CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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REP11/AMR

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Thirty fourth Session
Geneva, Switzerland, 4-9 July 2011

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

Muju, Republic of Korea
18-22 October 2010

NOTE: This report contains Codex Circular Letter CL 2010/51-AMR

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CX 4/100.2 **CL 2010/51-AMR**
October 2010

TO: Codex Contact Points
Interested International Organizations

FROM: Secretariat, Codex Alimentarius Commission
Joint FAO/WHO Food Standards Programme,
Viale delle Terme di Caracalla
00153 Rome, Italy

SUBJECT DISTRIBUTION OF THE REPORT OF THE FOURTH SESSION OF THE CODEX *AD HOC* INTERGOVERNMENTAL TASK FORCE ON ANTIMICROBIAL RESISTANCE (REP11/AMR)

The report of the Fourth Session of the Codex *Ad Hoc* Intergovernmental Task Force on Antimicrobial Resistance will be considered by the 34th Session of the Codex Alimentarius Commission (Geneva, Switzerland, 4-9 July 2011).

MATTERS FOR ADOPTION BY THE 34TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

Draft Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (N01-2008, N02-2008, N03-2008) (para. 80 and Appendix II) ***at Step 8 of the Procedure***

Governments and international organizations wishing to submit comments on the above text should do so in writing, preferably by e-mail, to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy (Email: codex@fao.org, telefax : +39 06 57054593) **before 31 March 2011.**

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SUMMARY AND CONCLUSIONS

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

Matters for Adoption by the Commission

The Task Force agreed to forward the draft Guidelines for the Risk Analysis of Foodborne Antimicrobial Resistance to the 34th Session of the Commission for adoption at Step 8 (para. 80 and Appendix II).

LIST OF ABBREVIATIONS USED IN THIS REPORT

AGISAR	Advisory Group on Integrated Surveillance of Antimicrobial Resistance
ALOP	Appropriate Level Of Protection
AMR	Antimicrobial Resistance
AMRD	Antimicrobial Resistance Determinant
AMRM	Antimicrobial Resistant Microorganism
AMU	Antimicrobial Use
CAC	Codex Alimentarius Commission
CAC/GL	Codex Alimentarius Commission / Guidelines
CAC/RCP	Codex Alimentarius Commission / Code of Practice
CL	Circular Letter
CRD	Conference Room Document
DALY	Disability Adjusted Life Year
FAO	Food and Agriculture Organization of the United Nations
FSO	Food Safety Objective
GHP	Good Hygiene Practices
GIFSA	Global Initiative for Food-related Scientific Advice
GMP	Good Manufacturing Practices
GVP	Good Veterinary Practices
HACCP	Hazard Analysis and Critical Control Point
IDF	International Dairy Federation
IFAH	International Federation for Animal Health
JEMRA	Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment
MICs	Minimal Inhibitory Concentrations
OIE	World Organisation of Animal Health
PC	Performance Criterion
PO	Performance Objective
RA	Risk Assessment
RM	Risk Management
RMO	Risk Management Option
SPS	Sanitary and Phytosanitary Measures
WHA	World Health Assembly
WHO	World Health Organization
WTO	World Trade Organization
WTO/SPS	World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures

INTRODUCTION

1. The Codex *Ad Hoc* Intergovernmental Task Force on Antimicrobial Resistance held its Fourth Session in Muju, Republic of Korea, from 18 to 22 October 2010, at the kind invitation of the Government of the Republic of Korea. Dr Kwang-Ho Lee, Director of the Food Safety Evaluation Department, Korea Food and Drug Administration, presided over the Session. The Session was attended by 136 delegates from 38 Member countries, 1 Member organization and Observers from 7 international organizations and FAO and WHO. A complete list of participants, including the Secretariats, is given in Appendix I to this report.

2. The Session was opened by Dr Yun-Hong Noh, Commissioner, Korea Food and Drug Administration. Dr Noh welcomed the delegates and stated that antimicrobial resistance was a global problem and developing the Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance was highly significant as it would contribute to the protection of consumers' health. He also said that the Task Force provided an opportunity for strengthening international co-operation.

3. Dr Seung-Hee Kim, General Director of the National Institute of Food and Drug Safety Evaluation, also welcomed the delegates. Dr Kim noted that international food trade had increased during recent years and that it was, therefore, crucial to establish reliable management systems that effectively manage risks, such as those related to foodborne antimicrobial resistance, thus making the work of the Task Force very timely.

4. Dr Karen Hulebak, Chairperson of the Codex Alimentarius Commission, also addressed the delegates. In her remarks, she complimented the delegates on their hard work to date and encouraged them to find sound and consensus solutions to any remaining issues before them at this session so that they complete work on the Guidelines.

5. Mr Jong Moon Park, Lieutenant Governor for Political Affairs, North Jeolla Province and Nak-Pyo Hong, Mayor of Muju also welcomed the delegates and wished the meeting success and participants an enjoyable stay in Muju.

Division of Competence[1]

6. The Task Force noted the division of competence between the European Union and its Member States, according to paragraph 5, Rule II of the Procedure of the Codex Alimentarius Commission, as presented in CRD 1.

ADOPTION OF THE AGENDA (Agenda Item 1)[2]

7. The Task Force adopted the Provisional Agenda as its Agenda for the Session.

8. The Task Force agreed to a proposal of the Chairperson to have a general discussion on how best to apply the draft Guidelines at national, regional and international levels, once adopted by the Commission under Other Business (Agenda Item 5).

MATTERS REFERRED TO THE TASK FORCE BY THE COMMISSION AND OTHER CODEX COMMITTEES (Agenda Item 2)[3]

9. The Task Force noted matters presented in document CX/AMR 10/4/2 arising from the 33rd Session of the Commission regarding the adoption of the proposed draft Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance at Step 5 and Codex future work on animal feeding.

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1 CRD 1 (Division of Competence Between the European Union and its Member States According to Rule of Procedure II Paragraph 5 of the Codex Alimentarius Commission)

2 CX/AMR 10/4/1

3 CX/AMR/10/4/2

INFORMATION ON THE WORK BY FAO, WHO AND OIE ON ANTIMICROBIAL RESISTANCE (Agenda Item 3)[4]

10. The Representative of FAO, while referring to document CX/AMR 10/4/3, provided information on the newly integrated results-based work planning and budgeting process in FAO and the specific strategic objectives, which include activities related to the containment of antimicrobial resistance associated with the use of antimicrobials in food-producing animals. She highlighted in particular activities in the East Africa region aimed at improving food safety in different value chains and a pilot study in the poultry value chain, in collaboration with WHO, to assess the levels and prevalence of pathogenic and antimicrobial resistant bacteria in different stages from production to consumption. She also reported on recent activities in the field of aquaculture food safety in relation to promotion of the responsible use of antimicrobials in the Asian region.

11. The Representative of WHO informed the Task Force on WHO's activities related to antimicrobial resistance. The WHO List of Critically Important Antimicrobials for Human Health (CIA) was first developped in 2005 and the list had subsequently been re-examined and updated in 2007 and 2009[5].

12. The WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance[6] (WHO-AGISAR) was established in 2008 to support WHO's effort to minimize the public health impact of antimicrobial resistance associated with the use of antimicrobials in food animals. The four WHO-AGISAR sub-committees are in the process of developing practical guidelines on antimicrobial usage monitoring, antimicrobial resistance monitoring and integrated data management, to support WHO Member Countries in their efforts to implement a national programme for integrated surveillance of antimicrobial resistance. WHO-AGISAR also contributes to enhancing the capacity of Member States, particularly developing countries, through training courses (using the Global Foodborne Infections training platform), focused research projects (currently in Costa Rica and Cameroon) and sentinel studies (currently pilot projects on integrated surveillance of antimicrobial resistance are conducted in China, Columbia and Kenya). The WHO Representative informed the Task Force that the theme of the 2011 World Health Day will be "Antimicrobial Resistance" and the public health impact of the use of antimicrobials in the agriculture sector would be addressed.

13. The Observer from OIE informed the Task Force on OIE's activities related to antimicrobial resistance, which were in line with the OIE Fifth Strategic Plan (2011-2015), in particular on the improvement of Veterinary Public Health, focussing on the link between animal health, food safety and food security. With regard to standards and guidelines, OIE had just finalised a new chapter on principles for responsible and prudent use of antimicrobial agents in aquatic animals, which would be proposed for adoption and publication in the *Aquatic Animal Health Code* in 2011. The four chapters on antimicrobial resistance published in the *Terrestrial Animal Health Code* (section Veterinary Public Health) would be updated with the participation of WHO and FAO starting in November 2010. The chapter published in the *Terrestrial Manual* was currently under revision and the updating of the OIE List of Antimicrobials of Veterinary Importance would also be considered.

14. Recognising the critical need for veterinary legislation as a basic component to implement Veterinary Public Health, the OIE had organised the first Global Conference on "Modernising Veterinary Legislation for Good Governance" to be held in Tunisia in December 2010. To raise awareness and to build capacity to allow the implementation of standards and guidelines, OIE had started a training programme for OIE focal points on veterinary products on a regional basis. Training Workshops had taken place or are scheduled in Europe (July 2010), the Americas (September 2010), in Africa (November 2010) and Asia (June 2011). WHO was invited to participate in these workshops as training was one of the areas identified for future collaboration.

15. The Task Force thanked FAO, WHO and OIE for the information submitted.

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4 CX/AMR/10/4/3

5 All three editions are available at : www.who.int/foodborne_disease/resistance/cia/en

6 WHO-AGISAR http://www.who.int/foodborne_disease/resistance/agisar/en/index.html

DRAFT GUIDELINES FOR RISK ANALYSIS OF FOODBORNE ANTIMICROBIAL RESISTANCE (N01-2008, N02-2008, N03-2008) (Agenda Item 4)[7]

16. The Delegation of Canada, speaking as the Chair of the physical Working Group which met immediately prior to the session, briefly introduced the Working Group's report, as presented in CRD 2.

17. The Task Force noted that the Working Group had considered the written comments and had made proposals for the revision of Appendix 1 "Elements for Consideration in a Foodborne AMR Risk Profile", Figure 1 "Framework for Foodborne Risk Analysis", Figure 2a "Considerations for Exposure Assessment in a Foodborne AMR Risk Assessment", Figure 2b "Considerations for Hazard Characterization in a Foodborne AMR Risk Assessment" and Table 1 "Examples of Foodborne AMR Risk Management Options". The Working Group had also made proposals for the revision of the corresponding paragraphs (i.e. paragraphs 15, 32 and 36) in the body of the document.[8]

18. The Task Force further noted that the Working Group had recommended removing the square brackets from Appendix 1. The Task Force was informed that the revised draft Guidelines also included editorial changes, made by the Delegation of Canada on the basis of written comments submitted at Step 6, which had not been discussed by the Working Group.

19. The Task Force thanked the Working Group for its constructive discussion and useful outcomes and agreed to the Working Group's recommendation to base the Task Force's discussion on the revised draft Guidelines, as presented in CRD 2.

20. The Task Force considered the draft Guidelines in detail and accepted the majority of the proposals of the Working Group and the editorial changes made by the Delegation of Canada (*see* above). In addition to some further minor editorial changes, it made the following comments and/or amendments:

Introduction

21. The Task Force noted that changes to the Introduction were mainly editorial to remove redundancies, improve clarity and readability. The Task Force agreed to the proposal to refer to "antimicrobial resistance" and "antimicrobial resistant" by the acronym "AMR" throughout the document. The "List of acronyms" was amended accordingly.

22. The Task Force agreed to remove the duplications in the footnotes throughout the document and to add in footnote #1 reference to the Joint FAO/OIE/WHO Expert Meeting on Antimicrobial Use in Aquaculture and Antimicrobial Resistance (Seoul, Republic of Korea, 13-16 June 2006).

Scope

23. The Task Force agreed to retain "reduce the risk" rather than "minimise the risk" in the second sentence of paragraph 7.

Definitions

24. The Task Force agreed:

- To retain the definition of "antimicrobial agent" without reference to "in vitro" concentration, as the scope of antimicrobial agent in the document did not include disinfectants;
- To move the definition of "antimicrobial class" in footnote #10 to the list of definitions, as the term was used more than once in the document;

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[7] CX/AMR 10/4/4 (Comments of Canada, Columbia, Kenya, New Zealand, Republic of Korea, Consumers International, International Federation for Animal Health and the World Organisation for Animal Health); CX/AMR 10/4/4 Add.1 (Comments of: Brazil, Japan, Philippines and the United States of America); CX/AMR 10/4/4 Add.2 (Comments of: European Union); CRD 2 (Report of the physical Working Group on draft Guidelines for risk analysis of foodborne antimicrobial resistance); CRD 3 (Comments of Indonesia and Thailand); CRD 4 (Proposals for revision of the definitions of "Co-resistance" and "Cross-resistance"); CRD 5 (Proposal for revision of Figure 1); CRD 6 (Comments of Japan); CRD 7 (Comments of Egypt); CRD 8 (Comments of Ghana); CRD 9 (Proposal of Canada for revision of paragraph 13 and Point 1 of Appendix 1); CRD 10 (Proposal of IFAH for revision of paragraph 13 and Point 1 of Appendix 1)

[8] Numbers of paragraphs and of footnotes in this section correspond to those in CRD 2

- To amend the definitions of "co-resistance" and "cross-resistance" to make them more technically correct. The revised definitions read as follows: "*Co-resistance: The ability of a microorganism to multiply or persist in the presence of different classes of antimicrobial agents due to possession of various resistance mechanisms*"; "*Cross-Resistance: The ability of a microorganism to multiply or persist in the presence of other members of a particular class of antimicrobial agents or across different classes due to a shared mechanism of resistance*". Since the definitions were no longer those of the Joint FAO/WHO/OIE Expert Meeting on Critically Important Antimicrobials (FAO, Rome, Italy, 26-30 November 2007), the Task Force removed footnote #9; and
- To simplify the definition of "Food producing animal" by no longer listing any examples, as they were not an exhaustive list. Thereby footnote #9 was also deleted as it was no longer that of the Joint FAO/WHO/OIE Expert Meeting on Critically Important Antimicrobials.

General Principles for Foodborne AMR Risk Analysis

25. The Task Force agreed to change "risk management decision" to "risk management measures" in Principle 7 to better reflect that measures, rather than decisions, could be evaluated for effectiveness and for consistency with the change made in Figure 1 "Framework for Foodborne Risk Analysis".

Framework for Foodborne AMR Risk Analysis

26. The Task Force agreed to the revised Figure 1, as presented in CRD 5, which more accurately aligned with the content of the Guidelines. In particular, by:

- Including a box "Establishment of preliminary risk management goals" as a decision point[9], which could lead to "No action", "Identification, evaluation and selection of risk management options" or "Establishment of a risk assessment policy and commission of a foodborne AMR risk assessment";
- Combining the "Establishment of risk assessment policy" and the "Commission of a risk assessment" in a single box, which was not a decision point; and
- Indicating that "Monitoring and review of risk management measures" was a decision point rather than "Implementation of risk management decision".

Identification of a foodborne AMR food safety issue

27. The Task Force agreed to a proposal to add a new sentence at the beginning of paragraph 13 to better describe this important step of the Preliminary Risk Management Activities. The clarification in paragraph 14 "i.e. AMR microorganisms and determinants" was deleted as it was redundant.

Development of a foodborne AMR risk profile

28. The Task Force noted that paragraph 15 had been amended by the Working Group to no longer include the fundamental elements of a foodborne AMR risk profile as these unnecessarily duplicated the content of Appendix 1. The footnote associated with the section was amended to refer to the WHO List of Critically Important Antimicrobials (CIA) and the OIE List of Antimicrobials of Veterinary Importance.

29. The text of paragraph 17 was rearranged for clarity.

Establishment of broad risk management goals

30. The Task Force amended the heading of the subsection to read "Establishment of preliminary risk management goals" to better reflect the content of the sub-section. The paragraph was amended to correspond to the step of "Ranking of the AMR food safety issues for risk assessment/risk management priority".

Establishment of risk assessment policy

31. It was agreed to add "or incomplete" at the end of the fourth sentence to better describe that uncertainties and assumptions should be addressed when data are inconsistent or incomplete.

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[9] Decision points are grey shaded in Figure 1.

Commission the foodborne AMR risk assessment

32. The Task Force deleted the text “based on the established risk management goals” at the beginning of paragraph 22 as it did not accurately reflect the decision on which risk managers might commission a risk assessment.

Process of foodborne AMR risk assessment and Hazard identification

33. The Task Force deleted the second and third sentence in paragraph 30 as these considerations were not specifically part of the hazard identification step. However, in recognising the importance of linking risk assessment activities with the previous steps of AMR risk analysis, paragraph 27 was amended to specifically refer to the steps that needed to be considered by risk assessors when starting work on an AMR risk assessment, i.e. risk profile, information documented during the establishment of risk assessment policy and commissioning of the risk assessment. The fourth sentence was amended to indicate that the identified hazard did not necessarily pose a risk.

Exposure assessment

34. The Task Force noted that the Working Group had split Figure 2 “Examples for Consideration of Foodborne AMR Exposure Assessment and Hazard Characterization” into two components, one related to exposure assessment (Figure 2a) and the other to hazard characterization (Figure 2b). Paragraph 32 was, therefore, amended to reference Figure 2a. It was noted that the texts in figure 2a had been aligned with the content of Appendix 2 “Suggested Elements for Consideration in Foodborne AMR-Risk Assessment”.

35. The Task Force also agreed to add a footnote to explain the relationship between the exposure assessment step of the Codex risk assessment and the release and exposure assessments steps of the OIE risk assessment scheme.

Hazard characterization

36. The Task Force noted that the Working Group had revised paragraph 36 to reflect the content of Figure 2b, which illustrated:

- Options that could be used to translate exposure to resistant microorganisms into the probability of infection and then the subsequent probability of disease (left side column); and
- Estimates of the further outcomes that could occur as a result of disease (right side column).

37. The Task Force had a discussion on whether, at this initial step of the hazard characterization, consideration should also be given to commensals. Arguments in favour of their inclusion were that consumers could be exposed to commensals, pathogens or opportunistic pathogens. Counter arguments against their inclusion were that the focus of hazard characterization was on adverse health effects only and, while consumers might be exposed to a commensal organism bearing resistance determinants, there would be no adverse health effects without the involvement and the effects of a pathogen.

38. After an extensive discussion, in recognising the complexity of this AMR risk assessment step and in order to ensure a certain level of flexibility in its application, the Task Force agreed to consider the exposure to AMR microorganisms. Therefore, “pathogens” was changed to “AMR microorganisms” in the third sentence of paragraph 36 and the lower boxes in the left and side columns of Figure 2b were amended accordingly. The Task Force also deleted “exposure to” in the transitional box of Figure 2b and maintained the term “pathogens” to avoid confusion that the exposure was limited to pathogens only. The last sentence was deleted as it was a carry-over from the previous version of the document.

Risk characterization

39. The Task Force agreed to amend the fourth bullet of paragraph 41 to indicate that quantitative uncertainty analysis should be based on professional or expert advice and to move the fifth bullet to paragraph 26 as it was more related to “source of information” than to risk characterization.

Consideration of the foodborne AMR risk assessment results

40. The Task Force agreed to the proposal in CRD 6 to:

- Combine paragraph 45 with the first sentence of paragraph 44 and to retain the resulting paragraph as part of the “risk characterization” sub-section; and

- Move sub-section “Consideration of the foodborne AMR risk assessment results” and the second sentence of paragraph 44 in the “Foodborne AMR-Risk management” section after the introductory paragraphs.

Foodborne AMR Risk Management

41. The Task Force discussed the appropriate use of terms “option”, “measures” and “decision” throughout the document. Some delegations suggested that, when risk management options are selected, they should be referred to as “measures” and that “decision” should refer to the measure(s) that has/have been implemented. Others suggested that “decision” should refer to option(s) that has/have been selected and implemented. The Task Force agreed to revise the appropriate use of these terms according to the context in which they appeared in the document.

42. The Task Force deleted the second sentence in paragraph 47, as it was unnecessary, and clarified the last sentence to indicate that risk management decisions should be proportionate to the risk, with the understanding that “decision” implied that measures had been implemented and noting that this wording was accurately reflected in Figure 1. The first sentence was clarified to state that risk managers should consider both non-regulatory measures and regulatory controls.

43. A reference to Good Veterinary Practices (GVP) was added in paragraph 49 to recognise their important role in the AMR risk management and the footnote referencing to the OIE *Terrestrial Animal Health Code* was revised for accuracy.

44. The Task Force amended the proposal in CRD 6 for the paragraph under sub-section “Consideration of the foodborne AMR risk assessment results” by:

- Deleting the initial part of the first sentence as unnecessary; and
- Clarifying that risk managers should consider strengths and weaknesses of the AMR-risk assessment results and were responsible for resolving both impact of uncertainties and assumptions of risk management options described in the risk assessment.

45. In paragraph 53, the reference to “economists” was deleted.

Table 1. Example of Foodborne AMR Risk Management Options

46. The Task Force noted that the majority of the changes proposed by the Working Group were editorial to align sections on food crop production with those on food animal production and that a number of examples of specific risk management options had been deleted.

47. In the sub-section “waste management” of the “Pre-harvest options”, “waste-water” was added to the examples of sources of contamination for which treatment procedures could be developed. To recognise the important role that “waste-water” played as a source of contamination, it was added, throughout the document, when referring to waste sources of contamination.

Evaluation of foodborne AMR-RMOs

48. The Task Force changed “can” to “should” in the second sentence of paragraph 58 to ensure that risk managers consider the existence of alternative options and “individually or in combination” was deleted at the end of the paragraph as unnecessary.

Selection of foodborne AMR-RMOs

49. The first sentence of paragraph 62 and the beginning of the second sentence were deleted as they referred to the establishment of an ALOP (appropriate level of protection) or public health goal, which was covered in the previous sub-section “Evaluation of foodborne AMR-RMOs”. The last two sentences were moved to paragraph 56 (after the first sentence) as they included an example of an ALOP and a reference to the approaches for setting ALOPs.

Implementation of foodborne AMR risk management decision(s)

50. The Task Force changed “option” to “decision” in paragraph 64 for consistency with the revised title of the sub-section. In paragraph 65, “food producers and processors” was changed to “parties involved in the food production chain” for completeness. Good Veterinary (GVP) and good agriculture practices were also

added to the examples of comprehensive approaches of food control systems, which should incorporate risk management measures specific to antimicrobial resistance.

Monitoring and review of foodborne AMR risk management measures

51. For clarity, the fifth bullet in paragraph 66 was amended to "number of human cases (or incidence rates) associated with adverse health effects …" and in paragraph 67 "measured" was changed to "evaluated". In paragraph 68, the Task Force changed "risk mitigation", which was not defined, to "risk management" and agreed to apply this change, where appropriate, throughout the document.

Surveillance of Use of Antimicrobial Agents and AMR Microorganisms and Determinants

52. In paragraph 69 the Task Force deleted the last sentence "The level of detail of data collection could be implemented according to the resources available" as it did not add specific value to the paragraph, which related to the type of data used in surveillance programmes.

53. In paragraph 70, the Task Force amended:

- The first sentence to refer to the need to have, to the extent possible, an internationally harmonised methodology of surveillance programme; and
- The last sentence to clarify that the use of standardised and harmonised methodology and interpretive criteria was to ensure data comparability.

54. The Task Force noted that, in the context of integrated surveillance programmes on the use of antimicrobial agents and antimicrobials resistance, there was a need to consider data from both human and non human use and, therefore, agreed not to specify the source of data in this section.

Foodborne AMR Risk Communication

55. The Task Force agreed to combine paragraphs 74 and 75 in a new paragraph, which emphasised the need to provide all interested parties with a better understanding of risks and risk management approaches and to well document the risk communication strategy.

Foodborne risk communication as a risk management tool

56. The Task Force amended paragraph 77 to refer to the need to provide information on all types of non-human use antimicrobial agents and to refer also to other relevant industries producing these products. Paragraphs 78-82 were revised to make them less prescriptive and to improve their clarity.

Appendix 1. Elements for consideration in a foodborne AMR-Risk Profiles

<u>Description of the AMR food safety issue</u>

57. The Task Force had an extensive discussion on the proposal in CRD 9 to more clearly define the AMR hazard and to distinguish the hazard from the food safety issue. Most delegations supported the changes proposed, while an observer, supported by a delegation, was of the view that reference to AMR hazard should be deleted as the proposal was not in accordance with the general Codex definition for hazard. In this regard, it was recalled that at the previous sessions of the Task Force it had been agreed that an AMR hazard of concern was the AMR microorganism or the AMR determinant and that this approach had been used throughout the document. The importance to differentiate between the hazard and the food safety issue and to illustrate that the food safety issue was a combination of the hazard, the antimicrobial agent and the food commodity was emphasized.

58. The Task Force agreed to amend Section 1, as proposed in CRD 9, and noted that the third bullet should read "the food commodity in which the AMR hazard is identified." Accordingly, paragraph 13 was further amended to more clearly illustrate that the AMR microorganism/determinant referred to the "hazard".

59. The Task Force did not agree with a proposal to delete reference to "use of non-approved antimicrobial agent(s)" in sub-bullet 5 of the second bullet as this information was useful for a risk profile and of interest in some situations where there is known use of non-approved antimicrobial agents, which could cause resistance.

60. The Task Force agreed to change "quality" to "evaluation" in the title of new Section 7 as more appropriate.

Appendix 2. Suggested Elements for Consideration in foodborne AMR-Risk Assessment

1. Hazard identification

61. The Task Force agreed to delete “in food and animal feed” in 1.1 as redundant and agreed to reorder sections 1.2 and 1.3.

62. It was agreed to delete “and/or multiple resistance” in the fourth bullet of 1.3 as this issue was covered by “cross resistance”. It was noted that although “multi resistance” was a term currently used, multi resistance was not defined in the document and this issue might need to be addressed in the future.

2. Exposure Assessment

63. The Task Force agreed to delete “on-farm” in 2.1.

Attributes of antimicrobial agent use at the population level

64. The second bullet was amended to more accurately refer to the “number of farms using the antimicrobial agent(s).”

65. The fourth bullet was amended to read “potential extra-label/off-label use of approved antimicrobial agent(s) and use of non-approved antimicrobial agent(s)” for consistency with other parts of the document.

Attributes of antimicrobial agent use at the individual level

66. The Task Force agreed to more clearly indicate in the third bullet that harvest referred to both animal and crop products and to also apply this change to the first bullet in section “Initial level of contamination of the food product”.

Target animal or crop and microbial factors affecting resistance development and spread

67. The Task Force agreed to:

- Rearrange the fourth bullet to “resistance mechanisms, location and occurrence of AMR determinants and resistance transfer rates between microorganisms”;
- Correct the fifth bullet by replacing “co-selection for resistance” with “co-resistance”. This bullet was further amended by inserting “based on” in lieu of the brackets;
- Delete in the sixth bullet “minimimal inhibitory concentration levels”; and
- Delete “affecting immunity” from the eighth bullet as redundant and insert “factors” to “food crop production/management” for consistency.

Other possible sources of foodborne AMR microorganisms for the target animal/crop

68. It was agreed to refer to feed ingredients in addition to animal feed in the second bullet for consistency with the Codex *Code of Practice on Good Animal Feeding* (CAC/RCP 54-2004). The third bullet was amended to reflect the examples of other sources of foodborne AMR microorganisms for consistency.

Food processing factors

69. The fourth bullet “packaging” was moved before “distribution and storage” to more accurately reflect the food processing steps and “starter cultures (type number of microorganisms) used as ingredients” was deleted as outside the scope of the document.

70. The Task Force did not agree with a proposal to delete “catering and food services” as the role of caterers and food services was relevant in a risk assessment.

Consumer behaviours

71. The heading was changed to “consumer factors” for consistency. The second bullet was amended by inserting “of food” and the fifth bullet by replacing “point” with “place” and “informal” with “elsewhere” for clarity.

2.3 Transfer of hazard and 2.4 Exposure to hazard

72. The Delegation of Canada clarified that sections 2.3 and 2.4 had been deleted as they were already covered in section 2.1 “Pre-harvest factors affecting prevelance of hazard”.

3. Hazard characterization

73. The Task Force considered a proposal to include "increased hospital costs" as an additional element in the section. It was noted that the document should be read in conjunction with other Codex documents and that paragraph 15 specifically referred to additional risk profile elements of the "*Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007), which included "hospital costs" and therefore the proposal was not supported.

74. The Task Force split section 3.2 into two sections (i.e. 3,2 and 3.3) as they were dealing with two separate issues.

4.1 Factors for consideration in risk estimation

75. The Task Force agreed to amend the last bullet to "methods to allow weighted summation of different risk impacts including consequences (e.g. disease and hospitalization)" for clarity.

Appendix 3. Examples of Qualitative foodborne AMR-Risk Assessment

76. In paragraph 2, the text of the second bullet was aligned with the first bullet for clarity

77. The Task Force recalled that the purpose of Appendix 3 was to provide examples of qualitative foodborne AMR-risk assessment and not to provide details on the process of foodborne AMR risk assessment, which were covered in the body of the document. Therefore, it deleted the second and third sentences of paragraph 6, which were already covered in the body and amended the last sentence to better introduce the example of hazard categorization scoring. The bullets were also amended to refer to exposure to "AMR microorganisms".

78. In the section "Illustrative Hazard Characterization Scoring", footnote #26 was amended to refer to the WHO List of Critically Important Antimicrobials in Human Medicine (CIA).

Conclusion

79. The Task Force congratulated all delegations, which had contributed through the four sessions to develop a comprensive guidance document to conduct risk analysis of food antimicrobial resistance for use by governments. It was further noted that, with the completion of the Guidelines, the Task Force had completed the task assigned to it by the Commission.

Status of the draft Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (N01-2008, N02-2008, N03-2008)

80. The Task Force agreed to forward the draft Guidelines to the 34th Session of the Commission for adoption at Step 8 (*see* Appendix II).

OTHER BUSINESS (Agenda Item 5)

81. The Representatives of WHO, FAO and OIE congratulated the Task Force on completion of its rather complex work. The Representative of WHO, speaking on behalf of WHO, FAO and OIE, thanked the Republic of Korea for successfully hosting the sessions of the Task Force and complimented all participants for their active participation and hard work. The Representative pointed out that the Guidelines, once adopted by the Commission in 2011, would provide countries useful guidance on how to identify and manage foodborne antimicrobial resistance in order to attain the goal of minimizing risks to human health and that it was up to countries to implement the Guidelines. She also stressed that it was important for countries to first identify problems associated with foodborne antimicrobial resistance by setting up surveillance programmes.

82. The Delegation of Republic of Korea informed the Task Force that it had been implementing the National Antimicrobial Resistance Safety Management Programme since 2003 and the programme had contributed to decreased use of veterinary antimicrobials in the country. The Delegation stated that the Guidelines would be very useful and expressed its willingness to cooperate with other countries in the implementation.

83. The Delegations of Egypt and Nigeria stated that many developing countries lacked clear strategies in coping with AMR related problems and indicated that any assistance to help create awareness and build capacity would be greatly appreciated.

84. The Representative of FAO informed the Task Force that the Guidelines, once adopted, would be very important and pointed out that bilateral assistance between countries when implementing the Guidelines would be also useful. The Observer from OIE also informed the Task Force that OIE would revise the relevant chapters of the OIE *Animal Terrestrial Health Code* and also to take the Guidelines into account and that OIE would contribute to assist member countries to foster common understanding. The Task Force noted that FAO, WHO and OIE would consider technical support to member countries, especially for those with limited resources, both in the framework of ongoing activities and in response to specific requests.

SUMMARY STATUS OF WORK

SUBJECT MATTER	STEP	ACTION BY:	DOCUMENT REFERENCE (REP11/AMR)
Draft Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (N01-2008, N02-2008, N03-2008)	8	34th CAC	Para. 80 and Appendix II

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Appendix II

DRAFT GUIDELINES FOR RISK ANALYSIS OF FOODBORNE ANTIMICROBIAL RESISTANCE

(N01-2008, N02-2008, N03-2008)

At Step 8 of the Procedure

Table of Contents

LIST OF ACRONYMS USED IN THE DOCUMENT

ALOP	Appropriate Level of Protection
AMR	Antimicrobial Resistance / Antimicrobial Resistant
CAC/GL	Codex Alimentarius Commission / Guidelines
CAC/RCP	Codex Alimentarius Commission / Code of Practice
FAO	Food and Agriculture Organization of the United Nations
FSO	Food Safety Objective
GHP	Good Hygiene Practices
GMP	Good Manufacturing Practices
GVP	Good Veterinary Practices
HACCP	Hazard Analysis and Critical Control Point
MICs	Minimal Inhibitory Concentrations
OIE	World Organisation for Animal Health
PC	Performance Criterion
PO	Performance Objective
RMO	Risk Management Option
WHO	World Health Organization
WTO/SPS	World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures

INTRODUCTION

1. Antimicrobial resistance (AMR; also used for "antimicrobial resistant" in this document) is a major global public health concern and a food safety issue. When pathogens become resistant to antimicrobial agents they can pose a greater human health risk as a result of potential treatment failure, loss of treatment options and increased likelihood and severity of disease. Problems related to AMR are inherently related to antimicrobial use in any environment, including human and non-human uses. The use of antimicrobial agents in food producing animals/crops provides a potentially important risk factor for selection and dissemination of AMR microorganisms and determinants from animals/food crops to humans via the consumption of food.

2. In accordance with Codex principles, risk analysis is an essential tool in assessing the risk to human health from foodborne AMR microorganisms and determining appropriate risk management strategies to control those risks. Over the past decade, there have been significant developments with respect to the use of risk analysis approaches in addressing AMR. A series of FAO/OIE/WHO expert consultations on AMR have led to agreement that foodborne AMR microorganisms are potential microbiological food safety hazards. Consequently, the need for the development of a structured and coordinated approach for AMR risk analysis has been emphasized[1,2,3,4]. WHO/FAO and OIE guidelines on risk analysis provide broad, structured approaches to address the potential public health impact of AMR microorganisms of animal/crop origin via food[5,6]. However, a consolidated framework specific to foodborne AMR risk analysis was considered necessary, due to the biological complexity of AMR, the multidisciplinary aspects of AMR within the entire food production to consumption continuum and the need to identify appropriate risk management strategies.

3. More specifically, these guidelines provide a structured risk analysis framework to address the risks to human health associated with the presence in food and animal feed, including aquaculture, and the transmission through food and animal feed, of AMR microorganisms or determinants linked to non-human use of antimicrobial agents.

4. The initial part of the risk analysis framework consists of a group of tasks collectively referred to as "Preliminary Risk Management Activities", which are carried out by the risk managers. This allows the risk manager to decide what action to take. This may involve the establishment of a risk assessment policy and the commissioning of a risk assessment or another appropriate action. If it is decided to commission a risk assessment, the preliminary risk management activities will provide some of the basic information required by risk assessor undertaking this task. Following parts of the risk analysis framework include the identification, evaluation, selection and implementation of appropriate risk management actions to, if necessary, minimise and contain the identified risk to human health. Risk managers are responsible for verifying that the risk management measures implemented are achieving the intended results, that unintended consequences associated with the measures are limited and that the risk management goals can be achieved. Good communication among risk assessors, managers and interested parties is essential for a transparent and informed risk analysis.

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[1] FAO/OIE/WHO. 2003. First Joint FAO/OIE/WHO Expert Workshop on Non-human Antimicrobial Usage and Antimicrobial Resistance: Scientific assessment, Geneva, Switzerland, 1-5 December 2003. *http://www.who.int/foodsafety/micro/meetings/nov2003/en/*.

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

[3] FAO/OIE/WHO. 2006. Joint FAO/OIE/WHO Expert Meeting on Antimicrobial Use in Aquaculture and Antimicrobial Resistance, Seoul, Republic of Korea, 13-16 June 2006 *ftp://ftp.fao.org/ag/agn/food/aquaculture_rep_13_16june2006.pdf*.

[4] FAO/OIE/WHO. 2008. Joint FAO/WHO/OIE Expert Meeting on Critically Important Antimicrobials Report of the FAO/WHO/OIE Expert meeting, FAO, Rome, Italy, 26–30 November 2007. *ftp://ftp.fao.org/docrep/fao/010/i0204e/i0204e00.pdf*.

[5] FAO/WHO. 2006. Food safety risk analysis: A guide for national safety authorities. (FAO Food and Nutrition Paper 87). *ftp://ftp.fao.org/docrep/fao/009/a0822e/a0822e00.pdf*.

[6] OIE. *Terrestrial Animal Health Code* (Section Veterinary Public Health). *http://www.oie.int/eng/normes/mcode/en_sommaire.htm*

5. These guidelines present components of foodborne AMR risk analysis in a chronological order of the risk analysis process. For better readability, the "Foodborne AMR risk communication" and "Surveillance of use of antimicrobial agents and AMR microorganisms and determinants" sections are placed at the end of the document, recognizing that the activities identified within these sections–are applicable throughout the process.

6. 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 *Code of Hygienic Practice for Meat* (CAC/RCP 58-2005), the *Code of Hygienic Practice for Milk and Milk Prod*ucts (CAC/RCP 57-2004) and the *Code of Hygienic Practice for Eggs and Eggs Products* (CAC/RCP 15-1976). 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[7] and the chapters related to the control of AMR in the OIE *Terrestrial Animal Health Code*[6].

SCOPE

7. The scope of these guidelines is to provide science-based guidance on processes and methodology for risk analysis and its application to foodborne AMR related to non-human use of antimicrobial agents. The guidelines aim to assess the risk to human health associated with the presence in food and animal feed, including aquaculture, and the transmission through food and animal feed, of AMR microorganisms and determinants, to provide advice on appropriate risk management activities to reduce such risk. The guidelines will further address the risk associated with different sectors of antimicrobial agent use such as veterinary applications, plant protection or food processing.

8. As there are existing Codex or internationally recognized guidelines, the following areas related to antimicrobial agents or AMR are outside the scope of this document: residues of antimicrobial agents in food; AMR marker genes in recombinant-DNA plants and recombinant DNA microorganisms[8]; non-genetically modified microorganisms (for example, starter cultures) intentionally added to food with a technological purpose[9]; and certain food ingredients, which could potentially carry AMR genes, such as probiotics[10].

DEFINITIONS

9. The following definitions are included to establish a common understanding of the terms used in this document. The definitions presented in the *Codex Procedural Manual* and the *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CAC/GL 30-1999) are applicable to this document.

Adverse Health Effect – An undesirable or unwanted outcome in humans. In this document, this refers to the human infections caused by AMR microorganisms and determinants in food or acquired from food of animal/crop origin as well as increased frequency of infections and treatment failures, loss of treatment options, and increased severity of infections manifested by prolonged duration of disease, increased hospitalization and mortality[1].

Antimicrobial Agent – Any substance of natural, semi-synthetic, or synthetic origin that at *in vivo* concentrations kills or inhibits the growth of microorganisms by interacting with a specific target[3].

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[7] FAO/WHO. 2008. Animal Feed Impact on Food Safety. Report of the FAO/WHO Expert Meeting FAO Headquarters, Rome 8-12 October 2007. *ftp://ftp.fao.org/docrep/fao/010/a1507e/a1507e00.pdf*.

[8] The food safety assessment on the use of antimicrobial resistance marker genes in recombinant-DNA plants is addressed in the *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* (CAC/GL 45-2003).

[9] The food safety assessment on the use of antimicrobial resistance marker genes in recombinant-DNA microorganisms is addressed in the *Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms* (CAC/GL 46-2003).

[10] The food safety assessment on the use of probiotics in foods is addressed in a Report of a Joint FAO/WHO Working Group on Drafting Guidelines for the Evaluation of Probiotics in Foods (FAO/WHO, 2002).

Antimicrobial Class - Antimicrobial agents with related molecular structures, often with a similar mode of action because of interaction with a similar target and thus subject to similar mechanism of resistance. Variations in the properties of antimicrobial agents within a class often arise as a result of the presence of different molecular substitutions, which confer various intrinsic activities or various patterns of pharmacokinetic and pharmacodynamic properties.

Antimicrobial Resistance (AMR) – The ability of a microorganism to multiply or persist in the presence of an increased level of an antimicrobial agent relative to the susceptible counterpart of the same species[9].

Antimicrobial Resistance Determinant – The genetic element(s) encoding for the ability of microorganisms to withstand the effects of an antimicrobial agent. They are located either chromosomally or extra-chromosomally and may be associated with mobile genetic elements such as plasmids, integrons or transposons, thereby enabling horizontal transmission from resistant to susceptible strains.

Commensal – Microorganisms participating in a symbiotic relationship in which one species derives some benefit while the other is unaffected. Generally, commensal microorganisms are considered to be non-pathogenic in their normal habitat but may, in certain circumstances, become opportunistic pathogens.

Co-Resistance – The ability of a microorganism to multiply or persist in the presence of different classes of antimicrobial agents due to possession of various resistance mechanisms.

Cross-Resistance – The ability of a microorganism to multiply or persist in the presence of other members of a particular class of antimicrobial agents or across different classes due to a shared mechanism of resistance.

Extra- or Off-Label Use – The use of an antimicrobial agent that is not in accordance with the approved product labelling.

Foodborne Pathogen – A pathogen present in food, which may cause human disease(s) or illness through consumption of food contaminated with the pathogen and / or the biological products produced by the pathogen.

Food Producing Animals – Animals raised for the purpose of providing food to humans.

Interpretive Criteria – These are specific values such as minimal inhibitory concentrations (MICs) or inhibition zone diameters on the basis of which bacteria can be assigned to categories of either 'susceptible' , 'intermediate' or 'resistant'.

Pathogen – A microorganism that can cause infection, illness or disease.

Risk Management Option (RMO) – A specific action that could be implemented to mitigate risk at various control points throughout the food production to consumption continuum.

GENERAL PRINCIPLES FOR FOODBORNE AMR RISK ANALYSIS

10. *The Working Principles for Risk Analysis for Food Safety for Application by Governments* (CAC/GL 62-2007) shall apply to all aspects of foodborne AMR risk analysis. General principles specific to foodborne AMR risk analysis are as follows.

Principle 1: Foodborne AMR risk analysis should consider the impact of foodborne AMR on human health as a result of non-human use of antimicrobial agents.

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

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 risk assessment and / or risk management activities.

Principle 4: Foodborne AMR risk analysis should consider national and regional differences in the use of antimicrobial agents, human exposure to and prevalence of foodborne AMR microorganisms and determinants, as well as available risk management options (RMOs).

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 disease resulting from exposure to AMR microorganisms.

Principle 6: Foodborne AMR risk analysis should focus on clearly defined combinations of the food commodity, the AMR microorganism and determinants and the antimicrobial agent(s) to which resistance is expressed. Co-resistance and cross-resistance should be considered in certain situations.

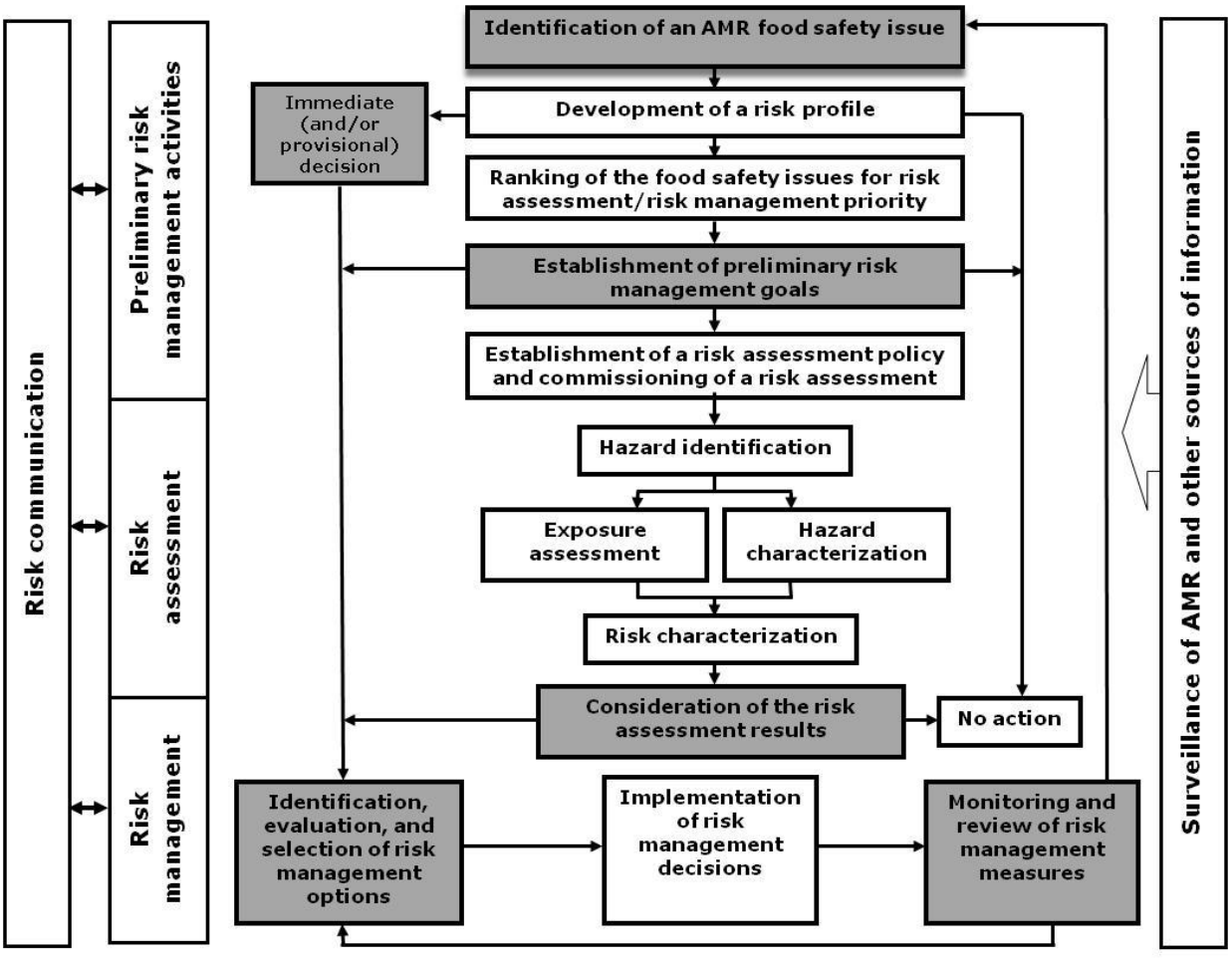
Principle 7: Monitoring and surveillance of the use of antimicrobial agents and prevalence of AMR microorganisms and determinants are critical to evaluating and determining the effectiveness of implemented risk management measures and informing all levels of risk analysis.

Principle 8: Evaluation of pre-harvest foodborne AMR RMOs should include, whenever appropriate, animal health aspects relevant to food safety. Foodborne AMR risk analysis when considering such animal health aspects should take into account relevant OIE standards.

FRAMEWORK FOR FOODBORNE AMR RISK ANALYSIS

11. Figure 1 provides an overview of the framework for foodborne AMR risk analysis as presented in this document. The diagram is intended to aid risk managers by identifying decision points and placing the components of risk analysis in relation to one another, such as: i) sequencing of steps that are included in preliminary risk management activities; ii) steps for conducting risk assessment; iii) the process for identification, evaluation, selection, implementation and monitoring and review of RMOs; and iv) elements and activities used throughout the process, including risk communication and surveillance of the use of antimicrobial agents and AMR. Surveillance, while not a conventional component of risk analysis, is considered integral to each step of the foodborne AMR risk analysis.

Figure 1. Framework for Foodborne AMR Risk Analysis



Note: The boxes in grey highlight the key decision points in the framework of foodborne AMR-risk analysis.

PRELIMINARY FOODBORNE AMR RISK MANAGEMENT ACTIVITIES

12. A potential food safety issue may arise when AMR microorganisms or determinants are present in, and / or transmitted to, humans from food. Foodborne exposure to these AMR microorganisms or determinants may adversely impact human health. The risk manager initiates the risk management process with the preliminary risk management activities to determine the scope and magnitude of the food safety issue and, where necessary, to commence activities to manage the identified risk.

Identification of an AMR food safety issue

13. This is the initial step in which risk managers identify and briefly describe the AMR food safety issue, i.e. the defined combination of the hazard(s) (AMR microorganisms and / or determinant(s)), the antimicrobial agent(s) to which resistance is expressed and the food commodity in which the hazard is identified. AMR food safety issues may be identified on the basis of information arising from a variety of sources, as described in paragraph 26.

Development of a foodborne AMR risk profile

14. The foodborne AMR risk profile is a description of a food safety problem and its context. This risk profile presents, in a concise form, the current state of knowledge related to the food safety issue, describes current control measures and RMOs that have been identified to date and the food safety policy context that will influence further possible actions. It is important to note that the risk profile is a scoping exercise to describe and define the pertinent factors that may influence the risk posed by the hazard. It is not intended to be an abbreviated version of a risk assessment. The risk profile is usually developed by personnel with specific scientific expertise on the food safety issue of concern and understanding of AMR risk assessment techniques. Interested parties who are familiar with the relevant food production chain and related production techniques should be consulted.

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. A list of elements for consideration in a foodborne AMR risk profile is described in Appendix 1 of this document. Additional risk profile elements can be found in The Principles and Guidelines for the Conduct of Microbiological Risk Management [CAC GL/63-2007]. In addition, it is important to consider critically important antimicrobial agent lists developed by international organizations and national/regional authorities (e.g., see Joint FAO/WHO/OIE Expert Meeting on Critically Important Antimicrobials, Rome 2008[11]).

16. Consideration of the information given in the risk profile may result in options leading to a range of initial decisions, such as determining that no further action is needed, commissioning a foodborne AMR risk assessment, establishing additional information gathering pathways or implementing immediate risk mitigation management.

17. 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 make 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 and the timeframe or circumstances under which the provisional decision will be reconsidered (e.g. after the completion of a risk assessment) should be communicated to all interested parties when the decision is initially made.

Ranking of the food safety issues and setting priorities for risk assessment and management

18. Given the potentially high resource costs associated with conducting risk assessments and / or implementing risk management decisions, the AMR risk profile provides the principal resource that should be used by risk managers in risk ranking or prioritization of this AMR food safety issue among numerous other food safety issues.

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[11] WHO List of Critically Important Antimicrobials (CIA) at: www.who.int/foodborne_disease/resistance/cia/en ; OIE List of Antimicrobials of Veterinary Importance at: http://www.oie.int/downld/Antimicrobials/OIE_list_antimicrobials.pdf

19. 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.

Establishment of preliminary risk management goals

20. Following development of the risk profile and the ranking of the AMR food safety issues for risk assessment/risk management priority, risk managers should decide on the preliminary risk management goals that determine the next steps to be taken, if any, to address the identified AMR food safety issue.

Establishment of a risk assessment policy

21. Following a decision as to the need for a risk assessment, risk assessment policy should be established by risk managers in advance of commissioning the risk assessment. The risk assessment policy should be developed 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, the need to address uncertainty and what assumptions to use when the available data are inconsistent or incomplete. Where necessary, risk managers should ask risk assessors to evaluate the potential changes in risk resulting from different RMOs.

Commission a foodborne AMR risk assessment

22. 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 activities.

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

- A description of the specific AMR food safety issue (as defined in the AMR risk profile);
- The scope and purpose of the risk assessment;
- The specific questions to be answered by the risk assessment;
- The preferred type (e.g. quantitative or qualitative) of risk assessment to be conducted;
- The expertise and resources required to carry out the risk assessment; and
- Timelines for milestones and completion of the risk assessment and its review.

FOODBORNE AMR RISK ASSESSMENT

24. The foodborne AMR risk assessment guidelines described in this section provide a transparent science-based approach to identify and assess a chain of events that affect the frequency and amount of AMR microorganisms to which humans are exposed through the consumption of food and to describe the magnitude and severity of the adverse health effects from that exposure. An AMR risk assessment addressing the specific risk to the defined population will examine the load and likelihood of contamination of all foods (domestic and imported) by AMR microorganisms and / or determinants and, to the extent possible, the factors that are relevant and could influence their prevalence in food.

Sources of information

25. Given the fact that multiple data sources are likely to be required for a foodborne AMR risk assessment and that these data can be limited, their strengths, limitations, discrepancies and gaps should be clearly described.

26. Possible sources of information:

- Surveillance programmes (see paragraphs 67-70);
- Epidemiological investigations of outbreaks and sporadic cases associated with AMR microorganisms;
- Clinical studies including case reports on the relevant foodborne infectious disease incidence, primary and secondary transmission, antimicrobial therapy and impacts of resistance on disease frequency and severity;

- National/regional treatment guidelines for foodborne microorganisms, including information on the medical importance of, and potential impacts of, increased resistance in target or other microorganisms to alternative treatments;
- Studies on interaction between microorganisms and their environment through the food production to consumption continuum (e.g. litter, water, faeces and sewage);
- Investigations of the characteristics of AMR microorganisms and determinants (*in vitro* and *in vivo*);
- Research on properties of antimicrobial agents, including their resistance to selection potential (*in vitro* and *in vivo*), and transfer of genetic elements and the dissemination of AMR microorganisms in the environment;
- Studies on the link between resistance, virulence and / or fitness (e.g. survivability or adaptability) of the microorganism;
- Studies on the pharmacokinetics / pharmacodynamics associated with selection of AMR in any given setting;
- Laboratory and / or field animal/crop trials addressing the link between antimicrobial agent usage and resistance (particularly regional data);
- Science-based expert opinion;
- Existing microbiological and AMR risk assessments.

Process of foodborne AMR risk assessment

27. At the beginning of the work, the risk assessor should consider the risk profile, information documented during commissioning the risk assessment and the risk assessment policy. In addition, risk assessors may require a preliminary investigation phase to define and map the work to be undertaken within the framework of the AMR risk assessment.

28. Foodborne AMR risk assessment is composed of hazard identification, exposure assessment, hazard characterization and risk characterization. Details of suggested elements for consideration of each component can be found in Appendix 2. Exposure assessment and hazard characterization can be conducted in parallel (Figure 1).

29. The general principles of a foodborne AMR risk analysis apply equally to both qualitative and quantitative risk assessment. While the design differences may yield different forms of output, both approaches are complementary. The selection of a qualitative or quantitative approach should be made based on the purpose or the type of questions to be answered and data availability for a specific AMR risk assessment. In accordance with the *Working Principles for Risk Analysis for Food Safety for Application by Governments* (CAC/GL 62-2007), quantitative data should be used to the greatest extent possible without discounting the utility of available qualitative information.

Hazard identification

30. The purpose of hazard identification is to describe the foodborne AMR hazard of concern (Appendix 2). Risk assessors should review literature and information from surveillance programmes to identify specific strains or genotypes of foodborne microorganisms that may pose risk~~s~~ by a particular combination of food commodity, AMR microorganism and / or determinants and antimicrobial agents to which resistance is expressed. Additionally, the biology of AMR microorganisms and / or determinants within different environments/niches (e.g. interactions in animal feeds or aquaculture environment as well as in food matrices) and information on the susceptible strains of the same organisms or related AMR microorganisms and / or determinants will be useful. When necessary, science-based opinions on hazard identification can be sought from relevant experts.

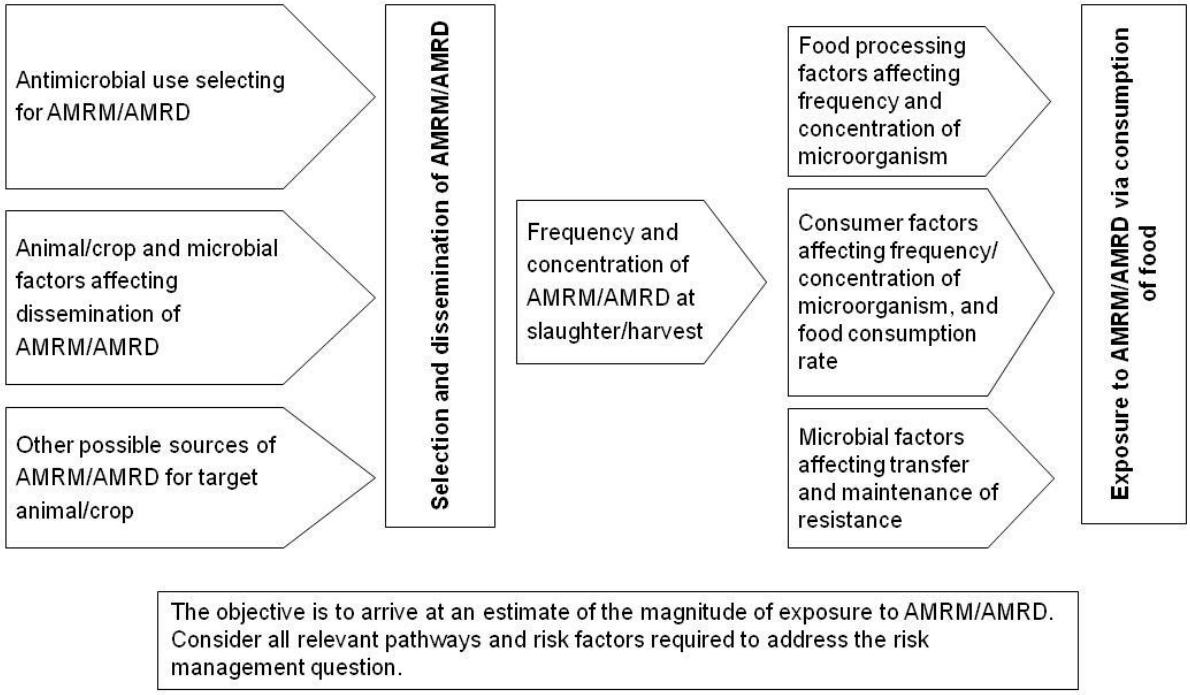
Exposure assessment

31. Use of antimicrobial agents occurs in different agricultural sectors and at different stages of production, including animal feed, food producing animal<u>s</u>, crop production and / or during food processing. Following antimicrobial use, selection of AMR microorganisms and determinants may occur, which then could be disseminated between these sectors, such as between animal feed and food producing animals, or

food producing animals' waste being spread on crops, etc. Other risk/preventive factors may affect either selection or dissemination of resistance.

32. The fundamental activities in exposure assessment should include: (a) clear depiction or drawing of the exposure pathway; (b) detailing the necessary data requirements based on the pathway; and (c) summarising the data. Considerations related to exposure assessment are illustrated in Figure 2a[12].

Figure 2a. Considerations for Exposure Assessment in a Foodborne AMR Risk Assessment – the Exposure Pathway



AMRM = antimicrobial resistant microorganism; AMRD = antimicrobial resistance determinant

33. Section 2.1 of Appendix 2 includes suggested pre-harvest factors for estimating the likelihood of selection and dissemination of resistance within animal or crop populations. A possible output from the pre-harvest component of exposure assessment is an estimate or probability of the influence of the use of antimicrobial agents on the prevalence of AMR microorganisms and / or determinants in the target animals or crops. Section 2.2 of Appendix 2 considers possible post-harvest factors related to the human exposure to food containing AMR microorganisms and / or determinants. A possible output from the post-harvest component of exposure assessment is an estimate of the likelihood and level of contamination of the food product with resistant microorganisms at the time of consumption.

34. When the hazard of interest is AMR determinants alone, including in commensal microorganisms, then an exposure assessment should consider whether these AMR determinants can transfer to human pathogens that subsequently become resistant. Assessment of the exposure through animal feed should also consider resistance selection in microorganisms present in animal feed due to exposure to in-feed antimicrobial agents and their transmission to food producing animals, including aquaculture species (refer to the *Code of Practice on Good Animal Feeding* - CAC/RCP 54-2004). Particular environmental reservoirs of AMR determinants may need to be considered in the foodborne AMR risk assessment.

[12] The exposure assessment covers the release and exposure assessments of the OIE risk assessment scheme (OIE. *Terrestrial Animal Health Code* (Risk assessment for AMR arising from the use of antimicrobials in animals)).

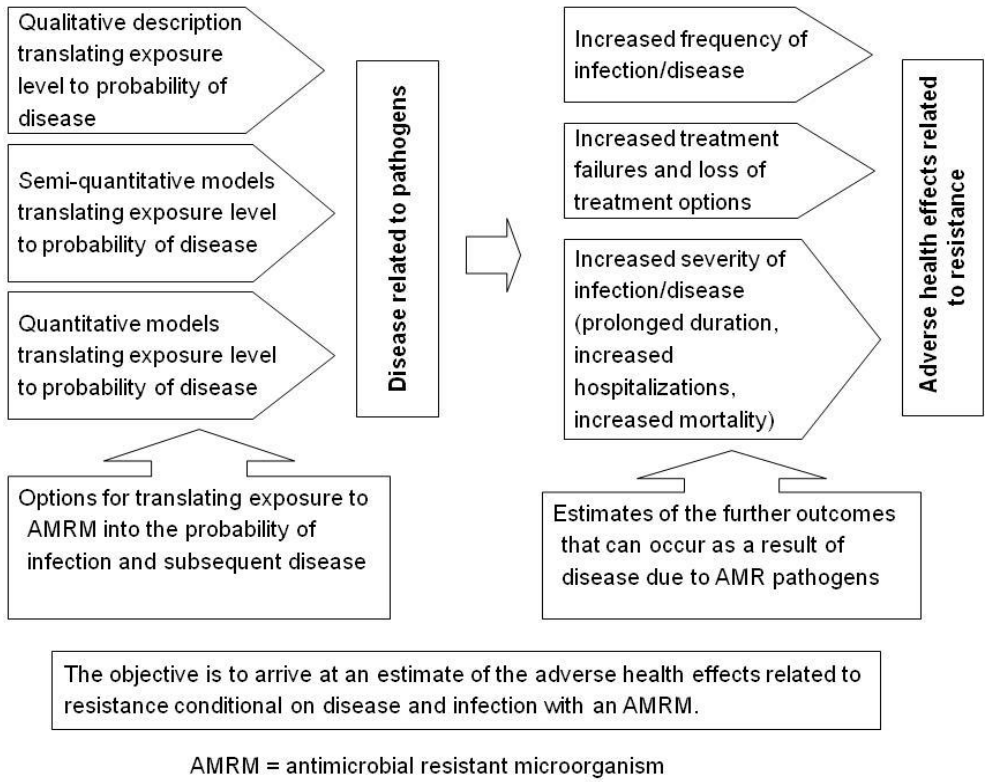
Hazard characterization

35. Hazard characterization step considers the characteristics of the hazard, food matrix and host in order to determine the probability of disease in humans upon exposure to the hazard. A foodborne AMR 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, such as increased frequency and severity of disease. Possible factors that can have an impact on the hazard characterization are included in Section 3 of Appendix 2.

36. The output from the hazard characterization, including the dose-response relationship where available, assists in translating levels of exposure to a likelihood of an array of adverse health effects or outcomes. The approach for conducting hazard characterization will be guided by the risk question(s) and the risk manager's needs. Figure 2b includes examples of different options (e.g. qualitative descriptions, semi-quantitative and quantitative models) that could be used to link exposure to AMR microorganisms to infection and subsequent disease, and depicts the further adverse health effects caused by an AMR pathogen.

37. Determining the number of cases with a particular foodborne disease based on exposure is similar to non-AMR microbiological risk assessment, except that potential increased virulence of resistant microorganisms and selection effects in patients treated with the antimicrobial agents of concern should be incorporated into the assessment. The risk outcome in an AMR risk assessment, like microbiological risk assessments will focus on diseases except, in this case, the focus is specifically on disease attributed to resistant microorganisms. The risk outcome considers the subsequent risk of treatment failure or other complications as a result of infection from microorganisms that have acquired resistance. It should also be noted that hazard characterization for AMR microorganisms and determinants, when appropriate, may be informed by hazard characterization for non-AMR microorganisms. Thus, compared to a non-AMR hazard characterization, these outcomes can be a series of additional consequences that occur following the initiating infection event. The hazard characterization step estimates the probability of infection and then, conditional to this event, the probability of disease. The other consequences that occur because infection is from a resistant microorganism are additional conditional probabilities, as disease is conditional on infection.

Figure 2b. Considerations for Hazard Characterization in a Foodborne AMR Risk Assessment



AMRM = antimicrobial resistant microorganism

Risk characterization

38. Risk characterization considers the key findings from the hazard identification, exposure assessment and hazard characterization to estimate the risk. The form that the risk characterization takes and the outputs it produces will vary from assessment to assessment as a function of the risk management request. This section provides guidance on the general types of outputs that may be informative in the risk characterization but specific outputs may need to be established at the onset of the assessment process based on the risk question(s) and the risk manager's needs. Suggested elements for risk characterization are included in Section 4 of Appendix 2.

39. Additional outputs of risk characterization, which would have been defined in the purpose of an AMR risk assessment, may include scientific evaluation of RMOs within the context of the risk assessment[13].

40. The adverse human health effects of concern in a foodborne AMR risk assessment encompass the severity and likelihood of the human infections associated with the resistant microorganisms. The risk estimate may be expressed by multiple risk measures, for example in terms of individual risk, population (including relevant subgroups) risk**,** per-meal risk or annual risk based on consumption. Health effects may be translated into burden of disease measurements. The selection of the final risk measures should generally have been defined within the purpose of the foodborne AMR risk assessment, during the commissioning of the AMR risk assessment, in order to determine the appropriate exposure assessment and hazard characterization outcomes for risk characterization

41. Other elements to consider in association with risk characterization, depending upon the purpose of the risk assessment and the details necessary to adequately characterize the risk, are:

- Sensitive sub-populations (i.e. human populations with special vulnerability) and whether the potential risks/exposures/health impacts are adequately characterized;
- Key scientific assumptions used (stated in clear and readily understandable language) and their impact on the assessment's validity;
- 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 steps[14]. 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 through professional and / or expert advice. 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 also can be used to evaluate the importance of model input uncertainties in terms of their relative contributions to uncertainty in the model outputs;
- Strengths and weaknesses/limitations of the risk assessment – what parts are more or less robust. Particularly for a complex issue such as the risk posed by AMR microorganisms, discussion of the robustness of data used, i.e. weight of evidence, will enhance the credibility of the assessment. Weaknesses linked to the limited number of microbial species considered or for which resistance data are available should be made clear;
- Alternatives to be considered, i.e. to what extent are there plausible alternatives or other opinions? Does the AMR risk assessment adequately address the questions formulated at the outset of the work? What confidence do the assessors have about whether the conclusions can be relied upon for making decisions?;
- Key conclusions as well as important data gaps and research needs.

42. Appendix 3 provides examples of the outputs from a qualitative foodborne AMR risk assessment. This appendix is not intended to imply that a qualitative AMR risk assessment is the preferred approach but

[13] FAO/WHO. 2006. The use of microbial risk assessment outputs to develop practical risk management strategies: metrics to improve food safety. Report, Kiel, Germany, 3-7 April, 2006. *ftp://ftp.fao.org/ag/agn/food/kiel.pdf*.

[14] FAO/WHO. 1999. *Principles and guidelines for the conduct of microbiological risk assessment* (CAC/GL 30-1999).

merely to illustrate ways in which qualitative findings can be presented. Quantitative risk assessments can be divided into two types, deterministic or probabilistic, which will have different forms of output[13].

43. The AMR risk assessment may also identify areas of research needed to fill key gaps in scientific knowledge on a particular risk or risks associated with a given combination of the food commodity(ies), the AMR microorganism(s) and / or determinant(s) and antimicrobial agent(s) to which resistance is expressed. 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.

FOODBORNE AMR RISK MANAGEMENT

44. The purpose of this section of the guidelines is to provide advice to risk managers on approaches to manage the risk of foodborne AMR microorganisms and / or determinants linked to the non-human use of antimicrobial agents.

45. Risk managers should consider both non-regulatory measures and regulatory controls. Risk management decisions should be proportionate to the level of risk, whether an intervention is a single RMO or a combination of RMOs.

46. Once a decision has been made to take action, RMOs should be identified, evaluated, selected, implemented, monitored and reviewed, with adjustments made when necessary.

47. It is implicit in the recommended approach to AMR risk management that good agricultural practices, Good Veterinary Practices (GVP) and Good Hygienic Practices (GHP) should be in place along the food production to consumption continuum and that relevant Codex codes of practices are implemented as fully as possible:

- *Code of Practice to Minimize and Contain Antimicrobial Resistance* (CAC/RCP 61- 2005);
- *Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals* (CAC/GL 71-2009);
- *Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007);
- *Code of Practice on Good Animal Feeding* (CAC/RCP 54-2004);
- *Recommended International Code of Practice General Principles of Food Hygiene* (CAC/RCP 1-1969);
- *Code of Hygienic Practice for Meat* (CAC/RCP 58-2005);
- *Code of Hygienic Practice for Milk and Milk Products* (CAC/RCP 57-2004);
- *Code of Hygienic Practice for Eggs and Eggs Products* (CAC/RCP 15-1976);
- *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CAC/RCP 53-2003);
- *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997).

48. Additionally, relevant sections of the OIE *Terrestrial Animal Health* Code[6], the FAO *Responsible Use of Antibiotics in Aquaculture*[15] and the WHO *Global Principles for the Containment of Antimicrobial Resistance in Animals Intended for Food*[16] should be consulted.

[15] FAO. 2005. Responsible Use of Antibiotics in Aquaculture. *ftp://ftp.fao.org/docrep/fao/009/a0282e/a0282e00.pdf*.
[16] WHO. 2000. WHO Global Principles for the Containment of Antimicrobial Resistance in Animals Intended for Food. *http://whqlibdoc.who.int/hq/2000/who_cds_csr_aph_2000.4.pdf*.

Consideration of the foodborne AMR risk assessment results

49. The risk manager should consider the strengths and weaknesses of foodborne AMR risk assessment results. The responsibility for resolving the impact of uncertainties and assumptions described in the risk assessment lies with the risk manager and not with the risk assessors.

Identification of foodborne AMR RMOs

50. Risk managers when identifying RMOs to control an AMR food safety issue should consider a range of points along the food production to consumption continuum, both in the pre-harvest and post-harvest stages, where control measures may be implemented and the interested parties, who have responsibility to implement such measures. 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 for more detailed evaluation.

51. To identify RMOs to address an AMR food safety issue, risk managers should ensure the previously listed Codex Codes of Practice, OIE and WHO documents are considered (paragraphs 47 and 48), as they may contain sources of RMOs that can be adapted to a particular AMR food safety issue. In certain instances, the RMOs therein may pertain only to specific commodities or circumstances in the food production to consumption continuum. Their applicability to foodborne AMR risks should be considered by risk managers as they may identify points at which foodborne microbiological hazards can be controlled, including those that potentially contribute to the selection and dissemination of AMR microorganisms and determinants.

52. Risk assessors, scientists, food policy analysts and other interested parties play important roles in identifying RMOs based on their expertise and knowledge. Specific RMOs may also be identified or developed during the process of constructing a risk profile and / or risk assessment.

53. The potential to combine one or more RMOs or integrate them into a comprehensive food safety approach, based on a generic system such as HACCP,[17] should be considered.

54. 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. The table is divided into pre-harvest RMOs, which include measures to reduce the risk related to the selection and dissemination of foodborne AMR microorganisms and / or determinants and post-harvest RMOs, which include measures to minimize the contamination of food by AMR microorganisms and / or determinants.

Table 1. Examples of Foodborne AMR Risk Management Options

PRE-HARVEST OPTIONS	
Animal feed production	Implement programmes to minimize the presence in feed and feed ingredients of AMR microorganisms and / or determinants and the transmission of these through feed. Prohibit or restrict the addition of feed ingredients containing AMR microorganisms and / or determinants identified as contributing to a specific food safety problem.
Food animal production	**Examples of regulatory controls on conditions of use of veterinary antimicrobial agents and additives:** • Marketing status limitation; • Restrict extra-/off-label use; • Extent of use limitation; • Major label restriction; and • Withdrawal of the marketing authorization.

[17] Hazard Analysis and Critical Control Points (HACCP) – A system which identifies, evaluates, and controls hazards which are significant for food safety.

	Examples of non-regulatory controls on condition of use of veterinary antimicrobial agents and additives: Develop and implement national or regional treatment guidelines[18] targeting a specific AMR food safety issue. Develop and regularly update antimicrobial responsible use guidelines[19] written by professional bodies or internationally recognized entities, such as OIE. Promote use of and improve availability, speed, and accuracy of diagnostic microbiological tests. Disseminate and use international standards for: • Bacterial culture and antimicrobial susceptibility testing[20]; and • Interpretive criteria. Implement biosecurity and animal health and infection control programmes to minimize the presence and transmission of foodborne AMR microorganisms and / or determinants between animals, to/from animals to humans and between flocks/herds.
Food crop production	**Examples of regulatory controls on conditions of use of antimicrobial agents on crops:** • Pre-market assessment and approval; • Marketing status limitation,; • Restrict extra-/off-label use; • Extent of use limitation; • Limit use to conditions when crops are known to be at risk of developing disease; and • Withdrawal of the marketing authorization. Evaluate the safety of viable microorganisms used in food and feed crop production for their potential to introduce and spread AMR. **Examples of non-regulatory controls of use:** Implement the use of alternative strategies for specific diseases: • Substitution of use of antimicrobial agent with non-antimicrobial treatments (chemical and non-chemical) and, if not feasible, use antimicrobial agents in combination with alternative treatments[21]; • Treating only specific developmental stages where the treatment is likely to be most effective, rather than treating at all developmental stages.

[18] National/Regional Treatment Guidelines (non-regulatory control) – An animal or crop species-specific guideline developed to address a specific disease or infection and could be implemented as a voluntary step prior to regulatory controls such as withdrawing an antimicrobial drug or making significant label restrictions.

[19] Responsible Use Guidelines – Judicious use, responsible use, and prudent use guidelines are all documents that contain broad principles with respect to the administration of antimicrobials; some may be species-specific. For the purposes of this document, these guidelines will be referred to as responsible use guidelines. Guidance on Responsible Use can be found, e.g. in the *Code of Practice to Minimize and Contain Antimicrobial Resistance* (CAC/RCP 61-2005) and OIE *Terrestrial Animal Health Code* (Section Veterinary Public Health). *http://www.oie.int/eng/normes/mcode/en_sommaire.htm*.

[20] OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (Laboratory Methodologies for Bacterial Antimicrobial Susceptibility Testing)

[21] While the use of alternative treatments and those targeting specific developmental stages could be considered a non-regulatory option, the treatment products (chemical or non-chemical) are likely to require approval from regulatory authorities.

	Development and implementation of national or regional treatment guidelines targeting a specific AMR food safety issue. Promote the use of and improve availability, speed and accuracy of diagnostic microbiological tests. Develop, disseminate and use international standards for: • Bacterial culture and antimicrobial susceptibility testing; and • Interpretive criteria. Implement biosecurity and infection control programmes to prevent the presence and transmission of foodborne AMR microorganisms and determinants between crops and from crops to humans.
Waste management	Implement control measures to limit the spread of AMR microorganisms and / or determinants through other sources of contamination, by assuring the appropriate use of human and animal waste (biosolids, waste-water, manure, other waste-based fertilizers) in fields for food and animal feed production: Design treatment procedures to control AMR microorganisms and / or antimicrobial agents that could lead to their emergence in biosolids, waste-water, manure and other waste-based fertilizers identified as contributing to a specific food safety problem.
POST-HARVEST OPTIONS	
	Prevent food containing AMR microorganisms from reaching the consumer when identified as constituting a risk to public health that requires urgent action. If already placed in the market, it may be appropriate to withdraw such food on the market for reprocessing or destruction. Develop and check compliance with microbiological criteria, which define the acceptability of a product or a food lot in accordance with *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997) and regulate action to be taken in cases of non-compliance at the level of: • Sorting; • Reprocessing; • Rejection; and • Further investigation.

Evaluation of foodborne AMR RMOs

55. 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[22] or a public health goal. For AMR, an example of an ALOP might be a specific target for the incidence of cases of resistant foodborne infectious diseases. A variety of approaches to setting ALOPs or public health goals are described in FAO Food and Nutrition Paper 87 "*Food Safety risk analysis – A guide for national food safety authorities*"[5]. The process by which options are evaluated may vary depending on the specific RMOs and their impact on different control points in the food production to consumption continuum. The option of not taking any action should also be evaluated.

[22] Appropriate Level of Protection (ALOP) – The level of protection deemed as appropriate by the member establishing sanitary and phytosanitary measures to protect human, animal, or plant life or health within its territory (World Trade Organization, Agreement on the Application of Sanitary and Phytosanitary Measures (WTO SPS).

56. In the ideal situation, the following information should be available for evaluating individual or combinations of possible RMOs. Risk managers may ask risk assessors to develop this information as part of the risk assessment:

- Estimates of risk that would result from application of different risk management measures (either singly or in combination), expressed either qualitatively or quantitatively.
- Technical information on the feasibility and practicality of implementing different options.
- Tools and resources to verify the correct implementation of the RMOs.

57. Any positive or negative impacts of RMOs on public health should be considered when evaluating RMOs. Risk managers should also consider whether alternatives exist, such as alternative antimicrobial agents, non-antimicrobial treatments or changes in livestock husbandry or food production practices. RMOs describing alternatives to using an antimicrobial agent should always be considered.

58. 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 select co-resistance to an antimicrobial agent critically important to human health.

59. Food safety approaches/systems, such as HACCP, include the concept of risk-based targets for control of hazards at particular steps in the food production chain. An ability to develop specific quantitative food safety metrics, such as food safety objective (FSO), performance objective (PO) and performance criterion (PC), will assist in evaluating RMOs.

60. RMOs for AMR should be evaluated based on their impact on the specific combination of the food commodity, the AMR microorganism and / or determinants and the antimicrobial agents to which resistance is expressed at a given control point in the entire food production to consumption continuum. Depending on the nature of the specific hazard, the RMO may be more or less effective at meeting a designated PO or FSO. The relative contribution of RMOs toward achieving a given FSO will provide criteria for risk managers to use when selecting RMOs.

Selection of foodborne AMR RMOs

61. Information obtained from the evaluation of RMOs (relative to the specific combination of the food commodity, the AMR microorganisms and / or determinants and the antimicrobial agent(s) to which resistance is expressed) can be used to determine the most efficient approach to achieving the desired goal or ALOP.

62. An important means of reducing human exposure to AMR microorganisms through the entire food production to consumption continuum is to ensure, as far as possible, that good hygienic practice and HACCP are being followed (*Codex Recommended International Code of Practice – General Principles of Food Hygiene* – CAC/RCP 1-1969). Over and above what can be put in place as good hygienic practice, specific RMOs can address AMR issues.

Implementation of foodborne AMR risk management decision(s)

63. Risk managers should develop an implementation plan that describes how the decisions will be implemented, by whom and when. National/regional authorities should ensure an appropriate regulatory framework and infrastructure.

64. To effectively execute food safety control measures parties involved in the food production chain generally implement complete food control systems using comprehensive approaches such as good agricultural practices, Good Veterinary Practices (GVP), Good Manufacturing Practices (GMP), Good Hygiene Practices (GHP) and HACCP systems. These approaches should be expanded to incorporate risk management measures specific to foodborne AMR.

Monitoring and review of foodborne AMR risk management measures

65. Risk managers should establish a process to monitor and review whether the risk management measures have been properly implemented and whether or not an outcome has been successful. This should also include the monitoring and review of provisional decisions. Effectiveness of the risk management measures should be evaluated against specific food safety metrics, the ALOP and / or public health goals. Possible end points include:

- Prevalence of foodborne AMR microorganisms and / or determinants at farm level;
- Prevalence of foodborne AMR microorganisms and / or determinants in food products at slaughter/harvest;
- Prevalence of foodborne AMR microorganisms and / or determinants in food products at retail level;
- Prevalence of foodborne AMR microorganisms and / or determinants in human clinical isolates.;
- Number of human cases (or incidence rates) associated with 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 mortality) attributable to foodborne AMR microorganisms and / or determinants;
- Trends in non-human use of antimicrobial agents, including critically-important antimicrobial agents.

66. National surveillance programmes, designed to monitor the presence of AMR microorganisms and the use of antimicrobial agents, can help establish a baseline against which the effectiveness of risk management measures can be evaluated.

67. Monitoring/control points related to implemented risk management decisions should be measured to assess the effectiveness and need for potential adjustment. Additional monitoring/control points may be measured to identify new information on the specific food safety issue. Risk managers are responsible for verifying the effectiveness and appropriateness of the risk management measures and for monitoring potential unintended consequences.

SURVEILLANCE OF USE OF ANTIMICROBIAL AGENTS AND AMR MICROORGANISMS AND DETERMINANTS

68. Surveillance programmes on the use of antimicrobial agents and prevalence of foodborne AMR provide information including baseline data that is useful for all parts of the risk analysis process. Data can be used to explore potential relationships between antimicrobial agent use and the prevalence of AMR microorganisms in humans, food producing animals, crops, food, feed, feed ingredients and biosolids, waste-water, manure and other waste-based fertilisers, as input for risk profiling and risk assessment, to measure the effect of interventions and to identify trends.

69. Methodology of surveillance programmes should be internationally harmonized to the extent possible. The use of standardized and validated antimicrobial susceptibility testing methods and harmonised interpretive criteria are essential to ensure that data are comparable.

70. Surveillance of use of antimicrobial agents should, to the extent possible, include all antimicrobial agents used in food producing animal and crop production. Ideally, such surveillance should provide data per animal species or crop. National/regional authorities may use guidelines such as those described in the OIE *Terrestrial Animal Health Code*, "Monitoring of the quantities of antimicrobial agents used in animal husbandry" and relevant WHO guidance.

71. Surveillance of AMR in microorganisms originating from food producing animals, crops and food should ideally be integrated with programmes that monitor resistance in humans. Consideration may also be given to inclusion of animal feed, feed ingredients and biosolids, waste-water, manure and other waste-based fertilisers in such programmes. National/regional authorities may use established guidelines such as those published in the OIE *Terrestrial Animal Health Code* "Harmonisation of national AMR surveillance and monitoring programmes" and relevant WHO guidance to describe key elements of programmes to monitor the prevalence of foodborne AMR microorganisms in animals.

FOODBORNE AMR RISK COMMUNICATION

72. 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.

73. Communication with all interested parties should be promoted at the earliest opportunity and integrated into all phases of a risk analysis (see Figure 1). . This will provide all interested parties, including risk managers, with a better understanding of risks and risk management approaches. Risk communication should be also well documented.

74. Mechanisms may be established for engaging interested parties routinely in food safety decision-making at the national/regional level. For foodborne AMR risk analysis, communication should bring industry (producer, food processor, pharmaceutical, etc.), consumer representatives, government officials and other interested parties (public health experts, medical professionals, etc) together to discuss problems, priorities and strategies.

Foodborne AMR Risk Communication as a Risk Management Tool

75. Information on antimicrobial agents should be made available by the pharmaceutical or other relevant industries in the form of labelling, data sheets or leaflets to ensure the safe and effective use of antimicrobial agents, in compliance with national regulations.

76. The food industry is responsible for developing and applying food safety control systems for effective implementation of risk management decisions. Depending on the nature of the decision, this may require risk communication activities, such as effective communication across the entire food supply chain, including consumers as appropriate, and training or instruction of its staff and internal communication.

77. Guideline documents, training programmes, technical bulletins and other information developed by industry (pharmaceutical, food producer, food processor, etc.) associations may assist to decrease foodborne AMR.

78. Training involving all the relevant professional organizations, regulatory authorities, the pharmaceutical and other relevant industries, veterinary sectors, research institutes, professional associations and other approved users is of importance to ensure consumer safety and, therefore, the protection of public health.

79. Public education programmes, appropriate labelling and public interest messages are important tools to enable consumers to limit their health risks by following food safety-related instructions. Consumer organizations play a significant role in communicating this information to consumers.

80. Where risk management measure include consumer information outreach programmes are often required, for example, by enlisting health care providers in disseminating the information. Messages aimed to inform and engage specific audiences need to be presented in appropriate media.

APPENDIX 1. ELEMENTS FOR CONSIDERATION IN A FOODBORNE AMR RISK PROFILE

The objective of a **foodborne** AMR risk profile is to present prerequisite scientific information on the identified food safety issue to inform risk managers prior to decision-making. A risk profile should be 'fit for purpose' and in some situations will be an elemental exercise**.** This list is provided for illustration and is not intended to be exhaustive and not all elements may be applicable in all situations. The risk profile should incorporate, to the extent possible, information on the following:

1. Description of the AMR food safety issue

The AMR food safety issue is a defined combination of:

- AMR hazard(s) of concern i.e. the AMR microorganism(s) and / or determinant(s);
- The antimicrobial agent(s) to which resistance is expressed.
- The food commodity in which the AMR hazard(s) is identified.

2. Information on AMR microorganism(s) and / or determinant(s)

- Characteristics of the identified foodborne microorganism(s)
  - Sources and transmission routes
  - Pathogenicity of particular strains
  - Growth and survivability of foodborne AMR microoganism(s) in the food commodity production to consumption continuum
  - Virulence and linkages to resistance
  - Inactivation in foods (e.g. D-value, minimum pH for growth, etc.)
  - Distribution, frequency and concentrations of the AMR hazard(s) in the food chain.
- Characteristics of the resistance expressed by the AMR microorganism(s) and / or determinant(s)
  - Resistance mechanisms and location of AMR determinants
  - Cross-resistance and / or co-resistance to other antimicrobial agents
  - Transferability of resistance determinants between microorganisms.

3. Information on the antimicrobial agent(s) to which resistance is expressed

- Class of the antimicrobial agent(s)
- Non-human uses of the antimicrobial agent(s)
  - Formulation of the antimicrobial agent(s)
  - Distribution, cost and availability of the antimicrobial agent
  - Purpose and use of antimicrobial agent(s) in feed, food animals, crop production and / or during food processing
  - Methods, routes of administration of the antimicrobial agent(s) (individual/mass medication, local/systemic application) and frequency
  - Potential extra-label/off-label, use of approved antimicrobial agent(s) and use of non-approved antimicrobial agent(s)
  - Potential role of cross-resistance or co-resistance with use of other antimicrobial agent(s) in food production
  - Trends in the use of the antimicrobial agent(s) in the agricultural and aquaculture sectors and information on emerging resistance in the food supply
  - Information on the relationship between the use of the antimicrobial agent(s) and the occurrence of AMR microorganisms or determinants in the food commodity of concern.
- Human uses of the antimicrobial agent(s)
  - Spectrum of activity and indications for treatment

- Importance of the antimicrobial agent(s) including consideration of critically important antimicrobial lists
- Distribution, cost and availability
- Availability of alternative antimicrobial agent(s)
- Trends in the use of the antimicrobial agent(s) in humans and information on emerging diseases due to microorganism(s) resistant to the antimicrobial agent(s) or classes.

4. Information on food commodity(ies)

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

5. Information on adverse public health effects

- Characteristics of the disease caused by the identified foodborne AMR microorganism(s) or by pathogens that have acquired resistance determinants via food
  - Trends in AMR foodborne disease
  - Frequency and 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(s)
  - Additional information on the relationship between the presence of the AMR microorganisms or determinants in the food commodity and the occurrence of the adverse health effect(s) in humans.
- 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

6. Risk management information

- Identification of 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 microorganism(s)
  - Measures to minimize the contamination and cross-contamination of food by AMR microorganism(s)
- Effectiveness of current management practices in place based on surveillance data or other sources of information.

7. Evaluation 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. SUGGESTED ELEMENTS FOR CONSIDERATION IN A FOODBORNE AMR RISK ASSESSMENT

This appendix lists suggested elements to include in an AMR risk assessment; the level of details of the data may vary on a case-to-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.

1. Hazard Identification

1.1 Identification of hazard of concern: foodborne AMR microorganisms and / or determinants

1.2 Microorganisms and resistance related information

- Potential human pathogens (phenotypic and genotypic characterization) that are likely to acquired resistance in non-human hosts
- Commensals with AMR determinants (phenotypic and genotypic characterization) and the ability to transfer them to human pathogens
- Mechanisms of AMR, location of AMR determinants, frequency of transfer and prevalence among human and non-human microflora
- Co- and cross-resistance and importance of other antimicrobial agents whose efficacy is likely to be compromised
- Pathogenicity, virulence and their linkage to resistance

1.3 The antimicrobial agent and its properties

- Description of the antimicrobial agent – name, formulation, etc.
- Class of antimicrobial agent
- Mode of action and spectrum of activity
- Pharmacokinetics of the antimicrobial agent
- Existing or potential human and non-human uses of the antimicrobial agents and related drugs

2. Exposure Assessment

2.1 Pre-harvest factors affecting prevalence of hazard

- Resistance selection pressure:
  - Attributes of antimicrobial agent use at the population level:
    - Number of animals or extent of crops exposed to the antimicrobial agent in the defined time period
    - Geographical distribution of antimicrobial agent use and / or number of farms using the antimicrobial agent
    - Prevalence of infection/disease that the antimicrobial agent is indicated for in the target (animal/crop) population
    - Potential extra-label/off-label and use of approved antimicrobial agent(s) and use of non-approved antimicrobial agent(s)
    - Data on trends in antimicrobial agent use and information on emerging diseases, changes in farm production system or other changes that are likely to impact antimicrobial agent use
  - Attributes of antimicrobial agent use at the individual level
    - Methods and routes of administration of the antimicrobial agent (individual/mass medication, local/systemic application)
    - Dosing regimen and duration of use

        - Pharmacokinetics and pharmacodynamics in animals
        - Time from antimicrobial agent administration to harvest of animal or crop products
        - Cumulative effects of use of other antimicrobial agents in the defined time period
    - Target animal or crop and microbial factors affecting resistance development and spread
        - Temporal and seasonal changes in foodborne AMR microorganism prevalence
        - Duration of infection/shedding of foodborne AMR microorganism(s) (zoonotic and / or commensal)
        - Rate of resistance development in commensal and zoonotic microorganisms in targets after administration of an antimicrobial agent
        - Resistance mechanisms, location of and occurrence of AMR determinants and resistance transfer rates between microorganisms
        - Cross-resistance and / or co-resistance to other antimicrobial agents based on phenotypic or genotypic characterization
        - Prevalence of commensals and zoonotic microorganisms in targets and proportion resistant to the antimicrobial agent
        - Transmission of AMR microorganisms and / or determinants between target animals/crops and from animals/crops to environment and back to target animals/crops
        - Animal management factors
        - Food crop production/management factors
    - Other possible sources of foodborne AMR microorganisms for the target animal/crop
        - Non-target animal/plant species
        - Animal feed and feed ingredients
        - Soil, water, animal and human waste products (biosolids, waste-water, manure and other waste-based fertilizers)

2.2 Post harvest factors affecting frequency and concentration of the AMR microorganism in food

- Initial level of contamination of the food product
    - Frequency and concentration of foodborne AMR microorganisms and / or determinants at harvest of animal or crop products
    - Frequency and concentration of foodborne AMR microorganisms and / or determinants present in retail food
    - Food matrix factors (food product formulation)
- Food processing factors
    - The level of sanitation and process control in food processing and likely environmental contamination
    - Methods of processing (including sanitation and process controls such as GMP, GHP and HACCP)
    - Cross-contamination points
    - Probable use of additives and preservatives (due to their activities or impacts on growth or numbers of microorganisms)
    - Packaging
    - Distribution and storage
    - Catering and food services

- Consumer factors
  - Human demographic data
  - Storage, cooking and handling of food
  - Overall human per capita consumption of the food identified with the hazard
  - Patterns of consumption and socio-economic, cultural, ethnic and regional differences
  - Place of food consumption (home, commercial establishment or elsewhere)
- Microbial factors
  - Capacity of food-derived AMR microorganisms to transfer resistance to human commensal and / or pathogenic microorganisms
  - Growth and survival characteristics and fate of AMR microorganisms along the food production to consumption continuum
  - Microbial ecology of food: survival capacity and redistribution of foodborne AMR microorganism in the food production to consumption continuum

3. Hazard Characterization

3.1 Human host and adverse health effects

- Host factors and susceptible population
- Nature of the infection, disease
- Diagnostic aspects
- Epidemiological pattern (outbreak or sporadic)
- Antimicrobial therapy and hospitalization
- Importance of the antimicrobial agents in human medicine
- 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
- Persistence of hazards in humans

3.2 Food matrix related factors that can influence the survival capacity of the microorganisms while passing through the gastrointestinal tract

3.3 Dose-response relationship: mathematical relationship between the exposure and probability of adverse outcome (e.g. infection, disease and treatment failure)

4. Risk Characterization

4.1 Factors for consideration in risk estimation

- Number of people falling ill and the proportion of that number with AMR microorganisms attributable to a foodborne source
- Effects on sensitive subpopulations
- Increased frequency of infections, frequency of treatment failures, severity or duration of infectious disease, rates of hospitalization and mortality with AMR microorganisms compared to susceptible microorganisms due to resistance
- Number of person-days of disease per year
- 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) linked to AMR microorganisms attributable to a foodborne source

- Importance of pathology caused by the target microorganisms
- Existence or absence of therapeutic alternatives
- Potential impact of switching to an alternative antimicrobial agent (e.g. alternatives with potential increased toxicity)
- Methods to allow weighted summation of different risk impacts including consequences (e.g. disease and hospitalization)

4.2 Evaluation of RMOs

- Comparison of public health burden before and after interventions
- Potential effect on animal health relevant to food safety

4.3 Sensitivity analysis

- Effect of changes in model input values and assumption on model output
- Robustness of model results (output)

4.4 Uncertainty and variability analysis

- Range and likelihood of model predictions
- Characterize the precision of model prediction
- Relative contributions of uncertainties in model input to uncertainty in the model output

APPENDIX 3. EXAMPLES OF QUALITATIVE FOODBORNE AMR RISK ASSESSMENT

1. Although quantitative risk assessments are encouraged, qualitative risk assessments are often preferred due to their potential lower data demands. The level of scrutiny, review and standards of logic and reasoning to which a qualitative approach should be held are, however, no less than those to which a quantitative approach is subjected.

2. The following examples illustrate potential approaches that can be used to conduct a qualitative risk assessment. However, these should not be viewed as recommended or accepted default approaches for adoption. The thought process and discussions that surround the development of categories for the exposure or the hazard characterization (e.g. "rare," "high," etc.), as well as how these categories translate into the ultimate risk outcome, are a key part of the decision making and risk management process. The essential parts of developing a qualitative risk assessment could be grouped into three basic tasks:

- The development of qualitative statements or scores to describe the exposure assessment (e.g. "high," "medium" , etc.) with careful consideration given to the implications and interpretation of these categorizations;
- The development of qualitative statements or scores to describe the hazard characterization (e.g. "mild", "moderate", "severe" etc.) with careful consideration given to the implications and interpretation of these categorizations The process through which the different exposure and hazard characterization categories or scores are combined and integrated into overall risk levels (e.g. what does a "low" in exposure and a "high" in hazard characterization translate to and is it different from a "medium" in both).

3. There are currently no pre-defined hazard characterization or exposure assessment categories that can be used and different categories may be more suitable for certain situations. The approach used to integrate the exposure assessment and hazard characterization can also vary.

Example 1

Illustrative Exposure Assessment Scoring

4. Typically, in a qualitative risk assessment, the probability of the population being exposed to the hazard is translated into a series of qualitative statements. The qualitative risk assessment requires expert opinions or other formalized, transparent and documented process to take the existing evidence and convert it into a measure of the probability of exposure. To illustrate, the probability has been converted into the following categories and scores:

- Negligible (0) – Virtually no probability that exposure to the hazard can occur;
- Moderate (1) – Some probability for exposure to occur;
- High (2) – Significant probability for exposure to occur.

5. The assignment of both a statement reflecting the exposure probability as well as a corresponding score is done in this example to facilitate the process through which the exposure and hazard characterization will subsequently be combined. The description of the categorical statements includes an assessment providing greater detail as to the interpretation behind each of the categories.

Illustrative Hazard Characterization Scoring

6. The hazard characterization translates the outcomes of this step into qualitative statements that reflect the implications of exposure to a hazard. The following is an example of categories that might be useful in the case of foodborne zoonotic disease:

- Negligible (0) – Probability of disease upon exposure to AMR microorganisms is the same as for susceptible organisms and the outcomes as a result of disease are not different;
- Mild (1) – Probability of disease upon exposure to AMR microorganisms is the same as for susceptible organisms, but the outcomes following disease are more serious requiring hospitalization;

- Moderate (2) – Probability of disease upon exposure to AMR microorganisms is higher and outcomes following disease are more serious requiring hospitalization;
- Severe (3) – Probability of disease upon exposure to AMR microorganisms is higher and outcomes following disease are very serious requiring hospitalization as well as creating the potential for treatment failures requiring lengthy hospitalization.

Illustrative Risk Characterization Output

7. Ultimately, the exposure assessment and hazard characterization need to be integrated in the risk characterization in order to estimate the risk. By assigning each of the qualitative categories (e.g. "high," "medium," etc.) with a numerical score (e.g. 0, 1, 2), the results can be produced in a transparent way by simply multiplying the scores. The resulting risk characterization score can then be translated into meaningful qualitative risk categories. In this example, the products of the exposure assessment and hazard characterization are assigned the following categories:

No Additional Risk:	Value of 0
Some Additional Risk:	Value between 1 and 2
High Additional Risk:	Value between 3 and 4
Very High Additional Risk:	Value between 5 and 6

8. The results could also be presented graphically as shown below, providing a clear picture of how outcomes are judged to be "very high additional risk" or "no additional risk," for example.

		Exposure Assessment		
		Negligible	Moderate	High
Hazard Characterization	Negligible	**0**	**0**	**0**
	Mild	**0**	**1**	**2**
	Moderate	**0**	**2**	**4**
	Severe	**0**	**3**	**6**

Legend	
Negligible	**0 = No additional risk**
Mild	**1-2 = Some additional risk**
Moderate	**3-4 = High additional risk**
Severe	**6 = Very high additional risk**

Example 2

Illustrative Exposure Assessment Scoring

9. The rankings of "Negligible," "Low," "Medium," "High" and "Not Assessable" may be used for qualitative determination of the probability of human exposure to a given AMR microorganism in a given food or feed commodity, animal species or plant. The different ranking is defined below:

- Negligible – The probability of exposure for susceptible people is extremely low;
- Low (Unlikely) – The probability of exposure for susceptible people is low but possible;
- Medium (Likely/Probable) – The probability of exposure for susceptible people is likely;
- High (Almost Certain) – The probability of exposure for susceptible people is certain or very high;
- Not assessable – The probability of exposure for susceptible people cannot be assessed.

Illustrative Hazard Characterization Scoring

10. The AMR-related adverse human health effects (i.e. risk endpoints) may be ranked qualitatively as below[23]. In this example, it is considered that adverse health effects associated with the microorganisms that are resistant to critically important antimicrobials in human medicine[3] are likely to have a more severe consequence than those with microorganisms resistant to other antimicrobial agents:

- Negligible – No adverse human health consequences or within normal limits;
- Mild – Symptoms are minimally bothersome and no therapy is necessary;
- Moderate – Symptoms are more pronounced or of a more systemic nature than mild symptoms but not life threatening; some form of treatment is usually indicated;
- Severe – Symptoms are potentially life threatening and require systematic treatment and / or hospitalization; increase severity may occur due to the foodborne AMR microorganism;
- Fatal – Directly or indirectly contributes to the death of the subject; treatment failure is likely expected due to the foodborne AMR microorganism.

Illustrative Risk Characterization Scoring

11. In a qualitative risk assessment, the risk estimate may be integrated into the qualitative (descriptive) considerations of "Negligible," "Low," "Medium," "High," and "Very High" from the outputs of the Exposure Assessment and Hazard Characterization steps. An example of integration is presented in Table 2.

Table 2. Integration of the Outputs of Hazard Characterization and Exposure Assessment into the Qualitative Risk Characterization

Exposure Assessment	**Hazard Characterization**	**Qualitative Risk Characterization**
Probability of Exposure	**Severity of Adverse Health Effect**	
Negligible	Negligible	Negligible
Low (Unlikely)	Negligible	Negligible
Medium (Possible)	Negligible	Low
High (Almost Certain)	Negligible	Low
Negligible	Low (Mild)	Low
Low (Unlikely)	Low (Mild)	Low
Medium (Possible)	Low (Mild)	Medium
High (Almost Certain)	Low (Mild)	Medium
Negligible	Medium (Moderate)	Low
Low (Unlikely)	Medium (Moderate)	Low
Medium (Possible)	Medium (Moderate)	High/Medium
High (Almost Certain)	Medium (Moderate)	High
Negligible	High (Severe)	Low
Low (Unlikely)	High (Severe)	Medium
Medium (Possible)	High (Severe)	High
High (Almost Certain)	High (Severe)	Very High
Negligible	Very High (Fatal)	Medium/Low
Low (Unlikely)	Very High (Fatal)	High
Medium (Possible)	Very High (Fatal)	Very High
High (Almost Certain)	Very High (Fatal)	Very High

[23] Modified after National Cancer Institute, 2006. Common Terminology Criteria for Adverse Events v3.0. http://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/ctcaev3.pdf.