

CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture
Organization of the
United Nations



World Health
Organization

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REP18/AMR

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

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

Jeju, Republic of Korea

27 November – 1 December 2017

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SUMMARY AND STATUS OF WORK

Responsible Party	Purpose	Text/Topic	Code	Step	Para(s)
EWG (United States of America, Chile, China, Kenya, United Kingdom) TFAMR6	Redrafting	Proposed draft Revision of <i>the Code of Practice to Minimise and Contain Antimicrobial Resistance</i> (CXC 61-2005)	N28-2917	2/3	27-28 and App. II
EWG (the Netherlands, Chile, China, New Zealand) TFAMR6	Redrafting	Proposed draft Guidelines on Integrated surveillance of antimicrobial resistance	N29-2017	2/3	60-61
FAO and WHO	information	Request for scientific advice from FAO and WHO in collaboration with OIE			

LIST OF ABBREVIATIONS

AG	Agriculture and Consumer Protection Department (FAO)
AM	Antimicrobial
AMR	Antimicrobial Resistance
AMU	Antimicrobial use
CAC	Codex Alimentarius Commission
COP	Code of Practice
CRD	Conference Room Document
CXC	Codex Code of Practice
CXG	Codex Guideline
EU	European Union
EWG	Electronic Working Group
FAO	Food and Agriculture Organization of the United Nations
FOS	Department of Food Safety and Zoonoses (WHO)
OECD	Organisation for Economic Co-Operation and Development
OIE	World Organization for Animal Health
TFAMR	Ad hoc Intergovernmental Task Force on Antimicrobial Resistance
TOR	Terms of Reference
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
WHO	World Health Organization

INTRODUCTION

1. The *ad hoc* Intergovernmental Task Force on Antimicrobial Resistance (TFAMR) held its Fifth Session in Jeju, Republic of Korea, from 27 November to 1 December 2017, at the kind invitation of the Government of the Republic of Korea. Prof Yong Ho Park, Seoul National University, chaired the Session. The Session was attended by participants from 44 member countries, one member organization, 11 observer organizations, and FAO and WHO. The list of participants, including the Secretariats, is contained in Appendix I to this report.

OPENING OF THE SESSION¹

2. Mr Ryu Young-jin, Minister of Food and Drug Safety of the Republic of Korea, opened the Session. Prof Purwiyarno Hariyadi, Vice-Chairperson of the Codex Alimentarius Commission, Mr Tom Heilandt, Codex Secretary, Dr Awa Aidara Kane, Department of Food Safety and Zoonoses (FOS) of WHO, and Dr Sarah Cahill, Agriculture and Consumer Protection Department (AG) of FAO, also addressed the Task Force.

Division of Competence²

3. The Task Force 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 AGENDA (Agenda item 1)³

4. The Task Force adopted the Agenda.

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

5. The Task Force noted matters referred.

MATTERS ARISING FROM THE WORK OF FAO, WHO AND OTHER INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS (Agenda Item 3)

Progress report on the request for scientific advice on foodborne AMR from FAO and WHO in collaboration with OIE (Agenda item 3(a))⁵

6. The Representative of FAO, on behalf of FAO, WHO and OIE, provided an update of the request for scientific advice on antimicrobial resistance (AMR).

Information on the work of FAO, WHO and OIE and other relevant international organisations on antimicrobial resistance (Agenda item 3(b))⁶

7. The Representatives of FAO, WHO and OIE informed the Task Force of relevant activities on AMR. The Task Force also noted the information provided by OECD.

Conclusion

8. The Task Force thanked FAO, WHO, OIE and congratulated them for the excellent collaboration.

PROPOSED DRAFT REVISION OF THE CODE OF PRACTICE TO MINIMIZE AND CONTAIN ANTIMICROBIAL RESISTANCE (CXC 61-2005) (Agenda item 4)⁷

9. The United States of America, as EWG Chair, explained the key elements considered by the EWG and noted that that the revision of CXC 61-2005 and the development of the new guidelines on integrated surveillance (see Agenda item 5) were closely linked to each other and to the *Guidelines for risk analysis of foodborne antimicrobial resistance* (CXG 77-2011) and that it was important to ensure coherence and consistency among the three documents.

¹ CRD7 (Speeches of opening session)

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

³ CX/AMR 17/5/1 Rev.1

⁴ CX/AMR 17/5/2

⁵ CX/AMR 17/5/3

⁶ CX/AMR 17/15/4 (Information of FAO and WHO); CX/AMR 17/15/4-Add.1 (Information of OIE and OECD)

⁷ CX/AMR 17/5/5; CX/17/5/5-Add.1 (Australia, Brazil, Canada, Colombia, China, Costa Rica, Ecuador, Egypt, Indonesia, Japan, Kenya, Russian Federation, Singapore, Thailand, United States of America, CI, FAO, FEFAC, Health for Animal, ICGMA, IACFO, IFIF, IMS, IPC and OIE); CRD2 (New Zealand); CRD3 (European Union); CRD4 (India); CRD5 (proposal for the revision of Introduction and scope sections, prepared by EWG Chair); CRD6 (report of the in-session Working Group on Agenda item 4)

10. The EWG Chair recommended to:
 - a. Consider the sections introduction and scope to identify any missing concepts;
 - b. Defer discussion of definitions and general principles until TFAMR6;
 - c. Consider the remaining parts of the document with the aim of identifying gaps, the need for scientific advice and agreeing/ or not on the proposed sections for deletion; and
 - d. Establish an EWG to continue work on the document.

Discussion

Introduction and scope

11. Delegations noted the importance of the introduction to highlight key concepts.
 - a. Introduction: Highlight the importance of the foodborne AMR risk; include the concepts of risk-based approach and prevention (not only minimisation); address the knowledge gaps; and, make reference to the elements covered by the scope;
 - b. Scope: Better reflect the broadened scope of the COP to include risk-based guidance on the management of foodborne AMR addressing the entire food chain, in line with the mandate of Codex; and
 - c. Both: Eliminate redundancy and repetition between the sections; the general framework should be in the introduction, the specific aspects covered by the COP should be in the scope.
12. A number of delegations highlighted the importance of including crops, environment, animal health and feed, in line with the mandate of Codex.
13. The importance to address the proportionality of risk management measures was also highlighted.
14. Further proposals for consideration
 - a. Clarify the meaning of “food chain” and “One Health approach” in the context of the COP;
 - b. Use consistent terminology within the text (e.g. agents / drugs) and with CXG 77 (e.g. adverse impact on public health); use new or different terminology only if it added value (i.e. food chain AMR integration) and consider existing definitions in Codex, FAO, WHO, OIE and IPPC, as appropriate;
 - c. Introduction: List key actors, the relationship to other texts, and where appropriate, add additional references, e.g. FAO Code of conduct for pesticide use;
 - d. Include environment as one aspect that impacts food, based on scientific evidence; and
 - e. Address the importance of science-based approach.

Conclusion

15. The Task Force agreed that:
 - a. CX/AMR 17/5/5 should be the basis for the further development of the COP;
 - b. The introduction should be concise and provide relevant concepts: the recognition that AMR is a globally important complex issue; the importance to minimize and contain AMR along the entire food chain; the application of the One Health approach; the relationship between the COP and the other two Codex texts on AMR; the importance of the shared responsibility of different actors; and cross-reference to OIE standards when relevant;
 - c. Redundancy and duplication should be eliminated and terminology used consistently; new or different terminology should be used only if it adds value;
 - d. Texts that should be read in conjunction with (implying the document cannot be stand-alone, but was dependent on the referred documents) the COP and to a lesser extent those that provide additional guidance should be listed; and
 - e. The scope should be based on the elements included in the project document⁸ and indicate what is covered by the COP, what it intends to accomplish and what lies outside its scope.

⁸ CX/CAC 17/40/12-Add.2, Appendix 1

16. The Task Force also agreed that further discussion was needed on important aspects such as environment, marketing authorization as a key tool to control and minimize the development of foodborne AMR; incremental/stepwise approach to the implementation of the COP; and the practicality and feasibility to implement the risk management measures.

Other sections

17. The Task Force agreed to collect additional comments on the remaining sections in order to inform the further development of the document.

Discussion

18. The Task Force agreed to the proposal of the EWG Chair to consider the sections on definitions and general principles at a later stage when the content of the document is further developed.

19. One delegation suggested to restructure the remaining sections to better reflect provisions along the food chain. This way the COP would not be limited to the use of AM agents but provide guidance on relevant risk management measures along the food chain to minimize the development and spread of foodborne AMR. In particular, it was suggested to add the following three sections after the general principles: (i) Practices on the responsible use of AM agents; (ii) Practices during production, processing, storage, transport, retail and distribution of food; and (iii) Consumer practices. This delegation explained that the work on the new proposed sections should maintain the relevant risk management measures of the current COP and should further develop other risk-based measures supported by scientific evidence to address the entire food chain also addressing identified gaps.

Responsibilities of the regulatory authorities

20. It was suggested to: include measures regarding the food processing and handling environment that impact food; add references to relevant OIE and VICH guidelines; retain or summarise the strike-out text in order to have an easier to use stand-alone document pending the result of the FAO/WHO scientific advice; better address responsibilities for crops pending the results of the FAO/WHO scientific advice; reconsider the section on advertising; clarify the meaning of medically important antimicrobials; consider using pharmaceutical industry throughout the document to cover both pharmaceutical manufacturers and marketing authorization holders; address appropriate control and use of AM agents at all points along the food chain, including antimicrobials used as pesticides and as food additives, and biocides and disinfectants pending the result of the FAO/WHO scientific advice; and, add measures to control and prevent the sale of counterfeit medicines.
21. The need to address measures regarding plants, crops, the environment and biocides and disinfectants pending the FAO/WHO scientific advice was also highlighted.

Responsibility of the pharmaceutical Industry

22. It was suggested to add obligations regarding advertising.

Responsibilities of the veterinarians and plant health professionals

23. It was suggested to: clarify the circumstances where off label use is acceptable; consider other professionals involved in the use of AM agents; and address the use of biocides and alternatives to AM agents.

Responsibilities of consumers

24. It was suggested to revise the entire section to clarify the responsibility of the competent authority to develop awareness programmes and educate consumers on the risk of transmitting AMR and the measures to mitigate such risks, e.g. the WHO Five Keys to Safer Food.

Advocacy and communication

25. It was suggested: to reconsider the need to retain the section as risk communication was already covered in CXG 77; clarify the meaning of “advocacy” and consider whether it should be retained or replaced by a more appropriate term; and, consider the responsibilities of other operators along the food chain to educate relevant stakeholders.

Next steps

26. The Task Force agreed to establish an in-session Working Group, chaired by the United States of America, to: (i) prepare detailed TORs of the EWG charged to further develop the revision of CXC 61; and (ii) provide more context to the request for scientific advice in support to the work of the TFAMR, prepared by the PWG, which met in London (United Kingdom) in December 2016⁹ for consideration under Agenda item 6.

⁹ CX/CAC 17/40/12-Add.2, Appendix 3

Conclusion

27. The Task Force agreed to:
- a. Establish an EWG, chaired by the United States of America and co-chaired by China, Chile, Kenya, United Kingdom, and, working in English and Spanish to further develop the revision of CXC 61 for circulation for comments and consideration at TFAMR6; and
 - b. The proposed TORs prepared by the in-session Working Group (CRD6) with some minor amendments to highlight that the EWG will consider all written comments submitted at the present session and that the revised COP will be in line with CXG 77 (see Appendix II).
28. The Task Force noted that the report of the EWG should be made available to the Codex Secretariat at least three months in advance of TFAMR6.

PROPOSED DRAFT GUIDELINES ON INTEGRATED SURVEILLANCE OF ANTIMICROBIAL RESISTANCE (Agenda item 5)¹⁰

29. The Netherlands, as EWG Chair explained the key elements considered by the EWG and the conclusions and recommendations. The EWG Chair proposed the following approach to facilitate the further development of the guidelines:
- a. Consideration of Recommendations 1 and 2;
 - b. General comments on the sections (and by doing so to address other recommendations); and
 - c. Additional comments in addition to written comments submitted to this session.

Discussion

Recommendation 1 – inclusion of “monitoring” in the title

30. Delegations were generally in favour of the inclusion of “monitoring” in the title to better reflect all the activities included in the scope. They noted that: “monitoring” was the first step of integrated surveillance programmes; “monitoring” provided data for more targeted surveillance activities; and the use of these terms should be consistent with relevant Codex, OIE and WHO texts.
31. The Codex Secretariat noted that CXG 77 contained Section 8.6 “Monitoring and Review of Foodborne AMR Risk Management Measures” and Section 9 “Surveillance of Use of Antimicrobial Agents and AMR Microorganisms and Determinants” and that in order to avoid confusion it might be advisable not to include “monitoring” in the title but describe it in the document. This would also be consistent with the approach taken in the WHO AGISAR Guidance on integrated surveillance of AMR in foodborne bacteria.
32. The Task Force agreed that a description of “monitoring” and “surveillance” in the document would assist to have a clear understanding of the two concepts in the context of the guidelines and so avoid confusion in the application of both terms.

Recommendation 2 – scope of integration

33. The Task Force considered that an integrated approach to monitoring and surveillance could include: coordinated sampling, testing and reporting of AMR and AMU along the food chain; the alignment of procedures and methodologies; and the integrated analysis of all these data and other information on AMR and AMU as to inform effective risk management across all sectors.

General considerations

Structure of the guidelines

34. The Task Force agreed that the structure of the three AMR texts should be consistent to the extent possible and that information provided on the purposes and use of the guidelines (sections 2 and 3) could be either removed, revised and/or reorganized within other sections as appropriate.

Prioritization of areas for the development of integrated surveillance of AMR

35. It was noted that while it was important to consider the various sources of foodborne AMR within the risk analysis process, it was not appropriate to attempt to address all risks from all sources but to prioritize sample collection. For areas where there is limited data, e.g. crops and environment, the Task Force should consider the results of the scientific advice from FAO and WHO.

¹⁰ CX/AMR 17/5/5; CX/AMR 17/5/5-Add.1 (Albania, Australia, Brazil, Canada, China, Colombia, Cuba, Indonesia, Kenya, Russian Federation, Thailand, United States of America, IACFO, Health for Animal, IMS, CI, FAO, ICGMA and OIE); CRD3 (European Union)

36. The Task Force noted that while the scope of the guidelines covers the design and implementation of an integrated surveillance programme for AMR and AMU along the food chain, the implementation of the guidelines follows a step-wise approach that allows for their incremental and flexible application according to the capacity and priorities of countries. Therefore, the guidelines did not envisage the immediate uptake of all areas covered in the scope.

Complementarities between Codex guiding texts on AMR

37. The Task Force reiterated that close articulation should be attained between the three Codex texts on AMR in order to avoid overlap, ensure coherence and provide added value.

General comments on the sections

38. The EWG Chair provided a summary of the written comments submitted, invited additional comments and noted that specific comments would be dealt in the further development of the guidelines. The EWG Chair further noted that sections 11 through 15 should be further developed.

Section 1 “Introduction” and Section 4 “Scope”

39. The Task Force noted that the similar consideration made regarding the approach and coverage of the introduction and scope sections of the COP (see Agenda item 4) would apply.
40. It was noted that: the scope should be broadened to include other actors / sectors in the food chain besides those recognized in the project document¹¹ e.g. environment, in order to provide an integrated analysis and reporting of data; the term “environment” was too broad and should be better defined for the purposes of the guidelines; data gaps on the potential contribution of environmental sources to foodborne AMR was a limitation for their inclusion in integrated surveillance programmes; preliminary risk management activities can be taken after developing a risk profile and without a risk assessment in accordance with relevant parts of CXG 77; and alignment of procedures and methodologies were an important element to ensure harmonized approach the collection and consideration of data
41. Delegations in favour of the exclusion of biocides and disinfectants emphasized the need for coherence with Codex texts as well as other texts developed by international organizations, for example OIE excludes these substances from their definition of antimicrobials.
42. These delegations reiterated their concerns about the inclusion of plant health-related substances and crops without further scientific data / advice. They re-emphasised the need to prioritize the scope of the surveillance depending on their capacity and priorities, and the availability of data to inform integrated surveillance programmes and to keep consistency between the three Codex texts on AMR.
43. Delegations in favour of the inclusion of biocides and disinfectants noted that some of them might lead to foodborne AMR thus they could stay as a low-priority within the step-wise approach of implementing surveillance. However, they did recognise that data gaps should be addressed..
44. These delegations recalled that the scope of the guidelines, as approved by CAC40, already covered the use of data from humans, animals, crops and food and that the step-wise approach allowed for incremental application depending on the capacity and priority of countries.

Section 5 “Definitions” and Section 6 “Principles”

45. It was noted that in addition to the WHO CIA list and the OIE list, where national lists exist they could be used
46. The Representative of WHO noted that the WHO CIA list represented a global list providing a ranking of AM agents according to their importance in human health, which could be used, especially by countries with limited resources, for risk prioritisation of non-human use of antimicrobial agents.
47. The Task Force agreed to consider sections on definitions and general principles at a later stage when the content of the document is further developed.

Section 7 “Risk-based approach”

48. The Task Force noted comments on the need to ensure consistency with definitions in CXG 77.

Section 8 “Regulatory frameworks (regulatory and non-regulatory frameworks)”

49. The Task Force agreed to revise the section to clearly indicate how activities carried out by non-regulatory actors could be considered by competent authorities in their integrated surveillance programmes.

¹¹ CX/CAC 17/40/12-Annex 2, Appendix 2

Section 9 “Step-wise approach to integrated monitoring and surveillance program of AMR”

50. The Task Force noted general support for a step-wise and flexible approach to the implementation of integrated surveillance programmes.
51. Several delegations expressed concerns that the way the steps were described was too prescriptive and did not provide sufficient flexibility for implementation of integrated surveillance programmes in line with the capacity and priorities of countries. The proposed approach suggested a hierarchical process with the potential for misinterpretation and labelling the status of implementation of national integrated surveillance programmes in certain “categories” (=“steps”) with potential trade implications. In addition, the lack of clarity on transitioning from one step to another was noted.
52. The Task Force agreed that a different presentation could better reflect the incremental and flexible nature of the approach.
53. The Task Force noted that the recommendation on having examples to facilitate understanding and implementation of the guidelines (in particular the step-wise approach) could be useful but such examples should not remain in the guidelines.
54. The Codex Secretariat indicated that examples were usually not part of Codex documents as they might be misinterpreted as provisions rather than an illustration of the provision. Examples developed by Codex committees in support of Codex texts could be transferred to information documents (having no status in Codex) or included in FAO and WHO manuals.

Section 10 “Design of monitoring and surveillance programs”

55. The following comments were noted: the design of integrated surveillance programmes should be driven by the risk to human health taking into consideration the resources available and technical capability of competent authorities; the section could be simplified and could better integrate relevant WHO and OIE texts; some provisions were unrealistic and should be adjusted to become more practical; some terms should be better framed / defined, e.g. public health / veterinary / pharmaceutical infrastructures; it would be useful to have recommendations for sampling, e.g. sizes and location; laboratory accreditation should not be compulsory when establishing national integrated surveillance programmes but should fulfil the proficiency testing.

Section 11 “Surveillance of national antimicrobial sales data for use in animals”

56. It was noted that the section should be broadened to include other sources of AMU data beyond sales data because sales data do not necessarily reflect use. It was also suggested to broaden the section to data for use in plants.

Section 12 “Implementation of the monitoring and surveillance programs”

57. It was noted that management of data did not require a single database but rather compatible systems that would allow integration of data.

Section 13 “Review”

58. It was noted that: pharmacovigilance programmes are a risk management activity and should be considered in the COP; and a section on evaluation of integrated surveillance programmes should be developed.

Section 14 “Risk communication”

59. Some delegations thought that “optimization of use” rather than “reduction of use” would better address prudent use of AM agents.

Conclusion

60. The Task Force agreed to establish a EWG, chaired by the Netherlands and co-chaired by Chile, China and New Zealand, working in English and Spanish and open to all Members and Observers to further develop the guidelines based on the written comments submitted to this session and the general guidance and comments provided above for circulation for comments and consideration at TFAMR6.
61. The Task Force noted that the report of the EWG would be made available to the Codex Secretariat at least three months before TFAMR6.

OTHER BUSINESS (Agenda item 6)**Request for scientific advice from FAO and WHO in collaboration with OIE¹²**

62. The Task Force confirmed the ongoing relevance of the request for scientific advice approved by CAC40¹³. It highlighted that the immediate priorities for scientific advice to inform the work of the Task Force were in the areas of crops, environment and biocides for both the revision of the COP (Agenda item 4) and the guidelines for integrated surveillance (Agenda item 5).
63. With reference to the outcome of the in-session Working Group discussions on providing more context to the request for scientific advice (CRD6), the Task Force agreed that this information would be made available to FAO and WHO to inform the scope and objectives of the Expert Consultation on foodborne antimicrobial resistance.
64. The Task Force further noted that scientific advice provided by FAO and WHO, in collaboration with OIE, would be limited by the available data. To support the work of the Expert Consultation, delegations were encouraged to respond to the call for data issued by FAO and WHO¹⁴.

DATE AND PLACE OF THE NEXT SESSION (Agenda item 7)

65. The Task Force was informed that the next Session was tentatively scheduled to be held from 3 to 7 December 2018, the final arrangements being subject to confirmation by the Secretariats.

¹² CRD6 (report of the in-session Working Group on Agenda item 4)

¹³ CX/CAC 17/40/12-Add.2, Appendix 3

¹⁴ Call for data is available at:
http://www.fao.org/fileadmin/user_upload/agns/pdf/Call_for_data_experts/DATA_Foodborne_AMR.pdf
http://www.who.int/foodsafety/Call_for_data_oct2017.pdf?ua=1
Call for experts is available at:
http://www.fao.org/fileadmin/user_upload/agns/pdf/Call_for_data_experts/EXPERTS_Foodborne_AMR.pdf and
http://www.who.int/foodsafety/Call_for_experts_oct2017.pdf?ua=1

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