

CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture
Organization of the
United Nations



World Health
Organization

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REP20/AMR

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX ALIMENTARIUS COMMISSION**

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

Pyeongchang, Republic of Korea

9 – 13 December 2019

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SUMMARY AND STATUS OF WORK

Responsible Party	Purpose	Text/Topic	Code	Step	Para(s)
CAC43 EWG (United States of America, Chile, China, Kenya, United Kingdom) TFAMR08	Adoption at Step 5	Proposed draft revision of the <i>Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance</i> (CXC 61-2005)	N28-2917	5	126
EWG (the Netherlands, Canada, Chile, China, New Zealand) TFAMR08	Redrafting	Proposed draft Guidelines on Integrated Monitoring and Surveillance of Foodborne Antimicrobial Resistance	N29-2017	2/3	132

INTRODUCTION

1. The *ad hoc* Intergovernmental Task Force on Antimicrobial Resistance (TFAMR) held its Seventh Session in Pyeongchang, Republic of Korea, from 9 to 13 December 2019, at the kind invitation of the Government of the Republic of Korea. Prof. Sangyeol Ryu, Seoul National University, chaired the Session. The Session was attended by participants from 43 member countries, one member organization, 12 observer organizations, FAO and WHO. The list of participants is included in Appendix I.

OPENING OF THE SESSION¹

2. Dr Lee Eui Kyung, Minister of Food and Drug Safety of the Republic of Korea, opened the session and welcomed the participants. She reminded the participants of the global threat posed by antimicrobial resistance (AMR) and emphasized the importance of international cooperation to combat AMR. Mr. Choi Moon-soon, the governor of Gangwon Province also addressed TFAMR07. Dr. Qu Dongyu, Director-General of FAO and Dr. Tedros Adhanom Ghebreyesus, Director-General of WHO addressed the meeting via video messages and encouraged TFAMR07 to advance their work on the Code of Practice and the Guidelines which is an integral part of both organizations' efforts to combat AMR.

Division of Competence²

3. TFAMR07 noted the division of competence between the European Union (EU) and its Member States, according to paragraph 5, Rule II, of the Rules of Procedure of the Codex Alimentarius Commission.

ADOPTION OF THE PROVISIONAL AGENDA (Agenda Item 1)³

4. TFAMR07 adopted the provisional Agenda as its Agenda for the Session.

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER SUBSIDIARY BODIES (Agenda Item 2)⁴

5. TFAMR07 noted the matters for information.

MATTERS ARISING FROM FAO, WHO and OIE (Agenda Item 3)⁵

6. The Representative of FAO highlighted the information on FAO activities on AMR, noting that further details would be provided during the side event on FAO/WHO/OIE Tripartite Support for Tackling Antimicrobial Resistance, and that this information may be a useful input to TFAMR07 discussions.
7. The Representative of WHO recalled that the World Health Assembly in May 2019 requested the Director-General to maintain and systematically update the *WHO List of Critically Important Antimicrobials for Human Medicine* (WHO CIA List); indicated that WHO would continue updating the list regularly; and encouraged delegations to consider and enhance the utility of the WHO CIA List by referring to it in the Code of Practice.
8. The Representative of WHO further informed TFAMR07 that WHO had proposed the inclusion of a new indicator on AMR (the proportion of bloodstream infections amongst patients due to methicillin-resistant *Staphylococcus aureus* (MRSA) and *Escherichia coli* resistant to 3rd-generation cephalosporin (e.g., ESBL- *E. coli*)) in the Sustainable Development Goal (SDG) monitoring framework. The proposal had been positively reviewed by the Inter-Agency Expert Group on SDG Indicators and was now pending final endorsement by the SDG Commission in March 2020. The Representative encouraged delegations to consider this new development in the context of their discussions on the proposed draft Guidelines on Integrated Monitoring and Surveillance of Foodborne Antimicrobial Resistance.
9. The Representative of OIE highlighted their increasing engagement in the Tripartite work on AMR in order to address this issue with a One Health Approach. The Representative noted the importance of building strong Tripartite leadership and providing support to countries and reminded TFAMR07 of the OIE standards related to AMR and the importance of developing coherent global standards to support country efforts to address AMR.

Conclusion

10. TFAMR07 thanked FAO, WHO and OIE for their excellent work on AMR, their continuous efforts in this area and ongoing support to countries.

¹ CRD17 (Opening Remarks)

² CRD1 (Annotated Agenda – Division of competence between the EU and its Member States)

³ CX/AMR 19/7/1

⁴ CX/AMR 19/7/2; CRD14 (Egypt)

⁵ CX/AMR 19/7/3; CRD14 (Egypt)

MATTERS ARISING FROM OTHER RELEVANT INTERNATIONAL ORGANIZATIONS (Agenda Item 4)⁶

11. The Codex Secretariat drew the attention of TFAMR07 to the relevant information on antimicrobial resistance provided by the Organization for Economic Cooperation and Development (OECD) and the World Customs Organization (WCO).

Conclusion

12. TFAMR07 noted the information and thanked the organizations for their collaboration.

PROPOSED DRAFT REVISION OF THE CODE OF PRACTICE TO CONTAIN AND MINIMIZE FOODBORNE ANTIMICROBIAL RESISTANCE (CXC 61-2005) (Agenda Item 5)⁷

13. The United States of America, as Chairperson of the Electronic Working Group (EWG) and Physical Working Group (PWG) on the revision of the Code of Practice (COP), introduced the item and summarized the key points of discussions, conclusions and recommendations of the EWG (CX/AMR 19/07/5) and the PWG (CRD02).
14. He further drew the attention of TFAMR07 to the three core Codex documents on foodborne AMR namely the *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance* (CXG 77-2011); the *Code of Practice to Contain and Minimize Foodborne Antimicrobial Resistance* (CXC 62-2005) (under revision) and the *Guidelines on Integrated Monitoring and Surveillance of Foodborne Antimicrobial Resistance* (under development). The COP and the *Guidelines on Integrated Monitoring and Surveillance of Foodborne AMR* are being developed within the One Health Approach and apply along the food chain (primary production, processing to consumption). The revision and development of these two documents are closely linked to each other and to the *Guidelines for Risk Analysis of Foodborne AMR* (which provides the three pillars for the conduct of risk analysis by Codex member countries i.e. risk assessment, risk management and risk communication). The COP is a compilation of risk management measures to contain and minimize foodborne AMR and the *Guidelines on Integrated Monitoring and Surveillance of Foodborne AMR* constitute a useful tool to generate inputs into the risk assessment process. As such, it was important that the three documents maintained coherence to the extent possible, to facilitate their application.
15. He also reminded delegations of the urgency to complete this work within the timeline agreed by the Codex Alimentarius Commission (CAC) (i.e. three years) and that after two sessions of TFAMR, in 2017 and 2018, it was important that the third session of the current TFAMR could advance the COP in the Step Procedure for consideration by CAC43 (2020).
16. He further recommended that delegations focus their discussion on the outstanding issues from the consideration of the COP in the PWG, in particular provisions in square brackets, for resolution by the plenary session.
17. TFAMR07 agreed with the above recommendations and decided to proceed with the consideration of the COP on the basis of a revised version provided in CRD02.

1. Introduction

18. TFAMR07 agreed on paragraphs 1 to 8 as recommended by the PWG.
19. In addition, TFAMR07 agreed on amendments to improve consistency with relevant Codex texts and previously agreed terminology in both the COP and the *Guidelines on Integrated Monitoring and Surveillance of Foodborne AMR* e.g. reference to “*along the food chain*”, “*One Health Approach*”, “*unjustified barriers to trade*”, etc. or to improve the accuracy or clarity of the text.
20. With regards the reference to the *WHO List of Critically List of Antimicrobials for Human Medicine* in paragraph 6, TFAMR07 noted that the term “specifically” allowed flexibility for member countries to take into account the whole WHO document (or provisions therein) or only the Annex listing the medically important antimicrobials categorized as critically important, highly important and important when setting priorities and identifying risk management measures to contain and minimize foodborne AMR.

2. Scope

21. TFAMR07 agreed on paragraphs 9 – 12 as recommended by the PWG.

⁶ CX/AMR 19/7/4; CRD14 (Egypt)

⁷ CL 2019/84/OCS-AMR; CX/AMR 19/7/5; CX/AMR 19/7/5-Add.1 (Australia, Brazil, Canada, China, Ghana, Iran, Iraq, Japan, Morocco, Norway, Republic of Korea, Switzerland, Uruguay, USA, CCTA Consumers International, HealthForAnimals, IACFO and OIE); CRD02 (Report of the PWG); CRD04 (EU, Norway, Thailand, GFSI); CRD06 (IFIF); CRD07 (Kenya); CRD08 (Chile); CRD09 (India); CRD10 (HealthForAnimal); CRD13 (Nicaragua); CRD14 (Egypt); CRD15 (Indonesia); CRD16 (Nigeria); CRD19 (Peru)

22. In addition, TFAMR07 agreed to delete the reference to “feed” in paragraph 9 as it was implicit since it was part of the definition of food chain.

Other matters

23. Following lengthy discussion and slow progress on the provisions of the COP, mainly related to the definition of medical important antimicrobials, vis-à-vis key principles and provisions under the responsible and prudent use of antimicrobials (section 5) and whether focus should be on “*medically important antimicrobials*” as opposed to “*all antimicrobials*”, which led to back and forth discussion for the first two days of the plenary session, and in recognition of the challenging nature of the discussions and the slow rate of progress, the Chairperson of TFAMR07 reminded the Task Force that many delegations had invested a significant amount of their scarce resources to attend this meeting and were keen to secure the objective of advancing the proposed texts (i.e. COP and the Guidelines on Integrated Monitoring and Surveillance of Foodborne AMR).
24. The Chairperson recalled that AMR was a current and growing threat that needed a global coalition to counter effectively and that the entire Codex family expected TFAMR to complete the work expeditiously. Highlighting the need to advance in a timely manner, the Chairperson called on all delegations to be open to mutual understanding and compromise, to recall the extensive work and high quality of the texts developed by the EWG/PWG and to keep in mind that the texts should be practical and applicable globally.
25. In supporting the intervention of the Chairperson, Brazil reminded participants of the expectation that TFAMR07 progressed its work this year and noted that this session had not yet been able to work on the Guidelines on Integrated Monitoring and Surveillance of Foodborne AMR which Codex Members had also agreed to elaborate. Brazil also noted the high level of awareness on AMR as a major global public health concern and the need for immediate action, highlighting that much had happened at both global and national levels, especially since approval of the Global Action Plan in 2015 and the UN Assembly in 2016. Brazil further recalled the clear messages to TFAMR07 from the Directors-General of FAO and WHO on their expectation of an outcome from this session, as well as that of the countries which send representatives to this meeting, despite their limited financial and human resources. Brazil emphasized that such resources cannot be wasted, that decisions had to be taken and text had to go out of brackets, in a sign of compromise. Recalling the mandate of TFAMR, Brazil noted that a majority of the countries present, coming from different regions of the world, agreed with the proposed text and that Members had been given the opportunity for full discussion and exchange of views on the issues under consideration. Brazil further noted that the recommendations in Codex documents should be science-based and applicable on a worldwide basis. In recalling the Codex Procedures, Brazil reminded Members that they can ask for a reservation on a specific issue, without preventing decisions by this TFAMR.

3. Definitions

Chapeau

26. TFAMR07 agreed that the terms defined in the Guidelines on Integrated Monitoring and Surveillance of Foodborne AMR would also be applicable to the COP.
27. TFAMR07 further agreed that, to ensure consistency, those definitions already available in the other Codex documents cited in the chapeau paragraph need not be repeated in the COP. However, definitions for some terms widely used in the COP would be retained in this section for ease of reference.

Antibacterial; Antimicrobial Agent; Antimicrobial Resistance; Antimicrobial Resistant Determinant; Extra- or Off Label; Food Producing Animal; Growth Promotion; Marketing Authorization; Pharmacovigilance; Plant/Crop Health Professional

28. TFAMR07 recalled that it had already agreed on these definitions at its last session. However, a few minor changes were made to some of them during the work of the EWG and PWG which are reflected in CRD02.
29. TFAMR07 agreed on the definitions as presented in CRD02.

Co- and Cross-Resistance

30. TFAMR07 agreed to remove definitions for these terms from this section as these terms were no longer used in the COP and in any case already available in the *Guidelines for Risk Analysis for Foodborne AMR*.

Competent Authority(ies)

31. Delegations made the following comments:
- The Codex Committee on Food Hygiene (CCFH) had proposed a definition for “competent authority” for final adoption by CAC43 (2020). However, this definition was not viewed as suitable in the context of this COP.

- The Codex Committee on General Principles (CCGP) and the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) had discussed a horizontal definition for “competent authority” but could not agree on a single definition for this term. Likewise, it might be difficult to concur a definition for “competent authority” in the framework of this COP.
- Proliferation of definitions of the same term in the Codex system was not advisable and, a definition for “competent authority”, was not necessary for the purposes of this COP.

32. TFAMR07 therefore agreed to remove this term from this section.

Control of disease/metaphylaxis; Prevention of disease/prophylaxis; Treatment of disease

33. TFAMR07 agreed on the definitions for these terms as presented in CRD02 while including the term “application” to reflect the different ways antimicrobial agents can be administered or applied to animals or plants/crops.

Food chain

34. Since the term plants/crops did not cover all of feed and feed ingredients (e.g. feed of animal origin), TFAMR07 agreed to retain “feed” in the definition of food chain such that the COP would apply to all components of feed within the “food chain”.

35. TFAMR07 further agreed that as “feed” was part of the primary production it should be listed together with the examples given in the text in parenthesis i.e. (food-producing animals, plants/crops and *feed*).

36. TFAMR07 agreed on the revised definition for “food chain”.

Food production environment

37. TFAMR07 considered the definitions for “food production environment” as proposed in CRD02.

38. TFAMR07 noted divergent views on the need for the term “immediate”. Those in favor of deleting “immediate” indicated that “vicinity” already limited the area of the environment close to the food (or feed, food-producing animal or plants/crops) where risk management measures could apply to contain / minimize foodborne AMR and the addition of this qualifier did not add more specificity to the term “vicinity”.

39. Delegations in favor of the retention of this qualifier indicated that the use of the term “vicinity” alone was not specific enough in this context to delimit the area that could contribute to foodborne AMR. This was viewed as an important element for monitoring and surveillance of foodborne AMR where this definition would also apply.

40. TFAMR07 noted divergent views on the term “reasonable probability”. Those delegations in favor of deleting this term noted it was very subjective and proposed “significant probability” as more appropriate in order to give a more definite certainty to the probability for the food production environment to contribute to foodborne AMR.

41. Those delegations in favor of the retention of the qualifier “reasonable” noted that this was the best practical compromise solution to address such probability. Other delegations could support this qualifier as long as scientific evidence / risk assessment / risk characterization indicated a “reasonable” probability that foodborne AMR might occur. These delegations indicated that the definition should be clear enough to avoid other AMR scenarios that might happen in the food production environment which are not foodborne but occupational-related AMR.

42. Other delegations indicated that they could not agree with the term “significant” as this would imply a level of certainty that could only be obtained through risk assessment (hazard or risk characterization) which was not always possible nor required especially in the context of monitoring and surveillance of foodborne AMR where such programs could be established based on “reasonable” or “relevant” evidence that foodborne AMR might occur.

43. In order to avoid further questions around how the term “food” should be considered in the context of food production environment, it was agreed that, as the risk management measures, including monitoring and surveillance, apply along the food chain (a term encompassing primary production, processing to consumption), it would be more appropriate to refer to the “food chain” in this definition as opposed to “food”.

44. Based on the above considerations, TFAMR07 therefore agreed on a compromise definition that could be applicable in the framework of the One Health Approach and be relevant to both the COP and the Guidelines on Integrated Monitoring and Surveillance of Foodborne AMR.

Medically important antimicrobials

45. While TFAMR06 eventually agreed upon a definition for *medically important antimicrobials*, concerns were expressed that this definition excluded those antimicrobials which were used only in animals but could contribute to cross- or co-resistance of medically important antimicrobials used in humans. It was further noted that the current definition referred to antimicrobial agents, rather than antimicrobial classes, and the insertion of “classes of” at the beginning of the definition was proposed. It was also highlighted that the definition of medically important antimicrobials could not be considered in isolation because it would impact on how the term could be used throughout the COP, in particular in sections 4 and 5.
46. Those delegations in favor of retaining the definition as proposed considered that this definition would enable countries to prioritize risk management activities on those antimicrobials important for therapeutic use for humans. While noting the concerns related to cross-resistance and co-resistance, it was considered that identifying those antimicrobials that could contribute to cross- or co-resistance of antimicrobials for therapeutic use in humans was part of risk assessment and that was covered by CXG-77-2011. Further, it was noted that cross-resistance was a consideration in developing the WHO CIA List, which was referenced in the current definition.
47. The representative of WHO clarified that the WHO CIA List categorized critically important antimicrobials for human medicines by classes of antimicrobials as in Table 1 of the List. Annex 1 lists these classes, providing a longer list of examples of antimicrobial agents for each of the relevant classes. The agents listed as examples are used either in humans, both in humans and animals or only in animals. While Annex 1 lists all the medically important classes, the list of agents under each class is not necessarily exhaustive, but the classes of critically important antimicrobials represented is complete.
48. Based on the above considerations, TFAMR07 therefore agreed on a revised definition for medically important antimicrobials which permitted further discussion and agreements in the remaining sections of the COP especially sections 4 and 5.

One Health Approach

49. TFAMR07 agreed that what was relevant to the definition was the multi-sectoral nature of the One Health Approach (i.e. human, animal and plant health) as opposed to the level of its application (i.e. local, national, regional or global) and consequently removed the geographical references from the definition.

Pharmaceutical industry

50. TFAMR07 noted that this term appeared only one time in the introduction and therefore agreed to remove this term from this section.

Plants/Crops

51. TFAMR07 agreed on the definition without the text in parenthesis (~~or part thereof~~).
52. TFAMR07 endorsed the recommendation of the PWG to remove the definition for the term “food of plant origin” as it was deemed not necessary.

Therapeutic use

53. TFAMR07 agreed to leave this definition in square brackets for further consideration at its next session (see section 4, Principle 6 and the mandate of the EWG).

4. Principles

54. TFAMR07 recalled that Principles 1-4, 8-11 and 13-14 were already agreed by TFAMR06. In view of minor edits made to these principles for further clarity and consistency during the deliberations of the EWG and PWG, TFAMR07 agreed on principles 2-4, 8-11 and 13-14 as presented in CRD02.
55. TFAMR07 considered the remaining principles and made the following comments and decisions:

Principles on AMR risk management (generally)**Principle 1**

56. TFAMR07 agreed to slightly amend this principle to reflect that the One Health Approach should always be considered and should apply whenever possible.
57. TFAMR agreed with the principle as revised.

Principle 4

58. TFAMR07 noted that the principle did not aim to place any obligation to WHO and OIE to update their respective Lists of critically important antimicrobials for human medicine and Antimicrobial Agents of Veterinary Importance but was rather an expression of encouragement to these organizations to do so on a regular basis.
59. On this understanding, TFAMR07 agreed to retain this principle as presented in CRD02.

Principle 9 and new Principle 1bis

60. TFAMR07 agreed that the last sentence in the principle did not relate to the purpose of this principle but that it was a principle in itself. It was therefore agreed to establish a new principle to call upon consideration of relevant OIE and IPPC texts in the context of the One Health Approach of this COP.

Principle on the responsible and prudent use of antimicrobials (generally)Principle 12

61. TFAMR07 noted divergent views on whether the square brackets should be removed from this principle. The debate centered around whether the principle should be inclusive to all antimicrobials or be focused only on medically important antimicrobials.
62. Delegations in favor of applying the principle to all antimicrobials as opposed to only medically important antimicrobials, noted that administration or application of antimicrobials (in particular critically important antimicrobials) to food-producing animals or plants/crops should not be allowed without prescription and that this was not consistent with relevant WHO documents nor the current COP. Delegations reminded TFAMR that its mandate stated that work on the COP and the Guidelines on Integrated Monitoring and Surveillance of Foodborne AMR take into account relevant available international guidance such as WHO and OIE documents. Concerns were also expressed by an Observer that this revision of the COP was limiting recommendations to a smaller set of antimicrobials and thereby not strengthening recommendations that increase the protection of consumers compared to the previous COP.
63. Delegations in favor of the retention of this principle noted that the concept of medically important antimicrobials allows countries to focus measures on those most important to protect antimicrobials for human therapeutic use and is consistent with Principle 15, which has already been agreed by the Task Force, directing countries to give priority to measures most relevant to public health. In addition, the principle provided flexibility to prescribe, administer or apply medically important antimicrobials to food-producing animals and plants/crops subject to professional oversight, such as under the direction of veterinarians or other suitably trained persons authorized in accordance with national legislation. These delegations noted that the COP should be inclusive to enable global application and that this principle did take account of public health protection by allowing use of medically important antimicrobials in agriculture, but only under the supervision of professionals or authorized persons and in line with the requirements established in national legislation.
64. Delegations also noted that the principle did not sufficiently describe those “suitably trained persons” and concerns were expressed that such persons could administer or apply medically important antimicrobials without prescription. Other delegations noted that national legislation could appropriately authorize persons qualified by training and experience to administer or apply medically important antimicrobials.
65. Based on the above considerations and the agreement on the revised definition for medically important antimicrobials, TFAMR07 agreed to retain this principle in the COP and noted the comments of the Russian Federation and Norway that this principle should refer to all antimicrobials and not be limited to medically important antimicrobials.

Principles on the use of antimicrobials in specific circumstancesPrinciple 5

66. This principle was discussed taking into consideration the revised definition of medically important antimicrobials. There was broad support by several members from different regions for its adoption, based on the extensive discussions and the compromise that had been reached on the definition of medically important antimicrobials.
67. Two Members expressed their continued concern with this principle highlighting that in their view, medically important antimicrobials should never be used for growth promotion as it could pose an unjustified risk for public health and that Principle 5 should not be limited to medically important antimicrobials but also include reference to antimicrobials that could cause cross- and/or co-resistance.
68. The European Union (EU) and its Member States and Norway will welcome the opportunity to continue the discussion of Principle 5 in the coming year. Norway also asked for further consideration of phasing-out antimicrobials used as growth promoters.

69. TFAMR07 agreed with Principle 5 as presented in CRD02. TFAMR07 further noted the reservations of the Russian Federation, Egypt, Thailand and India, and the statement of the EU and its Member States and Norway.

Principle 6

70. TFAMR07 noted comments from delegations to delete this principle as no longer needed considering other principles that had been agreed.
71. Delegations said that efforts were made to agree upon text in square brackets to allow progression of the COP in the step procedure. The delegations requesting retention of the square brackets around this principle and the definition of therapeutic use could consider entering a reservation in order to send the COP without square brackets for adoption by CAC43.
72. Delegations in favor of the retention of this principle noted that it would be useful to have another opportunity to discuss Principle 6 together with the definition for “therapeutic use” and the relevant sections of the COP where the term “therapeutic” was used. An EWG could facilitate further discussion and resolution of this principle and related matters at TFAMR08. These delegations requested to retain the principle in square brackets.
73. TFAMR07 agreed to leave this principle in square brackets pending the resolution of the definition of “therapeutic use” as the term (and Principle 6) were relevant to a number of provisions for the responsible and prudent use of antimicrobials in section 5.

Principle 7

74. Some delegations not in favor of this principle proposed its deletion, revision, or retention in square brackets for further consideration, noting their concerns that, as currently written, it was allowing for the use of “medically important antimicrobials” for preventative / prophylactic use. These delegations expressed concerns that the current wording of Principle 7 allows for misinterpretation and routine use for prophylaxis of critically important antimicrobials that are of highest priority for human medicine, and as such, poses a risk to human health. They stated that, medically important antimicrobials, notably those of critically importance and veterinary critically importance, as designated by WHO and OIE, respectively, should never be used prophylactically. It was further noted that reference to plants/crops and to exceptional use needed to be included. An Observer stated that the principle would not significantly limit the routine preventive use of antibiotics including those that create the greatest risks to human health.
75. Other delegations supported this principle, stating that it limited the scope to medically important antimicrobials for specific disease risk, in well-defined circumstances, based on clinical and epidemiological knowledge, under professional oversight, and it was not meant to be inclusive of all risk management options.
76. The principle was revised taking into consideration both the comments and concerns expressed at the session. TFAMR07 subsequently agreed on the revised principle, noting the reservations of the Russian Federation and Norway.
77. TFAMR07 further noted the following statement: The Russian Federation, Norway, and the EU and its Member States do not support the prophylactic use of medically important antimicrobials. We recognize the threat of developing AMR when using for prophylactic purposes those antimicrobial agents listed as the Highest Critically Importance with the highest priority for human use in the WHO CIA List, and the most important mentioned in the OIE list of Antimicrobial Agents of Veterinary Importance, such as Fluoroquinolones, 3- or 4 gen. Cephalosporines and Colistin. The work in Codex should aim at being ambitious in line with Codex mandate ensuring protection of public health. Furthermore, we are of the opinion that it is important to ensure consistency with FAO, WHO and OIE.

Principle 7bis

78. TFAMR07 agreed to retain this Principle as presented in CRD02.

Principle 7ter

79. TFAMR07 agreed to delete this principle as plants/crops were already covered under principles 7 and 7bis.

Principle on surveillance of antimicrobial resistance and use

Principle 10

80. TFAMR07 agreed to retain this principle as presented in CRD02.

5. Responsible and prudent use of antimicrobial agents

81. TFAMR07 agreed on paragraphs 13-14 as proposed by the PWG in CRD02.

5.1 Responsibilities of the competent authorities

82. TFAMR07 agreed on paragraphs 15-18 as proposed by the PWG in CRD02.
Quality control of antimicrobial agents
83. TFAMR07 agreed on paragraph 19 as proposed by the PWG in CRD02.
Assessment of efficiency
84. TFAMR07 agreed on paragraph 20 as proposed by the PWG in CRD02.
Assessment of the potential antimicrobial agents to select for resistant microorganisms
85. TFAMR07 agreed to reinsert the words “medically important” before antimicrobial agents in paragraph 21, as it was considered that this qualification enabled countries to prioritize their risk assessment resources for the benefit of public health.
86. Norway and the Russian Federation reserved their position noting that, in their view, since this provision related to risk assessment it should apply to all antimicrobials used along the food chain and enable consideration of potential cross- or co-resistance to medically important antimicrobials.
Assessment of the environmental impact of the food production environment
87. TFAMR07 agreed on paragraph 22 and the revised sub-section title as proposed by the PWG in CRD02.
Establishment of a summary of product characteristics for each antimicrobial agent
88. TFAMR07 revised the title to read “antimicrobial product” rather than “antimicrobial agent” since this section was considered to be specific for a product formulation rather than just the antimicrobial agent.
89. TFAMR07 further agreed to replace “veterinary medicinal product” with “antimicrobial product” and made several additions to the bullet list primarily to ensure that the text was relevant for products intended for plants/crops as well as animals, and thereby reflecting the one health nature of the document.
Surveillance and monitoring programs
90. TFAMR07 revised the title and paragraph 24 to “monitoring and surveillance programs” for consistency with the Guidelines on Integrated Monitoring and Surveillance of Foodborne AMR, included “foodborne” before “AMR” for consistency with the scope, and inserted a reference to relevant OIE standards at the end of the paragraph.
91. TFAMR07 agreed on paragraphs 25-26 as proposed by the PWG in CRD02.
Distribution of antimicrobial agents
92. TFAMR07 aligned the title with that of the previous section by changing “agents” to “products” and revised paragraph 27 by deleting reference to prescription or ordering of antimicrobials by relevant professionals as it was considered that this might be overly restrictive since the paragraph referred to all antimicrobials as indicated in paragraph 11 of the Scope.
93. TFAMR07 agreed on paragraph 28 as proposed by the PWG in CRD02.
Control of advertising
94. TFAMR07 agreed on paragraph 30 as proposed by the PWG in CRD02 and revised paragraph 31 to refer to “antimicrobial products” rather than antimicrobial agents in order to align with previous paragraphs and added “or policies” to the end of the sentence so as to better reflect the situation across Member countries.
95. TFAMR07 also discussed whether the term “antimicrobial product” should be used more extensively in the document, to reflect commercial products, and a delegation asked for a definition of this term. The EWG/PWG Chairperson noted that this issue had been discussed by the EWG, which recommended limited use of this term in the text.
96. TFAMR07 agreed on paragraph 31 as revised.
Training on topics related to antimicrobial resistance and the responsible of antimicrobial agents
97. TFAMR07 deleted “topics related to” from the title, added “foodborne” in front of AMR in line with the scope of the document and “use” was added after “responsible” for completeness. TFAMR07 revised the last sentence of paragraph 32 to refer to “public health related activities” for clarity, and deleted reference to campaigns for consumers as this was covered in Section 7. AMU was added to the last bullet for consistency with the Guidelines on Integrated Monitoring and Surveillance of Foodborne AMR.
98. TFAMR07 agreed with the paragraph as revised.

Knowledge gaps and research

99. TFAMR07 deleted “medically important” from bullet 5 and changed “regional” to “sub-national” so as to be clear that it was a region within a country that was being referred to.

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

100. TFAMR07 agreed on paragraph 35 as proposed by the PWG in CRD02.

5.2 Responsibilities of manufacturers and marketing authorization holdersMarketing and export of antimicrobial agents

101. TFAMR07 agreed on paragraphs 36, 37 and 40 as proposed by the PWG in CRD02.
102. Following some discussion on the meaning of paragraph 38, TFAMR07 clarified that in essence it was highlighting the importance of obeying the laws of the countries where a product is sold and so “as specified in the legislation” was added after “standards” for clarity and the square brackets were removed.
103. TFAMR07 added “when requested” after competent authorities in paragraph 39 to better reflect actual practice.

Advertising

104. TFAMR07 agreed on paragraph 41 as proposed by the PWG in CRD02.
105. TFAMR07 revised paragraph 42 to reflect concerns regarding monetary benefits for prescribers or suppliers of antimicrobials.

Training

106. As paragraph 43 cross-references an earlier paragraph with an extensive list of training areas, all of which may not apply to the manufacturers and marketing authorization holders, TFAMR07 added “as appropriate” to the end of the sentence to clarify that all examples did not necessarily apply here.

Research

107. TFAMR07 agreed on paragraphs 44 and 45 as proposed by the PWG in CRD02.

5.3 Responsibilities of wholesale and retail distributors

108. TFAMR07 deleted the square brackets that were around “medically important” in paragraph 46, recalling the definition for “medically important antimicrobials” and noting that not all antimicrobials as defined in the Scope (paragraph 11) required a prescription. A Delegation highlighted their concerns at having medically important antimicrobials ordered by a “suitably trained person” rather than a veterinarian or plant/crop health professional.
109. TFAMR07 also introduced “medically important” in front of “antimicrobials” in paragraph 47, to facilitate prioritization of resources for record keeping and in recognition of the burden associated with record keeping.
110. TFAMR07 removed the square brackets from paragraph 48, following the revision of paragraph 42 which eliminated inconsistencies between these two paragraphs and added “as appropriate” in relation to the cross reference to paragraph 32, in line with the decision on paragraph 43.

5.4 Responsibilities of veterinarians and plant/crop health professionals

111. TFAMR07 discussed whether the footnote to veterinarian was only relevant to this section or should rather be included at the first mention of veterinarian in the document. Clarification was also sought on the meaning of suitably trained person. TFAMR07 noted that this footnote was not entirely consistent with the OIE definition, but that OIE did have a definition of suitably trained person. It was further noted that the location of the footnote had been discussed in the EWG and the current location was considered optimal as this section specifically addressed veterinarians. It was agreed to retain the footnote in the current location for now but that its location and consistency with the OIE definition be considered at TFAMR08.
112. TFAMR07 added “at the national level” to the end of the first sentence in paragraph 49 to clarify the level at which strategies should be developed.
113. TFAMR07 agreed on paragraph 50 as proposed by the PWG in CRD02.
114. TFAMR07 removed the square brackets from “medically important” in both the first and second bullets of paragraph 51. Norway and the Russian Federation recorded their reservation to the removal of the square brackets around the 2nd bullet. TFAMR07 also added “consultation with a” before “plant/crop professional” to better reflect the relationship with such a professional.
115. TFAMR07 agreed to retain “medically important” in paragraph 52, noting the reservation of the Russian Federation to this decision.

116. TFAMR07 also agreed to retain the term “medically important” in paragraph 53.
117. TFAMR07 put square brackets around “therapeutic” in the last bullet of paragraph 54, given some concerns expressed about the appropriateness of this term here and considering that the definition of therapeutic use was still in square brackets.

Off-label use

118. TFAMR07 agreed on paragraphs 55 and 56 as proposed by the PWG in CRD02 and reinserted “medically important” before “antimicrobials” in paragraph 57, noting the reservations of Norway and the Russian Federation to this change. An additional phrase was added to the end of the paragraph noting an exception for emerging disease control in line with national legislation.

Record keeping and recording

119. TFAMR07 agreed on paragraphs 58 and 59 as proposed by in CRD02 and added a new paragraph to reflect that veterinarians and plant/crop health professionals may have a role to play in monitoring and surveillance programs.

Training

120. TFAMR07 added “as appropriate” to the end of paragraph 60 for consistency with changes to earlier paragraphs related to training.

5.5 Responsibilities of food animal and plant/crop producers

121. TFAMR07 agreed paragraphs 61, 63 and 63 bis as proposed in CRD02. In the fourth bullet of paragraph 62, TFAMR07 replaced “relevant authorities” with “competent authorities” for consistency with the rest of the document and deleted the text “in a manner to minimize foodborne AMR”, as was considered unhelpful and potentially confusing. TFAMR07 included additional text in the tenth bullet of paragraph 62 to reflect the fact that a food animal or plant/crop producer may receive the assistance of their veterinarian, plant/crop health professional, or other suitably trained individual in maintaining records. In bullet 11 (sub-bullet 9), TFAMR07 inserted “dose” as an alternative to “quantity” to better reflect the way the antimicrobial may be used. It was also suggested to number the bullets in this paragraph and others with long lists to facilitate usability of the document.
122. TFAMR07 changed “best agricultural practices” to “good agricultural practices” in paragraph 63ter to align with commonly used terminology.

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

123. TFAMR07 agreed on this section as proposed in CRD02.

7. Consumer practices and communication to consumers

124. TFAMR07 added the words “science-based” to the second bullet of paragraph 68 to clarify that information to consumers should have a sound scientific basis. In order not to limit the tools that countries can use to support awareness raising of consumers TFAMR07 deleted the specific reference to the *WHO five keys to safer food manual* and replaced it with a more general reference to the various manuals of international organizations. TFAMR07 agreed paragraph 69 as proposed in CRD02.
125. The Chairperson of TFAMR thanked delegations for their efforts and highlighted the substantial progress made at this session and the agreements secured on the most substantive parts of the COP. While noting that this progress on the COP came at the expense of having time to discuss the Guidelines on Integrated Monitoring and Surveillance of Foodborne AMR the Chairperson expressed the hope that with the progress made on the COP, TFAMR08 could dedicate most of its time to the development of the Guidelines on Integrated Monitoring and Surveillance of Foodborne AMR.

Conclusion

126. TFAMR07 agreed to:
- forward the proposed draft revision of the *Code of Practice to Contain and Minimize Foodborne Antimicrobial Resistance* (CXC 61-2005) to CAC43 for adoption at Step 5 (Appendix II); and
 - establish an EWG, chaired by the United States of America and co-chaired by Chile, China, Kenya and the United Kingdom, working in English only, and open to all Members to address the outstanding issues in square brackets and report back to the next session of TFAMR08
127. The report of the EWG should be made available to the Codex Secretariat at least three months before TFAMR08 for circulation for comments.

PROPOSED DRAFT GUIDELINES ON INTEGRATED MONITORING AND SURVEILLANCE OF FOODBORNE ANTIMICROBIAL RESISTANCE (Agenda Item 6)⁸

128. The Netherlands, as Chairperson of the EWG and PWG on the development of the Guidelines on Integrated Monitoring and Surveillance of Foodborne AMR, expressed its disappointment at not having been able to discuss this document during TFAMR07. She noted that the absence of progress on the Guidelines was a concern and urged the delegates for an equal level of collaboration and compromise demonstrated for the COP, in order to be able to also advance on the Guidelines. She recalled the work of the two WGs, noting that the PWG had revised Sections 1 to 7 but were unable to review Sections 8-13 due to time constraints. She further noted that the PWG had made some overarching proposals, specifically to replace “monitoring and surveillance *system*” with “monitoring and surveillance *program*”; to replace “*throughout the food chain*” with “*along the food chain*”; and to replace “*progressive approach*” with the concept of “*continuous improvement*”, noting that each replacement would need to be considered on a case-by-case basis. In view of the time constraints, she proposed that further work on the guidelines be based on the output of the PWG (CRD03) and that an EWG be established to continue their development.

Discussion

129. Delegations expressed their appreciation for the work of the Netherlands, reiterated their support for the development of the Guidelines, and noted their disappointment at not being able to have detailed discussions at this session. In this regard, it was requested that discussion of the Guidelines be prioritized on the Agenda of TFAMR08 and the possibility of having a PWG in conjunction with TFAMR08 be retained in order to ensure there would be adequate time to discuss and progress this document.
130. There was general agreement that CRD03 be used as the basis for further discussions. It was also suggested that: the agreement reached in the PWG on the three overarching issues identified by the Chairperson of the EWG/PWG should not be reopened by the EWG; the EWG should prioritize those sections of the guidelines that had not been reviewed by the PWG; the definitions section should respect the agreements on definitions reached in the discussions on the COP; and the Guidelines should be shared in their entirety rather than in sections in the course of the EWG in order to facilitate the review by members.
131. The Chairperson of TFAMR recalled the positive progress made at the PWG under the excellent chairpersonship of the Netherlands, that there was only one remaining scheduled session of TFAMR and shared the ambition that the objective for TFAMR08 should be to agree on the Guidelines that can be proposed for adoption at Step 5/8 by CAC44 (2021).

Conclusion

132. TFAMR07 agreed to return the proposed draft Guidelines on Integrated Monitoring and Surveillance of Foodborne Antimicrobial Resistance to Step 2/3 for re-drafting and to establish an EWG, chaired by the Netherlands, and co-chaired by Canada, Chile, China and New Zealand, working in English only and open to all members and observers with the following Terms of Reference:
- Review and revise the Guidelines based on the text in CRD03, focusing on those areas that were not considered at the PWG and not reopening definitions already agreed in the COP; and
 - Prepare a revised version of the Guidelines for consideration by TFAMR08.
133. The report of the EWG should be made available to the Codex Secretariat at least three months before TFAMR08 for circulation for comments at Step 3.

OTHER BUSINESS (Agenda Item 7)

134. TFAMR07 noted that no other business had been proposed.

DATE AND PLACE OF THE NEXT SESSION (Agenda Item 8)

135. TFAMR07 agreed to keep open the possibility of PWGs to meet immediately before its next session, to consider written comments submitted and prepare revised proposals for consideration by TFAMR08, or any other suitable arrangement that may facilitate progression of the documents in the Step Procedure.
136. TFAMR07 was informed that its next session was scheduled to be held in 12 months-time, the final arrangements being subject to confirmation by the Codex/Host Country Secretariats.

⁸ CL 2019/83/OCS-AMR; CX/AMR 19/7/6; CX/AMR 19/7/6-Add.1 (Australia, Brazil, Canada, China, Egypt, Ghana, Iran, Iraq, Japan, Morocco, Norway, Republic of Korea, Switzerland, Uruguay, USA, CCTA, Consumers International, HealthForAnimals, IFIF and OIE); CRD03 (Report of the PWG); CRD05 (EU, Iran, Thailand); CRD07 (Kenya); CRD08 (Chile); CRD09 (India); CRD10 (HealthForAnimals); CRD11 (Revised proposed draft Guidelines prepared by the EWG Chairperson); CRD12 (Canada); CRD13 (Nicaragua); CRD15 (Indonesia); CRD16 (Nigeria); CRD18 (Canada); CRD19 (Peru)

APPENDIX I

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APPENDIX II**PROPOSED DRAFT REVISION OF THE CODE OF PRACTICE TO MINIMIZE AND CONTAIN FOODBORNE ANTIMICROBIAL RESISTANCE (CXC 61-2005)****(For adoption at Step 5)****1. Introduction**

1. Antimicrobial resistance (AMR) poses an important, complex, and priority global public health challenge. Along 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 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. In keeping with the Codex mandate this Code of Practice addresses antimicrobial use along the food chain. It is recognized that the use of antimicrobial agents along 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 approach 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. 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 Resistance 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), 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. This Code of Practice provides risk management advice, including the responsible and prudent use of antimicrobial agents that can be applied proportionately to the 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 country and determining how best to reduce risk and protect public health.

6. 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 *OIE List of Antimicrobial Agents of Veterinary Importance*; and
- National lists of important antimicrobials for humans and animals where they exist.

7. 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. 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 implementation may be used by some countries to properly apply elements in this document proportionate to the foodborne AMR risk and should not be used to generate unjustified barriers to trade.

2. Scope

9. 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 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, and references other best management practices, as appropriate.

10. 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. Most of the recommendations in this Code of Practice focus on antibacterials, however some recommendations may also be applicable to antiviral, antiparasitic, antiprotozoal, and antifungal agents, where there is scientific evidence of foodborne AMR risk to human health.

12. 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/crops¹ and recombinant DNA microorganisms²; non-genetically modified microorganisms (for example, starter cultures) intentionally added to food with a technological purpose; certain food ingredients, which could potentially carry antimicrobial resistance determinants, such as probiotics³; and biocides. 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

The relevant definitions presented in the Codex Procedural Manual, *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance*, *General Principles of Food Hygiene* (CXC 1-1969), *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CXG 30-1999) and *Guidelines on Integrated Monitoring and Surveillance of Foodborne Antimicrobial Resistance* are applicable to this document.

The following definitions are included to establish a common understanding of the terms used in this document:

Antibacterial: A substance that acts against bacteria.

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.

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.

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

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 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).

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 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 the food chain where there is relevant evidence that it could 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 the *WHO List of Critically Important Antimicrobials for Human Medicine*, including the classes described in the Annex of the “*List of Medically Important Antimicrobials, categorized as Critically Important, Highly Important, and Important*”, or equivalent criteria established in a national list, where available. It does not include ionophores or other agents determined not to be a foodborne AMR risk consistent with the *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance*.

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

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 that is cultivated or harvested as food or feed.

Plant/crop health professional: An individual with professional or technical training, knowledge and experience in plant/crop health and protection practices.

Prevention of disease/prophylaxis: Administration or application of antimicrobial agents to an individual or a group of plants/crops or 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 or applied.

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

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

4. General principles to minimize and contain foodborne antimicrobial resistance

Principles on AMR Risk Management (generally)

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

Principle 1 bis: Considering that this document is to provide risk management guidance to address foodborne AMR risks to human health, for animal health and plant health aspects, relevant OIE and IPPC standards should be considered.

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.

Principle 4: The *WHO List of Critically Important Antimicrobials for Human Medicine*, the *OIE List of Antimicrobial Agents 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 prescribed, administered, 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*.

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

Principle 7:

Medically important antimicrobials should only be administered or applied for prevention/prophylaxis where professional oversight has identified well-defined and exceptional circumstances, appropriate dose and duration, based on clinical and epidemiological knowledge, consistent with the label, and in line with national legislation. Countries could use additional risk management measures for medically important antimicrobials considered highest priority critically important as described in the *WHO List of Critically Important Antimicrobials for Human Medicine*, the *OIE List of Antimicrobial Agents of Veterinary Importance*, or national lists, where available, including restrictions proportionate to risk and supported by scientific evidence.

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 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. 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. For more information on the data requirements for authorization of antimicrobial agents for food-producing animals see relevant national guidelines or internationally harmonized guidelines.

5.1 Responsibilities of the competent authorities

15. 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. 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 and contain 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.

16bis National action plans may include recommendations to relevant professional organisations to develop species or sector-specific guidelines.

17. In order to promote responsible and prudent use of antimicrobial agents, it is important to encourage the development, availability, and use of validated, rapid, reliable diagnostic tools, where available, to support veterinarians and plant/crop health professionals in diagnosing the disease and selecting the most appropriate antimicrobial, if any, to be administered/applied.

18. The competent authorities should determine appropriate labelling, including the conditions that will minimize the development of foodborne AMR while still maintaining efficacy and safety.

Quality control of antimicrobial agents

19. 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.

Assessment of efficacy

20. Assessment of efficacy is important to assure adequate response to the administration of antimicrobial agents. As part of the marketing authorization process, the assessment should include the efficacy with optimal dosages and durations, supported by clinical trials, microbiological data (including antimicrobial susceptibility testing), pharmacokinetic (PK) data, and pharmacodynamic (PD) data.

Assessment of the potential antimicrobial agents to select for resistant microorganisms

21. The competent authorities should assess the potential of medically important antimicrobial agents used along the food chain to select for foodborne AMR taking into account the *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance*, the *WHO List of Critically Important Antimicrobials for Human Medicine*, the *OIE List of Antimicrobial Agents of Veterinary Importance*, or national lists, where available.

Assessment of the impact on the food production environment

22. In accordance with their national guidelines, competent authorities should consider results of foodborne AMR risk assessment of sources that contribute to the food production environment, e.g. reuse of waste water for irrigation, and use of manure, and other waste-based fertilizers 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 should be considered.

Establishment of a summary of characteristics for each antimicrobial product

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

- brand/chemical/drug name
- product description
- dosage forms/strengths/application rates
- contraindications; warnings
- adverse reactions/phytotoxicity/incompatibilities
- product interactions and uses in specific populations for each authorized antimicrobial product, when available
- withdrawal periods
- application intervals
- duration of treatment
- indications for use
- storage conditions

Monitoring and surveillance programs

24. Competent authorities should establish systems for the monitoring and surveillance of foodborne antimicrobial resistance and antimicrobial use (AMU) following the Codex Guidelines on Integrated Monitoring and Surveillance of Foodborne Antimicrobial Resistance and OIE standards for monitoring of antimicrobial resistance and use in animals.

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

26. 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 antimicrobial agent marketing authorization should be reviewed, competent authorities shall endeavor to achieve this re-evaluation.

Distribution of antimicrobial products

27. Competent authorities should make sure antimicrobial products are distributed through licensed/authorized distribution systems in accordance with national legislation.

28. Competent authorities should prevent illegal medicines and unapproved formulations from entering distribution systems.

Control of advertising

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

31. Advertising and promotion of antimicrobial agents should be done in a manner consistent with specific regulatory recommendations for the product.

Training on foodborne antimicrobial resistance and the responsible use of antimicrobial agents

32. Training should be supported, to the extent possible, by the competent authorities on topics related to minimizing antimicrobial resistance and encouraging the responsible use of antimicrobial agents. Training may take the form of communication and outreach and should be 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 as appropriate. Training and communication may broadly address other public health-related activities.

Relevant information may include, but is not limited to:

- 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 adhere to responsible and prudent use principles 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 for Human Medicine*; the *OIE List of Antimicrobial Agents 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 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;
- understanding the process of identifying, evaluating, implementing, and monitoring the effectiveness of risk management options; and
- the collection and reporting of AMR and AMU monitoring and surveillance data.

Knowledge gaps and research

33. To further elucidate the risk from foodborne AMR, the relevant authorities could encourage public and private research in the following areas and not limited to:

- improve the knowledge about the mechanisms of action, pharmacokinetics and pharmacodynamics of antimicrobial agents to optimize the therapeutic regimens and their efficacy;
- improve the knowledge about the mechanisms of transmission, selection, co-selection, emergence and dissemination of resistance determinants and resistant microorganisms 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 foodborne AMR;
- 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 foodborne AMR development and spread;
- assess the primary drivers leading to use of antimicrobials at the farm, sub-national, and national levels, and the effectiveness of different interventions to change behavior and reduce the need to use antimicrobial agents in food production;
- improve the knowledge on behavior change and on cost-effective interventions to reduce the need of antimicrobial agents;
- develop safe and effective alternatives to antimicrobial agents, new antimicrobial agents, rapid diagnostics, and vaccines;
- improve knowledge on the role of the environment on the persistence of antimicrobial agents, and the emergence, transfer and persistence of foodborne antimicrobial resistance determinants and resistant microorganisms.

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

35. The competent authorities should develop effective procedures for the safe collection and disposal of unused, substandard and falsified drugs, illegally marketed, or out-of-date antimicrobial agents.

5.2 Responsibilities of Manufacturers and Marketing Authorization Holders

Marketing authorization of antimicrobial agents

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

38. Only antimicrobial agents meeting the quality standards as specified in the legislation of the importing country should be exported.

39. The amount of antimicrobial agents marketed should be provided to the national competent authority when requested, and in addition, when feasible, information on estimated of types of use (e.g. treatment, control, prevention), route of administration and target species.

40. 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. It is the responsibility of manufacturers and marketing authorization holders to advertise antimicrobial agents in accordance with the provisions of paragraphs 30 and 31, and not to inappropriately advertise antimicrobial agents directly to producers.

42. Manufacturers and marketing authorization holders should not provide incentives that have a financial value to prescribers or suppliers for the purpose of increasing the use or sales of medically important antimicrobials.

Training

43. It is the responsibility of the marketing authorization holders to support training on topics related to foodborne antimicrobial resistance and the responsible use of antimicrobial agents as described in paragraph 32, as appropriate.

Research

44. It is the responsibility of the marketing authorization holders to supply required data to register antimicrobial agents including data regarding the safety and efficacy of products as appropriate.

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

5.3 Responsibilities of wholesale and retail distributors

46. 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. Distributors should keep records of medically important antimicrobials supplied according to the national regulations and may include, for example:

- date of supply
- name of responsible veterinarian or plant/crop health professional or other suitably trained and authorized person
- name of medicinal product, formulation, strength and package size
- batch number
- quantity supplied
- expiration dates
- manufacturer name and address
- target species

48. Distributors should support training, as appropriate, on topics related to foodborne 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 in paragraph 32, as appropriate.

5.4 Responsibilities of Veterinarians⁴ and Plant/Crop Health Professionals

49. Veterinarians and plant/crop health professionals should identify new or recurrent disease problems and develop strategies in conjunction with competent authority to prevent, control, or treat infectious disease at the national level. These may include, but are not limited to, biosecurity, improved production practices, proper animal nutrition and safe and effective alternatives to antimicrobial agents, including vaccination or integrated pest management practices where applicable/available.

50. Professional organizations should be encouraged to develop species or sector-specific guidelines on the responsible and prudent use of antimicrobial agents.

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

- A prescription, 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. Prescriptions or orders should also indicate the owner and the location 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 of a veterinarian or consultation with a 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. For food-producing animals, the appropriate use of medically important antimicrobial agents in therapeutic practice is a clinical decision that should be based on the experience of the prescribing veterinarian, and epidemiological and clinical knowledge and, if available, based on adequate diagnostic procedures. When a group of food-producing animals, which may have been exposed to pathogens, they may need to be treated without recourse to a laboratory confirmed diagnosis based on antimicrobial susceptibility testing to prevent the development and spread of clinical disease.

53. 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.

54. 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;

⁴ Under some circumstances, this may refer to a suitably trained person authorized in accordance with national legislation, for example an Aquatic Animal Health Professional.

- previous published scientific information on the treatment of the specific disease and available scientific knowledge on antimicrobial use and resistance;
- evidence-based therapeutic 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.
- If the label conditions allow for flexibility, the veterinarian or plant/crop health professional should consider a [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. 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 use of approved or appropriate withdrawal periods. 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.

56. 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. Medically important antimicrobials should not be used off-label for plants/crops, except off-label use for emerging disease control, in accordance with national legislation.

Record keeping and recording

58. For food-producing animals and plants/crops, records on antimicrobial agent prescription or 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; when genomic information, when available;
- record the antimicrobial used, the dosage 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. Veterinarians and plant/crop health professionals should also periodically review farm records on the use of antimicrobial agents to ensure compliance with their directions.

59 bis. Veterinarians and plant/crop health professionals may have a role to play assisting the competent authorities in monitoring and surveillance programs related to AMU and AMR as appropriate.

Training

60. Professional or other organizations should support the development and/or delivery of training on issues related to antimicrobial resistance and the responsible use of antimicrobial agents as described in paragraph 32, as appropriate.

5.5 Responsibilities of food animal and plant/crop producers

61. Producers are responsible for implementing health programs on their farms to prevent and manage disease outbreaks 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 reducing the need to use antimicrobials agents to minimize risk of foodborne AMR.

62. 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 under conditions approved by competent authorities;
- to comply with the storage conditions of antimicrobial agents according to the approved product labelling;
- to comply with the recommended withdrawal periods or pre-harvest intervals;
- 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 suspected lack of efficacy of antimicrobial applications;
- to maintain or have their veterinarian, plant/crop health professional, or other suitably trained individual 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 to which the antimicrobial agent was administered;
 - disease treated, prevented, or controlled;
 - relevant information on animals or plants/crops treated (number, age, weight);
 - quantity/dose 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 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. The responsible and prudent use of antimicrobial agents should be supported by continuous efforts in disease prevention to minimize infection during production. Efforts should aim to improve health, thereby reducing the need for antimicrobial agents. This can be achieved by, for example, improving hygiene, biosecurity, 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.

63 bis Disease prevention through the use of vaccines, and other measures that have been clinically proven to be safe and efficacious for supporting animal health, such as adequate nutrition can be considered and applied when appropriate and available.

63 ter. Prevention and reduction of the incidence and severity of plant pests and diseases should be implemented by applying good 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 integrated pest management strategies and biological controls when appropriate and available.

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

64. Concerted efforts of all stakeholders along the food chain are required to minimize and contain foodborne illness, including illness related to foodborne AMR. While this Code 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. The food processing industry and food retailers should refer to the *Principles and Guidelines for the Conduct of Microbiological Risk Management*).

66. Food should be produced and handled in such a way as to minimize the introduction, 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* is a useful reference in this respect.

67. 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 resistant infections.

7. Consumer practices and communication to consumers

68. 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 science-based, clear, accessible, and targeted to a non-scientific audience;
- Considering local characteristics that affect how risks are perceived (e.g. religious belief, traditions).

Various manuals from international organizations, such as the FAO, WHO and OIE can be used as tools to assist in awareness raising for consumers on how to minimize foodborne bacteria in their food.

69. 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*.