codex alimentarius commission

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FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 5 **CX/AMR 08/2/5**
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PROPOSED DRAFT GUIDANCE ON CREATING RISK PROFILES FOR ANTIMICROBIAL RESISTANT FOODBORNE MICROORGANISMS FOR SETTING RISK ASSESSMENT AND MANAGEMENT PRIORITIES

At Step 3

(prepared by the physical Working Group led by the United States of America)

Governments and international organizations in Observer status with the Codex Alimentarius Commission wishing to submit comments at Step 3 on the Proposed Draft Guidance on Creating Risk Profiles for Antimicrobial Resistant Foodborne Microorganisms for Setting Risk Assessment and Management Priorities, are invited to do so **no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. The Codex *ad hoc* Intergovernmental Task Force on Antimicrobial Resistance at its First Session (ALINORM 08/31/42), agreed to propose new work by establishing three physical working groups to prepare three guidance documents on:

i) Science-based risk assessment of foodborne antimicrobial resistant microorganisms (Para. 32 and Appendix III), chaired by Canada;

ii) Risk management to contain antimicrobial resistant microorganisms (Para. 44 and Appendix IV), chaired by the European Community (EC) and co-chaired by Denmark and France; and

iii) Creation of risk profiles for antimicrobial resistant foodborne microorganisms for setting risk assessment and management priorities (Para. 52 and Appendix V), chaired by the U.S.

2. The Task Force agreed to forward the following proposed amendment to the Objectives section of the Terms of Reference to the Commission for consideration and approval: 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.

Meeting of the Working Group

3. In Seoul, an electronic Working Group on Risk Profiling (WGRP) was established to be chaired by the U.S. Written comments were solicited from the electronic (WGRP). Canada, Germany, the Netherlands, and the International Federation for Animal Health responded with written comments and an initial draft was

circulated in April 2008. Australia, Canada, France, the International Dairy Federation, and the International Federation for Animal Health sent written comments on the April 2008 draft prior to the physical meeting in Brussels.

4. The physical meeting of the WGRP took place at the kind invitation of the European Community in Brussels, Belgium on 26-27 May 2008. Seventy-five delegates representing 23 member governments and 4 observer organizations attended (see Appendix 1).

5. The U.S., chairing the WGRP, began with an introduction describing the principles behind how the document was drafted. Overarching principles in developing the draft include:

a. Consistency with existing Codex documents;

b. Flexibility to allow national authorities to apply the information to their conditions and problems as needed; and

c. Harmonization—the need to be consistent and coherent with what is developed in the Working Group on Risk Management (WGRM) so that activities can be integrated.

6. From Figure 2.1, p. 13, Food and Agriculture Food and Nutrition Paper 87, the U.S. explained that it sees the work of the WGRP to be encompassed in the top circle, preliminary risk management activities, and the work of the WGRM to be encompassed in the right side circle, identification and selection of risk management options. The groups would have to further address how the activities in the lower and left circles would be divided between groups.

7. The U.S. also referred to a flow diagram in Figure 1, p. 4, in the Joint FAO/WHO Expert Meeting in Kiel, Germany in 2006, "The Use of Microbiological Risk Assessment Outputs to Develop Practical Risk Management Strategies", and suggested that the Task Force develop a similar flow diagram specific to its charge to delineate how the different Risk Management Framework activities flow.

8. Participants were reminded that during the previous day's session of the Working Group on Risk Assessment (WGRA), the group agreed to harmonize introductions, a flow chart, definitions, general principles, risk communication, and documentation between the three working groups, and that the group envisioned a final integrated document. The three working groups will harmonize language on definitions using Codex definitions as much as possible and highlighting these in the text through the use of italics and expanding definitions as needed for specificity to the Task Force mandate in regular font to distinguish expansion from Codex definitions. It was suggested that as harmonized definitions will appear in an annex, references can be made in working documents to the developing annex.

Title, Introduction, Scope, Definitions, and Guidelines for Activities

9. The Task Force deliberated on whether or not the WGRP had exceeded its mandate in the title and scope of work. The U.S. agreed the title had been changed from the original title used in the WGRP Project Document developed in Seoul. The title was crafted to capture the preliminary risk management activities encompassed in the purpose and scope of the Project Document. The U.S. agreed to change the title back to the one used for the Project Document, but reiterated that work had remained within the scope of work identified in the Project Document as covering preliminary risk management activities.

10. After further discussion on whether the scope of work was restricted to foodborne antimicrobial resistant pathogens, it was decided that the scope was restricted to foodborne pathways and that the three working groups would additionally harmonize on properly articulating the scope for the Task Force work regarding non-human use including use in food animals, plant protection and food processing.

11. There was a request that "preliminary risk management activities" be changed to "risk profiling". The U.S. explained that the language was taken from both the Project Document and Codex Procedural Manual, so "preliminary risk management activities" was important language to retain.

12. Risk "assessment" was changed to "analysis".

General Principles

13. The word, "preliminary" was removed from principles 2, 3, 4, and 9 to make the general principles applicable to the entire document and language in the general principles were modified to make the principles more specific to antimicrobial resistant microorganisms. The term, "food animal" used in the

phrase "antimicrobial drug, the food animal species, and the human pathogen combination," was deemed to be too broad in Principle 3. The phrase was made more specific by replacing with: "food, antimicrobial drug, antimicrobial use, and human pathogen and/or resistance determinants". It was suggested that once the document is integrated, that it be articulated that the entire document follows the general principles for Codex, but some principles are made specific to antimicrobial resistance. A tenth principle was added taking into account international work in the area of antimicrobial resistance as discussed in the "Development of a risk profile and use of the WHO/OIE Expert Consultation, Rome 2008" section below.

Identification of a Food Safety Issue

14. After some discussion, it was agreed that risk profiling is a tool to be used by risk managers as an information-gathering exercise to review potential options and serve as a guide for further actions. After the exercise, the risk manager may decide to request more information, take action, or conduct a risk assessment.

15. There was some discussion as to whether setting guidelines on drug approval was outside the mandate of Codex. Further, it was discussed as to whether a mandatory finding of connection to antimicrobial drug usage was necessary to identify an antimicrobial resistance food safety issue. Codex has a precedence of making recommendations to drug approval authorities, so it was agreed that management options regarding drug use were appropriate and the Working Group could use language from existing Codex codes of practice (CAC/RCP 38-1993 and CAC/RCP 61-2005). Identification of a food safety issue was defined as when antimicrobial resistant microorganisms are found to be present in food or feed, as described in the mandate.

16. It was noted that several terms throughout the text would need to be clarified. "Through food and feed" would need to be added throughout the document to match the terms of reference. "Antimicrobial resistance will need to be added in front of "food safety issue" throughout the document to be more specific to the Task Force's mandate. "Must" will be changed to "should" throughout the document to be less prescriptive. "Disease" will be changed to "adverse health effects" to harmonize with the language used in the WGRA document.

Development of a risk profile and use of the WHO/OIE Expert Consultation, Rome 2008

17. The Working Group decided that fundamental elements of conducting a risk profile would be listed in this section to assist with prioritizing, with a more comprehensive list of items to include in a risk profile referenced in the annex.

18. The Working Group decided to change "public health problem" to "adverse health effect" to harmonize with the WGRA. Additionally, all of the bullet points of descriptive elements will be harmonized with the definitions section in the annex.

19. After some discussion on the appropriate use of the WHO/OIE Critically Important Antimicrobials list developed in Rome, 2007, it was decided that the WHO/OIE list would fit best in a part of the document where priority-setting for risk profiling would be rather than in general principles. However, the group agreed that a general principle taking into account relevant work conducted by international organizations was appropriate and was added as Principle 10.

20. There was some discussion on whether or not to keep the phrase, "Although the depth and breadth of the risk profile may vary depending on the needs of the risk managers and the food safety issue of concern…" The consensus was to keep the phrase because of the wide readership of the document and the need for different countries to adapt the document to their national conditions.

21. The Working Group deliberated over a statement regarding the need to identify a causal relationship during development of a risk profile. The consensus was to remove the statement as drug use data is not always available to verify causal relationships between drug use and development of antimicrobial resistant foodborne pathogens. Further discussions on including language on strength of association resulted in the Working Group agreeing to only state that a "relationship" should be established.

22. It was decided that language from CAC/GL 63-207 would be used to indicate that decision-making is done in a timely manner: "Codex and government decisions and recommendations have as their primary objective the protection of the health of consumers. Decision making should be timely to achieve that objective."

Rank food safety issues and set priorities for risk management

23. The U.S. asked for input as to whether the criteria for management options should be covered by the WGRP. Several member countries agreed that it should. There was some discussion on the difference between ranking antimicrobial resistance food safety issues for risk profiling, and then to further rank the issues once the risk profiling is completed for risk managers to set priorities on further actions. The information from the Critically Important List of Antimicrobials from the WHO/OIE Rome meeting in November, 2007 was seen as an important part of the latter. The U.S. drafted language to prioritize items from the annex and to develop the elements for criteria of risk management options. It was also decided that the title will be changed to reflect that the launching of a risk assessment would occur at the stage. The U.S. asked for other delegations to provide suggestions for a new title.

Establish broad management goals

24. There was some discussion on possibly deleting the section. However, as the section served as a bridge between risk profiling and risk management, the section was retained and reworded using language from FAO 87 and retitled. The Working Group decided that criteria will need to be developed here further and sequentially organized. It was explained that prior to a risk profile, a range of options are available, once the risk profile is completed, and the situation becomes clearer. If one fully does not know the risk after the risk profile is completed, one will need to commission a risk assessment. There is no venue for a provisional decision if the risk remains unknown after a risk profile is completed. It was mentioned that doing nothing is also a decision at this point that needs to be backed with information. It was suggested that language from FAO 87 (p. 7) be used with modifications suggested by other delegations.

Establish a risk assessment policy

25. The Working Group discussed the fact that the WGRA did not cover risk assessment policy, and that risk assessment would need to be covered in the WGRP document. It was decided that language from the Codex Procedural Manual will be used and language from the risk assessment document cited.

Commission the risk assessment

26. Discussion centered on whether or not to include cost-benefit analysis in the section, particularly as it appeared under commissioning of a risk assessment in the WHO/OIE Rome report on p. 23. After clarification from the FAO representative that cost-benefit was included in the Rome document in the risk assessment section to consider the cost of conducting a risk assessment, the Working Group decided that cost-benefit analysis should be considered under risk management rather than under risk profiling or risk assessment.

Consider the results of the risk assessment

27. The language was considered to be too prescriptive and will be changed to reflect language in the Codex Procedural Manual (p. 106 #26, p. 108 #40) and the WHO/OIE Rome 2007 document. The word “ensure” was removed and “judging” was changed to “reviewing” in the next iterations. The U.S. will include #40 in the risk communication section to be harmonized.

Annex

28. The overall structure and terms will be harmonized with appendix 2 in the WGRA document. A number of delegations offered suggested changes to the annex such as:

- “Economic” was changed to “added burden of disease due to antimicrobial resistance acquired from food”.
- The U.S. was asked to differentiate between information for risk profiling and a qualitative risk assessment. It was explained that the elements for both will be similar, but that the risk profiling will involve a higher level review of more easily available information than a risk assessment and that the point will be clarified in the text. Further, it was explained that the risk profile is flexible and does not estimate risk.
- The U.S. will make further changes to make the document specific to antimicrobial resistance such as adding: “molecular genetics of resistance determinant and mobile elements that may carry these determinants.”
- The U.S. suggested creating alternate versions of the annex for comment or will attempt to reconcile the two approaches:

1. A version suggested by Norway where the title of the third element becomes, "Description of risk factors" and #'s 3, 4, and 5 become 3b, 3c, and 3d;

2. A version comparable to MRA Codex 63 with the addition of antimicrobial resistance terminology.

- Compromise language on "evidence of a relationship between animals, plants, processing, and antimicrobial resistant disease in humans" was inserted in place of "evidence of a causal pathway".

Recommendation to the 2nd Session of the Task Force

The recommendation of the three Working Groups to the Task Force is that the three working group documents[1] could be most usefully read by intended audiences as one integrated guidance document. With this approach, certain sections, such as the introduction, definitions, documentation, and risk analysis general principles, could be harmonized, resulting in a more consistent and understandable guidance document. Furthermore, this approach would allow the inclusion of an overall flow chart that would guide the reader through the 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.

[1] Guidance on Creating Risk Profiles for Antimicrobial Resistant Foodborne Microorganisms for Setting Risk Assessment and Management Priorities, Science-Based Risk Assessment Guidance Regarding Foodborne Antimicrobial Resistant Microorganisms, and Risk Management Guidance to Contain Foodborne Antimicrobial Resistant Microorganisms

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

(at Step 3 of the Elaboration Procedure)

INTRODUCTION *[to be harmonized]*

1. Antimicrobial resistance resulting from the non-human use of antimicrobials is a recognized food safety concern. Given the complexity surrounding the field of antimicrobial resistance, food safety regulators require a structured approach to manage those concerns. Risk analysis has been implemented as a decision-making tool to estimate risks posed by food hazards and to determine appropriate risk mitigation strategies to control those hazards. General frameworks for managing foodborne risks have been developed by international and national authorities to establish principles and guidelines for the conduct of risk analysis. The Codex *Ad Hoc* Task Force on Antimicrobial Resistance is establishing such a risk management framework; this document is one of three guidance documents that describe those principles and guidelines specific to antimicrobial resistance risk analysis.

2. The initial phase of the risk management framework consists of a group of tasks collectively referred to as preliminary risk management activities. A systematic preliminary risk management process brings the food safety issues into focus and provides a guide for further actions. This document describes the steps to be used by Codex or national/regional authorities in conducting preliminary risk management activities as they relate to antimicrobial resistance. For the purpose of this guidance, preliminary risk management activities are taken to include identification of a food safety problem; development of a risk profile, ranking of the hazard for risk assessment and risk management prioritization; establishment of broad risk management goals; 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.

3. This document should be read in close conjunction with the *Principles and Guidelines for the Conduct of Antimicrobial Resistance Risk Assessment* and the *Principles and Guidelines for the Conduct of Antimicrobial Resistance Risk Management*, documents that are currently under development, as well as the *Joint FAO/WHO/OIE Expert Meeting on Critically Important Antimicrobials* (Rome 2007) and the *Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC/GL 62-2007)*. In addition, this guidance incorporates the prior work on microbial risk assessment, as described in the Codex documents *Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CAC/GL 30 - 1999)* and *Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63 - 2007)*. Additional background material with relevant technical information that should be consulted include documents developed by the World Health Organization, the Food and Agriculture Organization and the Codex Alimentarius (*e.g.*, *The Interaction between Assessors and Managers of Microbial Hazards in Food*, Kiel, Germany, March 2000; *Principles and Guidelines for Incorporating Microbiological Risk Assessment in the Development of Food Safety Standards, Guidelines and Related Texts*, Kiel, Germany, March 2002; *The Use of Microbiological Risk Assessment Outputs to Develop Practical Risk Management Strategies: Metrics to improve food safety*, Kiel, Germany, April 2006; and *Food Safety Risk Analysis, A Guide for National Food Safety Authorities* – FAO Food and Nutrition Paper 87, Rome, 2006).

1. Scope

4. These principles and guidelines are part of an overall framework for the antimicrobial resistance risk analysis process (along with the *Principles and Guidelines for the Conduct of Antimicrobial Resistance Risk Assessment* and the *Principles and Guidelines for the Conduct of Antimicrobial Resistance Risk Management*, documents that are currently under development). This document is intended for use by Codex and/or national/regional authorities for the conduct of preliminary risk management activities to address the food safety issues associated with the presence of antimicrobial resistant microorganisms and resistance determinants in food and feed, including aquaculture, and the transmission through food and feed of antimicrobial resistant microorganisms and antimicrobial resistance genes. In the course of implementing these preliminary risk management activities, the risk managers should consider the different areas of use of antimicrobials, such as veterinary applications, plant protection or food processing.

2. Definitions *[to be harmonized]*

5. The definitions of risk analysis terms related to food safety contained in the Procedural Manual of the CAC[2], shall apply. In particular, see definitions of hazard, risk, risk analysis, risk assessment, risk management, risk communication, risk assessment policy, risk profile, risk estimate, hazard identification, and hazard characterization.

6. Risk manager[3] is defined as follows: a national or international governmental organization with responsibility for antimicrobial resistance risk management activities.

3. 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.
- PRINCIPLE 3: Antimicrobial resistance risk management activities should focus on clearly defined combinations of the food, antimicrobial drug, antimicrobial use, and foodborne human pathogens and/or resistance determinants.
- PRINCIPLE 4: Antimicrobial resistance risk management activities should follow a structured approach.
- 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.
- PRINCIPLE 7: Risk managers and risk assessors should ensure effective interactions.
- PRINCIPLE 8: Risk managers should take into account risks resulting from regional differences in human exposure to foodborne antimicrobial microorganisms and resistant determinants 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.
- PRINCIPLE 10: Risk management activities should take into account recent work by international organizations on antimicrobial resistance.

4. Guidelines for Activities

7. These guidelines provide an outline of a series of steps that comprise the preliminary risk management activities, part of the general framework for antimicrobial resistance risk analysis. These activities are conducted by, or under the guidance of, the risk managers.

4.1. Identification of an antimicrobial resistance food safety issue

8. In the context of this document, a potential food safety issue may arise when antimicrobial resistant microorganisms and antimicrobial resistance genes are present in food and feed, including aquaculture, or are transmitted through food and feed. Foodborne exposures to resistant microorganisms or resistance determinants may adversely impact human health by reducing the therapeutic value of antimicrobials used in human medicine because of losses in susceptibility of pathogenic bacteria. The risk manager initiates the risk

[2] Codex Alimentarius Commission, Procedural Manual.

[3] The definition of Risk Manager is derived from the definition for risk management, which may not include all of the individuals who are involved in the implementation phase and related activities associated with managing the risks resulting from antimicrobial resistance; i.e., risk management decisions are largely implemented by industry and other interested parties. The focus of the definition of risk manager in this document is restricted to governmental organizations with authority to decide on the acceptability of risk levels associated with foodborne hazards.

management framework to evaluate scope and magnitude of the food safety issue and, where necessary, to commence activities to manage the associated risk.

9. Food safety issues may be identified by the risk manager or be the result of collaboration between different interested parties. Within Codex, a food safety issue may be raised by a member government, or by an intergovernmental or observer organization.

10. Antimicrobial resistance food safety issues may be identified on the basis of information arising from a variety of sources, such as antimicrobial resistance surveillance in animals and in foods of animal origin, food safety monitoring, antimicrobial usage surveys, animal and human surveillance data (including post-marketing surveillance data on approved antimicrobials), epidemiological or clinical studies, laboratory studies, research on resistance transfer, scientific, technological or medical advances, environmental monitoring, recommendations of experts, public input, etc. Additional potential sources of information are provided in the *Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005)*

11. To better define the food safety issue, the risk manager may need to pursue information from sources that have specific knowledge pertaining to the issue. An open process, in which the food safety issue is clearly identified and communicated by the risk managers to risk assessors, as well as affected consumers and industry, is essential to promote both an accurate definition and a well-understood and common perception of the issue.

4.2. Development of an antimicrobial resistance risk profile

12. The antimicrobial resistance risk profile is a description of a food safety problem and its context that presents, in a concise form, the current state of knowledge related to the food safety issue, describes current control measures and risk management options that have been identified to date, if any, and the food safety policy context that will influence further possible actions. The risk profile is usually developed by personnel with specific scientific expertise on the food safety issue of concern and some understanding of antimicrobial resistance risk assessment techniques.

13. The depth and breadth of the antimicrobial resistance risk profile may vary depending on the needs of the risk managers and the complexity of the food safety issue. An extensive list of suggested risk profile elements is provided in the Annex as guidance to risk managers at the national/regional level, and for bringing forward newly proposed work within the Codex process. In certain situations, however, it may be necessary to develop an abbreviated risk profile that could be used as a basis for further preliminary risk management activities, such as prioritizing the development of more comprehensive risk profiles or determining the need for commissioning a risk assessment. The abbreviated risk profile may be particularly useful for resource-challenged countries in determining priorities for further activities. Caution should be exercised in implementing these abbreviated risk profiles, as they may not provide as complete a picture of the food safety issue as needed for effective decision making by the risk managers. The fundamental elements that should comprise an abbreviated risk profile include:

- Description of the public health problem (the antimicrobial resistance food safety issue);
- Identification and characterization of the food commodity + antimicrobial resistant pathogen + antimicrobial use combination;
- Consideration of critically important antimicrobial lists developed by national and international groups (e.g., see *Joint FAO/WHO/OIE Expert Meeting on Critically Important Antimicrobials*, Rome 2007);
- Description of usage (extent and nature) of antimicrobials in food production, when available (such as veterinary applications, plant protection or food processing); and
- Identification of major knowledge gaps.

14. Consideration of the information given in the risk profile may result in a range of initial decisions, such as determining that no further action is needed, commissioning an antimicrobial resistance risk assessment, establishing additional information gathering pathways, or implementing immediate risk

mitigation for those food safety issues that require an immediate action[4] by the risk manager without further scientific consideration (e.g. requiring withdrawal / recall of contaminated products).

15. When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, it may be appropriate for risk managers 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 initially communicated.

4.3. Rank food safety issues and set priorities for risk assessment and management

16. Given the potentially high resource costs associated with conducting risk assessments and/or implementing risk management goals, a risk ranking or prioritization process is important in placing the risks from a specific food commodity + antimicrobial resistant pathogen + antimicrobial use combination in context with other risk scenarios that require the attention of risk managers. The output from the risk profile provides the principal criteria that should be used by risk managers in this risk ranking or prioritization process.

17. Beyond the description of the food safety issue provided by the risk profile, other criteria may be used for ranking or prioritization; these are generally determined by the risk mangers in conjunction with stakeholders, and in consultation with risk assessors on technical aspects of the issues. Such criteria include:

- Perceived relative level of risk to consumers;
- Capability to implement effective food safety control measures;
- Potential international trade implications associated with food safety control measures;
- Regulatory challenges; and
- Policy concerns/public demand.

4.4. Establish broad risk management goals

18. Following development of the risk profile and the conduct of the risk ranking/prioritization steps, risk managers should decide on the broader risk management goals in addressing the food safety issue. Ultimately, the outcome of the preliminary risk management activities and the risk assessment, if conducted, should be combined with the evaluation of available risk management options in order to reach a decision on management of the risk.

19. Risk management goals should have as their primary objective the protection of the health of consumers. Other considerations in selecting appropriate risk management goals include the potential impact on trade, as well as the feasibility of implementation, enforcement, and compliance of the risk mitigation measures associated with the goals.

20. The risk management goals may range from more general approaches, such as implementation of codes of practice, to more specific measures, such as the development of regulatory standards and guidelines or the estimation of risks in specific exposure scenarios to inform the risk managers in selecting specific risk mitigation measures. The determination of the need, or the feasibility, of a risk assessment, is often critical in establishing risk management goals. Thus, the risk management goals should be clearly stated prior to commissioning a risk assessment to ensure that the information provided by a risk assessment addresses the risk management goals.

21. The criteria for determining the need for a risk assessment depends on the nature of the risk management goals. Factors that may influence the desirability of a risk assessment include:

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[4] The International Health Regulation (2005) Agreement gives provisions for appropriate measures in case of public health emergencies, including food related events (www.who.int/csr/ihr/ihrwha58_3-en.pdf). The Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situation (CAC/GL 19-1995) defines a food safety emergency as a situation whether accidental or intentional that is identified by a competent authority as constitutes a serious and as yet uncontrolled foodborne risk to public health that requires urgent action. Emergency measures may be part of immediate action.

- If the nature and magnitude of the risk are not well characterized;
- When risk brings economic, social, cultural and ethical considerations;
- When the risk management goals have major trade implications;
- The availability of resources;
- The urgency of the food safety issue; or
- The availability of scientific information.

22. The establishment of these broad risk management goals should be accomplished as an interactive process between the risk managers, the risk assessors, and external stakeholders. It is imperative that the established goals be developed with full consideration of their ability to address the specific food safety issue of concern. The risk management goals should be clearly communicated to all interested parties.

4.5. Establish a risk assessment policy

23. Determination of risk assessment policy should be included as a specific component of risk management. Risk assessment policy should be established by risk managers in advance of risk assessment, in consultation with risk assessors and all other interested parties. This procedure aims at ensuring that the risk assessment is systematic, complete, unbiased and transparent. The mandate given by risk managers to risk assessors should be as clear as possible and provide guidance as to the scope of the risk assessment. Where necessary, risk managers should ask risk assessors to evaluate the potential changes in risk resulting from different risk management options.

24. For antimicrobial resistance risk assessment policy, risk managers may adopt the General Principles in the Draft Guideline for the Risk Assessment of Foodborne Antimicrobial Resistant Microorganisms (under development) related to non-human use of antimicrobials.

25. Additional elements specific to the food safety issue related to antimicrobial resistance should also be included in order to provide guidelines to risk assessors conducting the risk assessment. For example, the risk assessment policy should provide the risk assessors with guidance on the need to address uncertainty and what assumptions to use when the available data are inconsistent.

4.6. Commission of a risk assessment

26. Based on the established risk management goals, risk managers may commission a risk assessment to provide an objective, systematic evaluation of relevant scientific knowledge to help make an informed decision regarding appropriate risk management activities. The nature and scope of the risk assessment may vary, depending on the food safety issue of concern, but it is important to ensure that a clear mandate is given to risk assessors and that the risk assessment meets the needs of the risk manager. It is also important that all aspects of the commissioning and conduct of the risk assessment are documented and transparent.

27. Information that may be documented in the commissioning of the risk assessment includes:

- A description of the specific food safety issue (as defined in the risk profile);
- The scope and purpose of the risk assessment;
- The specific questions to be answered by the risk assessment;
- The type (e.g., quantitative, qualitative) of risk assessment to be conducted;
- The expertise and resources required to carry out the risk assessment;
- Timelines for milestones and completion of the risk assessment;
- Criteria to validate the risk model;
- Criteria to assess the scientific and technical adequacy of the risk assessment; and
- Analysis of any future data needs.

28. It is important to ensure that the composition of the risk assessment team is appropriate in terms of expertise and be free of conflicts of interest or bias. The risk managers should also ensure that there are

effective and iterative communication pathways between the risk assessors and risk managers during the risk assessment process, and that the risk assessment be adequately reviewed by the scientific community and if appropriate, the public.

29. The risk manager should refer to the Principles and Guidelines for the Conduct of Antimicrobial Resistance Risk Assessment (under development).

4.7. Consider the results of the risk assessment

30. The conclusion of the risk assessment including a risk estimate, if available, should be presented in a readily understandable and useful form to risk managers and made available to other risk assessors and interested parties so that they can review the assessment. In reviewing the completeness of the risk assessment, risk managers need to understand the nature, sources and extent of uncertainties and variability of the risk estimates expressed.

ANNEX

Suggested Elements to Include in an Antimicrobial Resistance Risk Profile

A risk profile should present, to the extent possible, information on the following:

1. Definition of the hazard-food commodity combination(s) of concern:
    - Hazard(s) of concern – the specific combination of:
        - food commodity;
        - antimicrobial resistant pathogen; and
        - antimicrobial use
    - Description of the food commodity and the associated cause for concern (e.g., antimicrobial resistant foodborne illness, trade restrictions) due to the hazard
    - Occurrence of the hazard in the food chain.
2. Description of the public health problem (*i.e.*, the adverse human health consequences):
    - Characteristics of the resistant microorganism(s) or resistance determinants, including key attributes that are the focus of its public health impact (e.g., cross resistance, co-resistance, horizontal gene transfer);
    - Characteristics of the antimicrobial-susceptible infection, illness or disease, including:
        - Susceptible populations;
        - Annual incidence rate in humans including, if possible, any differences between age and sex;
        - Severity of clinical manifestations (e.g., case-fatality rate, rate of hospitalization; and
        - Nature and frequency of long-term complications;
    - Characteristics of the antimicrobial-resistant infection, illness, or disease:
        - Added burden of the infection, illness or disease due to antimicrobial resistance, if readily available (e.g., medical and/or hospital costs; working days lost due to illness, etc.); and
        - Evidence of links between resistance, virulence, and/or fitness of the antimicrobial resistant microorganism
    - Characteristics of treatment of the antimicrobial resistant infection, illness, or disease:
        - Options for treating the infection, illness, or disease (e.g., importance of antimicrobial drug for treatment of human adverse health effect, possible side effects of alternate treatments);
        - Extent of human use of the antimicrobial agent for which resistance is the concern;
        - Availability and nature of treatment; and
        - Prevalence of resistance in human populations;
3. Description of food commodities associated with the antimicrobial resistant microorganisms or resistance determinants (Post-harvest factors);
    - Characteristics of the food commodity (commodities);
    - Food use and handling that influences transmission of the hazard;
    - Frequency and characteristics of foodborne sporadic cases;
    - Epidemiological data from outbreak investigations;
    - Prevalence of resistance on food commodity; and
    - Evidence of a relationship between the presence of the antimicrobial resistant microorganisms or resistance determinants on the food commodity and the occurrence of the adverse health effect in humans.

4. Description of antimicrobial(s) (Pre-harvest factors);
    - Chemical, physical and pharmacological properties of the antimicrobial agent;
    - Type of use (treatment/prevention/control/growth promotion);
    - Dose regimen and route of administration;
    - Final product specifications;
    - Specific rules of usage for the country concerned;
    - Frequency or incidence of use of the antimicrobial agent;
    - Factors influencing the persistence of resistance in the pre-harvest production stage;
    - Importance of antimicrobial drug to animal medicine;
    - Associations between usages and development and persistence of resistance;
    - Factors that may affect the dissemination of antimicrobial resistant microorganisms through the food chain;
    - Evidence of a relationship between the use of the antimicrobial and the occurrence of antimicrobial resistant microorganisms, or resistance determinants, in the food commodity of concern;
    - Persistence of the antimicrobial in the environment, and factors affecting the maintenance of antimicrobial resistant microorganisms and/or resistance determinants; and
    - Contribution of alternative (non-foodborne) sources of antimicrobial resistance
5. Antimicrobial resistance genes and resistance determinants:
    - Factors that may affect the frequency of transfer of genetic elements through the food chain; and
    - Description of the molecular genetics of the antimicrobial resistance of concern
6. Other Risk Profile Elements:
    - Summary of the extent and effectiveness of current risk management practices including food safety production/processing control measures, educational programs, and public health intervention programs (e.g., vaccines);
    - Identification of additional risk mitigation strategies that could be used to control the hazard;
    - The extent of international trade of the food commodity;
    - Existence of regional/international trade agreements and how they may affect public health with respect to the specific hazard-food commodity combination(s);
    - Public perceptions of the problem and the risk;
    - Initial assessment of the need and benefits to be gained from requesting an antimicrobial resistance risk assessment, and the feasibility that such an assessment could be accomplished within the required time frame; and
    - If a risk assessment is identified as being needed, recommended questions that should be posed to the risk assessor;
7. Assessment of available information and major knowledge gaps:
    - Existing antimicrobial resistance risk assessments on the food commodity + antimicrobial resistant pathogen + antimicrobial use combination(s) including, if possible;
    - Other relevant scientific knowledge and data that would facilitate risk management activities including, if warranted, the conduct of a risk assessment;
    - Existing Codex guidance documents (including existing Codes of Hygienic Practice and/or Codes of Practice);

- International and/or national governmental and/or industry codes of hygienic practice and related information; and
- Areas where major absences of information exist that could hamper risk management activities, including, if warranted, the conduct of a risk assessment.

Appendix 1

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