
Introduction

1. The 7th Session of the Ad Hoc Intergovernmental Task Force on Antimicrobial Resistance (TFAMR07, 2019) agreed to establish an electronic Working Group (EWG) chaired by the United States of America and co-chaired by China, Chile, 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 (originally 2020, now planned for 2021).

2. TFAMR07 further 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. These conclusions can be found in the report of the meeting (REP20/AMR) at paragraph 126.

3. The 43rd session of the Codex Alimentarius Commission (CAC43) (2020) adopted at Step 5 the Revision of the Codex of Practice to Minimize and Contain Foodborne Antimicrobial Resistance (CXC 61-2005). These conclusions can be found in the report of the meeting (REP20/CAC) at paragraph 113.

4. The EWG conducted two rounds of discussion on the outstanding issues in square brackets. The first round was completed in May 2020 and the second round was completed in February 2021. Both rounds of discussions included all text in square brackets.

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

6. In Round 1, the EWG received comments from a total of 22 participants--18 Codex Members, 1 Codex Member Organization, and 3 Observers. In Round 2, the EWG received comments from a total of 12 participants--10 Codex Members, 1 Codex Member Organization, and 1 Observer.

7. In summary, the EWG which initiated its work in February 2020 and concluded in March 2021, received a total of 34 sets of comments from 20 Codex Members, 1 Codex Member Organization, and 4 Observers.

8. When reviewing the comments, the EWG Co-Chairs gave consideration to comments from Codex Members (Argentina, Australia, Brazil, Canada, Chile, China, Colombia, France, Japan, Republic of Korea, Netherlands, New Zealand, Norway, Poland, Singapore, Sweden, Switzerland, Thailand, United States of America, Uruguay) and Member Organizations (European Union), followed by Observers, as appropriate in Codex. A complete list of Members and Observers is attached as Appendix II.

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

Summary of Comments by Codex Members and Observers and Main Points of Discussion in the EWG on Selected Sections (text in square brackets) of the Revision of the Recommended Code of Practice to Minimize and Contain Antimicrobial Resistance (CXC 61-2005)

3. Definitions

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

10. A majority of Members and Observers overall supported the retention of a definition of therapeutic use. The rationale for retaining the definition included: the terms therapeutic and therapy are used in several places throughout the document; the definition draws a distinction between those uses that are intended to address disease in animals and plants/crops and uses that are not intended to address disease (i.e. production uses, growth promotion, weight gain, feed efficiency); aligns with the definition of “veterinary medical use” in animals as adopted by the OIE; is consistent with national legislation in some countries; aligns with the common approach adopted by G7 Chief Veterinary Officers in 2017; supports the clinical and scientific judgement of veterinarians and plant/crop health professionals when using medically important antimicrobials; and maintains a One Health definition in line with the approach of the Code of Practice.

11. Some Members supported deletion of the definition providing a rationale which included: therapeutic use should not include prevention of disease/prophylaxis; definitions for treatment of disease, control of disease/metaphylaxis, and prevention of disease/prophylaxis have already been agreed in the document and the definition is not needed; the definition only occurs a few times in the document and could be replaced with other terms in paragraph 54; potential inconsistency with how the term “therapeutic” is used with respect to humans; and inconsistent with a phrase in FAO’s Action Plan on Antimicrobial Resistance 2016-2020.
12. The EWG Co-Chairs noted the majority of support to retain the definition. The EWG Co-Chairs further noted the desire by Codex Members and Observers to draw a clear distinction between uses of antimicrobials for disease as opposed for production purposes. Alignment with the World Organisation for Animal Health (OIE) standards and maintaining a One Health definition were also noted as important components of the rationale to retain the definition.

13. The EWG Co-Chairs noted the position of some Members that prevention of disease/prophylaxis should not be included within therapeutic use. However, this position does not align with veterinary medical use in OIE which was carefully pointed out by a Member to include treatment, control, and prevention of disease. As a compromise, the EWG Co-Chairs contemplated a Member’s alternative approach to replace the definition of therapeutic use with the OIE’s definition of veterinary medical use. The EWG Co-Chairs discussed that in doing so, one definition in the Code of Practice would now be sector-specific (i.e. animals). In favor of the approach, the EWG Co-Chairs noted that some paragraphs in the Code of Practice are sector-specific (e.g. para 52 (food-producing animals) and para 53 (plants/crops)). Against the approach, the EWG Co-Chairs noted that having a sector-specific definition could undermine the aim of the TFAMR to take a One Health Approach in the Code of Practice to the greatest extent possible and that OIE has appropriately addressed the issue for the animal sector.

14. The EWG Co-Chairs discussed the suggestions to harmonize with other relevant documents (i.e. OIE standards, FAO’s Action Plan on Antimicrobial Resistance 2016-2020, G7 Chief Veterinary Officers common approach). The EWG Co-Chairs felt strongly that harmonization with OIE standards, where appropriate, was essential to advancing coherence among internationally recognized texts on AMR and reinforcing the role of Codex Alimentarius with respect to global efforts to minimize and contain AMR. The EWG Co-Chairs noted that the FAO’s Action Plan on Antimicrobial Resistance 2016-2020 was not a Member State consensus document, with the FAO noting that it was “was developed by a multidisciplinary FAO team” in response to FAO Members Resolution 4/2015 at the Thirty-ninth Session of the FAO Conference. The EWG Co-Chairs observed the resolution does not mention “therapeutic use” and further the phrase from the Action Plan appears to be related to “extensive and smallholder livestock production systems” and perhaps should not be construed as a policy position by the Members of FAO. With respect to the G7 Veterinary Officers common approach, the EWG Co-Chairs noted the alignment between the definition in the common approach and the definition in the Code of Practice. Nevertheless, the EWG Co-Chairs noted the G7 may only reflect the views of its members—Canada, France, Germany, Italy, Japan, the United Kingdom, the United States, and the European Union.

15. The EWG Co-Chairs reflected on the frequency with which the terms “therapeutic use” or “therapy” are used in the Code of Practice as a consideration for the need to retain or delete the definition. Several Members noted that in addition to the definition, Principle 6, and Paragraph 54, these terms are used in other places (i.e., paragraphs 33, 52 and 55). Suggestions to modify these terms were made by some Members (see below under discussion of Paragraph 54).

16. Reflecting on the comment of a Member suggesting the definition of “therapeutic use” for the purpose of this document (i.e., animals, plants/crops) would not be an appropriate context for its use in the definition of medically important antimicrobials, the EWG Co-Chairs discussed differences in commonly used terminology between human medicine and the animal sector. The concept of administering antimicrobials to control the spread of disease within a population is common to both. While the term metaphylaxis is used more commonly in veterinary medicine, a similar therapeutic approach would likely be described as prevention/prophylaxis in human medicine. A useful example in human medicine would be where a child/children in a classroom are diagnosed with meningococcal meningitis necessitating urgent treatment of all other in-contact children.

17. Based on comments from Codex Members and Observers and further discussion and reflection, the EWG Co-Chairs concluded there is a need for a definition of “therapeutic use” in the Code of Practice. Further, the EWG Co-Chairs suggest a further refinement to the current definition could be useful to clarify its use within the context of the document. The EWG Co-Chairs propose inserting “food-producing animals or plants/crops” so that the definition would read as follows:

[Therapeutic use (food-producing animals or plants/crops): Administration or application of antimicrobial agents for the treatment, control/metaphylaxis or prevention/prophylaxis of disease.]

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4. General principles to minimize and contain foodborne antimicrobial resistance

**Principles on the use of antimicrobials in specific circumstances**

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

18. A majority of Members and commenters overall supported the retention of Principle 6, as written, limiting the use of medically important antimicrobials to therapeutic purposes only. The rationale for retaining the Principle included: the need to draw a clear distinction between uses of medically important antimicrobials to address disease as opposed to production purposes (i.e. growth promotion, weight gain, feed efficiency); alignment with OIE; Principle 6 is complimented by Principles 7 and 7bis; Principle 6 compliments Principle 5 and provides clarity on when medically important antimicrobials may be used; and limiting the use of medically important antimicrobials to address disease, together with other guidance in the document, promotes global antimicrobial stewardship efforts.

19. Some Members supported deletion of Principle 6 or significant modification with a rationale that included: the principle includes prevention/prophylaxis; the principle is unnecessary as sufficient guidance is provided elsewhere; the principle could be modified to limit the use of medically important antimicrobials to only individual animals when no other antimicrobial is available and only for prophylaxis and metaphylaxis under the conditions of Principles 7 and 7bis, respectively; an additional Principle 6bis could be added to encourage the adoption of additional risk management measures to further promote the prudent use of antimicrobial agents, in particular medically important antimicrobial agents, including restrictions proportionate to risk and supported by scientific evidence.

20. The EWG Co-Chairs noted the majority of support to retain Principle 6. Providing additional guidance, clarity, and limitations on the use of medically important antimicrobials were frequently cited by Members and Observers. The EWG Co-Chairs noted the alignment of Principle 6 with OIE standards.

21. The EWG Co-Chairs noted the interconnection of the comments between the definition of “therapeutic use” and Principle 6 reflecting similar rationales.

22. With respect to a suggestion to exclude prevention of disease/prophylaxis, the EWG Co-Chairs reflected on the same points as above: does not align with veterinary medical use in OIE; FAO’s Action Plan on Antimicrobial Resistance 2016-2020 was not a Member State consensus document and the referenced phrase should not be construed as a policy position by the Members of FAO; G7 Chief Veterinary Officers common approach may only reflect the views of its members-- Canada, France, Germany, Italy, Japan, the United Kingdom, the United States, and the European Union.

23. The EWG Co-Chairs carefully considered the suggestion to modify Principle 6 to include additional limitations and restrictions on the use of medically important antimicrobials for therapeutic purposes and the suggestion to develop an additional Principle 6bis to encourage countries to adopt additional risk management measures and restrictions.

24. The EWG Co-Chairs considered the suggestion to limit the use of medically important antimicrobials to individual animals could result in divergence of Codex texts with OIE standards. The EWG Co-Chairs reflected that the provisions of Principle 7 and 7bis can stand independently and, as above, noted the suggestion would result in a sector-specific, rather than a One Health Approach. While animal health is within the remit of OIE rather than Codex, the potential impact on animal health was raised, but was not given consideration for the purpose of the EWG.

25. The EWG Co-Chairs discussed the proposal for a new Principle 6bis, during which is was noted that the potential for countries to use “additional risk management measures” with respect to prevention of disease/prophylaxis is already described in Principle 7. As drafted, the EWG Co-Chairs observed the proposed Principle 6bis could have overarching consequences with respect to guidance on other uses of medically important antimicrobials in the Code of Practice that would be better discussed in the context of the TFAMR.

26. Therefore, after discussion and further reflection, the EWG Co-Chairs recommend retaining Principle 6, as written, taking note of the suggested refinement to the definition of “therapeutic use” above.
5. Responsible and prudent use of antimicrobial agents

5.4 Responsibilities of Veterinarians and Plant/Crop Health Professionals

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

(first two bullets are omitted here)

- 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.

27. A majority of Members and commenters overall supported the retention of the term “therapeutic” in this paragraph. The rationale for retaining the term included: reinforces the overall approach to limiting the use of medically important antimicrobials to address disease; the term “therapeutic” is widely used in the animal sector and retaining its use here and throughout the document provides helpful guidance to veterinarians and plant/crop health professionals; consistent with use of terminology in paragraphs 33, 52 and 55 in addition to Principle 6; reinforces the approach with respect to off-label use described in para 55.

28. While the majority of Members and Observers indicated concurrence with or no objections to the term “therapeutic” in para 54, there were a number of suggestions for replacement terms including: “dosing”, “administration/application”, “treatment”, “dosage” or simply deleting the term. In addition, a Member and an Observer provided further suggestions to improve the wording in para 54.

29. The EWG Co-Chairs reflected on the Terms of Reference for the EWG COP and observed the mandate to be limited to the text in square brackets. Replacement terms were considered, including simply deleting the term. Because the majority of Members indicated concurrence or no objections, because the term is used and adopted elsewhere in the document, and taking note of their recommendation to retain the definition, the EWG Co-Chairs recommend retaining the term in paragraph 54.

Conclusions and recommendations

30. The EWG Co-Chairs appreciate the participation of and thoughtful comments by Codex Members and Observers in the two rounds of discussion in the EWG.

31. The EWG Co-Chairs recommend making a refinement of the definition of “therapeutic use” as described on paragraph 17 of this report with the aim to have greater clarity on the guidance provided in Principle 6 and in places where this term is used throughout the Code of Practice.

32. With respect to Principle 6 and paragraph 54, the EWG Co-Chairs recommend retaining these as written for the reasons discussed above.

33. Reflecting on the conclusion of what we believe may be the final EWG for the Code of Practice, we are gratified that all the hard work, negotiation and compromise on the text of the document has resulted in a host of significant advancements in the area of risk management to minimize and contain antimicrobial resistance in Codex Alimentarius. We sincerely thank everyone once more for your dedication and devotion to this work to advance public health.

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

(Selected Sections Containing Text in Square Brackets)

3. Definitions

Therapeutic use (food-producing animals or plants/crops): Administration or application of antimicrobial agents for the treatment, control/metaphylaxis or prevention/prophylaxis of disease.

4. General principles to minimize and contain foodborne antimicrobial resistance

Principles on the use of antimicrobials in specific circumstances

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

5. Responsible and prudent use of antimicrobial agents

5.4 Responsibilities of Veterinarians and Plant/Crop Health Professionals

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

• The expected efficacy of the administration based on:
  o the expertise and experience of the veterinarian, plant/crop health professional or suitably trained and authorized person;
  o the spectrum of the antimicrobial activity towards the pathogens involved;
  o 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;
  o the appropriate route of administration;
  o results of initial administration;
  o previous published scientific information on the treatment of the specific disease and available scientific knowledge on antimicrobial use and resistance;
  o evidence-based therapeutic guidelines, such as species or sector-specific guidelines on the responsible and prudent use of antimicrobial agents, if available;
  o the likely course of the disease.

• The need to minimize the adverse health effect from the development of antimicrobial resistance based on:
  o the choice of the activity spectrum of the antimicrobial agent. Narrow-spectrum antimicrobials should be selected whenever possible/appropriate;
  o the targeting of specific microorganism;
  o known or predictable susceptibilities using antimicrobial susceptibility testing whenever possible;
  o optimized dosing regimens;
  o the route of administration;
  o 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
  o 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.

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

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Please contact the focal point of the Member Country or Observer Organization for the details of the delegates. The list of Codex contact points for members and observers are available from the Codex website at: