

# CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: [codex@fao.org](mailto:codex@fao.org) - [www.codexalimentarius.org](http://www.codexalimentarius.org)

REP21/AMR

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEX ALIMENTARIUS COMMISSION**

**44<sup>th</sup> Session**

**Virtual**

**8 – 18 November 2021**

**REPORT OF THE EIGHTH SESSION OF THE**

**CODEX *AD HOC* INTERGOVERNMENTAL TASK FORCE ON ANTIMICROBIAL RESISTANCE**

**Virtual**

**4-9, 13 and 16 October 2021**

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## SUMMARY AND STATUS OF WORK

Responsible Party	Purpose	Text/Topic	Code	Step	Para(s)
CCEXEC81 CAC44 Members	Critical Review Adoption at Step 8	Revised <i>Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance</i> (CXC 61-2005)	N28-2917	8	89
CCEXEC81 CAC44 Members	Critical Review Adoption at Step 5/8	Guidelines on Integrated Monitoring and Surveillance of Foodborne Antimicrobial Resistance	N29-2017	5/8	152

## 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 81 member countries, one member organization, 16 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 TFAMR 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)<sup>1</sup>

6. 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)<sup>2</sup>

7. TFAMR noted:
  - (i) the information from the Commission (CAC43) and the Executive Committee (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 continued to work closely with the Chair of TFAMR, Chairs of Electronic Working Groups (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))<sup>3</sup>

### Food and Agriculture Organization of the United Nations (FAO)

8. The Representative of FAO informed TFAMR of the ongoing efforts of the Tripartite, in collaboration with the United Nations Environment Program (UNEP), 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, the Independent Panel on Evidence for Action Against AMR, and a range of technical activities on legislation, surveillance, etc., many of which were supported by the AMR Multi-Partner Trust Fund (AMR MPTF).
9. He informed TFAMR 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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<sup>1</sup> CX/AMR 21/8/1

<sup>2</sup> CX/AMR 21/8/2

<sup>3</sup> CX/AMR 21/8/3; CX/AMR 21/8/3-Add.1

World Health Organization (WHO)

11. The Representative of WHO informed TFAMR 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 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 focused on fungal infections in humans and it was expected to be published in early 2022.

World Organisation for Animal Health (OIE)

12. The Representative of OIE informed TFAMR 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 considered 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 minimize and contain AMR.

**MATTERS ARISING FROM OTHER RELEVANT INTERNATIONAL ORGANIZATIONS (Agenda Item 4)<sup>4</sup>**Organisation for Economic Cooperation and Development (OECD)

15. The Representative of OECD informed TFAMR 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 (WB)

16. The Representative of WB informed TFAMR 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 (WCO)

17. The Representative of 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 two 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.

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<sup>4</sup> CX/AMR 21/8/4

World Trade Organization (WTO)

18. The Chairperson also drew the attention of TFAMR to the relevant information on AMR provided by 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 minimize and contain AMR.

**REVISION OF THE CODE OF PRACTICE TO MINIMIZE AND CONTAIN FOODBORNE ANTIMICROBIAL RESISTANCE (CXC 61-2005) (At Step 7) (Agenda Item 5)<sup>5</sup>**

20. The Chairperson recalled the discussions and agreements from TFAMR07 (2019) on the Code of Practice (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 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 Antimicrobial Resistance* (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 minimize and contain 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 re-emphasized the approach proposed by the Chairperson to focus on the outstanding substantive issues and to avoid reopening discussion on sections that had 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 paragraphs 20-21) 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 the provisions therein unchanged.

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<sup>5</sup> 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, 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 minimize 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 had 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 paragraphs 28 and 29.

### 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 revise Principle 13. The definition of “therapeutic use” should then be revised.

32. Delegations were invited to express their views in favour of one or more of the proposed options:

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

33. 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.
34. Delegations in favour 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.
35. 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.
36. Observers supporting Option A for the reasons stated above also concurred with Option B as a compromise solution.
37. 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.
38. 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.”<sup>6</sup>
  - 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.
39. 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.*
40. 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”.
41. Delegations in favour 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.

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<sup>6</sup> [https://www.salute.gov.it/imgs/C\\_17\\_notizie\\_3118\\_listaFile\\_itemName\\_0\\_file.pdf](https://www.salute.gov.it/imgs/C_17_notizie_3118_listaFile_itemName_0_file.pdf)

*Option C: 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.*

42. 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.
43. Delegations in favour 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 minimize and contain 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.
44. In view of the above, delegations in favour of Option C offered the following rationale 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 favour 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”.
45. 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.
46. 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 to further delay the completion of the COP in view of all the progress made so far to update risk management measures to minimize and contain 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.*

47. 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 paragraphs 34, 42 and 44). 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”.
48. 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)*

49. 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.
50. The EWG Chair indicated that this was a proposal from the EWG Chairs that 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.
51. 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 45).
52. Delegations generally expressed their willingness to compromise on Option D as presented while reiterating their preference for Options A/B or C.
53. 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/practice(s) to contain/minimize AMR .
54. 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.
55. Other delegations were of the view that with the text in Option D a definition was no longer required.
56. 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*

57. 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.
58. 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.
59. The Russian Federation therefore reserved its position on any of the options presented for consideration by TFAMR.

## **Conclusion**

60. 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 paragraphs 57-59.

## **Section 3 – Definitions**

### **Therapeutic use**

61. 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.
62. 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”.
63. 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.
64. Norway expressed their strong concerns on the inclusion of the definition because the definition of “therapeutic use” in the original CXC 61-2005 reflected the long understanding of this concept by Codex Members and should be included also in this revised version to avoid misunderstanding. In addition to the rationale given in paragraph 63, Norway indicated that the inclusion of the definition could lead to different interpretations in different countries. Furthermore, they stated that avoiding misunderstanding is crucial for the continuous fight against antimicrobial resistance. This concern was shared by Canada and the Russian Federation.
65. 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.
66. 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: <sup>5</sup> “Also recognized as therapeutic use in some jurisdictions/organizations”.
67. 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” was 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 had 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 risked 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.
68. 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.
69. The footnote could also refer to organizations in addition to some jurisdictions to facilitate consensus.

70. 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 was widely used across countries and regions.
71. 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 minimize and contain 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 minimize and contain AMR.
72. 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.
73. 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 71. In addition, Canada and Norway provided the following statements:
74. Canada noted its reservation to the inclusion of Footnote 5 in this document. The term “therapeutic” was a synonym for treatment in the current COP (CXC 61-2005), and the inclusion of footnote 5 in this draft revised COP meant that the term “therapeutic” could be interpreted by certain jurisdictions as a synonym for “veterinary medical use” which encompassed treatment, control and prevention. The inclusion of footnote 5 introduced confusion and could favour continued non-responsible uses of medically important antimicrobials in animals.
75. Norway indicated that, in their view, the additional footnote added to the confusion on how the term “therapeutic use” was interpreted globally, because not all countries interpreted it as stated in this footnote. Norway's interpretation of the term “therapeutic use” was in line with the definition in the original CXC 61-2005 as adopted in 2005 where “therapeutic use” was 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”**

76. Following the decision on the definition for “veterinary medical use/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

77. 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 use/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.
78. Views were expressed that “dosage regimes” included all treatments and therefore the reference to “veterinary medical use/phytosanitary use” was not necessary.

#### **Section 5.4 – Responsibilities of veterinarians and plant/crop health professionals**

##### Paragraph 52

79. 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.

80. 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

81. TFAMR agreed to retain the term “therapy” as it did not refer to “therapeutic use” nor any other use.

Paragraph 54

Last bullet

82. TFAMR agreed to refer to “dosage regimen” as opposed to “~~therapeutic~~ regimen” as more appropriate and general.

Off-label use

Paragraph 55

83. TFAMR agree to refer to “dosage regimen” as opposed to “~~therapeutic~~ regimen” as more appropriate and general.

84. In line with paragraph 34, a proposal was made to include the reference to “veterinary medical use/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**

85. 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.
86. 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**

87. TFAMR noted no comments on this Section.

**Status of the COP**

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

**Conclusion**

89. TFAMR agreed to forward the revised *Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance* (CXC 61-2005) to CAC44 for adoption at Step 8.

90. TFAMR recalled the reservations expressed by:

- the Russian Federation on Principles 12 and 13 (paragraphs 28-30 and 57-60;
- Thailand on Principle 12 (paragraphs 28 and 30); and
- the EU and its Member States, Canada, Colombia, Jamaica, Kazakhstan, Morocco, Norway, Russian Federation and Uganda on footnote 5 to the definition on “veterinary medical use/phytosanitary use” (paragraphs 71, 73-75).

with the rationale provided in the above-mentioned paragraphs.

**GUIDELINES ON INTEGRATED MONITORING AND SURVEILLANCE OF FOODBORNE ANTIMICROBIAL RESISTANCE (At Step 4) (Agenda Item 6)<sup>7</sup>**

91. The Chairperson, in introducing the item, outlined his ambition to finalize 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 EWG, a webinar and a virtual meeting of the working group, where five sessions were dedicated to discussion of the Guidelines.
92. 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 rationale 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).
93. The Netherlands, as Chair of the 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 EWG, acknowledged the huge progress that had been made, and appreciated the continuing efforts of the EWG Chair and Co-chairs to find consensus on the outstanding issues and facilitate completion of the Guidelines.
94. 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 CCEXEC79 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 finalize 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.
95. 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<sup>8</sup> 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.
96. For the purposes of the report the paragraph numbers reflect those of the tracked change version of the Guidelines (CRD17).

<sup>7</sup> 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, 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)

<sup>8</sup> [https://cdn.who.int/media/docs/default-source/antimicrobial-resistance/amr-gcp-tjs/ghg-statement-on-codex-guidelines-and-code-of-practice-en.pdf?sfvrsn=1ab899f6\\_11](https://cdn.who.int/media/docs/default-source/antimicrobial-resistance/amr-gcp-tjs/ghg-statement-on-codex-guidelines-and-code-of-practice-en.pdf?sfvrsn=1ab899f6_11)

**Section 1 - Introduction**

97. 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.
98. 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 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 .
99. 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.
100. 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**

101. There were extensive discussions on paragraph 14 of the Scope and whether or not AMU should be retained therein.
102. 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.
103. 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.
104. Following agreement in Section 9 on a description for AMU, it was agreed to retain AMU within the scope.
105. TFAMR agreed with paragraphs 15 and 16 with a small edit to paragraph 15 changing “would” to “may” for increased flexibility.
106. 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 (*Code of Hygienic Practice for Fresh Fruits and Vegetables* (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**

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

**Section 4 - Principles**

108. TFAMR agreed with Principles 2, 3, 4, 5, 7 and 8 as presented in CRD2.

**Principle 1**

109. 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 was widely recognized as key to addressing cross-cutting issues such as AMR.
110. Taking the different views into consideration the EWG Chair and Co-chairs made a new proposal, in line with language in the COP and paragraph 1 of these Guidelines, 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**

111. Some delegations were of the view that Principle 6 was not consistent with Section 6.1 of CXG 77-2011 and proposed to replace “foodborne AMR issues” with “AMR food safety issues” and the description of that in CXG 77-2011. Others noted that CXG 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.
112. 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**

113. TFAMR extensively discussed whether the concept of data sharing should be deleted from Principle 9. The EWG Chair 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.
114. 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.
115. 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**

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

**Section 6 - Regulatory framework, policy and roles.**

117. 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 unanalyzed 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 its 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**

118. 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).
119. 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, did not agree to the content of the Figure and 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.
120. The EWG chair clarified that the Figure had been amended taking into consideration written comments received. In the interests of completing the Guidelines and considering that it was more important to discuss the content of the whole text of the Guidelines than to discuss and review the Figure, to try to achieve consensus, TFAMR agreed to delete paragraph 29ter and Figure 1, although delegations that had been in favour of its retention expressed disappointment at their exclusion.
121. 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**

122. 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**

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

**Section 8.2 - Sampling Plan**

124. 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 two delegations 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**

125. 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, in particular at the risk profiling stage. It was highlighted by the EWG chair, that the term was added to make it more specific, as indirect pathways was too broad. Other Members noted that Codex is 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 return on their investment . Hence “scientifically relevant” was retained here and elsewhere in the Guidelines.
126. 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 as it could cause a barrier to trade. 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 and the term “fresh produce” was suggested, but it was noted that there was sufficient linkage to food to prevent misunderstanding in this regard.
127. 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**

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

#### **Section 8.5 - Laboratories**

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

#### **Section 8.6 - Antimicrobial susceptibility testing**

##### **Section 8.6.1 - Methods and interpretative criteria**

130. 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.
131. 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.
132. 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, 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.
133. The remaining paragraphs in the Section were agreed as proposed in CRD14.

##### **Section 8.6.2 - The panel of antimicrobials for susceptibility testing**

134. TFAMR agreed with the text as proposed in CRD14 for paragraphs 68 and 69 and included an amendment in paragraph 70 to enhance flexibility of the provision.
135. 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**

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

**Section 8.6.4 - Molecular testing**

137. 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**

138. 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**

139. 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: “antimicrobial 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 and throughout the rest of the document.
140. 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.
141. 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**

142. 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.
143. 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.
144. TFAMR agreed with the remaining paragraphs in the Section as proposed in CRD11.

**Section 9.2 - Sources of sales/use data**

145. 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**

146. 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 data. 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.
147. 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**

148. 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)**

149. TFAMR 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**

150. 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**

151. 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**

152. 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**

153. The TFAMR noted that there was no other business to discuss.
154. Delegations commended the finalization of the COP and the GLIS, which would provide countries with useful guidance to minimize and contain 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.
155. The Chairperson additionally acknowledged the huge efforts of delegates and their willingness to compromise in order to complete this work. He further highlighted the important follow-up actions that would be required to ensure the successful implementation of the COP and GLIS.
156. 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**

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

**APPENDIX I**

**LIST OF PARTICIPANTS  
LISTE DES PARTICIPANTS  
LISTA DE PARTICIPANTES**

**CHAIRPERSON - PRÉSIDENT - PRESIDENTE**

Prof Yong Ho Park  
Professor  
Seoul National University

**CHAIR'S ASSISTANT - ASSISTANT DU PRÉSIDENT - ASISTENTE DEL PRESIDENTE**

Prof Sang Ryeol Ryu  
Professor  
Seoul National University

**MEMBERS NATIONS AND MEMBER ORGANIZATIONS  
ÉTATS MEMBRES ET ORGANISATIONS MEMBRES  
ESTADOS MIEMBROS Y ORGANIZACIONES MIEMBROS**

**ALBANIA - ALBANIE**

Mrs Lindita Molla  
AMR Food Safety  
National Public Health Institute  
Tirane

**ARGENTINA - ARGENTINE**

Mr Federico Luna  
Coordinador de Medicamentos Veterinarios  
SENASA  
Ciudad Autónoma de Buenos Aires

Mr Lisandro Ruiz  
Asistente Técnico  
SENASA  
Ciudad Autónoma de Buenos Aires

Ms Josefina Cabrera  
Jefa Departamento laboratorio Nacional de Referencia  
Instituto Nacional de Alimentos  
Ciudad Autónoma de Buenos Aires

Ms Mariángelos Fernandez  
Jefa del Servicio de Gestión de Riesgo  
Instituto Nacional de Alimentos  
Ciudad Autónoma de Buenos Aires

Mrs Maria Noel Olivera  
Asistente Técnica  
Instituto Nacional de Alimentos  
Ciudad Autónoma de Buenos Aires

Ms Eleonora Tassara  
Asistente Técnico  
Instituto Nacional de Alimentos  
Ciudad Autónoma de Buenos Aires

**AUSTRALIA - AUSTRALIE**

Dr Leigh Nind  
Director A/g Epidemiology and One Health  
Department of Agriculture, Water and the Environment

Dr Barbara Butow  
Director Microbiology and Biotechnology  
Food Standards Australia New Zealand

Dr Adele Yates  
Microbiologist  
Food Standards Australia New Zealand

**AUSTRIA - AUTRICHE**

Dr Elfriede Oesterreicher  
Deputy Head of Department  
Federal Ministry of Social Affairs, Health, Care and Consumer  
Protection  
Vienna

Mr Florian Fellingner  
Head of Department  
Federal Ministry of Social Affairs, Health, Care and Consumer  
Protection  
Vienna

**AZERBAIJAN - AZERBAÏDJAN - AZERBAÏYÁN**

Ms Narmin Akhundova  
Head of department  
Food Safety Institute of the Republic of Azerbaijan  
Baku

Ms Kamala Aliyeva  
Specialist  
Food Safety Institute of the Republic of Azerbaijan  
Baku

Mr Abdul Etibaroglu  
Specialist  
Food Safety Institute of the Republic of Azerbaijan  
Baku

Ms Gulnara Guluzade  
Leading specialist  
Food Safety Institute of the Republic of Azerbaijan  
Baku

Mr Giyasaddin Jalladov  
Head of department  
Food Safety Institute of the Republic of Azerbaijan  
Baku

Ms Sabina Mammadova  
Leading specialist  
Food Safety Institute of the Republic of Azerbaijan  
Baku

**BELGIUM - BELGIQUE - BÉLGICA**

Ms Katie Vermeersch  
DVM  
Federal Agency for the Safety of the Food Chain  
Brussel

**BENIN - BÉNIN**

Mr E. Jacques Hougbenou Hougla  
Secrétaire Permanent du Comité National du Codex  
Alimentarius  
Ministère de l'Agriculture, de l'Elevage et de la Pêche  
Porto-Novo

**BRAZIL - BRÉSIL - BRASIL**

Mrs Ligia Lindner Schreiner  
Health Regulation Expert  
Brazilian Health Regulatory Agency - ANVISA  
Brasília

Ms Angela Maria Queiroz Pellegrino Missaglia  
Consultant  
Brazilian Feed Manufacturers Association  
Brasília

Ms Ester Aguiar  
Veterinary Official Inspector  
Ministry of Agriculture, Livestock and Food Supply  
Brasília

Ms Carolina Araujo Vieira  
Health Regulation Expert  
Brazilian Health Surveillance Agency - ANVISA  
Brasília

Ms Renata Batista Rau  
Federal Agricultural Auditor  
Ministry of Agriculture, Livestock and Food Supply

Mrs Suzana Bresslau  
Official Veterinarian Inspector  
Ministry of Agriculture, Livestock and Food Supply  
Brasília

Ms Clea Camargo  
Regulatory Affairs Senior Manager  
ABIQUIFI  
São Paulo

Mr Guilherme Da Costa  
Food safety Expert  
Ministry of Agriculture, Livestock and Food Supply Brasilia

Mrs Jalusa Deon Kich  
Researcher  
Brazilian Agricultural Research Corporation  
Concórdia - SC

Mr Wanderson Dos Reis  
Regulatory Affairs Manager  
ALANAC - Association of National Pharmaceutical  
Laboratories

Ms Bernadete Ferraz Spisso  
Head of the Laboratory for Veterinary Drug Residues  
Instituto Nacional de Controle de Qualidade em  
Saúde/Fundação Oswaldo Cruz

Ms Danielle Ferreira Alves Modena  
Technical Consultant  
Assocon - Associação Nacional da Pecuária Intensiva

Mrs Marina Ferreira Goncalves  
Health Regulation Expert  
Brazilian Health Surveillance Agency – ANVISA  
Brasília

Ms Silvana Lima Górnaiak  
Full Professor Pharmacology and Toxicology  
Federal Council of Veterinary Medicine/ University of São  
Paulo - Brazil

Ms Renata Lomele  
Quality Assurance Coordinator  
ABIEC – Brazilian Beef Exporters Association

Ms Fatima Machado Braga  
Health Regulation Expert  
Brazilian Health Regulatory Agency – ANVISA  
Brasília

Ms Milene Martini Berbel  
Official Veterinarian  
Ministry of Agriculture, Livestock and Food Supply

Mr Diego Menezes De Brito  
Official Veterinarian  
Ministry of Agriculture, Livestock and Food Supply – MAPA

Mr Luiz Monteiro  
Technical Director  
Sindan

Ms Gabriela Mura  
Marketing & Regulatory Affairs Director  
Sindan

Dr João Palermo-neto  
Senior Professor  
University of São Paulo, SP , Brasil  
São Paulo

Ms Giovanna Pansonato  
Technical Analyst  
Brazilian Association of Animal Protein

Ms Mônica Pinho Cerqueira  
Consultant  
VIVA LÁCTEOS

Ms Anna Júlia Portz  
Technical Assistant (regulatory affairs)  
VIVA LÁCTEOS

Ms Marília Rangel Campos  
Institutional Affairs and Market Access Associate Director  
ABPA - Brazilian Association of Animal Protein

Mr Aldemir Reginato Ribeiro  
Federal Agricultural Auditor  
Ministry of Agriculture, Livestock and Food Supply – MAPA

Ms Cristina Mara Teixeira  
Official Veterinarian  
Ministry of Agriculture, Livestock and Supply

Ms Renata Tigulini De Souza Peral  
Technical Consultant - Public Health Laboratories Service  
Ministry of Health

Ms Isabela Ávila  
Federal Veterinary Inspector - Veterinary Products Licensing  
and Inspection Service (CPV)  
Ministry of Agriculture, Livestock and Food Supply

**BULGARIA - BULGARIE**

Mrs Iva Yancheva  
Chief Expert  
Ministry of Agriculture, Food and Forestry

**BURKINA FASO**

Mr Abdoulaye Gueye  
Responsable de la sécurité sanitaire des aliments  
Ministère de la Santé Publique  
Ouagadougou

Mrs Pelagie Kafando Zoungrana  
Inspectrice phytosanitaire et de la qualité  
Ministère de l'Agriculture et des Aménagements Hydro-agricoles  
Ouagadougou

Mr Dominique Ouedraogo  
Ingénieur Agronome  
Ministère en charge de l'Agriculture  
Ouagadougou

**CAMBODIA - CAMBODGE - CAMBOYA**

Dr Chamnan Chhoun  
Director  
Ministry of Agriculture, Forestry and Fishery  
Phnom Penh

**CANADA - CANADÁ**

Dr Manisha Mehrotra  
Director, Human Safety Division  
Veterinary Drugs Directorate  
Health Products and Food Branch  
Health Canada  
Ottawa, Ontario

Dr Reem Barakat  
Deputy Director, Trade Agreements Division  
International Affairs Branch  
Canadian Food Inspection Agency  
Ottawa, Ontario

Dr Carolee Carson  
Surveillance Manager / Veterinary Epidemiologist  
Centre for Foodborne, Environmental and Zoonotic Infectious Diseases  
Infectious Diseases Programs Branch  
Public Health Agency of Canada  
Guelph, Ontario

Dr Xian-Zhi Li  
Team Leader  
Veterinary Drugs Directorate  
Health Products and Food Branch  
Health Canada  
Ottawa, Ontario

Ms Kimberley Meadows  
Policy and Program Leader  
Animal Health Directorate  
Policy and Programs Branch  
Canadian Food Inspection Agency  
Ottawa, Ontario

Mr Stephen Parker  
A/Director  
Centre for Foodborne, Environmental and Zoonotic Infectious Diseases  
Infectious Diseases Programs Branch  
Public Health Agency of Canada  
Guelph, Ontario

Mr Mark Reist  
Policy Analyst  
Veterinary Drugs Directorate  
Health Product and Food Branch  
Health Canada  
Ottawa, Ontario

Dr Pablo Romero-Barrios  
Food Epidemiologist  
Food Directorate  
Health Products and Food Branch  
Health Canada  
Ottawa, Ontario

**CHILE - CHILI**

Mrs Constanza Vergara  
Asesor Técnico  
Ministerio de Agricultura  
Santiago

Mr Miguel Adasme  
Encargado de Inocuidad  
Asociación de Exportadores de Carnes de Chile (CHILECARNE)  
Santiago

Mrs Gabriela Converte Mitrione  
Profesional Subdepartamento de Verificación Analítica  
Ministerio de Agricultura  
Santiago

Mr David Guerra Maldonado  
Profesional de la División de Protección Pecuaria  
Ministerio de Agricultura  
Santiago

Mr Rolando Ibarra Olmedo  
Consultor Senior en Sanidad en Acuicultura  
Consultor  
Puerto Varas

Mr Alexander Jaramillo  
Coordinación de Salud e Inocuidad  
INTESAL  
Puerto Montt

Ms Pilar Lillo Lobos  
Profesional Subdepartamento Control Predial para la Exportación  
Ministerio de Agricultura  
Santiago

Mr Diego Varela  
Coordinador Asuntos Internacionales.  
Ministerio de Agricultura.  
Santiago

Mr Fernando Zambrano  
Jefe Subdepto. Registro y Control de Medicamentos Veterinarios  
Ministerio de Agricultura  
Santiago

**CHINA - CHINE**

Mrs Hejia Wang  
Deputy Director  
China Institute of Veterinary Drug Control  
Beijing

Mr Xiao Chen  
Research Assistant  
China National Center for Food Safety Risk Assessment  
Beijing

Mrs Guyue Cheng  
Associate Professor  
Huazhong Agricultural University

Dr Tsz Kit Chong  
Scientific Officer (Microbiology)  
Centre for Food Safety, Food and Environmental Hygiene  
Department, HKSAR Government  
Hong Kong

Mrs Hao Ding  
Assistant Researcher  
China National Center for Food Safety Risk Assessment  
Beijing

Mrs Fang Gao  
Deputy Division Director  
Center for Agro-Food Quality & Safety, Ministry of  
Agriculture and Rural Affairs, P.R. China  
Beijing

Prof Haihong Hao  
Professor  
Huazhong Agricultural University

Mr Qi Huang  
Associate Professor  
Huazhong Agricultural University

Prof Fengqin Li  
Professor/Director of the microbiology laboratory  
China National Center for Food Safety Risk Assessment  
Beijing

Ms Chang Li  
Agronomist  
Center for Agro-Food Quality & Safety, Ministry of  
Agriculture and Rural Affairs, P.R. China  
Beijing

Prof Jian-Hua Liu  
Professor  
South China Agricultural University  
Guangzhou

Mrs Hanyang Lyu  
Assistant Researcher  
China National Center for Food Safety Risk Assessment  
Beijing

Mr Jun Shang  
Deputy Department director  
Shanghai animal disease control and prevention centre  
Shanghai

Prof Jian Sun  
Professor  
South China Agricultural University

Mrs Jing Tian  
Researcher  
China National Center for Food Safety Risk Assessment  
Beijing

Prof Shaolin Wang  
Professor  
China Agricultural University  
Beijing

Prof Liping Wang  
Professor  
College of Veterinary Medicine, Nanjing Agricultural  
University  
Nanjing

Mr Chi Yan Yung  
Scientific Officer (Risk Management)  
Centre for Food Safety, Food and Environmental Hygiene  
Department, HKSAR Government  
Hong Kong

Prof Jing Zeng  
Professor  
Science and Technology Center of China Customs  
Beijing

Prof Chunping Zhang  
Professor  
China Institute of Veterinary Drug Control  
Beijing

**COLOMBIA - COLOMBIE**

Eng Blanca Cristina Olarte Pinilla  
Profesional especializada  
Ministerio de Salud y Protección Social  
Bogotá

Eng Delcy Yaneth Lugo Ramos  
Profesional universitaria  
Instituto Nacional de Vigilancia de Medicamentos y  
Alimentos - Invima  
Bogotá

Dr Cristian José Monsalve Pico  
Profesional Universitario  
Instituto Nacional de Vigilancia de Medicamentos y  
Alimentos - Invima  
Bogotá

**COSTA RICA**

Mrs Heilyn Fernandez  
Médico Veterinario  
Servicio Nacional de Salud Animal  
Heredia

Mrs Amanda Lasso Cruz  
Asesor Codex  
Ministerio de Economía Industria y Comercio  
San José

**CUBA**

Mrs Ana Granda  
Especialista en Microbiología  
Ministerio de la Agricultura  
La Habana

**CZECH REPUBLIC - RÉPUBLIQUE TCHÈQUE - REPÚBLICA CHECA**

Mrs Lucie Pokludová  
National expert  
Institute for State Control of Veterinary Biologicals and Medicines  
Brno - Medlánky

**CÔTE D'IVOIRE**

Dr Akoua Assunta Adayé  
Enseignant-chercheur  
Université Félix Houphouët Boigny  
Abidjan

Dr Brah Therese Agbessi Epouse Kouassi  
Maître de conférence - Chef de service adjoint  
Institut National d'Hygiène public  
Abidjan

Mrs Adeline Galé  
Sous-directeur  
Ministère d'État, Ministère de l'Agriculture et du Développement Rural  
Adeline

Dr Solange Gbezo  
Enseignant-chercheur  
Centre Suisse de Recherches Scientifiques  
Abidjan

Dr Emmanuel Tia  
Enseignant-chercheur  
Université Alassane Ouattara  
Abidjan

Dr Gopeyue Maurice Yeo  
Chercheur  
Centre de Recherches Océanologiques  
Abidjan

**DENMARK - DANEMARK - DINAMARCA**

Mrs Elisabeth Okholm Nielsen  
Veterinary Officer DVM PhD Dipl ECPHM  
Danish Veterinary and Food Administration

Mrs Ann-Sofie Hintzmann  
Scientific Advisor  
Danish Veterinary and Food Administration

Mrs Pia Jul  
Veterinary Officer  
Danish Veterinary and Food Administration  
Glostrup

**ECUADOR - ÉQUATEUR**

Mrs Geovanna Del Pilar Amancha Vega  
Analista de Vigilancia y Control de Contaminantes en la producción primaria  
Agencia de Regulación y Control Fito y Zoonositaria - AGROCALIDAD  
Quito

Mr Israel Vaca Jiménez  
Analista de certificación de producción primaria y buenas prácticas  
Agencia de Regulación y Control Fito y Zoonositaria - AGROCALIDAD  
Quito

Ms Daniela Vivero  
Analista de certificación de producción primaria y buenas prácticas  
Agencia de Regulación y Control Fito y Zoonositario - AGROCALIDAD  
Quito

**EGYPT - ÉGYPTE - EGIPTO**

Eng Reda Mohamed Sayed Ismail  
Food Standards Specialist  
Egyptian Organization for Standardization and Quality (EOS)  
Cairo

Dr Mona Abdelmeseeh Mankerious Botros  
Veterinary Senior  
General Organization for Veterinary Services (GOVS)  
Giza

Eng Khadeja Elkelany  
General Manager Assistant  
General Organization for Export and Import Control  
Cairo

Dr Gehad Fathy Ahmed Fath Elbab  
Head of Researcher and Quality Manager of Food Hygiene  
Animal Health Research Institute (AHRI)  
Giza

Dr Noha Ibrahim  
Regulatory Affairs Specialist  
National Food Safety Authority - Egypt  
Cairo

Dr Lamia Abdou Mohamed Ryad  
Head of Researcher and Group Head of Veterinary Drugs  
Agriculture Research Center (ARC)  
Giza

Dr Marwa Soliman  
Technical Manager for Hormones and Veterinary Drugs  
Central Public Health Laboratories - Ministry of Health and Populations  
Cairo

Eng Mohamed Mamdouh Yassien  
Technical Specialist  
Egyptian Chamber of Food Industries  
Cairo

**ESTONIA - ESTONIE**

Ms Piret Aasmäe  
Chief Specialist  
Ministry of Rural Affairs  
Tallinn

**EUROPEAN UNION - UNION EUROPÉENNE - UNIÓN EUROPEA**

Mr Risto Holma  
Senior Administrator  
European Commission  
Brussels

Ms Barbara Freischem  
Head of Department  
European Medicines Agency (EMA)  
Amsterdam

Mr Sebastien Goux  
Deputy Head of Unit  
European Commission  
Brussels

Mr Ernesto Liebana  
Senior Scientific Officer, Deputy Head of Unit  
European Food Safety Authority (EFSA)  
Parma

#### **FRANCE - FRANCIA**

Mrs Claire Fuentes  
Cheffe de bureau  
Ministère de l'agriculture

Mr Damien Bouchard  
Deputy Head of pharmaceuticals assessment unit  
French agency for food, environmental and occupational  
health safety  
Fougères CEDEX

Mrs Louise Dangy  
Point de contact national  
SGAE  
Paris

Mr Maxime Jarnoux  
chargé de mission  
Ministère de l'agriculture

#### **GEORGIA - GÉORGIE**

Dr Marine Baidauri  
Chief specialist of the Security Policy Division  
Ministry of Internally Displaced Persons from the Occupied  
Territories, Labour, Health and Social Affairs of Georgia

Dr Giorgi Chakhunashvili  
Head of the Unified Health Division  
LEPL National Center for Disease Control and Public Health

Ms Ketevan Kavtaradze  
Specialist of the Division of Alimentary, Nosocomial and  
Parasitic Diseases  
LEPL National Center for Disease Control and Public Health

#### **GERMANY - ALLEMAGNE - ALEMANIA**

Ms Anne Beutling  
Officer  
Federal Ministry of Food and Agriculture  
Berlin

Prof Annemarie Käsbohrer  
Senior Officer  
Germany

Mrs Iwona Piechowiak  
Manager  
Council of the European Union

Dr Heike Preiss  
Scientist  
BMEL  
Berlin

Mrs Outi Tyni  
Administrator Council of the European Union  
Council of the European Union  
Brussels

#### **GHANA**

Prof Kwasi Addo  
Head  
Noguchi Institute  
Accra

Ms Pokuaa Appiah-Kusi  
Assistant Standards Officer  
Ghana Standards Authority  
Accra

Ms Vanessa Asante  
Codex Contact Point Officer  
Ghana Standards Authority  
Accra

Mrs Doreen Koranteng  
Codex Contact Point Officer  
Ghana Standards Authority  
Accra

Mr Andrew Lartey  
Codex Contact Point Manager  
Ghana Standards Authority  
Accra

Ms Lilian Kabukuor Manor  
Scientific Officer  
Ghana Standards Authority  
Accra

Mrs Harriet Ayebea Ofori-Antwi  
Principal Regulatory Officer  
Food and Drugs Authority  
Accra

#### **HONDURAS**

Mrs María Eugenia Sevilla  
Gerente Técnico  
Servicio Nacional de Sanidad e Inocuidad Agroalimentaria  
(SENASA)  
Tegucigalpa

#### **INDIA - INDE**

Dr Kiran Narayan Bhilegaonkar  
Principal Scientist and Head of Regional Centre  
ICAR-Indian Veterinary Research Institute  
Pune

Mr Sabeerali A M  
Assistant director (T)  
Export Inspection Council

Dr Firdaus Jahan  
Technical Officer  
Food Safety and Standards Authority of India  
New Delhi

Dr K. Abhirami  
Assistant Director  
Food Safety and Standard Authority of India  
New Delhi

Dr Lokendra Kumar  
Assistant director (T)  
Export Inspection Council

Dr S K Rana  
General Manager & Group Head  
National Dairy Development Board,

Dr Madhusudhana Rao  
Principal Scientist  
CIFT, Vishakhapatnam, India

Dr Dhanesh V  
Technical Officer  
Food Safety and Standards Authority of India  
Delhi

#### **INDONESIA - INDONÉSIE**

Prof Purwiyatno Hariyadi  
Vice Chairperson of the Codex Alimentarius Commission  
Bogor Agricultural University (IPB)  
Bogor

Dr Nuryani Zainuddin  
Director of Animal Health  
Ministry of Agriculture  
Jakarta

Dr Liys Desmayanti  
Veterinary Officer  
Ministry of Agriculture  
Jakarta

Dr Ni Made Ria Isriyanthi  
Coordinator of Veterinary Drug Control Division  
Ministry of Agriculture  
Jakarta

Mr Aji Barbora Niasono  
Staff  
Ministry of Agriculture Republic Indonesia  
Jakarta

Dr Susan Maphilindawati Noor  
Head of Bacteriology Laboratory  
Ministry of Agriculture Republic Indonesia  
Bogor

Mr Apriyanto Nugroho  
Fresh Food Safety Coordinator  
Ministry of Agriculture  
Jakarta

Mrs Nelly Puspendari  
Head of Section for Biomedical of Communicable Disease  
National institute of Health Research and Development  
Jakarta

Mrs Ratih Dian Saraswati  
Researcher  
National institute of Health Research and Development  
Jakarta

Dr Yurike Elisadewi Ratna Sari  
Veterinary Office at Veterinary Drug Control Division  
Ministry of Agriculture  
Jakarta

Mrs Theista Savanty  
Codex Contact Poin of Indonesia  
National Standardization Agency of Indonesia  
Jakarta

Dr Sunarno Sunarno  
Researcher  
National institute of Health Research and Development  
Jakarta

Dr Fadjar Sumping Tjatur Rasa  
Senior Veterinary Officer  
Ministry of Agriculture  
Jakarta

#### **IRAN (ISLAMIC REPUBLIC OF) – IRAN (RÉPUBLIQUE ISLAMIQUE D') – IRÁN (REPÚBLICA ISLÁMICA DEL)**

Mrs Fahimdokht Mokhtari  
Secretary of mirror committee (AMR) in Iran  
institute of standard

Mr Alireza Rafiepoor  
D.G  
Ministry of agriculture

#### **IRELAND - IRLANDE - IRLANDA**

Ms Julie Bolton  
Veterinary Inspector  
Department of Agriculture Food and the Marine (DAFM)

#### **ITALY - ITALIE - ITALIA**

Mr Giulio Cardini  
Senior Officer  
Ministry of Agricultural Food and Forestry Policies  
Rome

Ms Dalma Benedicta Battisti  
Intern  
Ministry of Agricultural, Food and Forestry Policies  
Rome

Dr Francesca Ponti  
Senior Officer  
Ministry of Agricultural Food and Forestry Policies  
Rome

#### **JAMAICA - JAMAÏQUE**

Dr Suzan McLennon-Miguel  
Senior Veterinary Specialist (Public Health)  
Ministry of Agriculture

#### **JAPAN - JAPON - JAPÓN**

Dr Michiko Kawanishi  
Deputy Director  
Ministry of Agriculture, Forestry and Fisheries

Dr Akihito Furuta  
Director  
Ministry of Agriculture, Forestry and Fisheries

Dr Yukari Furuya  
Inspector  
National Veterinary Assay Laboratory Tokyo

Dr Ryuto Hiramatsu  
Risk Assessment Expert Officer  
Cabinet Office, Government of Japan  
Tokyo

Dr Mayuko Nakakoshi  
Science Officer  
Ministry of Agriculture, Forestry and Fisheries

Dr Manao Ozawa  
Senior Research Officer  
National Veterinary Assay Laboratory Tokyo

Dr Yoko Shimazaki  
Section Leader  
National Veterinary Assay Laboratory Tokyo

Dr Takahiro Shirakawa  
Science Officer  
Ministry of Agriculture, Forestry and Fisheries

Ms Aya Tanaka  
Science Officer  
Ministry of Agriculture, Forestry and Fisheries

Dr Takako Yano  
Deputy Director  
Cabinet Office, Government of Japan  
Tokyo

#### **JORDAN - JORDANIE - JORDANIA**

Eng Faten Al-nawaiseh  
Risk analysis  
Jordan food and drug administration  
Amman

Dr Tamador Maayah  
Head of risk management unit  
JFDA  
Amman

#### **KAZAKHSTAN - KAZAJSTÁN**

Mr Zeinulla Sharipov  
expert on veterinary and phytosanitary, KZ Codex Team  
Ministry of Healthcare of the Republic of Kazakhstan  
Astana

Dr Nailya Karsybekova  
Regional Coordinator, CCEURO  
Ministry of Healthcare the Republic of Kazakhstan  
Astana

#### **KENYA**

Dr Allan Azegele  
Deputy Director  
Ministry of Agriculture, Livestock & Fisheries  
Nairobi

Mr Lawrence Aloo  
Chief Biochemist  
Ministry of Health  
Nairobi

Ms Maryann Kindiki  
Manager, National Codex Contact Point  
Kenya Bureau of Standards  
Nairobi

Dr Teresa Kinyungu  
Assistant Director  
Ministry of Agriculture, Livestock and Fisheries

Mr Max Mutuku  
Laboratory Analyst  
Ministry of Health

Ms Anima Sirma  
Chief Veterinary Officer  
Ministry of Agriculture, Livestock and Fisheries  
Nairobi

#### **KUWAIT - KOWEÏT**

Mrs Jeehan Alestad  
First Secretary  
Permanent Representation of Kuwait to FAO & WFP

#### **LEBANON - LIBAN - LÍBANO**

Ms Mariam Eid  
Head Agro-Industries department  
Ministry of Agriculture

#### **MADAGASCAR**

Dr Ilo Tsिमok'haja Ramahatafandry  
Chef de Service Santé Publique et Médicaments Vétérinaires  
- Point focal OIE sur la RAM - Point focal national RAM en  
Santé Animale - Présidente du Comité National du Codex  
Alimentarius  
Ministère de l'agriculture de l'élevage  
Antananarivo

Mrs Lantomalala Raharinosy  
Point de contact du Codex  
Ministère de l'Industrie du Commerce et de la  
Consommation  
Antananarivo

Mr Berthod Rambohitrarivo  
chargé de laboratoires - point focal RAM  
Autorité Sanitaire Halieutique  
Antananarivo

Prof Jean Marie Razafindrajaona  
Professeur Titulaire des Universités  
Ecole Supérieure des Sciences Agronomiques  
ANTANANARIVO

Mr Vaillant Tosy  
Responsable Analyses Microbiologiques  
Ministère de l'Industrie, du Commerce et de la  
Consommation  
Antananarivo

#### **MALAWI**

Mr Demster Kumvenji  
Certification Officer  
Malawi Bureau of Standards  
Blantyre

#### **MALAYSIA - MALAISIE - MALASIA**

Ms Kasumawaty Sudin  
Principal Assistant Director  
Ministry of Health Malaysia

Ms Laila Rabaah Ahmad Suhaimi  
Senior Principal Assistant Director  
Ministry of Health Malaysia

Dr Suraya Amir Husin  
Senior Principal Assistant Director  
Ministry of Health Malaysia

Ms Nurul Hidayati Surawi  
Principal Assistant Director  
Ministry of Health Malaysia

Ms Ani Fadhlina Mustaffa  
Senior Assistant Director  
Ministry of Health Malaysia

Dr Rohaya Mohd Ali  
Senior Director of Veterinary Public Health Division  
Ministry of Agriculture and Food Industry

Ms Hafizah Mohd  
Senior Head of Assistant Director  
Ministry of Agriculture and Food Industry

Mr Mohammad Nazrul Fahmi Abdul Rahim  
Deputy Director  
Ministry of Agriculture and Food Industry

Dr Alifah Ismail  
Head of Veterinary Medicine and Biologics Section  
Ministry of Agriculture and Food Industry

Mr Mohd Ghazali A. Manap  
Head of Fish and Public Health Section  
Department of Fisheries Malaysia

Mrs Nor Fasiah Abdullah Sani  
Senior Research Officer  
Department of Veterinary Services Malaysia

Dr Mariani Hashim  
Veterinary Officer  
Department of Veterinary Services Malaysia

Dr Rohaidah Hashim  
Pathologist (Clinical Microbiology)  
Institute for Medical Research, National Institute of Health

#### **MALTA - MALTE**

Dr Vito Domenico Benvenga  
Veterinarian  
Veterinary Regulation Directorate  
Marsa

#### **MEXICO - MEXIQUE - MÉXICO**

Ms Nidia Coyote Estrada  
Directora Ejecutiva de Manejo de Riesgos.  
COFEPRIS  
CDMX

Mrs María Guadalupe Arizmendi Ramírez  
Verificador o Dictaminador Especializado Asuntos Internacionales  
COFEPRIS

Mr Gerardo Cruz Galan  
Jefe de Departamento de Regulación y Registro de Productos Veterinarios  
SENASICA

Mrs Carolina Quiroz Santiago  
Verificador o Dictaminador Especializado  
COFEPRIS

Mrs Lorena Reyes Guerra  
Jefa del Departameto de Regulación de Establecimientos e Insumos Para Uso o Consumo Animal  
Servicio Nacional de Sanidad Inocuidad y Calidad Agroalimentaria (Senasica)

Mrs Mara Hatziri Ramírez Sánchez  
COFEPRIS

Mrs Luz María Magdalena Ruíz Gonzalez  
Gerente de Políticas Regulatorias Comisión de Evidencia y Manejo de Riesgos  
COFEPRIS

#### **MOROCCO - MAROC - MARRUECOS**

Dr Younes El Wahli  
Head of Department of Registration and Inspection  
Office National de Sécurité Sanitaire des produits Alimentaires  
Rabat

Dr Hayat El Bouchtaoui  
in charge of antibioresistance dossier (veterinary sector)  
ONSSA  
Rabat

Mrs Hanane Moulelbab  
Pharmacienne responsable PI de l'Observatoire National des Médicaments et des Produits de Santé  
Ministère de la Santé

Dr Samah Tahri  
Veterinarian  
ONSSA  
Rabat

Mrs Bahija Zouatni  
Cadre au Service de l'Hygiène Alimentaire  
Ministère de la Santé

#### **NETHERLANDS - PAYS-BAS - PAÍSES BAJOS**

Mrs Rosa Maria Peran Sala  
Chairperson EWG GLIS  
Coordinator/special advisor  
Ministry of Health Welfare and Sport  
The Hague

Mr Eric Pierrey  
Senior Policy Officer  
Ministry of Agriculture, Nature and Food Quality  
The Hague

Mrs Ana Viloría  
Senior Policy Officer  
Ministry of Health, Welfare and Sport  
The Hague

#### **NEW ZEALAND - NOUVELLE-ZÉLANDE – NUEVA ZELANDIA**

Mr Allan Kinsella  
Director  
Ministry for Primary Industries

Ms Jennifer Doyle  
Team Manager Assessments, ACVM, Assurance  
Ministry for Primary Industries  
Wellington

Mr Raj Rajasekar  
Senior Programme Manager  
Codex Coordinator and Contact Point for New Zealand  
Wellington

#### **NIGERIA - NIGÉRIA**

Dr Mabel Kamweli Aworh  
Assistant Director  
Federal Ministry of Agriculture & Rural Development  
Abuja

Dr Mairo Gujba Lawan Kachalla  
ASSISTANT DIRECTOR  
Federal Ministry of Agriculture and Rural Development  
Abuja

Dr Olumuyiwa Tunde Sigbeku  
Deputy Director  
National Agency for Food and Drug Administration and Control (NAFDAC)  
Abuja

Mr Oluwatobi Aduraleke Vaughan  
Chief Regulatory Officer  
National Agency for Food and Drug Administration and Control  
Abuja

**NORTH MACEDONIA - MACÉDOINE DU NORD - MACEDONIA DEL NORTE**

Mr Martin Josheski  
Junior associate  
Food and Veterinary Agency  
Skopje

**NORWAY - NORVÈGE - NORUEGA**

Mrs Kjersti Nilsen Barkbu  
Senior Adviser  
Ministry of Agriculture and Food  
Oslo

Mr Knut Berdal  
Specialist Director  
Royal Norwegian Ministry of Agriculture and Food  
Oslo

Mrs Gerda Ingrid Heglebäck  
Senior Adviser  
Norwegian Food Safety Authority  
Oslo

Mrs Vigdis S. Veum Møllersen  
Specialist Director  
Norwegian Food Safety Authority  
Oslo

**PARAGUAY**

Mrs Elva Maldonado  
Técnica  
INAN  
Asunción

Dr Gloria Alarcón  
Técnica  
SENACSA  
Asunción

Mrs Demetria Vega  
Técnica  
SENACSA  
San Lorenzo

Mrs Maria Alejandra Zaracho  
Técnica  
INTN  
Asunción

**PHILIPPINES - FILIPINAS**

Dr January Nones  
Chairperson, NCO-TFAMR  
National Meat Inspection Service-Department of Agriculture

Dr Alicia Layson  
Member, NCO-TFAMR  
Bureau of Animal Industry- Department of Agriculture

Dr Alpha Mateo-Ilanuza  
Member, NCO-TFAMR  
Bureau of Agriculture and Fisheries Standards-Department of Agriculture

Ms Remedios Micu  
Member, NCO-TFAMR  
National Meat Inspection Service- Department of Agriculture

Ms Marissa Mojica  
Co-Chairperson, NCO-TFAMR  
Food and Drug Administration-Department of Health

**POLAND - POLOGNE - POLONIA**

Prof Dariusz Wasyl  
Head of Department of Omics Analyses,  
Deputy Head of Department of Microbiology  
National Veterinary Research Institute  
Pulawy

Ms Magdalena Kowalska  
Main expert in the International Cooperation Department  
Agricultural and Food Quality Inspection  
Warsaw

**PORTUGAL**

Mrs Andrea Cara D'Anjo  
Head of Unit  
Directorate-General for Food and Veterinary (DGAV)  
Lisboa

Ms Inês Almeida  
Head of Unit  
Directorate-General for Food and Veterinary (DGAV)  
Lisboa

Mr Francisco Santos  
Senior Regulatory Officer  
Directorate-General for Food and Veterinary (DGAV)  
Lisboa

**REPUBLIC OF KOREA - RÉPUBLIQUE DE CORÉE - REPÚBLICA DE COREA**

Mr Soon Han Kim  
Director  
National Institute of Food and Drug Safety Evaluation

Ms Ji Hye Jeon  
Scientific Officer  
National Institute of Food and Drug Safety Evaluation

Mrs Mi Gyeong Kim  
Senior Scientific officer  
National Institute of Food and Drug Safety Evaluation

Mr Bongjae Jeong  
Assistant Director  
Ministry of Agriculture, Food and Rural Affairs

Mr Myoung Sug Kim  
Senior Scientific officer  
National Institute of Fisheries Science

Ms Soyoung Lee  
Researcher  
Ministry of Agriculture, Food and Rural Affairs

Dr Suk-kyung Lim  
Senior Researcher  
Animal and Plant Quarantine Agency  
Gimcheon-si

Mr Kwang Kyo Oh  
Scientific Officer  
National Institute of Agricultural Science, Rural Development  
Administration  
Wanju-gun

Dr Kyoung Yul Ryu  
Senior Researcher  
National Institute of Agricultural Science, Rural Development  
Administration  
Wanju-gun

Ms Jeong Hwa So  
Deputy Director  
Ministry of Oceans and Fisheries

Ms Jihye Yang  
Codex researcher  
Ministry of Oceans and Fisheries

Ms Sooryeon Yu  
CODEX Researcher  
Ministry of Food and Drug Safety

#### **ROMANIA - ROUMANIE - RUMANIA**

Mr Adrian Ardelean  
Permanent Representation of Romania to the EU in Brussels  
Bucharest

Dr Mirela Nicola  
Counselor  
National Sanitary Veterinary and Food Safety Authority  
Bucharest

#### **RUSSIAN FEDERATION – FÉDÉRATION DE RUSSIE – FEDERACIÓN DE RUSIA**

Ms Anna Koroleva  
Consultant  
Federal Service for Surveillance on Consumer Rights  
Protection and Human Well-being

Prof Pavel Shur  
Secretary of the Academic Council  
FBSI “Federal Scientific Center for Medical and Preventive  
Health Risk Management Technologies”

#### **SAUDI ARABIA - ARABIE SAOUDITE – ARABIA SAUDITA**

Mrs Latifah Almasaud  
Senior Risk Assessment Specialist  
Saudi Food and Drug Authority  
Riyadh

Dr Suliman Alajel  
Microbiology Reference lab Director  
Saudi Food and Drug Authority  
Riyadh

Mrs Sarah Alfaifi  
Senior Risk Assessment Specialist  
Saudi Food and Drug Authority  
Riyadh

#### **SENEGAL - SÉNÉGAL**

Prof Cheikh Sadibou Boye  
Enseignant Chercheur  
Faculté Médecine et Pharmacie

Mrs Mame Faye  
Point de Contact National  
Comité National Codex  
Dakar

#### **SINGAPORE - SINGAPOUR - SINGAPUR**

Ms Wei Ling Tan  
Specialist Team Lead (Virology)  
Singapore Food Agency

Dr Edmund Choo  
Assistant Director  
Singapore Food Agency

Dr Lee Kim Tan  
Director-General, Food Administration  
Singapore Food Agency

#### **SLOVAKIA - SLOVAQUIE - ESLOVAQUIA**

Dr Andrea Mojžišová  
Head of Department  
Veterinary and Food Institute  
Dolný Kubín

#### **SLOVENIA - SLOVÉNIE - ESLOVENIA**

Ms Maja Bajt  
Undersecretary  
The Administration of The Republic of Slovenia for Food  
Safety, Veterinary Sector and Plant Protection  
Ljubljana

#### **SOUTH AFRICA - AFRIQUE DU SUD - SUDÁFRICA**

Dr Mphane Molefe  
Director: Veterinary Public Health  
Department of Agriculture, Forestry and Fisheries  
Pretoria

Ms Penelope Campbell  
Director: Food Control  
Department of Health  
Pretoria

Dr Alice Sigobodhla  
Manager  
South African Health Products Regulatory Authority  
Pretoria

#### **SPAIN - ESPAGNE - ESPAÑA**

Ms Cristina Muñoz Madero  
Jefe de Área de preclínica y clínica y centralizados  
Agencia Española de Medicamentos y Productos Sanitarios  
(AEMPS)-Ministerio de Sanidad  
Madrid

Ms Sonia Sanz Hernández  
Técnico Superior  
Agencia Española de Seguridad Alimentaria y Nutrición-  
Ministerio de Consumo  
Madrid

**SRI LANKA**

Mrs Sujatha Pathirage  
Consultant Microbiologist  
Ministry of Health  
Colombo

**SWEDEN - SUÈDE - SUECIA**

Dr Gunilla Eklund  
Deputy Director, DVM, Ph.D.  
The Swedish Government  
Stockholm

Mrs Eva Fredberg Bawelin  
Principal Regulatory Officer, DVM  
Swedish Food Agency  
Uppsala

**SWITZERLAND - SUISSE - SUIZA**

Dr Katharina Stärk  
Head, Animal Health  
Federal Food Safety and Veterinary Office FSVO  
Bern

**THAILAND - THAÏLANDE - TAILANDIA**

Dr Pitak Chaisom  
Veterinarian, Expert level  
The National Bureau of Agricultural Commodity and Food Standards (ACFS)  
Ministry of Agriculture and Cooperative  
Bangkok

Dr Thitiporn Laoprasert  
Director of Aquatic Animal Health Research and Development Division  
Department of Fisheries, Ministry of Agriculture and Cooperatives  
Bangkok

Mr Pramote Talawat  
Committee of Food Processing Industry Club  
The Federation of Thai Industries  
Bangkok

Mr Pisan Pongsapitch  
Secretary General of the National Bureau of Agricultural Commodity and Food Standards  
National Bureau of Agricultural Commodity and Food Standards, Ministry of Agriculture and Cooperatives  
Bangkok

Dr Namaporn Attaviroj  
Senior Standards Officer  
National Bureau of Agricultural Commodity and Food Standards (ACFS), Ministry of Agriculture and Cooperatives  
Bangkok

Dr Thanida Harintharanon  
Veterinarian Expert in International Livestock Standards  
Department of Livestock Development  
Ministry of Agriculture and Cooperatives  
Bangkok

Dr Nuttima Kositcharoenkul  
Plant Pathologist, Senior Professional Level  
Department of Agriculture, Ministry of Agriculture and Cooperatives  
Bangkok

Dr Sakranmanee Krajangwong  
Veterinarian, Professional level  
The National Bureau of Agricultural Commodity and Food Standards (ACFS)

Ministry of Agriculture and Cooperatives  
Bangkok

Mr Visit Limlurcha  
Chairman of Food Processing Industry Club  
The Federation of Thai Industries  
Bangkok

Dr Mintra Lukkana  
Veterinarian, Senior professional level  
National Bureau of Agricultural Commodity and Food Standards (ACFS), Ministry of Agriculture and Cooperatives  
Bangkok

Dr Julaporn Srinha  
Veterinarian, Senior professional level  
Department of Livestock Development, Ministry of Agriculture and Cooperatives  
Pathumthani

Dr Preeyanan Sriwanayos  
Veterinary officer, Practitioner level  
Department of Fisheries, Ministry of Agriculture and Cooperatives  
Bangkok

Dr Suchana Sukklad  
Veterinarian, Professional level  
Department of Livestock Development, Ministry of Agriculture and Cooperatives  
Pathumthani

Ms Jiraratana Thesasilpa  
Food and Drug Technical Officer, Senior Professional Level  
Food and Drug Administration, Ministry of Public Health  
Nonthaburi

Dr Kwanhatai Thongpalad  
Veterinarian, Senior professional level  
The National Bureau of Agricultural Commodity and Food Standards (ACFS), Ministry of Agriculture and Cooperatives  
Bangkok

Dr Nanthiya Unprasert  
Advisor  
Thai Chamber of Commerce, Board of Trade of Thailand  
Bangkok

Dr Supaporn Wongsrichai  
Veterinarian, Senior professional level  
Department of Livestock Development, Ministry of Agriculture and Cooperatives  
Pathumthani

**TOGO**

Mr Bougra Badjonama Batimsoga  
Ingénieur en production animale  
Ministère de l'Agriculture  
Lomé

Dr Yempabou Damitoti  
Vétérinaire  
Ministère Agriculture  
Lomé

**TRINIDAD AND TOBAGO - TRINITÉ-ET-TOBAGO - TRINIDAD Y TOBAGO**

Dr Victoria Lashley  
 Technical Officer  
 Ministry of Agriculture Land and Fisheries  
 Port-of-Spain

**TURKEY - TURQUIE - TURQUÍA**

Dr Betül Vazgecer  
 Engineer  
 Ministry of Agriculture and Forestry  
 Ankara

Mrs Hatice Aykir  
 Engineer  
 Ministry of Agriculture and Forestry  
 Ankara

Mr Umit Ugur Bahce  
 Working group manager  
 Ministry of Agriculture and Forestry  
 Ankara

Dr Guler Demiroren  
 Veterinarian  
 Ministry of Agriculture and Forestry  
 Ankara

Dr Hatice Eren  
 Engineer  
 Ministry of Agriculture and Forestry  
 Ankara

Dr Gonca Oztap Ozen  
 Veterinarian  
 Ministry of Agriculture and Forestry  
 Ankara

**UGANDA - OUGANDA**

Dr Sylvia Angubua Baluka  
 Senior Lecturer  
 College of Veterinary Medicine, Animal Resources &  
 Biosecurity (COVAB), Makerere University  
 Kampala

Mr Hakim Baligeya Mufumbiro  
 Principal Standards Officer  
 Uganda National Bureau of Standards  
 Kampala

Dr Lawrence Mugisha  
 Associate Professor  
 College of Veterinary Medicine, Animal Resources &  
 Biosecurity (COVAB), Makerere University  
 Kampala

Prof Charles Muyanja  
 Professor  
 Makerere University  
 Kampala

Prof George William Nasinyama  
 Vice Chancellor  
 UNICAF University, Uganda  
 Kampala

**UNITED KINGDOM - ROYAUME-UNI – REINO UNIDO**

Dr Kitty Healey  
 Head of Surveillance Division  
 Veterinary Medicines Directorate  
 Surrey

Mr Niloy Acharyya  
 International Delivery Lead (antimicrobial resistance)  
 Veterinary Medicines Directorate  
 Surrey

Dr Tamsin Dewé  
 Head of AMR Surveillance and Evidence  
 Veterinary Medicines Directorate  
 Surrey

Dr Fraser Keith Broadfoot  
 Head of Antibiotic Stewardship and Usage Team  
 Veterinary Medicines Directorate  
 Surrey

Dr Iulia Turiac  
 Senior Policy Advisor  
 Defra  
 London

Mr Steve Wearne  
 Director of Global Affairs  
 Food Standards Agency  
 London

**UNITED REPUBLIC OF TANZANIA – RÉPUBLIQUE-UNIE DE TANZANIE – REPÚBLICA UNIDA DE TANZANÍA**

Dr Jeremiah Seni  
 University Professor  
 Catholic University of Health & Allied Science  
 Dar Es Salaam

Mr Kaunara Azizi  
 Researcher  
 Tanzania Food and Nutrition Centre

Ms Mwajuma Iddi Dukulai  
 Standards Officer  
 Tanzania Bureau of Standards  
 Dar-es-Salaam

Mr Ali Haji Mohamed  
 Officer  
 Zanzibar Food and Drugs Agency

Ms Yunus Mssika  
 Officer  
 Cereals and other produce Board of Tanzania

Dr Gabriel Shirima  
 University Professor  
 Nelson Mandela African Institute of Science & Technology  
 Arusha

**UNITED STATES OF AMERICA – ÉTATS-UNIS D'AMÉRIQUE – ESTADOS UNIDOS DE AMÉRICA**

Dr Donald Prater  
 Associate Commissioner for Imported Food Safety  
 United States Food and Drug Administration  
 Silver Spring, Maryland

Dr James Adaskaveg  
Professor and Plant Pathologist  
Department of Plant Pathology  
Riverside, CA

Mr Robert Ahern  
Director, WTO Agricultural Affairs  
Office of the U.S. Trade Representative (USTR)  
Washington, DC

Dr Neena Anandaraman  
Veterinary Science Policy Advisor  
United States Department of Agriculture  
Washington DC

Mrs Marielsie Avila  
Senior Trade Advisor  
United States Department of Agriculture  
Washington, DC

Dr Susan Bright-Ponte  
Veterinary Medical Officer  
U.S. Food and Drug Administration  
Rockville, MD

Dr John Brooks  
Research Microbiologist  
USDA-ARS  
Mississippi State, MS

Mr James Cranney  
President  
California Citrus Quality Council  
Auburn, CA

Dr Jose Emilio Esteban  
Chief Scientist  
Food Safety and Inspection Service U.S. Department of  
Agriculture  
Washington, DC

Dr Julius Fajardo  
Senior Plant Pathologist  
USDA  
Washington, DC

Ms Mallory Gaines  
Director, Market Access and Trade Policy  
American Feed Industry Association  
Washington DC

Mr Nicholas Gardner  
Vice President, Codex and International Regulatory Affairs  
U.S. Dairy Export Council  
Arlington, VA

Ms Marie Maratos Bhat  
International Issues Analyst  
U. S. Department of Agriculture  
Washington, DC

Dr Amber McCoig  
Office of the Center Director  
U.S. Food and Drug Administration  
Rockville, MD

Dr Ron Miller  
Regulatory Review Microbiologist  
United States Food and Drug Administration  
Rockville, Maryland

Dr Dawn Sievert  
Senior Science Advisor  
Centers for Disease Control and Prevention  
Atlanta, GA

Dr Randall Singer  
Professor of Epidemiology  
University of Minnesota  
St. Paul, MN

Dr Ruby Singh  
Senior Regulatory Review Microbiologist  
U.S. Food and Drug Administration

Dr Liz Wagstrom  
Chief Veterinarian  
NPPC  
Des Moines, IA

Dr Corey Watts  
AAAS Science & Technology Policy Fellow  
U.S. Department of State

#### **URUGUAY**

Dr. Norman Bennett  
Gerente de Inocuidad  
Dirección General de Bioseguridad e Inocuidad Alimentaria  
Ministerio de Ganadería, Agricultura y Pesca  
Montevideo

Dra Cecilia Dieste  
Asistente Técnica  
Dirección General de Bioseguridad e Inocuidad Alimentaria  
Ministerio de Ganadería, Agricultura y Pesca  
Montevideo

Dr. Federico Fernández  
Asesor Técnico  
Dirección General de Servicios Ganaderos  
Ministerio de Ganadería, Agricultura y Pesca  
Montevideo

#### **VENEZUELA (BOLIVARIAN REPUBLIC OF) - VENEZUELA (RÉPUBLIQUE BOLIVARIENNE DU) - VENEZUELA (REPÚBLICA BOLIVARIANA DE)**

Mrs Roxana Abreu  
Director  
SENCAMER  
Caracas

Mrs Corina Camacho  
Professional  
SENCAMER  
Caracas

**INTERNATIONAL GOVERNMENTAL ORGANIZATIONS  
ORGANISATIONS GOUVERNEMENTALES INTERNATIONALES  
ORGANIZACIONES GUBERNAMENTALES INTERNACIONALES**

**AFRICAN UNION (AU)**

Mr John Oppong-Otoo  
Food Safety Officer  
African Union Interafrican Bureau for Animal Resources  
Nairobi

**INTER-AMERICAN INSTITUTE FOR COOPERATION ON  
AGRICULTURE (IICA)**

Ms Ericka Calderon  
Agricultural Health and Food Safety Specialist  
IICA  
Vázquez de Coronado

Dr Horrys Friaca  
Agricultural Health and Food Safety Specialist  
IICA  
Washington

**ORGANISATION FOR ECONOMIC CO-OPERATION AND  
DEVELOPMENT (OECD)**

Mr Michele Cecchini  
Technical officer  
OECD

**WORLD ORGANISATION FOR ANIMAL HEALTH (OIE)**

Dr Elisabeth Erlacher-Vindel  
Head of the Antimicrobial Resistance and Veterinary  
Products Department  
OIE  
Paris

**NON-GOVERNMENTAL ORGANIZATIONS  
ORGANISATIONS NON GOUVERNEMENTALES  
ORGANIZACIONES NO GUBERNAMENTALES**

**ASSOCIATION OF AMERICAN FEED CONTROL OFFICIALS  
(AAFCO)**

Mr Richard Ten Eyck  
Feed Safety Specialist  
Oregon Department of Agriculture  
Champaign

Mr Mike Stage  
Division Manager  
Arkansas Department of Agriculture  
Champaign

**CONSUMERS INTERNATIONAL (CI)**

Mr Steve Roach  
Representative  
Consumers International

**CROPLIFE INTERNATIONAL (CROPLIFE)**

Dr Manojit Basu  
Managing Director, Science Policy  
CropLife America  
Arlington

Dr Ray Mcallister  
Sr. Regulatory Policy  
CropLife America  
Arlington

Mr Olafur Valsson  
Deputy Head of the Antimicrobial Resistance and Veterinary  
Products Department  
OIE  
Paris

**UNITED NATIONS ENVIRONMENT PROGRAMME (UNEP)**

Ms Aitziber Echeverria  
Programme Management Officer  
United Nations Environment Programme (UNEP)

**WORLD CUSTOMS ORGANIZATION (WCO)**

Mr Maurice Adefalou  
Technical officer  
WCO

Mr Ozlem Soysanli  
Technical Officer  
WCO

**WORLD BANK**

Ms Ana Cristina Canales Gómez  
Health specialist  
World Bank

Ms Anna Elisabeth Larsen  
Health specialist  
World Bank

Ms Naomi Rupasinghe  
Health Specialist  
World Bank

**INTERNATIONAL CO-OPERATIVE ALLIANCE (ICA)**

Mr Kazuo Onitake  
Senior Scientist, Department of Quality Assurance  
International Co-operative Alliance  
Tokyo

Mr Yuji Gejo  
Officer  
International Co-operative Alliance  
Tokyo

**INTERNATIONAL COUNCIL OF BEVERAGES ASSOCIATIONS  
(ICBA)**

Ms Kimberly Turner  
Manager – Food Safety Regulatory  
The Coca-Cola Company  
Atlanta

**INTERNATIONAL DAIRY FEDERATION (IDF/FIL)**

Dr Jamie Jonker  
Chair of the IDF Science and Programme Coordination  
Committee  
International Dairy Federation  
Brussels

**INTERNATIONAL FEED INDUSTRY FEDERATION (IFIF)**

Ms Alexandra De Athayde  
Executive Director  
International Feed Industry Federation (IFIF)  
Wiehl

Ms Leah Wilkinson  
Chair, IFIF Regulatory Committee  
International Feed Industry Federation (IFIF)  
Arlington, VA

**INTERNATIONAL MEAT SECRETARIAT (IMS)**

Ms Trachelle Carr  
International Technical Services Specialist  
International Meat Secretariat  
Washington, DC

Mr Phil Corrigan  
Scientific Advisor  
International Meat Secretariat  
St. Thomas

Mr Ian Jenson  
Market Access Science and Technology  
International Meat Secretariat

Ms Cassidy Klima  
Technical Director  
International Meat Secretariat  
Calgary, Alberta

Dr Kathy Simmons  
Chief Veterinarian  
International Meat Secretariat  
Washington, DC

**THE INTERNATIONAL POULTRY COUNCIL (IPC)**

Mr Nicolò Cinotti  
Secretary General  
International Poultry Council

Mr Dennis Erpelding  
Science Advisor  
International Poultry Council

**HEALTH FOR ANIMALS (HEALTHFORANIMALS)**

Mr Carel Du Marchie Sarvaas  
Executive Director  
HealthforAnimals

Dr Alexander Boettner  
Exec. Dir. Regulatory Affairs  
MSD Animal Health Innovation GmbH  
Schwabenheim

Dr Richard Coulter  
Senior Vice President  
Phibro Animal Health Corporation  
Teaneck NJ

Dr Rachel Cumberbatch  
Director, International and Regulatory Affairs  
HealthforAnimals

Mrs Catherine Filejski  
Delegate  
HealthforAnimals

Mr Jeff Howe  
Technical Director  
HealthforAnimals

Mrs Gabriella Ippolito  
Advisor, Government Affairs  
HealthforAnimals

Mr Jesse Sevcik  
Executive Advisor, Government Affairs  
HealthforAnimals  
Washington, D.C.

Dr Richard Sibbel  
President and owner  
Executive Veterinary & Health Solutions LLC

Dr Shabbir Simjee  
HealthforAnimals  
Washington, D.C.

Dr Jeffrey L. Watts  
Research Director

External Innovation – Anti-Infectives  
HealthforAnimals

**FAO**

Mrs Daniela Battaglia  
Livestock Production Officer  
FAO  
Rome

Ms Carmen Bullon  
Legal Officer  
FAO

Ms Marisa Caipo  
Food Safety and Quality Officer  
FAO

Dr Alejandro Dorado Gracia  
Animal Health Officer (AMR and Public Health)  
FAO  
Rome

Ms Maria Gatica  
Consultor en gestión de riesgos Resistencia a los  
Antimicrobianos e Inocuidad Alimentos  
FAO

Ms Francesca Latronico  
AMR laboratory specialist  
FAO

Dr Jeffrey LeJeune  
Food Safety Officer  
FAO  
Rome

Dr Jorge Pinto Ferreira  
Food Safety Officer  
FAO  
Rome

Mr Artur Shamilov  
Agricultural Officer  
FAO

**WHO - OMS**

Dr Peter Beyer  
Unit Head a.i.  
World Health Organization  
Geneva

Mr Jorge Raul Matheu Alvarez  
Team Lead  
World Health Organization  
Geneva

**TFAMR SECRETARIAT**

Mr Jae Woo Park  
Deputy Director  
Ministry of Food and Drug Safety

Ms Sung Myung Bae  
Deputy Director  
Ministry of Food and Drug Safety

Ms Yun Jeong Cho  
Assistant Director  
Ministry of Food and Drug Safety

Mr Cheol Hee Kim  
Director  
Ministry of Food and Drug Safety

Ms Min Ji Kim  
CODEX Researcher  
Ministry of Food and Drug Safety

Mr Jae Yong Lee  
Director General  
Ministry of Food and Drug Safety

Mr Sang Mok Lee  
Scientific Officer  
Ministry of Food and Drug Safety

Ms Yeo Jin Min  
CODEX Researcher  
Ministry of Food and Drug Safety

Ms Hyun Kyung Woo  
CODEX Researcher  
Ministry of Food and Drug Safety

**CODEX SECRETARIAT**

Ms Gracia Brisco  
Food Standards Officer  
Joint FAO/WHO Food Standards Programme  
Food and Agriculture Organization of the U.N.  
Geneva

Dr Sarah Cahill  
Senior Food Standards Officer  
Joint FAO/WHO Food Standards Programme  
Food and Agriculture Organization of the U.N.  
Rome

Mrs Myoengsin Choi  
Food Standard Officer  
Joint FAO/WHO Food Standards Programme  
Food and Agriculture Organization of the U.N.  
Rome

Mr Tom Heilandt  
Secretary  
Joint FAO/WHO Food Standards Programme  
Food and Agriculture Organization of the U.N.  
Rome

Mr Roberto Sciotti  
Knowledge Management Officer  
Joint FAO/WHO Food Standards Programme  
Food and Agriculture Organization of the U.N.  
Rome

Ms Jocelyne Farruggia  
Office Assistant  
Joint FAO/WHO Food Standards Programme  
Food and Agriculture Organization of the U.N.  
Rome

Ms Ilaria Tarquinio  
Programme Assistant  
Joint FAO/WHO Food Standards Programme  
Food and Agriculture Organization of the U.N. (FAO)  
Rome

Mr Robert Damiano  
IT Clerk  
Joint FAO/WHO Food Standards Programme  
Food and Agriculture Organization of the U.N.  
Rome

**APPENDIX II**

**REVISION OF THE  
CODE OF PRACTICE TO MINIMIZE AND CONTAIN FOODBORNE ANTIMICROBIAL RESISTANCE  
(CXC 61-2005)  
(For adoption at Step 8)**

**1. Introduction**

1. Antimicrobial resistance (AMR) poses an important, complex, and priority global public health challenge. Along the food chain, there is a need to address the risks associated with development, selection and dissemination of foodborne resistant microorganisms and resistance determinants. Responsible and prudent use of antimicrobial agents in all sectors following a One Health Approach and strategies for best management practices in animal production (terrestrial and aquatic), plant/crop production and food/feed processing, packaging, storage, transport, and wholesale and retail distribution should form a key part of multi-sectoral national action plans to address risks of foodborne AMR.
2. This Code of Practice addresses the responsible and prudent use of antimicrobial agents by participants in the food chain, including, but not limited to, the role of competent authorities, the pharmaceutical industry, veterinarians, and plant/crop health professionals, and food producers and processors. It provides guidance on measures and practices at primary production, and during processing, storage, transport, wholesale and retail distribution of food to prevent, minimize and contain foodborne antimicrobial resistance in the food supply. It also identifies knowledge gaps and provides guidance on communication strategies to consumers.
3. In keeping with the Codex mandate this Code of Practice addresses antimicrobial use along the food chain. It is recognized that the use of antimicrobial agents along the food chain may result in exposure to antimicrobial resistant bacteria or their determinants in the food production environment. As part of a One Health approach to minimize and contain antimicrobial resistance, only authorized products should be used and best practices in the food production sector should be followed to minimize the occurrence/persistence in the food production environment of antimicrobials and their metabolites from food production related activities, and to minimize the risks associated with the selection and dissemination of resistant microorganisms and resistance determinants in the food production environment.
4. This Code of Practice is an integral part of risk analysis focusing on risk management options and should be read in conjunction with other Codex texts including the Guidelines on Integrated Monitoring and Surveillance of Foodborne Antimicrobial Resistance and the *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance* (CXG 77-2011). In addition, the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003), the *Code of Practice on Good Animal Feeding* (CXC 54-2004), and the *Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Program associated with the Use of Veterinary Drugs in Food Producing Animals* (CXG 71-2009) are particularly relevant for use of agricultural chemicals on plants/crops, animal feed, and veterinary drugs, respectively.
5. This Code of Practice provides risk management advice, including the responsible and prudent use of antimicrobial agents that can be applied proportionately to the risks identified through the risk analysis process described in the *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance*. Risk managers are responsible for prioritizing and assessing foodborne AMR risks appropriate to the country and determining how best to reduce risk and protect public health.
6. The *Principles and Guidelines for the Conduct of Microbiological Risk Management* (CXG 63-2007) contains guidance for developing and implementing risk management measures. Setting priorities and identifying risk management measures should take into account the following:
  - *WHO Guidance on Integrated Surveillance of Antimicrobial Resistance in Foodborne Bacteria, application of a One Health Approach*;
  - *WHO List of Critically Important Antimicrobials for Human Medicine*, specifically the Annex with the complete list of antimicrobials for human use, categorized as critically important, highly important and important;
  - Relevant chapters of the *OIE Terrestrial and Aquatic Animal Health Codes* and the *OIE List of Antimicrobial Agents of Veterinary Importance*; and
  - National lists of important antimicrobials for humans and animals where they exist.
7. Where available, national and local guidelines to prevent, minimize and contain foodborne AMR should be taken into consideration. Best management practices and guidelines on the responsible and prudent use of antimicrobials developed by governmental and professional organizations should also be considered.

8. This document is designed to provide a framework, for the development of measures to mitigate the risk of foodborne AMR that countries may implement, as part of their national strategy on AMR, in accordance with their capabilities, based on their national priorities and capacities, and within a reasonable period of time. A progressive implementation may be used by some countries to properly apply elements in this document proportionate to the foodborne AMR risk and should not be used to generate unjustified barriers to trade.

## 2. Scope

9. This Code of Practice provides risk management guidance to address the risk to human health of the development and transmission of antimicrobial resistant microorganisms or resistance determinants through food. It provides risk-based guidance on relevant measures and practices along the food chain to minimize and contain the development and spread of foodborne antimicrobial resistance, including guidance on the responsible and prudent use of antimicrobial agents in animal production (terrestrial and aquatic) plant/crop production, and references other best management practices, as appropriate.
10. This document includes guidance for all interested parties involved in the authorization, manufacture, sale and supply, prescription and use of antimicrobial agents in the food chain together with those involved in the handling, preparation, food processing, storage, transport, wholesale and retail distribution and consumption of food who have a role to play in ensuring the responsible and prudent use of antimicrobial agents and/or who have a role with limiting the development and spread of foodborne antimicrobial resistant microorganisms and resistance determinants.
11. Most of the recommendations in this Code of Practice focus on antibacterials, however some recommendations may also be applicable to antiviral, antiparasitic, antiprotozoal, and antifungal agents, where there is scientific evidence of foodborne AMR risk to human health.
12. As there are existing Codex or internationally recognized guidelines, the following areas related to antimicrobial agents or AMR are outside the scope of this document: residues of antimicrobial agents in food; AMR marker genes in recombinant-DNA plants/crops<sup>1</sup> and recombinant DNA microorganisms<sup>2</sup>; non-genetically modified microorganisms (for example, starter cultures) intentionally added to food with a technological purpose; certain food ingredients, which could potentially carry antimicrobial resistance determinants, such as probiotics<sup>3</sup>; and biocides. In addition, AMR from non-food animals, non-food plants/crops, or non-food routes are also outside the scope of this document.

## 3. Definitions

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

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

**Antibacterial:** A substance that acts against bacteria.

**Antimicrobial agent:** Any substance of natural, semi-synthetic, or synthetic origin that at *in vivo* concentrations kills or inhibits the growth of microorganisms by interacting with a specific target.

**Antimicrobial resistance (AMR):** The ability of a microorganism to multiply or persist in the presence of an increased level of an antimicrobial agent relative to the susceptible counterpart of the same species.

**Antimicrobial resistance determinant:** The genetic element(s) encoding for the ability of microorganisms to withstand the effects of an antimicrobial agent. They are located either chromosomally or extra-chromosomally and may be associated with mobile genetic elements such as plasmids, integrons or transposons, thereby enabling horizontal transmission from resistant to susceptible strains.

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<sup>1</sup> The food safety assessment on the use of antimicrobial resistance marker genes in recombinant-DNA plants is addressed in the *Guidelines for the Conduct of Food Safety Assessment of Foods derived from Recombinant-DNA Plants* (CXG 45-2003).

<sup>2</sup> The food safety assessment on the use of antimicrobial resistance marker genes in recombinant-DNA microorganisms is addressed in the *Guideline for the Conduct of Food Safety Assessment of Foods produced using Recombinant-DNA Microorganisms* (CXG 46-2003).

<sup>3</sup> The food safety assessment on the use of probiotics in foods is addressed in the Report of the *Joint FAO/WHO Working Group on drafting Guidelines for the Evaluation of Probiotics in Foods* (FAO/WHO, 2002).

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

**Extra- or off-label use:** The use of an antimicrobial agent that is not in accordance with the approved product labelling.

**Food chain:** Production to consumption continuum including, primary production (food-producing animals, plants/crops, feed), harvest/slaughter, packing, processing, storage, transport, and distribution to the point of consumption.

**Food-producing animals:** Animals raised for the purpose of providing food to humans.

**Food production environment:** The immediate vicinity of the food chain where there is relevant evidence that it could contribute to foodborne AMR.

**Growth promotion:** Administration of antimicrobial agents to only increase the rate of weight gain and/or the efficiency of feed utilization in animals. The term does not apply to the use of antimicrobials for the specific purpose of treating, controlling, or preventing infectious diseases.

**Marketing authorization:** Process of reviewing and assessing a dossier to support an antimicrobial agent to determine whether to permit its marketing (also called licensing, registration, approval, etc.), finalized by granting of a document also called marketing authorization (equivalent: product license).

**Medically important antimicrobials:** Antimicrobial agents important for therapeutic use in humans, taking into account the *WHO List of Critically Important Antimicrobials for Human Medicine*, including the classes described in the Annex of the “*List of Medically Important Antimicrobials, categorized as Critically Important, Highly Important, and Important*”, or equivalent criteria established in a national list, where available. It does not include ionophores or other agents determined not to be a foodborne AMR risk consistent with the *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance*.

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

**Pharmacovigilance:** The collection and analysis of data on how products perform in the field after authorization and any interventions to ensure that they continue to be safe and effective. These data can include information on adverse effects to humans, animals, plants or the environment; or lack of efficacy.

**Plants/crops:** A plant or crop that is cultivated or harvested as food or feed.

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

**Prevention of disease/prophylaxis:** Administration or application of antimicrobial agents to an individual or a group of plants/crops or animals at risk of acquiring a specific infection or in a specific situation where infectious disease is likely to occur if the antimicrobial agent is not administered or applied.

**Veterinary medical use<sup>4</sup> /phytosanitary use<sup>6</sup>** (food-producing animals or plants/crops): Administration or application of antimicrobial agents for the treatment, control/metaphylaxis or prevention/prophylaxis of disease.

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

#### 4. General principles to minimize and contain foodborne antimicrobial resistance

##### *Principles on AMR Risk Management (generally)*

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

<sup>4</sup> See also OIE Terrestrial Animal Health Code, specifically the chapter on Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals.

<sup>5</sup> Also recognized as therapeutic use in some jurisdictions/organizations.

<sup>6</sup> See also IPPC International Standard for Phytosanitary Measures, Glossary of Phytosanitary Terms.

**Principle 2:** Considering that this document is to provide risk management guidance to address foodborne AMR risks to human health, for animal health and plant health aspects, relevant OIE and IPPC standards should be considered.

**Principle 3:** Foodborne AMR risk management measures should be implemented in a way that is proportionate to the risk and reviewed on a regular basis as described in the *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance*. Risk managers should consider potential unintended consequences to humans, animal, and plant health of recommended risk management measures.

**Principle 4:** The *WHO List of Critically Important Antimicrobials for Human Medicine*, the *OIE List of Antimicrobial Agents of Veterinary Importance*, or national lists, where available, should be considered when setting priorities for risk assessment and risk management to minimize and contain antimicrobial resistance. The lists should be regularly reviewed and updated as necessary when supported by scientific findings as new scientific data emerges on resistance patterns.

**Principle 5:** On a continuous and progressive implementation of risk management measures along the food chain to minimize the possible risks associated with foodborne AMR, priority should be given to the most relevant elements from a public health perspective.

***Principle on preventing infections and reducing the need for antimicrobials***

**Principle 6:** Biosecurity, appropriate nutrition, vaccination, animal and plant/crop best management practices, and other alternative tools where appropriate, and that have been proven to be efficacious and safe, should be considered to reduce the need for use of antimicrobial agents.

***Principles on the responsible and prudent use of antimicrobials (generally)***

**Principle 7:** The decision to use antimicrobial agents should be based on sound clinical judgement, experience, and treatment efficacy. Where feasible and appropriate the results of bacterial cultures and integrated resistance surveillance and monitoring should also be considered.

**Principle 8:** Medically important antimicrobials should be prescribed, administered, or applied only by, or under the direction of, veterinarians, plant/crop health professionals, or other suitably trained persons authorized in accordance with national legislation.

**Principle 9:** Antimicrobial agents should be used as legally authorized and following all applicable label directions; except where specific legal exemptions apply.

**Principle 10:** The choice of which antimicrobial agent to use should take into consideration relevant professional guidelines, where available, results of antimicrobial susceptibility testing of isolates from the production setting, where appropriate, and make adjustments to the antimicrobial agent selection based on clinical outcomes or when foodborne AMR risks become evident.

**Principle 11:** Science-based species or sector-specific responsible and prudent antimicrobial use guidelines should be developed, implemented, and reviewed on a regular basis to maintain their effectiveness in minimizing the risk of foodborne antimicrobial resistance. Such guidelines could be included as a part of national action plans or stakeholder-led plans on antimicrobial resistance with development and dissemination shared among countries and organizations.

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

**Principle 12:** Responsible and prudent use of antimicrobial agents does not include the use for growth promotion of antimicrobial agents that are considered medically important. Antimicrobial agents that are not considered medically important should not be used for growth promotion unless potential risks to human health have been evaluated through procedures consistent with the *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance*.

**Principle 13:** Medically important antimicrobial agents should only be used for veterinary medical use/phytosanitary use-(treatment, control/metaphylaxis or prevention/prophylaxis of disease).

**Principle 14:** Medically important antimicrobials should only be administered or applied for prevention/prophylaxis where professional oversight has identified well-defined and exceptional circumstances, appropriate dose and duration, based on clinical and epidemiological knowledge, consistent with the label, and in line with national legislation. Countries could use additional risk management measures for medically important antimicrobials considered highest priority critically important as described in the *WHO List of Critically Important Antimicrobials for Human Medicine*, the *OIE List of Antimicrobial Agents of Veterinary Importance*, or national lists, where available, including restrictions proportionate to risk and supported by scientific evidence.

**Principle 15:** When used for the control of disease/metaphylaxis, medically important antimicrobial agents should only be used on the basis of epidemiological and clinical knowledge and a diagnosis of a specific disease and follow appropriate professional oversight, dose, and duration.

**Principle on surveillance of antimicrobial resistance and use**

**Principle 16:** Monitoring and surveillance of the use of antimicrobial agents and the incidence or prevalence, and in particular trends, of foodborne antimicrobial resistant microorganisms and resistance determinants are among the critical factors to consider when developing risk management measures and evaluating the effectiveness of implemented risk management measures. Use of antimicrobial agents in humans, food-producing animals, and plants/crops and transmission of pathogens and resistance genes between humans, food-producing animals, plants/crops, and the environment are additional factors to consider, through the foodborne AMR risk analysis process described in the *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance*.

**5. Responsible and prudent use of antimicrobial agents**

13. The *OIE Terrestrial and Aquatic Animal Health Codes* and the *OIE List of Antimicrobial Agents of Veterinary Importance* contain detailed information with respect to the control of veterinary medicines for use in food-producing animals and aquaculture.
14. For more information on the data requirements for authorization of antimicrobial agents for food-producing animals see relevant national guidelines or internationally harmonized guidelines.

**5.1 Responsibilities of the competent authorities**

15. The competent authorities, including the authority responsible for granting the marketing authorization for antimicrobials for use along the food chain, have a significant role in specifying the terms of the authorization and in providing appropriate information to the veterinarian and plant/crop health professionals, or other suitably trained persons authorized in accordance with national legislation and producers through product labelling and/or by other means, in support of the responsible and prudent use of antimicrobial agents along the food chain. It is the responsibility of competent authorities to develop up-to-date guidelines on data requirements for evaluation of antimicrobial agent applications, as well as ensuring that antimicrobial agents used in the food chain are used in accordance with national legislation.
16. National governments in cooperation with animal, plant/crop, and public health professionals should adopt a One Health Approach to promote the responsible and prudent use of antimicrobial agents along the food chain as an element of a national strategy to minimize and contain antimicrobial resistance. Good animal production (terrestrial and aquatic) and best management practices for plant/crop production, vaccination and biosecurity policies and development of animal and plant/crop health programs at the farm level contribute to reduce the prevalence of animal and plant/crop disease requiring antimicrobial administration and can be incorporated into national strategies to complement activities in human health.
17. National action plans may include recommendations to relevant professional organizations to develop species or sector-specific guidelines.
18. In order to promote responsible and prudent use of antimicrobial agents, it is important to encourage the development, availability, and use of validated, rapid, reliable diagnostic tools, where available, to support veterinarians and plant/crop health professionals in diagnosing the disease and selecting the most appropriate antimicrobial, if any, to be administered/applied.
19. The competent authorities should determine appropriate labelling, including the conditions that will minimize the development of foodborne AMR while still maintaining efficacy and safety.

**Quality control of antimicrobial agents**

20. Competent authorities should ensure that quality controls are carried out in accordance with national or international guidance and in compliance with the provisions of good manufacturing practices.

**Assessment of efficacy**

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

**Assessment of the potential antimicrobial agents to select for resistant microorganisms**

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

**Assessment of the impact on the food production environment**

23. In accordance with their national guidelines, competent authorities should consider results of foodborne AMR risk assessment of sources that contribute to the food production environment, e.g. reuse of waste water for irrigation, and use of manure, and other waste-based fertilizers for soil fertilization. When a foodborne AMR risk is determined through the *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance* the need for monitoring and proportionate risk management measures should be considered.

**Establishment of a summary of characteristics for each antimicrobial product**

24. Competent authorities should establish a Summary of Product Characteristics or similar document for each authorized antimicrobial product. The information in these documents can be utilized in labelling and as a package insert. Such information may include:
- brand/chemical/drug name;
  - product description;
  - indications for use;
  - dosage forms/strengths/application rates;
  - duration of treatment or application interval;
  - contraindications; warnings;
  - adverse reactions/phytotoxicity/incompatibilities;
  - product interactions and uses in specific populations for each authorized antimicrobial product, when available;
  - withdrawal periods or pre-harvest intervals; and
  - storage conditions.

**and surveillance programs**

25. Competent authorities should establish systems for the monitoring and surveillance of foodborne antimicrobial resistance and antimicrobial use (AMU) following the Codex Guidelines on Integrated Monitoring and Surveillance of Foodborne Antimicrobial Resistance and OIE standards for monitoring of antimicrobial resistance and use in animals.
26. Competent authorities should have in place a pharmacovigilance program for the monitoring and reporting of suspected adverse reactions to veterinary antimicrobial agents, including lack of the expected efficacy that could be related to foodborne antimicrobial resistance. The information collected through the pharmacovigilance program can contribute to a comprehensive strategy to minimize antimicrobial resistance along the food chain.
27. In cases where the assessment of data collected from pharmacovigilance and from other post-authorization surveillance including, if available, targeted surveillance of antimicrobial resistance in veterinary or plant/crop pathogens, suggests that the conditions of use of the given antimicrobial agent marketing authorization should be reviewed, competent authorities shall endeavour to achieve this re-evaluation.

**Distribution of antimicrobial products**

28. Competent authorities should make sure antimicrobial products are distributed through licensed/authorized distribution systems in accordance with national legislation.
29. Competent authorities should prevent illegal medicines and unapproved formulations from entering distribution systems.

**Control of advertising**

30. Competent authorities should ensure that advertising and promotion of antimicrobial products is done in accordance with national legislation or policies.
31. Advertising and promotion of antimicrobial agents should be done in a manner consistent with specific regulatory recommendations for the product.

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

32. Training should be supported, to the extent possible, by the competent authorities on topics related to minimizing antimicrobial resistance and encouraging the responsible use of antimicrobial agents. Training may take the form of communication and outreach and should be relevant to veterinarians and plant/crop health professionals, manufacturers and marketing authorization holders, wholesale and retail distributors, food animal and plant/crop producers, and other participants along the food chain as appropriate. Training and communication may broadly address other public health-related activities.
33. Relevant information may include, but is not limited to:
- information on disease prevention and management strategies to reduce the need to use antimicrobial agents;
  - relevant information to enable the veterinarians and plant/crop health professionals to use or prescribe antimicrobial agents responsibly and prudently;
  - the need to adhere to responsible and prudent use principles and using antimicrobial agents in production settings in agreement with the provisions of the marketing authorizations and professional advice;
  - utilizing the *WHO List of Critically Important Antimicrobials for Human Medicine*; the *OIE List of Antimicrobial Agents of Veterinary Importance*, and national lists where they exist;
  - information on appropriate storage conditions for antimicrobial agents before and during use and the safe disposal of unused and out of date antimicrobials;
  - understanding relevant risk analysis of antimicrobial agent products and how to use that information;
  - national action plans, if available, and international strategies to fight and control antimicrobial resistance;
  - good antimicrobial use practices, antimicrobial prescription writing and establishment of withdrawal period;
  - training in new methodologies for molecular analysis of resistance; understanding methods and results of susceptibility testing of antimicrobials and molecular analysis;
  - the ability of antimicrobial agents to select for resistant microorganisms or resistance determinants that may contribute to animal, plant/crop, or human health problems;
  - understanding the process of identifying, evaluating, implementing, and monitoring the effectiveness of risk management options; and
  - the collection and reporting of AMR and AMU monitoring and surveillance data.

**Knowledge gaps and research**

34. To further elucidate the risk from foodborne AMR, the relevant authorities could encourage public and private research in the following areas and not limited to:
- improve the knowledge about the mechanisms of action, pharmacokinetics and pharmacodynamics of antimicrobial agents to optimize the dosage regimens for veterinary medical use/phytosanitary use and their efficacy;
  - improve the knowledge about the mechanisms of transmission, selection, co-selection, emergence and dissemination of resistance determinants and resistant microorganisms along the food chain;
  - develop practical models for applying the concept of risk analysis to assess the public health concern precipitated by the development of foodborne AMR;
  - further develop protocols to predict, during the authorization process, the impact of the proposed use of the antimicrobial agents on the rate and extent of foodborne AMR development and spread;
  - assess the primary drivers leading to use of antimicrobials at the farm, sub-national, and national levels, and the effectiveness of different interventions to change behavior and reduce the need to use antimicrobial agents in food production;
  - improve the knowledge on behavior change and on cost-effective interventions to reduce the need of antimicrobial agents;
  - develop safe and effective alternatives to antimicrobial agents, new antimicrobial agents, rapid diagnostics, and vaccines; and
  - improve knowledge on the role of the environment on the persistence of antimicrobial agents, and the emergence, transfer and persistence of foodborne antimicrobial resistance determinants and resistant microorganisms.

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

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

**5.2 Responsibilities of Manufacturers and Marketing Authorization Holders****Marketing authorization of antimicrobial agents**

36. It is the responsibility of the antimicrobial agent marketing authorization holders:
- to supply all the information requested by the national competent authority in order to establish objectively the quality, safety and efficacy of antimicrobial agents;
  - to ensure the quality of this information based on the implementation of procedures, tests and trials in compliance with the provisions of good manufacturing, good laboratory and good clinical practices; and
  - to utilize manufacturing standards/practices and comply with national regulations in order to minimize contamination of the food production environment.

**Marketing and export of antimicrobial agents**

37. Only officially licensed/authorized antimicrobial agents should be marketed, and then only through distribution systems in accordance with national legislation.
38. Only antimicrobial agents meeting the quality standards as specified in the legislation of the importing country should be exported.
39. The amount of antimicrobial agents marketed should be provided to the national competent authority when requested, and in addition, when feasible, information on estimated of types of use (e.g. treatment, control, prevention), route of administration and target species.
40. Package size and the concentration and composition of antimicrobial formulations should be adapted, as far as possible, to the approved indications of use in order to avoid improper dosing, overuse, and leftovers.

**Advertising**

41. It is the responsibility of manufacturers and marketing authorization holders to advertise antimicrobial agents in accordance with the provisions of paragraphs 30 and 31, and not to inappropriately advertise antimicrobial agents directly to producers.
42. Manufacturers and marketing authorization holders should not provide incentives that have a financial value to prescribers or suppliers for the purpose of increasing the use or sales of medically important antimicrobials.

**Training**

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

**Research**

44. It is the responsibility of the marketing authorization holders to supply required data to register antimicrobial agents including data regarding the safety and efficacy of products as appropriate.
45. Research on the development of new antimicrobials, safe and effective alternatives to the use of antimicrobials, rapid diagnostics and vaccines are encouraged.

**5.3 Responsibilities of wholesale and retail distributors**

46. Wholesalers and retailers distributing medically important antimicrobial agents should only do so on the prescription of a veterinarian or order from a plant/crop health professional or other suitably trained person authorized in accordance with national legislation. All distributed products should be appropriately labelled.
47. Distributors should keep records of medically important antimicrobials supplied according to the national regulations and may include, for example:

- date of supply;
  - name of responsible veterinarian or plant/crop health professional or other suitably trained and authorized person;
  - name of medicinal product, formulation, strength and package size;
  - batch number;
  - quantity supplied;
  - expiration dates;
  - manufacturer name and address; and
  - target species.
48. Distributors should support training, as appropriate, on topics related to foodborne antimicrobial resistance and the responsible use of antimicrobial agents using information provided by the competent authorities, manufacturers and marketing authorization holders, veterinarians and plant/crop professionals and other relevant entities as described in paragraph 32, as appropriate.

#### **5.4 Responsibilities of Veterinarians<sup>7</sup> and Plant/Crop Health Professionals**

49. Veterinarians and plant/crop health professionals should identify new or recurrent disease problems and develop strategies in conjunction with competent authority to prevent, control, or treat infectious disease at the national level. These may include, but are not limited to, biosecurity, improved production practices, proper animal nutrition and safe and effective alternatives to antimicrobial agents, including vaccination or integrated pest management practices where applicable/available.
50. Professional organizations should be encouraged to develop species or sector-specific guidelines on the responsible and prudent use of antimicrobial agents.
51. Antimicrobial agents should only be prescribed or administered when necessary, only as long as required, and in an appropriate manner:
- A prescription, order for application, or similar document for medically important antimicrobial agents should indicate the dose, the dosage intervals, route and the duration of the administration, the withdrawal period, when appropriate, and the amount of antimicrobial agent to be delivered, depending on the dosage and the characteristics of the individual or population to be treated, in accordance with national legislation. Prescriptions or orders should also indicate the owner and the location of the food-producing animals or plants/crops to which the antimicrobials are to be administered;
  - All medically important antimicrobial agents should be prescribed or applied and used according to label directions and/or the direction of a veterinarian or consultation with a plant/crop health professional, and the conditions stipulated in the national legislation; and
  - Protocols for monitoring use to allow for data collection or for quality assurance purposes should be considered as recommended in the Guidelines on Integrated Monitoring and Surveillance of Foodborne Antimicrobial Resistance.
52. For food-producing animals, the appropriate use of medically important antimicrobial agents in veterinary practice is a clinical decision that should be based on the experience of the prescribing veterinarian, and epidemiological and clinical knowledge and, if available, based on adequate diagnostic procedures. When a group of food-producing animals, which may have been exposed to pathogens, they may need to be treated without recourse to a laboratory confirmed diagnosis based on antimicrobial susceptibility testing to prevent the development and spread of clinical disease.
53. For plant/crop production, the appropriate use of medically important antimicrobial agents to manage disease/pests should be based on the principles of integrated pest management (IPM), consultation with a plant/crop health professional, historical and epidemiological knowledge of the disease/pest situation, and monitoring of the current disease/pest status. Only authorized products should be used following label directions. Alternatives to medically important antimicrobials should be considered when available and their safety and effectiveness has been determined. Medically important antimicrobial agents should only be used to the extent necessary for a specific disease and follow appropriate professional oversight, dose, and duration.

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<sup>7</sup> Under some circumstances, this may refer to a suitably trained person authorized in accordance with national legislation, for example an Aquatic Animal Health Professional.

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

- The expected efficacy of the administration based on:
  - the expertise and experience of the veterinarian, plant/crop health professional or suitably trained and authorized person;
  - the spectrum of the antimicrobial activity towards the pathogens involved;
  - the history of the production unit particularly in regard to the antimicrobial susceptibility profiles of the pathogens involved. Whenever possible, the antimicrobial susceptibility profiles should be established before the commencement of the administration. If this is not possible, it is desirable for samples to be taken before the start of the administration to allow, if necessary, for adjustment of therapy based on susceptibility testing. Should a first antimicrobial administration fail, or should the disease recur, the use of a second antimicrobial agent should ideally be based on the results of microbiological susceptibility tests derived from relevant samples;
  - the appropriate route of administration;
  - results of initial administration;
  - previous published scientific information on the treatment of the specific disease and available scientific knowledge on antimicrobial use and resistance;
  - evidence-based therapeutic guidelines, such as species or sector-specific guidelines on the responsible and prudent use of antimicrobial agents, if available; and
  - the likely course of the disease.
- The need to minimize the adverse health effect from the development of antimicrobial resistance based on:
  - the choice of the activity spectrum of the antimicrobial agent. Narrow-spectrum antimicrobials should be selected whenever possible/appropriate;
  - the targeting of specific microorganism;
  - known or predictable susceptibilities using antimicrobial susceptibility testing whenever possible;
  - optimized dosing regimens;
  - the route of administration;
  - the use of fixed combinations of antimicrobial agents (i.e. only combinations contained in authorized veterinary medicinal products) which are effective against the target pathogens; and
  - the importance of the antimicrobial agents to human and veterinary medicine.
- If the label conditions allow for flexibility, the veterinarian or plant/crop health professional should consider a dosage regimen that is long enough to allow an effective treatment, but is short enough to limit the selection of resistance in foodborne and/or commensal microorganisms.

#### **Off-label use**

55. For food-producing animals, the off-label use of a veterinary antimicrobial agent may be permitted in appropriate circumstances and should comply with the national legislation including the use of approved or appropriate withdrawal periods. It is the veterinarian's responsibility to define the conditions of use including the dosage regimen, the route of administration, and the duration of the administration and the withdrawal period.
56. Human health risk related to foodborne antimicrobial resistance should be an important factor when considering the off-label use of veterinary antimicrobial agents in food-producing animals.
57. Medically important antimicrobials should not be used off-label for plants/crops, except off-label use for emerging disease control, in accordance with national legislation.

#### **Record keeping and recording**

58. For food-producing animals and plants/crops, records on antimicrobial agent prescription or application should be kept in conformity with national legislation or best management practice guidelines.
59. In particular, for investigation of antimicrobial resistance, veterinarians and plant/crop health professionals or suitably trained persons authorized in accordance with national legislation should:

- record the antimicrobial susceptibility testing results; when genomic information, when available; and
  - record the antimicrobial used, the dosage and the duration; investigate adverse reactions to antimicrobial agents, including lack of expected efficacy, and report it, as appropriate, to the competent authorities (through a pharmacovigilance system, if available).
60. Veterinarians and plant/crop health professionals should also periodically review farm records on the use of antimicrobial agents to ensure compliance with their directions.
61. Veterinarians and plant/crop health professionals may have a role to play assisting the competent authorities in monitoring and surveillance programs related to AMU and AMR as appropriate.

#### **Training**

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

#### **5.5 Responsibilities of food animal and plant/crop producers**

63. Producers are responsible for implementing health programs on their farms to prevent and manage disease outbreaks with assistance of veterinarians, plant/crop health professionals, or other suitably trained persons authorized in accordance with national legislation. All participants involved in primary production of food have an important role to play in preventing disease and reducing the need to use antimicrobials agents to minimize risk of foodborne AMR.
64. Producers of food animals and plants/crops have the following responsibilities:
- to use antimicrobial agents only when necessary, under the supervision of a veterinarian or plant/crop health professional when required, and not as a replacement for good management and farm hygiene practices, or other disease prevention methods;
  - to implement a health plan in cooperation with the veterinarian, plant/crop health professional, or other suitably trained person authorized in accordance with national legislation that outlines measures to prevent disease;
  - to use antimicrobial agents in the species, for the uses and at the doses on the approved labels and in accordance with the prescription, product label instructions or the advice of a veterinarian, plant/crop health professional or other suitably trained person authorized in accordance with national legislation familiar with the food-producing animals or the plant/crop production site;
  - to isolate sick and dying animals, dispose of dead animals, diseased plants/crops promptly under approved condition by competent authorities;
  - to comply with the storage conditions of antimicrobial agents according to the approved product labelling;
  - to comply with the recommended withdrawal periods or pre-harvest intervals;
  - to not use out-of-date antimicrobial agents and to dispose of all unused or out-of-date antimicrobial agents in accordance with the provisions on the product labels and national legislation;
  - to inform the veterinarian, plant/crop health professional, or other suitably trained person authorized in accordance with national legislation in charge of the production unit of recurrent disease problems or suspected lack of efficacy of antimicrobial applications;
  - to maintain or have their veterinarian, plant/crop health professional, or other suitably trained individual maintain all clinical and laboratory records of microbiological diagnosis and susceptibility testing. These data should be made available to the professional in charge of the administration in order to optimize the use of antimicrobial agents;
  - to keep adequate records of all antimicrobial agents used, including, for example, the following:
    - copy of the prescription, order for application or other documentation, when available;
    - name of the antimicrobial agent/active substance and batch number;
    - name of supplier;
    - date of administration; species and number of animals or plants/crops;

- identification of the production unit to which the antimicrobial agent was administered;
  - disease treated, prevented, or controlled;
  - relevant information on animals or plants/crops treated (number, age, weight);
  - quantity/dose and duration of the antimicrobial agent administered;
  - withdrawal periods or pre-harvest intervals;
  - result of treatment, in consultation with the veterinarian or plant/crop health professional; and
  - name of the prescribing veterinarian, plant/crop health professional or other suitably trained person authorized in accordance with national legislation.
- to ensure sound management of wastes and other materials to minimize dissemination of excreted antimicrobial agents, resistant microorganisms and resistance determinants into the environment where they may contaminate food;
  - to address on-farm biosecurity measures and take infection prevention and control measures as appropriate and as provided in the *OIE Terrestrial and Aquatic Animal Health Codes*;
  - to participate in training on issues related to antimicrobial resistance and the responsible use of antimicrobial agents as described in paragraph 32, as appropriate; and
  - to assist the relevant authorities in surveillance programs related to antimicrobial use and antimicrobial resistance, as appropriate.
65. The responsible and prudent use of antimicrobial agents should be supported by continuous efforts in disease prevention to minimize infection during production. Efforts should aim to improve health, thereby reducing the need for antimicrobial agents. This can be achieved by, for example, improving hygiene, biosecurity, health management on farms, improving animal and plant/crop genetics, and implementing national or international good animal production (terrestrial and aquatic), and plant/crop production practices.
66. Disease prevention through the use of vaccines, and other measures that have been clinically proven to be safe and efficacious for supporting animal health, such as adequate nutrition can be considered and applied when appropriate and available.
67. Prevention and reduction of the incidence and severity of plant pests and diseases should be implemented by applying good agricultural practices, such as crop rotation, accurate and timely diagnosis and monitoring of diseases, use of disease resistant crop varieties, exclusionary practices that prevent introduction of pathogens into a crop, careful site selection integrated pest management strategies and biological controls when appropriate and available.
- 6. Practices during production, processing, storage, transport, retail and distribution of food**
68. Concerted efforts of all stakeholders along the food chain are required to minimize and contain foodborne illness, including illness related to foodborne AMR. While this Code focuses on responsible and prudent use of antimicrobial agents in primary production at the farm level, the later phase of the food chain also plays an important role in preventing foodborne AMR infection and illness.
69. The food processing industry and food retailers should refer to the *Principles and Guidelines for the Conduct of Microbiological Risk Management*).
70. Food should be produced and handled in such a way as to minimize the introduction, presence and growth of microorganisms, which apart from having the potential to cause spoilage and foodborne illnesses can also disseminate foodborne AMR. Slaughterhouses and processing plants should follow good manufacturing practices and the Hazard Analysis and Critical Control Points (HACCP) principles. The *General Principles of Food Hygiene* is a useful reference in this respect.
71. Food business operators should provide training on good hygienic practices, including those for minimizing cross-contamination. The *WHO Five Keys to Safer Food* contains useful information for food handlers to minimize the transmission of foodborne illness, including resistant infections.
- 7. Consumer practices and communication to consumers**
72. Government, food industry and other stakeholders along the food chain should inform and educate consumers on the risks of foodborne illness, including infections with resistant microorganisms and ways to minimize the risk of infection.

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73. Some aspects to consider when communicating to consumers are:
- identifying all the stakeholders and having a common message;
  - providing information that is science-based, clear, accessible, and targeted to a non-scientific audience; and
  - considering local characteristics that affect how risks are perceived (e.g. religious belief, traditions).
74. Various manuals from international organizations, such as the FAO, WHO and OIE can be used as tools to assist in awareness raising for consumers on how to minimize foodborne bacteria in their food.
75. For more information on risk communication refer to *WHO Integrated Surveillance of Antimicrobial Resistance in Foodborne Bacteria, Application of a One Health Approach* and *FAO/WHO Risk Communication applied to Food Safety Handbook* and *the Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance*.

**APPENDIX III****GUIDELINES ON INTEGRATED MONITORING AND SURVEILLANCE  
OF FOODBORNE ANTIMICROBIAL RESISTANCE  
(For adoption at Step 5/8)****1. Introduction and purpose**

1. Antimicrobial resistance (AMR) is a global public health threat at the human, animal and environmental interface which necessitates a “One Health” Approach. Monitoring and surveillance of foodborne AMR contributes to the food safety component of such an approach.
2. For the purpose of these Guidelines, monitoring refers to the collection and analysis of foodborne AMR, antimicrobial use (AMU<sup>1</sup>) and related data and information. Surveillance is the systematic, continuous or repeated, measurement, collection, collation, validation, analysis and interpretation of data and trends from defined populations to inform risk analysis. These data may enable the measurement of the impact of risk management measures.
3. Ideally the integrated monitoring and surveillance programme(s) includes the coordinated and systematic collection of data or samples at appropriate stages along the food chain and within the food production environment, and the testing, analysis and reporting of data. The integrated programme(s) 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, plants/crops and the food production environment.
4. National priorities, AMR food safety issues and scientific evidence, capabilities and available resources should guide the development of integrated monitoring and surveillance programme(s), which should undergo continuous improvement as resources permit. This does not imply that a country needs to implement both monitoring and surveillance in all stages or areas covered by the programme(s).
5. The data generated by integrated monitoring and surveillance programme(s) provide valuable information for the risk analysis (risk assessment, risk management and risk communication) of foodborne AMR. These data may also be useful for trend analysis, epidemiological studies, food source attribution studies and research.
6. While this document’s focus is on foodborne AMR, there is an implicit connection between the goal of addressing foodborne AMR with the goal of reducing foodborne illness, and thus a connection to the national food safety control system.
7. These Guidelines are intended to assist governments in the design and implementation of integrated monitoring and surveillance programme(s). They provide flexible options for implementation and expansion, considering resources, infrastructures, capacity, and priorities of countries. Each monitoring and surveillance programme should be designed to be relevant for national, and when appropriate, regional circumstances. While these Guidelines are primarily aimed at action at the national level, countries may also consider creating or contributing to international, multi-national or regional, monitoring and surveillance programme(s) to share laboratory, data management and other necessary resources.
8. The design and implementation of monitoring and surveillance programme(s) should be assessed or re-assessed based on their relevance to foodborne AMR priorities at the national and, when appropriate, at the international level.
9. Continuous improvement of the monitoring and surveillance programme(s) should take into account identified priorities and broader capacity issues. Continuous improvement may include: collecting more information or having new sources of data on AMU and AMR in humans, animals and/or plants/crops, availability of food consumption, agriculture and aquaculture production data, and improvement in cross-sector laboratory proficiency and quality assurance and reporting.
10. Data generated from national monitoring and surveillance programme(s) on AMR in food should not be used to generate unjustified barriers to trade.
11. These Guidelines should be applied in conjunction with the *Code of Practice to Minimize and Contain Antimicrobial Resistance* (CXC 61-2005) and the *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance* (CXG 77-2011). Design and implementation aspects of these Guidelines should also take into account other relevant Codex texts including the *Principles and Guidelines for National Food Control Systems* (CXG 82-2013) and the *General Guidelines on Sampling* (CXG 50-2004).

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<sup>1</sup> See description of AMU in paragraph 81 in Section 9.

12. Where appropriate, the standards of other international standard setting organizations, including the standards of the World Organization for Animal Health (OIE standards) should be considered. These Guidelines may also be used taking into consideration guidance already developed by other advisory bodies including the World Health Organization (WHO) Advisory Group on Integrated Surveillance of AMR (WHO-AGISAR) Integrated Surveillance of Antimicrobial Resistance in Foodborne Bacteria: Application of a One Health Approach.

## 2. Scope

13. These Guidelines cover the design and implementation of integrated monitoring and surveillance programme(s) for foodborne AMR and AMU along the food chain and the food production environment.
14. Although these Guidelines do not cover the design and implementation of monitoring and surveillance of AMR and AMU in humans, an integrated programme within the context of overall risk management of AMR (One Health Approach) may be informed by data, trends, methodology and epidemiology regarding AMR and AMU in humans.
15. The microorganisms covered by these Guidelines are foodborne pathogens of public health relevance and indicator bacteria.
16. Antimicrobials used as biocides including disinfectants, are excluded from the scope of these Guidelines.

## 3. Definitions

17. The definitions presented in the *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance* (CXG 77-2011) and the *Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance* (CXC 61-2005) are applicable to these Guidelines.
18. The following definitions are included to establish a common understanding of the terms used in these Guidelines.

### Antimicrobial agent

Any substance of natural, semi-synthetic or synthetic origin that at in vivo concentrations kills or inhibits the growth of microorganisms by interacting with a specific target<sup>2</sup>.

### Antimicrobial resistance (AMR)

The ability of a microorganism to multiply or persist in the presence of an increased level of an antimicrobial agent relative to the susceptible counterpart of the same species<sup>2</sup>.

### Food chain

Production to consumption continuum including, primary production (food producing animals, plants/crops, feed), harvest/slaughter, packing, processing, storage, transport, and retail distribution to the point of consumption.

### Foodborne pathogen

A pathogen present in food, which may cause human disease(s) or illness through consumption of food contaminated with the pathogen and/or the biological products produced by the pathogen<sup>2</sup>.

### Food production environment

The immediate vicinity of the food chain where there is relevant evidence that it could contribute to foodborne AMR.

### Hazard

For the purpose of these Guidelines, the term “hazard” refers to antimicrobial resistant microorganism(s) and/or resistance determinant(s)<sup>2</sup>.

### One health approach

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

### Plants/Crops

A plant or crop that is cultivated or harvested as food or feed.

<sup>2</sup> *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance* (CXG 77-2011)

#### 4. Principles

19.

**Principle 1:** A One Health approach should be applied whenever possible and applicable when establishing monitoring and surveillance programme(s) for foodborne AMR; contributing to the food safety component of such an approach.

**Principle 2:** Monitoring and surveillance programme(s) are an important part of national strategy(ies) to minimize and contain the risk of foodborne AMR.

**Principle 3:** Risk analysis should guide the design, implementation and evaluation of monitoring and surveillance programme(s).

**Principle 4:** Monitoring and surveillance programme(s) should be designed to generate data on AMR and AMU, in relevant sectors to inform risk analysis.

**Principle 5:** Monitoring and surveillance programme(s) should be tailored to national priorities and should be designed and implemented to allow continuous improvement as resources permit.

**Principle 6:** Priority for implementation of monitoring and surveillance programme(s) should be given to the most relevant foodborne AMR and/or AMR food safety issues (which are the defined combinations of the food commodity, the AMR microorganism and determinants and the antimicrobial agent(s) to which resistance is expressed as described in the *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (CXG 77-2011)*) from a public health perspective, taking into account national priorities.

**Principle 7:** Monitoring and surveillance programme(s) should incorporate, to the extent practicable, the identification of new and emerging foodborne AMR or trends and should be designed to inform epidemiological investigation.

**Principle 8:** Laboratories involved in monitoring and surveillance should have effective quality assurance/management systems in place.

**Principle 9:** Monitoring and surveillance programme(s) should aim to harmonize laboratory methodology, data collection, analysis and reporting across sectors according to national priorities and resources as part of an integrated approach. Use of internationally recognized, standardized and validated methods and harmonized interpretative criteria, where available, contributes to the comparability of data, facilitates the multisectoral exchange and analysis of data and enhances an integrated approach to data management, analysis and interpretation.

#### 5. Risk-based approach

20. For the purpose of these Guidelines, a risk analysis approach as described in the framework for foodborne AMR risk analysis (CXG 77-2011), may inform the development, implementation and evaluation of monitoring and surveillance programme(s) with data and scientific knowledge regarding the likely occurrence of foodborne AMR hazards along the food chain and their potential to pose risks to human health.

21. Information from monitoring and surveillance programme(s) and available data from other sources, are important for risk assessment and may inform decisions on the appropriateness of control measures to minimize and contain foodborne AMR.

22. When information or data of foodborne AMR within a country is limited, monitoring and surveillance programme(s) may initially be designed according to the relevant data and/or scientific knowledge that is available on AMR hazards and their potential to result in public health risks. AMR food safety issues may be identified on the basis of information arising from a variety of sources, as described in the *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (CXG 77-2011)*.

#### 6. Regulatory framework, policy and roles

23. Integrated monitoring and surveillance programme(s) requires good governance by the competent authorities. As part of national action plans (NAPs) for AMR, the competent authorities responsible for the monitoring and surveillance activities along the food chain, including the food production environment, should ensure collaboration with human health, animal health, plant/crop health, environment and other relevant authorities.

24. Activities related to monitoring and surveillance programme(s) should involve a wide range of relevant stakeholders who may contribute to the development, implementation and evaluation of integrated monitoring and surveillance.

25. Sharing of knowledge, and monitoring and surveillance results with international organizations on a voluntary basis, should be encouraged since it may improve the global understanding of foodborne AMR and inform risk analysis.

26. It is important for competent authorities to have access to all available sources of relevant data in their country.

### **7. Preliminary activities for the implementation of an integrated monitoring and surveillance programme(s) for foodborne AMR**

27. Preliminary activities for implementation are part of the framework for monitoring and surveillance programme(s). Undertaking pilot studies and testing provide valuable insights into the design of monitoring and surveillance programme(s).

28. Countries should strive for continuous improvement of monitoring and surveillance activities and progress according to country specific objectives, priorities, infrastructure, technical capability, resources and new scientific knowledge.

#### **7.1 Establishing the monitoring and surveillance objectives**

29. The establishment of monitoring and surveillance objectives should be done in a consultative manner by the competent authorities and stakeholders and should take into consideration existing food safety programmes, the AMR NAPs, relevant information on AMR and AMU in the country, as well as any existing activities to address AMR in the different sectors (human, animal, plant/crop, food and the environment). Competent authorities should identify the challenges they currently face during the implementation of these activities.

30. The following aspects should be considered:

- The primary reasons for the data collection (e.g., to evaluate trends over time and space, to provide data useful for risk assessments, to obtain baseline information).
- The representativeness of the data collection (e.g., randomized samples; systematic sampling).
- The setting of proposed timelines for sampling and reporting.
- A description of how and to whom the information will be reported and communicated.

#### **7.2 Considerations for prioritization**

31. When establishing monitoring and surveillance priorities, the competent authorities should consider the epidemiology and public health implications of foodborne AMR, AMU patterns and available information on food production systems, food distribution, food consumption patterns and food exposure pathways.

32. Monitoring and surveillance priorities for microorganisms and resistance determinants, antimicrobial agents and sample sources should be informed by national, regional and international public health data and scientific knowledge where it exists. Competent authorities should identify existing data sources and data gaps on foodborne AMR and AMU including data required for risk analysis or results of risk analysis.

#### **7.3 Infrastructure and resources**

33. Once objectives and priorities have been established, competent authorities should determine the infrastructure, capacity and resources required to meet the objectives.

34. Implementation of AMR monitoring and surveillance may proceed at a different rate than that of AMU monitoring and surveillance and vice versa. As both types of data benefit from a joint analysis, it is useful if the components of the programme(s) are aligned during development to allow for integrated analysis. The evolution of integrated monitoring and surveillance programme(s) does not need to strictly follow the order described in these Guidelines.

35. As part of initial planning, the competent authorities should also consider where harmonization and standardization are required to meet monitoring and surveillance objectives. In order to optimize resources and efforts, the competent authorities should consider the possibilities of expansion and/or integration of monitoring and surveillance activities with other ongoing activities.

36. The competent authorities should also consider coordination of sampling and laboratory testing, collaboration with relevant stakeholders, and development of a plan for receiving, analyzing, reporting and archiving data. When possible, a central repository facilitates data management and could improve the efficiency of data analysis.

#### **7.4 Key design elements to be established before initiating the monitoring and surveillance activities**

37. When designing the monitoring and surveillance programme(s), the following elements should be considered:
38. AMR:
- The highest priority microorganisms, panels of antimicrobials and sample sources to be targeted.
  - Points in the food chain and frequency of sampling.
  - Representative sampling methods, sampling plans, laboratory analysis and reporting protocols.
  - Standardized and/or harmonized methodologies for sampling, testing and reporting.
39. AMU:
- Antimicrobial distribution chains from manufacturing or import to end-user including sales/use data providers.
  - Identification of the appropriate points of data collection and the stakeholders that can provide the data.
  - An assessment of the need to establish a legal framework before initiating collection and reporting of antimicrobial sales and use data in food producing animals and plants/crops may be useful.
  - The collection of AMU data may be started on a voluntary basis in agreement with stakeholders who have these data.
40. Consideration should be given to additional information provided in the OIE Terrestrial Animal Health Code and Aquatic Animal Health Code.

#### **8. Components of integrated monitoring and surveillance programme(s) for AMR**

41. This section is intended to provide an enabling framework which countries can utilize to establish integrated monitoring and surveillance of foodborne antimicrobial resistance appropriate to their national situation, and which includes considerations of available resources. As such, integrated monitoring and surveillance may vary between countries.
42. Integrated monitoring and surveillance programme(s) for foodborne AMR should consider the following elements:
- Sampling design.
  - Sampling plans.
  - Sample sources.
  - Target microorganisms and resistance determinants.
  - Antimicrobials to be tested.
  - Laboratory testing methodologies and quality assurance systems.
  - Data management activities.
43. The initial scope and design of the monitoring and surveillance programme(s) for AMR should consider previous research or surveillance findings, national priorities or national and/or international experience and agreed recommendations. As the AMR programme develops, the scope and design may be adjusted based on one or more of the following factors:
- Monitoring and surveillance findings.
  - Epidemiology of antimicrobial-resistant microorganisms as available.
  - Risk profile and risk assessment findings.
  - Evaluation of the integrated monitoring and surveillance programme(s).

##### **8.1. Sampling design**

44. The design of monitoring and surveillance programme(s) for AMR may build on or be integrated with existing monitoring and surveillance programme(s), or may involve development of new infrastructures and activities specifically for the purpose of foodborne AMR data collection. If data are collected through existing programmes designed for another purpose, this will need to be specified and the methodologies, data limitations and data interpretation should be described.
45. The sampling design should consider temporal and geographical coverage of data collection.

46. Once a sampling design is established, consistency in sample types and methodology is desirable to achieve long-term, comparability and accurate interpretation of results, especially when new methodologies are added and the programme is adjusted.

### 8.2. Sampling plan

47. The sampling plan should describe the following:
- The procedure to collect a sample from the selected sample source(s) at the selected point(s) in the food chain.
  - Sample size, statistical methods and underlying assumptions (e.g., representativeness, frequency of recovery, the initial or expected prevalence of AMR in that microorganism and the size of the population to be monitored) of the data used to calculate the number of samples and isolates.
  - Statistical power, precision and objectives of testing.
  - Strengths and limitations that affect data interpretation.
48. The following elements should be considered in the sampling plan:
- Whether the sampling strategy is active (i.e., designed for AMR surveillance) or passive (i.e., using a system already in place).
  - Target animal or plant/crop species, food commodities or food production environment.
  - Point(s) in the food chain where the samples will be taken and sample type.
  - Strata (levels) or risk clusters (groups) to best meet surveillance objectives.
  - Opportunities to collect metadata if available.
  - Target microorganisms, resistance phenotypes and resistance determinants.
  - Frequency of sampling.
  - Prevalence and seasonality of the microorganisms under study, if known.
  - Standard operating procedures for sample collection:
    - Who should collect the samples.
    - Procedures for collection of samples in accordance with the defined sampling strategy and to guarantee that traceability, biosecurity and quality assurance are maintained from collection through to analysis and storage.
    - Procedures for storing and transporting the samples in order to maintain sample integrity for testing.
49. Initial implementation of the sampling plan may include a limited selection of sample sources at one or more specific points along the food chain.
50. As the programme(s) develop, and implementation advances according to priorities and resources, the sample sources within the sampling plan may be broadened. This may include additional animal or plant/crop species, production types, or food commodities or stages in the food chain to gradually be more representative of the populations of interest.
- ### 8.3. Sample sources
51. When identifying the sample sources to be included in the monitoring and surveillance programme(s), consideration should be given to the major direct and scientifically relevant indirect food exposure pathways.
52. The selection of samples should reflect production and consumption patterns in the population and the likely prevalence of foodborne AMR. The prevalence of the bacterial species should be considered to maximize the likelihood of detection.
53. The integrated programme(s) should reflect food production in the country and cover samples from relevant stages of the food chain where there is science-based evidence that they could contribute to foodborne AMR. For integration, samples should be collected from the same species at the different but relevant points along the food chain. Samples should be, to the greatest extent possible, representative of the target animals and plants/crops species and the epidemiological unit being targeted. Possible sample sources are:
- **Food producing animals**

Samples taken from healthy animals may be collected on-farm or at slaughter. Collection of samples from animals not immediately entering the food chain may provide additional information on foodborne AMR at the population-level but may be a lower priority than those animals directly entering the food supply.

- At the farm-level, samples may include faeces, feed, water, or other relevant food production inputs.

Consideration may be given to samples described in the OIE Terrestrial Animal Health Code and Aquatic Animal Health Code, specifically the chapters on Harmonization of National Antimicrobial Resistance Surveillance and Monitoring Programmes and the Development and Harmonization of National Antimicrobial Resistance Surveillance and Monitoring Programmes for Aquatic Animals.

- At slaughter, samples may include carcass swabs, caecal contents or lymph nodes. In some animal species, caecal contents or lymph nodes may be representative of the pre-slaughter environment and may or may not provide an estimate of AMR arising at the farm-level. Samples collected after slaughter (e.g., carcass) may provide an estimate of contamination arising from the slaughterhouse.

- **Food**

Food product samples may be collected at processing plants, packaging plants, wholesale or retail.

The place where the food samples are collected should reflect the production system in the country and the purchasing habits of the consumer (e.g., sampling open markets or chain stores).

At the retail-level, food samples may include raw meat, fish or seafood, dairy products, other edible tissues, raw produce, and minimally processed food products. Food selection may be modified periodically in order to capture multiple commodities, seasonality, or where products have been identified as high risk.

- **Plants/crops**

The selection of plants/crops should be risk-based and/or guided by the relevant standard setting bodies where available.

Samples may be collected from farms, pre-harvest or post-harvest.

- **Food production environment**

The selection of samples from the food production environment should be risk-based and relevant to the food production system.

Samples may be collected from the immediate environment<sup>3</sup> of food producing animals and plants/crops, processing plants, wholesale facilities or retail outlets.

#### 8.4. Target microorganisms and resistance determinants

54. Selection of the target microorganisms and resistance determinants should be considered based on their relevance to food safety and public health.
55. Bacterial species may include:
  - Foodborne pathogens such as *Salmonella*, *Campylobacter* or other food borne pathogens depending on national or regional epidemiology and risks.
  - Indicator bacteria such as *Escherichia coli* and enterococci (e.g., *Enterococcus faecium* and *Enterococcus faecalis*), which can contaminate food and harbor transferable resistance genes.
56. Target microorganisms from aquatic animals and food of non-animal origin may be determined based on available scientific evidence and/or relevance to public health.
57. The selection of target microorganisms should consider the presence of high priority AMR genes or mobile genetic elements and horizontal gene transfer in a given bacterial population.

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<sup>3</sup> E.g., soil, water, litter and bedding, organic fertilizers, sewage or manure.

58. Monitoring and surveillance programme(s) may begin with phenotypic susceptibility testing for AMR in representative foodborne pathogens and/or indicator bacteria. Options for expansion may include a broader range of foodborne pathogens, or indicator bacteria, testing for genetic determinants of resistance, virulence and mobile genetic elements.
59. Whenever possible the characterization of bacterial isolates to the species-level and, as feasible, molecular analysis of particular isolates that may present a public health concern should be undertaken.

#### **8.5. Laboratories**

60. Laboratories participating in the monitoring and surveillance programme(s) should consider:
  - Bacterial isolation, identification (to species and serotype level, where relevant), typing and antimicrobial susceptibility testing (AST) using standardized and validated methods performed by trained personnel.
  - Laboratories should have quality assurance/management systems in place, or accreditation in accordance with national or international guidance.
  - Participating in external quality assurance/management system testing including proficiency testing in identification, typing and AST of the microorganisms included in the monitoring and surveillance programme(s).
  - Being equipped with facilities and having procedures to maintain sample integrity including appropriate storage temperatures and records that track the time between sample reception and analysis and ensure traceability.
  - Storing isolates and reference strains using methods that ensure viability and absence of change in the characteristics and purity of the strain.
  - Access to a national reference laboratory or an international laboratory that can provide technical assistance if necessary and carry out molecular characterization.

#### **8.6. Antimicrobial susceptibility testing**

61. Methods that are standardized and validated by nationally or internationally recognized organizations should be used where available.

##### **8.6.1. Methods and interpretative criteria**

62. Quality control strains of bacteria should be included and used according to international standards where available to support validation of results and data harmonization.
63. Interpretation of results for MICs or disk diffusion, should be undertaken consistently according to European Committee on Antimicrobial Susceptibility Testing (EUCAST) tables or the Clinical and Laboratory Standards Institute (CLSI) standards, and should include quantitative results (i.e., inhibition zone diameters including the disk content or MIC values). When neither tables nor standards are available, programme-specific interpretive criteria or categories may be used.
64. Categorization of the isolate and reporting of results may be undertaken based on the epidemiological cut off values (ECOFFs) which should be reported as wild-type, non-wild type or by clinical breakpoint which should be reported according to the interpretive category. The use of ECOFFs as interpretive criteria will allow for optimum sensitivity for detection of acquired resistance, temporal analysis of trends and comparability between isolates from different origins. Clinical breakpoints may differ between animal species and countries or regions. The interpretive criteria or category used should be included in the analysis and reporting of the data.
65. Raw quantitative data should be maintained in order to allow comparability of results, for early recognition of emerging AMR or reduced susceptibility in order to maximize the ability to analyze and compare results across sample sources.
66. Quantitative results are necessary for the analysis of resistance patterns over time and when retrospective data analysis is needed due to changes in clinical breakpoints or ECOFFs. Quantitative results are necessary for quantitative microbiological risk assessment.

### 8.6.2. The panel of antimicrobials for susceptibility testing

67. The panel of antimicrobials for phenotypic susceptibility testing should be harmonized within national monitoring and surveillance programme(s) as to ensure continuity and comparability of data. Attempts should be made to use the same antimicrobial class representatives across sample sources, geographic regions, and over time.
68. The antimicrobials included in the panel should depend on the target bacteria, the clinical or epidemiological relevance of these antimicrobials and should allow for the tracking of isolates with particular patterns of resistance.
69. The antimicrobials included may take into account the classes and uses in the relevant animal and/or plant/crop production sectors, as well as their influence in the selection or co-selection of resistance. Antimicrobials that would give the best selection of cross-resistance profiling should be considered for inclusion in the panel. Other antimicrobials which have the potential for co-selection of resistance due to gene linkage may also be included even if they are not used in animal and/or plant/crop production sectors.
70. Antimicrobials to be tested may be prioritized based on their higher priority ranking for human health, the national context, and/or their influence on the selection or co-selection of resistance.

### 8.6.3. Concentration ranges of antimicrobials

71. The concentration ranges used should ensure that both ECOFFs and clinical breakpoints, when available, are included to allow for the comparability of results with human data. The concentration range of each antimicrobial agent should also cover the full range of allowable results for the quality control strain(s) used for each antimicrobial agent.

### 8.6.4. Molecular testing

72. Whenever possible, molecular testing should be conducted for the detection and characterization of resistance determinants and for epidemiological analysis according to country specific scenarios and resources.
73. Molecular testing may be useful in addressing or confirming inconclusive phenotypic results and may be used for the early detection or detection of resistant microorganisms of high public health importance.
74. For the rapid identification of resistance clusters and outbreak investigations, molecular characterization may be used. Molecular characterization in conjunction with epidemiological information, informs the determination of source and transmission chains, the detection of emergence and investigation of the spread of new resistant strains or resistance determinants, and source attribution by linking to molecular monitoring of pathogens or resistant microorganisms or resistance determinants across sectors.
75. Sequence data generated and stored with appropriate metadata may be used for retrospective and prospective surveillance.
76. Molecular methods may allow for the integration of resistance data with other relevant public health data (e.g., virulence determinants, antimicrobial resistance determinants).

### 8.7. Collection and reporting of resistance data

77. The information collected and recorded may differ depending on the stage of sampling along the food chain, sampling design and the specific monitoring and surveillance objectives. To ensure consistency, sampling information should be recorded at the isolate and sample level.
78. Information for each individual sample should include:
  - Reference to the general description of the sampling design and plan.
  - Specific information about the origin of the sample such as from what, where and when the sample was collected.
  - General information to identify the isolate, bacterial species, serotype, other subtyping information as appropriate.
  - Specific information about the isolation of the bacteria and the AST (e.g., date of testing, method used, quantitative results). In the case of qualitative results, the interpretative criteria should be recorded.
79. Reporting of results from the monitoring and surveillance programme(s) should be timely.

80. Sample sources, analytical methods, antimicrobial susceptibility testing methods, and interpretive criteria should be clearly described, and differences transparently explained to show where data may not be directly comparable.

#### **9. Components of integrated monitoring and surveillance programme(s) for AMU**

81. For the purpose of these Guidelines “antimicrobial use” and its abbreviation “AMU” are used to refer to antimicrobials intended for use as it relates to sales, prescriptions/orders, manufacturing, imports and exports, information on actual administration or application, or any combination of these antimicrobials used for food-producing animals or plants/crops. It is also important to note that antimicrobial sales data represent a summary of the volume of product sold or distributed through various outlets by the manufacturer intended for sale to the end user, not the volume of product ultimately purchased by the end user for administration to food-producing animals or application to plants/crops.

82. This section is intended to provide an enabling framework which countries can utilize to establish monitoring and surveillance of AMU appropriate to their national situation, and which includes considerations of available resources. As such, monitoring and surveillance activities and the data collection may vary between countries.

83. For the monitoring and surveillance of AMU, including sources of data and the collection and reporting of AMU data in food-producing animals, the OIE’s Terrestrial Animal Health and Aquatic Animal Health Codes should be considered.

#### **9.1. Design of an integrated monitoring and surveillance programme(s) for antimicrobial agents intended for use in food producing animals or plants/crops**

84. Each country may decide to collect different types of data, sales and/or use, according to their monitoring and surveillance objectives. The antimicrobial sales data collection may evolve into the collection of use data. The competent authority should consider the limitations of each type of data. Some aspects of data collection or reporting need to be specified for sales versus other types of use data; this is reflected below.

85. AMU data is important information to be considered during the interpretation of the results from the AMR monitoring and surveillance programme(s), along with other relevant epidemiological data.

86. Sales data may be used to monitor trends although sales data do not always reflect the real use, administration or application of antimicrobials.

87. The collection of data on the use of antimicrobials at farm/primary producer level, although may be challenging and resource demanding, should be considered, as it can provide information on the magnitude of species-specific use and on how and why antimicrobials are being administered.

88. The choice of units of measurement<sup>4</sup> and/or indicators<sup>5</sup> for AMU should be established depending on method and scope of the data collection and the monitoring and surveillance objectives.

89. The following elements should be considered when deciding on the approach to collect sales and/or use data.

- Identification of the scope of the data to be captured (e.g., the antimicrobial agents, classes or sub-classes). The scope may also consider mechanisms of antimicrobial action, relevant resistance data and reporting requirements.
- Development of a protocol to collect qualitative (e.g., types of antimicrobials on farm) and/or quantitative information on the antimicrobials intended for use in food producing animals or plants/crops.
- Harmonization of the nomenclature of antimicrobial agents with international standards where available.
- Identification of the plant/crop type and/or species of food-producing animals for which the antimicrobials were intended to be used.
- Identification of the level of detail required to meet the surveillance requirements (e.g., production type, route of administration or reason for use).
- Information on antimicrobial dose, dosing interval and duration.
- Technical units of measurement for reporting antimicrobial sales or use.

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<sup>4</sup> Unit of measurement (i.e., numerator): a metric that expresses the quantities of antimicrobial agents

<sup>5</sup> Indicator of AMU: a metric which combines a numerator with a denominator to contextualize the quantities of antimicrobial agents measured

## 9.2. Sources of AMU data

90. Sources of data may include:

- a. Sales data: may be collected from registration authorities, marketing authorization holders, wholesalers, veterinarians, retailers, pharmacies, feed mills, farm shops/agricultural suppliers, pharmaceutical associations, cooperatives or industry trade associations or any combination of these.
  - o Import data: may be collected from the competent authorities in charge of registration of medicinal products, the marketing authorization holder or customs. Care must be taken to avoid double counting with sales data in the country and take into account that some imported antimicrobials may not be intended for use within the country.
- b. Use data: may be collected from farm/plant health professional records, livestock/plant production company records or estimated from veterinary prescriptions or farm surveys.

91. Data on quantities of antimicrobials sold or used within a country may differ. Differences may include loss during transport (package damage), storage (due expiry date) and administration (whole package not administered), stock purchased and held for future use, and fluctuations in animal or plant/crop populations.

## 9.3. Collection and reporting of AMU Collection of data

92. The numerator may be an expression qualitatively describing AMU (e.g., classes of antimicrobials agents) or may be the antimicrobial quantity representing the amount of antimicrobial agents sold or used in food-producing animals and/or plants/crops. The calculation of the numerator should consider the quantities of antimicrobial agents which may be reported in different units of measurement according to monitoring and surveillance objectives and the types of data collected.

93. To interpret and/or analyze the data, considerations for the numerator may include identification of the antimicrobial agent or product, the quantity of packages sold or used, and the strength per unit.

94. The denominator when used is the total food producing animal population or plant/crop area or quantities harvested that maybe exposed to the antimicrobials reported during the monitoring and surveillance period. Relevance to the food production systems in the country may be considered. The denominator may provide the context for reporting and analyzing the sales and/or use data.

95. Additional considerations for the denominator may include the characteristics of the population of food producing animals or plants/crops treated with the relevant antimicrobial during the monitoring and surveillance period (e.g., species, type, number, body weight, age).

### Reporting of data

96. Multiple units of measurement and/or indicators for reporting of sales and/or use may be appropriate depending on the national situation and the monitoring and surveillance objectives.

## 10. Integrated analysis and reporting of results

### 10.1. Management of data

97. To facilitate the management of data, database(s) should be structured, and where feasible, centralized or coordinated to allow for the appropriate and easy extraction of data when required and to accommodate expansion as the integrated monitoring and surveillance programme(s) improves.

98. A confidentiality and data management policy should be put in place. Data should be collected and stored to maintain data integrity and to protect the confidentiality of personal and proprietary information.

99. To facilitate the management of data, ongoing or regular validation of the data should be considered.

100. A description of the sampling design(s) and sampling plan(s), such as stratification and randomization procedures, for the food producing animals, plants/crops, food production environment or food categories, should be recorded to link data within and across monitoring and surveillance components.

### 10.2. Analysis of results

101. The data from the integrated monitoring and surveillance programme(s) may be analyzed as described in the *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (CXG 77-2011)* for risk assessment purposes and to inform the development and implementation of risk management options and policies to drive responsible and prudent use of antimicrobials to address foodborne AMR.

102. Analysis of data from the integrated monitoring and surveillance programme(s) may include the assessment within or between sectors across the One Health spectrum, to evaluate temporal or geographical trends over time, across host species, across bacterial species or antimicrobial classes. When available, other contextual information such as epidemiological data may be considered.
103. The detailed methodology and the epidemiological context of the monitoring and surveillance programme(s) should be considered for the analysis. Where data are available, exposure pathways among people, food producing animals, plants/crops and their shared environment connecting resident bacterial populations may be incorporated into the analysis.
104. Data may originate from different monitoring and surveillance programme(s), so comparability is an important consideration. The choice of analytic approaches, when possible, should allow the investigation of relationships between AMU and AMR within or across food producing animals, plants/crops and human populations, provided that AMR and AMU data are representative of the target population. Integrated monitoring and surveillance of foodborne AMR should be harmonized, when possible, across these sectors to assist in the understanding of relationships between AMR and AMU, including other factors that may influence the emergence and spread of AMR.
105. AMR data from relevant human isolates may be considered for inclusion in the analysis and reporting based on information from significant foodborne pathogens according to national epidemiological information and, whenever possible, indicator flora.
106. Integration of data from surveillance of human clinical isolates should facilitate the ability to identify trends in resistance to specific antimicrobials important for use in human medicine, as well as to identify trends in the occurrence of resistance between humans, food-producing animals, plants/crops and/or food.
107. Statistical analysis should be used to ensure proper interpretation of results.

### **10.3. Reporting of results**

108. Results of integrated monitoring and surveillance programme(s) should be reported regularly, where resources allow.
109. Whenever possible, reports on the integrated monitoring and surveillance programme(s) data across humans, animals, plants/crops, food and the food production environment should be made publicly available.
110. Transparent and open communication for the reporting of the results between the competent authorities and the different stakeholders including the public should be considered.

### **11. Evaluation of the integrated monitoring and surveillance programme(s)**

111. Evaluation of the integrated monitoring and surveillance programme(s) provides assurance that the data and information reported are robust and the programme objectives are being met. The evaluation will also guide the best use of data collection resources.
112. Potential foodborne AMR risks to human health are subject to change over time. Evaluation and review should be undertaken at a frequency appropriate to integrate evolving monitoring and surveillance methodologies, identification of new resistance patterns, new exposure pathways along the food chain and changing patterns of AMU in humans, animals and plants/crops, and to respond to changing national priorities.
113. Competent authorities should develop a framework and plan to facilitate the evaluation and review of monitoring and/or surveillance activities, which may include the following:
  - Identify the skills needed by evaluators.
  - Describe the monitoring and surveillance programme(s) to be evaluated, including the objectives and desired outcomes. This may involve a specific or single component of the entire programme(s) (e.g., the sample collection, laboratories, analysis and reporting).
  - Identify relevant stakeholders for the evaluation.
  - Identify key performance criteria to be evaluated.
  - Collect data to facilitate evaluation based on the key performance criteria.
  - Consider relevant stakeholder input/feedback.
  - Report results of evaluation.
  - Draw conclusions on components of the evaluation.
  - Identify or provide identification of relevant monitoring and surveillance programme adjustments.
  - Share evaluation outcomes with stakeholders.

114. If the design of the monitoring and surveillance programme(s) changes or expands, adjustments should ensure the ability of the programme(s) to identify trends over time remains, that historical data are maintained and that the programme continues to meet the established objectives.

**12. Training and capacity building**

115. Training and capacity building are important components of the integrated monitoring and surveillance programme(s) and should be supported where possible, by the competent authorities.
116. Training of the relevant competent authorities should include different aspects of the monitoring and surveillance programme(s) (e.g., collection, analysis, interpretation and reporting of the data).
117. Training of relevant stakeholders at the national level on different aspects of the monitoring and surveillance programme(s) are recommended.