codex alimentarius commission E

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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CODEX ALIMENTARIUS COMMISSION

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REPORT OF THE 1st SESSION OF THE CODEX *AD HOC* INTERGOVERNMENTAL TASK FORCE ON ANTIMICROBIAL RESISTANCE

Seoul, Republic of Korea
23-26 October 2007

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SUMMARY AND CONCLUSIONS

The First Session of the Codex *Ad Hoc* Intergovernmental Task Force on Antimicrobial Resistance reached the following conclusions:

Matters for consideration by the Commission

Amendment to the Terms of Reference

The Task Force agreed to forward proposed Amendment to the Terms of Reference to the Commission for consideration and approval (para. 9 and Appendix II).

Proposals for new work

The Task Force agreed to submit to the Commission, through the Executive Committee, the proposals for new work on the development of guidance documents on:

i) Science-based risk assessment of foodborne antimicrobial resistant microorganisms (para. 32 and Appendix III);

ii) Risk management to contain antimicrobial resistant microorganisms (para.44 and Appendix IV); and

iii) Creating risk profiles for antimicrobial resistant foodborne microorganisms for setting risk assessment and management priorities (para. 52 and Appendix V).

Matters of Interest to the Commission

Physical Working Groups

The Committee agreed to establish three physical working groups to prepare three proposed draft guidance documents for circulation at Step 3 and consideration at Step 4 at the next session of the Task Force, pending the formal approval of new work by the Commission (paras 33, 45 and 53).

LIST OF ABBREVIATIONS USED IN THIS REPORT

AMR	Antimicrobial Resistance
CAC	Codex Alimentarius Commission
CL	Circular Letter
CRD	Conference Room Document
FAO	Food and Agriculture Organization of the United Nations
GIFSA	Global Initiative for Food-related Scientific Advice
GL	Guidelines
JEMRA	Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment
OIE	World Organization for Animal Health
WHO	World Health Organization

INTRODUCTION

1. The Codex ad hoc Intergovernmental Task Force on Antimicrobial Resistance held its First Session in Seoul, Republic of Korea, from 23 to 26 October 2007, by courtesy of the Government of the Republic of Korea. Dr Gun-Jo Woo, Director, Center for Food Safety, Korea Food and Drug Administration, presided over the Session. The Session was attended by 138 delegates from 36 Member countries and 1 Member organization and Observers from 9 international organizations. A list of participants, including the Secretariat, is given in Appendix I to this report.

2. The Session was opened by Mr Myung-Hyun Kim, Commissioner, Korea Food and Drug Administration. He welcomed the participants to Seoul and expressed his appreciation for the timely establishment of the Task Force and wished every success in the future. Dr Chang-Jin Moon, Vice Minister, Ministry of Health and Welfare, also delivered a congratulatory speech to the participants. He emphasised the importance of developing internationally harmonized approaches and guidance to minimize the spread of antimicrobial resistance at all stages of the food chain.

Division of Competence

3. The Committee noted the division of competence between the European Community and its Member States, according to paragraph 5, Rule II of the Procedure of the Codex Alimentarius Commission, as presented in document CRD 1.

ADOPTION OF THE AGENDA (Agenda Item 1)[1]

4. The Commission adopted the Provisional Agenda as its Agenda for the Session.

MATTERS REFERRED TO THE TASK FORCE BY THE COMMISSION AND OTHER CODEX COMMITTEES (Agenda Item 2)[2]

5. The Task Force noted the information presented in document CX/AMR 07/1/2 concerning the matters of interest to the Codex ad hoc Intergovernmental Task Force on Antimicrobial Resistance arising from the 29th and 30th Sessions of the Codex Alimentarius Commission. In particular, the Task Force commented and/or made decision on the following matters:

Terms of Reference of the Task Force

6. The Delegation of Portugal, speaking on behalf of the member states of the European Community and referring to the latter's written comments as contained in document CX/AMR 07/1/4, stated that, while supporting the approach decided by the Commission, it was in favour of activities aimed at preventing the development of antimicrobial resistance being considered in a balanced way with respect to all relevant areas: human medicine, veterinary medicine related in particular to food production, and plant protection. Thus, the Delegation proposed: i) to add a sentence under "Objectives" with a view to putting in perspective the risks presented by the use/misuse of antimicrobials used both in animals and in humans in order to avoid overestimating the impact of the use of antimicrobials in animals and to keep proportionate the measures to be adopted; and ii) to amend the text under "Terms of reference" to add references to antimicrobial resistance in humans and to the use of antimicrobials in human, plant and food processing.

7. The Representative of WHO stated that it would be problematic to include, in the scope of the Task Force, the use of antimicrobials in human medicine in view of the activities already undertaken and ongoing in WHO in this area and the need for additional expertise in the Task Force to deal with this subject. The Observer from the World Organization for Animal Health (OIE) highlighted the importance of having an integrated approach and maintaining a global perspective to antimicrobial resistance. Other delegations and observers, supporting the view of the WHO Representative, stated that the Task Force's activities should focus on aspects related to the non human use of antimicrobials and to the development of antimicrobial resistance in human pathogens in and through food, including both animal and vegetable products. They recommended to keep the terms of reference of the Task Force unchanged and not to broaden its scope in view of the limited time assigned to the Task Force to complete its work and the work priority of the Task Force which had been discussed at the Commission.

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1 CX/AMR 07/1/1 Rev.

2 CX/AMR 07/1/2; CX/AMR 07/1/4 (Comments of the European Community); CRD 6 (Comments of Kenya)

8. After some debate, the Task Force agreed to: i) add a sentence under “Objectives” to clarify that the Task Force should attempt to put into perspective the risk of increase of antimicrobial resistance in human beings and animals generated by different areas of use of antimicrobials, such as veterinary applications, plant protection or food processing, without adding a reference to human medicine; and ii) keep the text under “Terms of reference” unchanged. It was understood that the issue regarding the use of antimicrobial resistance genes as a marker genes in the development of recombinant-DNA plants, remained outside the scope of the Task Force on Antimicrobial Resistance, since the matter had been dealt with by the Task Force on Foods derived from Biotechnology.

9. The Task Force agreed to forward the proposed amendment to its Terms of Reference to the 31st Session of the Commission for consideration and approval (see Appendix II).

Elaboration of New Standards and Related Texts

10. The Task Force was informed that the 30th Session of the Commission had requested that in the future all project documents for new work should be prepared properly in accordance with the provisions in the Procedural Manual. The Chairperson emphasized the importance of properly preparing project documents that comply with the requirements set out in the Procedural Manual to expedite the work of the Task Force.

REVIEW OF THE WORK BY FAO, WHO AND OIE ON ANTIMICROBIAL RESISTANCE (Agenda Item 3)[3]

11. The Task Force noted with appreciation the information presented in document CX/AMR 07/1/3, submitted by FAO, WHO and OIE concerning their work related to antimicrobial resistance.

12. The Representative of WHO outlined the work undertaken by WHO and its partner agencies since the first World Health Assembly resolution on antimicrobial resistance in 1998. He stated that approximately half or more of the total tonnage of antimicrobials produced was currently used to treat diseased animals, to prevent disease and as growth promoters, and that continuous and low-level dosing of antimicrobials, as growth promoters, favoured the development of drug-resistant bacteria. He further noted that such uses had been banned in several countries mainly in Europe, in accordance with WHO recommendations.

13. The Representative of WHO underlined that the Task Force needed to build on all previous work done and that there was a need for general risk assessment policy guidance as well as specific scientific advice in this area. He further highlighted the need to develop management options for non-human use of antimicrobials that were critically important to human medicine.

14. The Representative of OIE acknowledged the importance for both public and animal health of the potential antimicrobial resistance resulting from the use of antimicrobials in the veterinary sector. He highlighted the main outcomes of the OIE activities since the last decade aiming at containing and preventing antimicrobial resistance. Three specific areas of action were highlighted: adoption of specific guidelines; establishment of the list of veterinary critically important antimicrobials; and capacity building in member countries, including strengthening of veterinary services.

15. The Representative highlighted, among several specific OIE guidelines on antimicrobial resistance, those on the responsible and prudent use of antimicrobial agents in veterinary medicine and on the risk assessment for antimicrobial resistance arising from the use of antimicrobials in animals. He underlined the multidisciplinary aspect of antimicrobial resistance and the need to cover the whole food chain. He also stressed the need to create synergy between the different international organisations by using existing work in order to avoid duplication of work.

16. The Representative of FAO informed the Task Force of the activities carried out by the organization in this field, related to: provision of scientific advice; development of guidelines for good agriculture practices, including animal husbandry and aquaculture practices, which contribute to the containment of foodborne antimicrobial resistance; and capacity building. All activities were carried out under a multidisciplinary approach, directly or in coordination with other international organizations, such as WHO, OIE and other stakeholders.

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[3] CX/AMR 07/1/3 Rev.

17. The Representative of FAO also mentioned that the Joint FAO/WHO/OIE Expert Meeting on Critically Important Antimicrobials, to be held in November 2007 in Rome, would provide recommendations on future work to the three organizations. The Task Force was also informed of the Global Initiative for Food-related Scientific Advice (GIFSA), launched by FAO and WHO in July 2007, to facilitate the mobilization of technical, financial and human resources to support activities on the provision of scientific advice, including those related to antimicrobial resistance. She invited all delegates to make use of this new mechanism to ensure that the provision of scientific advice which might be required by the Task Force could be provided in a timely manner.

18. The Task Force also recalled that an international workshop, held in Seoul on 22 October 2007, immediately prior to the Task Force session, had provided a venue for many participants to obtain update information on national and international activities for the containment of antimicrobial resistance.

CONSIDERATION OF THE ELABORATION OF STANDARDS, GUIDELINES OR OTHER TEXTS ON ANTIMICROBIAL RESISTANCE (Agenda Item 4)[4]

19. The Task Force reviewed the twelve project documents and other proposals forwarded by members and observers in response to CL 2006/38-AMR, as contained in documents CX/AMR 07/1/4, CX/AMR 07/1/4 Add.1, CX/AMR 07/1/4 Add.2 and CRD 2.

20. The Task Force noted that all proposals submitted fell under one of the three main clusters: risk assessment, risk management and risk profile/prioritization and agreed to discuss the various proposals for new work according to the three clusters and to prepare one project document for each of these clusters. Due to the limited time and in order to expedite its work, the Task Force agreed to establish three in-session working groups to prepare three project documents on risk assessment, risk management and risk profile/prioritization, respectively, for consideration by the plenary.

21. The Task Force agreed that the three in-session working groups, opened to all delegations and observers and working in English, French and Spanish, would be chaired by the delegations of Canada (risk assessment), the European Community (risk management) and the United States of America (risk profile/prioritization). It was agreed that each of the working groups would use one of the proposals submitted as a starting point for their work, eliminate redundancies and duplications and focus their discussion, in particular, on section 3 “Main aspects to be covered”.

22. The Task Force, in its plenary, considered the proposals submitted by the in-session Working Groups as follows:

Risk assessment

23. The Task Force noted that the in-session Working Group had agreed to use as a starting point for its discussion the project document prepared by the United States of America, as contained in document CX/AMR 07/1/4 and to include, as appropriate, elements from other proposals submitted in response to CL 2006/38-AMR. The Task Force noted that the Working Group: had considerable discussion on the inclusion of a reference to “the positive effects of the use of antimicrobial drugs in animals” in section 1 “Purpose and scope of the proposed work” and agreed not to include it in Section 1 because of lack of consensus; expressed the desire to avoid duplication of work already undertaken by other international organizations; and had also had discussions on the importance of assistance to member countries with limited capacity to undertake risk assessments.

24. The Task Force noted that the proposal prepared by the working group aimed at building upon the processes already in place within Codex, JEMRA and within OIE for risk assessment with regard to human health concerns and adapt and consolidate them in the framework of risk assessment for antimicrobial resistance, similar to the OIE risk analysis work included in its Terrestrial Animal Health Code.

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[4] CL 2006/39-AMR; CX/AMR 07/1/4 (Comments of Canada, Cuba, European Community, Japan, Mexico, Republic of Korea, United States of America, Consumers International, IFAH and OIE); CX/AMR 07/1/4 Add.1 (Comments of United States of America); CX/AMR 07/1/4 Add.2 (Comments of Indonesia); CRD2 (Comments of Norway); CRD3 (Preliminary report of in-session Working Group on Risk Assessment); CRD3 Rev.1 (Preliminary report of in-session Working Group on Risk Assessment); CRD3 Rev.2 (Report of in-session Working Group on Risk Assessment); CRD 4 (US proposal for in-session Working Group on Risk Profile); CRD4 Rev.1 (Report of in-session Working Group on Risk Profile); CRD5 (Report of in-session Working Group on Risk Management)

25. The Working Group had agreed that section 5 “Relevance to the Codex strategic objectives” refers to the objectives and activities in the new Codex Strategic Plan 2008-2013. Under section 7 “Identification of any requirement for and availability of expert scientific advice”, the Working Group had recommended to include all relevant scientific documents on risk assessment and to allow for the possibility to request additional scientific advice from FAO/WHO/OIE, including JEMRA. With regards to the time-line (section 9), the Working Group had agreed to use the timeline as presented in the Canadian document.

26. The Task Force considered in detail the proposal prepared by the in-session Working Group, as contained in document CRD3 Rev.2. In addition to some editorial changes and amendments, the Task Force agreed to the following changes:

1. Purpose and Scope of the proposed work

27. The Task Force amended the first paragraph to clarify that the intent of the guidance was to support JEMRA and/or national/regional authorities in assessing the potential overall risk to human health, associated with the presence of antimicrobial resistant microorganisms and resistant determinants.

3. Main aspect to be covered

28. The Task Force discussed whether to limit the scope of the new work to the determination of risks to human health relating to antimicrobial resistant microorganisms and resistance determinants arising from the use of antimicrobials “in animals”. Some delegations, referring to the discussion held on the Terms of Reference of the Task Force and the addition of a new sentence under “Objectives” (see Agenda Item 2), were of the opinion that it was appropriate for the Task Force to also consider the use of antimicrobials in plant protection. Other delegations were of the opinion that focusing on the use of antimicrobials in animals was consistent with the “terms of reference” which referred to human and veterinary medicine. The Delegation of Australia proposed to include, in the scope, both the human and non-human antimicrobials uses. After some discussion the Task Force agreed to amend the text to refer to “non human use” of antimicrobials. In this regard, the Task Force was informed that pending future provisions of the proposed document particularly in relation to plants and if necessary, the Task Force was entitled to refer any technical matters or questions to other Codex subsidiary bodies having competence in such technical areas, including the Codex Committee on Pesticide Residues.

29. The Task Force further agreed to remove the square brackets from the last sentence of the first paragraph, while keeping the text unchanged.

30. The first bullet point, under the second paragraph, was amended for clarity purpose and a new fifth bullet point was added to refer to the evaluation of risk management options.

6. Information on the relation between the proposal and other existing Codex documents

31. The Task Force agreed to replace the entire section with a new paragraph containing specific references to relevant Codex texts in accordance with the scope of the section. It further agreed that relevant documents of other organization (e.g. FAO, WHO, OIE) would be listed under section 7 “Identification of any requirements for and availability of expert scientific advice” and that the list of documents after section 9 would be deleted. The Task Force agreed to amend, for consistency, the relevant sections of the other two project documents accordingly.

Status of the proposal for new work

32. The Task Force agreed to forward the project document as amended (see Appendix III) to the 61st Session of the Executive Committee for Critical Review and to the 31st Session of the Commission for approval as new work.

33. It further agreed to establish a physical Working Group, under the leadership of Canada, 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 approximately by April 2008 and further consideration at Step 4 at the Second Session of the Task Force.

34. It was agreed that the physical Working Group would meet as early as possible in order to allow for timely circulation of the proposed draft. It was also agreed that, in order to facilitate the initial work of the Working Group, Codex members and observers be invited to electronically submit elements for the proposed draft document to the Delegation of Canada by December 2007.

35. The Task Force noted that consideration of the proposed draft at Step 4 was subject to approval of the proposed new work by the Commission in July 2008.

Risk management

36. The Task Force noted that the in-session Working Group had agreed to use as a starting point for its discussion the proposals of the United States of America, as contained in documents CX/AMR 07/1/4 and CX/AMR 07/1/4 Add.1 and to include, as appropriate, elements from others proposals submitted in response to CL 2006/38-AMR.

37. The Working Group had considered the scope and purpose of the project and had discussed, in particular, if guidance on Risk Profile should be developed as part of this project. It had been agreed that discussion on risk profile would be dealt with during the in-session working group on risk profile/priority.

38. The Task Force noted that in section 2 “Relevance and timeliness” the Working Group had referred to Annex 2 of CL 2006-38-AMR and to the terms of reference of the Task Force. This section had been amended to include two sentences highlighting the importance of antimicrobials for human and animal health and had been aligned with the section of the two others project documents. In section 3 “Main aspect to be covered”, the Working Group had included the elements contained in document CX/AMR/07/1/04 Add1. The list of risk management options had been integrated with points from other proposals, while noting that the list was not intended to be prescriptive or exhaustive. The Working Group had added references to the capacity building programmes and activities for strengthening risk management carried out by FAO, OIE and WHO. The Working Group had discussed and agreed that the project should address aspects of risk communication between risk assessors and risk managers, taking into account the guidance in the FAO/WHO Guide on Food Safety Risk Analysis.

39. The Working Group had further agreed that sections 4 to 9 of the project documents be consistent with the corresponding sections of the other two projects documents, while ensuring certain specificities to the scope of the work.

40. The Task Force considered in detail the proposal prepared by the in-session Working Group, as contained in document CRD5. In addition to some editorial changes and amendments, the Task Force agreed to the following changes:

3. Main aspect to be covered

41. A suggestion was made to include, in the list of management options in the first paragraph, a separate bullet point covering measures to prevent infectious agents in animals; however, the Task Force agreed that this point was already covered in the section.

42. Two new sentences were added at the end of the fourth paragraph to address situations where there is evidence of the existence of a risk to human health but scientific data are insufficient or incomplete. These sentences were taken from Section 5.1 of the Codex Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007).

4. Assessment against the criteria for the establishment of work priorities

43. The Task Force agreed to delete reference to JEMRA in this section for consistency with the scope of the work proposed and to refer to relevant documents available on risk management.

Status of the proposal for new work

44. The Task Force agreed to forward the project document as amended (see Appendix IV) to the 61st Session of the Executive Committee for Critical Review and to the 31st Session of the Commission for approval as new work.

45. 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.

46. It was agreed that the physical Working Group would meet as early as possible in order to allow for timely circulation of the proposed draft. It was also agreed that, in order to facilitate the initial work of the Working Group, Codex members and observers be invited to electronically submit elements for the proposed draft document to the Delegation of the European Community by December 2007.

47. The Task Force noted that consideration of the proposed draft at Step 4 was subject to approval of the proposed new work by the Commission in July 2008.

Risk profile

48. The Task Force noted that the in-session Working Group had generally agreed that the establishment of risk profiles with respect to the presence in food (including aquaculture) and feed of antimicrobial resistant microorganisms and resistance determinants was critical to the development of the appropriate risk assessment and risk management options and strategies. The Working Group had therefore agreed that the purpose of the proposed work was to develop guidance on i) identifying food safety issues related to antimicrobial resistant foodborne microorganisms; ii) identifying the data needed for creation of risk profiles; and iii) how to set priorities with respect to risks related to antimicrobial resistant foodborne microorganisms. The guidance was intended for use by JEMRA and/or national/regional authorities when undertaking possible full risk assessments in the future.

49. The Working Group had agreed that the proposed guidance document proposal would take into full account the prior work on risk analysis principles and standards of Codex and other relevant international organizations, such as FAO WHO and OIE as well as of national/regional authorities.

50. The Working Group had aligned Sections 5, 6 and 9 of the proposed project document with the corresponding sections of the other two project documents.

51. The Task Force considered in detail the proposal prepared by the in-session Working Group, as contained in document CRD4 Rev.1. In addition to some minor editorial changes and amendments, the Task Force agreed to merge the first two sentences of Section 3 to avoid possible confusion as to the scope of the work, and agreed to align sections 4-9 with the corresponding sections of the other two documents.

Status of the proposal for new work

52. The Task Force agreed to forward the project document as amended (see Appendix V) to the 61st Session of the Executive Committee for Critical Review and to the 31st Session of the Commission for approval as new work.

53. It further agreed to establish a physical Working Group, under the leadership of the United States of America, 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 approximately by April 2008 and further consideration at Step 4 at the Second Session of the Task Force.

54. It was agreed that the physical Working Group would meet as early as possible in order to allow for timely circulation of the proposed draft. It was also agreed that, in order to facilitate the initial work of the Working Group, Codex members and observers be invited to electronically submit elements for the proposed draft document to the Delegation of the United States of America by December 2007.

55. The Task Force noted that consideration of the proposed draft at Step 4 was subject to approval of the proposed new work by the Commission in July 2008.

56. Noting that as many as three physical Working Groups had been established, the Task Force invited the leading delegations of the Working Groups to explore possibility for arranging their physical meetings back-to-back in a same venue to facilitate participation of members and observers and communication between the working groups addressing related subjects.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 5)

57. The Task Force noted that no new item had been put forward under “Other Business”.

DATE AND PLACE OF NEXT SESSION (Agenda Item 6)

58. The Task Force noted that its 2nd Session was tentatively scheduled to be held in October/November 2008.

SUMMARY STATUS OF WORK

SUBJECT MATTERS	STEP	ACTION BY:	DOCUMENT REFERENCE (ALINORM 08/31/42)
Proposed Amendments to the Terms of Reference of the Codex *Ad Hoc* Intergovernmental Task Force on Antimicrobial Resistance	for approval	31st CAC	Para. 9 and Appendix II
Proposed draft Risk Assessment Guidance Regarding Foodborne Antimicrobial Resistant Microorganisms	1/2/3/4	Physical working group 31st CAC Members and Observers 2nd Session of the Task Force	Paras 32-35 and Appendix III
Proposed draft Risk Management Guidance to Contain Foodborne Antimicrobial Resistant Microorganisms	1/2/3/4	Physical working group, 31st CAC Members and Observers, 2nd Session of the Task Force	Paras 44-47 and Appendix IV
Proposed draft Guidance on Creating Risk Profiles for Antimicrobial Resistant Foodborne Microorganisms for Setting Risk Assessment and Management Priorities	1/2/3/4	Physical working group, 31st CAC Members and Observers, 2nd Session of the Task Force	Paras 52-55 and Appendix V

Appendix I

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Appendix II

PROPOSED AMENDMENT TO THE TERMS OF REFERENCE OF THE *AD HOC* CODEX INTERGOVERNMENTAL TASK FORCE ON ANTIMICROBIAL RESISTANCE

Objectives

To develop science based guidance, taking full account of its risk analysis principles and the work and standards of other relevant international Organizations, such as FAO, WHO and OIE. The intent of this guidance is to assess the risks to human health associated with the presence in food and feed including aquaculture and the transmission through food and feed of antimicrobial resistant microorganisms and antimicrobial resistance genes and to develop appropriate risk management advice based on that assessment to reduce such risk. The Task Force should attempt to put into perspective the risk of increase of antimicrobial resistance in human beings and animal generated by different areas of use of antimicrobials such as veterinary applications, plant protection or food processing.

Terms of reference

[No Change]

Time frame

[No Change]

Appendix III

PROJECT DOCUMENT

DEVELOPMENT OF SCIENCE-BASED RISK ASSESSMENT GUIDANCE REGARDING FOODBORNE ANTIMICROBIAL RESISTANT MICROORGANISMS

1. Purpose and scope of the proposed work

The purpose of the proposed work is to develop rational, science-based guidance, taking full account of the prior work on risk assessment principles and standards of Codex and other relevant international organizations, such as FAO, WHO and OIE, as well as of national/regional authorities. The intent of this guidance is to support JEMRA and/or national/regional authorities in assessing the potential overall risk to human health associated with the presence in food and feed (including aquaculture), and the transmission through food and feed, of antimicrobial resistant microorganisms and resistance determinants.

Other relevant completed or on-going work undertaken in similar areas at national, regional and international levels should also be taken into account, keeping in mind that the focus of the proposed work should be the food safety risk assessment, built on Codex and OIE foundational documents.

The Codex guidance developed by the Task Force may provide a framework for member countries to respond to antimicrobial resistance risk when they have limited capacity to carry out risk assessments.

2. Relevance and timeliness

This work would be consistent with the proposed activities detailed in Annex 2 of CL 2006/38-AMR as well as the Terms of Reference of the Task Force. It is also consistent with Codex Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005) and with the OIE Risk Assessment for Antimicrobial Resistance Arising from the Use of Antimicrobials in Animals (OIE Terrestrial Animal Health Code 2007) guidance as well as the Codex Guideline CAC/GL 30-1999) on the Conduct of Microbiological Risk Assessment and the specific guidelines developed by JEMRA (see section 7).

One key point from the FAO/WHO/OIE consultations is that certain antimicrobial resistant foodborne microorganism were identified as being a possible microbiological food safety hazard. As such, Codex work on microbiological risk assessment for foodborne microorganisms are relevant because the presence of resistance gene reservoirs, acquisition, amplification, transmission and spread to susceptible hosts require propagation of resistance determinants within microbial hosts. In addition, Codex and other work on risk analysis principles as applied to veterinary drugs used in food-producing animals are relevant because these drugs can select for resistant microrganisms in animals, which can be the source of antimicrobial resistant microorganism on food and/or in human patients with relevant illness. Therefore, the application of the relevant existing and developing Codex and other documents and guidelines on risk assessment should be used and modified or extended where necessary to encompass risk analysis of the human health concerns associated with antimicrobial resistant foodborne microorganisms.

3. Main aspects to be covered

The Task Force will develop an appropriate risk assessment set of criteria and a process for JEMRA and/or national/regional authorities to use to determine the overall risk to human health relating to antimicrobial resistant microorganisms and resistance determinants in feed, food animals (including aquaculture), food production/processing, and retail foods, arising from the non human use of antimicrobials. When considering the risk related to a specific antimicrobial resistance concern, the Task Force will take into consideration the impact on human health.

The completed guidance should:

- Address, if possible, the overall risk to human health for each antimicrobial use (e.g. usage, species, micoorganisms, dosage, regime)
- be a sequence of assessment steps covering the likelihood of transfer of resistant microorganims and resistance determinants from animals to humans;
- provide techniques to evaluate the parameters at each step, using the appropriate data input to that step. These parameters and input need to be identified;

- provide techniques to enable the output of one step to be used as the input for the next step (e.g. flow charts, decision trees);
- provide techniques to evaluate risk management options as appropriate;
- include a method to document datasources, procedures and results.

This proposed new work will build upon the risk analysis processes already in place within Codex, JEMRA and within OIE for risk assessment with regard to human health concerns by adapting and consolidating them in the framework of risk assessment for antimicrobial resistance, similar to the OIE work on risk analysis included in its Terrestrial Animal Health Code (http://www.oie.int/eng/normes/mcode/en_chapitre_3.9.4.htm).

4. Assessment against the criteria for the establishment of work priorities

Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries: This proposed new work would provide additional guidance for JEMRA and national/regional authorities to use in assessing the overall risk of food containing antimicrobial resistant microorganism, thus assisting in establishing the overall safety of the food and the subsequent risk management options and appropriate level of protection for consumers. The project could particularly assist countries that have limited experience with food safety risk assessments, particularly for evaluating antimicrobial resistant microorganisms.

Diversification of national legislations and apparent resultant or potential impediments to international trade: This proposed new work would provide internationally-recognized scientific guidance that JEMRA and national/regional authorities may use to carry out risk assessment activities. Such internationally-agreed guidance can help ensure consistent approaches for the food safety assessment for such foods.

Scope of work and establishment of priorities between the various sections of the work: The scope of the work relates to work previously undertaken by Codex on a high priority basis.

Work already undertaken by other organizations in this field: This proposed new work is consistent with, complements, and builds upon work already undertaken by other international organizations such as WHO, OIE and FAO; and is an extension or adaptation of work developed in the CCFH, CCRVDF, and JEMRA that focuses on foodborne microorganism that are resistant to antimicrobials.

5. Relevance to the Codex strategic objectives

This proposal is consistent with the following strategic goals presented in the Codex Strategic Plan 2008-2013:

- Promoting Sound Regulatory Frameworks (Activity 1.5);
- Promoting Widest and Consistent Application of Scientific Principles and Risk Analysis (Activities 2.3 and 2.5); and
- Promoting Cooperation between Codex and other Relevant International Organizations (Activities 4.1 and 4.3).

6. Information on the relation between the proposal and other existing Codex documents

The proposed document will fully take into account the provisions in the Codex Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005), in the Codex Recommended International Code of Hygiene Practice for Control of the Use of Veterinary Drugs (CAC/RCP 38-1993) and in the Codex Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CAC/GL 30-1999).

7. Identification of any requirement for and availability of expert scientific advice

Scientific input contained in the following reports and documentation will be taken into consideration:

- Second Joint FAO/OIE/WHO Expert Workshop on Non-Human Antimicrobial Usage and Antimicrobial Resistance: Management options (Oslo, Norway, 15–18 March 2004) http://www.who.int/foodsafety/publications/micro/mar04/en/index.html);

- First Joint FAO/OIE/WHO Expert Workshop on Non-human Antimicrobial Usage and Antimicrobial Resistance: Scientific assessment (Geneva, Switzeland, 1-5 December 2003) http://www.who.int/foodsafety/publications/micro/nov2003/en/index.html
- OIE List of Antimicrobials of Veterinary Importance, RESOLUTION No. XXXIII http://www.oie.int/downld/SG/2006/A_RF_2006_WEBPUB.pdf p.152;
- Critically important antibacterial agents or human medicine for risk management of non-human use. Report of a WHO working group consultation (Canberra, Australia, 15 - 18 February 2005) http://www.who.int/foodborne_disease/resistance/FBD_CanberraAntibacterial_FEB2005.pdf;
- Report of a Joint FAO/OIE/WHO Expert Consultation on Antimicrobial Use in Aquaculture and Antimicrobial Resistance (Seoul, Republic of Korea, 13–16 June 2006) http://www.fao.org/ag/agn/food/risk_antimicrobial_en.stm;
- OIE Terrestrial Animal Health Code – Part 3, Section 3.9. Antimicrobial resistance http://www.oie.int/eng/normes/mcode/en_titre_3.9.htm ;
- Second WHO Expert Meeting on Critically Important Antimicrobials for Human Medicine (Copenhagen, Denmark, 29-31 May 2007) http://www.who.int/foodborne_disease/resistance/antimicrobials_human.pdf);
- FAO/OIE/WHO expert meeting on critically important antimicrobials (Rome, Italy, 26-30 November 2007) ;
- WHO documents/guidelines on containment of antimicrobial resistance in animals for food. http://www.who.int/foodborne_disease/resistance/en/index.html;
- JEMRA Guidelines:
  Hazard characterization for pathogens in food and water
  Microbiological risk assessment series 3, FAO/WHO (2004)
  http://www.fao.org/ag/agn/agns/jemra_guidelines_hazard_en.asp;
  Exposure Assessment Microbiological Risk Assessment Series 7, FAO/WHO
  http://www.fao.org/ag/agn/agns/jemra_guidelines_exposure_en.asp; and
  Risk Characterization
  http://www.fao.org/ag/agn/agns/jemra_guidelines_risk_en.asp.
  FAO/WHO Food Safety Risk Analysis Guide for National Food Safety Authorities (Food and Nutrition Paper #87, FAO, 2006).

8. Identification of any need for technical input to the standard from external bodies so that this can be planned for

The Task Force will take into consideration existing scientific information including the reports referenced in 7 above. If required, the Task Force may request additional input including from FAO/WHO/OIE, including JEMRA, to establish an expert consultation to provide additional scientific advice.

9. The proposed time-line for completion of the new work, including the start date, the proposed date for adoption at Step 5, and the proposed date for adoption by the Commission; the time frame for developing a standard should not normally exceed five years.

Envisaging the use of inter-sessional working groups, the following is a proposed time-line:

Activity	Step/date
Task Force agrees on the work to be undertaken	October 2007
Commission approves new work	July 2008
Step 5	2010
Adoption by the Commission	2011

Appendix IV

PROJECT DOCUMENT

DEVELOPMENT OF RISK MANAGEMENT GUIDANCE TO CONTAIN FOODBORNE ANTIMICROBIAL RESISTANT MICROORGANISMS

1. Purpose and scope of the proposed work

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.

The Task Force, in developing guidance, 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 microorganisms and resistance determinants.

2. Relevance and timeliness

This work would be consistent with the proposed activities detailed in Annex 2 of CL 2006/38-AMR as well as the Terms of Reference of the Task Force. It is also consistent with Codex Code of Practice to minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005) and with the OIE Guidelines relating to risk management for antimicrobial resistance (Section 3.9 of OIE Terrestrial Animal Health Code 2007). Antimicrobial agents are essential for human and animal health and welfare. Antimicrobial agents are widely used in humans, food-producing animals, including aquaculture, plants and food processing in order to treat or prevent disease or as a production aid (growth promotion) or as a preservative.

Antimicrobial resistance of important human pathogenic microorganisms is increasingly perceived as a threat to public health. Any use of antimicrobials, whether in humans, animals, plants or food-processing, may potentially lead to antimicrobial resistance.

The 2001 WHO Global Strategy for Containment of Antimicrobial Resistance (http://www.who.int/csr/resources/publications/drugresist/WHO_CDS_CSR_DRS_2001_2_EN/en/) recognizes that antimicrobial resistance is a serious human health problem and that "improving antimicrobial use must be a key action in efforts to contain resistance." In order to address that portion of resistance in human pathogens attributable to antimicrobial resistant foodborne microorganisms, additional consultations were convened. Antimicrobial resistance has been discussed at two prior joint consultations of WHO/OIE/FAO (cited above) and the 29th CAC Session (July, 2006) recommended that the formation of the Task Force and the development of a Project Document are relevant next steps to be taken in a timely manner. Initial discussion of antimicrobial resistance within Codex is contained in CX/RVDF 01/10 July 2001. One key point from the FAO/OIE/WHO consultations is that certain antimicrobial resistant foodborne microorganisms were identified as being possible microbiological food safety hazard agents.

As such, Codex work on microbiological risk management for foodborne microbes is very relevant because the presence of resistance gene reservoirs, gene acquisition, amplification, transmission and spread to susceptible hosts requires propagation of resistance determinants within microbial hosts. In addition, Codex and other work on risk analysis principles as applied to veterinary drugs used in food-producing animals are very relevant because these drugs can select for resistant microorganisms in animals which can be the source of resistant microorganisms on food and/or in human patients with relevant illness.

Therefore, the application of the relevant existing and developing Codex and other documents and guidelines on risk assessment, risk management, and risk communication should be used and modified or extended where necessary to encompass risk analysis of the human health concerns associated with antimicrobial resistant foodborne microorganisms.

3. Main aspects to be covered

The Task Force will develop appropriate risk management options throughout the "farm-to-table" continuum. This will be done by utilizing relevant Codex, OIE, WHO and FAO documents. The goal is to protect human health by minimizing and containing antimicrobial resistant foodborne microorganisms and resistance determinants that may be transmitted through the food chain. Risk management options that can be implemented by the various food chain participants may include but are not limited to:

- Regulatory authorities - antimicrobial product approval/non-approval/withdrawal; surveillance/compliance; regulatory controls on conditions of use; establishment of co-ordinated and coherent surveillance networks at national/regional/international levels that may include links between established surveillance networks in human and veterinary medicines.
- National/regional/international authorities - resistance monitoring of foodborne pathogens and selected commensal microorganisms isolated from food-producing animals, food, humans, and plants, as appropriate; foodborne disease surveillance; development and implementation of responsible use guidelines
- National authorities or other stakeholders - Antimicrobial usage monitoring; accounting of use.
- Veterinary associations and allied organizations – development and implementation of responsible use guidelines; education of veterinarians and clients.
- Animal feed industry – processes and controls on animal feed production.
- Food animal (including aquaculture) producers – quality assurance programs.
- Food production industry – food processing; hygiene controls (e.g. HACCP; decontamination of carcasses).
- Veterinary pharmaceutical industry – development and implementation of responsible use guidelines; compliance with regulatory controls; good manufacturing practices for quality products.

Additionally, risk management options may include programmes promoting the development of new antimicrobial agents, alternative treatments, and prevention programmes such as vaccination.

The Task Force will provide guidance for national/regional authorities as to the most appropriate actions to be implemented for a particular foodborne antimicrobial risk. The guidance will take into account that antimicrobials administered to animals also play a major role in animal health.

The Task Force will provide guidance on how the recommendations might be implemented on a regional/national basis taking into account the feasibility (for example, infrastructure, expertise, funding, etc.) of implementation. 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 provisional nature of the 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 the completion of a risk assessment) should be articulated when the decision is communicated initially.

For those antimicrobial products and associated foodborne antimicrobial resistant microorganisms that will be of the highest risk classification, the guidance will provide the following additional options that should be considered for priority implementation by the national/regional authorities:

- Regulatory review of currently approved antimicrobials by national risk assessment guidelines.
- Resistance monitoring and usage monitoring (specifics to be determined).
- Responsible use guidelines including consideration of alternative treatments or conditions of use.
- The Task Force will describe methods to measure the effectiveness of the risk management options such as:
- Trends in antimicrobial resistant foodborne microorganisms by monitoring of animals, foods and humans.
- Trends in human foodborne disease (matched to public health goals).

- Antimicrobial usage monitoring trends, etc.

The Task Force will recommend actions to be taken for capacity building to enable implementation in resource-limited regions/nations. To enable implementation of risk management options, it is proposed that resource-limited regional/national authorities work cooperatively with nations/organizations/companies that have programs in place. Capacity building has been discussed such as in the following three examples:

- http://www.fao.org/docrep/009/a0083e/a0083e00.htm
- http://www.who.int/topics/foodborne_diseases/aquaculture_rep_13_16june2006%20.pdf
- http://www.oie.int/eng/oie/organisation/en_vet_eval_tool.htm?e1d2

Risk Communication strategies will be addressed within the context of the FAO/WHO Food Safety Risk Analysis Guide for National Food Safety Authorities (Food and Nutrition Paper #87, FAO, 2006). Risk assessors and risk managers must communicate effectively to ensure that the appropriate work is undertaken. The Task Force will detail in its guidance the specific steps to be taken. For example, see "The application of risk communication to food standards and safety matters" FAO/WHO, FAO Food and Nutrition Paper no.70; http://www.fao.org/docrep/005/x1271e/x1271e00.htm.

4. Assessment against the criteria for the establishment of work priorities

Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries: This proposed new work would provide additional guidance for national/regional authorities to use in assessing the overall risk of food containing antimicrobial resistant microorganisms, thus assisting in establishing the overall safety of the food and the subsequent risk management options and appropriate level of protection for consumers. The project could particularly assist countries that have limited experience with food safety risk management for antimicrobial resistant microorganisms.

Diversification of national legislations and apparent resultant or potential impediments to international trade: This proposed new work would provide internationally-recognized risk management guidance that national/regional authorities may use to carry out risk management activities. Such internationally-agreed guidance can help ensure consistent approaches for the food safety risk management for such foods.

Scope of work and establishment of priorities between the various sections of the work: The scope of the work relates to work previously undertaken by Codex on a high priority basis.

Work already undertaken by other organizations in this field: This proposed new work is consistent with, complements, and builds upon work already undertaken by other international organizations such as WHO, OIE and FAO; and is an extension or adaptation of work developed in the CCFH and CCRVDF that focuses on foodborne microorganisms that are resistant to antimicrobials.

5. Relevance to the Codex strategic objectives

This proposal is consistent with the following strategic goals presented in the Codex Strategic Plan 2008-2013:

- Promoting Sound Regulatory Frameworks (Activity 1.5);
- Promoting Widest and Consistent Application of Scientific Principles and Risk Analysis (Activities 2.3 and 2.5).
- Promoting Cooperation between Codex and other Relevant International Organizations (Activities 4.1 and 4.3).

6. Information on the relation between the proposal and other existing Codex documents

The proposed document will fully take into account the provisions in the Codex Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005), in the Codex Recommended International Code of Hygiene Practice for Control of the Use of Veterinary Drugs (CAC/RCP 38-1993) and in the Codex Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007). 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.

7. Identification of any requirement for and availability of expert scientific advice

Scientific input contained in the following reports and documentation will be taken into consideration:

- Second Joint FAO/OIE/WHO Expert Workshop on Non-Human Antimicrobial Usage and Antimicrobial Resistance: Management options (Oslo, Norway, 15-18 March 2004) http://www.who.int/foodsafety/publications/micro/mar04/en/index.html
- First Joint FAO/OIE/WHO Expert Workshop on Non-human Antimicrobial Usage and Antimicrobial Resistance: Scientific assessment (Geneva, Switzerland, 1-5 December 2003) http://www.who.int/foodsafety/publications/micro/nov2003/en/index.html
- OIE List of Antimicrobials of Veterinary Importance, RESOLUTION No. XXXIII http://www.oie.int/downld/SG/2006/A_RF_2006_WEBPUB.pdf, p.152
- Critically important antimicrobial agents or human medicine for risk management of non-human use. Report of a WHO working group consultation (Canberra, Australia, 15 - 18 February 2005,) http://www.who.int/foodborne_disease/resistance/FBD_CanberraAntimicroorganismsl_FEB2005.pdf
- Report of a Joint FAO/OIE/WHO Expert Consultation on Antimicrobial Use in Aquaculture and Antimicrobial Resistance (Seoul, Republic of Korea, 13–16 June 2006) http://www.fao.org/ag/agn/food/risk_antimicrobial_en.stm
- OIE Terrestrial Animal Health Code – Part 3, Section 3.9. Antimicrobial Resistance http://www.oie.int/eng/normes/mcode/en_titre_3.9.htm
- Second WHO Expert Meeting on Critically Important Antimicrobials for Human Medicine (Copenhagen, Denmark, 29-31 May 2007) http://www.who.int/foodborne_disease/resistance/antimicrobials_human.pdf
- FAO/OIE/WHO expert meeting on critically important antimicrobials (Rome, 26-30 November 2007)
- WHO documents/guidelines on containment of antimicrobial resistance in animals for food http://www.who.int/foodborne_disease/resistance/en/index.html
- FAO/WHO Food Safety Risk Analysis Guide for National Food Safety Authorities (Food and Nutrition Paper #87, FAO, 2006).

8. Identification of any need for technical input to the standard from external bodies so that this can be planned for

The Task Force will take into consideration existing risk management information including the reports referenced in 7 above. If required, the task force may request additional input including from FAO/OIE/WHO to establish an expert consultation to provide additional advice.

9. The proposed time-line for completion of the new work, including the start date, the proposed date for adoption at Step 5, and the proposed date for adoption by the Commission; the time frame for developing a standard should not normally exceed five years.

Envisaging the use of inter-sessional working groups the following is a proposed time-line:

Activity	Step/date
Task Force agrees on the work to be undertaken	October 2007
Commission approves new work	July 2008
Step 5	2010
Adoption by the Commission	2011

Appendix V

PROJECT DOCUMENT

DEVELOPMENT OF GUIDANCE ON CREATING RISK PROFILES FOR ANTIMICROBIAL RESISTANT FOODBORNE MICROORGANISMS FOR SETTING RISK ASSESSMENT AND MANAGEMENT PRIORITIES

1. Purpose and scope of the proposed work

The purpose of this project is to develop guidance on:

- identifying food safety issues related to antimicrobial resistance;
- data needed for risk profiles; and
- setting priorities with respect to risks related to antimicrobial resistant foodborne microorganisms.

This guidance can be used by JEMRA and/or national/regional authorities when undertaking possible full risk assessments in the future. For the purpose of these principles, preliminary risk management activities are taken to include identification of a food safety problem; establishment of a risk profile[1], ranking of the hazard for risk assessment and risk management priority; establishment of risk assessment policy for the conduct of the risk assessment, commissioning of the risk assessment, and consideration of the results of the risk assessment.

Establishment of risk profiles with respect to the presence in food (including aquaculture) and feed of antimicrobial resistant microorganisms and resistance determinants is critical to the development of the appropriate risk assessment and risk management options and strategies.

This guidance will take into full account of the prior work on risk analysis principles and standards of Codex and other relevant international organizations, such as FAO, WHO and OIE, as well as of national/regional authorities. Other relevant completed or on-going work undertaken in similar areas directed at assessing preliminary data and setting priorities at national, regional and international levels should also be taken into account.

2. Relevance and timeliness

Antimicrobial resistance has been discussed at two prior joint consultations of WHO/OIE/FAO and the 29th CAC Session (July, 2006) recommended that the formation of the Task Force and the development of Project Documents are relevant next steps to be taken in a timely manner. One key point from the consultations is that certain antimicrobial resistant foodborne microorganisms were identified as being possible microbiological food safety hazards.

3. Main aspects to be covered

Preliminary risk management activities include the establishment of a risk profile to facilitate consideration of the issue within a particular context, and provide as much information as possible to guide further action. As a result of this process, the risk manager may commission a risk assessment as an independent scientific process to inform decision-making. 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 provisional nature of the 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 the completion of a risk assessment) should be articulated when the decision is communicated initially.

Criteria to be used for establishing risk priorities will build upon the processes that have already been identified, particularly those that are in place within Codex and within OIE (see OIE Risk Analysis Terrestrial Animal Code guideline) (http://www.oie.int/eng/normes/mcode/en_chapitre_3.9.4.htm).

[1] See the definition in the Codex Procedural Manual.

Other relevant activities undertaken in this area at international, regional and national levels should also be considered. For example, WHO and OIE information about critically important antimicrobials used in human and veterinary medicine, the Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL63-2007), Risk profile on antimicrobial resistant microorganisms in food (CX/FH 00/11) and the 2006 Joint FAO/WHO expert meeting Report from Kiel, Germany. The development of these criteria should also take into account national resistance monitoring program data, published sources and other data recognized as valid.

It is expected that this work could consider but not be limited to:

- Antimicrobial agents or classes used in food producing animals that would significantly impact on human medicine due to the development or dissemination of antimicrobial resistance?
- Importance of the drug in human medicine (indications, extent of use, level of resistance, availability of alternative drugs, resistance mechanisms, etc.).
- Information on drug use in various animal species.
- Relevant data that is available concerning antimicrobial resistant microorganisms in feed, food animals (including aquaculture), food production/processing, and retail foods as well as identification of important data that may need to be collected and analyzed; relying on national resistance monitoring program data, published sources and other data recognized as valid.
- Information about human exposure to hazard including routes of exposure.
- Information on adverse health effects in humans (e.g., dose-response, type and severity of adverse health effects, and at-risk population characteristics).

4. Assessment against the criteria for the establishment of work priorities

Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries: This proposed new work would provide additional guidance for JEMRA and national/regional authorities to use in assessing the overall risk of food containing antimicrobial resistant microorganisms, thus assisting in establishing the overall safety of the food and the subsequent risk management options and appropriate level of protection for consumers. The project could particularly assist countries that have limited experience with food safety risk assessments, particularly for evaluating antimicrobial resistant microorganisms.

Diversification of national legislations and apparent resultant or potential impediments to international trade: This proposed new work would provide internationally-recognized scientific guidance that JEMRA and national/regional authorities may use to carry out risk assessment activities. Such internationally-agreed guidance can help ensure consistent approaches for the food safety assessment for such foods.

Scope of work and establishment of priorities between the various sections of the work: The scope of the work relates to work previously undertaken by Codex on a high priority basis.

Work already undertaken by other organizations in this field: This proposed new work is consistent with, complements, and builds upon work already undertaken by other international organizations such as WHO, OIE and FAO; and is an extension or adaptation of work developed in the CCFH, CCRVDF, and JEMRA that focuses on foodborne microorganisms that are resistant to antimicrobials.

5. Relevance to the Codex strategic objectives

This proposal is consistent with the following strategic goals presented in the Codex Strategic Plan 2008-2013:

- Promoting Sound Regulatory Frameworks (Activity 1.5);
- Promoting Widest and Consistent Application of Scientific Principles and Risk Analysis (Activities 2.3 and 2.5).
- Promoting Cooperation between Codex and other Relevant International Organizations (Activities 4.1 and 4.3).

6. Information on the relation between the proposal and other existing Codex documents

The proposed document will fully take into account the provisions in the Codex Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005), in the Codex Recommended International Code of Hygiene Practice for Control of the Use of Veterinary Drugs (CAC/RCP 38-1993), and in the Codex Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007).

7. Identification of any requirement for and availability of expert scientific advice

Scientific input contained in the following reports and documentation will be taken into consideration:

- Second Joint FAO/OIE/WHO Expert Workshop on Non-Human Antimicrobial Usage and Antimicrobial Resistance: Management options (Oslo, Norway 15-18 March 2004) http://www.who.int/foodsafety/publications/micro/mar04/en/index.html
- OIE List of Antimicrobials of Veterinary Importance, RESOLUTION No. XXXIII http://www.oie.int/downld/SG/2006/A_RF_2006_WEBPUB.pdf, p.152
- Critically important antibacterial agents or human medicine for risk management of non-human use. Report of a WHO working group consultation (Canberra, Australia, 15 - 18 February 2005) http://www.who.int/foodborne_disease/resistance/FBD_CanberraAntibacterial_FEB2005.pdf
- Report of a Joint FAO/OIE/WHO Expert Consultation on Antimicrobial Use in Aquaculture and Antimicrobial Resistance (Seoul, Republic of Korea, 13-16 June 2006) http://www.fao.org/ag/agn/food/risk_antimicrobial_en.stm
- OIE Terrestrial Animal Health Code – Part 3, Section 3.9 Antimicrobial Resistance
- http://www.oie.int/eng/normes/mcode/en_titre_3.9.htm
- Joint FAO/WHO/OIE Expert meeting on Critically Important Antimicrobials (Copenhagen, Denmark, 29-31 May 2007)
- Joint FAO/WHO/OIE Expert meeting on Critically Important Antimicrobials (Rome, Italy, 26-30 November 2007)
- WHO documents/guidelines on containment of antimicrobial resistance in animals for food http://www.who.int/foodborne_disease/resistance/en/index.html
- FAO/WHO Food Safety Risk Analysis Guide for National Food Safety Authorities (Food and Nutrition Paper #87, FAO, 2006).

8. Identification of any need for technical input to the standard from external bodies so that this can be planned for

The Task Force will take into consideration existing risk profiling information including the reports referenced in 7 above. If required, the task force may request additional input including from FAO/OIE/WHO to establish an expert consultation to provide additional advice.

9. The proposed time-line for completion of the new work, including the start date, the proposed date for adoption at Step 5, and the proposed date for adoption by the Commission; the time frame for developing a standard should not normally exceed five years

Envisaging the use of inter-sessional working groups the following is a proposed time-line:

Activity	Step/date
Task Force agrees on the work to be undertaken	October 2007
Commission approves new work	July 2008
Step 5	2010
Adoption by the Commission	2011