E

CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 5 **CX/AMR 19/7/5**
October 2019

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

***AD HOC* CODEX INTERGOVERNMENTAL TASK FORCE ON ANTIMICROBIAL RESISTANCE**

Seventh Session
Pyeongchang, Republic of Korea, 9-13 December 2019

PROPOSED DRAFT REVISION OF THE CODE OF PRACTICE TO MINIMIZE AND CONTAIN FOODBORNE ANTIMICROBIAL RESISTANCE (CXC 61-2005)

(Prepared by the Electronic Working Group
led by the United States of America and co-chaired by China, Chile, Kenya, United Kingdom)

Codex members and observers wishing to submit comments at Step 3 on this document should do so as instructed in CL 2019/84-AMR available on the Codex webpage/Circular Letters: http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/.

Introduction

1. The 6th Session of the Ad Hoc Intergovernmental Task Force on Antimicrobial Resistance (TFAMR06, 2018) agreed to establish an electronic working group (EWG) chaired by the United States of America and co-chaired by China, Chile, Kenya, United Kingdom, working in English and Spanish, to further develop the revision of Code of practice (CXC 61) for circulation for comments and consideration at TFAMR07, 2019.

2. The following Terms of Reference were agreed by TFAMR06 and can be found in the report of the session (REP19/AMR) at paragraph 82.

- To further develop the Code of Practice (COP) based on the discussion held and agreements made including written comments submitted using Conference Room Document CRD20 as the basis for the discussion.
- To address in particular the following topics on the understanding that agreed text should not be re-opened to the extent possible.
    - Sections 1 – 2 – consideration of bracketed provisions.
    - Section 3 – consideration of definitions for food of plant origin, plant/crop professional, therapeutic use and additional definitions as needed or proposed by TFAMR including food production environment.
    - Section 4 – further development of Principles 5, 6, 7, and 12.
    - Section 5 – further development of this section in particular the following topics: reference to the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH), inclusion/exclusion of paragraphs 21 and 22 on surveillance and monitoring, paragraphs 25-27 and 35-36 on control of advertising, paragraphs 51-53 on off-label use.

  Additional areas as needed to progress the text.
    - Section 6 – consideration of bracketed provisions.
    - Section 7 – consideration of bracketed provisions taking note of guidance from the Codex Secretariat.
- TFAMR further agreed that in discussing the above sections, the EWG should consider the report of the Joint FAO/WHO Expert Meeting in collaboration with OIE on Foodborne Antimicrobial Resistance: Role of Crops, Environment, and Biocides.

3. The EWG conducted two rounds of discussion on the COP based on the discussion held and agreements made including written comments submitted using CRD20 as the basis for the discussion. The first round was launched in April 2019 and the second round was launched in July 2019. Both rounds of discussion included the entire text of the document.

4. A system of "light-shading" was used in the working document to identify text that had previously been agreed at TFAMR06 and text with apparent consensus following Round 1. The aim of this system was to focus participants comments on areas identified for further discussion at TFAMR06 and areas of the text that had not yet received adequate discussion. Nevertheless, minor suggestions were taken to improve the clarity of the text in the lightly-shaded sections.

5. Following Round 2 of the discussion, the paragraphs of the entire text were re-numbered deleting certain paragraphs as identified at TFAMR06 and in Round 1. Previous paragraph numbers were retained in strikethrough for clarity with the suggestion that new paragraph numbers be used at TFAMR07. For the purpose of this report, reference will be made to the new paragraph numbers.

6. Based on a suggestion at TFAMR06 and comments in Round 1, the General Principles were grouped according to thematic areas and a proposed re-ordering is offered in the revised text for further consideration at TFAMR07.

7. Comments were received over approximately two four-week periods and were posted to the Codex Forum. The revised text was available in English and Spanish on the platform.

8. Based on comments received in Round 1 and Round 2, draft revised text was prepared by the EWG Co-Chairs and is available in Appendix I.

9. In Round 1, the EWG received comments from a total of 31 participants, 22 Codex Members, 1 Codex member Organization, and 8 Observers. In Round 2, the EWG received comments from a total of 23 participants, 17 Codex Members, 1 Codex member Organization, and 5 Observers.

10. In summary, the EWG was held from April 2019 through August 2019 and received a total of 54 sets of comments from 26 Codex Members, 1 Codex Member Organization, and 8 Observers. The list of participants is attached as Appendix II.

11. Following is a summary of comments and main points of discussion during the two rounds of the EWG.

Summary of comments by Codex members and observers and main points of discussion in the EWG on the revision of the *Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance* (CXC 61-2005) – COP3

Section 1. Introduction

12. The Introduction appears to have good consensus with only a few points outstanding.

13. The first instance of the term "food of animal origin" occurs here. The majority of comments received suggest replacing "food of animal origin" with "plants/crops" throughout the document. However, a minority of participants continue to advocate the term is valuable and should be retained for a number of reasons, including that there is an important distinction centering around the portion of the plant/crop that is edible vs. non-edible. The distinction being important because different risk management options could be taken toward the portion of the plant/crop that is edible (food) vs. non-edible (not food for human or animal consumption).

14. The EWG Co-Chairs observe that replacement of the term "food of animal origin" with "plant/crop production" does not make a significant difference with respect to the minority opinion in Paragraph 1 and replacement could help facilitate closure of this section without prejudicing further discussion and edits in later sections of the document.

15. The second significant area of discussion was on Paragraph 6, bullet 2. Most participants commented on this text with a number of comments favoring retention of the text as drafted at TFAMR06. The EWG Co-Chairs observe that the text, as drafted, places emphasis on the Annex containing the actual list without necessarily being exclusive.

16. Other minor edits, Paragraph 4 and Paragraph 6, bullet 4, were suggested during Round 2 and may not require significant discussion in the opinion of the EWG Co-Chairs.

Section 2. Scope

17. The Scope appears to have good consensus with only a few points outstanding.

18. **Paragraph 9** contains another reference to “food of animal origin” with comments submitted by participants falling largely along the same lines as in Section 1. Again, the EWG Co-Chairs observe that replacement of the term “food of animal origin” with “plant/crop production” does not make a significant difference in Paragraph 9 with respect to the minority opinion described above and replacement could help facilitate closure of this section without prejudicing discussion and edits in later sections of the document. A minor edit was suggested in Round 2 to remove the word “feed” as this would be covered by “plant/crop production”.

19. **Paragraph 11** received comments from many participants. Overall, more participants favored retention of both the initial bracketed text “however some recommendations may also be applicable to antiviral, antiparasitic, antiprotozoal, and antifungal agents” and the additional text “where scientific evidence supports foodborne AMR risk to human health”.

20. **Paragraph 12**, a suggestion was made in Round 2 to add “non-food plants/crops” to the list of areas agreed at TFAMR06 that are outside the scope of the document. The rationale is to further distinguish plants/crops that are not used for food, for example ornamental shrubs and trees.

Section 3. Definitions

21. Three definitions received the most discussion during the EWG: food production environment, food of plant origin, and therapeutic use - and may require additional discussion at TFAMR07 to arrive at consensus.

22. **Food production environment**: This definition was drafted at TFAMR06 and received good support in Round 1 for inclusion in the text. In Round 2, additional comments were received questioning and making suggestions for specific words in the definition. Specifically, clarification of “immediate vicinity” and “reasonable probability” were requested along with a suggestion to add “or otherwise handled”. While good support for the concept of “food production environment” was apparent – including several requests that it be included in the Guidelines on Integrated Monitoring and Surveillance for Foodborne AMR (GLIS) – some additional discussion at TFAMR07 will help obtain consensus.

23. **Food of animal origin**: This term was requested by several delegations during discussion of the text at TFAMR06. In Rounds 1 & 2, more participants favored replacing it throughout the text with “plant/crop” and modifying that definition, if needed. Still, a number of delegations continue to advocate there is an important distinction centering around the portion of the plant/crop that is edible vs. non-edible. The distinction being important because different risk management options could be taken toward the portion of the plant/crop that is edible (food) vs. non-edible (not food for human or animal consumption). Some additional discussion at TFAMR07 will help obtain consensus.

24. **Therapeutic use**: This term was not discussed at TFAMR06. The terms “therapeutic” or “therapy” appear in the text. While the term “therapeutic use” was not discussed at TFAMR06, adoption of the components of the definition were agreed, specifically: treatment of disease, control of disease / metaphylaxis, prevention of disease/prophylaxis. Comments in Round 2 suggested alignment with the term “veterinary medical use” as adopted by the OIE. The EWG Co-Chairs note the adoption of the term by OIE is related to use in animals and is likely not fit for purpose as a definition that applies also to plants/crops. As a possible solution, the EWG Co-Chairs suggest adding a sentence to the definition as follows. “The term is generally understood to have the same meaning as “veterinary medical use” with respect to food-producing animals for the purpose of this text.” Additional discussion at TFAMR07 will help obtain consensus.

25. **Adverse health effect**: A suggestion was made in Round 2 for a revision to the definition to eliminate the phrase “of animal/crop origin”. The rationale is that the phrase is not necessary for the definition. Further, removing the phrase would reduce the need to have separate definitions for “food of crop (plant) origin” and “food of animal origin”.

26. **Competent Authority(ies)**: A new definition was proposed in Round 2 following the agreement in Round 1 to replace “Regulatory Authority(ies)” with “Competent Authority(ies)”. The proposal cites a footnote in the *Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods* (CXG 32-1999) as the basis for the definition.

27. **Food chain**: Addition of the word “feed”. A suggestion was made in Round 1 to include “feed” in the definition of food chain for completeness.

28. **Medically important antimicrobials**: A suggestion was made in Round 1 to revise the placement of the phrase on ionophores to improve clarity.

29. **Plants/crops**: A suggestion was made in Round 1 to add “(or parts thereof)” in order to highlight the distinction between edible and non-edible portion of the plant/crop.

30. **Plant/crop health professional**: Revisions were suggested in Rounds 1 & 2 to improve clarity. In addition, a comment in Round 2 stated that the term “phytosanitary professional” has the same meaning when translated into Spanish and suggested that an explanatory sentence could be added to the Spanish translation. If this is needed, the EWG Co-Chairs propose the following, “This term has the same meaning as phytosanitary professional in Spanish.”

Section 4. General Principles

31. General Principles 1-4, 8-11, and 13-14 were agreed at TFAMR06. Further, it was agreed at TFAMR06 that General Principle 11 should be moved to Section 1. Introduction. It was further suggested at TFAMR06 and in Rounds 1 & 2 that the General Principles should be re-ordered to improved clarity.

32. **Principle 5**: Many delegations in Round 1 indicated support for this Principle as revised at TFAMR06. In Round 2 there was again support for the Principle, however some delegations suggested the Principle could be further revised and streamlined to improve clarity. The EWG Co-Chairs suggest this Principle be further discussed at the physical working group (PWG) to be held in advance of TFAMR07 to help obtain consensus.

33. **Principle 6**: Round 1 comments indicate a preponderance of support for this Principle. Clarification of the phrase “or in certain circumstances for research and conservation” was requested. An example of “research and conservation” would be the use of oxytetracycline as a skeletal marker in fish to distinguish hatchery-reared fish from wild fish populations. Round 2 comments continue to include support for the Principle, but also include some diversity of opinion and suggestions for improving clarity. The EWG Co-Chairs suggest this Principle be further discussed at the PWG to be held in advance of TFAMR07 to help obtain consensus.

34. **Principle 7**: Round 1 comments indicated a need for clarification of Principle 7. The principle was revised taking into account suggestions in Round 1 to emphasize specific conditions when medically important antimicrobials are used for prevention/prophylaxis. Round 2 comments continue to indicate a diversity of opinion on the wording for this Principle. The EWG Co-Chairs suggest this Principle be further discussed at the PWG to be held in advance of TFAMR07 to help obtain consensus.

35. **Principle 7bis**: In Round 1 there was a suggestion for a new Principle that describes specific conditions when medically important antimicrobials are used for control of disease/metaphylaxis. Round 2 comments included a range of suggestions to improve the clarity of the Principle. The EWG Co-Chairs suggest this Principle be further discussed at the PWG to be held in advance of TFAMR07 to help obtain consensus.

36. **Principle 7ter**: In Round 1 there was a suggestion for a new Principle that describes specific conditions when medically important antimicrobials are used for plant/crop protection. Round 2 comments include a range of suggestions for improving the clarity of this Principle along with an observation that Principle 7 and 7bis could also apply to plants/crops and therefore 7ter could be deleted. The EWG Co-Chairs suggest this Principle be further discussed at the PWG to be held in advance of TFAMR07 to help obtain consensus.

37. **Principle 9**: An additional sentence was suggested in Round 2 to reference OIE and the International Plant Protection Convention (IPPC).

38. **Principle 10**: The addition of “plants/crops” was suggested in Round 1 as an additional factor to consider through the foodborne AMR risk analysis process.

39. **Principle 12**: Comments in Round 2 included a suggestion that “medically important” should be deleted making this Principle applicable to all antimicrobial agents while other comments suggested the Principle is now redundant with text in Section 5 and could be deleted. The EWG Co-Chairs suggest this Principle be further discussed at the PWG to be held in advance of TFAMR07 to help obtain consensus.

40. **Principle 14**: Comments in Round 1 included a suggestion to add “antimicrobial” before susceptibility testing to improve clarity. A comment in Round 2 suggested replacing “production setting” with “food production environment”.

41. The Principles were reordered by grouping them by overarching themes. The thematic section headings are for the purpose of review at TFAMR07 and may not be retained in the final version. The EWG Co-Chairs suggest the order of the Principles be further discussed at the PWG to be held in advance of TFAMR07 to help obtain consensus.

Section 5. Responsible Use of Antimicrobial Agents

41. **Paragraph 13**: A suggestion was made to add the OIE List of Antimicrobial Agents of Veterinary Importance.

42. **Paragraph 14**: TFAMR06 noted proposals to delete reference to VICH, given its nature and membership. Others were in favor of retaining. The Representative of OIE informed the TFAMR that the OIE Code does make reference to VICH. With regard to referencing external documents the Codex Secretariat clarified that there were no specific procedures in this regard and so the decision to include such a reference was up to the TFAMR; however in making their decision they should consider that the membership of VICH was narrower than that of Codex, not all Codex Members contribute to the development of VICH guidelines and decide on their adoption. Other options such as including relevant text in the COP could also be considered but this may present consistency issues in the future.

43. The EWG Co-Chairs suggested a revision. Round 1 comments indicated support for the revision suggested by the EWG Co-Chairs. Round 2 comments include suggestions to replace the reference to VICH with “internationally harmonized guidelines”.

44. **Section 5.1**: Replace “regulatory authorities” with “competent authorities” based on a decision at TFAMR06.

45. **Paragraph 15**: A suggestion was made to move the first sentence of Paragraph 16 to the end of Paragraph 15.

46. **Paragraph 16**: A minor edit was suggested to align the text with the title of the COP.

47. **Paragraph 17**: Additional text was suggested in Round 1 and amended in Round 2.

48. **Paragraph 18**: Round 1 comments include a suggestion of 14alt as a replacement for paragraph 14. Round 2 comments included suggestions for combining paragraph 14 and 14 alt.

49. **Paragraph 19**: Additional text was suggested to strengthen the paragraph in terms of quality control.

50. **Paragraph 20**: Edits were suggested to improve the clarity of the text regarding assessment of efficacy.

51. **Paragraph 21**: Minor edits were made to improve clarity.

52. **Previous paragraph 18**: Merged with paragraph 22.

53. **Paragraph 22**: The text from the preceding paragraph was merged with this paragraph and substantive edits were made to improve the clarity. The EWG Co-Chairs suggest this text be further discussed at the PWG to be held in advance of TFAMR07 to help obtain consensus.

54. Further, a Round 2 comment suggested the following as alternative criteria in the first sentence: “environmental fate and behavior data of antimicrobial agents (e.g. degradation of the active constituents, mobility, likely transport and final destination in the environment) to help estimate the predicted environmental concentrations in different environmental compartments—soils, sediment, water and dung —as appropriate, based on the proposed use pattern and physicochemical properties of the chemical.”

55. **Paragraph 23**: In Round 1 there was a request for clarification on the items to be included. Round 2 comments included proposed bullets. In addition, pharmacokinetic (PK), pharmacodynamic, and susceptibility breakpoints for target pathogens were suggested. The EWG Co-Chairs question whether this paragraph can be generalized to include plant/crop protection products by removing “veterinary medicinal”. The EWG Co-Chairs suggest this text be further discussed at the PWG to be held in advance of TFAMR07 to help obtain consensus.

56. **Paragraph 24**: Round 1 comments suggest the GLIS will have taken into account all of the references in this paragraph. There was a suggestion to insert a reference to the GLIS and to delete of the remainder. Comments in Round 2 indicate a preponderance of support for the proposal. The EWG Co-Chairs also note the previous paragraph 22 has been deleted as agreed at TFAMR06.

57. **Paragraph 25**: Minor edits were suggested to the agreed text for clarity.

58. **Paragraph 26**: Minor edits were suggested to the agreed text for clarity.

59. **Paragraph 27**: A Round 2 comment suggested deleting the second half of the sentence starting with “…including that and medically important antimicrobials…” The EWG Co-Chairs suggest this text be further discussed at the PWG to be held in advance of TFAMR07 to help obtain consensus.

60. **Paragraph 28**: A Round 2 comments requested deletion of the phrase “to the extent possible”. The EWG Co-Chairs suggest this text be further discussed at the PWG to be held in advance of TFAMR07 to help obtain consensus.

61. **Paragraph 29**: Round 1 comments stated that monitoring of antimicrobial use is described in the GLIS and therefore the second half of the sentence is no longer needed based on a previous reference to the GLIS.

62. **Paragraphs 30 and 31**: Round 2 comments generally support control of advertising by competent authorities (CAs) according to national legislation and specific regulatory requirements, which should conform to the marketing authorization and any content required. Comments also stated that policies and prudent use guidelines may not be enforceable by the CA and therefore may be better suited for consideration in other sections. Redundant text was been removed and consolidated into 2 paragraphs. The EWG Co-Chairs suggest this text be reviewed at the PWG to be held in advance of TFAMR07 to help obtain consensus.

63. Revision of the section header based on comments received in Rounds 1 & 2.

64. **Paragraph 32**: The EWG Co-Chairs proposed revised text to focus on the role of the CAs based on comments in Round 2 including a new name for the title of the section. In addition, the EWG Co-Chairs note the list of examples has grown quite long and may no longer be practical and feasible. The EWG Co-Chairs suggest this text be discussed at the PWG to be held in advance of TFAMR07 to help obtain consensus.

65. **Paragraph 33**: Based on comments in Rounds 1 & 2, the text has been revised for clarity. A comment in Round 2 stated that bullet 5 is not a knowledge gap. A Round 2 comment questions the use of the term “agricultural chemical use”, should it be defined?

66. **Paragraph 34**: The first sentence is deleted based on a Round 2 comment indicating it is redundant with the elements in paragraph 33.

67. **Paragraph 35**: The paragraph was revised based on comments in Rounds 1 & 2. The phrase “including proper disposal of containers and packaging materials” was deleted based on a comment questioning the evidence for this part of the recommendation. The EWG Co-Chairs suggest this phrase be discussed at the PWG to be held in advance of TFAMR07 to help obtain consensus.

68. **Paragraph 36**: Based on Round 2 comments taking into consideration comments provided on Paragraph 22, a new bullet is proposed.

69. **Paragraph 37**: Appears to have good consensus.

70. **Paragraph 38**: The phrase “from a country in which the products were produced” is proposed for deletion. A Round 2 comment questions the value of this paragraph given paragraph 15 (new paragraph 19) above. The EWG Co-Chairs suggest this phrase be discussed at the PWG to be held in advance of TFAMR07 to help obtain consensus.

71. **Paragraph 39**: Based on comments in Round 2, edits were made to improve the clarity and content of this paragraph.

72. **Paragraph 40**: Appears to have good consensus.

73. **Paragraph 41**: Round 1 & 2 comments reflect a diversity of opinion on whether it should apply to all antimicrobials or only medically important antimicrobials. The EWG Co-Chairs suggest this phrase be discussed at the PWG to be held in advance of TFAMR07 to help obtain consensus.

74. **Paragraph 42**: Round 1 & 2 comments reflect a diversity of opinion on this paragraph, including whether it should apply to all antimicrobials or only medically important antimicrobials.

75. The EWG Co-Chairs note that manufacturers and marketing authorization holders could consider prudent use guidelines and other policies when developing advertising programs.

76. The EWG Co-Chairs suggest this phrase be discussed at the PWG to be held in advance of TFAMR07 to help obtain consensus.

77. **Paragraph 43**: Revisions to the text were made based on comments in Rounds 1 & 2.

78. **Paragraph 44**: A Round 2 comment states the breadth of research currently described above exceeds that which is appropriate for manufacturers and marketing authorization holders. Revisions were made to focus on the required information noting the general need for research and the development of new antimicrobials in the next paragraph.

79. **Paragraph 45**: The text was revised to reflect that research of new and alternative products by the pharmaceutical industry should be encouraged based on comments received in Round 2.

80. **Paragraph 46**: Based on comments in Rounds 1 & 2, the paragraph was expanded to include orders from plant/crop professionals. A round 2 comment questions whether this sentence should be limited to medically important antimicrobial agents. The EWG Co-Chairs suggest this phrase be discussed at the PWG to be held in advance of TFAMR07 to help obtain consensus.

81. **Paragraph 47**: A Round 2 comment suggested the phrase “encourage compliance with the national guidelines on the responsible and prudent use of medically important antimicrobial agents” is more appropriate for veterinarians and plant/crop health professionals than for wholesale and retail distributors. Sub-bullets 2 & 3 were revised to eliminate redundancy and to include plant/crop health professionals. Some comments raised the potential for this information to be held confidential. The first sentence was revised the read “…according to the national regulations and may include, for example:” to provide flexibility. The EWG Co-Chairs suggest this paragraph be reviewed at the PWG to be held in advance of TFAMR07 to help obtain consensus.

82. **Paragraph 48**: The EWG Co-Chairs provided new text based on comments received in Round 2 to describe the role of wholesale and retail distributors in training on issues related to antimicrobial resistance. The EWG Co-Chairs suggest this paragraph be reviewed at the PWG to be held in advance of TFAMR07 to help obtain consensus.

83. **Paragraph 49**: Edits were made based on comments in Round 2 to improve clarity. A Round 2 comment indicated biotechnology could also help improve animal and plant health in ways that could reduce the need for antimicrobials.

84. **Paragraph 50**: Based on comments in Round 2, the paragraph was expanded to include “other organizations” and revised to “encourage” development of species or sector-specific guidelines.

85. **Paragraph 51**: Based on comments in Rounds 1 & 2, the paragraph was edited to provide clarity. A round 2 comment questions whether this sentence should be limited to medically important antimicrobial agents. The EWG Co-Chairs suggest this phrase be discussed at the PWG to be held in advance of TFAMR07 to help obtain consensus.

86. **Paragraph 52**: The paragraph was edited for clarity based on comments in Rounds 1 & 2.

87. **Paragraph 53**: Based on draft text in 49alt1, 49alt2, 49alt3, and comments received in Round 2, the EWG Co-Chairs assembled new text for this paragraph to describe appropriate use of medically important antimicrobials in plant/crop production. The EWG Co-Chairs suggest this paragraph be reviewed at the PWG to be held in advance of TFAMR07 to help obtain consensus.

88. **Paragraph 54**: The paragraph was edited for clarity based on comments in Rounds 1 & 2.

89. **Paragraph 55**: The paragraph was edited for clarity based on comments in Rounds 1 & 2.

90. **Previous paragraph 51bis**: The paragraph is proposed for deletion based on Comments in Rounds 1 & 2. Reasons cited included; redundant with Principle 5, ambiguous with respect to Principle 5 (could imply exceptions), including specific classes is redundant with Principle 5 as well as ambiguous (could imply exceptions for certain classes).

91. **Paragraph 56**: The paragraph was edited for clarity based on a suggestion in Round 2.

92. **Paragraph 57**: The paragraph was edited based on suggestions in Rounds 1 & 2. Round 2 included a comment that off-label use occurs in plants/crops and should be considered under the supervision of plant/crops health professionals. The EWG Co-Chairs suggest this paragraph be reviewed at the PWG to be held in advance of TFAMR07 to help obtain consensus.

93. **Paragraph 58**: The paragraph was edited to improve clarity based on comments in Rounds 1 & 2. A comment in Round 2 questions the feasibility of recording genomic information.

94. **Paragraph 59**: This paragraph appears to have good consensus.

95. **Paragraph 60**: The paragraph was edited to align with the revision of related paragraphs in other sections.

96. **Paragraph 61**: The paragraph was edited for clarity based on suggestions in Rounds 1 & 2.

97. **Paragraph 62**: The paragraph was revised based on comments in Rounds 1 & 2 to improve clarity and eliminate redundancy. Round 2 comment states this bullet is duplicative of the bullet describing on-farm biosecurity in the remit of OIE and suggests deletion.

98. **Paragraph 63**: Based on comments in Round 1 & 2, the paragraph was edited to improve clarity and eliminate redundancy. A comment in Round 2 observed the paragraph is quite long and could be divided into smaller paragraphs.

Section 6. Practices during Production, Processing, Storage, Transport, Retail and Distribution of Food

99. **Paragraph 64**: Minor revisions were suggested in Round 1 to improve clarity.

100. **Paragraph 65**: Minor revisions were suggested in Round 1 to improve clarity.

101. **Paragraph 66**: Minor revisions were suggested in Round 1 to improve clarity.

102. **Paragraph 67**: Minor revisions were suggested in Round 1 to improve clarity.

Section 7. Communication to Consumers

103. **Paragraph 68**: Previous Paragraph ~~61~~ revised and Paragraph ~~63~~ deleted based on the suggestion of the Codex Secretariat, see TFAMR06 report, paragraph 81. Round 1 comments indicated a preponderance of support for the paragraph as revised. Few comments were received in Round 2.

104. **Paragraph 69**: Round 1 comments indicated a preponderance of support for the paragraph as revised. Few comments were received in Round 2.

105. **Paragraph ~~63~~** (previous): Support for deleting with inclusion of some text into Paragraph 68.

Points for comment and discussion at TFAMR07

106. The EWG Co-Chairs recommend adoption of text revised during the EWG or suggest points for further comments and discussion at a PWG and TFAMR07 with the aim to advance the document to Step 5. Reference will be made using the new paragraph numbers.

Section 1. Introduction

107. The EWG Co-Chairs recommend adoption of the text as revised during the EWG.

108. **Paragraph 1**: Substantive point: Replacement of “food of animal origin” with “plant/crop production” for the purpose of this paragraph and defer discussion of “plant/crop” and “food of animal origin” to the Definition section.

109. **Paragraph 4**: Minor point: Addition of reference to CXG 71-2009 to include veterinary drugs.

110. **Paragraph 6, sub-bullet 2**: Substantive point: Adoption the revised text as drafted at TFAMR06.

111. **Paragraph 6, sub-bullet 4**: Minor point: Adoption the addition of “Regional”.

Section 2. Scope

112. The EWG Co-Chairs recommend adoption of the text as revised during the EWG.

113. **Paragraph 9**: Substantive point: Replacement of “food of animal origin” with “plant/crop production” for the purpose of this paragraph and defer discussion of “plant/crop” and “food of animal origin” to the Definition section.

114. **Paragraph 9**: Minor point: Delete “feed”.

115. **Paragraph 11**: Substantive point: Adoption of both the initial bracketed text and the additional text.

116. **Paragraph 12**: Minor point: Add “non-food plants/crops”.

Section 3. Definitions

117. The EWG Co-Chairs recommend further discussion or adoption on the following points to obtain consensus.

Substantive points:

118. **Food production environment**: Adoption of the definition along with any amendments arising from discussion in the PWG/TFAMR07.

119. **Food of animal origin**: Review the text for instances where the term is needed for risk management. If the term is needed, retain the definition along with any amendments arising from discussion in the PWG/TFAMR07. If the term is not needed, delete the definition.

120. **Therapeutic use**: Adoption of the definition along with any amendments arising from discussion in the PWG/TFAMR07.

121. The EWG Co-Chairs recommend adoption of the text as revised during the EWG.

Minor points:

122. **Adverse health effect**: Adoption of the proposed definition.

123. **Competent Authority(ies)**: Adoption of the proposed definition.

124. **Food chain**: Addition of the word “feed”.

125. **Medically important antimicrobials**: Adoption of the proposed revision.
126. **Plants/crops**: Adoption of the proposed revision.
127. **Plant/crop health professional**: Adoption of the revised definition along with an additional sentence in the Spanish version, if needed.

Section 4. General Principles

128. The EWG Co-Chairs recommend further discussion or adoption on the following points to obtain consensus.

Substantive points:

129. **Principle 5**: Adoption of revisions subsequent to discussion in the PWG/TFAMR07.
130. **Principle 6**: Adoption of revisions subsequent to discussion in the PWG/TFAMR07.
131. **Principle 7**: Adoption of revisions subsequent to discussion in the PWG/TFAMR07.
132. **Principle 7bis**: Adoption of revisions subsequent to discussion in the PWG/TFAMR07.
133. **Principle 7ter**: Adoption of revisions subsequent to discussion in the PWG/TFAMR07 or deletion.
134. **Principle 12**: Adoption of revisions subsequent to discussion in the PWG/TFAMR07 or deletion.
135. The EWG Co-Chairs recommend adoption of the text as revised during the EWG.

Minor points:

136. **Principle 9**: Adoption of revisions subsequent to discussion in the PWG/TFAMR07.
137. **Principle 10**: Adoption of revisions subsequent to discussion in the PWG/TFAMR07.
138. **Principle 14**: Adoption of revisions subsequent to discussion in the PWG/TFAMR07.
139. **Ordering of the Principles**: Adoption of the order of the General Principles according to the discussion in the PWG/TFAMR07.

Section 5. Responsible Use of Antimicrobial Agents

140. **Paragraph 13**: Recommend adoption of the revised text.
141. **Paragraph 14**: Recommend adoption of the revised text.
142. 5.1: Replace “regulatory authorities” with “competent authorities” based on a decision at TFAMR06. Recommend adoption of the revised text.
143. **Paragraph 15**: Recommend adoption of the revised text.
144. **Paragraph 16**: Recommend adoption of the revised text.
145. **Paragraph 17**: Recommend adoption of the revised text.
146. **Paragraph 18**: Recommend adoption of the revised text.
147. **Paragraph 19**: Recommend adoption of the revised text.
148. **Paragraph 20**: Recommend adoption of the revised text.
149. **Paragraph 21**: Recommend adoption of the revised text.
150. **Paragraph 22**: Recommend discussion at the PWG/TFAMR07 followed by adoption of revised text.
151. **Paragraph 23**: Recommend discussion at the PWG/TFAMR07 followed by adoption of revised text.
152. **Paragraph 24**: Recommend adoption of the revised text.
153. **Paragraph 25**: Recommend adoption of the revised text.
154. **Paragraph 26**: Recommend adoption of the revised text.
155. **Paragraph 27**: Recommend discussion at the PWG/TFAMR07 followed by adoption of revised text.
156. **Paragraph 28**: Recommend discussion at the PWG/TFAMR07 followed by adoption of revised text.
157. **Paragraph 29**: Recommend adoption of the revised text.
158. **Paragraphs 30 & 31**: Recommend discussion at the PWG/TFAMR07 followed by adoption of revised text.

159. **Paragraph 32**: Recommend discussion at the PWG/TFAMR07 followed by adoption of revised text.
160. **Paragraph 33**: Recommend adoption of the revised text.
161. **Paragraph 34**: Recommend adoption of the revised text.
162. **Paragraph 35**: Recommend discussion at the PWG/TFAMR07 followed by adoption of revised text.
163. **Paragraph 36**: Recommend discussion at the PWG/TFAMR07 followed by adoption of revised text.
164. **Paragraph 37**: Apparent consensus on text. Recommend adoption.
165. **Paragraph 38**: Recommend discussion at the PWG/TFAMR07 followed by adoption of revised text.
166. **Paragraph 39**: Recommend adoption of the revised text.
167. **Paragraph 40**: Apparent consensus on text. Recommend adoption.
168. **Paragraph 41**: Recommend discussion at the PWG/TFAMR07 followed by adoption of revised text.
169. **Paragraph 42**: Recommend discussion at the PWG/TFAMR07 followed by adoption of revised text.
170. **Paragraph 43**: Recommend adoption of the revised text.
171. **Paragraph 44**: Recommend adoption of the revised text.
172. **Paragraph 45**: Recommend adoption of the revised text.
173. **Paragraph 46**: Recommend discussion at the PWG/TFAMR07 followed by adoption of revised text.
174. **Paragraph 47**: Recommend discussion at the PWG/TFAMR07 followed by adoption of revised text.
175. **Paragraph 48**: Recommend discussion at the PWG/TFAMR07 followed by adoption of revised text.
176. **Paragraph 49**: Recommend adoption of the revised text.
177. **Paragraph 50**: Recommend adoption of the revised text.
178. **Paragraph 51**: Recommend discussion at the PWG/TFAMR07 followed by adoption of revised text.
179. **Paragraph 52**: Recommend adoption of the revised text.
180. **Paragraph 53**: Recommend discussion at the PWG/TFAMR07 followed by adoption of revised text.
181. **Paragraph 54**: Recommend adoption of the revised text.
182. **Paragraph 55**: Recommend adoption of the revised text.
183. **Paragraph 56**: Recommend adoption of the revised text.
184. **Paragraph 57**: Recommend discussion at the PWG/TFAMR07 followed by adoption of revised text.
185. **Paragraph 58**: Recommend discussion at the PWG/TFAMR07 followed by adoption of revised text.
186. **Paragraph 59**: Apparent consensus on text. Recommend adoption.
187. **Paragraph 60**: Revised text including edits aligned with those in related paragraphs. Recommend adoption of the revised text.
188. **Paragraph 61**: Recommend adoption of the revised text.
189. **Paragraph 62**: Recommend adoption of the revised text.
190. **Paragraph 63**: Recommend adoption of the revised text.

Section 6. Practices during Production, Processing, Storage, Transport, Retail and Distribution of Food

Minor points:

191. **Paragraph 64**: Recommend adoption of the revised text.
192. **Paragraph 65**: Recommend adoption of the revised text.
193. **Paragraph 66**: Recommend adoption of the revised text.
194. **Paragraph 67**: Recommend adoption of the revised text.

Section 7. Communication to Consumers

Minor points:

195. **Paragraph 68**: Recommend adoption of the revised text.
196. **Paragraph 69**: Recommend adoption of the revised text.
197. **Previous Paragraph ~~63~~**: Agreement for deletion. Recommend deletion.

APPENDIX I

PROPOSED DRAFT REVISION OF THE CODE OF PRACTICE TO MINIMIZE AND CONTAIN FOODBORNE ANTIMICROBIAL RESISTANCE (CXC 61-2005)

(Revised following Round 2 COP EWG, October 2019)

The paragraphs have been re-numbered with previous numbering from the working document reflected in strikethrough for clarity. Suggestions for re-ordering the General Principles have also been considered and a new order has been proposed for further discussion while retaining the existing number of the Principle.

1. Introduction

1. Antimicrobial resistance (AMR) poses an important, complex, and priority global public health challenge. Throughout the food chain, there is a need to address the risks associated with development, selection and dissemination of foodborne resistant microorganisms and resistance determinants. Responsible and prudent use of antimicrobial agents in all sectors following a One Health Approach and strategies for best management practices in animal production (terrestrial and aquatic), plant/crop production ~~of food of plant origin~~ and food/feed processing, packaging, storage, transport, and wholesale and retail distribution should form a key part of multi-sectoral national action plans to address risks of foodborne AMR.

2. This Code of Practice addresses the responsible and prudent use of antimicrobial agents by participants in the food chain, including, but not limited to, the role of competent authorities, the pharmaceutical industry, veterinarians, and plant/crop health professionals, and food producers and processors. It provides guidance on measures and practices at primary production, and during processing, storage, transport, wholesale and retail distribution of food to prevent, minimize and contain foodborne antimicrobial resistance in the food supply. It also identifies knowledge gaps and provides guidance on communication strategies to consumers.

3 ~~2bis~~. In keeping with the Codex mandate this Code of Practice addresses antimicrobial use in the food chain. It is recognized that the use of antimicrobial agents in the food chain may result in exposure to antimicrobial resistant bacteria or their determinants in the food production environment. As part of a One Health strategy to minimize and contain antimicrobial resistance, only authorized products should be used and best practices in the food production sector should be followed to minimize the occurrence/persistence in the food production environment of antimicrobials and their metabolites from food production related activities, and to minimize the risks associated with the selection and dissemination of resistant microorganisms and resistance determinants in the food production environment.

4 ~~3~~. This Code of Practice is an integral part of risk analysis focusing on risk management options and should be read in conjunction with other Codex texts including the *Guidelines on integrated monitoring and surveillance of foodborne antimicrobial resistanc*e and the *Guidelines for risk analysis of foodborne antimicrobial resistance* (CXG 77-2011). In addition, the *Code of hygienic practice for fresh fruits and vegetables* (CXC 53-2003), ~~and~~ the *Code of practice on good animal feeding* (CXC 54-2004), and the *Guidelines for the design and implementation of national regulatory food safety assurance program associated with the use of veterinary drugs in food producing animals* (CXG 71-2009) are particularly relevant for use of agricultural chemicals on plants/crops, animal feed, and veterinary drugs, respectively.

5 ~~3bis~~. This Code of Practice provides risk management advice, including the responsible and prudent use of antimicrobial agents that can be applied proportionate to risks identified through the risk analysis process described in the *Guidelines for risk analysis of foodborne antimicrobial resistance*. Risk managers are responsible for prioritizing and assessing foodborne AMR risks appropriate to the region and determining how best to reduce risk and to introduce levels of protection appropriate for circumstances.

6 ~~4~~. The *Principles and guidelines for the conduct of microbiological risk management* (CXG 63-2007) contains guidance for developing and implementing risk management measures. Setting priorities and identifying risk management measures should take into account the following:

- *WHO guidance on integrated surveillance of antimicrobial resistance in foodborne bacteria, application of a One Health Approach;*
- [*WHO list of critically important antimicrobials for human medicine, specifically the Annex with the complete list of antimicrobials for human use, categorized as critically important, highly important and important;*]
- Relevant chapters of the *OIE terrestrial and aquatic animal health codes* and the *List of antimicrobial agents of veterinary importance; and*
- *National/Regional lists of important antimicrobials for humans and animals where they exist.*

7 ~~5~~. Where available, national and local guidelines to prevent, minimize and contain foodborne AMR should be taken into consideration. Best management practices and guidelines on the responsible and prudent use of antimicrobials developed by governmental and professional organizations should also be considered.

8 ~~5bis:~~. This document is designed to provide a framework, for the development of measures to mitigate the risk of foodborne AMR that countries may implement, as part of their national strategy on AMR, in accordance with their capabilities, based on their national priorities and capacities, and within a reasonable period of time. A progressive approach may be utilized by some countries to properly implement applicable elements in this document proportionate to the foodborne AMR risk and should not be used inappropriately to generate barriers to trade.

2. Scope

9 ~~7~~. This Code of Practice provides risk management guidance to address the risk to human health of the development and transmission of antimicrobial resistant microorganisms or resistance determinants through food. It provides risk-based guidance on relevant measures and practices along the food and feed chain to minimize and contain the development and spread of foodborne antimicrobial resistance, including guidance on the responsible and prudent use of antimicrobial agents in animal production (terrestrial and aquatic), plant/crop production, [~~food of plant origin~~] and ~~feed~~ and references other best management practices, as appropriate. Its objectives are to minimize the risk and adverse impact on human health from foodborne AMR resulting from the use of antimicrobial agents in the food chain.

10 ~~8~~. This document includes guidance for all interested parties involved in the authorization, manufacture, sale and supply, prescription and use of antimicrobial agents in the food chain together with those involved in the handling, preparation, food processing, storage, transport, wholesale and retail distribution and consumption of food who have a role to play in ensuring the responsible and prudent use of antimicrobial agents and/or who have a role with limiting the development and spread of foodborne antimicrobial resistant microorganisms and resistance determinants.

11 ~~8bis~~. Recognizing there are mechanisms of co-resistance or co-selection in a range of antimicrobial agents, most of the recommendations in this Code of Practice will focus on antibacterials, [however some recommendations may also be applicable to antiviral, antiparasitic, antiprotozoal, and antifungal agents, where scientific evidence supports foodborne AMR risk to human health.]

12 ~~9~~. As there are existing Codex or internationally recognized guidelines, the following areas related to antimicrobial agents or AMR are outside the scope of this document: residues of antimicrobial agents in food; AMR marker genes in recombinant-DNA plants/crops[1] and recombinant DNA microorganisms[2]; non-genetically modified microorganisms (for example, starter cultures) intentionally added to food with a technological purpose[3]; and certain food ingredients, which could potentially carry antimicrobial resistance determinants, such as probiotics[4]. In addition, AMR from non-food animals, non-food plants/crops, or non-food routes are also outside the scope of this document.

3. Definitions

Antibacterial: A substance that acts against bacteria.

Adverse health effect: An undesirable or unwanted outcome in humans. In this document, this refers to the human infections caused by AMR microorganisms and determinants in food or acquired from food ~~of animal/crop origin~~ as well as increased frequency of infections and treatment failures, loss of treatment options, and increased severity of infections manifested by prolonged duration of disease, increased hospitalization and mortality[5].

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.

---

1 The food safety assessment on the use of antimicrobial resistance marker genes in recombinant-DNA plants is addressed in the *Guidelines for the conduct of food safety assessment of foods derived from recombinant-DNA plants* (CXG 45-2003).

2 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* (CXG 46-2003).

3 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* (CXG 46-2003).

4 The food safety assessment on the use of probiotics in foods is addressed in the Report of the *Joint FAO/WHO working group on drafting guidelines for the evaluation of probiotics in foods* (FAO/WHO, 2002).

5 *First Joint FAO/OIE/WHO expert workshop on non-human antimicrobial usage and antimicrobial resistance: scientific assessment* (December 2003).

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.

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.

[**Competent Authority(ies):** The official government organization/agency(ies) having jurisdiction.]

Control of disease/metaphylaxis: Administration of antimicrobial agents to a group of animals containing sick and healthy individuals (presumed to be infected), to minimize or resolve clinical signs and to prevent further spread of the disease.

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

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

Extra- or off-label use: The use of an antimicrobial agent that is not in accordance with the approved product labelling.

Food chain: Production to consumption continuum including, primary production (food-producing animals, plants/crops), feed, harvest/slaughter, packing, processing, storage, transport, and retail distribution to the point of consumption.

Food-producing animals: Animals raised for the purpose of providing food to humans.

[Food production environment: The immediate vicinity of food to be harvested or processed that has reasonable probability to contribute to foodborne AMR.]

Growth promotion: Administration of antimicrobial agents to only increase the rate of weight gain and/or the efficiency of feed utilization in animals. The term does not apply to the use of antimicrobials for the specific purpose of treating, controlling, or preventing infectious diseases.

Marketing authorization: Process of reviewing and assessing a dossier to support an antimicrobial agent to determine whether to permit its marketing (also called licensing, registration, approval, etc.), finalized by granting of a document also called marketing authorization (equivalent: product license).

Medically important antimicrobials: Antimicrobial agents important for therapeutic use in humans taking into account those described in the *WHO list of critically important antimicrobials* and categorized according to specified criteria as important, highly important, and critically important for human medicine or equivalent criteria established in national lists, where available. It does not include ~~ionophores or other~~ antimicrobial agents not important for human therapeutic use, such as ionophores.

One Health Approach: A collaborative, multisectoral, and trans-disciplinary approach - working at the local, regional, national, and global levels - with the goal of achieving optimal health outcomes recognizing the interconnection between humans, animals, crops, and their shared environment.

Pharmaceutical industry: Manufacturers and marketing authorization holders of antimicrobial agents.

Pharmacovigilance: The collection and analysis of data on how products perform in the field after authorization and any interventions to ensure that they continue to be safe and effective. These data can include information on adverse effects to humans, animals, plants or the environment; or lack of efficacy.

Plants/crops: A plant or crop (or part thereof) that is cultivated or harvested as food or feed.

[**Food of plant origin**: All edible parts of plants/crops used as foods.]

[Plant/crop health professional ~~/ plant pathologist~~: An individual ~~professionally trained person~~ with current training, knowledge and experience in plant/crop health and protection practices.]

Prevention of disease/prophylaxis: Administration of antimicrobial agents to an individual or a group of animals at risk of acquiring a specific infection or in a specific situation where infectious disease is likely to occur if the antimicrobial agent is not administered.

[Therapeutic use: Administration/Application of antimicrobial agents for the treatment, control/metaphylaxis or ~~and~~ prevention/prophylaxis of disease.]

Treatment of disease: Administration of antimicrobial agents to an individual or group of animals showing clinical signs of infectious disease.

4. General principles to minimize and contain antimicrobial resistance

Principles on AMR Risk Management (generally)

Principle 1: A One Health Approach should be considered, wherever possible and applicable, when identifying, evaluating, selecting, and implementing foodborne AMR risk management options.

Principle 9: Foodborne AMR risk management measures should be implemented in a way that is proportionate to the risk and reviewed on a regular basis as described in the *Guidelines for risk analysis of foodborne antimicrobial resistance*. Risk managers should consider potential unintended consequences to humans, animal, and plant health of recommended risk management measures. When considering animal or plant health aspects risk managers should take into account relevant OIE and IPPC standards.

Principle 4: The *WHO list of critically important antimicrobials*, the *OIE list of antimicrobials of veterinary importance*, or national lists, where available, should be considered when setting priorities for risk assessment and risk management to minimize and contain antimicrobial resistance. The lists should be regularly reviewed and updated as necessary when supported by scientific findings as new scientific data emerges on resistance patterns.

Principle 15: On a continuous and progressive implementation of risk management measures along the food chain to minimize the possible risks associated with foodborne AMR, priority should be given to the most relevant elements from a public health perspective.

Principle on preventing infections and reducing the need for antimicrobials

Principle 2: Biosecurity, appropriate nutrition, vaccination, animal and plant/crop best management practices, and other alternative tools where appropriate, and that have been proven to be efficacious and safe, should be considered to reduce the need for use of antimicrobial agents.

Principles on the responsible and prudent use of antimicrobials (generally)

Principle 13: The decision to use antimicrobial agents should be based on sound clinical judgement, experience, and treatment efficacy. Where feasible and appropriate the results of bacterial cultures and integrated resistance surveillance and monitoring should also be considered.

[Principle 12: Medically important antimicrobials should be administered, prescribed, or applied only by, or under the direction of, veterinarians, plant/crop health professionals, or other suitably trained persons authorized in accordance with national legislation.]

Principle 8: Antimicrobial agents should be used as legally authorized and following all applicable label directions; except where specific legal exemptions apply.

Principle 14: The choice of which antimicrobial agent to use should take into consideration relevant professional guidelines, where available, results of antimicrobial susceptibility testing of isolates from the production setting, where appropriate, and make adjustments to the antimicrobial agent selection based on clinical outcomes or when foodborne AMR risks become evident.

Principle 3: Science-based species or sector-specific responsible and prudent antimicrobial use guidelines should be developed, implemented, and reviewed on a regular basis to maintain their effectiveness in minimizing the risk of foodborne antimicrobial resistance. Such guidelines could be included as a part of national action plans or stakeholder-led plans on antimicrobial resistance with development and dissemination shared among countries and organizations.

Principles on the use of antimicrobials in specific circumstances

[Principle 5: Responsible and prudent use of antimicrobial agents does not include the use for growth promotion of antimicrobial agents that are considered medically important. Antimicrobial agents that are not considered medically important should not be used for growth promotion unless potential risks to human health have been evaluated through procedures consistent with the Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance CXG 77-2011.~~:~~

- ~~considered medically important; or~~
- ~~able to cause cross- or co-resistance to antimicrobial agents that are considered medically important.~~

~~Antimicrobial agents, others than those referred to above should not be used for growth promotion in the absence of risk analysis in accordance with CXG77.]~~

[Principle 6: Medically important antimicrobial agents should only be used for therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease); or in certain circumstances for research and conservation.]

[Principle 7: When used for prevention/prophylaxis of a specific disease risk, medically important antimicrobials should only be administered in well-defined circumstances, based on epidemiological and clinical knowledge, and follow appropriate professional oversight, dose, and duration. ~~Medically important antimicrobial agents should only be used in well-defined circumstances for the prevention/prophylaxis of a specific disease risk and follow appropriate professional oversight, dose, and duration.~~]

[**Principle 7bis:** When used for the control of disease/metaphylaxis, medically important antimicrobial agents should only be used on the basis of epidemiological and clinical knowledge and a diagnosis of a specific disease and follow appropriate professional oversight, dose, and duration.]

[**Principle 7ter:** When used for plant/crop protection, medically important antimicrobial agents should only be used to the extent necessary for a specific disease and follow appropriate professional oversight, dose, and duration.]

Principle on surveillance of antimicrobial resistance and use

Principle 10: Monitoring and surveillance of the use of antimicrobial agents and the incidence or prevalence, and in particular trends, of foodborne antimicrobial resistant microorganisms and resistance determinants are among the critical factors to consider when developing risk management measures and evaluating the effectiveness of implemented risk management measures. Use of antimicrobial agents in humans, food-producing animals, and plants/crops and transmission of pathogens and resistance genes between humans, food-producing animals, plants/crops, and the environment are additional factors to consider, through the foodborne AMR risk analysis process described in the *Guidelines for risk analysis of foodborne antimicrobial resistance*.

[5. Responsible and prudent use of antimicrobial agents

13 ~~10~~. The *OIE terrestrial and aquatic animal health codes* and the OIE list of antimicrobial agents of veterinary importance contain detailed information with respect to the control of veterinary medicines for use in food-producing animals and aquaculture.

14 ~~11~~. For more information on the data requirements for authorization of antimicrobial agents for food-producing animals see relevant national guidelines or internationally harmonized guidelines, ~~such as the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) guidelines~~.

5.1 Responsibilities of the competent authorities

15 ~~12~~. The competent authorities, including the authority responsible for granting the marketing authorization for antimicrobials for use along the food chain, have a significant role in specifying the terms of the authorization and in providing appropriate information to the veterinarian and plant/crop health professionals, or other suitably trained persons authorized in accordance with national legislation and producers through product labelling and/or by other means, in support of the responsible and prudent use of antimicrobial agents along the food chain. It is the responsibility of competent authorities to develop up-to-date guidelines on data requirements for evaluation of antimicrobial agent applications, as well as ensuring that antimicrobial agents used in the food chain are used in accordance with national legislation.

16 ~~13~~. ~~It is the responsibility of competent authorities to develop up-to-date guidelines on data requirements for evaluation of antimicrobial agent applications.~~ National governments in cooperation with animal, plant/crop, and public health professionals should adopt a One Health Approach to promote the responsible and prudent use of antimicrobial agents along the food chain as an element of a national strategy to minimize ~~for the prevention~~ and contain~~ment of~~ antimicrobial resistance. Good animal production (terrestrial and aquatic) and best management practices for plant/crop production, vaccination and biosecurity policies and development of animal and plant/crop health programs at the farm level contribute to reduce the prevalence of animal and plant/crop disease requiring antimicrobial administration and can be incorporated into national strategies to complement activities in human health.

[17 ~~13bis:~~. In order to promote responsible and prudent use of antimicrobial agents, it is important to encourage the ~~use~~ development, ~~and~~ availability, and use of validated, rapid, reliable diagnostic tools, where available, to support veterinarians and plant/crop health professionals in selecting the most appropriate antimicrobial to be administered/applied ~~prescribed for treatment~~.]

[18 ~~14alt~~. Following risk analysis, the competent ~~regulatory~~ authorities should determine appropriate labelling, including the conditions that will minimize the development of foodborne AMR while still maintaining efficacy and safety, when this information is available. Furthermore, the professional judgement ~~in prescribing from~~ of the veterinarian or plant/crop health professional, who holds the responsibility of oversight, should be considered ~~a factor~~ when competent ~~regulatory~~ authorities develop ~~such~~ guidance for approved product labelling.]

~~14. If dose ranges/application rates or different durations/re-application intervals of antimicrobial agent administration are indicated, the competent authorities should give guidance on the approved product labelling regarding the conditions that will minimize the development of foodborne AMR based on a risk assessment, while still maintaining efficacy and safety, when this information is available.~~

Quality control of antimicrobial agents

19 ~~15~~. Competent authorities should ensure that quality controls are carried out in accordance with national or international guidance and in compliance with the provisions of good manufacturing practices, including with regard to ensuring quality and purity in manufacture, storage, and when mixed with feed, water, or other ingredients.

Assessment of efficacy

20 ~~16~~. Assessment of efficacy is important to assure adequate response to the administration of antimicrobial agents. As part of the marketing authorization process, ~~it~~ the assessment should include the efficacy with optimal dosages and durations, supported by clinical trials, microbiological data (including antimicrobial susceptibility testing,~~) and~~ pharmacokinetic (PK) data, and ~~as well as~~ pharmacodynamic (PD) data. The ~~It may also include~~ assessment may also include evaluation of ~~through proper veterinary care,~~ health ~~program evaluation and~~ good pharmacovigilance practices.

Assessment of the potential antimicrobial agents to select for resistant microorganisms

21 ~~17~~. The competent authorities should assess the potential of ~~medically important~~ antimicrobial agents to select for ~~resistant microorganisms~~ foodborne AMR taking into account *Guidelines for risk analysis of foodborne antimicrobial resistance*, the *WHO list of critically important antimicrobials*, the *OIE list of antimicrobial~~s~~ agents of veterinary importance*, or national lists, where available.

Assessment of environmental impact

~~18. Competent authorities should assess the impact of proposed antimicrobial agent use on the environment in accordance with national guidelines or recognized international guidelines.~~

22 ~~19~~. In accordance with their national guidelines, ~~C~~competent authorities should consider foodborne AMR risk characterization ~~from~~ of ~~environmental~~ sources that contribute to the food production environment, such as pollution from pharmaceutical manufacture, reuse of waste water for irrigation, and use of manure, ~~and~~ other waste-based fertilizers and/or municipal wastes for soil fertilization. ~~the environmental aspects on foodborne AMR e.g. pollution from pharmaceutical manufacture, impacts of reusing waste water for irrigation, and using manure, and other waste-based fertilizers and/or municipal wastes for soil fertilization.~~ When a foodborne AMR risk is determined through the *Guidelines for risk analysis of foodborne antimicrobial resistance* the need for monitoring and proportionate risk management measures ~~can~~ should be considered.

Establishment of a summary of product characteristics for each antimicrobial agent

23. ~~20~~. Competent authorities should establish a Summary of Product Characteristics or similar document for each authorized antimicrobial veterinary medicinal product. The information in these documents ~~the summary of product characteristics~~ can be utilized in labelling and as a package insert. Such information may include:

- brand/chemical/drug name;
- drug description;
- dosage forms/strengths;
- contraindications; warnings;
- adverse reactions;
- drug interactions and uses in specific populations for each authorized antimicrobial veterinary medicinal product, when available.

Surveillance and monitoring programs

24 ~~21~~. Competent authorities should establish systems for the surveillance and monitoring of antimicrobial resistance and antimicrobial use following the *Guidelines on integrated monitoring and surveillance of foodborne antimicrobial resistance* as developed by Codex~~, taking into consideration relevant sections of *Guidelines for risk analysis of foodborne antimicrobial resistance*; *WHO guidelines on integrated surveillance of antimicrobial resistance in foodborne bacteria, application of a One Health Approach*; and *OIE terrestrial animal health code* Chapter 6.7 Harmonization of national antimicrobial resistance surveillance and monitoring programmes and Chapter 6.8 Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals, the *OIE aquatic animal health code* Chapter 6.3 Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals and Chapter 6.4 Development and harmonization of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals and section 8 of chapter 6.9.3 on post-marketing antimicrobial surveillance~~.

25 ~~22bis~~. Competent authorities should have in place a pharmacovigilance program for the monitoring and reporting of suspected adverse reactions to veterinary antimicrobial agents ~~drugs~~, including lack of the expected efficacy that could be related to antimicrobial resistance. The information collected through the pharmacovigilance program can contribute to a ~~should form part of the~~ comprehensive strategy to minimize antimicrobial resistance in food.

26 ~~22ter~~. In cases, where the assessment of data collected from pharmacovigilance and from other post-authorization surveillance including, if available, targeted surveillance of antimicrobial resistance in veterinary or plant/crop pathogens, suggests that the conditions of use of the given ~~veterinary~~ antimicrobial agent marketing authorization ~~drug~~ should be reviewed, competent authorities shall endeavor to achieve this re-evaluation.

Distribution of antimicrobial agents

27 ~~23~~. Competent authorities, ~~to the extent possible,~~ should make sure approved antimicrobial agents are distributed through appropriate distribution systems in accordance with national legislation, including that ~~and~~ medically important antimicrobials are distributed to appropriately credentialed/registered veterinarians, plant/crop health professionals, or other suitably trained persons authorized in accordance with national legislation.

28 ~~23bis~~. Competent authorities~~, to the extent possible,~~ should prevent illegal medicines and unapproved formulations from entering distribution systems.

29 ~~24~~. Distribution should be ~~regularly~~ controlled by the competent authorities in accordance with national legislation.~~, and monitoring of sales of antimicrobial agents could be undertaken and information could be analyzed with appropriate context to identify areas of concern and potential follow up.~~

Control of advertising

30 ~~25~~. Competent authorities should ~~assure~~ ensure that advertising and promotion of antimicrobial agents is done in accordance with national legislation ~~or policies~~.

31 ~~26~~. Advertising and promotion of antimicrobial agents should be done in a manner consistent with ~~prudent use guidelines and any other~~ specific regulatory recommendations for the product.

~~27. All advertising of medically important antimicrobial agents should be controlled by the competent relevant authorities.~~

- ~~The authorities should ensure that advertising of antimicrobial agents:~~
    - ~~complies with the marketing authorization granted, in particular with the content of the summary of product characteristics or similar document; and~~
    - ~~complies with each country's national legislation or policies.~~

Training on issues related to antimicrobial resistance and the responsible ~~of~~ user~~s~~ of antimicrobial agents

32 ~~28~~. Training should be supported, to the extent possible, by the competent authorities on issues related to antimicrobial resistance and the responsible use of antimicrobial agents. Training may take the form of communication and outreach and should be ~~involve~~ ~~the competent authorities, all the~~ relevant to veterinarians and plant/crop health professionals, manufacturers and marketing authorization holders, wholesale and retail distributors, food animal and plant/crop producers, and other participants along the food chain. Training and communication may broadly address other public health constituencies.

~~professional and paraprofessional organizations, competent authorities, pharmaceutical industry, distributors, schools, research institutes, professional associations, trade associations and other approved users such as farmers and food animal, plant/crop, and feed producers and should may focus on:~~

Relevant information may include:

- information on disease prevention and management strategies to reduce the need to use antimicrobial agents;
- relevant information to enable the veterinarians and plant/crop health professionals to use or prescribe antimicrobial agents responsibly and prudently;
- ~~the need to observe~~ observing responsible and prudent use recommendations and using antimicrobial agents in production settings in agreement with the provisions of the marketing authorizations and professional advice;
- utilizing the WHO list of critically important antimicrobials; the OIE List of antimicrobials of veterinary importance, and national lists where they exist;

- information on appropriate storage conditions for antimicrobial agents before and during use and the safe disposal of unused and out of date antimicrobials;
- understanding relevant risk analysis of ~~veterinary~~ antimicrobial agent products and how to use that information;
- national action plans, if available, and international strategies to fight and control antimicrobial resistance;
- good antimicrobial use practices, antimicrobial prescription writing and establishment of withdrawal period;
- training in new methodologies for molecular analysis of resistance; understanding methods and results of susceptibility testing of antimicrobials and molecular analysis;
- the ability of antimicrobial agents to select for resistant microorganisms or resistance determinants that may contribute to animal, plant/crop, or human health problems; and
- understanding the process of identifying, evaluating, implementing, and monitoring the effectiveness of risk management options.

Knowledge gaps and research

33 ~~29~~. The relevant authorities ~~should~~ can encourage public and private research to:

- improve the knowledge about the mechanisms of action, pharmacokinetics and pharmacodynamics of antimicrobial agents to optimize the ~~dosage~~ therapeutic regimens and their efficacy;
- improve the knowledge about the mechanisms of transmission, selection, co-selection, emergence and dissemination of resistance determinants and ~~AMR~~ resistant microorganisms ~~through food~~ along the food chain;
- develop practical models for applying the concept of risk analysis to assess the public health concern precipitated by the development of resistance;
- further develop protocols to predict, during the authorization process, the impact of the proposed use of the antimicrobial agents on the rate and extent of resistance development and spread;
- ~~develop and encourage good animal production and plant/crop production best management practices and alternative methods to prevent and treat infectious diseases that would to reduce the need to use antimicrobial agents~~
- assess the primary drivers leading to use of ~~medically important~~ antimicrobials at the farm, regional, and national levels, and the effectiveness of different interventions to change behavior and reduce the use of ~~medically important~~ antimicrobial agents in food production;
- improve the knowledge on behavior change and on cost-positive interventions to reduce the need of antimicrobial agents;
- develop safe and effective alternatives to antimicrobial agents, new antimicrobial agents, rapid diagnostics, and vaccines;
- determine the potential transfer to fresh produce and other plants/crops of resistant microorganisms and resistance determinants from animal manures or other biological materials used as fertilizer or selected for during the use of production practices, and if there is subsequent transfer through food to consumers;
- improve knowledge on the role of the environment on the persistence of antimicrobial agents, and the emergence, transfer and persistence of antimicrobial resistance determinants and resistant microorganisms;
- ~~improve the knowledge and on the role of the environment on the emergence, transfer and persistence of antimicrobial agents, resistance determinants and AMR microorganisms~~;
- determine the potential transfer to animals and plants/crops ~~of~~ resistant microorganisms and resistance determinants due to agricultural chemical use.

34 ~~30~~. ~~Research should be conducted, as resources permit, on antimicrobials, their metabolites, and risks of~~ pathogenic ~~foodborne resistant microorganisms and resistance determinants in the primary production environment, and if feasible, factors affecting and the magnitude of resistance determinant transfer among microorganisms in the environment leading to foodborne AMR risk for human health.~~ The importance of filling knowledge gaps by conducting relevant research should be considered as it relates to foodborne AMR risk for human health.

Collection and destruction of unused or out-of-date antimicrobial agents

35 ~~31~~. The competent authorities should develop and ~~progress~~ implement effective procedures for the safe collection and destruction of unused, counterfeit, illegally marketed, or out-of-date antimicrobial agents~~, including proper disposal of containers and packaging materials~~.

5.2 Responsibilities of Manufacturers and Marketing Authorization Holders

Marketing authorization of antimicrobial agents

36 ~~32~~. It is the responsibility of the antimicrobial agent marketing authorization holders:

- to supply all the information requested by the national competent authority in order to establish objectively the quality, safety and efficacy of antimicrobial agents;
- to ensure the quality of this information based on the implementation of procedures, tests and trials in compliance with the provisions of good manufacturing, good laboratory and good clinical practices; and
- to utilize manufacturing standards/practices and comply with national regulations in order to minimize contamination of the food production environment.

Marketing and export of antimicrobial agents

37 ~~33~~. Only officially licensed/authorized antimicrobial agents should be marketed, and then only through distribution systems in accordance with national legislation.

[38 ~~33bis:~~. Only antimicrobial agents meeting the quality standards of the importing country should be exported ~~from a country in which the products were produced~~;]

[39 ~~33ter~~. The information necessary to evaluate the ~~amount~~ quantity (sales or volume) of antimicrobial agents marketed should be provided to the national competent authority and, when feasible, information on estimated of types of use (e.g. treatment, control, prevention), route of administration and target species]

40 ~~34~~. Package size and the concentration and composition of antimicrobial formulations should be adapted, as far as possible, to the approved indications of use in order to avoid improper dosing, overuse, and leftovers.

Advertising

41 ~~35~~. It is the responsibility of the marketing authorization holders to only advertise antimicrobial agents in accordance with the provisions of paragraphs 30-31~~25-27~~ on the Responsibilities of the Competent Authorities, Control of Advertising and to not advertise medically important antimicrobials to producers.

42 ~~36~~. Advertising should only be targeted to persons permitted to prescribe or supply antimicrobial agents. Promotional campaigns involving economic or material benefits for prescribers or suppliers of antimicrobials should ~~be discouraged~~ not be used.

Training

43 ~~37~~. It is the responsibility of the marketing authorization holders to support ~~participate in the~~ training on issues related to antimicrobial resistance and the responsible use~~rs~~ of antimicrobial agents as ~~defined~~ described in paragraph 32 ~~28~~.

Research

44 ~~38~~. It is the responsibility of the marketing authorization holders to supply ~~support the development of research~~ required data to register antimicrobial agents including data regarding ~~and appropriately assess~~ the safety and efficacy of products ~~as defined described in paragraph 29~~, as appropriate.

45 ~~39~~. Research on the development of new antimicrobials, safe and effective alternatives to the use of antimicrobials, rapid diagnostics and vaccines are encouraged ~~should be performed~~.

5.3 Responsibilities of wholesale and retail distributors

46 ~~40~~. Wholesalers and retailers distributing medically important antimicrobial agents should only do so on the prescription of a veterinarian or order from a plant/crop health professional or other suitably trained person authorized in accordance with national legislation. All distributed products should be appropriately labelled.

47 ~~41~~. Distributors should ~~encourage compliance with the national guidelines on the responsible~~ ~~and prudent use of medically important antimicrobial agents and should~~ keep records of all antimicrobials supplied according to the national regulations and may include ~~including~~, for example:

- date of supply
- name of receiving ~~prescribing~~ veterinarian or plant/crop health professional or other suitably trained and authorized person
- ~~name of user~~
- name of medicinal product, formulation, strength and package size
- batch number
- quantity supplied
- expiration dates

48 ~~42~~. Distributors should support training, as appropriate, on issues related to antimicrobial resistance and the responsible use of antimicrobial agents using information provided by the competent authorities, manufacturers and marketing authorization holders, veterinarians and plant/crop professionals and other relevant entities as described ~~defined~~ in paragraph 32.

5.4 Responsibilities of Veterinarians[6] and Plant/Crop Health Professionals

49 ~~43~~. Veterinarians and plant/crop health professionals should identify new or recurrent disease problems and work toward developing ~~alternative~~ strategies to prevent, control, or treat infectious disease. These may include, but are not limited to, biosecurity, improved production practices, and safe and effective alternatives to antimicrobial agents, including vaccination or integrated pest management practices where applicable/available.

50 ~~45~~. Professional or other organizations should be encouraged to develop species or sector-specific guidelines on the responsible and prudent use of antimicrobial agents. National action plans may include recommendations to develop species or sector-specific guidelines.

51 ~~47~~. Antimicrobial agents should only be ~~used~~ prescribed or administered when necessary, ~~as~~ only as long as necessary, and in an appropriate manner:

- A prescription, ~~or~~ order for application, or similar document for medically important antimicrobial agents should indicate the dose, the dosage intervals, route and the duration of the administration, the withdrawal period, when appropriate, and the amount of antimicrobial agent to be delivered, depending on the dosage and the characteristics of the individual or population to be treated, in accordance with national legislation;
- The quantity of the antimicrobial provided to the end-user should, if feasible, be limited only for the administration concerned. Prescriptions or orders should also indicate the owner and the identification of the food-producing animals or plants/crops to which the antimicrobials are to be administered;
- All medically important antimicrobial agents should be prescribed or applied and used according to label directions and/or the direction ~~advice~~ of a veterinarian or plant/crop health professional, and the conditions stipulated in the national legislation.
- Protocols for monitoring use to allow for data collection or for quality assurance purposes should be considered as recommended in the Guidelines on Integrated Monitoring and Surveillance of Foodborne Antimicrobial Resistance.

52 ~~48~~. For food-producing animals, the appropriate use of ~~medically important~~ antimicrobial agents in practice is a clinical decision that should be based on the experience ~~and local expertise~~ of the prescribing veterinarian~~,~~ and epidemiological and clinical knowledge ~~the accurate diagnosis, based on adequate diagnostic procedures~~. ~~There will be occasions~~ When a group of food-producing animals~~,~~ ~~which~~ may have been exposed to pathogens, they may need to be treated without recourse to a~~n~~ ~~accurate~~ laboratory confirmed diagnosis based on ~~and~~ antimicrobial susceptibility testing to prevent the development and spread of clinical disease and for reasons of animal welfare.

53 ~~49~~. For plant/crop production, the appropriate use of medically important antimicrobial agents to manage disease/pests should be based on the principles of integrated pest management (IPM), consultation with a plant/crop health professional, historical and epidemiological knowledge of the disease/pest situation, and monitoring of the current disease/pest status. Only authorized products should be used following label directions. Alternatives to medically important antimicrobials should be considered when available and their safety and effectiveness has been determined. Medically important antimicrobial agents should only be used to the extent necessary for a specific disease and follow appropriate professional oversight, dose, and duration.

---

6 Under some circumstances, this may refer to a suitably trained person authorized in accordance with national legislation, for example an Aquatic Animal Health Professional.

~~[49alt1: For food-producing plants/crops, the appropriate use of antimicrobial agents to manage disease/pests should be based on historical knowledge of the disease/pest situation, undertake monitoring on the current disease/pest status and input from a plant/crop health professional who has experience and local expertise.]~~

~~[49alt2: The monitoring and diagnostic of crop diseases allows farmers to know the phytosanitary situation and therefore to target and choose the appropriate treatment methods. It is done by the publication of phytosanitary alerts.~~

~~The plant protection against diseases should be based on the principles of integrated pest management~~

- ~~Assess the situation, environmental conditions, abundance of harmful and beneficial organisms and crop stage;~~
- ~~Use of intervention thresholds allows not only to use a pesticide or other control at the right time, with maximum efficiency, but also to achieve significant savings by not intervening when it is not justified;~~
- ~~Combining the different control methods - curative, biological, mechanical, cultural, genetic and chemical - ensures a more sustainable and effective reduction in pest populations and helps to reduce the risks associated with the exclusive use of pesticides;~~
- ~~Use of registered pesticides as a last resort and combine active ingredients with different modes of action to reduce the risk of resistance;~~
- ~~Evaluation of the process by assessing whether the intervention was effective, whether it produced unacceptable side effects, whether to continue, revise or abandon the program.]~~

~~[49alt3: "For plant/crop, when the disease of plant/crop is identified as a new problematic disease or regulatory quarantine disease in accordance with the appropriate diagnostic procedure, plant/crop protection professional can prescribe or treat with medically important antimicrobial agents to prevent the development and spread of disease without recourse to an accurate diagnosis and antimicrobial susceptibility testing.]~~

54 ~~50~~. Determination of the choice of an antimicrobial agent should be based on:

- The expected efficacy of the administration based on:
    - the expertise and experience of the veterinarian, plant/crop health professional or suitably trained and authorized person;
    - the spectrum of the antimicrobial activity towards the pathogens involved;
    - the history of the production unit particularly in regard to the antimicrobial susceptibility profiles of the pathogens involved. Whenever possible, the antimicrobial susceptibility profiles should be established before the commencement of the administration. If this is not possible, it is desirable for samples to be taken before the start of the administration to allow, if necessary, for adjustment of therapy based on susceptibility testing. Should a first antimicrobial administration fail, or should the disease recur, the use of a second antimicrobial agent should ideally be based on the results of microbiological susceptibility tests derived from relevant samples;
    - the appropriate route of administration;
    - results of initial administration;
    - previous published scientific information on the treatment of the specific disease and available scientific knowledge on antimicrobial use and resistance;
    - evidence-based therapeutic ~~treatment~~ guidelines, such as species or sector-specific guidelines on the responsible and prudent use of antimicrobial agents, if available;
    - the likely course of the disease.
- The need to minimize the adverse health effect from the development of antimicrobial resistance based on:
    - the choice of the activity spectrum of the antimicrobial agent. Narrow-spectrum antimicrobials should be selected whenever possible/appropriate;
    - the targeting of specific microorganism;
    - known or predictable susceptibilities using antimicrobial susceptibility testing whenever possible;
    - optimized dosing regimens;

- the route of administration
- the use of fixed combinations of antimicrobial agents (i.e. only combinations contained in authorized veterinary medicinal products) which are effective against the target pathogens; and
- the importance of the antimicrobial agents to human and veterinary medicine.
- ~~the route of administration~~

- If the label conditions allow for flexibility, the veterinarian or plant/crop health professional should consider a ~~dosage~~ therapeutic regimen that is long enough to allow an effective treatment, but is short enough to limit the selection of resistance in foodborne and/or commensal microorganisms.

Off-label use

55 ~~51~~. For food-producing animals, the off-label use of a veterinary antimicrobial agent may be permitted in appropriate circumstances and should comply with the national legislation including the ~~appropriate and/or~~ use of approved or appropriate withdrawal periods ~~to be used~~. It is the veterinarian's responsibility to define the conditions of use including the therapeutic regimen, the route of administration, and the duration of the administration and the withdrawal period.

~~51bis: Off-label use of medically important antimicrobial agents should not be permitted for growth promotion. Fluoroquinolones, colistin and third and fourth generations of cephalosporins should be urgently prohibited for use as growth promotors.~~

56 ~~52~~. Human health risk related to foodborne antimicrobial resistance should be an important factor when considering the off-label use of veterinary antimicrobial agents in food-producing animals.

57 ~~53~~. ~~Medically important~~ Antimicrobials should not be used off-label for plants/crops.

Record keeping and recording

58 ~~54~~. For food-producing animals and plants/crops, records on antimicrobial agent prescription or ~~administration~~ application should be kept in conformity with national legislation or best management practice guidelines.

In particular, for investigation of antimicrobial resistance, veterinarians and plant/crop health professionals or suitably trained persons authorized in accordance with national legislation should:

- record the antimicrobial susceptibility testing results and genomic information, when available;
- record the antimicrobial used, the dosage ~~regimen~~ and the duration; investigate adverse reactions to antimicrobial agents, including lack of expected efficacy, and report it, as appropriate, to the competent authorities (through a pharmacovigilance system, if available).

59 ~~55~~. Veterinarians and plant/crop health professionals should also periodically review farm records on the use of antimicrobial agents to ensure compliance with their directions.

Training

60 ~~56~~. Professional or other organizations should ~~participate in~~ support the development and/or delivery of training on issues related to antimicrobial resistance and the responsible use~~rs~~ of antimicrobial agents as ~~defined~~ described in paragraph 32~~28~~.

5.5 Responsibilities of food animal and plant/crop producers

61 ~~57~~. Producers are responsible for implementing health programmes on their farms to prevent and manage disease outbreaks~~. They should call on the~~ with assistance of veterinarians, plant/crop health professionals, or other suitably trained persons authorized in accordance with national legislation. All participants involved in primary production of food have an important role to play in preventing disease and ~~to reduce~~ reducing the need to use antimicrobials ~~ensuring the responsible and prudent use of antimicrobial~~ agents to minimize risk of foodborne AMR.

62 ~~58~~. Producers of food animals and plants/crops have the following responsibilities:

- to use antimicrobial agents only when necessary, under the supervision of a veterinarian or plant/crop health professional when required, and not as a replacement for good management and farm hygiene practices, or other disease prevention methods;
- to implement a health plan in cooperation with the veterinarian, plant/crop health professional, or other suitably trained person authorized in accordance with national legislation that outlines measures to prevent disease;

- to use antimicrobial agents in the species, for the uses and at the doses on the approved labels and in accordance with the prescription, product label instructions or the advice of a veterinarian, plant/crop health professional or other suitably trained person authorized in accordance with national legislation familiar with the food-producing animals or the plant/crop production site;
- to isolate sick animals and dispose of dead or dying animals or plants/crops promptly in a manner to minimize foodborne AMR under conditions approved by relevant authorities;
- to comply with the storage conditions of antimicrobial agents according to the approved product labelling;
- ~~to address infection prevention and control measures regarding contacts between people, veterinarians, plant/crop health professional, breeders, owners, children, pets, wildlife and the food-producing animals or plants/crops treated~~;
- to comply with the recommended withdrawal periods or pre-harvest intervals ~~to ensure that residue levels in or on the food do not present a foodborne AMR risk for the consumer~~;
- to not use out-of-date antimicrobial agents and to dispose of all unused or out-of-date antimicrobial agents in accordance with the provisions on the product labels and national legislation;
- to inform the veterinarian, plant/crop health professional, or other suitably trained person authorized in accordance with national legislation in charge of the production unit of recurrent disease problems or ~~failures of~~ suspected lack of efficacy of antimicrobial applications;
- to maintain all clinical and laboratory records of microbiological diagnosis and susceptibility testing. These data should be made available to the professional in charge of the administration in order to optimize the use of antimicrobial agents.
- to keep adequate records of all antimicrobial agents used, including, for example, the following:
    - copy of the prescription, order for application or other documentation, when available;
    - name of the antimicrobial agent/active substance and batch number;
    - name of supplier;
    - date of administration; species and number of animals or plants/crops;
    - identification of the production unit ~~(animal age, numbers, weights)~~ to which the antimicrobial agent was administered;
    - disease treated, prevented, or controlled;
    - ~~number of~~ relevant information on animals or plants/crops treated (number, age, weight);
    - ~~daily dose and number of treatment days~~;
    - quantity and duration of the antimicrobial agent administered;
    - withdrawal periods;
    - result of treatment, in consultation with the veterinarian or plant/crop health professional;
    - name of the prescribing veterinarian, plant/crop health professional or other suitably trained person authorized in accordance with national legislation.
- To ensure sound management of wastes and other materials to minimize dissemination of excreted antimicrobial agents, resistant microorganisms and resistance determinants into the environment where they may contaminate food;
- To address on-farm biosecurity measures and take ~~basic~~ infection prevention and control measures as appropriate and as provided in the *OIE terrestrial and aquatic animal health codes*;
- To participate in training on issues related to antimicrobial resistance and the responsible use of antimicrobial agents as described in paragraph 32, as appropriate;
- To assist the relevant authorities in surveillance programs related to antimicrobial use and antimicrobial resistance, as appropriate.

63 ~~59~~. The responsible and prudent use of antimicrobial agents should be supported by continuous efforts in disease prevention to minimize infection during production. ~~and decrease exposure to antimicrobial agents.~~ Efforts should aim to improve health, thereby reducing the need for ~~antibiotics~~ antimicrobial agents. This can be achieved by, for example, improving hygiene, biosecurity, ~~and~~ health management on farms, improving animal and plant/crop genetics, and implementing national or international good animal production (terrestrial and aquatic), and plant/crop production practices.

Disease prevention through the use of vaccines, ~~integrated pest management,~~ and other measures that have been clinically proven to be safe and efficacious for supporting animal health, such as adequate nutrition ~~and feed additives, such as probiotics (beneficial bacteria found in various foods), prebiotics (non-digestible foods that help probiotic bacteria grow and flourish) or competitive exclusion products (intestinal bacterial flora that limit the colonization of some bacterial pathogens) may should/~~can be considered and applied ~~wherever~~ when appropriate and available. ~~Disease prevention through the use of vaccines and other appropriate measures aimed at supporting animal health (such as adequate nutrition and whenever available feed additives such as prebiotics, probiotics) should be considered.~~

Prevention and reduction of the incidence and severity of plant pests and diseases should be implemented by applying best agricultural practices, such as crop rotation, accurate and timely diagnosis and monitoring of diseases, use of disease resistant crop varieties, exclusionary practices that prevent introduction of pathogens into a crop, careful site selection ~~and pest impact reduction strategies using host resistance, induced resistance~~, integrated pest management strategies and biological controls when appropriate and available.

6. Practices during production, processing, storage, transport, retail and distribution of food

[64 ~~60bis (a)~~. Concerted efforts of all stakeholders ~~within the entire~~ along the food chain are required to minimize and contain foodborne illness, including illness related to foodborne AMR. While this Code ~~such efforts include~~ focuses on responsible and prudent use of antimicrobial agents in primary production at the farm level, the later phase of the food chain also plays an important role in preventing foodborne AMR infection and illness.]

[65 ~~60bis (b)~~. The food processing industry and food retailers should ~~follow~~ refer to the Principles and Guidelines for the Conduct of Microbiological Risk Management (CXG 63-2007).]

[66 ~~60bis (c)~~. Food should be produced and handled in such a way as to minimize the introduction, ~~the~~ presence and growth of microorganisms, which apart from having the potential to cause spoilage and foodborne illnesses can also disseminate foodborne AMR. Slaughterhouses and processing plants should follow good manufacturing practices and the Hazard Analysis and Critical Control Points (HACCP) principles. The General Principles of Food Hygiene (CXC 1-1969) is a useful reference in this respect.]

[67 ~~60ter~~. Food business operators should provide training on good hygienic practices, including those for minimizing cross-contamination. The WHO Five Keys to Safer Food contains useful information for food handlers to minimize the transmission of foodborne illness, including ~~AMR~~ resistant infections.]

7. Consumer practices and communication to consumers

68 ~~61~~. Government, food industry and other stakeholders along the food chain should inform and educate consumers on the risks of foodborne illness, including infections with resistant microorganisms and ways to minimize the risk of infection.

Some aspects to consider when communicating to consumers are:

- Identifying all the stakeholders and having a common message;
- Providing information that is clear, accessible, and targeted to a non-scientific audience;
- Considering local characteristics that affect how risks are perceived (e.g. religious belief, traditions).~~;~~

The *WHO Five Keys to Safer Food Manual* can be used as a tool to assist in awareness raising for consumers on how to minimize foodborne bacteria in their food.]69 ~~62~~. For more information on risk communication refer to *WHO integrated surveillance of antimicrobial resistance in foodborne bacteria, application of a One Health approach* and *FAO/WHO risk communication applied to food safety handbook* and *the Guidelines for risk analysis of foodborne antimicrobial resistance.*

~~[63. The best way for consumers to minimize foodborne illness, including infections with resistant microorganisms, is through proper food handling and personal hygiene. The *WHO Five Keys to Safer Food Manual* can be used as a tool to assist in awareness raising for consumers on how to minimize foodborne bacteria in their food.]~~

APPENDIX II

LIST OF PARTICIPANTS

- **Chair**: United States of America
- **Vice-Chairs**: Chile, China, Kenya and the United Kingdom

Codex Members

1. Australia
2. Brazil
3. Canada
4. Chile
5. China
6. Costa Rica
7. Denmark
8. Ecuador
9. Finland
10. France
11. Germany
12. Ghana
13. India
14. Japan
15. Malaysia
16. Mexico
17. Morocco
18. New Zealand
19. Nicaragua
20. Nigeria
21. Republic of Korea
22. Thailand
23. Uganda
24. United Kingdom
25. Uruguay
26. United States of America

Codex Member Organization

1. European Union

Codex Observes

1. Consumers International
2. Health for Animals
3. International Association of Consumer Food Organizations (IACFO)
4. International Dairy Federation (IDF)
5. International Feed Industry Federation (IFIF)
6. International Meat Secretariat (IMS)
7. European Feed Manufacturer's Federation (FEFAC)
8. World Organization for Animal Health (OIE)