INTRODUCTION

1. The ad hoc Intergovernmental Task Force on Antimicrobial Resistance (TFAMR) held its Eighth Session virtually, from 4 to 13 October 2021, 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 ** member countries, one member organization, ** observer organizations, FAO, and WHO. The list of participants is included in Appendix I.

OPENING OF THE SESSION

2. KIM Gang-lip, Minister of Food and Drug Safety of the Republic of Korea, opened the session and welcomed the participants. He reminded the participants of the global threat posed by antimicrobial resistance (AMR) and the importance of a One Health approach in combating this threat. He emphasized the importance of demonstrating leadership and working together, noting an obligation to address AMR for future generations.

3. Dr. Qu Dongyu, Director-General of FAO, and Dr. Tedros Adhanom Ghebreyesus, Director-General of WHO, addressed the meeting reiterating the urgent need for sustained action to address AMR and encouraging TFAMR08 to finish its task.

4. Mr. Guilherme Antonio Da Costa, Chairperson of the Codex Alimentarius Commission, and Mr. Tom Heilandt, Codex Secretary, also provided remarks and urged participants to make every effort to complete the work considering this was the last session of TFAMR.

Division of Competence

5. 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)[1]

6. TFAMR08 adopted the provisional Agenda as its Agenda for the session.

MATTERS REFERRED BY CAC AND OTHER SUBSIDIARY BODIES (Agenda Item 2)[2]

7. TFAMR noted:

   (i) the information from CAC43, CCEXEC78, CCEXEC79 and CCEXEC80.

   (ii) the advice of CCEXEC79 (paragraphs 12-15) in relation to completion of the work on the COP and GLIS; and

   (iii) that the Codex Secretariat continues to work closely with the Chair of TFAMR, Chairs of EWGs and the Host Country Secretariat on ways to improve work management (paragraph 16).

MATTERS ARISING FROM FAO, WHO, OIE and IPPC (Agenda Items 3(a) and (b))[3]

<u>Food and Agriculture Organization of the United Nations</u>

8. The Representative of FAO informed TFAMR08 of the ongoing efforts of the Tripartite to work together to address AMR. In particular, he noted the establishment of the Tripartite Joint Secretariat on AMR and the forthcoming Tripartite strategic framework on AMR. In response to the recommendation of the Inter-agency Coordination Group on AMR (IACG), he also highlighted the tripartite follow-up initiatives, including the progress on the AMR Multi-Stakeholder Partnership Platform, the advocacy of the Global Leaders Group, Independent Panel of Evidence on Antimicrobial Resistance, and a range of technical activities on legislation, surveillance, etc., many of which are supported by the AMR Multi-Partner Trust Fund (AMR MPTF).

9. He informed TFAMR08 that the FAO action plan on AMR 2021-2025 had been endorsed; and noted the progress made in a number of technical areas including the development of the International FAO AMR monitoring database (InFARM), which will compliment and support Tripartite surveillance efforts, and FAO efforts to address AMR within a One Health framework.

10. In reply to the question on the schedule for the roll-out of InFARM and the Tripartite Integrated Surveillance System on AMR/AMU (TISSA), the Representative clarified that InFARM had been included as an output in the FAO AMR action plan, and that its development was underway although the pace of global roll-out was linked to resource availability, while TISSA would be launched within the first half of 2022.

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1 CX/AMR 21/8/1

2 CX/AMR 21/8/2

3 CX/AMR 21/8/3; CX/AMR 21/8/3-Add.1

World Health Organization

11. The Representative of WHO informed TFAMR08 of progress on several key activities including the work to monitor and support the implementation of Multisectoral National Action Plans (NAPs) on AMR, the launch of a global protocol on surveillance of extended spectrum beta-lactamase (ESBL) producing *Escherichia coli* using a One Health Approach ("Tricycle ESBL *E. coli* surveillance project") and the extensive participation of countries in the Global Antimicrobial Resistance and Use Surveillance System (GLASS) for humans. He further noted that WHO were about to begin new work to revise and develop the 7th revision of the WHO Critically Important Antimicrobials (CIA) list and to update the WHO Priority Pathogen List (PPL), and the recent launch of the WHO policy guidance on integrated antimicrobial stewardship. In reply to the question on the development of a fungal PPL for humans, he clarified that the list is focused on fungal infections in humans and it was expected to be published in early 2022.

World Organization for Animal Health

12. The Representative of the OIE informed TFAMR08 of the establishment and activities of the OIE Working Group on AMR and highlighted the publication of the 5th report of the OIE Global Database on Antimicrobial Agents Intended for Use in Animals (OIE AMU Database) noting an overall decreasing trend in antimicrobial use in animals reflected therein. She also noted the ongoing work to complement the OIE List of antimicrobial agents of veterinary importance by animal species specific information (finalized for poultry, ongoing for swine and aquatic animals) and new work on responsible and prudent use on antiparasitic agents in response to concerns of its Members.

International Plant Protection Convention

13. The Representative of FAO, on behalf of the International Plant Protection Convention (IPPC), recognized the lack of robust data on the extent and volume of antimicrobial use by the plant sector worldwide. He noted that antimicrobial use in agriculture was dependent on numerous factors including needs, legislation, availability and type of production system. He further noted that IPPC consider that their involvement in AMR should be limited to the prevention of introduction and spread of plant pests and recommendations in relation to plant health.

Conclusion

14. TFAMR:

(i) noted the FAO/WHO/OIE and IPPC progress report on AMR activities since its last session, and

(ii) expressed appreciation to the Tripartite for all their efforts to assist countries to contain and minimize AMR.

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

Organization for Economic Cooperation and Development

15. The representative of the Organisation for Economic Co-operation and Development (OECD) informed TFAMR08 that OECD's work involved close interaction between the work on livestock/agriculture and human health within a One-Health framework. OECD co-operates with other intergovernmental organizations to complement work of the tripartite with a focus on economic issues. The representative introduced a recent publication on assessing NAPs on AMR in the livestock and agriculture sector and their implementation in several countries and highlighted some of the lessons learned, including the need for greater investment in the prevention, mitigation and containment actions to tackle AMR. He further noted the future relevant work of OECD, including an assessment of food safety and other policies in livestock production.

World Bank

16. The Representative of the World Bank (WB) informed TFAMR08 that WB was providing financing to address AMR within 56 projects, across 35 countries to strengthen and develop agriculture, health, and water and sanitation systems to prevent the emergence of diseases and reduce the emergence and spread of AMR. Among the examples provided were the Africa Center for Disease Control and Prevention Regional (ACDCP) project and the West Africa Regional Disease Surveillance capacity strengthening project (REDISSE), both of which would strengthen laboratory capacity and surveillance systems including for AMR. Other relevant efforts include the development of an operational framework for AMR, a landscape analysis of tools to address AMR, and an ongoing analysis of evidence and interventions.

World Customs Organization

17. The Representative of the World Customs Organization (WCO) highlighted the activity of Operation STOP to address the resurgence in the illegal trafficking of medicines and medical supplies linked to the COVID-19 pandemic. He highlighted that in a 2 month period of targeted inspection, antibacterials/antibiotics were among the medical products most often seized or detained, and noted the importance of addressing the illicit movement of these kinds of medicines.

[4] CX/AMR 21/8/4

World Trade Organization

18. The Chairperson also drew the attention of TFAMR08 to the relevant information on AMR provided by the World Trade Organization (WTO).

Conclusion

19. TFAMR:

(i) noted the information provided by the aforementioned international organizations on their AMR work, and

(ii) thanked these organizations for their collaboration on the global efforts to contain and minimize AMR.

REVISION OF THE CODE OF PRACTICE TO CONTAIN AND MINIMIZE FOODBORNE ANTIMICROBIAL RESISTANCE (CXC 65-2005) (At Step 7) (Agenda Item 5)[5]

20. The Chairperson recalled the discussions and agreements fromTFAMR07 (2019) on the COP, its subsequent adoption by CAC43 (2020) at Step 5, and further rounds of comments at Step 6, including the organization of a webinar and virtual session of the Working Group, to assist TFAMR to address the outstanding issues in the COP, in particular those related to the mandate of the EWG, namely the definition of "therapeutic use" in Section 3 and its impact on certain principles/provisions in Sections 4 and 5 respectively.

21. The Chairperson further recalled that the COP was at its final stage of discussion, Step 7, and this was a recognition that the COP had been thoroughly discussed for the past three sessions of TFAMR and thus the current document contained significant improvements in AMR risk management and fulfilled the mandate of TFAMR given by CAC. He further noted that the process followed, especially in the period since TFAMR07, had given ample time and opportunities for comments and consensus-building around the remaining issues for consideration at this session. Based on comments received in reply to CL 2021/65-AMR, the Chairperson identified 3 areas of discussion in Section 3 (definition of "therapeutic use"), Section 4 (principles 8, 12, 13 and 15) and Section 5 (provisions relevant to "therapeutic use") and therefore proposed to focus the discussion on these issues to finalize the revision of the COP and encouraged Codex members and observers to avoid reopening discussions on provisions which had already been agreed by TFAMR in order to conclude work at this session.

22. The EWG Chair introduced the COP and provided a summary of the status of work on the COP recalling discussions and agreements made by previous sessions of TFAMR on the COP and the few substantive issues that required resolution by this session, notably the definition of "therapeutic use" and its linkages to Principle 13 and certain provisions in Section 5. He recalled the important progress made on the revision of the COP that enabled TFAMR to fulfil its mandate namely to expand the scope of the COP to cover the entire food chain and to introduce the One Health Approach to address multiple sectors in particular plants/crops in addition to animal production as well as food processing, storage, transport and distribution in addition to primary production.

23. The revised COP also includes cross-references to other key AMR risk management documents developed by Codex, in particular the Risk Analysis Principles for Foodborne AMR (CXG 77-2011) and by relevant international organizations, such as FAO, WHO and OIE, to maintain coherence while remaining focused on food safety and to complement ongoing efforts being carried out by these Organizations to contain and minimize AMR. The EWG Chair further referred to the linkages between the COP and the Guidelines for integrated monitoring and surveillance of foodborne AMR (GLIS) as shown in different sections of the COP, notably definitions and principles, which, together with the COP and the Risk Analysis Principles constitute the three core Codex texts on foodborne AMR.

24. He reemphasized the approach proposed by the Chairperson to focus on the outstanding substantive issues and to avoid reopening discussion on sections that have been exhaustively discussed and agreed upon at previous sessions of TFAMR.

25. Based on the above considerations, TFAMR, while considering each section, agreed to focus its discussion on the outstanding issues as identified by the Chairperson (see paragraph XX) as follows:

Section 1 – Introduction
Section 2 – Scope

26. TFAMR recalled that these sections had already been agreed at previous sessions and thus agreed to leave provisions unchanged.

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5 CL 2021/65-AMR; CX/AMR 21/5/8; CX/AMR 21/5/8-Add.1 (Australia, Brazil, Canada, Chile, China, Colombia, Costa Rica, Cuba, Ecuador, Egypt, European Union (EU), Iraq, Japan, Malaysia, Morocco, Norway, Republic of Korea, Saudi Arabia, Switzerland, Thailand, Uruguay, USA); CRD4 (HealthforAnimals); CRD5 (Kenya); CRD6 (Nigeria); CRD7 (Ghana); CRD8 (Philippines); CRD9 (Indonesia); CRD10 (Morocco); CRD12 (Revision of the Code of practice to minimise and contain foodborne AMR- proposal of the chair and co-chairs of the EWG)

Section 4 – Principles

Principle 8

27. TFAMR noted a comment to refer to "all antimicrobial agents" as opposed to "medically important antimicrobials", since this was a general principle and would be consistent with OIE. However, to be consistent with the approach not to reopen discussion on provisions that were already agreed, TFAMR agreed to keep this principle unchanged.

Principle 12

28. The EU and its Member States reiterated their view that the use of all antimicrobials for purposes of growth promotion or yield increase should be phased out starting immediately with the medically important antimicrobials. This position was supported by Norway, the Russian Federation, Switzerland and Thailand.

29. The Russian Federation further noted that using antimicrobials as growth promoters posed serious risks to public health and thus should be phased out as recommended by the United Nations.

30. TFAMR noted the statement and comment provided by the above delegations and agreed to retain this principle consistent with its decision to not reopen provisions that have been extensively discussed and agreed at previous sessions of the Task Force. The Russian Federation and Thailand expressed their reservations to this decision for the reasons expressed in paragraph XX.

Principle 13

31. TFAMR agreed to base its discussion on Conference Room Document (CRD) 12 prepared by the EWG Chairs that provided options on possible wording for Principle 13, including the potential merging of Principles 8 and 13, to facilitate achieving consensus on this principle as well as the definition and use of the term "therapeutic use" in the COP. The following options were proposed in CRD12:

- Option A: To retain Principle 13 as proposed. The definition of "therapeutic use" could then be retained as proposed.
- Option B: To combine Principles 8 and 13. The definition of "therapeutic use" could then be retained as proposed.
- Option C: To revise Principle 13. The definition of "therapeutic use" could then be deleted.
- Option D: To revised Principle 13. The definition of "therapeutic use" should then be revised.

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

32. The EWG Chair explained that this option corresponded to the current wording in the revised COP as shown in CX/AMR 21/8/5, Appendix I.

33. Delegations in favor of Option A indicated the following.

- The term "therapeutic use" was widely applied by countries to define treatment, control and/or prevention of diseases and as such it was important to retain this term in Principle 13 as proposed in Option A. This would also provide consistency with OIE documents and with the mandate of TFAMR and provide adequate flexibility to address animal and plant health within the One Health Approach.
- Option A clearly differentiated the use of antimicrobials for growth promotion from their use for animal/plant health purposes and, in conjunction with the other principles, in particular those related to the responsible and prudent use of antimicrobials, ensured that medically important antimicrobials should only be used for "therapeutic use" i.e. treatment, control or prevention.
- Option A was a self-standing, concise, precise and easy to understand principle, as opposed to Option C that included reference to other principles defined in the COP and introduced unnecessary complexity for the interpretation and operationalization of this Principle.
- Option A would not lead to improper use of antibiotics as it clearly described the conditions under which medically important antimicrobials could be used and provided clarity on the understanding of the term "therapeutic use".
- The COP had been extensively discussed and a significant amount of consensus had been achieved since the re-establishment of TFAMR. The revisions provided important advancements for foodborne AMR risk management, and a good balance in order to address the different needs, priorities and capacities of Codex Members worldwide. In particular, since the completion of TFAMR07, great efforts had been made to reach consensus on the remaining substantial issues concerning the definition of "therapeutic use" and related Principle 13.

- International standards such as Codex cannot accommodate all national and regional practices and legislations; however, the Codex procedures allowed Codex Members to enter reservations in order not to block the advancement of a Codex standard in the Step Procedure. Moving forward with Option A prevented further delay to the finalization of the COP and would also allow for more time to discuss and progress the GLIS.

34. Some of these delegations indicated their readiness to compromise on Option B while retaining Option A as their preferred Option. They could not support Option C as in their view it did not recognize the suite of therapeutic uses that might be necessary within the framework of responsible and prudent use of antimicrobials and the need to have an agreed overarching terminology that defined these options in the COP.

35. Observers supporting Option A for the reasons stated above also concurred with Option B as a compromise solution.

36. An observer supported Option A with the removal of the term "therapeutic use" from Principle 13 as treatment, control or prevention and the conditions under which they are applied were all defined in the definitions section and the relevant principles for the responsible and prudent use of antimicrobials (notably Principles 14 and 15) and therefore, the term "therapeutic use" was not necessary nor added any value to the concept raised in this Principle. This would also facilitate consensus as there were countries and regions that were concerned about this term being applied for uses other than treatment.

37. In expressing its support to Option A, the United States of America provided the following statement on Principle 13 regarding the retention of the term "therapeutic use" in this Principle:

- The concept of "therapeutic use" has been critical to progressing global stewardship by limiting use to purposes necessary to assure health *in contrast* to growth promotion.
- This was evidenced at the 2017 G7, when the Chief Veterinary Officers of Canada, Germany, Italy, France, the UK, Japan and the US included the term, **therapeutic use**, with the definition of treatment, control, and **prevention** in a document entitled, "A Common Approach on Definitions of **Therapeutic**, Responsible and Prudent Use of Antimicrobials.[6]
- The EU, and perhaps some other countries, have national legislation restricting certain uses in their territories and disease risks vary between countries and require different approaches to managing them.
- The term "therapeutic use" is relevant on a worldwide basis, and therefore makes sense to include in a Codex document. One region and the legislative agendas of a few countries should not dictate the strategy of how to reach our common global goals in Codex.
- It is imperative that Codex remain true to its mandate and not overstep its bounds into the purview of National Governments. It is equally important, that National Governments refrain from trying to use Codex as a means of promoting *their* views in areas not within the Codex mandate. Codex procedures do not call for **unanimity** to advance work; rather, they are **intentionally** designed to allow dissenting Members to register a reservation to allow work to advance.

38. The Delegation encouraged Codex Members who continued to have concerns to register a reservation, allowing the definition of "therapeutic use" to remain in the COP and to send it for final adoption to CAC.

Option B: Medically important antimicrobial agents should only be used for therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease) and be prescribed, administered, or applied only by, or under the direction of, veterinarians, plant/crop health professionals, or other suitably trained persons authorized in accordance with national legislation.

39. The EWG Chair explained that this Option combined Principles 8 and 13 as concerns had been expressed by certain Codex Members on the need to provide some additional advice to complement Principle 13 as described in Principle 8 and in the view of these countries this might be a compromise solution to overcome the issues raised by Codex Members on Option A and the proposed definition for "therapeutic use".

40. Delegations in favor of this Option noted that Principle 13 must be qualified to provide clarity and professional oversight on the specific circumstances under which medically important antimicrobials can be used and how they should be prescribed, administered or applied. It was noted that Principle 8 was more related to the specific use of medically important antimicrobials rather than their general use and should thus be better housed within a combined Principle 13 for the prudent and responsible use of antimicrobials in specific circumstances.

[6] https://www.salute.gov.it/imgs/C_17_notizie_3118_listaFile_itemName_0_file.pdf

<u>Option C</u>: Medically important antimicrobial agents should only be used for disease treatment or control/metaphylaxis and/or prevention/prophylaxis purposes and only under the conditions laid down in Principles 7-10, and 14 and 15.

41. The EWG Chair explained that in this Option the term "therapeutic purposes" was deleted and reference was only made to the different health based uses of medically important antimicrobials namely treatment, control or prevention and that the condition for such uses would be those laid down in Principles 7 through 10, 14 and 15.

42. Delegations in favor of Option C did not support Option A for the following reasons:

- There were still serious concerns with Option A as it extended the current definition of "therapeutic use" to cover "control" and "prevention" while this term was widely used for "treatment" only. This was in line with the definition of "therapeutic use" in the existing COP which refers to "treatment" only.
- The inclusion of "control", and in particular "prevention", under the term "therapeutic use" would encourage the use of antimicrobials, in particular medically important antimicrobials, for uses other than "treatment", notably for "prevention". This would compromise global efforts, including the aim of the current revised version of the COP, to contain and minimize AMR by limiting or reducing the use of antimicrobials for "prevention". This would therefore be inconsistent with the concept of prudent and responsible use of antimicrobials.
- The same discussion took place in OIE and there was no agreement to use the term "therapeutic use" to cover "treatment", "control" and "prevention" and an alternative term "veterinary medical use" was adopted to overcome the impasse. Delegations and observers in support of Option A may wish to consider a similar alternative to facilitate achieving consensus as Codex Members had invested lots of time and resources into the revision of the COP in order to finalize the document for adoption by CAC.

43. In view of the above, delegations in favor of Option C offered the following rational in support of this option:

- The key concepts contained in Option A remained the same, just without an overarching term, thus making it more acceptable to those countries having concerns that the term "therapeutic use" would be extended to uses other than "treatment".
- The proposed wording provided a more complete framework for the use of medically important antimicrobials and the conditions under which they should be used.
- "Treatment", "control" and "prevention" have already been defined and agreed upon in the revised version of the COP and therefore there was no need to retain the term "therapeutic use/purposes" in Principle 13 nor the revised version of the COP to avoid confusion around this term in view of the different interpretations of this term expressed by countries from different regions. In this regard, proposals had also been made to address the use of the term "therapeutic use" in the relevant sections of the COP in support of this approach.
- Although a broader definition of the term "therapeutic use/purposes" might have been agreed upon in other forums, they might not have had the same level of inclusiveness as TFAMR, where the variety of views expressed in favor of Options A or C by countries from different regions clearly indicated that it would be difficult to agree on a single international definition for the term "therapeutic use" covering "treatment", "control" and "prevention".
- If consensus could not be reached on the definition of "therapeutic use" in the revised version of the COP, the definition as currently stands in the existing COP should prevail and remain i.e. "therapeutic use" should only apply to "treatment". In addition, the concept of "therapeutic use" being applied for "treatment" only had received quite broad support by countries from different regions such as Europe, Asia and Africa.
- Option C thus provided a good balance between countries having concerns that "therapeutic use" should only apply to "treatment" and those who support the extension of this term to cover "control" and "prevention".

44. These delegations did not support Option B as this option also extended the definition of "therapeutic use/purposes" to cover "control" and "prevention" in addition to "treatment" so the same concerns raised for Option A remained for Option B. In addition, they did not favour combining Principles 8 and 13 as Principle 8 was a general principle and Principle 13 was reflecting a specific use; therefore Principle 8 should remain a stand-alone principle. A delegation indicated they could accept Option B as long as the reference to "therapeutic use/purposes" was removed from this Option and therefore from the COP.

45. They reiterated their preference for Option C as a compromise agreement and encouraged TFAMR to move forward and finalize the remaining sections in the COP in order not for further delay the completion of the COP in view of all the progress made so far to update risk management measures to contain and minimize foodborne AMR as part of the global effort to combat the threat of AMR.

Option C (revised): Medically important antimicrobial agents should only be used for disease treatment or control/ metaphylaxis and/or prevention/prophylaxis purposes.

46. In an effort to achieve consensus a simplified Option C to address comments on the need for principles to be stand-alone was proposed by removing the cross-reference to other principles (see paragraph XX). It was suggested that this revised option would still retain all the essential points in Option A while also giving the most flexibility for countries to have their own interpretation of the term "therapeutic use".

47. However, this option was not supported by members in favour of Options A or B who in indicating their willingness to compromise, noted that any alternative option needed to retain an overarching term encompassing treatment. prevention and control.

Option D: Medically important antimicrobial agents should only be used for veterinary medical use/phytosanitary use (treatment, control/metaphylaxis or prevention/prophylaxis of disease).

48. In view of the opposing views expressed in relation to Options A/B and C, the Chairperson invited TFAMR to consider Option D which replaced "therapeutic use/purposes" by an alternative term "veterinary medical use/phytosanitary use" noting that this was in line with the approach taken by OIE and also acknowledged plant health issues which were within the scope of the COP. The option would still retain the key concept in Options A, B and C that medically important antimicrobials should only be used for treatment, control and prevention.

49. The EWG Chair indicated that this was a proposal from the EWG Chairs took into account other terms that were used for "treatment", "control" and "prevention" in addition to "therapeutic use/purposes". The term "veterinary medical use" was in line with the OIE terminology and that a similar term was being proposed to cover plants/crops

50. A suggestion to combine option D with option B was supported by some delegations as an alternative Option D. However other delegations noted that they could not support this for the same reasons they could not support Option B, noting their concerns relating to combining Principles 8 and 13 remained (see paragraph XX).

51. Delegations generally expressed their willingness to compromise on Option D as presented while reiterating their preference for Options A/B or C.

52. Those delegations who expressed their support for Option A and/or B indicated that such a compromise would be subject to keeping a definition for "veterinary medical use/phytosanitary use" in the COP that would in turn allow the revision of the relevant provisions in Section 5 as appropriate. They re-emphasized that it was important to have a term that clearly differentiated between the use of antimicrobials for growth promotion and for animal/plant health and provided an overarching concept on the use of these treatments in the COP. This would also allow the necessary degree of flexibility and clarity when using this concept/practices to contain/minimize AMR .

53. Delegations also expressed their concern as to whether a similar interpretation for the term "veterinary medical use" as agreed by OIE was available from the IPPC for "phytosanitary use" and that this may need to be addressed in the definition of these terms for clarity and consistency with relevant OIE and IPPC texts.

54. Other delegations were of the view that with the text in Option D a definition was no longer required.

55. The Observer from OIE indicated that the concept in both Codex and OIE as per "veterinary medical use" were consistent although there might be some differences in the definition of the individual elements that conform to this term (i.e. treatment, control and prevention) which may originate from the different mandates of Codex and OIE and should not impact negatively on the definitions of these terms in the COP.

Options A, B, C and D: Other comments

56. The Russian Federation did not support any of the options offered for consideration because in their view, the options presented allowed for medically important antimicrobials to be used routinely for control or prevention of diseases, especially taking into account that the definition of medically important antimicrobials in the revised version of the COP included the list of antimicrobials of highest priority that are critically important to human health and so posing a serious risk to public health. The Delegation could thus not support the use of such critically important antimicrobials for routine use other than treatment.

57. The Russian Federation further noted that Principle 14 already addressed the use of medically important antimicrobials for prevention in well-defined circumstances as opposed to on a routine basis as currently stated in the aforesaid options.

58. The Russian Federation therefore reserved its position on any the options presented for consideration by TFAMR.

Conclusion

59. Based on the above considerations, TFAMR agreed to retain Option D as presented in CRD12 for Principle 13 and agreed to further consider the revised definition for the term "therapeutic use" and corresponding adjustments in Section 5 where such terms were used as appropriate. The Russian Federation expressed its reservation to this decision for the reasons explained in paragraph XX.

Section 3 – Definitions
Therapeutic use

60. Following agreement on Option D for Principle 13, and in recognition that for some members the agreement was dependent on the retention and revision of the definition of "therapeutic use" to refer to "veterinary medical use/ phytosanitary use" as well as the need to keep consistency between the proposed new terms and the corresponding ones used in OIE and IPPC texts, TFAMR considered a proposed definition.

61. The EWG Chair explained that reference to the OIE Terrestrial Animal Health Code had been included under the term "veterinary medical use" specifically the chapter on monitoring quantities and usage patterns of antimicrobial agents used in food-producing animals. In addition, to ensure consistency, a reference to the IPPC Glossary of Phytosanitary Terms had been added to the term "phytosanitary use" that contained a variety of terms recalling treatment, control and prevention although there was not a specific reference to the term "phytosanitary use"

62. Delegations who had expressed support for Option C for Principle 13 reiterated their view that this definition was not needed as the content was already embedded in Principle 13; the term "therapeutic use" was only used in a few places in the COP where a more appropriate term could be used in replacement; definitions in Codex texts should only be used if the term was not understood by reading the text in context; and the three definitions already defined (treatment of disease, control of disease/metaphylaxis and prevention of disease/prophylaxis) provided sufficient clarity and should be used throughout the COP when relevant. However, in the spirit of compromise, delegations could agree to the inclusion of the definition with footnotes referencing OIE and IPPC.

63. Delegations in support of Options A or B reiterated the need for such a definition to provide for clarity and flexibility in the application of these treatments throughout the COP and to clearly differentiate between use of antimicrobials for growth promotion and animal/plant health.

64. TFAMR had a lengthy discussion on a proposal to include an additional footnote 5 in the definition of "veterinary medical use/phytosanitary use" to recognize the term "therapeutic use". The proposed text for the footnote was: 5 "Also recognized as therapeutic use in some jurisdictions/organizations".

65. The United States of America strongly recommended inclusion of a footnote in the definition of veterinary medical use/phytosanitary use to recognize that the term therapeutic use is an established and widely used alternate term for describing the administration of antimicrobial agents for treatment, control, and prevention of specific diseases in food-producing animals and plants/crops in many jurisdictions. Many national and professional bodies around the world have used the term for many years and using clear language is critical to progressing global antimicrobial stewardship to limiting use to purposes necessary to assure health, in contrast to production purposes including growth promotion. Failure to acknowledge the term therapeutic use in this guidance from Codex risks making it out-of-step with antimicrobial stewardship programs in many jurisdictions. Recognizing the significant amount of support for this term throughout the plenary and in various electronic and virtual fora, the Delegation solicited TFAMR to acknowledge its use through incorporation of this footnote.

66. Delegations who were in favour of Option A for Principle 13 supported this statement. They also noted that the addition of footnote 5 would acknowledge different practices applied by countries and organizations worldwide and so would ensure inclusiveness and consistency and would also provide for clarity and flexibility in the application of the provisions in the COP which would in turn facilitate its uptake by Codex members and other relevant stakeholders and promote global harmonization.

67. The footnote could also refer to organizations in addition to some jurisdictions to facilitate consensus.

68. Observers supporting inclusion of this footnote highlighted the importance of global consistency and understanding of a well-recognized definition for the reasons explained above. Exclusion of the footnote referencing the term, "therapeutic use", could therefore create unnecessary confusion globally. The divergent views expressed on the definition of the term "therapeutic use" indicated the need to have clarity on this term and that the additional footnote provided such clarity and consistency for a definition that is widely used across countries and regions.

69. Delegations against the addition of this footnote indicated the following:

- The COP was a global document and as such should not make reference to 'some national legislation or jurisdictions'. This would not preclude countries to use other definitions as more suitable to their national or regional practices.
- The inclusion of this footnote in a global code of practice brings further confusion to the concept of "therapeutic use" as it does not recognize that in some jurisdictions the term "therapeutic use" refers to treatment only and therefore does not contribute to attainment of the goal of harmonization of risk management practices to contain and minimize foodborne AMR.
- There might be instances where the term "therapeutic use" could envisage treatment, control and prevention, however, such instances were not related to the prudent and responsible use of antimicrobials to contain and minimize AMR.

70. In view of the limited time available and in order to allow progression of the COP in the Step Procedure, TFAMR agreed to include the three footnotes in the definition of veterinary medical use/phytosanitary use and add organizations to footnote 5 for inclusiveness.

71. The EU and its Member States, Canada, Colombia, Jamaica, Kazakhstan, Morocco, Norway, Russian Federation and Uganda expressed their reservation to the inclusion of footnote 5 for the reasons described in paragraph XX. In addition, Canada and Norway provided the following statements:

72. Canada noted its reservation to the inclusion of Footnote 5 in this document. The term "therapeutic" is a synonym for treatment in the current Code of Practice (CXC 61- 2005), and the inclusion of footnote 5 in this draft revised code means that the term "therapeutic" could be interpreted by certain jurisdictions as a synonym for "veterinary medical use" which encompasses treatment, control and prevention. The inclusion of footnote 5 introduces confusion and could favour continued non-responsible uses of medically important antimicrobials in animals."

73. Norway indicated that, in their view, the additional footnote added to the confusion on how the term "therapeutic use" is interpreted globally, because not all countries interpret it as stated in this footnote. Norway's interpretation of the term "therapeutic use" is in line with the definition in the original CXC 61/2005 as adopted in 2005 where "therapeutic use" is defined as "*Disease treatment/Therapeutic use- Treatment/Therapeutic Use refers to use of an antimicrobial(s) for the specific purpose of treating an animal(s) with a clinically diagnosed infectious disease or illness.*" Norway therefore reserved their position on the inclusion of footnote 5.

Revision of the sections including the term "therapeutic use".

74. Following the decision on the definition for veterinary medical/phytosanitary use, the EWG Chair indicated that the following sections needed to be addressed by TFAMR:

Section 5.1 - Responsibilities of the competent authorities
Knowledge gaps and research
Paragraph 34, first bullet

75. TFAMR agreed to refer to "dosage regimens" as opposed to "~~therapeutic~~ regimens" as a more general and appropriate term. In addition, TFAMR agreed to include a reference to "veterinary medical/phytosanitary use" to reflect the revised terminology agreed upon by TFAMR which provided greater specificity of the type of regimen and strengthened the One Health Approach by making it clear that the knowledge gaps in need of research applied to both food producing animals and plants crops.

76. Views were expressed that "dosage regimes" included all treatments and therefore the reference to veterinary medical/ phytosanitary use was not necessary.

Section 5.4 – Responsibilities of veterinarians and plant/crop health professionals
Paragraph 52

77. TFAMR agreed to refer to "veterinary practice" as opposed to "~~therapeutic~~ practice" as the term "therapeutic" was not relevant for this provision since the appropriate use of medically important antimicrobial agents should be based on clinical knowledge and judgment.

78. In reply to a proposal to refer instead to "veterinary medical use", to be consistent with principle 13, it was noted that this provision did not relate to the use of this term and that "veterinary practice" would be an appropriate term based on the context of the paragraph.

Paragraph 54
First bullet, third sub-bullet

79. TFAMR agreed to retain the term "therapy" as it did not refer to "therapeutic use" nor any other use.

Paragraph 54
Last bullet

80. TFAMR agreed to refer to "dosage regimen" as opposed to "~~therapeutic~~ regimen" as more appropriate and general.

Off-label use
Paragraph 55

81. TFAMR agree to refer to "dosage regimen" as opposed to "~~therapeutic~~ regimen" as more appropriate and general.

82. In line with paragraph 34, a proposal was made to include the reference to "veterinary medical/phytosanitary use"; however, concerns were expressed that this section referred to off-label use and such an inclusion may open the door to preventive uses that were off-label which would not be appropriate. It was further noted that the term "dosage regimen" was the term that currently applied in the existing COP.

Revision of other sections

Section 5 - Responsible and prudent use of antimicrobial agents
Section 6 - Practices during production, processing, storage, transport, retail and distribution of food

83. TFAMR noted additional minor amendments had been proposed in these sections through the written comments; however, consistent with its decision not to reopen provisions that had been extensively discussed and agreed upon at previous sessions of TFAMR, the Task Force agreed not take up any changes to these sections.

84. In addition, TFAMR endorsed all changes that had been made by the virtual meeting of the Working Group (WG) that met in mid-June 2021 on Section 5.5 - Responsibilities of food animal and plant/crop producers, paragraph 64 as described in the report of the virtual meeting of the WG (CX/AMR 21/8/5).

Section 7 – Consumer practices and communication to consumers

85. TFAMR noted no comments on this section.

Status of the COP

86. TFAMR agreed that it had completed the revision of the COP, Sections 1-7, and that no issues remained for discussion.

Conclusion

87. TFAMR agreed to forward the revised Code of practice to contain and minimize foodborne AMR (CXC 61-2005) to CAC44 for adoption at Step 8.

88. TFAMR recalled the reservations expressed by the Russian Federation on Principles 12 and 13, Thailand on Principle 12 and the EU, Canada, Colombia, Jamaica, Kazakhstan, Morocco, Norway, Russian Federation and Uganda on footnote 5 to the definition on veterinary medical use/phytosanitary use with the rationale provided in paragraphs XX, XX, XX.

GUIDELINES ON INTEGRATED MONITORING AND SURVEILLANCE OF FOODBORNE ANTIMICROBIAL RESISTANCE (At Step 4) (Agenda Item 6)[7]

89. The Chairperson, in introducing the item, outlined his ambition to finalise the Guidelines at this session despite the challenges, and requested the collaboration of all delegates to achieve this ambitious goal. Although still at Step 4, the Chairperson noted that the Guidelines had been extensively discussed at TFAMR05 and TFAMR06, at a physical working group in advance of TFAMR07 and since then there had been a number of opportunities to provide input to the Guidelines through written comments, the electronic working group (EWG), a webinar and a virtual meeting of the working group, where five sessions were dedicated to discussion of the Guidelines. To facilitate progress, the Chairperson noted his intent to follow the same approach as the virtual meeting of the working group, with the Chair and co-chairs of the EWG presenting proposed revisions to the Guidelines, based on the comments received in response to CL 2019/83/OCS-AMR together with the rational for those proposals. He further noted that while the Task Force would review all of the Guidelines he would focus discussions on those areas where consensus was yet to be reached. The Task Force agreed to use a series of CRDs prepared by the EWG co-chairs in response to the written comments as the basis for discussions (CRD2 – Sections 1-7; CRD13 and CRD14 – Section 8; CRD11 – Section 9; CRD15 - principles and footnote, CRD16 – Section 10).

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7 CL 2019/83/OCS-AMR; CX/AMR 21/6/8; CX/AMR 21/6/8-Add.1 (Australia, Brazil, Canada, Chile, China, Colombia, Costa Rica, Cuba, Ecuador, Egypt, European Union (EU), Honduras, Indonesia, Iraq, Japan, Malaysia, Norway, Paraguay, Switzerland, Thailand, Uruguay, USA, Consumers International, International Feed Industry Federation and International Union of food Science and Technology); CRD2 (Revised draft guidelines on integrated monitoring and surveillance of foodborne AMR prepared by the Chair and co-chairs of the EWG); CRD3 (United Kingdom); CRD4 (HealthforAnimals); CRD5 (Kenya); CRD6 (Nigeria); CRD7 (Ghana); CRD8 (Philippines); CRD9 (Indonesia); CRD10 (Morocco); CRD11 (Section 9); CRD13 (Sections 8.1 to 8.3); CRD14 (Sections 8.4 to 8.6); CRD15 (Principles and footnotes); CRD16 (Section 10); and CRD17 (revised GLIS)

90. The Netherlands, as Chair of EWG, assisted by two of its co-chairs, Canada and New Zealand, introduced the Guidelines, and highlighted the extensive efforts made since TFAMR07 to progress the Guidelines. The EWG Chair noted that the EWG Co-chairs had attempted to address all the written comments received and would be presenting their proposals through a series of CRDs with the aim of achieving consensus and finalising the guidelines. In addition the EWG Chair noted that the Chair and Co-chairs had tried to provide flexibility and had included paragraphs at the beginning of sections 8 and 9 to recognize the variations in the national context and resource availability and thereby highlight that integrated monitoring and surveillance may vary between countries. In addition some editorial corrections, and several amendments to improve technical accuracy, clarity and consistency within the Guidelines had been made. Delegations expressed their appreciation for the extensive work of the Chair and Co-chairs of the working group, acknowledged the huge progress that had been made, and appreciated the continuing efforts of the EWG chair and o-chairs to find consensus on the outstanding issues and facilitate completion of the Guidelines.

91. In the course of the discussions the Chairperson on several occasions asked for the collaboration and support of delegations to work together towards completion of the Guidelines at this session of TFAMR, noting that this was the last scheduled session of TFAMR and recalling the requests from CCEXEC and CAC43 to make every effort to complete this task. The Chairperson considered it was his duty, as well as that of delegates, to make every effort to facilitate completion of the work, including the provision of and participation in additional discussion time, and reminded delegates that given the urgency in addressing AMR, discussions could not continue endlessly in an attempt to develop the perfect Guidelines. Rather there was a need to find consensus and finalise Guidelines that were good enough to support countries in their efforts to tackle AMR. This was reiterated by a number of delegations who noted that; the longer it took to agree the Guidelines, the more real world opportunities to tackle AMR that would be missed; finalising a consensual Guidelines document during this Task Force would make more impact in the fight against AMR than delaying work in an effort to perfect the Guidelines; and the importance of working together with the shared ambition to tackle AMR to achieve as much as possible during this session of TFAMR.

92. On the final day of discussions the Representatives of WHO and FAO lauded the progress made by TFAMR8, supported the Chairperson's ambition to complete the work and urged delegates to use the remaining time to bring the Guidelines to their conclusion. In addition the Representative of WHO alerted delegates to a statement[8] of the Global Leaders Group on Antimicrobial Resistance congratulating the efforts of TFAMR, highlighting the importance of their achievements to promote and further improve global food safety and food security based on science and encouraging TFAMR to complete both texts so that they could be sent to CAC44 for final adoption.

93. For the purposes of the report the paragraph numbers reflect those of the tracked change version of the Guidelines (CRD17).

Section 1 - Introduction

94. TFAMR agreed on paragraphs 1, 5 to 8 and 11 to 13 as presented in CRD2 and further agreed with the proposal to move paragraph 2 which included a description of “Antimicrobial Use (AMU)” to Section 9 of the Guidelines and added a footnote to paragraph 3 to direct the readers of the Guidelines to that description in Section 9.

95. There was a proposal to include the words “and/or sales data” immediately after AMU, in paragraph 3 and elsewhere throughout the guidelines for the purposes of clarity as some delegations considered there was confusion around the terms, antimicrobial use and sales data. Others considered that AMU was adequate as it was widely understood to also include sales data. Following the revision of Section 9 where a new comprehensive description of antimicrobial use (AMU) was developed including a description of what sales data represented, it was agreed that there was no longer any need to include the words “and/or sales data” in paragraph 3 or elsewhere in the Guidelines in conjunction with the term AMU .

96. Some delegations highlighted the importance of ensuring the guidelines were sufficiently flexible to take into consideration the different levels of capacities, expertise and resources in Member Countries. While recognizing the progress made on this, these delegations noted that it may be necessary to add further flexibility in certain parts of the Guidelines. In the Introduction a number of amendments were made to further enhance the flexibility for members who would subsequently apply the Guidelines including: removal of the brackets from around the words "where appropriate" in paragraph 9; adding the word "or" after "and" in paragraph 10 such that it referred to humans, animals and/or plants/crops, and the inclusion of the word 'Ideally' at the beginning of paragraph 4 to highlight the aim of integrated monitoring and surveillance, while allowing flexibility for the various components to be developed as resources and expertise permit.

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[8] Available at https://cdn.who.int/media/docs/default-source/antimicrobial-resistance/amr-gcp-tjs/glg-statement-on-codex-guidelines-and-code-of-practice-en.pdf?sfvrsn=1ab899f6_11

97. An Observer suggested removal of the term "unjustified" as a descriptor to trade barriers in paragraph 11 as in their view it was a subjective term. However, one Member recalled that this had been extensively discussed and that measures to address public health could create justified barriers to trade, therefore it was important to make a distinction between those and unjustified trade barriers.

Section 2 - Scope

98. There were extensive discussions on paragraph 14 of the Scope and whether or not AMU should be retained therein.

99. Those in favour of retaining AMU noted that AMU was an integral part of an integrated monitoring and surveillance programme; that the scope had been discussed at previous sessions of TFAMR and AMU retained; its inclusion was in line with the terms of reference for the development of the Guidelines, and that AMU was a component of integrated surveillance of AMR in other international documents such as those of the WHO AGISAR.

100. Those delegations proposing to remove AMU from the scope considered that its inclusion in the scope was inconsistent with the title of the Guidelines; its deletion from the scope did not equate to removing it from the Guideline as its the importance would still be addressed from the perspective of national foodborne AMR programmes but with a more appropriate balance and the provision of high level or overarching guidance in Section 9 and other relevant parts of the document.

101. Following agreement in Section 9 on a description for AMU, it was agreed to retain AMU within the scope.

102. TFAMR agreed with paragraphs 15 and 16 with a small edit to paragraph 15 changing "would" to "may" for increased flexibility.

103. TFAMR discussed paragraph 17 with the objective of ensuring clarity on what biocides were included in or excluded from the Guidelines. A concern was raised by one delegation that the words "Antimicrobials used as" to qualify biocides was confusing and it was proposed to delete these words since biocides were already defined within Codex (CXC 53/2003) and it could be interpreted that if certain antimicrobials were used for what was considered a biocidal function e.g. streptomycin, they would not be covered by this Guideline. Other Members were of the view that the current text was sufficiently clear and since the focus of the Guidelines was on antimicrobials in terms of resistance and use it was logical to focus here on biocides used as antimicrobials since the description of biocides was very broad. It was also considered whether to replace "Antimicrobials" with "Antimicrobial Agents", which, unlike "Antimicrobials" was defined within the Guidelines, but there was no agreement on that proposal. As there was general agreement with the original text, including "Antimicrobials", rather than "Antimicrobial Agent" which had a specific definition in the context of this Guideline, TFAMR agreed to retain the paragraph as "Antimicrobials used as biocides……".

Section 3 - Definitions

104. There were no changes to the definitions as presented in CRD2, only a request t to ensure that common definitions would be aligned with the definitions in the COP.

Section 4 - Principles

105. TFAMR agreed with Principles 2, 3, 5, 7 and 8 as presented in CRD2.

Principle 1

106. Some delegations expressed concerns with regard to the proposed wording for Principle 1 noting that it did not recognize the broader nature of a One Health approach and that it was important to ensure flexibility for those that could not immediately apply a One Health approach to monitoring and surveillance. Others noted that it was important to maintain the linkage to a One Health approach, which is widely recognised as key to addressing cross-cutting issues such as AMR.

107. Taking the different views into consideration the EWG Chair and Co-chairs made a new proposal as follows: *"A One Health approach should be applied whenever possible and applicable when establishing monitoring and surveillance programmes for foodborne AMR; contributing to the food safety component of such an approach"* . Considering it provided flexibility while still taking the One Health approach into account and recognizing that monitoring and surveillance of foodborne AMR were only part of a broader One Health approach, TFAMR agreed with this revision of Principle 1.

Principle 6

108. Some delegations were of the view that Principle 6 was not consistent with Section 6.1 of CXL 77/2011 and proposed to replace "foodborne AMR issues" with "AMR food safety issues" and the description of that in CXL 77/2011. Others noted that CXL 77/2011 extensively referred to foodborne AMR and hence there was no inconsistency, and referring to AMR food safety issues might be premature as monitoring and surveillance was key to identifying such issues.

109. As a compromise the principle was revised to cover both foodborne AMR issues and/or AMR food safety issues. In addition reference was made to taking national priorities into account at the end of the principle to highlight the reality of what happened at country level.

Principle 9

110. TFAMR extensively discussed whether the concept of data sharing should be deleted from Principle 9. The Chair of the EWG recalled that this issue had been subject to considerable comment and discussion and that the proposed text was a compromise based on concerns raised earlier, noting that the current version had been softened to refer to "facilitating sharing of data" and did not infer any obligation to share data.

111. Delegations that proposed removal of the reference to data sharing noted that this concept should not be included in Codex texts as it was a decision of countries on whether or not they wanted to share data.

112. Those in favour of retaining this concept recalled that the original project document indicated that the purpose of the Guidelines made reference to facilitating the "….multisectoral exchange and analysis of data from different areas, countries and regions…" and removal of the concept of data sharing would be inconsistent with the agreed purpose of the document. In line with the original project document TFAMR agreed to replace data sharing with "multisectoral exchange and analysis of data". In addition TFAMR agreed to retain reference to national priorities in the principle and replace "strive" with "aim" at the beginning of the principle to enhance flexibility; and to retain the concept of data comparability which was considered important as a basis for any data exchange and analysis.

Section 5 - Risk based approach

113. TFAMR agreed with the text as proposed in CRD2 including the deletion of paragraph 24.

Section 6 - Regulatory framework, policy and roles.

114. TFAMR agreed with paragraphs 25, 26 and 28 as proposed in CRD2. Risk assessment and risk management were replaced by the term risk analysis at the end of paragraph 27 for completeness. Similar to discussions on principle 9, concerns were expressed with regard to making reference to sharing of data in this paragraph. FAO and OIE informed TFAMR that while they encouraged countries to share data, it was up to countries to decide whether or not they did so; nevertheless the tools developed at international level could facilitate data collection, analysis and management at the local level. Some delegations also highlighted the importance of encouraging data sharing and noted that the language in the bullet provided much flexibility. There was no agreement to retain reference to sharing of data in a generic sense as some delegations considered it could be perceived as being the raw unanalysed data and as a compromise TFAMR made the sentence more specific in terms of the type of data, who it could be shared with and it voluntary nature by making reference to "sharing monitoring and surveillance results with international organizations on a voluntary basis".

Section 7 - Preliminary activities for the implementation of an integrated monitoring and surveillance program(s) for foodborne AMR

115. TFAMR agreed with paragraphs 29 and 29bis as presented in CRD2, with the removal of "may" in paragraph 29 to recognize that pilot studies do provide valuable insights into the design of monitoring and surveillance program(s).

116. There were a range of views expressed on paragraph 29ter and Figure 1 with some delegations noting that this provided an overview of the guidelines and its link to other Codex texts on AMR (CXG 77-2011 and CXC 61-2005) thereby adding value to the Guidelines and facilitating their application and use. Other delegations considered that the Figure could lead to confusion in application of the Guidelines. Consideration was also given as to whether the Figure could be made available in an Annex or as a separate document on the Codex webpage but such approaches were not supported by some delegations, since the content of the figure was not discussed and agreed. The EWG chair clarified that the Figure had been amended taking into consideration written comments received. In the interests of completing the Guidelines TFAMR eventually agreed to delete para 29ter and Figure 1, although delegations that had been in favour of its retention expressed disappointment at their exclusion.

117. TFAMR agreed with paragraphs 30 to 35 and 38 to 41 as proposed in CRD2 with editorial changes to paragraphs 32 and 40. Paragraph 36 was revised with the inclusion of expansion before integration as it was considered that in many countries monitoring and surveillance activities needed to be expanded before they could be integrated. While some concerns were expressed on the flexibility of paragraph 37, the chairperson noted that the inclusion of 'consider' provided sufficient flexibility and so the paragraph was agreed as proposed except with the replacement of 'can' by 'could' in the last sentence.

Section 8 - Component of integrated monitoring and surveillance program(s) for AMR

118. TFAMR agreed with paragraphs 41bis to 43 as presented in CRD13 with an amendment in paragraph 43 in response to requests from some delegations for more flexibility and some language edits for clarity.

Section 8.1 - Sampling design

119. TFAMR agreed with the text as proposed in CRD13.

Section 8.2 - Sampling Plan

120. TFAMR agreed with the text as proposed in CRD13 with the inclusion of an additional bullet in paragraph 48, to address opportunities to collect metadata, and the deletion of "biosafety" from the same paragraph. Although one delegation supported the retention of "biosafety" for completeness and accuracy in terms of laboratory standard operating procedures, others expressed a concern that "biosafety" had multiple meanings and these often differed between countries and its meaning in the context of the Guidelines would therefore not be clear.

Section 8.3 - Sample sources

121. TFAMR agreed with the text as proposed for paragraphs 51 and 52. In doing so TFAMR considered a concern raised regarding the inclusion of the term 'scientifically relevant' in paragraph 51 with one delegation indicating that its inclusion could limit the consideration of different indirect food exposure pathways considered by countries. It was highlighted by others that Codex aimed to be science based and as this was a guideline it was appropriate to provide guidance that helped direct the user to those areas where they would get optimal investment on their return. Hence "scientifically relevant" was retained here and elsewhere in the Guidelines.

122. TFAMR extensively discussed paragraph 53 and generally supported the proposals made in CRD13. In response to a question raised on the potential duplication with OIE text it was clarified that Codex texts were intended to be stand-alone documents in line with the mandate of Codex; there should be consistency with other relevant international standards such as those of OIE; overlaps may be unavoidable but there should not be any potential contradictions, which would impact their ultimate application. TFAMR made several further revisions to the paragraph including:

- Removal of lairage as a possible sampling point as it was not considered a priority for sampling and the term may not be well understood;
- Removal of reference to both domestically produced and imported food sources for consistency with the COP as the COP does not distinguish between these food sources; However, some concern was expressed regarding this deletion as the distinction may be relevant especially for integration purposes and in terms of ensuring the guidance remained equally relevant to those countries highly dependent on imported foods. The EWG Chair also noted that the purpose of having a distinction here was different to that of the COP as it would allow a country to better distinguish the source or AMR and thereby facilitate use of the data.
- Replacement of animal products and produce with food products to improve clarity on the type of samples that may be taken. A concern was raised that the use of the term raw produce was too broad for the guidelines but it was noted that there was sufficient linkage to food to prevent misunderstanding in this regard.

123. A discussion on the replacement of "species" with "sources" in the chapeau of paragraph 53 led to the retention of the original text as it was considered that introducing "sources" changed the meaning of the sentence and lead to ambiguity on the type of samples to be collected. There were also proposals to delete "feed", in addition to feed ingredients, which had already been deleted in CRD13, as an example of what could be sampled at farm level and concern was raised by an observer on the removal of the footnote on feed, noting that sampling of feed at the farm level was not necessarily representative of feed due to the risk of cross-contamination. Others highlighted the importance of making direct reference to feed as an important part of the food chain and the EWG Chair noted that a footnote suggesting that cross-contamination was only relevant to feed was inaccurate and could be misleading. Reference to feed was thereby retained in the paragraph.

Section 8.4 - Target microorganisms and resistance determinants

124. TFAMR agreed with the text as proposed in CRD14.

Section 8.5 - Laboratories

125. TFAMR agreed with the text as proposed in CRD14.

Section 8.6 - Antimicrobial susceptibility testing

Section 8.6.1 - Methods and interpretative criteria

126. Some delegations raised concerns regarding the inclusion of genotypic methods in paragraph 61 as there were currently no internationally validated standards for genotypic methods and therefore they proposed deletion of such methods from this paragraph. Others were of the view that genotypic methods were already being used and internationally validated standards were also in preparation, hence its inclusion ensured that the Guidelines would not be quickly outdated.

127. As a compromise it was agreed to remove reference to both phenotypic and genotypic methods in the paragraph and focus on the importance of using methods that were standardized and validated. This also allowed maximum flexibility for the future, noting that method development may go beyond phenotypic and genotypic but the overarching guidance regarding standardization and validation remained the same. Due to the more generic nature of the sentence following its revision, it was also moved above the subheading 8.6.1.

128. One Delegation expressed concern with regard to the use of the term "consistently' in para 64 noting that it may not always be necessary or possible to apply EUCAST tables or CSLI standards, as other appropriate standards may also exist or may be developed in the future or there may be a gap in the EUCAST or CSLI standards. The Chairperson recalled the flexibility already provided in the paragraph such as through the last sentence and so no further changes were made to the text.

129. The remaining paragraphs in the section were agreed as proposed in CRD14.

Section 8.6.2 - The panel of antimicrobials for susceptibility testing

130. TFAMR agreed with the text as proposed in CRD14 for paragraphs 68 and 69 and included an amendment in paragraph70 to enhance flexibility of the provision.

131. A proposal to include reference to antimicrobials of importance to animal health in the context of prioritizing antimicrobials to be tested in paragraph 71 was considered. There were a range of views on this with some noting that within the national context this can be an important consideration while others expressed concern at further broadening the considerations for prioritization of the antimicrobials to be tested. Considering the scope of Codex was consumer protection rather than animal health and noting the goal of the paragraph was to promote use of existing lists such as those on Medically Important Antimicrobials for human health it was agreed to retain as proposed in CRD14. In addition the last sentence was amended for clarity.

Section 8.6.3 - Concentration ranges of antimicrobials

132. TFAMR agreed with the text as proposed in CRD14.

Section 8.6.4 - Molecular testing

133. TFAMR agreed with the text as proposed in CRD14 and additionally moved paragraph 76 to immediately after paragraph 73 for improved flow, and added "antimicrobial resistance determinants" as an additional example in paragraph 77 for further clarity.

Section 8.7 - Collection and reporting of resistance data

134. TFAMR agreed with the text as proposed in CRD14 with a couple of amendments including the deletion of 'how' in bullet b of paragraph 78 as it was considered duplicative of point a and the rearrangement of the wording in paragraph 81 for clarity.

Section 9 - Components of integrated monitoring and surveillance program(s) for AMU

135. Having agreed to move the description of AMU from the Introduction to Section 9, TFAMR reviewed the existing description and considered a new proposal from a Member, who indicated that the aim was to make it more accurate with regard to use and/or sales data, to increase clarity for relevant stakeholders, and to ensure it did not conflict with the OIE, while also remaining flexible towards plant health purposes. There was general support for the new proposal although it did raise the issue of the use of the abbreviation AMU and what it would actually stand for: "antimicrobials use" or "antimicrobials intended for use". A proposal was made by one delegation to delete the term AMU from the description and ultimately from the Guidelines to avoid the confusion, that in their view, was caused by this term. Others noted that AMU was a widely used and understood term across the international organizations as well as in many countries and in that context it would be appropriate to retain it. TFAMR agreed with the new description of AMU and to retain the abbreviation AMU in the description.

136. One delegation continued to express concerns regarding the use of the abbreviation of AMU. To address their concern, they proposed, as a compromise, some additional text to clarify the difference between sales data and use data and an illustrative example of this. There was general support to the proposed clarifying sentence with the addition of a reference to plants/crops. Concerns were however expressed with regard to the proposed illustrative example which was considered by some delegations as exemplifying poor practice. TFAMR agreed to inclusion of the proposed clarifying sentence on antimicrobial sales data with deletion of the example. With this addition the revised extended description of AMU was agreed.

137. TFAMR agreed with the remaining paragraphs in the section as proposed in CRD11, with the deletion of 'sales/use data' in paragraph 81quater, noting the agreed revised description of AMU in this section meant such text was no longer needed.

Section 9.1 - Design of an integrated monitoring and surveillance program(s) for antimicrobial agents intended for use in food producing animals or plants/crops

138. Given the challenges faced and resources required to collect AMU data at the farm level, paragraph 84 was revised to recognize the challenge and provide more clarity and flexibility to the end user of the Guidelines. In addition 'or' was added in points c and e of paragraph 86 to give more flexibility according to the available capacity/resources at country level.

139. Clarity was sought as to the meaning of measurement units and indicators in paragraph 85 and it was agreed to add a footnote to provide further explanation of these terms, one of which was proposed by the EWG co-chairs and presented in CRD15. The need for greater flexibility such that countries would not always have to apply both measurement units and indicators and to recognize that in some cases qualitative approaches may be used was discussed. Some delegations noted that the footnote did not sufficiently address the concerns around clarity and flexibility. The aspect of qualitative approaches was therefore subsequently included in Section 9.3. The option not to require use of both measurement units and indicators was captured by inserting "and/or" between these two terms, thereby providing the requested flexibility.

140. TFAMR agreed with the remaining paragraphs in the section as proposed in CRD11.

Section 9.2 - Sources of sales/use data

141. TFAMR agreed to change the title to "Sources of AMU data" to reflect the revision that was made to the description of AMU and agreed with the paragraph text as proposed in CRD11.

Section 9.3 - Collection and reporting of AMU

142. Some delegations expressed concerns regarding the use of the numerator and denominator in this section, and the challenges users of the Guidelines may face in trying to understand these terms. Several suggestions were made to address these concerns, including through inclusion of an introductory chapeau or an explanatory footnote. On reviewing the proposed footnote from the EWG co-chairs as presented in CRD15 concerns remained that more flexibility may be required for countries who still needed to begin collection of AMU data. Concerned delegations noted that it was critical that the section be sufficiently flexible to consider qualitative as well as quantitative date. Other delegations, that supported the existing text, noted that incorporation of qualitative options reduced the technical accuracy of the section and that it was not clear what was meant by qualitative data. In the spirit of compromise paragraph 90 was revised to include the potential for the numerator to be either qualitative or quantitative in nature. An example of a qualitative numerator was included for clarity. Further flexibility was introduced in paragraph 92 to acknowledge that a denominator may not always be used, particularly in the case of qualitative data collection.

143. With the aim of further increasing flexibility reference was made to the relevance to food production in a country in paragraph 92. TFAMR agreed with the remaining paragraphs in the section as proposed in CRD11.

Section 10 - Integrated analysis and reporting of results

144. TFAMR agreed with the changes proposed in CRD16 with some amendments to paragraphs 99, 101 105 and 107 to increase the flexibility of the provisions.

Section 11 - Evaluation of the integrated monitoring and surveillance program(s)

145. TFARM agreed with the text in this section as presented in CX/AMR 21/6/8 with several small amendments to improve clarity.

Section 12 - Training and capacity building

146. TFAMR agreed with this section as presented in CX/AMR 21/6/8 with minor amendments including the addition of "on different aspects of the monitoring and surveillance program(s) are" to paragraph 118 for clarity. A proposal to combine paragraphs 117 and 118 was rejected since the levels and priority of training for national authorities compared to stakeholders can vary substantially and therefore the separate paragraphs were retained in recognition of such differences.

Status of the Guidelines

147. TFAMR agreed that it had completed its work on the development of Guidelines on Integrated Monitoring and Surveillance of Foodborne AMR and that there were no outstanding issues for discussion.

Conclusion

148. TFAMR agreed to forward the Guidelines on Integrated Monitoring and Surveillance of Foodborne Antimicrobial Resistance to CAC44 for final adoption at Step 5/8 with the omission of Steps 6 and 7 (Appendix III).

OTHER BUSINESS

149. The TFAMR noted that there was no other business to discuss.

150. Delegations commended the finalization of the COP and the GLIS, which would provide countries useful guidance to contain and minimize foodborne AMR in order to attain the goal of minimizing risks to human health. They unanimously acknowledged the leadership of the Chairperson, Dr Yong Ho Park, the assistance of the Chairs of the EWGs, Dr Donald Prater (USA, COP) and Dr Rosa Peran (The Netherlands, GLIS), their Co-chairs and the Codex Secretariat, in bringing this second round of TFAMR to a successful completion in accordance with the mandate given by CAC.

151. The Chairperson additionally acknowledged the huge efforts of delegates and their willingness to compromise in order to compete this work. He further highlighted the important follow-up actions that would be required to ensure the successful implementation of the COP and GLIS.

152. TFAMR noted the proposal of one delegation to acknowledge the importance of Codex, OIE and IPPC in developing coherent texts to support efforts to address AMR and to urge member countries to advocate that IPPC prioritize the development of guidance on the use of antimicrobials for phytosanitary purposes.

DATE AND PLACE OF NEXT SESSION

153. TFAMR confirmed that it had completed its work and fulfilled the mandate given by CAC, therefore no further meeting would need to be planned.