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FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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ALINORM 10/33/42
October 2009

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Thirty third Session
Geneva, Switzerland, 5-9 July 2010

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

Jeju, Republic of Korea
12-16 October 2009

NOTE: This report contains Codex Circular Letter CL 2009/30-AMR

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CX 4/100.2 **CL 2009/30-AMR**
October 2009

TO: Codex Contact Points
Interested International Organizations

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

SUBJECT DISTRIBUTION OF THE REPORT OF THE THIRD SESSION OF THE CODEX *AD HOC* INTERGOVERNMENTAL TASK FORCE ON ANTIMICROBIAL RESISTANCE (ALINORM 10/33/42)

The report of the Third Session of the Codex *Ad Hoc* Intergovernmental Task Force on Antimicrobial Resistance will be considered by the 33rd Session of the Codex Alimentarius Commission (Geneva, Switzerland, 5-9 July 2010).

MATTERS FOR ADOPTION BY THE 33RD SESSION OF THE CODEX ALIMENTARIUS COMMISSION

Proposed Draft Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (N01-2008, N02-2008, N03-2008) (para. 124 and Appendix II)

Governments and international organizations wishing to submit comments on the above texts 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 2010.**

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SUMMARY AND CONCLUSIONS

The Third 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 proposed draft Guidelines for the Risk Analysis of Foodborne Antimicrobial Resistance to the 33rd Session of the Commission for adoption at Step 5 (para. 124 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
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 Organization 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 Third Session in Jeju, Republic of Korea, from 12 to 16 October 2009, at the kind invitation of the Government of the Republic of Korea. Dr Kwang-Ho Lee, Director of Food Safety Evaluation Department, Korea Food and Drug Administration, presided over the Session. The Session was attended by 148 delegates from 43 Member countries, 1 Member organization and Observers from 8 international organizations and FAO and WHO. A complete list of participants, including the Secretariat, is given in Appendix I to this report.

2. The Session was opened by Dr Yeo-Pyo Yun, Commissioner, Korea Food and Drug Administration. Dr Yun welcomed the delegates and indicated that the development of the Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance would contribute to the protection of consumers' health. He also pointed out that the Task Force provided an opportunity for strengthening international co-operation and wished the delegates a pleasant stay in Jeju.

3. Dr Seung-Hee Kim, General Director of 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 consumers all over the world were paying more attention to food safety, and thus making the work on the Task Force very timely. Dr Kim briefly informed about the activities of the Korean surveillance programme on antimicrobial resistance and wished the delegates a successful work.

Division of Competence

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

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

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

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

6. The Task Force noted matters presented in document CX/AMR 09/3/2 regarding: general decisions of the 32nd Session of the Commission; the adoption of the *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); and future work on animal feeding.

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

7. The Representative of FAO, while referring to document CX/AMR 09/3/3, highlighted in particular, projects and workshops in the field of aquaculture to promote biosecurity and food safety through prudent and responsible use of antimicrobials.

8. In response to a question on the possibility of extending such activities to other countries, the Representative of FAO indicated that projects of this nature were part of the ongoing work of FAO and that further activities could be undertaken based on specific requests. The Representative further informed the Task Force that the Guidelines on Risk Characterization of Microbiological Hazards in Foods, prepared by the Joint FAO/WHO Expert Meeting on Microbiological Risk Assessment (JEMRA), had been recently published.

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1 CX/AMR 09/3/1; CRD 1 (Division of Competence Between the European Community and its Member States According to Rule of Procedure II Paragraph 5 of the Codex Alimentarius Commission)

2 CX/AMR/09/3/2

3 CX/AMR/09/3/3

9. The Representative of WHO informed the Task Force of the establishment of a WHO Advisory Group on Integrated Surveillance (WHO-AGISAR) to support WHO activities on integrated surveillance and containment of foodborne antimicrobial resistance. The Representative also informed the Task Force that the World Alliance for Patient Safety Programme in WHO had elected "Antimicrobial Resistance" as topic for the Third Global Patient Safety Challenge. The challenge would be launched in 2010 and WHO was preparing a policy document with specific intervention and implementation strategies to control and contain antimicrobial resistance in various areas, including animal husbandry.

10. The Observer of OIE informed the Task Force on OIE's activities to promote the responsible and prudent use of antimicrobials and to favour a harmonized approach to surveillance and monitoring of antimicrobial resistance, based on the development and regular updating of international standards and guidelines published in the Terrestrial Animal Health Code (4 chapters) and Manual (1 chapter); and that OIE was currently developing similar standards related to aquaculture. OIE activities to support its Members include: the development of tools to evaluate the performance of veterinary services (the OIE-PVS and PVS Gap analysis); a laboratory twining programme; support to modernize or update Members' national legislation for marketing approval and control of veterinary products; and implementation of a coherent communication and training programme directed to OIE Delegates and designated focal points on veterinary products.

11. The Representative of WHO further informed the Task Force about ongoing discussion between FAO, OIE and WHO on future activities related to antimicrobial resistance.

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

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

13. The Delegation of United States of America, speaking as the Chairperson of the electronic working group on the development of proposed draft guidelines, briefly introduced document CX/AMR 09/3/4. The Task Force noted that the electronic working group had prepared a consolidated document, which took into account the decisions of the previous session and attempted to include and reconcile all comments received.

14. The Task Force expressed it appreciation to the electronic working group and generally supported the recommendation that the proposed draft Guidelines be progressed in the Step procedure.

General comments

15. The Task Force noted that the electronic working group put forward several issues, which required further discussion at the present session. The Task Force considered those issues and made the following decisions:

Introduction and Scope

16. The Task Force agreed with the inclusion of a new "Scope" section for the consolidated document and the retention of relevant introductory information under each section.

General Principles

17. The Task Force noted that the electronic working group could not reach consensus as to the inclusion of a general principle to address animal health and welfare. It agreed that this matter would be discussed when considering the document in detail (*see* paras 54-55).

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[4] CX/AMR 09/3/4; CX/AMR 09/3/4 Add.1 (Comments of: Argentina, Australia, Indonesia, New Zealand, Norway, Philippines, CI, CIAA, IDF, IFAH and OIE); CX/AMR 09/3/4 Add.2 (Comments of: Canada, Japan, Republic of Korea and United States of America); CX/AMR 09/3/4 Add.3 (Comments of: Costa Rica, European Community and Kenya); CRD 2 (Comments of Thailand); CRD 4 (Comments of United States of America); CRD 4 (Comments of United States of America); CRD 5 (Report in-session working group on revision of Table 1); CRD 6 (Comments of Canada; suggested revision paras 51-63); CRD 7 (Report in-session working group on monitoring and surveillance); CRD 8 (Comments of United States of America); CRD 9 (Comments of United States of America); CRD 10 (Report in-session working group on figures); CRD 11 (Report in-session working group on definitions); CRD 12 (Comments of United States of America).

Organization of Risk Management Activities

18. After some discussion, the Task Force agreed to the current structure of the document, which described risk analysis of foodborne antimicrobial resistance in a chronological sequence of events in order to improve the readability and applicability of the document.

Long document/specific to Antimicrobial Resistance (AMR) vs. short document /more general

19. The Task Force agreed that the guidelines should be practical, relevant, specific to foodborne AMR and not overly prescriptive. Therefore, it was agreed to shorten the document, where possible, to avoid repetitions and not to duplicate other existing Codex documents, while ensuring Guidelines' readability and usefulness.

Risk Communication

20. The Task Force acknowledged that risk communication was an essential element of the risk analysis process and applied throughout the entire risk analysis process. The Task Force agreed that the section on risk communication could be shortened and made more specific to antimicrobial resistance, where possible.

References

21. The Task Force agreed to remove the "Reference" section and to footnote relevant references throughout the document, consistent with the format of other Codex texts.

Elements of a Risk Profile

22. The Task Force noted that the electronic working group had revised the "Risk profile" section to reinforce the concept that a risk profile was an information-gathering exercise and not an "abbreviated" risk assessment. The revised section listed the fundamental elements required and emphasized the concept that risk profile should be flexible to fit the nature and the complexity of the food safety issue. The Task Force agreed to revise the section to make it consistent with other parts of the document. It further agreed that the inclusion of an Appendix to describe the elements of a risk profile would be discussed after revising the section (*see* paras 62-63).

Broad Risk Management Goals

23. The Task Force agreed to consider this section in detail (*see* para. 65).

Figure 2, Schematic showing the scope and relationship of the components of AMR risk assessment / Figure 3, Schemes for hazard characterization in AMR risk assessment

24. The Task Force agreed to revise the figures included in the document to ensure that they properly reflect the content of the document and are relevant to the text.

Placement of supplemental Risk Management Options (RMO)

25. The Task Force noted that different views were expressed regarding the content and placement of supplemental antimicrobial resistance RMOs.

26. Some delegations and one observer were of the view that the table on RMOs be placed in an appendix, as these were only examples of antimicrobial resistance RMOs and that the structure of the Guideline follow the structure of the *Working Principles of Risk Analysis for Food Safety for Application by Governments* (CAC/GL 62-2007).

27. Many other delegations were of the view that the Table on RMOs should be revised and placed in the main body of the Guidelines in order to help in identifying, evaluating, selecting, implementing and monitoring and reviewing RMOs with emphasis on aspects related to foodborne AMR.

28. After some discussion, the Task Force agreed to maintain the Table in the main body of the Guidelines and agreed to establish an in-session working group to review the content of the Table based on comments received for consideration by the Plenary (*see* para. 32).

Monitoring of RMOs versus surveillance of AMR

29. The Committee noted that a new section to address monitoring and surveillance of antimicrobial usage and antimicrobial resistant microorganisms and antimicrobial resistance determinants had been introduced to avoid confusion about the difference between monitoring and review of RMOs and monitoring and surveillance of antimicrobial usage and antimicrobial resistant microorganisms and antimicrobial resistance determinants.

Other matters (definitions)

30. The Task Force agreed to remove from the "Definition" section the definitions already included in the Codex Procedural Manual and to incorporate in the text of the Guidelines the definitions of terms which appeared only once.

31. The Task Force noted that it was necessary to ensure that the definitions presented in the Guidelines be consistent with definitions already elaborated by FAO/WHO or by the Codex Alimentarius Commission.

Specific comments[5]

32. In view of the many comments submitted on several parts of the proposed draft Guidelines and in order to facilitate the discussion of the Plenary, the Task Force agreed to establish the following in-session working groups on:

- Table 1 " Examples of Risk Management Options Supplemental to Codex Code of Practice", under the chairmanship of United States of America (CRD 5);
- "Monitoring and Surveillance" Section, under the chairmanship of European Community (CRD 7);
- Figures 1,2 and 3 and related paragraphs, under the chairmanship of Canada (CRD 10); and
- Definitions, under the chairmanship of Denmark (CRD 11).

33. The Task Force agreed to consider the proposed draft Guidelines paragraph by paragraph. In addition to some minor editorial changes, including amendments to the French and Spanish translations, it agreed to the following:

34. The Task Force agreed to refer to "foodborne antimicrobial resistance" (abbreviated "foodborne AMR") rather than AMR, where appropriate throughout the text.

Introduction

35. The Task Force did not agree to the proposal to amend the first sentence of paragraph 1 to state that antimicrobial resistance poses a greater risk not only to human but also to animal health. The third sentence was amended to improve its clarity and to ensure consistency with the terminology used in other parts of the document.

36. The fifth sentence of paragraph 2 was amended to also refer to the potential public health impact of antimicrobial resistant microorganisms not only from animals but also from crops.

37. In paragraph 3, the first sentence was amended to include reference to aquaculture for consistency with other part of the document; and the last sentence was deleted as redundant and too restrictive.

38. The Task Force revised paragraph 4 to better clarify the relationship of preliminary risk management and risk assessment. An additional sentence was added to clarify that risk managers were responsible to verify that implemented risk mitigation measures were achieving the intended results. An additional paragraph was inserted to explain the structure of the document and thus improving its readability.

39. Additional references to Codex texts were included in paragraph 5; and the numbers of specific chapters of the OIE Terrestrial Animal Health Code were deleted because they could change during the revision of OIE Code.

[5] Section's headings and paragraph' numbers listed below are related to document CX/AMR 09/3/4.

40. The United States of America proposed to: include appropriate references to international trade obligations under paragraph 5 by adding *"These guidelines should be applied in a manner consistent with countries WTO SPS obligations and other international agreements, as appropriate"*. However, the Task Force did not support the proposal. The Secretariat also clarified that not all Codex members were members of WTO and that all Codex texts were voluntary in nature and therefore reference to SPS were not appropriate in this text.

Scope

41. The Task Force noted that the revised first paragraph of the "Scope" section might give the impression that veterinary, plant and plant processing sources of antimicrobial use as well all microorganisms have identical importance in foodborne antimicrobial resistance; however, after some discussions and in view that situation might change in the future, the Task Force agreed to retain the paragraph with some editorial changes.

42. The Task Force agreed to add footnotes in paragraph 7 to clarify the source of definitions on recombinant-DNA plants and recombinant microorganisms; non-genetically modified microorganisms and probiotics, which could be intentionally added to food for technological or nutritional purposes.

Definitions

43. The Task Force expressed its appreciation to the in-session working group for their work (*see* para. 32) and decided to base its consideration on the proposals as contained in CRD 11 and, made the following decisions.

44. The Task Force agreed to the proposal of the in-session working group to delete all definitions taken from the Codex Procedural Manual. The Task Force considered the definitions that the in-session working group had not been able to agree upon and deleted the definitions on: *exposure assessment, hazard, risk manager* and *weight of evidence*.

45. The Task Force agreed to move the definition of terms which occurred only once in the Guidelinese as footnotes in relevant parts of the document. These terms include: *antimicrobial class, appropriate level of protection (ALOP), HACCP* and *responsible use guideline*. The definition on *responsible use guideline*, inserted as a footnote in Table 1, was amended to include a reference to the *Code of Practice to Minimize and Contain Antimicrobial Resistance* (CAC/RCP 61-2005).

46. The Task Force further agreed to insert two new definitions on *food producing animal* and on *interpretive criteria* and not to include definitions on *feed* and *DALYs*, because: the first was already defined in the *Code of Practice on Good Animal Feeding* (CAC/RCP 54-2004); and the second had been deleted from the document as a result of the discussion on "Risk Characterization" section.

47. The Task Force considered the remaining definitions and made the following modifications:

- The term *antimicrobial* was amended to read "*antimicrobial agent*", as presented in the report of the Joint FAO/OIE/WHO Expert Meeting on Critically Important Antimicrobials (Rome, 2008);
- The definition on *commensal* was amended by deleting its last part for clarity; and "rare" was changed with "certain";
- The definition on *extra- and off-label use* was amended by deleting the reference to "non human";
- The definition of *food chain partner* was deleted as the Task Force agreed to use "interested parties" throughout the text;
- The definition on *pathogen* was amended to read "*A microorganism that can causes infection, ilness or diseases*";
- The definitions on *pre-harvest* and *post-harvest* were deleted as they were considered not necessary for the scope of the guidelines;
- The definition on *resistance determinant* was amended to make it clear that it refers to *antimicrobial resistance determinant*.

General Principles for Foodborne AMR Analysis

48. The references to CAC/GL 30-1999 and CAC/GL 63-2007 were moved from paragraph 9 to Principle 5.

49. Principle 1 was amended to clarify that foodborne AMR should consider the impact of AMR on human health because of non-human uses of antimicrobials.

50. Some editorial amendments were made in Principles 2 and 3 for clarity.

51. In Principle 4 the reference to "pattern of resistant microorganisms" was deleted and the second part of sentence was reordered for clarity.

52. Principle 5 was amended to make it clearer that foodborne AMR-risk analysis should consider consequences to treatment of diseases resulting from antimicrobial resistant microorganisms.

53. The Task Force agreed to reword Principle 6 as follows: *"Foodborne AMR risk analysis should focus on clearly defined combinations of the food commodity, the microorganism/resistance determinant and the antimicrobial to which resistance was expressed. Co-resistance should be considered in certain situations"*. It further agreed to use "*combination of the food commodity, the microorganism/resistance determinant and the antimicrobial to which resistance was expressed"* consistently throughout the document.

54. The Task Force discussed a proposal to include a new Principle on animal welfare and health. New Zealand was opposed to the inclusion of the reference to animal welfare and pointed out that the Codex Alimentarius Commission had promulgated statements of *Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken Into Account*; and had adopted *Criteria for Other Factors Referred to it in the Second Statement of Principle*, which state that *"Recognizing that some legitimate concerns of governments when establishing their national legislation are not generally applicable or relevant worldwide"*. The Delegation emphasized that the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* highlighted that risk analysis should be conducted in accordance with these Statements of Principle. This view was supported by number of delegations.

55. The Task Force noted that animal welfare was outside the mandate of the Codex Alimentarius Commission. The Task Force also noted that animal health aspects related to food safety were addressed in other Codex documents, e.g. the *Code of Hygienic Practice for Milk and Milk Products* (CAC/RCP 57-2004) and the *Code of Practice on Good Animal Feeding* (CAC/RCP 54-2004) and that OIE was responsible for standards on animal health. Therefore, it agreed to add a new Principle 8, which reads: *"Evaluation of pre-harvest foodborne AMR-risk management options 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

56. The Task Force agreed with the proposal of the in-session working group to substitute paragraph 10 with a new paragraph, as proposed in CRD 10. The Task Force agreed to the content of Figure 1, as proposed by the in-session working group in CRD 10, with the inclusion of an additional note to clarify the relationship of surveillance and foodborne AMR-risk analysis.

57. The Task Force agreed to delete paragraphs 11, 12 and 13 as they were not specific to foodborne AMR or already covered in other parts of the document.

Preliminary risk management activities

58. The reference to animal feed and aquaculture was deleted in the first sentence of paragraph 14 and it was clarified that potential for food safety might arise when AMR microorganisms or antimicrobial resistance determinants were present and/or transmitted to humans via food. The last sentence was deleted as its concept was covered in the "Introduction" and "Scope" sections.

Identification of an AMR food safety issue

59. The Task Force noted that paragraph 15 was too prescriptive and that examples given were covered elsewhere in the document; therefore, it agreed to retain only the first sentence and to include a reference to the relevant paragraph on source of information.

Development of an AMR-risk profile

60. The Task Force agreed to amend the second bullet point in paragraph 17 to make it consistent with food commodity and AMR combinations, as agreed earlier (*see* para. 53). Some delegations proposed to delete the reference to national/regional authorities in the third bullet point, as they were of the view that only international lists of critically important antimicrobial lists should be considered. It was noted that some countries and regional organizations had developed their own lists of critically important antimicrobials and that some antimicrobial agents could be used differently in various countries and regions. Therefore, the Task Force agreed to maintain the reference to national/regional authorities. A new bullet point regarding list of current control measures was added.

61. Paragraph 18 was deleted as its content was already covered in paragraph 17; and the last part of paragraph 19 was deleted to make it more concise.

62. The Task Force discussed the proposal to reinsert the Appendix containing elements for risk profile on the basis of a proposal of the United States of America, as presented in CRD 3. Some delegations were of the view that the Appendix included useful information and provided clarity to the document; other delegations opposed the reinsertion of the Appendix as, in their view, it could add more confusion on this matter.

63. The Task Force considered a revised Appendix, prepared by the United States of America and presented in CRD 12. In view of time constraints, the Task Force agreed to put the entire Appendix in square brackets for consideration at its next session.

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

64. The Task Force agreed to delete the last sentence in paragraph 22 and the three related bullet point to reduce redundancy and clarify the text.

Establishment of broad risk management goals

65. The Task Force noted that concepts covered in paragraphs 23 to 26 were not specific to foodborne AMR and were covered elsewhere; therefore, it agreed to their deletion with the exception of the first sentence of paragraph 23 on risk managers' responsibilities.

Commission the AMR-risk assessment

66. The Task Force agreed to delete paragraph 28, including relevant bullet points and with the exception of the first sentence containing provisions related to responsibilities of risk managers in commissioning a risk assessment.

Consideration of results of AMR-risk assessments

67. The Task Force noted that paragraphs 30 and 31 were related to the consideration of results of foodborne AMR-risk assessments; therefore, it decided to move these paragraphs to the end of the section on risk assessment.

AMR-risk assessment

Sources of information

68. The Task Force agreed to delete the reference to "weight evidence approach" in paragraph 33 as it was not appropriate in this section.

69. The Task Force considered different proposals put forward by delegates to improve clarity of bullet points in paragraph 34, which listed possible sources of information. After some discussion, the Task Force agreed to replace greater part of the first bullet point with a reference to relevant paragraphs of the section on surveillance programmes.

70. Brazil proposed to change "sporadic" to "endemic" cases in the second bullet point; the Task Force noted that epidemiology always consider sporadic cases and therefore it agreed to retain the bullet point unchanged. Brazil expressed their reservation to this decision.

71. The Task Force further agreed:

- To delete the last sentence of the fifth bullet point, as difficulties in the interpretation of information were outside the scope of the section;

- To delete the sixth bullet point as redundant;
- To move the reference to transferring genetic elements and other elements in seventh bullet point to the eighth bullet point;
- To insert a reference to regional data at the end of the ninth bullet point to recognize their importance in laboratory trials; and
- To add two new bullet points on: science-based and sound expert opinions; and on field and laboratory data that study the environmental persistence and residue levels of antimicrobial agents in the plant/crop trials.

Process of AMR-risk assessment

72. The Task Force agreed with the proposal of the in-session working group on Figures 1, 2 and 3 (*see* CRD 10) to delete Figure 2; therefore the reference to this figure was deleted from the relevant paragraph proposed by the in-session working group and the paragraph was amended to refer to the content of the figure.

Hazard identification

73. In paragraph 38, the second sentence was amended to make it consistent with previous decision on combinations to be considered during foodborne AMR-risk analysis and two new sentences were added to clarify the content of the paragraph. Additional wording was inserted in the second sentence to clarify the nature of preliminary risk management activities. The last sentence was amended by deleting the reference to studies on surrogate microorganisms and to emphasize that science-based opinions on hazard identification could be sought from relevant experts.

Exposure assessment

74. The Task Force agreed to new wording of paragraph 39 proposed by the in-session working group, as presented in CRD 10, with minor editorial amendments.

Hazard characterization

75. The second sentence of paragraph 42 and the fifth sentence in paragraph 44 were amended to clarify that they referred to hazard characterization rather that AMR-risk assessment.

76. The Task Force agreed to the proposal of the in-session working group for paragraph 43, as presented in CRD 10; it agreed to refer to “adverse health effect” instead of “disease” and to other minor changes to improve the clarity of the text. The Task Force had a discussion whether to maintain the revised Figure “Example for Consideration of Foodborne AMR Exposure Assessment and Hazard Characterization”.

77. The Observer from IFAH was not in favor of retaining the proposed figure and indicated that in the third set of arrows, under Hazard Characterization, there were references to terms, such as quantitative, semi-quantitative and qualitative models that were not reflected or explained in the document. Some other delegations supported retaining the figure as, in their view, it was useful and provided examples which could help in understanding foodborne AMR exposure assessment and risk characterization.

78. The Task Force agreed to retain the Figure and to amend its title to refer to examples for foodborne AMR exposure assessment and hazard characterization; the Task Force also clarified the second bullet point in the horizontal arrow, under exposure assessment and inserted “exposure” before pathways and “and dissemination” in the left vertical box on selection for Antimicrobial Resistant Microorganism / Antimicrobial Reistance Determinant (AMRM/AMRD). The Task Force agreed to delete the square brackets in the left vertical box on hazard characterization.

Risk characterization

79. The Task Force agreed to replace the first two sentences in paragraph 45 with the first sentence of paragraph 48 to improve its readability; and to remove the example of specific output in the fourth sentence. The example of DALYs (disability adjusted life years) was removed in paragraphs 45 and 47.

80. The last bullet point of paragraph 48 was replaced with the corresponding bullet point agreed by the 2nd Session of the Task Force[6].

AMR-Risk Management

81. The Task Force agreed to consider paragraphs 51-63, i.e. "Risk Management" chapter up to and including "Identification of AMR-RMOs" section, based on a proposal from Canada, as contained in CRD 6. The Task Force agreed to replace paragraphs 51-63 with the new paragraphs 51-60 and made the following changes.

82. The Task Force agreed to revise the title of the chapter to "Foodborne AMR-Risk Management" for consistency with previous decisions.

83. In paragraph 51[7], the Task Force changed "national and regional authorities" with "risk managers" to recognise the responsibility of different organizations for risk management activities; the last part of the sentence was amended to clarify that the risk of foodborne antimicrobial resistant microorganisms and resistance determinants is linked to, and is not arising from, the non-human use of antimicrobials.

84. The list of Codex codes of practice, listed under paragraph 54, was updated to include the *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) and to list the texts along the production to consumption continuum.

Identification of AMR-RMOs

85. The Task Force amended the first part of paragraph 56 to improve its readability. "Food chain partners" was changed with "interested parties" in paragraphs 56 and 58 for consistency with previous decision. At the end of paragraph 60, the Task Force added "and resistance determinants" for consistency.

Table 1. Examples of Risk Management Options Supplemental to Codex Code of Practices

86. The Task Force agreed to replace Table 1 with the proposal prepared by the in-session working group (*see* para. 32), as contained in CRD 5. The Task Force considered those parts of the revised Table 1 that were put in square brackets for further discussion in plenary and agreed to the following.

Title of the Table 1

87. The Task Force agreed to delete the text in square brackets, recognising that the table included examples of options.

Animal feed production

88. The Task Force agreed to delete the two bullets points. It further deleted the square brackets from the last paragraph, which was revised to make the example more specific.

Food animal production

89. The Task Force agreed to delete the texts in square brackets and to change "veterinary medicinal products" with "veterinary antimicrobial drugs" in regulatory and non-regulatory controls, as this term was defined in the *Code of Practice to Minimize and Contain Antimicrobial Resistance* (CAC/RCP 61-2005).

Food crop production

90. The Task Force agreed: to delete all the texts in square brackets not agreed by the in-session working group; and to refer to "viable microorganisms" instead of "probiotic supplements". The Task Force further decided to move the paragraph on the evaluation of viable organism used in food and in feed crop production to "Regulatory controls" sub-section.

[6] See ALINORM 09/32/42, Appendix II

[7] Paragraph numbers included in this section refer to CRD 6

Waste management

91. The Task Force agreed: to revise the language of the first paragraph to make it consistent with the other parts of the table and to add "manure and other natural fertilizers" in the parenthesis related to human and animal waste; to delete the four bullet points, which was in square brackets; and to make the fifth bullet point on the example of design of treatment procedures more specific.

Post Harvest Option

92. The Task Force considered a proposal to revise the first paragraph on post-harvest risk management options. After some discussion it agreed to the following text "*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"*.

Evaluation of AMR-RMOs

93. In paragraph 65, the Task Force agreed to:

- Amend the first bullet point for clarity;
- Delete the third bullet point as it was very difficult to get an agreement on all aspects of consideration of cost/benefit analysis;
- Delete the fourth bullet point regarding the reference to WTO SPS implications. The United States of America expressed their reservation to this decision (*see* also para. 40); and
- Add a new bullet point regarding verification of the correct implementation of RMOs.

94. Paragraph 67 was deleted as it was already covered by Principle 8 and in paragraph 66.

95. The Task Force revised paragraph 69 for clarity and paragraph 70 to be consistent with Principle 6.

Selection of AMR-RMOs

96. In paragraph 71, the Task Force revised specific food and AMR combinations to be consistent with its previous decision; and deleted paragraph 72 as information of this paragraph was contained in other Codex texts.

97. Paragraph 73 was amended for clarity; and paragraph 75 was deleted as its content was already addressed in Table 1.

Implementation of AMR-RMOs

98. The Task Force noted that paragraphs 76 and 77 were redundant and not specific to foodborne AMR; therefore, it agreed to delete the last two sentences in paragraph 76 and all paragraph 77. The Task Force also agreed to add additional wording to paragraph 76 regarding responsibilities of national/regional authorities in ensuring regulatory framework and infrastructure.

Monitoring and review of AMR-RMOs

99. The Task Force noted that this section has been revised by the in-session working group on monitoring and surveillance (*see* para. 32); and therefore, it agreed to base its consideration on the proposal presented in CRD 7.

100. The Task Force agreed to amend the last sentence of paragraph 79 to accommodate bullet points regarding effectiveness of measuring RMOs, which were moved from Appendix 3 (*see* also para. 121).

101. The paragraph 81 was deleted as its content was already covered by revised paragraph 82.

Surveillance of antimicrobial use and antimicrobial resistant microorganisms and determinants

102. The proposed new paragraph 84 was revised for clarity.

AMR-Risk Communication

103. In order to simplify and shorten this section, the Task Force agreed to delete paragraph 87 and paragraphs from 91 to 97, as they were of a very general nature and not specific to antimicrobial risk analysis.

104. The last sentence in paragraph 88 was deleted as it was reiterating the previous phrase and a reference to Figure 1 was added in paragraph 89.

105. The first sentence of paragraph 90 was amended to clarify that interested parties were engaged in food safety decision making “routinely” and the last part of this sentence was deleted.

106. The Task Force noted that it was important for antimicrobial resistance risk analysis to also consult public health experts and medical professionals; therefore, it amended the second sentence of paragraph 90 to this effect. The Task Force deleted the last part of the sentence as there was no need to specify in detail which problems, priorities and strategies should be discussed together by all interested parties.

Risk communication as a risk management tool

107. Some minor editorial amendments were made in paragraphs 99 and 102.

108. Paragraph 100 was amended to make it less prescriptive and additional wording was added to the end of the paragraph to emphasize that activities foreseen were targeted to decrease foodborne antimicrobial resistance.

Appendix 1. Suggested elements for consideration of AMR-Risk assessment

109. The Task Force, in addition to minor editorial changes, agreed to the following changes:

- The introductory paragraph was amended to clarify that the list of presented elements was only for illustration and was not exhaustive;
- The heading on the purpose and scope was deleted as it did not contain any elements;
- The first and second bullet points in section 2.3 were amended to clarify that they referred to phenotypic and genotypic characterization rather than species/strains; and
- Two new bullet points on AMR surveillance data and pathogenicity, virulence and their linkage to resistance were inserted at the end of this section.

110. It was noted that section 2.4 “Potential adverse effects in humans” was more relevant to hazard characterization; therefore, the two bullet points of this section were moved to section 4.3 “Human host and adverse health effects”. Section 2.5 “Relationship of presence of antimicrobial resistance microorganisms or determinants in/on food and potential adverse human health impacts” was deleted as it was covered elsewhere in the text.

111. In “Exposure assessment” section, the Task Force noted that there was a need to distinguish elements at population and individual levels; therefore, it agreed to revise the first white sub-bullet point to read “Attributes of antimicrobial use at the population level” and the second white sub-bullet point to read “Attributes of antimicrobial use at the individual level”.

112. The black bullet point on other possible sources of AMR microorganisms for target animal/crop was revised to clarify that it covers sources but not prevalence of AMR microorganisms.

113. The Task Force noted that bullet points in Section 3.2 referring to “prevalence and level” of resistant microorganisms should refer to “frequency and concentration” for consistency with other Codex documents.

114. The Task Force further agreed to delete:

- The first sub-bullet point under “Food processing factors” as redundant;
- The two last bullet points in Section 3.3 on “Transfer of hazard”, as they were adequately covered by the first bullet point of the Section.

115. In “Hazard characterization” section, the Task Force deleted section 4.1 “Resistant microorganism and resistance determinants” as the elements described therein were relevant to hazard identification and not to hazard characterization.

116. The Task Force further moved the last bullet point on food matrix related factors to section 4.3 “Human host and adverse health effects” as more appropriate; and deleted section 4.2 “Antimicrobials” as it was covered by bullet points 7 in section 4.3.

117. In section 4.3, the Task Force amended:

- The bullet point on epidemiological pattern to clarify that this element covered outbreak or sporadic cases; and
- The bullet point on the overall antimicrobial drug importance ranking to read "Importance of antimicrobial drug in human medicine";

118. In "Risk characterization" section, the Task Force agreed:

- To amend the first bullet point of section 5.1 "Factors in risk estimation" to clarify that resistant strains of microorganisms were attributable to foodborne sources; and
- To add a new bullet point regarding potential effect on animal health relevant to food safety in 5.2 "Evaluation of RMOs".

Appendix 2. Examples of Qualitative AMR-Risk Assessment

119. In Example 1 "Illustrative Exposure Assessment Scoring", the Task Force deleted the numerical scores on probabilities, as their interpretation might not be universally acceptable. No other changes were made in other parts of the Appendix.

Appendix 3. Suggested endpoints for monitoring the effectiveness of AMR-Risk Management Measures

120. The Task Force noted that the Appendix listed endpoints for both evaluation of effectiveness of risk management measures and monitoring the effectiveness of foodborne AMR management measures and that this mixed listing of elements might create confusion. Therefore, it agreed to retain bullet points #1-3, 9 and 13, which were specific to monitoring of effectiveness of foodborne AMR management measures.

121. A new bullet point was inserted to monitor the effects of risk management measures in food products at slaughter and/or harvest. The Task Force agreed to eliminate the Appendix and to move the remaining content to the "Monitoring and review of foodborne AMR-RMOs" section of the Guidelines (*see* para. 100).

Conclusions

122. In concluding its discussion on the proposed draft Guidelines, the Task Force acknowledged the substantial progress made during the session.

123. In order to facilitate the discussion and the finalisation of the document at its next session, the Task Force agreed to establish a physical working group, under the chairmanship of Canada and working in English, French and Spanish, which should meet immediately prior to its next session to further consider Appendix 1 "Elements of Risk Profile" and prepare a revised document on the basis of comments submitted for consideration of the Plenary.

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

124. The Task Force agreed to forward the proposed draft Guidelines to the 33rd Session of the Commission for adoption at Step 5 (*see* Appendix II).

OTHER BUSINESS AND FUTURE WORK (Agenda Item 5)

125. The Task Force noted that no other business had been put forward.

DATE AND PLACE OF NEXT SESSION (Agenda Item 6)

126. The Task Force was informed that its Fourth Session was tentatively scheduled to be held in one year time, subject to further discussions between the Korean and Codex Secretariats.

SUMMARY STATUS OF WORK

SUBJECT MATTERS	STEP	ACTION BY:	DOCUMENT REFERENCE (ALINORM 10/33/42)
Proposed draft Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (N01-2008, N02-2008, N03-2008)	5	Members and Observers 33rd CAC Members and Observers 4th Session of the Task Force	Para. 124 and Appendix II

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Appendix II

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

At Step 5 of the Procedure

Table of Contents

Appendix 3. Examples of Qualitative foodborne AMR-Risk Assessment

LIST OF ACRONYMS USED IN THE DOCUMENT

ALOP	Appropriate Level Of Protection
AMR	Antimicrobial Resistance
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
GMP	Good Manufacturing Practices
GHP	Good Hygiene Practices
HACCP	Hazard Analysis and Critical Control Point
MICs	Minimal Inhibitory Concentrations
OIE	World Organization of 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) 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 antimicrobial resistant microorganisms and antimicrobial resistance 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 overall risk to human health from foodborne AMR microorganisms and determining appropriate risk mitigation 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 agreed that foodborne AMR microorganisms are possible microbiological food safety hazards. Consequently, the need for the development of a structured and coordinated approach for AMR-risk analysis has been emphasized[1]. 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[2]. However, 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 mitigation strategies, these guidelines present a consolidated framework specific to foodborne AMR-risk analysis.

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 antimicrobial resistance determinants linked to non-human use of antimicrobial agents.

4. The initial phase 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, perhaps, a more 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. Later phases 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 mitigation measures implemented are achieving the intended results, that unintended consequences associated with the measures are limited and that the risk management goals can be sustained. Good communication between risk assessors, managers and interested parties is essential for a transparent and informed risk analysis.

5. These guidelines present components of foodborne AMR-Risk Analysis in a chronological order. For better readability, the "Foodborne AMR-Risk communication" and "Surveillance and information source" sections are placed at the end of the document, recognizing that these sections can be 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*

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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/.
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/foodborne_disease/resistance/fdb_antimicrobial_Mar04.pdf.
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. http://www.fao.org/ag/agn/agns/files/Prepub_Report_CIA.pdf.

[2] FAO/WHO. 2006. Food safety risk analysis: a guide for national safety authorities. (FAO Food and Nutrition Paper 87). http://www.who.int/foodsafety/publications/micro/riskanalysis06.pdf.
OIE. 2008. Terrestrial Animal Health Code (2008). http://www.oie.int/eng/normes/mcode/en_sommaire.htm.

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 61-2005). 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[3] and the chapters related to the control of AMR in the OIE Terrestrial Animal Health Code.

SCOPE

7. The scope of these guidelines is to provide science-based guidance on methodology and processes for risk analysis and its application to foodborne AMR related to non-human use of antimicrobial agents. The intent of the guidelines is to assess the risks to human health associated with the presence in food and feed, including aquaculture, and the transmission through food and feed, of AMR microorganisms and antimicrobial resistance determinants, by developing advice on appropriate risk management activities to reduce such risk. The guidelines will further address the risks associated with different areas of use of antimicrobial agents 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 are outside the scope of the guideline: residues of antimicrobial agents in food; AMR marker genes in recombinant-DNA plants and recombinant DNA microorganisms[4]; non-genetically modified microorganisms (for example, starter cultures) intentionally added to food with a technological purpose[5]; and certain food ingredients, which could potentially carry AMR genes, such as probiotics[6].

DEFINITIONS

9. The following definitions are included to establish a common understanding of the terms used in this document. The definitions presented in 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 or their frequency caused by AMR microorganisms and antimicrobial resistance determinants in food or acquired from food of animal/plant origin as well as the 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 increased mortality[7].

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[8].

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[8].

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[3] 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*

[4] 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)

[5] 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).

[6] 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).

[7] 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/*.

[8] 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. *http://www.fao.org/ag/agn/agns/files/Prepub_Report_CIA.pdf*.

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 – Various resistance mechanisms, each conferring resistance to an antimicrobial class[9], associated within the same microbiological host[8].

Cross-Resistance – A single resistance mechanism in a bacterium conferring resistance at various levels to other members of the class or to different classes. The level of resistance depends on the intrinsic activity of the antimicrobial agent, in general the higher the activity, the lower the level of resistance. Cross-resistance implies cross-selection for resistance[8].

Extra- and Off-Label Use – The use of an antimicrobial agent that is not in accordance with the approved product labelling. Such uses may be allowed under certain national regulations.

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. Most commonly this term refers to poultry, swine, cattle, sheep, fish and crustacean but it does not exclude other domestically managed animals[8].

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 follow.

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 agent, human exposure, prevalence, foodborne AMR microorganisms and antimicrobial resistance determinants, as well as available 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*

[9] Antimicrobial Class – Antimicrobials 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 antimicrobials 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.

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 antimicrobials resistant microorganisms.

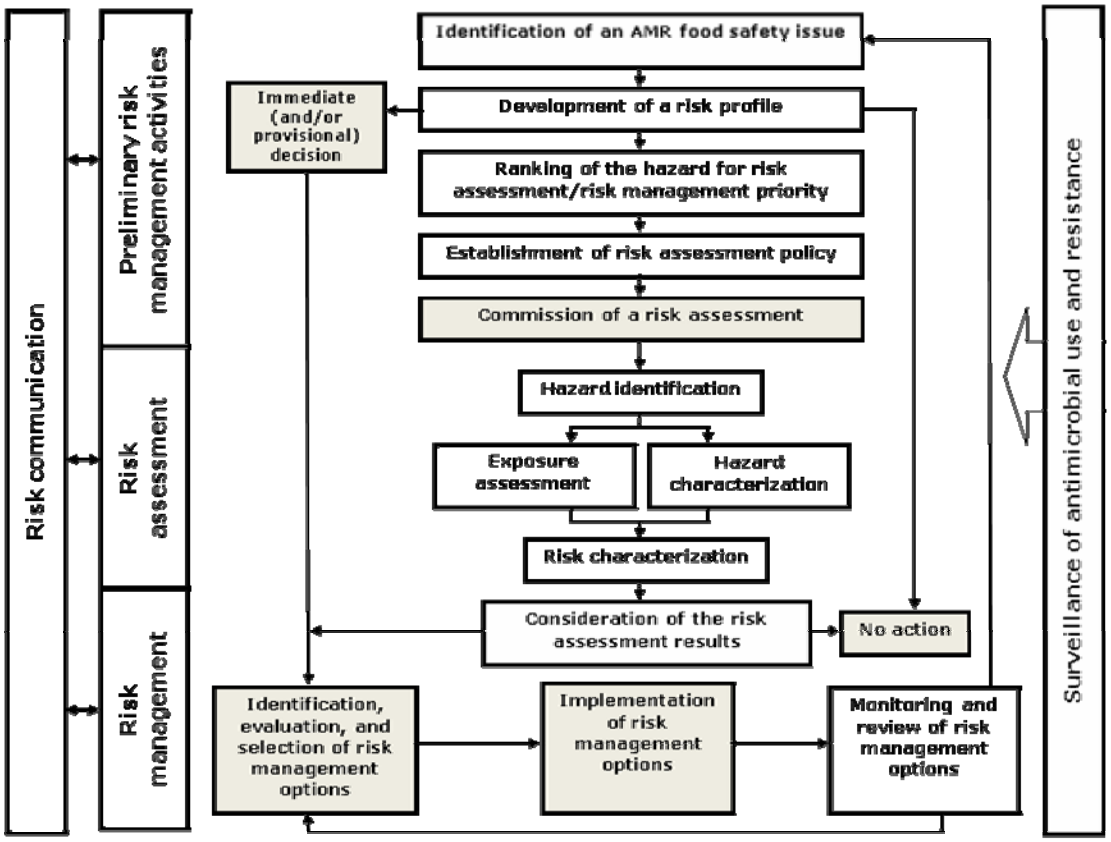
Principle 6: Foodborne AMR-risk analysis should focus on clearly defined combinations of the food commodity, the microorganism/resistance determinants and the antimicrobial agent to which resistance is expressed. Co-resistance should be considered in certain situations.

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

Principle 8: Evaluation of pre-harvest foodborne AMR risk management options 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 antimicrobial resistance. Surveillance, while not a conventional component of risk analysis, is considered integral to each step of the foodborne AMR-risk analysis.



Note: The boxes in grey highlight the key decision points in the framework of foodborne AMR-risk analysis; the box on "Surveillance of antimicrobial use and resistance" is not a component of conventional risk analysis, however, it is useful at various steps of the foodborne AMR-risk analysis process

PRELIMINARY FOODBORNE AMR-RISK MANAGEMENT ACTIVITIES

12. A potential food safety issue may arise when AMR microorganisms or antimicrobial resistance determinants are present in, and/or transmitted to humans, via food. Foodborne exposure to resistant microorganisms or antimicrobial resistance determinants may adversely impact human health. The risk

manager initiates the risk management process, beginning with the preliminary risk management activities, to evaluate the scope and magnitude of the food safety issue and, where necessary, to commence activities to manage the identified risk.

Identification of a foodborne AMR food safety issue

13. AMR food safety issues may be identified on the basis of information arising from a variety of sources, as described in para. 26.

Development of a foodborne AMR-risk profile (Appendix 1)

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 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. The fundamental elements that comprise a foodborne AMR risk profile include:

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

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 measures.

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 select a provisional decision, while obtaining additional information that may inform and, if necessary, modify the provisional decision. In those instances, the provisional nature of the decision should be communicated to all interested parties and the timeframe or circumstances under which the provisional decision will be reconsidered (e.g., reconsideration after the completion of a risk assessment) should be articulated when the decision is initially communicated.

Ranking of 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 RMOs, the AMR risk profile provides the principal resource that should be used by risk managers in risk ranking or prioritization this food safety issue among numerous other food safety issues.

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 broad risk management goals

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

Establishment of 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 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. 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. Based on the established risk management goals, risk managers may commission a risk assessment to provide a transparent, systematic evaluation of relevant scientific knowledge to help make an informed decision regarding appropriate risk management activities.

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

- A description of the specific food safety issue (as defined in the risk profile);
- The scope and purpose of the risk assessment;
- The specific questions to be answered by the risk assessment;
- The preferred type (e.g., quantitative, 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 by the consumption of food and to describe the magnitude and severity of the adverse effects of 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 resistant microorganisms and/or antimicrobial resistance 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 presented.

26. Possible sources of information:

- Surveillance programs (*see* paras 83-86);
- Epidemiological investigations of outbreaks and sporadic cases associated with resistant 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 production to consumption continuum (litter, water, feces and sewage);
- Investigations of the characteristics of resistant microorganisms and antimicrobial resistance determinants (in vitro and in vivo studies);
- Research on properties of antimicrobial agents including their resistance selection (in vitro and in vivo) potential and transfer of genetic elements and the dissemination of resistant microorgansims in the environment;
- Laboratory and/or field animal/crop trials addressing the linkage of use of antimicrobial agents and resistance (particularly regional data);
- 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 linkage of antimicrobial usage (particularly regional data) and resistance;
- Science-based and expert opinion.

Process of foodborne AMR-risk assessment

27. At the beginning of the work, risk assessment 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 elements for each component may be found in Appendix 2. Exposure assessment and hazard characterization can be conducted in parallel.

29. The principles of an AMR-risk assessment 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 identify the foodborne AMR concern. The food safety issues associated with the hazard may have been identified and prioritised in the preliminary risk management activities. Risk assessors should use this as the starting point for further identifying risks. Risk assessors should review literature and information from surveillance programs to identify specific strains or genotypes of foodborne microorganisms that pose risks by particular combination of a food commodity, microorganism/antimicrobial resistance determinants and antimicrobial agent to which resistance is expressed. Additionally, interaction of resistant microorganisms or antimicrobial resistance determinants with the appropriate environment (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 resistant microorganisms (or antimicrobial resistance determinants) will be useful. When necessary, science-based opinions on hazard identification can be sought from relevant experts.

Exposure assessment

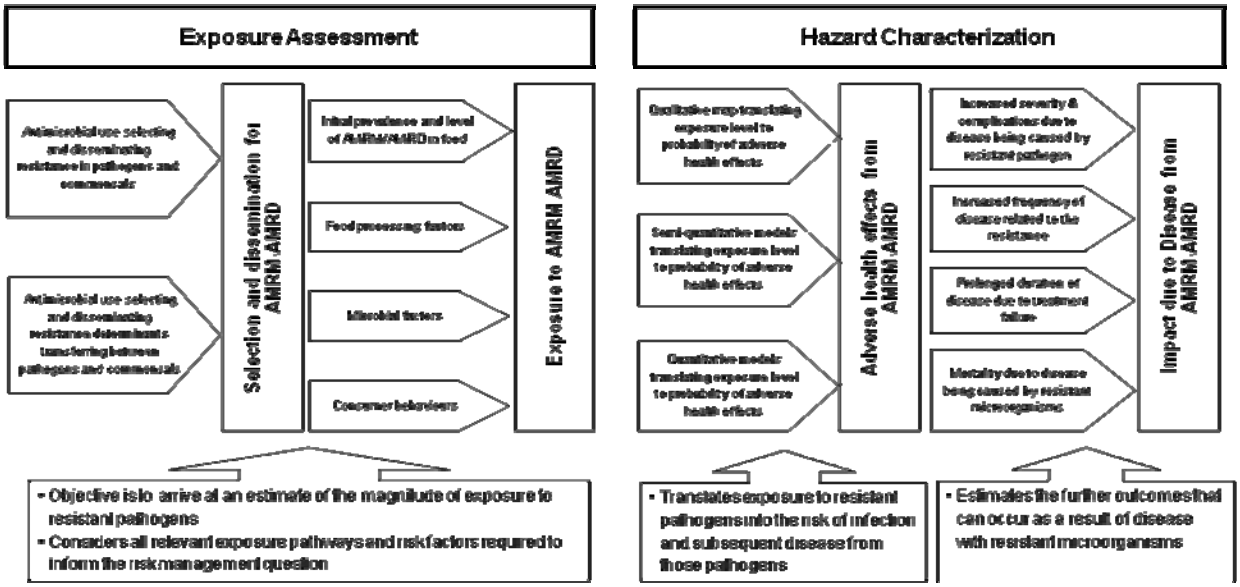
31. Use of antimicrobial agents occurs in different agricultural sectors and at different stages of production, including feed, food producing animal, crop production and/or during food processing. Following antimicrobial use, selection of resistant microorganisms and determinants may occur, which then 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. Figure 2 includes risk factors related to the release assessment and exposure assessment of the OIE risk assessment scheme[10]. 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.

33. Section 2.1 of Appendix 2 includes pre-harvest factors for estimating the likelihood of selection and dissemination of resistance within animal or plant 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 resistance microorganisms 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 antimicrobial resistance 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.

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



34. When the hazard of interest is the antimicrobial resistance determinants alone, including in commensal microorganisms, then an exposure assessment should consider whether these antimicrobial resistance determinants can transfer to human pathogens that subsequently become resistant. Assessing the exposure through animal feed should also consider resistance selection in microorganisms 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 antimicrobial resistance determinants may need to be considered in the AMR-risk assessment.

Hazard characterization

35. The hazard characterization step considers the characteristics of the hazard, food matrix and host in order to determine the probability of disease upon exposure to the hazard. A hazard characterization also includes the characteristics of the acquired resistance so as to estimate the additional consequences that can occur when humans are exposed to resistant pathogens, including increased frequency and severity of disease.

[10] OIE, Terrestrial Animal Health Code

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 2 includes examples of different types of approaches (e.g., qualitative mapping, semi-quantitative and quantitative models) that could be used to link exposure to adverse health effects. Figure 2 also includes a depiction of selected inputs to the exposure assessment and hazard characterization processes, which are listed in detail in Appendix 2.

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 antimicrobial resistance determinants, when appropriate, may be informed by hazard characterization for non-AMR microorganisms. Thus, compared to a non-AMR-hazard characterization, these outcomes are just a series of additional consequences that can 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.

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 guidelines on the types of outcomes that may be informative in the risk characterization but specific outputs may need to be established at the onset of the assessment process in conjunction with risk managers.

39. Additional outcomes 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[11].

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(s), 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 detail 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 language and understandable by non-mathematicians) 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

[11] 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*

steps[12]. Risk assessors must be sure that risk managers understand the impacts of these aspects on the risk characterization;

- Sensitivity and uncertainty analysis. Quantitative uncertainty analysis is preferred; however, it may be arrived at subjectively. In the context of quality assurance, uncertainty analysis is a useful tool for characterizing the precision of model predictions. In combination with sensitivity analysis, uncertainty analysis also can be used to evaluate the importance of model input uncertainties in terms of their relative contributions to uncertainty in the model outputs;
- Existing microbial and AMR-risk assessments;
- 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. The potential points for consideration in the risk characterization are presented in Section 4 of Appendix 2.

43. Appendix 2 provides examples of the outputs from a qualitative foodborne AMR-risk assessment. The Appendix is not intended to imply that a qualitative AMR-risk assessment is the preferred approach, but 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] .

Consideration of the foodborne AMR-risk assessment results

44. The conclusions of the risk assessment including a risk estimate, if available, should be presented in a readily understandable and useful form to risk managers and made available to other risk assessors and interested parties so that they can review the assessment. The responsibility for resolving the impact of uncertainties described in the risk assessment on RMOs lies with the risk manager and not with the risk assessors.

45. 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 hazard – combination of food, antimicrobial drug(s), antimicrobial use pattern and resistant foodborne microorganisms/or genetic determinants of resistance.

FOODBORNE AMR-RISK MANAGEMENT

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

47. Risk managers should consider non-regulatory measures in addition to regulatory controls. Any regulatory measures should be able to be enforced on the basis of the national framework of legal and regulatory authorities. Whether an intervention is a single RMO or a combination of RMOs, the intervention should be implemented in a manner that is proportional to the level of risk.

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[12] FAO/WHO. 1999. *Principles and guidelines for the conduct of microbiological risk assessment* (CAC/GL 30-1999). http://www.codexalimentarius.net/download/standards/357/cxg_030e.pdf

[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

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

49. It is implicit in the recommended approach to AMR risk management that good agricultural practices and good hygienic practices should be in place along the production to consumption continuum and that relevant Codex Codes of Practice 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 Prod*ucts (CAC/RCP 57-2004);
- *Code of Hygienic Practice for Eggs and Eggs Products* (CAC/RCP 61-2005);
- *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).

50. Additionally, relevant sections of the OIE Terrestrial Animal Health Code[14], 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.

Identification of foodborne AMR-RMOs

51. Risk managers when identifying RMOs to control an AMR food safety issue should consider a range of points along the production to consumption continuum, both in the pre-harvest and post-harvest stages where control measures may be implemented, and the interested parties, which 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.

52. 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 54 and 55), 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 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.

53. Risk assessors, scientists, food policy analysts, economists 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.

54. 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.

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[14] OIE. 2008. Terrestrial Animal Health Code (2008). http://www.oie.int/eng/normes/mcode/en_sommaire.htm

[15] T 469; FAO, 2005

[16] WHO, 2000

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

55. 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 post-harvest RMOs, which include measures to minimize the contamination of food by AMR microorganisms and antimicrobial resistance determinants.

Table 1. Examples of Foodborne AMR Risk Management Options	
PRE-HARVEST OPTIONS	
Animal feed production	Implement programs to minimize the presence in feed and feed ingredients of AMR microorganisms and antimicrobial resistance determinants and the transmission of these through feed. Prohibit or restrict the addition of feed ingredients containing AMR microorganisms and/or antimicrobial resistance determinants identified as contributing to a specific food safety problem.
Food animal production	**Regulatory controls on conditions of use of veterinary antimicrobial drugs and additives:** • Marketing status limitation, • Restrict extra-/off-label use • Extent of use limitation, • Major label restriction, and • Withdrawal of authorization. **Non-regulatory controls on condition of use of veterinary antimicrobial drugs and additives:** Development and implementation of national or regional treatment guidelines[18] targeting a specific AMR problem. Development and regular update of species-specific responsible use guidelines[19] by professional bodies. Improve accuracy of microbiological diagnosis in the development, dissemination and use of international standards for: • Bacterial culture and antimicrobial susceptibility testing[20]; and • Interpretive criteria. Implement biosecurity and animal health and infection control programs to minimize the presence and transmission of foodborne microorganisms and antimicrobial resistance determinants between animals, to/from animals to humans and between flocks/herds.
Food crop production	**Regulatory controls on conditions of use:** • 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 authorization. Evaluate the safety of viable microorganisms used as supplements in food and feed crop

[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, prudent use, clinical practice guidelines, and guidelines for prudent use are all terms that refer to 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).

[20] OIE Manual for Terrestrial Animals, specifically "Laboratory Methodologies for Bacterial Antimicrobial Susceptibility Testing"

	production for their potential to introduce and spread AMR. **Non-regulatory controls of use:** Implement 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; • Treating only specific developmental stages where the treatment is likely to be most effective, rather than treating at all developmental stages. Development and implementation of national or regional treatment guidelines[17] targeting a specific AMR problem. Improve accuracy of microbiological diagnosis in the development, dissemination and use of international standards for: • Bacterial culture and antimicrobial susceptibility testing; and • Interpretive criteria. Implement biosecurity and infection control programs to prevent the presence and transmission of foodborne resistant AMR microorganisms and antimicrobial resistance determinants between crops and from crops to humans.
Waste management	Implement control measures to limit the spread of AMR microorganisms and antimicrobial resistance determinants of microorganisms through other sources of contamination, by assuring the appropriate use of human and animal waste (biosolids, manure, other natural fertilizers) in fields for food and animal feed production: • Design treatment procedures to control resistant microorganisms and antimicrobial substances that could lead to their emergence in biosolids, manure and other fertilizers, as 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

56. 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[21]. The process by which options are evaluated may vary depending on the specific RMOs and their impact on different control points in the production to consumption continuum. The option of not taking any action should also be evaluated.

57. 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.

[21] 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)).

- Estimates of risk that would result from application of potential 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.

58. Any positive or negative impacts of RMOs on public health should be considered when evaluating RMOs. Risk managers can 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 use of antimicrobial agent should always be considered individually or in combination.

59. 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 critically important to human health.

60. 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.

61. RMOs for AMR should be evaluated based on their impact on the specific combination of the food commodity, the microorganism/antimicrobial resistance determinants and the antimicrobial agent 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

62. In order to select the best RMO or combination of RMOs to address an AMR food safety issue, risk managers should first determine an ALOP or public health goal. Once the goal is established, information obtained from the evaluation of RMOs (relative to the specific combination of the food commodity, the AMR microorganism/antimicrobial resistance determinants and the antimicrobial agent to which resistance is expressed) can be used to determine the most efficient approach to achieving the desired 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).

63. 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-RMOs

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

65. To effectively execute control measures, food producers and processors generally implement complete food control systems using comprehensive approaches such as Good Manufacturing Practices (GMP), Good Hygiene Practices (GHP) and HACCP systems.

Monitoring and review of foodborne AMR-RMOs

66. Risk managers should establish a process to monitor and review whether the RMOs 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 RMOs should be measured by specific food safety metrics, the ALOP and/or public health goals; possible end points include:

- Prevalence of foodborne AMR microorganisms and/or antimicrobial resistance determinants at farm level;
- Prevalence of foodborne AMR microorganisms and/or antimicrobial resistance determinants in food products at slaughter/harvest;
- Prevalence of foodborne AMR microorganisms and/or antimicrobial resistance determinants in food products at retail level;
- Prevalence of foodborne AMR microorganisms and/or antimicrobial resistance determinants in human clinical isolates from foodborne diseases;
- Number of (incidence) adverse health effects such as treatment failure, loss of treatment options and/or severity of infections (e.g., prolonged duration of disease, increased frequency of bloodstream infections, increased hospitalization, and increased mortality) attributable to foodborne AMR microorganisms and/or determinants;
- Trends in non-human use of antimicrobial agents, including critically-important antimicrobial agents.

67. National surveillance programmes, designed to monitor the presence of AMR microorganisms and the use of antimicrobials, can help establish a baseline against which the effectiveness of RMOs can be measured.

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

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

69. 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 use and the prevalence of AMR microorganisms in food producing animals, crops, food, feed, feed ingredients and biosolids, manure and other natural fertilisers, as input for risk profiling and risk assessment, to measure the effect of interventions and to identify trends. The level of detail of data collection could be implemented according to the resources available.

70. Methodology of surveillance programmes should be harmonized between countries. The use of standardized and validated antimicrobial susceptibility testing methods and harmonised interpretive criteria are essential to the ability to use information from such programs.

71. 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.

72. Surveillance of AMR in microorganisms originating from food producing animals, plants and food should ideally be integrated with programs that monitor resistance in humans. Consideration may also be given to inclusion of feed, feed ingredients and biosolids, manure and other natural fertilisers materials 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” to describe key elements of programs to monitor the prevalence of foodborne AMR microorganisms in animals and relevant WHO guidance.

FOODBORNE AMR-RISK COMMUNICATION

73. 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.

74. Risk communication decision-makers can obtain vital information, provide information and solicit feedback from interested parties. Communication with all interested parties promotes better understanding of risks and greater understanding on risk management approaches.

75. Communication between interested parties should be integrated into all phases of a risk analysis at the earliest opportunity (see Figure 1).

76. 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 Risk Communication as a Risk Management Tool

77. Information on veterinary antimicrobial products considered essential by the national authority to ensure their safe and effective use, in compliance with national regulations, should be made available by the veterinary drug industry in the form of labelling, data sheets or leaflets.

78. The food industry is responsible for developing and applying food safety control systems for effective implementation of risk mitigation measures. Depending on the nature of the option, this may require risk communication activities such as effective communication with suppliers, customers and/or consumers, as appropriate, training or instruction of its staff and internal communication.

79. Industry (pharmaceutical, food producer, food processor, etc.) associations should be encouraged to develop and provide guideline documents, training programs, technical bulletins and other information that assists industry to decrease foodborne AMR.

80. Training should be undertaken to ensure the safety to the consumer of animal derived food and, therefore, the protection of public health. Training should involve all the relevant professional organizations, regulatory authorities, the pharmaceutical industry, veterinary schools, research institutes, professional associations and other approved users.

81. Consumers can enhance both their personal and the public’s health by being responsible for keeping aware of and following food safety-related instructions. Multiple means of providing this information to consumers should be undertaken, such as public education programs, appropriate labelling and public interest messages. Consumer organizations can play a significant role in getting this information to consumers. Information to promote food safety should be disseminated.

82. When RMOs include consumer information, outreach programs are often required, for example to enlist health care providers in disseminating the information. When the goal is to inform and engage the public, messages intended for specific audiences need to be presented in media the audiences pay attention to.

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

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

1. Description of the AMR food safety issue
    - What is the potential hazard – the defined combination of the food commodity, the microorganism/antimicrobial resistance determinant, and the antimicrobial agent to which resistance is expressed?
2. Food commodity information
    - How and where does the identified microorganism/ antimicrobial resistance determinant enter the food supply?
    - Which foods expose consumers to the identified microorganism/ antimicrobial resistance determinant?
    - How much of those foods are consumed by the target populations?
    - What are the frequency, distribution and levels of occurrence of the identified microorganism/ antimicrobial resistance determinant in foods?
3. Microorganism/ antimicrobial resistance determinant information
    - What are the microbiological characteristics of the identified food borne microorganism (e.g., virulence, growth conditions, etc.)?
    - What are the characteristics of the resistance expressed by the microorganism (e.g., spectrum of resistance, involvement of co- or cross-resistance, transferability, etc.)?
4. Information on the antimicrobial agent to which resistance is expressed
    - How important is the antimicrobial agent in the treatment of human disease?
    - How important is the antimicrobial agent to animal medicine?
    - What pathways may have led to the presence of resistance to the antimicrobial agent?
        - Was the antimicrobial agent used in food production? If so, how was it used (e.g., applications, amounts)?
        - Were related antimicrobial agents used in food production (potential role of cross-resistance or co-resistance)?
        - What other factors may affect the dissemination of AMR microorganisms and antimicrobial resistance determinants through the food chain?
5. Information on adverse public health effect(s)
    - What are the characteristics of the disease caused by the identified food borne microorganism (e.g., severity of effects, susceptible populations)?
    - What are the effects of antimicrobial resistance in the identified food borne microorganism (e.g., loss of treatment options, availability of alternative treatments, added burden of disease)?
6. Other Relevant Information
    - What is the evidence of a relationship between the presence of the AMR microorganisms or antimicrobial resistance determinants on the food commodity and the occurrence of the adverse health effect(s) in humans?

- What is the evidence of a relationship between the use of the antimicrobial agent and the occurrence of
- AMR microorganisms, or antimicrobial resistance determinants, in the food commodity of concern?
- What are potential risk mitigation strategies that could be used to control the hazard?
- Are there current risk management practices in place? What is their effectiveness?

7. Assessment of available information and major knowledge gaps

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

APPENDIX 2. SUGGESTED ELEMENTS FOR CONSIDERATION IN 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 antimicrobial resistance determinants in food and animal feed

1.2 The antimicrobial agent and its properties

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

1.3 Microorganisms and resistance related information

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

2. Exposure Assessment

2.1 Pre-harvest factors affecting prevalence of hazard on-farm

- Resistance selection pressure:
    - Attributes of antimicrobial use at the population level:
        - Number of animal or extent of crop exposed to the antimicrobial agent in the defined time period
        - Geographical distribution of use and/or farms
        - Prevalence of infection/disease that the antimicrobial agent is indicated for in the target (animal/crop) population
        - Potential extra-label, off-label, and non-approved use of antimicrobial agent
        - Data on trends in antimicrobial use and information on emerging diseases, changes in farm production system, or other changes that are likely to impact antimicrobial use
    - Attributes of antimicrobial 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 administration to harvest
        - 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) of interest
    - Rate of resistance development in commensal and zoonotic microorganisms in targets after administration of an antimicrobial agent
    - Resistance mechanisms, location of antimicrobial resistance determinants, occurrence and rate of transfer of resistance between microorganisms
    - Cross-resistance and/or co-selection for resistance to other antimicrobial agents (phenotypic or genotypic characterization)
    - Prevalence of commensals and zoonotic microorganisms in targets and proportion resistant to the antimicrobial agent (and minimal inhibitory concentration levels)
    - Transmission of AMR microorganisms/antimicrobial determinants between target animals/crops, and from animals/crops to environment and back to target animals/crops
    - Animal management factors affecting immunity
    - Food crop production/management
- Other possible sources of foodborne AMR resistant microorganisms for the target animal/crop
    - Non-target animal/plant species
    - Animal feed
    - Soil or water, animal and human waste products

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

- Initial level of contamination of the food product
    - Frequency and concentration of foodborne AMR microorganisms and/or their antimicrobial resistance determinants at slaughter or time of crop harvest
    - Frequency and concentration foodborne AMR microorganisms and/or antimicrobial resistance 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)
    - Points for cross-contamination
    - Packaging
    - Probable use of additives and preservatives (due to their activities or impacts on growth or numbers of microorganisms)
    - Starter cultures (type and number of microorganisms) used as ingredients
    - Distribution and storage
    - Catering and food services

- Consumer behaviours
  - Storage, cooking, and handling
  - Overall per capita consumption
  - Patterns of consumption and socio-economic, cultural, ethnic, and regional differences
- Microbial factors
  - Capacity of food-derived resistant microorganisms to transfer resistance to human commensal and/or pathogenic microorganisms
  - Growth and survival characteristics of resistant microorganisms
  - Microbial ecology in food: survival capacity and redistribution of foodborne AMR microorganism in the production to consumption continuum

2.3 Transfer of hazard

- Transmission of antimicrobial resistance determinants/resistant microorganisms among animals, food, feed, environment and humans
- Occurrence and probability of resistance gene transfer from resistant microorganisms to human commensals/pathogens

2.4 Exposure to hazard

- Quantity of various food commodities consumed
- Point of food consumption (home, commercial establishment, or informal establishment)
- Human demographics data
- Socio-cultural etiquettes and susceptibility in relation to food consumption habits; consumption of a particular food commodity could be qualitatively classified as low, medium, or high
- Practices associated with food handling and processing

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)
- Treatment with antimicrobial therapy and hospitalization
- Drug selection for infections
- Importance of antimicrobial drug 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. 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 in risk estimation

- Number of people falling ill and the proportion of that number with resistant strains of microorganisms attributable to foodborne source
- Effects on sensitive subpopulations
- Increased severity or duration of infectious disease 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)
- Importance of pathology caused by the target microorganisms
- Existence or absence of therapeutic alternatives; absence of alternative antimicrobial agent and alternatives with potential
- Alternatives available in case of resistance, and potential impact of switching to alternative antimicrobial agent; absence of alternative antimicrobial agents or potential impact of switching to alternative antimicrobial agent (e.g., alternatives with potential toxicity).
- Incidence of resistance
- Consequences to allow weighted summation of (e.g., disease and hospitalization) or some arbitrary scale of impact to allow weighted summation of different risk impacts

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, this should not be viewed as a recommended or accepted default approach 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 categorization of hazard characterization into qualitative statements or scores, with similar considerations as the exposure assessment into interpretation and implications; and
- 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. While the exposure assessment qualitatively captures the probability of being exposed, the hazard characterization qualitatively estimates the implications of being exposed. In microbiological risk assessment, the focus of the hazard characterization step is to translate the probability of exposure to the probability of disease; however, in foodborne AMR-risk assessments, the focus is likely to be the implications of exposure to resistant microorganisms that are over and above those of being exposed to susceptible organisms. To illustrate, the following categories are proposed:

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

- Moderate (2) – Probability of disease upon exposure is higher and outcomes following disease are more serious requiring hospitalization;
- Severe (3) – Probability of disease 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 foodborne resistant microorganism in a given food or feed commodity, animal species, or plant. The different ranking is defined below:

- Negligible – The probability of exposure to susceptible people is extremely low;
- Low (Unlikely) – The probability of exposure to susceptible people is low but possible;
- Medium (Likely/Probable) – The probability of exposure to susceptible people is likely;
- High (Almost Certain) – The probability of exposure to susceptible people is certain or very high;
- Not assessable – The probability of exposure to 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[22] . In this example, it is considered that adverse health effects associated with the microorganisms that are resistant to critically important antimicrobials in human medicine[23] (will likely have a more severe consequence than those with microorganisms resistant to antimicrobials of other categories:

- 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 **Probability of Exposure**	**Hazard Characterization** **Severity of Adverse Health Effect**	**Qualitative Risk Characterization**
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

[22] Modified after National Cancer Institute, 2006. Common terminology criteria for adverse events v3.0. http://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/ctcaev3.pdf

[23] 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. *http://www.fao.org/ag/agn/agns/files/Prepub_Report_CIA.pdf*