

CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture
Organization of the
United Nations



World Health
Organization

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REP19/AMR

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

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

Busan, Republic of Korea

10 – 14 December 2018

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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) TFAMR07	Redrafting	Proposed draft Revision of <i>the Code of practice to minimize and contain antimicrobial resistance</i> (CXC 61-2005)	N28-2917	2/3	82
EWG (the Netherlands, Chile, China, New Zealand) TFAMR07	Redrafting	Proposed draft Guidelines on integrated surveillance of antimicrobial resistance	N29-2017	2/3	115

LIST OF ABBREVIATIONS

AG	Agriculture and Consumer Protection Department (FAO)
AM	Antimicrobial
AMR	Antimicrobial Resistance
AMU	Antimicrobial Use
AU	African Union
ATLASS	FAO Assessment Tool for Laboratories and Antimicrobial Resistance Surveillance Systems
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)
GAPs	Good Agricultural Practice(s)
IPM	Integrated Pest Management
OECD	Organization for Economic Co-Operation and Development
OIE	World Organization for Animal Health
PMP	Progressive Management Pathway
TFAMR	Ad hoc Intergovernmental Task Force on Antimicrobial Resistance
TOR	Terms of Reference
VICH	International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products
UK	United Kingdom
USA	United States of America
WHA	World Health Assesmbly
WHO	World Health Organization
WHO-AGISAR	WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance
WHO CIA List	WHO List of Critically Important Antimicrobials for Human Medicine

INTRODUCTION

1. The ad hoc Intergovernmental Task Force on Antimicrobial Resistance (TFAMR) held its Sixth Session in Busan, Republic of Korea, from 10 to 14 December 2018, 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 45 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. Dr. Jeffrey Lejeune, Food Safety and Quality Officer of FAO, Dr. Awa Aidara-Kane, Coordinator of the Foodborne and Zoonotic Diseases Unit at the WHO and Mr. Steve Wearne, the Vice Chairperson of Codex Alimentarius Commission also addressed the meeting.

Division of Competence²

3. TFAMR 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. TFAMR 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. TFAMR noted the matters for information.

MATTERS ARISING FROM THE WORK OF FAO, WHO AND OIE INCLUDING THE REPORT OF THE JOINT FAO/WHO EXPERT MEETING (IN COLLABORATION WITH OIE) ON FOODBORNE ANTIMICROBIAL RESISTANCE (Agenda Item 3)⁵

6. The Representatives of FAO, WHO and OIE highlighted key activities since TFAMR05 as follows:

Part I: Scientific advice to Codex

7. The Representative of FAO recalled that the final report of the *Joint FAO/WHO Expert Meeting in collaboration with OIE on Foodborne Antimicrobial Resistance: Role of Crops, Environment, and Biocides* had been shared with all Codex Members and Observers, prior to the session and highlighted key points from the report, in particular the following:

- Widespread reports of contamination of foods of plant origin with antimicrobial-resistant bacteria together with numerous documented outbreaks of antimicrobial-resistant foodborne infections traced to foods of plant origin clearly indicate the potential for these products to transmit antimicrobial resistant organisms to humans.
- Crops can be contaminated with antimicrobial resistant organisms from multiple sources: water, soil, wildlife, humans, and equipment.
- The use of Good Agricultural Practices (GAPs) to reduce microbial contamination and integrated pest management (IPM) practices to reduce the need for antimicrobials are expected to reduce the contamination of foods of plant-origin with antimicrobial resistant organisms.
- The food production environment (direct food contact e.g. soils, water, etc.) serves as both a sink and a source for antimicrobial resistant organisms with respect to agriculture and food production.
- Steps should be taken to reduce the likelihood of antimicrobial agents and antimicrobial-resistant bacteria entering the environment from agricultural practices and agricultural food production should be protected from environmental sources of contamination.

1 CRD11-14 (Speeches of opening session)

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

3 CX/AMR 18/6/1 Rev.1

4 CX/AMR 18/6/2

5 CX/AMR 18/6/3; CRD17 (African Union)

- There is strong theoretical and laboratory evidence to indicate that biocides (used for premise and equipment disinfection and sanitation) select for increased resistance to antimicrobials through cross-resistance or co-resistance, but empirical evidence to document the extent to which this occurs in food production or processing environments is limited. The expert meeting recommended good practices in the use of these products in line with manufacturers' instructions.
- Regarding integrated surveillance, the expert meeting recommended: 1) inclusion of plant-based and aquatic animal-origin foods; 2) that testing of environmental components in direct contact with foods (water, soil, wastes) could complement food-centric approaches; and 3) the scope of sampling be expanded progressively, starting with country-level priorities, noting the existence of tools that may support the implementation of a progressive approach e.g. the *FAO Assessment Tool for Laboratories and Antimicrobial Resistance Surveillance Systems (ATLASS)*.

Part II: FAO/WHO/OIE Tripartite activities on foodborne AMR

8. The Representative of WHO drew the attention of TFAMR to the key Tripartite activities outlined in CX/AMR 18/6/3 and in addition informed TFAMR on the agreement of the Tripartite to have a single technical advisory body working on AMR from a One Health perspective and the establishment of a Tripartite Plus Advisory Group on Inter-Sectoral Support on AMR (T plus-AGISAR).

Part III: Other related matters arising from FAO, WHO and OIE

9. In addition to their collaborative activities, the Representatives of FAO, WHO and OIE highlighted key or additional AMR related activities of their organizations over the past year.

FAO

10. Further to the information provided in CX/AMR 18/6/3, the Representative of FAO noted the recent development and forthcoming pilot testing of the Progressive Management Pathway (PMP) tool to support countries in their AMR management activities. He also reiterated the appreciation of FAO to donor countries namely France, the Russian Federation, Sweden, the United Kingdom (UK) and the United States of America (USA) and experts who enabled the extensive work that FAO was now undertaking on AMR.

WHO

11. Further to the information provided in CX/AMR 18/6/3, the Representative of WHO noted that the 8th Meeting of AGISAR (November 2018) had advanced the work on the Global Protocol on Integrated Surveillance of Extended Spectrum Beta-lactamase (ESBL) producing *Escherichia coli*, WHO aims to publish the protocol in 2019. The meeting also revised the *WHO List of Critically Important Antimicrobials for Human Medicine* (WHO CIA List) and the 6th edition will be published in the first quarter of 2019.
12. In responding to a request for clarification on the status of WHO documents, e.g. the WHO CIA List and the *WHO Guidelines on Use of Medically Important Antimicrobials in Food-producing Animals*, the Representative of WHO explained that the CIA list for human medicine was first developed in 2005 as a result of a Tripartite recommendation and is revised regularly by a group of selected experts. The list provides a ranking of antimicrobial agents used in human medicine based on two criteria a) importance to human health and b) the likelihood of resistance transmission through the food chain. She clarified that WHO guidelines are documents which contain recommendations developed by selected experts from a wide range of disciplines (human and animal health and welfare, food producers, economists etc.); are science-based; are not open to negotiation and have a primary focus to protect public health. She further clarified that the WHO guideline development process required the collection and analysis of all available scientific evidence through systematic and literature reviews to inform respective recommendations. Adoption of these documents by the World Health Assembly is not required under WHO rules and implementation by Member States is voluntary.

OIE

13. The Representative of OIE provided more detailed information on the outcome of the last OIE General Session (May 2018) when OIE Member Countries adopted a definition for veterinary medical use; agreed additional restrictions on the use of 3rd and 4th generation cephalosporins, fluoroquinolones and colistin; and recommended that the classes in the WHO category of Highest Priority Critically Important Antimicrobials should be the highest priorities for countries in phasing out use of antimicrobial agents as growth promoters.
14. The Representative further noted that the 3rd *OIE Annual Report on Antimicrobial Agents intended for Use in Animals* will be published in January 2019 and that the continuous progress in the amount and quality of data received with the support of the countries and National Veterinary Product Focal Points was very encouraging. She highlighted that the fourth questionnaire had already been sent to all OIE Members. With reference to the 2nd *OIE Global Conference on Antimicrobial Resistance and Prudent Use of Antimicrobial Agents in Animals: Putting Standards into Practice* (October 2018), she noted that the recommendations adopted provided guidance on the work to be carried out to support the implementation of standards.

Conclusion

15. TFAMR thanked the three organizations for their excellent work on AMR and were encouraged by the range of activities and level of collaboration. With reference to the scientific advice requested by TFAMR, appreciation was expressed for the report of the Expert Meeting and the recommendations provided.

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

16. The Secretariat drew the attention of the Task Force to the information on antimicrobial resistance relevant to its work that was provided by the Organization for Economic Cooperation, the World Bank, the World Customs Organization and the World Trade Organization.

Conclusion

17. TFAMR 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

18. The TFAMR Chair called upon delegations to make progress on the different provisions of the COP in order to advance the document in the Step Procedure. He drew the attention of TFAMR on those sections that, based on the comments submitted, indicated good possibilities to reach consensus e.g. the introduction; scope; several definitions and principles; practices during production, processing, storage, transport, retail and distribution of food; and communication to consumers. This would allow TFAMR to focus its discussion on the critical issues related to certain definitions and principles that could allow further progress on the various sections on the responsible use of antimicrobial agents.
19. The EWG Chair (United States of America) summarized the key points of discussions, conclusions and recommendations in the EWG as regards the revision of the COP. The EWG Chair supported the approach proposed by the TFAMR Chair to focus on the areas where consensus could be reached and discuss key issues related to certain definitions, principles and provisions under the responsible use of antimicrobials that could further progress the development of the COP at TFAMR07.
20. TFAMR agreed with the proposed approach.
21. The following general comments based on a revised version of the COP (CRD10) were made:
- The revision should apply to the entire food chain, include crops/plants and environment, and be consistent with relevant international guidance in particular the OIE Terrestrial and Aquatic Animal Health Codes. The scope of the COP should remain broad to cover all antimicrobials rather than only medically important antimicrobials consistent with the current COP and corresponding OIE documents.
 - The revision should be science-based and risk-based to support the risk management recommendations for foodborne AMR in line with the guidance provided in the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* and the *Guidelines for Risk Analysis of Foodborne AMR (CXG 77-2011)*. The revised COP should be flexible to allow countries to base their risk management measures on national / regional risk assessments when no international risk assessments were available.
22. TFAMR proceeded with the revision of the COP and made the following comments, changes, and decisions:

Section 1 – Introduction

23. TFAMR agreed on several adjustments to improve the clarity and accuracy of the text including consistency with the terminology used in Codex (e.g. “competent” authority as opposed to “regulatory” authority). Main changes referred to the limitation of the term “environment” to “food production environments”; introduction of the term “feed” as the COP covers “food” and “feed”; the introduction of national lists to provide flexibility for countries to establish risk management measures based on national risk assessment which are more applicable to national risks and conditions; the use of the term “veterinarian” as opposed to “animal health professional”; and the use of the term “plant/crop health professional” instead of “plant/crop advisor or consultant”.

⁶ CX/AMR 18/6/4

⁷ CL 2018/74-AMR; CX/AMR 18/6/5; CX/AMR 18/6/5-Add.1 (Australia, Brazil, Canada, China, Colombia, Guyana, Indonesia, Iran, Japan, Kenya, Malaysia, Norway, Thailand, USA, Consumer Goods Forum, Consumers International, FEFAC, HealthForAnimals, IACFO, IFIF, International Meat Secretariat, IUFoST); CRD2 (Costa Rica, Mauritius, New Zealand, IDF); CRD4 (OIE); CRD5 (EU); CRD6 (Chile), CRD7 (Ghana); CRD8 (Nicaragua); CRD9 (India); CRD10 (Revised COP, Sections 1 and 2, prepared by the Chair and Co-Chairs of the EWG/COP); CRD15 (China); CRD16 (Russian Federation); CRD17 (African Union); CRD19 (Revised COP, Sections 4, 6, 7 prepared by the Chair and Co-Chairs of the EWG/COP); CRD20 (Revised COP, all sections, prepared by the Codex Secretariat)

24. TFAMR had an exchange of views on the whether to refer to the entire document, *WHO List of Critically Important Antimicrobials for Human Medicine*, or to limit the reference to Annex 1 of the WHO CIA List related to the *Complete List of Antimicrobials for Human and Veterinary Use, categorized as Critically Important, Highly Important and Important*.
25. Delegations in favour of referring to Annex 1 indicated that the Annex contained information relevant to the scope of the COP and that other information contained in the WHO CIA List document was not required for the application of the COP. Delegations in favour of referencing the complete WHO CIA List indicated that other sections of the document may provide useful information to support risk management measures in the COP. TFAMR could not reach consensus and agreed to refer the matter for further discussion in the EWG.
26. TFAMR also agreed that provisions in paragraph 6 should be transferred to the scope as it was the more appropriate location. However, there was not consensus to remove reference to antimicrobials other than antibacterials, such as antivirals, antiprotozoal, antifungal agents, etc., for which resistance is also a problem in some countries and the use of which may contribute to co-resistance or cross-resistance which thus remained in brackets for further consideration by the EWG. Delegations in favour of keeping the full paragraph indicated that this would be consistent with the broadened scope of the COP and the definition of antimicrobials in Section 3 of CX/AMR 18/6/5.

Section 2 - Scope

Paragraph 7

27. Consistent with the inclusion of “feed” in addition to “food” in the introduction, TFAMR recalled that the scope of the COP covered both “food” and “feed” and discussed whether the term “food” applied to both “food” for human consumption and “feed” for animal feeding as indicated in footnote 1.
28. TFAMR noted the following comments: the *Guidelines for Risk Analysis of Foodborne AMR* refer to “food” and “feed”; terminology used along the three core AMR documents i.e. the code of practice, the guidelines for monitoring / surveillance, and the guidelines for risk analysis should be consistent to avoid confusion; and Codex commonly apply separate terms for “food” and “feed” each of them having their own definitions as stated in the Procedural Manual and other Codex texts such as the *Code of Practice for Good Animal Feeding* (CXC 54-2004), the *Classification of Food and Animal Feed* (CXM 4-1989), etc.
29. TFAMR thus agreed that the scope of the COP would refer to “food” and “feed”. Consequently, footnote 1 was deleted.
30. TFAMR agreed to delete the third sentence as repetitive of the second sentence. It further agreed that the objectives of the COP were to minimize the “risk” in addition to the adverse impacts on human health from foodborne AMR resulting from the use of antimicrobial agents in the food chain.

Paragraph 9

31. TFAMR noted a request to delete “probiotics” as there were questions on the safety assessment of these products to sustain their inclusion in the COP. It was noted that the reference to “probiotics” was given to avoid ambiguity as to their exclusion from the COP.
32. TFAMR therefore agreed to retain the reference excluding “probiotics” in the scope.

Other changes

33. Other changes were made in paragraphs 7-8 to improve the clarity and accuracy of the text.

Definitions

34. TFAMR recalled that only definitions of terms used in the COP were presented under this section. TFAMR considered the definitions as proposed in CX/AMR 18/6/5, Appendix I, Section 3 as follows:

Antimicrobial class; Antimicrobial resistance food safety issue

35. TFAMR agreed not to include definitions for these terms as they were either not used or not necessary. It was noted that definition for antimicrobial class can be found in CXG77.

Antibiotic; Antibiotic resistance

36. TFAMR agreed to delete these definitions as they are not used in the COP.

Antibacterial; Adverse Health Effect; Antimicrobial resistance; Antimicrobial resistance determinant; Co-resistance; Cross-resistance; Extra- or Off-label; Food chain; Food producing animal; Growth promotion; Marketing authorization; Pharmaceutical industry; Control of disease/metaphylaxis; Prevention of disease/prophylaxis; Treatment of disease

37. TFAMR agreed to the proposed definitions for these terms.

Antimicrobial agent

38. As most of the recommendations in the COP focus on antibacterials, TFAMR agreed to delete the reference to antimicrobial agents other than antibacterials, e.g. antivirals, antiprotozoal, antifungal agents, which could also be selected for co-resistance or co-selection of AMR. A proposal to include anthelmintics and antiseptics was not agreed as they were outside of the scope of the COP.

Medically important antimicrobials

39. TFAMR noted views from delegates on whether the definition should include reference to the *WHO List of Critically Important Antimicrobials* only or whether references to national lists should also be included. Delegations also proposed adding more specificity on the categories included in the WHO List.
40. Delegations wishing to keep the reference to national lists noted that there should be flexibility for countries to develop their own national lists that are based on their priorities and resources, are science-risk based, and take into account the recommendations in the WHO CIA List noting that the nature of this list had already been acknowledged by TFAMR05 (REP18/AMR, paragraph 46).
41. Delegations also discussed whether or not to include therapeutic use in the definition noting that: although all classes of antimicrobials used in humans are considered “medically important” and all antimicrobial uses in humans are considered “therapeutic” (i.e. there is no use of antimicrobials outside of the purposes of treatment, control, and prevention of human disease), TFAMR agreed to retain the term “therapeutic” in the definition to provide emphasis on the difference between medically important antimicrobials used in humans and those antimicrobials not used in humans at all (those not categorized in the WHO CIA for human use list), notably the ionophores.
42. TFAMR agreed that the definition would refer to both the WHO CIA List and national lists based on equivalent criteria where available and that antimicrobial agents not important for therapeutic use in human medicine, such as ionophores, are excluded from the definition (see CRD20). TFAMR also agreed that this definition would go to the EWG. A comment was made on whether there should be reference to antimicrobial agents not important for therapeutic use in humans in the definition.

One Health Approach

43. TFAMR noted the following comments:
- The goal of achieving optimal health outcomes should apply to both humans and animals as well as to crops and environment as appropriate since “one health” cover all sectors as opposed to limiting the interpretation of the approach to human health based on collaborative work among various sectors. Referring to “animal” and “crop” would clarify the intent of the approach in this context, which aims for optimal health for all relevant sectors.
 - The terms “multistakeholder”, “multistrategy”, “multilevel” could replace the terms “multisectoral”, “trans-disciplinary” “national, regional, global levels” as more appropriate.
44. TFAMR retained the definition as proposed in the COP as it was considered to be sufficient to capture these considerations and sufficient for the purposes of Codex work.

Pharmacovigilance

45. TFAMR agreed with the definition as proposed in CRD20.

Plants/crops; Food of plant origin; Plant/crop professional

46. TFAMR had an exchange of views on the correct way to address “plants/crops” in the COP and whether the term “food of plant origin” would better define the scope of the COP i.e. food of plant origin may direct focus on the edible portions of the plant whereas using the term “plants/crops grown for food or feed” could be more broadly applied to any part or portion of a food (or feed) producing plant. Delegations in favour of the term “food of plant origin” indicated that it was consistent with similar terms used in other Codex texts such as the *Classification of Food and Animal Feed* and in the report of the FAO/WHO Expert Meeting. Delegations in favour of the term “plants/crops” indicated that this term was consistent with CXG77 and was commonly used in Codex texts.
47. TFAMR agreed on a definition for “plants/crops” and “food of plant origin”, but not on whether the latter was needed throughout the text. A Delegation indicated that it would be preferable to keep both terms for the time being in order to determine which would be the most appropriate term or whether both terms could be applicable depending on the provisions in the COP. TFAMR therefore agreed to leave the definition “food of plant origin” in brackets for further deliberation in the EWG.

48. TFAMR could not agree on a term / definition for “plant / crop professional” and left the definition in brackets for further consideration in the EWG in particular as to the most appropriate term to define this discipline i.e. “plant / crop professional” vs. “plant pathologist”.

Therapeutic use

49. TFAMR did not consider this definition and agreed to leave it in brackets for further discussion in the EWG.

Sections 4 - 7

50. TFAMR considered these sections based on CRD19 containing proposals for sections 4, 6 and 7 and general questions on key issues identified from the written comments submitted for the further development of section 5.

Section 4 - Principles

51. TFAMR considered the proposed principles as follows:

Principles 1; 3

52. TFAMR agreed with the principles as proposed in the COP.

Principle 2

53. TFAMR agree to refer to “other alternative tools” as opposed to “other alternatives to antimicrobials” as biosecurity, nutrition, vaccination, etc., were not a substitute to antimicrobials but could reduce the need for their use. The term “other” provide flexibility to accommodate future innovation as regards to such tools.

Principle 4

54. TFAMR had an exchange of views on the introduction of national lists and the potential to become technical barriers to trade. It was noted that such lists were introduced to provide for flexibility when countries may wish to develop their own lists to prioritise risks and associated risk management measures based on their priorities and capacities and on safety risk assessment while taking into account the WHO CIA List.

Principle 5

55. TFAMR noted divergent views on the Principle.

56. The United States of America, urged TFAMR to join with it to protect consumers by eliminating the use of medically important antimicrobial agents in food-producing animals for production purposes, that is, for growth promotion and feed efficiency. The United States stated that it had eliminated the use of medically important antimicrobials in food-producing animals for production purposes since 2017. The Delegation further encouraged that TFAMR should define medically important antimicrobials as antimicrobial agents important for therapeutic use in humans as described by established national lists, or where not available, by the WHO CIA List. The Delegation concurrently urged the Task Force to ground the work of TFAMR in science and risk through the addition of a proposed separate general principle regarding risk analysis based on scientific evidence.

57. Delegations held different views about the use of antimicrobials as growth promoters.

58. There were delegations which stated that antimicrobial growth promoters had been banned in their countries and, taking into account the risks of using antimicrobials for growth promotion in food producing animals, specified that antimicrobials must neither be used in animals for the purpose of promoting growth nor increasing yield. These delegations further stated that no antimicrobials should be granted regulatory approval for growth promotion in animals under any condition and their use must be phased out.

59. Other delegations also agreed that the use of 1) medically important antimicrobials identified in the WHO CIA List or equivalent risk-based national lists of CIAs or; 2) antimicrobial uses that are able to cause co- or cross-resistance to antimicrobials in the aforementioned CIA lists is neither responsible nor prudent and, as such, their use as growth promoters must be phased out. These delegations also highlighted that the use of all other antimicrobials (i.e. those not specifically falling into either of the two categories mentioned above) for growth promotion is likewise neither responsible nor prudent, unless supported by an appropriate risk analysis.

60. It was also proposed that Principle 5 should be in alignment with the text of the same intent in the recently adopted *OIE List of Antimicrobial Agents of Veterinary Importance*, which should be agreeable for all.

61. Of note, these delegations reiterated the right of countries to develop national CIA lists based on nationally-identified priorities and capacities, emphasizing that the development of these lists, in the absence of agreed global safety risk assessment carried by recognized international organizations, should be science and risk based.

62. Based on the above, TFAMR agreed on incorporating these ideas into this principle and to let the EWG further work on drafting Principle 5 (see CRD20).
- Principles 6, 7 and 12*
63. TFAMR agreed to place these principles in brackets for further consideration in the EWG in light of the agreed definition for medically important antimicrobials and to consider how principles 5, 6 and 7 could be better integrated.
- Principle 8*
64. TFAMR agreed with this principle as presented in the COP.
- Principle 9*
65. TFAMR agreed to include reference to plant health for as it was important to consider unintended consequences to plant health of risk management recommendations for foodborne AMR.
66. A delegation noted that they did not agree with the reference to plant health and also suggested to exclude animal health.
- Principle 10*
67. TFAMR agreed to retain this principle as a means of showing the value of having integrated monitoring and surveillance systems for foodborne AMR in place, and made amendments to refer to “antimicrobials” as opposed to “medical important antimicrobials” as it did not apply only to this set of antimicrobials and to introduce a reference to plants/crops for consistency with the scope of the COP.
68. A delegation noted that they did not agree with the deletion of “medical important” antimicrobials.
- Principle 11*
69. TFAMR agreed that provisions under this principle were more appropriately located under the introduction. TFAMR further agreed to replace the term “stepwise” by “progressive” as the latter better reflects the continuous increase in uptake of provisions in the COP according to countries priorities and resources.
- Principles 13 and 14*
70. TFAMR agreed with these principles with some amendments to improve the intent of the provisions and to revert their order under this section.
- Principle 15*
71. TFAMR agreed to delete this principle as it was not widely understood.
- Principle 16*
72. TFAMR agreed to replace the term “stepwise” by “progressive” consequential to their decision for Principle 11.
- Section 5: Responsible and prudent use of antimicrobial agents**
73. The EWG Chair noted the extensive written comments that had been provided on this section and highlighted key areas for consideration by TFAMR, as outlined in CRD19, feedback on which would facilitate the future development of the section. TFAMR considered the identified issues one by one and the following points were noted:
- Reference to VICH**
74. TFAMR noted proposals to delete reference to VICH, given its nature and membership. Others were in favour of retaining. The Representative of OIE informed TFAMR that the OIE Code does make reference to VICH. With regard to referencing external documents the Codex Secretariat clarified that there were no specific procedures in this regard and so the decision to include such a reference was up to TFAMR; however in making their decision they should consider that the membership of VICH was narrower than that of Codex, not all Codex Members contribute to the development of VICH guidelines and decide on their adoption. Other options such as including relevant text in the COP could also be considered but this may present consistency issues in the future.
75. TFAMR concluded that the issue would be further considered by the EWG
- Surveillance and monitoring programmes**
76. TFAMR agreed to delete paragraph 22, retain paragraphs 21 and 22bis and refer to competent authorities rather than regulatory authorities in paragraph 21 for consistency with terminology used in Codex.

Control of advertising

77. TFAMR agreed to keep this section in the document for further revision by the EWG.

Advertising

78. TFAMR agreed to further discuss this section in the EWG.

Off-label use

79. TFAMR agreed to review these paragraphs following agreement on the Principles, some of which (Principle 5) were directly relevant to the content of this section.

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

80. TFAMR discussed the revised version, based on written comments, and agreed that the proposed text needed further consideration, including a review of the title to ensure it reflected the content of the section, and the inclusion of references to the appropriate Codex hygiene texts, in particular the General Principles of Food Hygiene.

Section 7 - Consumer practices and communication to consumers

81. TFAMR discussed the revised version, based on written comments, agreed with the proposal to delete the bullet relating to product label claims, accepted the text on AMR infections, and acknowledged the advice of the Codex Secretariat that Codex texts do not directly target consumers and their suggestion to revise or delete paragraph 63 such that the guidance advised governments and those with a role in informing / educating consumers, in line with other Codex texts.

Conclusion

82. TFAMR agreed to return the proposed draft COP to Step 2/3 for re-drafting and establish an EWG, chaired by USA and co-Chaired by UK, Kenya, Chile and China working in English and Spanish to prepare a revised version of the COP for consideration by TFAMR07 with the following Terms of Reference:

- To further develop the COP based on the discussion held and agreements made including written comments submitted using CRD20 as the basis for the discussion.
- To address in particular the following topics on the understanding that agreed text should not be re-opened to the extent possible.
 - Sections 1 – 2 – consideration of bracketed provisions.
 - Section 3 – consideration of definitions for food of plant origin, plant/crop professional, therapeutic use and additional definitions as needed or proposed by TFAMR including food production environment.
 - Section 4 – further development of Principles 5, 6, 7, and 12.
 - Section 5 – further development of this section in particular the following topics: reference to VICH, inclusion/exclusion of paragraphs 21 and 22 on surveillance and monitoring, paragraphs 25-27 and 35-36 on control of advertising, paragraphs 51-53 on off-label use.
Additional areas as needed to progress the text.
 - Section 6 – consideration of bracketed provisions.
 - Section 7 – consideration of bracketed provisions taking note of guidance from the Codex Secretariat.
- TFAMR further agreed that in discussing the above sections, the EWG should consider the report of the *Joint FAO/WHO Expert Meeting in collaboration with OIE on Foodborne Antimicrobial Resistance: Role of Crops, Environment, and Biocides*.

83. The report of the EWG should be made available to the Codex Secretariat at least three months before TFAMR07 for circulation for comments at Step 3.

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

84. The Chair, as under Agenda Item 5, reiterated his desire to make progress on the different provisions of the Guidelines in order to advance the document in the Step Procedure and urged the members and observers to work together towards consensus-based agreement. He proposed to discuss sections 1- 6 and 11-13 to get an agreement and to discuss key points in the remaining sections, especially Section 7.3 on the description of step-wise approach, in order to provide feedback to the EWG to further develop the document for the consideration by TFAMR07.
85. The EWG Chair (The Netherlands), explained the changes that had been made to the document since TFAMR05 and noted that based on the comments submitted, the main issues to be addressed included the scope and the stepwise approach to establishment of a monitoring and surveillance system. The Chair and co-Chairs had prepared a revised proposal (CRD18) for sections 1-6 and 11-13 of the document based on all written comments and proposed to use this as a basis for discussion of these sections, while CX/AMR 18/6/6 would be used for discussion of the remaining sections.

Discussion**Section 1 - Introduction (CRD18)**

86. TFAMR agreed on paragraph 1 as presented in CRD18.
87. Some delegations expressed concerns that paragraph 2 did not adequately differentiate the fundamental differences between monitoring and surveillance, noting that these were distinct activities carried out in a different manner and for different purposes. The need for consistency with other internationally recognized definitions or descriptions; recognition that this document was part of a series of Codex texts on AMR; and the importance of getting the fundamental concepts right were expressed. TFAMR also confirmed that residue monitoring was not within the scope of the guidelines. Following extensive discussion, new text for the paragraph was agreed as follows:

For the purpose of these guidelines, monitoring refers to the collection and analysis of AMR and AMU related data and information. Surveillance is the systematic, continuous or repeated, measurement, collection, collation, validation, analysis and interpretation of AMR and AMU related data and trends from defined populations to inform actions that can be taken and to enable the measurement of their impact.

A delegation noted that they would like to have information on the purpose of monitoring included in the paragraph.

88. Delegations expressed a range of views on paragraph 3, including the need for the guidelines to be practical; to provide guidance relevant to all countries; to recognize differences in resources and capabilities; to adhere to the fundamental science-based principles of Codex; to provide flexibility for the inclusion of all relevant sectors, including crops and the environment, in integrated monitoring and surveillance systems; and facilitate the progressive implementation of such systems. Based on this, the paragraph was extensively revised as follows with the agreement that food production environment be defined and the inclusion of scientific evidence be further considered.

An integrated monitoring and surveillance system includes the coordinated collection of data or samples at appropriate stages along the food chain and the testing, analysis and reporting of AMR and AMU. An integrated system includes the alignment and harmonization of sampling, testing, analysis and reporting methodologies and practices as well as the integrated analysis of relevant epidemiological information from humans, animals, foods, crops and the food production/relevant environment (definition) Depending on national priorities, food safety AMR issues, [scientific evidence,] capabilities and available resources, an integrated surveillance system can be implemented progressively.

89. TFAMR agreed on paragraph 4 with the inclusion of foodborne before “public health risk” to better reflect the scope of the document.

⁸ CL 2018/75-AMR; CX/AMR 18/6/6; CX/AMR 18/6/6-Add.1 (Australia, Brazil, Canada, China, Colombia, Cuba, Egypt, Guyana, Indonesia, Iran, Japan, Kenya, Malaysia, Mexico, Morocco, Norway, Thailand, USA, Consumers International, HealthForAnimals, IACFO, IFIF, International Meat Secretariat and IUFoST); CRD3 (Canada, Costa Rica, New Zealand, EU and IDF); CRD4 (OIE), CRD5 (EU), CRD6 (Chile); CRD7 (Ghana); CRD8 (Nicaragua); CRD9 (India); CRD15 (China); CRD16 (Russian Federation); CRD17 (African Union); CRD18 (Revision to GLIS prepared by the Chair and co-Chairs of the EWG/GLIS)

90. TFAMR agreed on paragraph 5 with the addition of “burden of illness” before “information” and “foodborne” before AMR. TFAMR further agreed to include “foodborne” before “AMR” throughout the document, where technically appropriate, and to change “along the food chain” to “throughout the food chain” for consistency and that program would be changed to system throughout the text when referring to monitoring and surveillance programs.
91. TFAMR agreed with the first sentence of paragraph 6 with the inclusion of “data on AMU and” before foodborne AMR. It was further agreed that in those parts of the texts where reference to AMR is intended to mean both AMR and AMU, explicit mention of AMU would be included. TFAMR exchanged views on the last phrase of paragraph 6 which states that monitoring and surveillance systems “are an important component of a comprehensive national food control system”. Those in favour of deleting this phrase, highlighted that this could put a heavy burden on countries to have such systems in place in order to be considered by trading partners to have a comprehensive national food safety systems in place and may create trade barriers. Delegations in favour of retaining considered that it was fundamental to include the linkage to national food safety systems as the guidelines were addressing foodborne AMR. TFAMR agreed that the inclusion/deletion required further discussion in the EWG.
92. TFAMR agreed on paragraph 7 with the inclusion of “international” before “monitoring and surveillance systems” to reflect that there are international AMU and AMR monitoring and surveillance systems which countries may use to share data.
93. TFAMR agreed on paragraphs 8, 9, 10 and 11 as presented in CRD18 and agreed to revise paragraph 12 to clarify that OIE was an international standard setting body and WHO-AGISAR was an advisory body.

Section 2 - Scope (CRD18)

94. In addition to editorial amendments, TFAMR agreed to remove reference to animals and crops as these were covered in the agreed definition of food chain (CRD20) and to include this definition in the guidelines; qualified environment as relating to the food production environment for consistency with the *Proposed Draft Revision of the Code of Practice* and reiterated the need to define this; excluded biocides from the scope and text indicating how the guidelines might relate to biocides as this was not related to scope; and agreed to move paragraph 19 to the Introduction (after paragraph 4) as a more appropriate location for this text.
95. With these changes TFAMR agreed on the following scope for the guidelines:
- *These guidelines cover the design and implementation of an integrated monitoring and surveillance system for foodborne AMR and AMU along the food chain, and the food production environment.*
 - *These guidelines address foodborne AMR.*
 - *Though these guidelines do not cover the design and implementation of monitoring and surveillance of AMR and AMU in humans, an integrated system within the context of overall risk management of AMR (One Health Approach) would be informed by data, trends and epidemiology regarding AMR and AMU in humans.*
 - *The microorganisms covered by these guidelines are foodborne pathogens and indicator bacteria of public health relevance.*
 - *Antimicrobials used as biocides, including disinfectants, are excluded from the scope of these guidelines.*
96. The importance of including feed in the scope was highlighted; however, there was no agreement on how it could be directly incorporated into the text on scope. It was proposed to address this by including feed in the definition of food chain and TFAMR agreed to further consider this under Definitions.

Section 3 - Definitions

Antimicrobial agent, Crops / Plants and One Health Approach

97. TFAMR agreed to align these definitions with the agreed definitions presented in CRD20.

Biocides

98. TFAMR agreed not to define biocides although one Delegation noted that it would be useful to define this in order to clarify the scope .

Foods of plant origin

99. TFAMR agreed to include the proposed definition from CRD20 for further consideration.

Food chain

100. Following the proposal to include “feed” in this definition, delegations exchanged views on this proposal including that: feed was implicitly included as the definition covered primary production; feed was also covered in the definition of plant/crops, hence adding it to the food chain definition could cause confusion; and feed does not only come from plant/crops but also from animal sources and food waste so therefore it was necessary to explicitly include it in the definition of food chain. TFAMR agreed to request the EWG to further consider the inclusion of “feed”, immediately after plant / crops in the currently agreed definition presented in CRD20.

Hazard

101. TFAMR agreed the definition as proposed, noting that it was based on the existing definition of Hazard in the Codex procedural manual and information from CXG77.

Prioritized antimicrobial agent

102. TFAMR agreed to delete this definition as the concept was already captured in the text of the guidelines and such a definition may create further confusion with regard to the WHO CIA List and national lists.

Risk-based approach

103. TFAMR agreed with the proposal of the Chair and co-Chairs to delete this from the definitions and include the text in Section 5.

Food production environment

104. TFAMR agreed to request the EWG to further consider the following proposed definition “*The immediate vicinity of food to be harvested or processed that has reasonable probability to contribute to foodborne AMR.*”

Foodborne pathogen

105. TFAMR agreed to include the definition from CXC77.

Section 4 - Principles (CRD18)

106. TFAMR had a general discussion on the Principles. The following comments and suggestions were made for consideration by the EWG in the further development of the Guidelines.

- Include AMU in Principle 1.
- Revise or delete principle 2 considering the range of comments from Delegations who noted that it is currently written as a statement and does not guide action; it is repetitive of text in the introduction; it includes the concept that monitoring and surveillance is a core component of a national food safety program which suggests that countries must have such a program and the lack of one may lead to trade barriers; it is a fundamental concept to be included when addressing foodborne AMR and therefore should be reflected in the principles; and that these guidelines should not create barriers to trade.
- Consider inclusion of text in Principle 3 to reflect the need to consider international standards to ensure that data are comparable and to facilitate reporting at the international level and replace ‘continuous improvement and enhancement’ with “progressive improvement”.
- Revert to “practical” rather than “possible” in Principle 7 to reflect the need for pragmatic guidelines.
- Include “according to national priorities and resources” after “across all sectors” at the end of Principle 9.
- Consider merging Principles 7 and 10 as they are very similar.
- Remove “inappropriately” from Principle 11 to avoid any suggestion that there are appropriate trade barriers.
- Change “stepwise” to “progressive approach” throughout for consistency with the proposed draft revision of the COP (see paragraph 69 of this report).

Section 5 - Risk-based approach (CRD18)

107. TFAMR proposed to review the use of the word “relationship” in the first paragraph and consider “level” as a possible replacement.

Section 6 - Regulatory framework, policy and roles (CRD18)

108. TFAMR proposed revision/deletion of the first two sentences in paragraph 28 as they seem to go beyond the mandate of Codex and to make reference to programs rather than interventions in paragraph 29.

Section 7 - A stepwise approach to the implementation of an integrated monitoring and surveillance program of foodborne AMR (CX/AMR 18/6/6)

109. Delegations reiterated their concerns about Section 7.3 *Options for stepwise development of integrated monitoring and surveillance of foodborne AMR and AMU programs* highlighting the prescriptive nature of the section, the lack of flexibility and the potential for misinterpretation. It was further noted that; this format creates a clear possibility of categorization of the monitoring and surveillance systems that countries have in place; may lead to a misrepresentation of the status of systems in countries and may create trade barriers; Codex guidelines were not about creating the most sophisticated systems but rather to propose recommendations based on the principles of sound scientific analysis and evidence that protect the health of consumers and ensure fair practices in the food trade; and that Codex guidelines need to be applicable worldwide, and take into account countries capacities, with particular attention to the impact on developing countries. Highlighting the need for a progressive approach, it was proposed that TFAMR consider how the information in the section could be presented in another way to avoid any suggestion of categorization.
110. Other delegations highlighted the value of the stepwise approach presented in Section 7.3 noting that it ensured that Codex guidelines were indeed applicable to all countries, giving guidance to those who have no systems, as well as those who want to improve their systems. They highlighted the value of the information contained in the section and the need to retain this in the guidelines.
111. There was general recognition that this guidance should not be seen as creating potential trade barriers and it was proposed that consideration be given to inclusion of a new principle to indicate that the status of a monitoring and surveillance system within a country should not constitute a barrier to trade.
112. TFAMR agreed to review and revise Section 7.3 ensuring that presentation of the content does not give any suggestion of categorization; and different approaches to presenting the information such as organizing the information in structured lists or using a tool box approach to present different options be considered. The usefulness of the general content of the table was acknowledged but the content was not discussed in the plenary.

Sections 8, 9 and 10 (CX/AMR 18/6/6)

113. TFAMR agreed that these sections be revised in response to the written comments to this meeting.

Sections 11, 12 and 13 (CRD18)

114. It was proposed that paragraph 35 be further considered by the EWG.

Conclusion

115. The Committee agreed to return the proposed draft document to Step 2/3 for redrafting and establish an EWG, chaired by the Netherlands and co-chaired by Chile, China and New Zealand, working in English and Spanish, with the following Terms of Reference:
- Review and revise the texts in CRD18 (sections 1-6 and 11-13) and CX/AMR 18/6/6 (sections 7-10) taking into account the discussions at TFAMR06 and written comments received and not reopening agreed text to the extent possible;
 - Review and revise the presentation of the content of Section 7.3 so that it provides useful guidance to member countries without any suggestion of categorization and taking into consideration comments received at TFAMR06 and the toolbox approach presented;
 - For sections 1-3, focus on the revision of the text identified in the report as needing further consideration.
 - Consider the report of the *Joint FAO/WHO Expert Meeting in collaboration with OIE on Foodborne Antimicrobial Resistance; Role of the Environment, Crops and Biocides*; and
 - Prepare a revised version of the guidelines for consideration by TFAMR07. Chile and Spain will facilitate the work of the EWG in Spanish.
116. The report of the EWG should be made available to the Codex Secretariat at least three months before TFAMR07 for circulation for comments at Step 3.

OTHER BUSINESS (Agenda Item 7)

117. TFAMR noted that no other business had been proposed.

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

118. TFAMR agreed to keep open the possibility of PWGs, to meet immediately before its next session to consider written comments submitted and prepare a revised proposal for consideration by TFAMR07.
119. TFAMR 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.

APPENDIX I

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LISTE DES PARTICIPANTS
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