 provides general guidance on the selection of risk management options (sections 4 & 6).

[8] "Appropriate Level of Protection" (ALOP). ALOP is defined in the SPS Agreement as "the level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory". ALOPs may range from general to specific depending upon the level of information available with regards to the source of hazards and risks and will depend on the public health goals.

A.3- Precautionary approach:

20. When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, it may be appropriate for countries to select a provisional decision, while obtaining additional information that may inform and if necessary modify the provisional decision. In those instances, the nature of the provisional decision should be communicated to all interested parties and the timeframe or circumstances under which the provisional decision will be reconsidered (e.g. reconsideration after completion of a risk assessment) should be articulated when the decision is communicated initially.

A.4- ALARA approach

14. (Further comments to be submitted by Philippines)

B.- Reaching a decision on the preferred risk management options

21. The decisions should be based on risk assessment and taking into account, where appropriate, other legitimate factors relevant to health protection of consumers and for the promotion of fair practice in the food trade[9].

22. Cross-resistance, co-resistance issues should be considered.

23. control measures may be placed on the use of specific antimicrobial agent in some species or some route of administration or specific production processes (see GENERAL PRINCIPLE 3)

VII.- IMPLEMENTATION OF RISK MANAGEMENT OPTIONS

24. Risk managers should develop an implementation plan that describes how the options will be implemented, by whom, and when.

25. National/regional authorities should ensure an appropriate regulatory framework and infrastructure.

26. Prudent use guidelines, monitoring of antimicrobial usage and general food hygiene principles should be implemented as a minimum; additional measures could be envisaged following a stepwise approach (see annex 2).

VIII.- MONITORING AND REVIEW OF RISK MANAGEMENT OPTIONS

27. Governments should define an evaluation process to assess whether the risk management options have been properly implemented and an assessment whether or not an outcome has been successful (see also GENERAL PRINCIPLES).

28. Monitoring and surveillance should be supported by regulation and the enforcement of control measures

29. A minimum level of monitoring should be established in order to measure usage and risk management effects.

30. Monitoring schemes should be harmonized (RCP 61 & GL 63) between countries, to the extent possible (in a general consideration about sharing info between countries; more comments are requested on this issue & review OIE Terrestrial Animal Code for existing wording).

31. risk management options should be reviewed and evaluated, regularly, or at a predetermined moment in time, or whenever new relevant information becomes available

32. A variety of endpoints (see Annex 1) may be measured with respect to antimicrobial resistance. Endpoints related to specifically implemented risk management options should be measured to assess the effectiveness and need for potential adjustment.

33. Additional endpoints may be measured to identify new information (e.g., emerging hazard, virulence of a pathogen, prevalence and concentration in foods, sensitivity of sub-populations, changes in dietary intake patterns,...).

IX.- RISK COMMUNICATION

15. (to be harmonized)

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[9] WPRAC para 28, 2nd sentence

Annex 1: possible endpoints (exposure end points to be separated from adverse health effect end points)

(refers to section VIII – para 38)

In order to monitor variations in AM usages and AMR and the effects of risk management measures, possible endpoints include:

a. Nature and extent of antimicrobial resistance.

b. Nature and extent of antimicrobial resistance in animal-derived food products at retail level.

c. Prevalence of antimicrobial-resistant bacteria on farm level.

d. Prevalence of antimicrobial-resistant bacteria in animal-derived food products at retail level.

e. Prevalence of antimicrobial-resistant bacteria or resistant genes in human clinical isolates of foodborne diseases.

f. Development of new bacterial resistance patterns.

g. Prevalence of foodborne pathogens on farms.

h. Prevalence of foodborne pathogens in food.

i. Prevalence of food borne disease in humans.

j. Number of deaths attributable to foodborne antimicrobial-resistant bacteria.

k. Number of treatment failures attributable to foodborne antimicrobial-resistant bacteria.

l. Frequency of human infections attributable to foodborne antimicrobial-resistant bacteria.

m. Frequency of adverse human health effects attributable to foodborne antimicrobial resistant bacteria.

n. Mortality due to foodborne antimicrobial-resistant bacterial infections in “vulnerable populations”.

o. Level of awareness of antimicrobial resistance risk (producers, consumers, industry and others).

p. Level of compliance with specific drug use restriction or compliance with prudent use guidelines.

q. Trends in usage of antimicrobials in food-producing animals.

r. Trends in usage of critically important antimicrobials (CIA) in food-producing animals.

Annex 2: step wise approach

(refers to section VII – para 32)

Step 1

a). Ensure adequate veterinarian (or equivalent animal health professionals) coverage for the country, veterinarian training in judicious/appropriate/responsible antimicrobial use and animal production practices, and appropriate involvement in food production and food safety processes.

b). Ensure adequate infrastructure for food production/food hygiene with respect to existing Codex standards and guidelines.

c). National authorities should capitalize upon regulatory precedents and expertise of "peer" authorities in the region when capabilities are limited.

d). Communicate to the public the necessity of proper food preparation and hygiene.

Step 2

e). Implement responsible use guidelines via professional veterinary organizations.

f). Ensure reliable national food safety authority oversight of food safety activities consistent with Codex food hygiene guidance.

g). Implement adequate infrastructure and enforcement capacity to ensure compliance with quality product availability and veterinary involvement in antimicrobial usage.

h). Implement local/regional surveillance programs for foodborne disease.

Step 3

i). Implement national surveillance programs for foodborne disease.

j). Implement national resistance monitoring program, and where possible, usage monitoring.

k). Implement regulatory review of new antimicrobial agents prior to product approval.

l). Work in collaboration with food producing companies to maintain vigilance for implementation of food hygiene practices (i.e. HAACP) that safeguard against food contamination.

m). Work with professional associations (e.g. veterinary profession, species specific groups, etc.) to ensure compliance with responsible use guidelines by all members. Implement research programs to develop new research to fill data gaps that will improve antimicrobial use practices, or minimize the need for antimicrobial use by preventing disease, etc.

n). Encourage animal health companies to develop products that will avoid resistance selection of currently used human use antibiotic classes.

Appendix 2

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