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Agenda Item 4

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME
AD HOC CODEX INTERGOVERNMENTAL TASK FORCE
ON ANTIMICROBIAL RESISTANCE

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**DRAFT GUIDELINES FOR RISK ANALYSIS OF FOODBORNE ANTIMICROBIAL
RESISTANCE (N01-2008, N02-2008, N03-2008)**

COMMENTS AT STEP 6

*(Replies to CL 2009/25-AMR of Canada, Columbia, Kenya, New Zealand, Republic of Korea,
Consumers International, IFAH and OIE)*

CANADA

Canada appreciates the opportunity to provide comments on the proposed draft guidelines at the Step 6 of the Procedure. Canada believes that substantial progress has been made by the Task Force and looks forward to working with member countries and observers at the working group meeting and the fourth session of the Task Force to finalize the guidelines. Canada acknowledges outstanding efforts undertaken by the host country, Republic of Korea.

Canada provides below specific comments aimed at strengthening the proposed guidelines. In particular, a revised version of Appendix 1 on Risk Profile is included. Please note that the suggested deletions are marked by strikethrough and insertions/revised texts are in bold/underlined. Additional editorial comments will be provided for consideration at the next session of the Task Force.

INTRODUCTION

1. Para 2 last sentence: is proposed to be revised as follows for better readability and clarity: **“However, a consolidated framework specific to foodborne AMR risk analysis was considered necessary due to the biological complexity of AMR, its multidisciplinary aspects within the entire production to consumption continuum and the need to identify appropriate risk mitigation strategies.”**
2. Para 5, line 3: “...recognizing that the **activities identified within these sections are** ~~sections can be~~ applicable throughout the process

DEFINITIONS

3. **Cross-Resistance** – A single resistance mechanism in a ~~bacterium~~ **microorganism** conferring resistance ~~at various levels~~ to other members of the **antimicrobial** class or to different classes. ~~The level of resistance depends on the intrinsic activity of the antimicrobial agent, in general the higher the activity, the lower the level of resistance.~~ Cross-resistance implies cross-selection for resistance⁸.”
4. It is suggested to refer the following definitions to the Codex Committee on Food Hygiene for review and consideration for inclusion in the Codex Procedural Manual: foodborne pathogen, pathogen, food-producing animals, commensal.
5. **Risk Management Option (RMO):** It is suggested to delete the definition of “Risk Management Option” from the Definitions section. The term “Risk Management” is defined in Codex texts, and the term “Options” is a commonly used and a well understood term. More importantly, a whole section of

the document explains what risk management is and addresses how RMOs are evaluated, selected and implemented. Therefore, the inclusion of a definition for the term is redundant.

GENERAL PRINCIPLES

6. Para 10, Principle 6: Suggest including “**cross-resistance**” in the last sentence. The revised sentence would read as: “Co-resistance and cross-resistance should also.....situations.”

PRELIMINARY FOODBORNE AMR-RISK MANAGEMENT ACTIVITIES

7. Para 14, line 5, “the hazard”. This is the first appearance of “the hazard” in this document. It is suggested to identify the specific hazard being referred to as follows: “...the hazard, i.e., **antimicrobial resistant microorganisms and resistance determinants**”.
8. Para 15, Suggest reformulating para 15 based on the discussions on Appendix 1, so that they both are aligned.
9. Para 20: The title of this section is “Establishment of *broad* risk management goals”, while the contents of this paragraph only make reference to “*preliminary* risk management goals”, indicating inconsistency between the title and its contents. The “broad” in the title may be replaced by “preliminary”.
10. Para 21, 1st sentence: For better readability it is suggested to revise this sentence as: “Following a decision **to conduct a** ~~as to the need for a~~ risk assessment, risk assessment policy should be established by risk managers in advance of **commissioning the** risk assessment.”
11. Para 22: this para repeats what is stated in Para 21. Suggest revising this para and combining with Para 23 as “Based on the established risk management goals, risk managers may commission a risk assessment to provide a transparent, systematic evaluation of relevant scientific knowledge to help make an informed decision regarding appropriate risk management activity. Information that may documented...”.

FOODBORNE AMR-RISK ASSESSMENT

12. Figure 2: The title is suggested to be revised as “**Examples for Consideration for Integrating Information within and between of Foodborne AMR Exposure Assessment and Hazard Characterization in a Foodborne AMR Risk Assessment**”.
13. Para 38: 3rd sentence, following amendments are proposed for further clarity and consistency: “This section provides ~~guidance lines~~ on the **general** types of outcomes that may be informative in the risk characterization but specific ~~outputs~~ **outcomes** may need to be established at the onset of the assessment process ~~in conjunction with risk managers~~ **based on the risk question(s) and the risk manager’s needs.**”
14. Para 40: lines 3-4: Suggest harmonization with rest of the document as “...for example in terms of individual risk, population (including **unique relevant subgroups** ~~populations with special vulnerability~~) risk(s), per-meal risk, or annual risk based on consumption.”
15. Para 41, bullet 1: Suggest deleting this bullet as this is already covered in para 40.
16. Para 41, bullet 2: suggest deleting “~~by non-mathematicians~~” and revising the contents in parenthesis to “stated in clear language and **readily** understandable”.
17. Para 41, bullets 3 and 4: suggest combining these as they both refer to uncertainty. New bullet 3 could read: "An explicit description of the variability and uncertainty. The degree of confidence in the final estimation of risk will depend on the variability, uncertainty, and assumptions identified in all previous steps¹². ~~Risk assessors must be sure that risk managers understand the impacts of these aspects on the risk characterization. Sensitivity and uncertainty analysis.~~ Quantitative uncertainty analysis is preferred; however, it may be arrived at subjectively. In the context of quality assurance, uncertainty analysis is a useful tool for characterizing the precision of model predictions. In combination with sensitivity analysis, uncertainty analysis can also be used to evaluate the importance of model input uncertainties in terms of their relative contributions to uncertainty in the model outputs."
18. Para 41, bullet 3 The last sentence that is struck out in this bullet, "Risk assessors must be sure that risk managers understand the impacts of these aspects on the risk characterization", is suggested to be

moved to paragraph 44 as follows: Para 44. "The conclusions 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. **Risk assessors must be sure that risk managers understand the impacts of these aspects uncertainty, variability, and assumptions on the risk characterization.** The responsibility for resolving the impact of uncertainties described in the risk assessment on RMOs lies with the risk manager and not with the risk assessors.

19. Para 42: "~~The~~—Potential points for consideration in the risk characterization are presented in Section 4 of Appendix 2". Suggest including this para as part of para 38 as follows: "**Suggested elements for risk characterization are included in Section 4 of Appendix 2.**"

FOODBORNE AMR-RISK MANAGEMENT

20. Para 55, line 1: "Table 1 provides examples of RMOs for the control of foodborne AMR risks, inclusive but not exhaustive of existing Codex Codes of Practice, ~~and RMOs specific to foodborne AMR.~~".
21. Table 1. Food animal production. Non-regulatory controls: The differences between the following two possible options "Development and implementation of national or regional treatment guidelines targeting a specific AMR problem" and "Development and regular update of species-specific responsible use guidelines by professional bodies" is not clear .
22. Table 1. Food animal production & Food crop production: the recommendation to improve accuracy of microbiological diagnosis is not a risk management option, and thus is not appropriate in this section. It is suggested to move this recommendation to the section on Surveillance.
23. Para 56, line 2: "an ALOP **or public health goal**" to align with Para 62.
24. Para 62: "In order to select the best RMO or combination of RMOs to address an AMR food safety issue, risk managers should first determine an ALOP or public health goal" seems out of chronological order, whereas Para 56 indicates "After a range of RMOs have been identified, the next step is to evaluate one or more options with respect to their ability to reduce risk and thereby achieve an ALOP." The determination of the ALOP should come before para 56. Para 62 should also refer back to Para 20. Therefore, Paras 56-63 are suggested to be combined under one heading "**Evaluation and Selection of Foodborne AMR-RMOs**" as the distinction between evaluation and selection remains unclear.
25. Para 62, last sentence. A footnote is suggested for Paper 87.
26. Para 65: This para which reads "To effectively execute control measures, food producers and processors generally implement complete food control systems using comprehensive approaches such as Good Manufacturing Practices (GMP), Good Hygiene Practices (GHP) and HACCP systems." This is what food producers and processors currently do, but does not state what they should do in case of an AMR food safety issue. There needs to be a tie back into implementation of Foodborne AMR-RMOs. Suggest adding to this para a new sentence at the end: "**HACCP systems could be expanded to incorporate RMOs specific to AMR hazards.**"
27. Paras 66 to 68 can be merged into one paragraph as there is repetition in the text. The following is proposed:

"Risk managers should establish a process to monitor and review—whether the **selected** RMOs have been properly implemented and are achieving the required level of control over the hazard **and to allow adjustment of the implementation plan or RMO, where necessary.** ~~and whether or not an outcome has been successful. This should also include the monitoring and review of provisional decisions the selected control measures have been properly whether or not an outcome has been successful.~~"

Monitoring/control points related to specifically implemented RMOs should be ~~measured~~ **verified** to assess the effectiveness and need for potential adjustment. Additional monitoring/control points may be needed ~~measured~~ to identify new information on the specific food safety issue.

Furthermore, the relevance, effectiveness and impacts (including unintended consequences) of risk management decisions, including provisional decisions, and their implementation should be regularly monitored and the decisions and/or their implementation reviewed as necessary. Risk managers are responsible for verifying the effectiveness and appropriateness of the risk mitigation measures and for monitoring potential unintended consequences. Effectiveness of **risk management decisions RMOs in achieving the intended outcomes** should be measured by specific food safety metrics, the ALOP and/or public health goals. National surveillance programmes, designed to monitor the presence of AM microorganisms and the use of antimicrobials, can help establish a baseline against which the effectiveness of RMOs can be measured. Possible end points for **monitoring the effectiveness of selected RMOs** include:

- Prevalence of foodborne AMR microorganisms and/or resistance determinants at the farm level, **at slaughter/harvest, and/or in retail food;**
- ~~Prevalence of foodborne AMR microorganisms and/or antimicrobial resistance determinants in food products at slaughter/harvest;~~
- ~~Prevalence of foodborne AMR microorganisms and/or antimicrobial resistance determinants in food products at retail level;~~
- Prevalence of foodborne AMR microorganisms and/or antimicrobial resistance determinants in human clinical isolates from foodborne diseases;
- Number (incidence) of adverse health effects;
- Trends in non-human use of antimicrobial agents, including critically-important antimicrobial agents.

~~Monitoring/control points related to specifically implemented RMOs should be measured to assess the effectiveness and need for potential adjustment. Additional monitoring/control points may be monitored/measured to identify new information on the specific food safety issue. (moved to first paragraph in this section) Risk managers are responsible for verifying the effectiveness and appropriateness of the risk mitigation measures and for monitoring potential unintended consequences”~~

SURVEILLANCE OF USE OF ANTIMICROBIAL AGENT AND AMR MICROORGANISMS AND ANTIMICROBIAL RESISTANCE DETERMINANTS

28. Para 69, 2nd sentence: Suggest including humans such as “Data can be used to explore potential relationships between antimicrobial use and the prevalence of AMR microorganisms in humans, food producing animals, ...”.

FOODBORNE AMR-RISK COMMUNICATION

29. Paras 74 and 75: Suggest merging these two paras as follows “At the earliest opportunity, communication with all interested parties should be promoted and integrated into all phases of a risk analysis (see Figure 1). This will provide participants a better understanding of risks and risk management approaches. Risk communication should also be well documented”.
30. Para 77. This para currently deals with veterinary antimicrobials. It is suggested to consider whether a paragraph dealing with all types of non-human use antimicrobial agents is needed. As well, the original para seems confusing as written. Perhaps, it can be revised as “Information on antimicrobial agents ~~veterinary antimicrobial products considered essential by the national authority to ensure their safe and effective use, in compliance with national regulations,~~ should be made available by the pharmaceutical ~~veterinary drug~~ industry in the form of labelling, data sheets or leaflets; to ensure the safe and effective use of antimicrobial agents, in compliance with national regulation”.
31. Para 78. Need to clarify the 1st sentence and to include government standards and implementation by food industry. In line 3, “customers” remains unclear.
32. Para 80: The first sentence should not be limited to “animal derived food”.

APPENDIX 1 (Revised)

SUGGESTED ELEMENTS FOR CONSIDERATION IN A FOODBORNE AMR RISK PROFILE

This appendix lists suggested elements to include in an AMR-risk profile; the level of details of the data may vary on a case-by-case basis. This list is to provide for illustration and is not intended to be exhaustive and not all elements may be applicable in all situations. The risk profile is intended to result in a recommendation for one of the following: 1. a provisional RM measure is needed; 2. a risk assessment should be commissioned; 3. more data/research is needed to be able to make a recommendation; and 4. the risk is negligible and nothing needs to be done at this point in time. An AMR risk profile should incorporate, to the extent possible, information on the following:

1. Description of the AMR food safety issue

- Identification and description of the hazard—the defined combination of the food commodity, the microorganism/AMR determinant, and the antimicrobial agent to which resistance is expressed.

2. Food commodity information

- Source(s) (domestic or imported), production volume, distribution and per capita consumption of foods or raw materials identified with the AMR hazard of concern
- Characteristics of the food product that may impact risk management (e.g. further processed, consumed cooked, pH, water activity, etc)
- Description of the food production to consumption continuum (i.e., primary production, processing, distribution, and consumption) and the risk factors that affect the microbiological safety of the food product of concern.

3. Microorganism/antimicrobial resistance determinant information

- Characteristics of the identified foodborne microorganisms
 - Sources and transmission routes
 - Strains causing disease or opportunistic pathogens
 - Growth and survivability and fate of foodborne AMR microorganisms in the production to consumption continuum
 - Virulence and linkages to resistance
 - Inactivation in foods (e.g. D-value, minimum pH for growth, etc.)
- Characteristics of the resistance expressed by the microorganism and/or AMR determinant
 - Resistance mechanisms and location of AMR determinants
 - Cross-resistance and/or co-selection for resistance to other antimicrobial agents
 - Transferability of resistance determinants between microorganisms

4. Information on the antimicrobial agent to which resistance is expressed

- Class of the antimicrobial agent
- Non-human uses of the antimicrobial agent
 - Formulation of the antimicrobial agent
 - Distribution and availability of the antimicrobial agent
 - Purpose and use of antimicrobial agent in feed, food animals, crop production and/or during food processing
 - Methods and routes of administration of the antimicrobial agent (individual/mass medication, local/systemic application)
 - Potential extra-label, off-label and non-approved use of antimicrobial agent
 - Use of related antimicrobial agents in food production (potential role of cross-resistance or co-resistance)

- Trends in the use of the antimicrobial agent in the agricultural sector and information on emerging resistance in the food supply
- Human uses of the antimicrobial agent
 - Spectrum of activity and indications for treatment
 - Importance of the antimicrobial agent; consideration of critically important antimicrobial lists
 - Distribution, cost and availability
 - Availability of alternative antimicrobial agent
 - Trends in the use of the antimicrobial agent and information on emerging diseases due to microorganisms resistant to the antimicrobial agent or class

5. Information on adverse public health effects

- Characteristics of the disease caused by the identified AMR foodborne microorganism
 - Trends in AMR foodborne disease
 - Severity of effects including case-fatality rate, hospitalisation rate and long-term complications
 - Susceptible populations and risk factors
 - Epidemiological pattern (outbreak or sporadic)
 - Regional, seasonal and ethnic differences in the incidence of foodborne disease due to the AMR hazard
- Consequences of AMR on the outcome of the disease
 - Loss of treatment options and treatment failures
 - Increased frequency and severity of infections, including prolonged duration of disease, increased frequency of bloodstream infections, hospitalization and mortality
- Added burden of disease

6. Risk management information

- Existing or potential risk management options to control the AMR hazard along the production to consumption continuum, both in the pre-harvest and post-harvest stages
 - Measures to reduce the risk related to the selection and dissemination of foodborne AMR microorganisms
 - Measures to minimize the contamination and cross-contamination of food by AMR microorganisms
 - Effectiveness of current management practices in place based on surveillance data or other sources of information

7. Other risk profile elements

- Public and industry perceptions of the problem and risk
- Extent of international trade and potential trade or other economic impacts
- Description of requirements (if any) specified by international trade agreements

8. Assessment of available information and major knowledge gaps

- Uncertainty of available information
- Areas where major gaps of information exist that could hamper risk management activities, including, if warranted, the conduct of a risk assessment

APPENDIX 2

1.2 and 1.3: Suggest switching these two sections to align with Appendix 1.

1.3: Suggest moving the last bullet “Pathogenicity, virulence, and their linkage to resistance (**phenotypic and genotypic characterization**)” to be as the 1st bullet and also adding a new 2nd bullet on microorganism information: “**Microbial ecology: growth, survival capacity and redistribution of foodborne AMR microorganism in the production to consumption continuum**”.

1.3: Suggest deleting the 5th bullet “~~AMR surveillance data~~” as this is just a type of information.

2.1, 1st bullet, 1st sub-bullet, 2nd sub-sub-bullet, suggest revising as “Geographical distribution of **antimicrobial agent** use and/or **number of farms using the antimicrobial agent**”.

2.1, 1st bullet, 2st sub-bullet: Suggest adding a new bullet as 2nd sub-sub-bullet: “**Distribution, cost, and availability of antimicrobial agent**”.

2.1, 2nd bullet: Suggest adding a new bullet (as the 1st bullet): “**Numbers of animals and their progeny, and transport to other facilities**”.

2.1, 3rd bullet, “Animal feed” sub-bullet (2nd before last of item 2.1): Suggest revising as “Animal feed and **the ingredients used to prepare the animal feed, as well as biosolids, fertilizer and other natural fertilizers**”. This would be consistent with other sections of the document where such products are referred to.

2.2, 2nd bullet, last sub-bullet: Suggest deleting “~~Catering and food services~~” since this bullet is captured under the 3rd bullet “Consumer Behaviour” of this section.

2.3 Transfer of hazard and 2.4 Exposure to hazard: These two sections can be deleted since most of their contents are already covered in sections 2.1 and 2.2. As such, two bullets in 2.4 (i.e., 2nd and 3rd bullets “**Human demographic data**” and “**Point of food consumption (home, commercial establishment, or informal establishment)**”) can be moved to 2.2 under bullet “Consumer behaviours” (as new 1st and last bullets, respectively”).

3.1, 6th bullet: Suggest deleting this bullet as this is covered under the 5th and 7th bullets.

4.1, “Factors **for consideration** in risk estimation”

4.1, 1st bullet: “Number of people falling ill and the proportion of that number with **antimicrobial** resistant ~~strains of~~ microorganisms attributable to foodborne sources”.

4.1, 3rd bullet: “Increased **frequency of infections, frequency of treatment failures**, severity and duration of disease, **rates of hospitalization, and mortality with antimicrobial resistant microorganisms compared to susceptible microorganisms**”

4.1, 7th bullet, “Existence or absence of therapeutic alternatives ~~absence of alternative antimicrobial agent and alternatives with potential~~”.

4.1, 7th bullet, “~~Alternatives available in case of resistance, and Potential impact of switching to an alternative antimicrobial agent; absence of alternative antimicrobial agents or potential impact of switching to alternative antimicrobial agent~~ (e.g., alternatives with potential **increased** toxicity).”

4.1, 9th bullet: Suggest deleting this bullet “~~Incidence of resistance~~”.

4.2: Suggest changing the title “~~Evaluation of RMOs~~” to “**Risk assessment consideration of risk management options**” as the original title is in conflict with the Risk Management section.

4.2, 1st bullet, “Comparison of public health burden before and after interventions **as explored via risk assessment**”. Clarity is also needed here to avoid to further define what public health burden is (Risk estimate?)

COLOMBIA

Colombia has the pleasure of submitting the following comments regarding the document “**Proposed Draft Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance**” at step 5 of the procedure, sent by the Secretariat of the Codex Alimentarius Commission.

The following comments are made with reference to the Spanish version of the annex to document CX/AMR 10/33/42, Appendix II.

I. Paragraph 4 - Introduction

In order to ensure good communication between risk assessors, managers and interested parties it is necessary to create collection points.

It is thus recommended that the following be added at the end of paragraph 4 of the document: ...”Good communication between risk assessors, managers and interested parties is essential for a transparent and informed risk analysis, establishing a collection point for an efficient exchange of information between the parties.”

II. Paragraph 6 - Introduction

In order to complement the documents in conjunction with which these guidelines should be read, it is suggested adding the document relating to the “Hazard Analysis And Critical Control Point (HACCP) System And Guidelines For Its Application” since the Codes of Hygienic Practice for Meat and for Milk mention it but do not describe it. The paragraph would read as follows:

This document should be read in conjunction with the Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC/GL 62-2007), the Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CAC/GL 30-1999), the Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007), the Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005), the Hazard Analysis And Critical Control Point (HACCP) System And Guidelines For Its Application, the Code of Hygienic Practice for Meat (CAC/RCP 58-2005), the Code of Hygienic Practice for Milk and Milk Products (CAC/RCP 57-2004)

III. Paragraph 7 - Scope

As an adjustment of the translation of the document, it is recommended to replace the wording “~~se relaciona con el suministro de~~” with the word proporciona since one cannot use the phrase “suministro de orientación” but rather “establecer” or “dar un lineamiento” or a similar language. (No change in the English version).

IV. Paragraph 8 - Scope

In line with principles 4 and 7, “residues of antimicrobial agents in foods” should not be outside the scope of the guidelines, since the majority of the antibiotics are not 100% absorbed by animals treated for either therapeutic or preventive reasons. Scientific literature reports that over 60% of an antibiotic are eliminated into the environment through urine and fecal matter.

It is also known that some crops are irrigated with solutions containing antibiotics to prevent attacks from pathogenic microorganisms.

It is thus proposed to add “and the residues of antimicrobial agents in foods” at the end of paragraph 7, since this is where the risks associated with their different areas of use are addressed.

V. Paragraph 9 – Definitions – Antimicrobial risk determinant

It is proposed to change the heading of this definition since it is not in line with the definition, where the language refers to genetic resistance mechanisms. The recommended heading for this definition should read: Antimicrobial resistance mechanisms

VI. Paragraph 9 – Definitions – Adverse health effect

In order to adjust the translation of the document it is recommended to eliminate the language ~~or acquired from food~~, since it is repeated within the paragraph.

VII. Paragraph 9 – Bottom of the page – Antimicrobial agent

This definition refers to *in vivo* antimicrobial agents administered to hosts. Yet no reference is made to *in vitro* antimicrobial agents, which are used by external application on organisms of surfaces. It is known that the latter ones can also produce resistance in microorganisms.

It is considered necessary to add the term *in Vitro* in the definition:

Antimicrobial agent: Any substance of natural, semi-synthetic, or synthetic origin that at *in vivo or in vitro* concentrations kills or inhibits the growth of microorganisms by interacting with a specific target.

VIII. Paragraph 9 – Definition - Commensal

In the definition of Commensal, in the sentence stating “Generally, commensal microorganisms are considered to be non-pathogenic in their normal habitat, but may, in certain circumstances, become opportunistic pathogens”, it is requested to add “*or transmit resistance factors*” at the end of the sentence

IX. Paragraph 10 – General Principles for Foodborne AMR-Risk Analysis – Principle 2

In order to complement the scope of the principle it is suggested to include the word primary.

Principle 2: Foodborne AMR-risk analysis should consider the selection and dissemination of foodborne AMR through the primary food production to consumption continuum

X. Paragraph 12 – Preliminary Foodborne AMR-Risk Management Activities

As an adjustment of the translation of the document, it is recommended to delete ~~de gestión de riesgos, que comienza~~ (the risk management..., beginning); ~~comenzar las actividades de gestión del riesgo señalado~~ (to commence activities to manage the identified risk). Also to replace the word ~~evaluar~~ (evaluate) with determinar (determine), in order to avoid any confusion with the risk assessment. The paragraph would thus read:

The risk manager initiates the process with the preliminary activities to determine the scope and magnitude of the food safety issue and, where necessary, commences the risk management activities that may be appropriate.

XI. Paragraph 18 – Ranking of Food Safety Issues and Setting Priorities for Risk Assessment and Management

As an adjustment of the paragraph in the light of repetitions, it is recommended to delete the word ~~opciones~~ (options), since it is repeated in the paragraph.

XII. Paragraph 19 – Ranking of Food Safety Issues and Setting Priorities for Risk Assessment and Management

It is suggested that it would be important to include an annex to the document describing how to rank or determine priorities with a risk profile.

XIII. Paragraph 24 – Risk Assessment

As an adjustment of the translation of the document, it is recommended to replace the word ~~aborda~~ (addressing) with the word contemple ~~o captados a través de alimentos~~. (No change in the English version)

XIV. Paragraph 26 – Possible Sources of Information

In order to be accurate, it is necessary to correct the numbers ~~83–86~~ and replace them with 69–72 according to the document.

XV. Paragraph 47 – Foodborne AMR-Risk Management

In order to harmonise criteria with the document of the Codex General Principles, it is suggested replacing the word “legal” with “competent”.

XVI. Paragraph 48 – Foodborne AMR-Risk Management

As an adjustment of the repetition in the paragraph, it is recommended to replace the word “~~adoptado~~” with the word “tomado” (No change in the English version).

XVII. Paragraph 52 – Identification of Foodborne AMR-RMOs

In order to be accurate, it is necessary to correct the paragraph numbers ~~54 and 55~~ and replace them with 49 and 50 according to the document.

KENYA

Kenya would like to submit the following comment as indicated below.

APPENDIX 1. SUGGESTED ELEMENTS TO INCLUDE IN AN FOODBORNE AMR RISK PROFILE

The objectives of an AMR risk profile are to present prerequisite scientific information on the identified food safety issue to inform risk managers prior to decision-making. An AMR risk profile should incorporate, to the extent possible, information on the following:

Comment

Kenya has no objection with numbers 1 and 2 as they are and propose that bullet one and two under clause 2 to be under "exposure assessment" since they refer to the type of food and the quantity respectively. We also accept number 4 with few modifications as indicated therein.

1. Description of the AMR food safety issue
 - What is the potential hazard – the defined combination of the food commodity, the microorganism/antimicrobial resistance determinant, and the antimicrobial agent to which resistance is expressed?
2. Food commodity information
 - How and where does the identified microorganism/ antimicrobial resistance determinant enter the food supply?
 - Which foods expose consumers to the identified microorganism/ antimicrobial resistance determinant? – **(TYPE OF FOOD)**
 - How much of those foods are consumed by the target populations? (**quantity**)
 - What are the frequency, distribution and levels of occurrence of the identified microorganism/ antimicrobial resistance determinant in foods?
3. Microorganism/ antimicrobial resistance determinant information
 - What are the microbiological characteristics of the identified food borne microorganism (e.g., virulence, growth conditions, etc.)?
 - What are the characteristics of the resistance expressed by the microorganism (e.g., spectrum of resistance, involvement of co- or cross-resistance, transferability, etc.)?
4. Information on the antimicrobial agent to which resistance is expressed
 - How important is the antimicrobial agent in the treatment of human disease?
 - How important is the antimicrobial agent to animal medicine?
 - What pathways may have led to the presence of resistance to the antimicrobial agent?
 - Was the antimicrobial agent used in food production? If so, how was it used (e.g., *method* of applications, amounts, *frequency*)? --- ***We accept this with the modification of adding "method of" and "frequency" in the statement.***
 - Were related antimicrobial agents used in food production (potential role of cross-resistance or co-resistance)?
 - What other factors may affect the dissemination of AMR microorganisms and antimicrobial resistance determinants through the food chain?- ***Kenya has no objection to this statement.***
5. Information on adverse public health effect(s)
 - What are the characteristics of the disease caused by the identified food borne microorganism (e.g., severity of effects, *susceptible populations*)? – ***Kenya has no objection to this statement.***
 - What are the effects of antimicrobial resistance in the identified food borne microorganism (e.g., loss of treatment options, availability of alternative treatments, added burden of disease)? - ***Kenya has no objection to this statement.***
6. Other Relevant Information
 - What is the evidence of a relationship between the presence of the AMR microorganisms or antimicrobial resistance determinants on the food commodity and the occurrence of the adverse health effect(s) in humans?

- What is the evidence of a relationship between the use of the antimicrobial agent and the occurrence of
 - AMR microorganisms, or antimicrobial resistance determinants, in the food commodity of concern? - *Kenya has no objection to this statement*
 - What are potential risk mitigation strategies that could be used to control the hazard?
 - Are there current risk management practices in place? What is their effectiveness? - *Kenya has no objection to these statements*
7. Assessment of available information and major knowledge gaps
- How much uncertainty exists in the available data?
 - Are there areas where major absences of information exist that could hamper risk management activities, including, if warranted, the conduct of a risk assessment? (*e.g. awareness creation, capacity building*) - *Kenya has no objection to these statements but like to clarify the statements by giving some of the examples such as awareness creation and capacity building.*
8. *Are there any practices which would reduce risk exposure? - (NEW) Kenya proposes to add this eighth statement under this risk profile*

NEW ZEALAND

New Zealand wishes to acknowledge the significant progress that has been made by the Ad Hoc Intergovernmental Task Force on Antimicrobial Resistance in advancing the Draft Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance to Step 6 and the work done by Korea as the host country.

New Zealand is satisfied with the main sections of the Draft guidelines that were agreed at the last session of the Task Force and does not see any need to revisit this text. We do however have some comments on the appendix on risk profiling which was left in [] at the last Taskforce meeting.

APPENDIX 1 - SUGGESTED ELEMENTS TO INCLUDE IN A FOODBORNE AMR RISK PROFILE

General Comments

New Zealand supports strongly the inclusion of such an Appendix. Its purpose should be to illustrate what may be included in an AMR risk profile and to distinguish this stage of preliminary risk management from a risk assessment. New Zealand believes that it will add clarity to the document and, even as presently drafted, includes useful information.

While supportive of much of the current draft prepared by the United States of America and recognising the time constraints in its preparation at the last Taskforce meeting, New Zealand considers that further work on the document is required and will participate in the face to face Working Group that is scheduled to be held immediately prior to the forthcoming session.

Specific Comments / Amendments to Text

The ordering of the present draft in terms of elements is not in accord with that of the main document (Para 15). New Zealand judges that these need to be harmonised, with the appendix following the sequence in the main text. Ordering proposals are made.

While accepting that this is an Appendix and the main text introduces the topic, New Zealand believes it has to be able to 'stand alone' so that the user can comprehend the purpose of a risk profile. Therefore the introduction should be expanded as follows:

The objectives of an AMR risk profile ~~are~~ **is** to present prerequisite scientific information on the identified food safety issue to inform risk managers prior to decision-making. **It is an opportunity to gather scientific data and other information on possible food safety risks associated with a food safety issue and provides a lead for risk managers to assess whether further action is required. A risk profile should be 'fit for purpose' and in some situations will be an elemental exercise.**

An AMR risk profile should incorporate, to the extent possible, information on the following:

1. Description of the AMR food safety issue

- What is the potential hazard – the defined combination of the food commodity, the microorganism/antimicrobial resistance determinant, and the antimicrobial agent to which resistance is expressed?

2. Food commodity information

- How and where does the identified microorganism/ antimicrobial resistance determinant enter the food supply?
- Which foods expose consumers to the identified microorganism/ antimicrobial resistance determinant?
- How much of those foods are consumed by the target populations?
- What are the frequency, distribution and levels of occurrence of the identified microorganism/antimicrobial resistance determinant in **these** foods?

Rationale - Need to make clear that it is the food commodity defined earlier

3. Microorganism/ antimicrobial resistance determinant information

- • What are the microbiological characteristics of the identified food borne microorganism (e.g., virulence, growth conditions, etc.)?
- • What are the characteristics of the resistance expressed by the microorganism (e.g., spectrum of resistance, involvement of co- or cross-resistance, transferability, etc.)?

4. Information on the antimicrobial agent to which resistance is expressed

- How important is the antimicrobial agent in the treatment of human disease?
- How important is the antimicrobial agent to animal medicine?
- What pathways may have led to the presence of resistance to the antimicrobial agent?
 - Was the antimicrobial agent used in food production? If so, how was it used (e.g., applications, amounts)?
 - Were related antimicrobial agents used in food production (potential role of cross-resistance or co-resistance)?
 - What other factors may affect the dissemination of AMR microorganisms and antimicrobial resistance determinants through the food chain?
- **What is the evidence of a relationship between the use of the antimicrobial agent and the occurrence of AMR microorganisms, or antimicrobial resistance determinants, in the food commodity of concern?**

Rationale – suggest include an additional bullet as above to clarify ordering/context

5. Information on adverse public health effect(s)

- What are the characteristics of the disease caused by the identified food borne microorganism (e.g., severity of effects, susceptible populations)?
- What are the effects of antimicrobial resistance in the identified food borne microorganism (e.g., loss of treatment options, availability of alternative treatments, ~~added~~ **additional** burden of disease)?

Rationale – The above amendment is to improve clarity

- **What is the evidence of a relationship between the presence of the AMR microorganisms or antimicrobial resistance determinants on the food commodity and the occurrence of the adverse health effect(s) in humans?**

Rationale – ordering/context

If the above is accepted New Zealand would propose deletion of Para 6 as the text would be redundant.

7.6. Assessment of available information and major knowledge gaps

- How much uncertainty exists in the available data?
- Are there areas where major absences of information exist that could hamper risk management activities, including, if warranted, the conduct of a risk assessment?

New Zealand proposes that the last two bullets in Para 6 be moved to a new Para 7 titled control measures and amended as follows:

7. Control measures

- Are there current risk management practices in place? ~~What is their effectiveness?~~

Rationale - Examination of effectiveness of risk management measures is not part of a risk profile; it is part of monitoring and review in the risk analysis cycle.

- What are potential risk mitigation ~~strategies~~ **options** that could be used to control the hazard?]

Rationale – to make clear that this is separate from risk management activities.

REPUBLIC OF KOREA

General Comments

Korea believes that this guideline could make a progress at Step 6 through collaboration and cooperation of Codex member countries and International Organizations. In this regard Korea appreciates to all of the Codex member countries and especially to the chair of Working Group including the United States, EC, Canada and Denmark for their efforts to develop the guidelines.

We, Korea generally agree to the scope, structure, and the contents of the current guidelines. In the 3rd Codex TFAMR, it was suggested to reinsert Appendix 1 in the document, but there were arguments for and against between the member countries. We, Korea believe that in order to maintain conciseness of the document, it is necessary to be provided as Appendix.

However, bullets of paragraph 15 need to be harmonized with Appendix 1. In addition, we, Korea suggest that instead of using ‘antimicrobial drug(s)’ (paragraph 45, Table 1, Appendix 2) and ‘antimicrobials’ (paragraph 67, Appendix 3), they should be replaced for ‘antimicrobial agent(s)’ as it is generally used throughout the document.

Specific Comments

1. We, Korea suggest that bullets of the paragraph 15 need to be revised to harmonize with Appendix 1 as follows. Moreover, we would like to insert deleted 4th bullet as a sentence after the last bullet of paragraph 15.

o Paragraph 15

The depth and breadth of the foodborne AMR risk profile may vary depending on the needs of the risk managers and the complexity and urgency of the food safety issue. The fundamental elements that comprise a foodborne AMR risk profile include:

- ~~Description of the hazard~~ ~~Description of the hazard and public health problem (the AMR food safety issue);~~
- **Description of the AMR food safety issue (the hazard and public health problem);**
- ~~Identification and characterization of the combination of the food commodity, the microorganism/resistance determinants and the antimicrobial agent to which resistance is expressed;~~
- **Identification of the combination of the food commodity, the microorganism/resistance determinants and the antimicrobial agent to which resistance is expressed**

- **Description of the related food commodity;**
- **Description of the related microorganism/resistance determinants;**
- **Description of the antimicrobial agent to which resistance is expressed;**
- **Description of the adverse health effect(s);**
- ~~Consideration of critically important antimicrobial lists developed by international organizations and national/regional authorities (e.g., see Joint FAO/WHO/OIE Expert Meeting on Critically Important Antimicrobials, Rome 2008);~~
- ~~Description of usage (extent and nature) of the antimicrobial agent(s) in food production, when available (such as veterinary applications, aquaculture, plant protection or food processing);~~
- A list of current control measures; and
- Identification of major knowledge gaps.

Consideration of critically important antimicrobial lists developed by international organizations and national/regional authorities (e.g., see Joint FAO/WHO/OIE Expert Meeting on Critically Important Antimicrobials, Rome 2008) is also needed;

2. And also we suggest adding the contents of the deleted 5th bullet in paragraph 15 at the first sub-bullet of 3rd bullet in Number 4 of Appendix 1 with a few modifications.

○ Appendix 1

4. Information on the antimicrobial agent to which resistance is expressed

- How important is the antimicrobial agent in the treatment of human disease?
- How important is the antimicrobial agent to animal medicine?
- What pathways may have led to the presence of resistance to the antimicrobial agent?
- Was the antimicrobial agent used in food production? If so, how was it used **in food production (such as veterinary applications, aquaculture, plant protection or food processing)?**
 - Were related antimicrobial agents used in food production (potential role of cross-resistance or co-resistance)?
 - What other factors may affect the dissemination of AMR microorganisms and antimicrobial resistance determinants through the food chain?

3. Although it is true that antimicrobial resistant bacteria is hard to treat with antimicrobial therapy, it does not mean that AMR pathogens are more spreadable or highly toxic compared to the same kind of pathogens that are not resistant. Thus, the following statements of antimicrobial resistance to increase frequency of disease may lead policy analysts or consumers to misunderstand AMR microorganisms as more infectious and more pathogenic than non-resistant microorganisms. So, we would like to revise it as below.

○ Paragraph 26 (3rd bullet)

- Clinical studies including case reports on the relevant foodborne infectious disease incidence, primary and secondary transmission, antimicrobial therapy, and impacts of resistance on **the severity of** disease ~~frequency and severity~~;

○ Paragraph 35, 2nd sentence

A hazard characterization also includes the characteristics of the acquired resistance so as to estimate the additional consequences that can occur when humans are exposed to resistant pathogens, including increased ~~frequency and~~ severity of disease.

○ Paragraph 66 (5th bullet)

- Number of (incidence) adverse health effects such as treatment failure, loss of treatment options and/or severity of infections (e.g., prolonged duration of disease, ~~increased frequency of bloodstream infections~~, increased hospitalization, and increased mortality) attributable to foodborne AMR microorganisms and/or determinants;

- Appendix 2(3.1, 8th and 9th bullet)
 - Increased ~~frequency of infections and~~ treatment failures
 - Increased severity of infections, including prolonged duration of disease, ~~increased frequency of bloodstream infections~~, increased hospitalization and increased mortality
- 4. We, Korea would like to add ‘antimicrobial’ to clarify the sentence in ‘regulatory controls on conditions of use’ under the ‘Crop production’ in Table 1.

‘regulatory controls on conditions of **antimicrobial** use’
- 5. The sentence in Principle 5 needs to be amended as below.
 - in addition, needs to consider factors relating to the antimicrobial susceptibility of the microorganism(s) in question and related consequences to treatment of human disease resulting from **antimicrobial**~~antimicrobials~~ resistant microorganisms.

CI (CONSUMERS INTERNATIONAL)

Consumers International (CI) appreciates this opportunity to submit these brief comments on the Draft Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance. CI would also like to express our appreciation to Canada for agreeing to head the working group in Muju, Korea on October 16 and would also like to thank Korea for hosting the Task Force for this meeting and in prior years.

CI believes that the current draft guidelines reflect the hard work over many years of participating delegations and will limit our comments to the still bracketed Appendix 1.

General Comments:

The current Appendix 1 assumes that it will be possible to isolate a single microorganism, commodity, and antimicrobial agent when completing a risk profile. In many cases this approach will not work because of co-resistance and cross-resistance. In addition a single resistance determinant may be carried by multiple bacterial species. Finally this approach is inconsistent with other Codex texts in particular Annex 1 of CAC/GL 63-2007 “Suggested Elements to Include in A Microbiological Risk Profile”. CI recommends that antimicrobial agent, commodity, microorganism, and determinant include the plural in parenthesis throughout Appendix 1.

CI also recommends that the TFAMR consider aligning the bullet points in Appendix 1 with those used in Annex 1 of CAC/GL 63-2007 to create consistency across texts in Codex. For example, paragraph 1 would be “Hazard-food commodity combination(s) of concern” followed by bullets on the resistant microorganism(s), the food commodity (commodities), and the antimicrobial agent(s). Paragraph 2 would then be “Description of the public health problem” and would include bullets that contain what is in paragraphs 3 and 5. The other bullets could then be moved to the appropriate paragraphs.

Finally CI recommends that Appendix 1 be modified to acknowledge that resistance determinants may be transferred to non-foodborne microorganisms after consumption. Our specific comment on paragraph 5 below provides a suggestion to cover this possibility.

Specific comments to Appendix 1. Suggested Elements to Include in an Foodborne AMR Risk Profile:

Paragraph 5 (both bullet points) does not consider the potential for resistance determinants to be transferred to non- foodborne microorganisms after consumption and should be modified to address this possibility. CI recommends that the following text be used with new text underlined and the text to be removed struck out:

5. Information on adverse public health effect(s)
 - What are the characteristics of the disease caused by the identified foodborne microorganism or non-foodborne microorganism that may acquired resistance from determinants in food (e.g., severity of effects, susceptible populations)?
 - What are the effects of antimicrobial resistance in the identified ~~food-borne~~ microorganism (e.g., loss of treatment options, availability of alternative treatments, added burden of disease)?

Paragraph 6. Bullet point 1. The information for bullet point 1 of paragraph 6 is what is described in paragraph 5, so this bullet is redundant and should be deleted.

Paragraph 6. Bullets 2 and 3 seem to be the result of a typo and should be combined into a single bullet, but like bullet 1 this point contains information already covered in earlier paragraphs so should be deleted.

IFAH (INTERNATIONAL FEDERATION FOR ANIMAL HEALTH)

IFAH, the International Federation for Animal Health, has provided the following comments on the draft guidelines and Risk Profile Bracketed text in Appendix 1 for consideration in improving the current document.

Definitions (page 33)

Cross-resistance is incorrectly defined, even though it is referenced to the Rome consultation. Currently the definition reads: A single resistance mechanism in a bacterium conferring resistance at various levels to other members of the class or to different classes. The level of resistance depends on the intrinsic activity of the antimicrobial agent, in general the higher the activity, the lower the level of resistance. Cross-resistance implies cross-selection for resistance.

To improve clarity, the first sentence should read: A resistance mechanism in a microorganism that confers the ability to survive in the presence of related members of a particular antibiotic class, or across antibiotic classes if the target site is modified (e.g Macrolide-lincosamide-streptogramin B).

To reduce confusion, the second sentence should be deleted. As written, it is technically incorrect because the intrinsic activity of an antimicrobial agent is not correlated to a “level of resistance”. Potency has nothing to do with cross-resistance.

To improve clarity, the third sentence should read: Cross-resistance is often used to imply selection pressure exists when any of the included antibiotics are used.

Risk profile (page 35, paragraph 15)

Clarification of the risk profile paragraph and Appendix 1 should be based on previous Codex texts and WHO/OIE/FAO recommendations. The proposed Canadian-led Working Group scheduled to meet prior to the 4th Task Force meeting will be critical to achievement of this goal. It is anticipated that once the Working Group completes its work, that paragraph 15 and Figure 1 will be aligned.

- Figure 1 and paragraph 15 Development of a foodborne AMR-risk profile (Appendix 1) are connected to Appendix 1. Paragraph 15 currently contains an abbreviated list of the elements of the foodborne AMR risk profile but these are not aligned with those in Appendix 1. In order to keep the flow of the document streamlined, it would seem to make sense to simply limit paragraph 15 to a minimum of text by referring users to Appendix 1, which would contain the full Risk Profile outline. There is no obvious advantage to having a short list of “elements”. Proposed revised text would be:
- The depth and breadth of the food borne AMR risk profile may vary depending on the needs of the risk managers and the complexity and urgency of the food safety issue. The fundamental elements are contained in Appendix 1.

Risk profile and provisional decisions (Page 35, Paragraph 16-17): Even at this late stage of drafting of the Guidelines, the trigger for early, provisional, risk management decisions (prior to risk assessment) is still very unclear. It is essential to clarify the conditions which trigger an “immediate risk mitigation measure” or “provisional decision”. Since an action may not be taken prior to completion of the Risk Profile, as per Figure 1, the wording in paragraph 17 implies that insufficient or incomplete data in a Risk Profile (which is obviously expected) are not an impediment to implementing a provisional decision. This precautionary approach could be interpreted liberally to justify any food/antibiotic/resistance concern simply because it is “possible” to have a risk (no matter how small). It is therefore recommended that additional clarification for risk managers should be provided as to the necessary circumstances that are appropriate. Although the first sentence in paragraph 17 was modified from CAC/GL-63, the concern is that the mere presence of foodborne AMR microorganisms in food (i.e. detectable at very low amounts by sensitive techniques and below an infectious dose) could be used as the justification for invoking a provisional decision and thereby “skipping” the risk assessment process.

Ranking of Food Safety issues and setting priorities for risk assessment and management (Page 35, Paragraph 19): Current text: “Beyond the description of the AMR food safety issue provided by the risk profile, other criteria may be used for ranking or prioritization. These are generally determined by the risk

managers in conjunction with interested parties and in consultation with risk assessors on scientific aspects of the issues.” It is in the best interests of transparency to provide some examples of “other criteria” and how those will be factored into Risk Profile after it is completed. The second sentence suggests that these “other criteria” are on “scientific aspects” but it is curious that such aspects would not have been made available during the process of Risk Profiling. It is recommended that additional discussion is needed on these points for clarification.

Page 37, Process of foodborne AMR-risk assessment.

In order to further clarify the process of risk assessment, it is proposed in paragraph 27 that the work should be mapped. Paragraph 27 could easily be combined with paragraph 28. It would then be helpful to provide Figure 3.1, Risk Assessment flow chart (from FAO #87) just below existing paragraph 28. The boxes of the four components in the imported figure would be re-labeled; i.e. delete content from FAO#87 figure and insert new text to refer the reader to the appropriate sections of Appendix 2 for details of content and also to the subsequent paragraphs within the Risk Assessment section. The value of this approach is to provide a visual “table of contents” and activity flow for the section, which is very complicated. Currently, only Figure 1 contains this “diamond” diagram and because it is so important, it is worth “expanding” the diagram at this point in the document.

Figure 3.1. Generic Codex description of the components of risk assessment

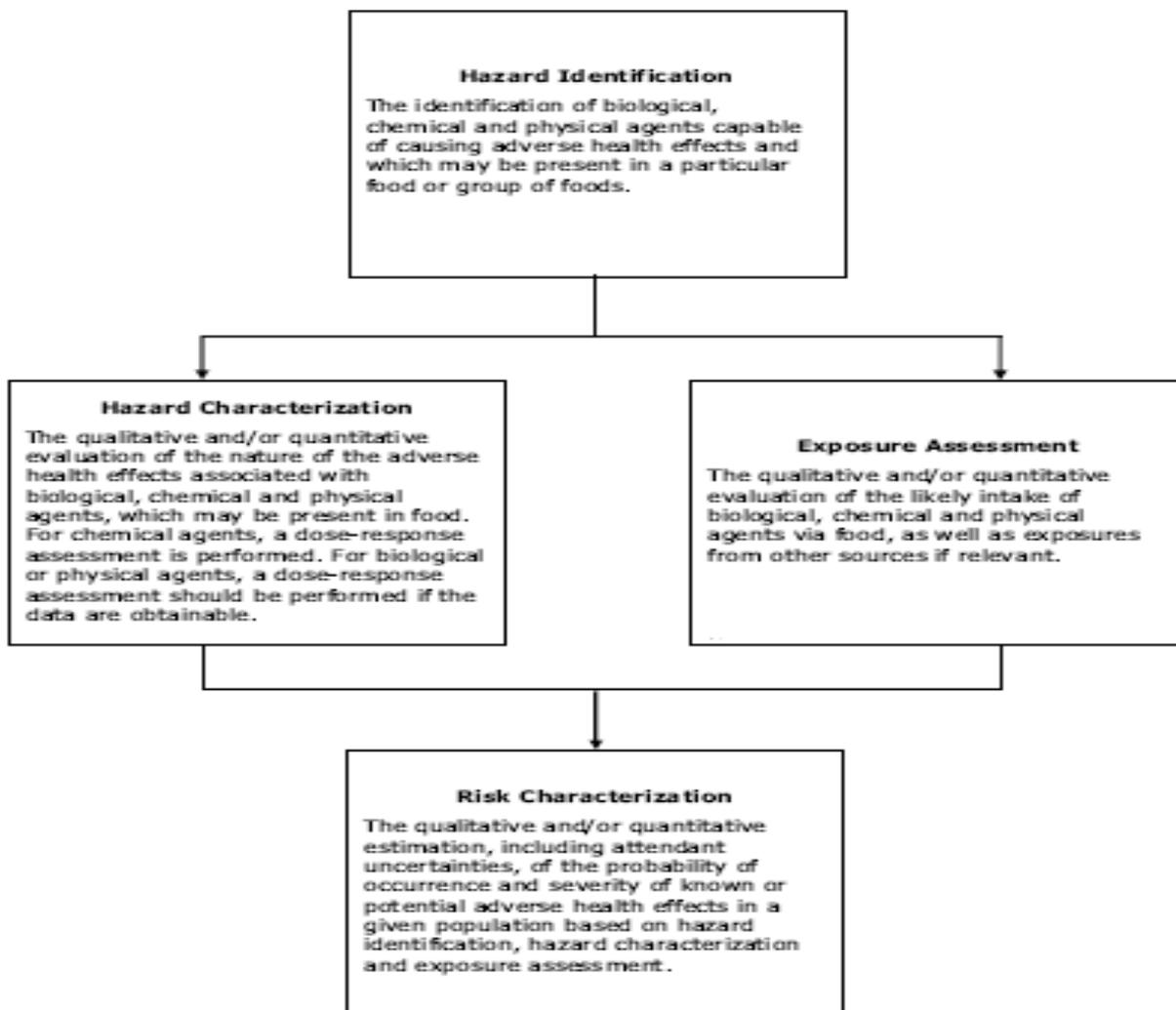


Figure 3.1 WHO/FAO#87

Figure 2 and paragraphs 32, 33, 34, 35 and 36, in conjunction with Appendix 2.

Figure 2. Examples for Consideration of Foodborne AMR Exposure Assessment and Hazard Characterization

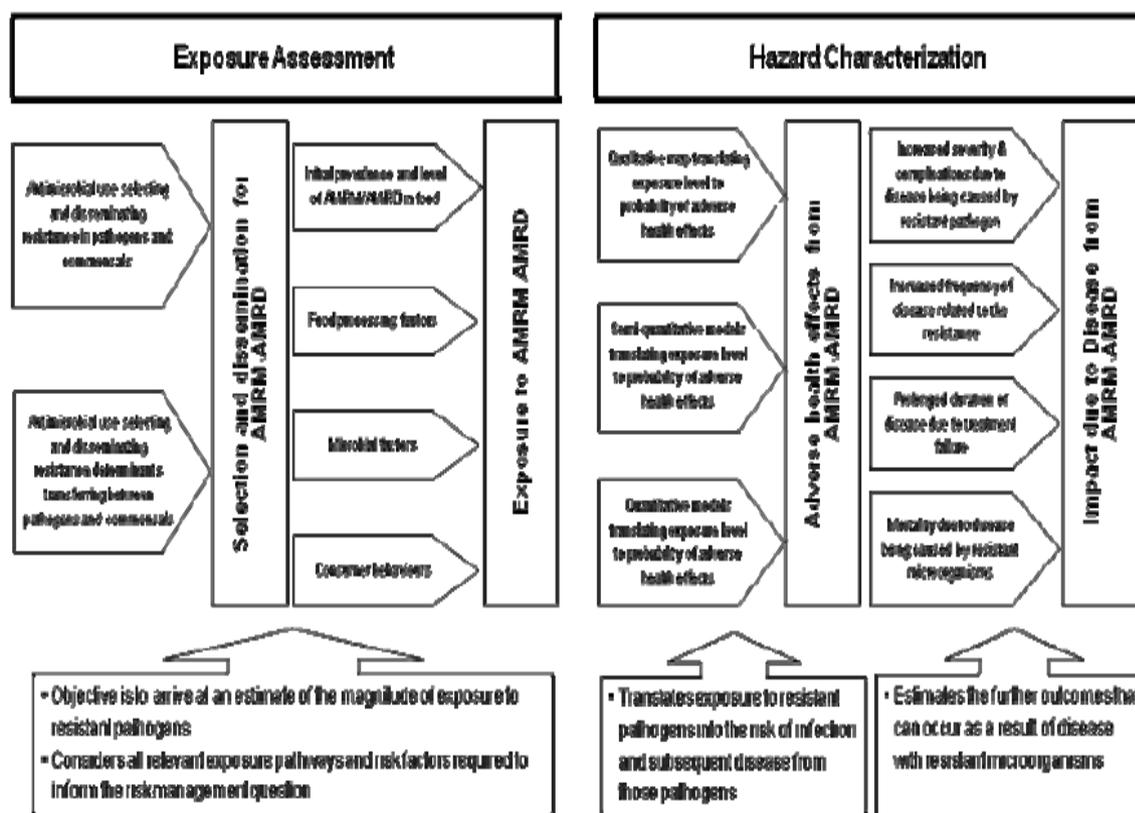


Figure 2 content and placement. The Exposure Panel in Figure 2 has many boxed arrows with various “factors” that somehow lead to a total output of “exposure to resistant pathogens”. It is not apparent how the parallel tracks are combined to the final output on the right side of the diagram. While reference to Appendix 2, Section 2.1 for Exposure Assessment is made, it is very difficult to match up the components in the figure with those in Section 2.1. It is not obvious how a risk assessor will be able to process the available information.

The Hazard Characterization Panel in Figure 2 has even more boxed arrows with unclear outputs and which is not entirely matched with text in paragraphs 36 and 37, nor in Appendix 2, Section 3. Again, it is not obvious how a risk assessor will be able to process the available information.

For both panels, it is not clear whether the output can pertain to all pathogens or to susceptible pathogens as an additional output, because the focus seems to be exclusively on “resistance”. It is not known how the proposed approach will distinguish outputs of resistant microorganisms or determinants from “baseline” susceptible populations.

Furthermore, since both panels are placed side-by-side, it appears that the outputs of the Exposure Panel flow directly into the Hazard Characterization panel. Actually, as illustrated in Figure 1 and FAO #87 Figure 3.1, the output of Exposure and Hazard Characterization are integrated in the Risk Characterization component.

Options to Address the Content and Placement Issues of Figure 2 (Exposure Assessment panel and Hazard Characterization Panel)

- o Re-location within the text. In order to achieve the goal of supporting the process of Exposure and Hazard Characterization, the respective panels could be cut and pasted in the paragraphs that pertain to those topics.

- Re-location to Appendix 2. As above, the respective panels could be re-located to the appropriate sections within the Appendix.
- Revise the Exposure and Hazard Characterization paragraphs and the Appendix 2 sections to appropriately explain the content within Figure 2 panels.
- Delete Figure 2 and references to it in the appropriate paragraphs.

Document page 42, Table 1, Non-regulatory controls within Food Animal production and Food Crop production boxes.

Interpretive criteria for antibiotic resistance: Antibiotic resistance is scientifically defined by interpretive criteria. There are different types of interpretive criteria, some of them are not indicative of clinical resistance such as epidemiological cut-off values. IFAH recommends use of clinical resistance breakpoints as the criteria for defining resistance in these Guidelines because the use of other endpoints may lead to inappropriate conclusions as to the true human health risks. Diagnostic tests are used for identification and characterization of microorganisms and, in the context of this paragraph, are to be considered as distinct from antimicrobial susceptibility tests.

- Table 1 Under the section entitled “Food Animal Production”, and “Food Crop Production”, Non-regulatory controls on conditions of use of veterinary antimicrobial drugs and additives, the third sentence is awkwardly written and needs clarification: (Current version: “Improve accuracy of microbiological diagnosis in the development, dissemination and use of international standards for: Bacterial culture and antimicrobial susceptibility testing and Interpretive criteria”). In order to clarify the meaning of the sentence and to amend technical misstatements regarding international standards, a suggested re-wording follows:

“Improve availability, speed and accuracy of diagnostic microbiological tests. To relate clinical treatment outcomes (see Appendix 2), clinical breakpoints from internationally recognized organizations should be used; for other AMR surveillance purposes, the epidemiological cut-off value approach may be useful.”

Appendix 1 Risk profile – bracketed text

IFAH would like to recommend clarification and alignment of the risk profile definitions in harmony with previous Codex texts and WHO/OIE/FAO recommendations. The proposed Canadian-led Working Group scheduled to meet prior to the 4th Task Force meeting will be critical to achievement of this goal. IFAH has not specific wording to offer at this time but offers the following considerations:

- Three Risk Profiling documents should be consulted for wording
 - FAO #87 (pp. 16-17)
 - PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK MANAGEMENT (MRM) CAC/GL-63 (2007)
 - Codex CX/FH 00/11 (2000) Risk Profile on Antimicrobial-Resistant Bacteria in Food.
- IFAH also suggests that the risk profiles developed by the New Zealand Food Safety Authority (NZFSA) for a large number of food-borne hazards also be consulted for format and content purposes. They are posted on the authority’s web site (<http://www.nzfsa.govt.nz/science/risk-profiles/index.htm>). While these provide insight into food borne microorganisms, it is recognized that AMR aspects will need to be incorporated into the process.
- Within the currently bracketed text, the outline of the Risk Profile differs in format and structure from that outline in two of the above cited documents (Codex GL-63 and FAO #87).
- After the Working Group agrees to the appropriate Appendix 1 text, the Plenary session will then need to align it with Figure 1 and paragraph 14-15. To facilitate this editing, the Working Group should be mindful of this need during its deliberations.

OIE (WORLD ORGANISATION FOR ANIMAL HEALTH)

OIE would like once more to thank the government of Korea for having hosted and organised since four years now the meetings of the *Ad Hoc* Codex Intergovernmental Task Force on Antimicrobial Resistance.

OIE recognises the progress achieved at the last meeting and the quality of the document reached so far. It is nevertheless regrettable that the impact of antimicrobial resistance on veterinary public health is not taken into account, in particular in the Introduction.

OIE is looking forward to participating to the next meeting including the physical working group that will meet the 16 October to further discuss on Appendix 1 “Suggested Elements to include in a Foodborne AMR Risk Profile”.

Please see the OIE specific comments and proposed revisions in the table below. The proposed deletions are crossed out and the proposed additions are in bold and underlined.

Position in the text	OIE SPECIFIC COMMENTS
List of Acronyms used in the document	Correction on the OIE acronym: OIE World Organization of for Animal Health
Introduction, paragraph 1, second sentence	Proposal for new wording: When pathogens become resistant to antimicrobial agents they can pose a greater human <u>and veterinary public</u> health risk as a result of potential treatment failure, loss of treatment options and increased likelihood and severity of disease. <i>Rationale: The proposed wording for the Introduction reflects general concerns linked to antimicrobial resistance including the importance of animal health related to food safety.</i>
Introduction, paragraph 2, Footnote 1	Proposal for adding the following reference: FAO/OIE/WHO. 2016 Joint/OIE/WHO Expert Meeting on Antimicrobial Use in Aquaculture and Antimicrobial Resistance, Seoul, Republic of Korea, 13-16 June 2006 http://www.who.int/topics/foodborne_diseases/aquaculture_rep_13_16june2006%20.pdf <i>Rationale: As aquaculture is included in the scope of the document, the above reference needs to be included.</i>
Introduction, paragraph 2, Footnote 2, second reference	Reference to the OIE Terrestrial Code should be written as follows throughout the document: OIE. 2008. Terrestrial Animal Health Code <u>Terrestrial Animal Health Code (Section Veterinary Public Health)</u> (2008). Http://www.oie.int/eng/normes/mcode/en_sommaire.htm
Introduction, paragraph 6, last sentence	Reference to the OIE Terrestrial Code should be written in italics: Risk analysis of AMR on animal feeds may also consider the Code of Practice on Good Animal Feeding (CAC/RCP 54-2004), as well as Animal Feed Impact on Food Safety and the chapters related to the control of AMR in the OIE Terrestrial Animal Health Code <u>Terrestrial Animal Health Code</u> .
Definitions	Proposal for the following adding: Food Producing Animals – Animals raised for the purpose of providing food to humans. Most commonly this term refers to poultry, swine, cattle, sheep, <u>goats</u> , fish and crustaceans but it does not exclude other domestically managed animals. <i>Rationale: Goats are major species in several countries of the Southern Hemisphere</i>

Position in the text	OIE SPECIFIC COMMENTS
General Principles for Foodborne AMR-Risk Analysis, paragraph 10, Principle 3	<p>Proposal for the following deletion:</p> <p>Principle 3: Foodborne AMR-risk analysis should give consideration to relevant international documents (for example, recommendations of the “Joint FAO/WHO/OIE Expert Meeting on Critically Important Antimicrobials”) for setting priorities for further risk assessment and/or risk management activities.</p> <p><i>Rationale: OIE suggests either deleting here the example or adding other references.</i></p>
General Principles for Foodborne AMR-Risk Analysis, paragraph 10, Principle 5	<p>Proposal for the following change:</p> <p>Principle 5: Foodborne AMR-risk analysis should build on 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) and, in addition, needs to consider factors relating to the antimicrobial susceptibility of the microorganism(s) in question and related consequences to treatment of human and animal disease resulting from antimicrobials resistant microorganisms.</p> <p><i>Rationale: Animal health related to food safety should also be taken into account in the first steps of Risk Analysis.</i></p>
Foodborne AMR-risk Management, Identification of foodborne AMR-RMOs, paragraph 50, footnote 14	<p>Reference to the OIE Terrestrial Code should be written as follows throughout the document:</p> <p>OIE. 2008. Terrestrial Animal Health Code <i>Terrestrial Animal Health Code (Section Veterinary Public Health)</i> (2008). Http://www.oie.int/eng/normes/mcode/en_sommaire.htm</p>
Foodborne AMR-risk Management, Identification of foodborne AMR-RMOs, paragraph 51, last sentence	<p>Proposal for the following change:</p> <p>In general, it is valuable to identify initially as broad a range of possible options as practicable and then select the most promising and applicable interventions, proportionate to the identified risk, for more detailed evaluation.</p>
Foodborne AMR-risk Management, Identification of foodborne AMR-RMOs, Table 1, second line, Food animal production	<p>Proposal for the following corrections:</p> <p>Regulatory controls on conditions of use of veterinary antimicrobial drugs agents and additives: ...</p> <p>Non-regulatory controls on condition of use of veterinary antimicrobial drugs agents and additives:...</p> <p><i>Rationale: It was decided during the last Session to replace the term “product” by “agent” all over the document.</i></p>
Foodborne AMR-risk Management, Identification of foodborne AMR-RMOs, Table 1, second line, footnote 19	<p>Proposal for adding the following reference at the end of the footnote:</p> <p>OIE. <i>Terrestrial Animal Health Code</i> (Section Veterinary Public Health). Http://www.oie.int/eng/normes/mcode/en_sommaire.htm</p> <p><i>Rationale: The OIE Terrestrial Code has to be mentioned as the section on Veterinary Public Health is dealing with measures linked to the treatment of animals.</i></p>
Foodborne AMR-risk Management, Identification of foodborne AMR-RMOs, Evaluation of foodborne AMR-RMOs, paragraph 58, first sentence	<p>Proposal for the following change:</p> <p>Any positive or negative impacts of RMOs on human and veterinary public health should be considered when evaluating RMOs.</p> <p><i>Rationale: This proposed wording is consistent with the farm – food continuum.</i></p>

Position in the text	OIE SPECIFIC COMMENTS
Foodborne AMR-risk Management, Identification of foodborne AMR-RMOs, Monitoring and review of foodborne AMR-RMOs, paragraph 59, second sentence	<p>Proposal for the following change:</p> <p>Consideration should be given to how cross resistance or co-resistance will affect the outcomes of different RMOs. For example, the use of an alternative antimicrobial agent may be a better option or may select co-resistance to an antimicrobial critically important to human health.</p> <p><i>Rationale: the use of an alternative antimicrobial agent might be one of the management measures requested.</i></p>
Foodborne AMR-risk Management, Identification of foodborne AMR-RMOs, Evaluation of foodborne AMR-RMOs, paragraph 66, first bullet	<p>Proposal for the following change:</p> <ul style="list-style-type: none"> • Prevalence of foodborne AMR microorganisms and/or antimicrobial resistance determinants in food products at farm level; <p><i>Rationale: The prevalence of foodborne AMR microorganism and/or determinants should be linked to food, to assure coherence with the scope of the document where environment was excluded.</i></p>
Surveillance of use of antimicrobial agent and AMR microorganism and antimicrobial resistance determinants, paragraph 71, third sentence	<p>Proposal for the following change:</p> <p>National/regional authorities may use established should use guidelines such as based on those described in the OIE Terrestrial Animal Health Code <u>Terrestrial Animal Health Code</u>, “Monitoring of the quantities of antimicrobials used in animal husbandry” and relevant WHO guidance.</p> <p><i>Rationale: The OIE standards are the references for all issues related to animal health according to the mandate given by the WTO to OIE.</i></p>
Foodborne AMR-Risk Communication, Foodborne Risk Communication as a Risk Management Tool, paragraph 77	<p>Proposal for the following correction:</p> <p>Information on veterinary antimicrobial products agents considered essential by the national authority to ensure their safe and effective use, in compliance with national regulations, should be made available by the veterinary drug industry in the form of labelling, data sheets or leaflets.</p> <p><i>Rationale: It was decided during the last Session to replace the term “product” by “agent” all over the document.</i></p>
Appendix 2, 4. Risk Characterization, 4.1. Factors in risk estimation, fifth bullet	<p>Proposal for the following change:</p> <p>Deaths (total per year; probability per year or lifetime for a random member of the population or a member of a specific more-exposed or more-vulnerable subgroup) <u>linked to resistance strains of microorganisms attributable to foodborne source.</u></p>