

CODEx ALIMENTARIUS COMMISSION



Food and Agriculture
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Organization

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

Agenda Item 5

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

AD HOC CODEX INTERGOVERNMENTAL TASK FORCE ON ANTIMICROBIAL RESISTANCE

Eighth Session

Virtual

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REVISION OF THE CODE OF PRACTICE TO MINIMIZE AND CONTAIN FOODBORNE ANTIMICROBIAL RESISTANCE (AT STEP 7)

(Prepared by the by Working Group led by the United States of America and
co-chaired by Chile, China, Kenya and the United Kingdom)

Codex members and observers wishing to submit comments at Step 6 on this document
should do so as instructed in CL 2021/65 OCS-AMR¹

Introduction

1. The 7th Session of the *Ad Hoc* Intergovernmental Task Force on Antimicrobial Resistance (TFAMR07, 2019) agreed to establish an electronic working group (EWG) chaired by the United States of America and co-chaired by Chile, China, Kenya and the United Kingdom, working in English only, and open to all Members and Observers to address the outstanding issues in square brackets and report back to TFAMR08 (October 2021).
2. TFAMR07 further agreed to forward the revised *Code of Practice to Contain and Minimize Foodborne Antimicrobial Resistance* (CXC 61-2005) (COP) to the 43rd Session of the Codex Alimentarius Commission (CAC43, 2020) for adoption at Step 5.² CAC43 adopted the COP at Step 5, as revised by the Task Force, and advanced it to Step 6 for comments and further consideration by TFAMR08 at Step 7.³
3. The EWG conducted two rounds of discussion on the outstanding issues in square brackets. The first round was completed in May 2020 and the second round was completed in February 2021. The report of the EWG together with a request for comments at Step 6 can be found in CL 2021/32-AMR⁴ (April 2021).
4. In addition, a webinar was held in April 2021 to provide an overview of the revised COP, review the advances on AMR risk management and identify key issues for Codex members and observers⁵.
5. Based on comments⁶ received at Step 6, a virtual meeting of the Working Group was held on June 14 and 17, 2021, to review all sections of the COP⁷. The WG was chaired by the United States with Chile, China, Kenya, and the United Kingdom participating as member countries rather than as co-chairs.
6. Following is a summary of main points of discussion during the virtual meeting.

¹ Codex circular letters are available on the Codex webpage/Circular Letters:

<http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/>

or on the dedicated TFAMR/Circular Letters:

<http://www.fao.org/fao-who-codexalimentarius/committees/committee/related-circular-letters/en/?committee=TFAMR>

² REP20/AMR, para. 126 <http://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=TFAMR&session=7>

³ REP20/CAC, para. 113

⁴ See Footnote 1 as per where to find CLs relevant to TFAMR.

⁵ Information about the webinar can be found at

<http://www.fao.org/fao-who-codexalimentarius/meetings/detail/pt/?meeting=TFAMR&session=8>.

⁶ Comments in reply to CL 2021/32-AMR are available at:

[http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en?lnk=1&url=https%3A%2F%2Fworkspace.fao.org%2Fsites%2Fcodex%2FMeetings%2FCX-804-08%2FCOMMENTS%2520COP%2520\(CL%25202021-32-AMR\)%2FCOP_CL2021-32-AMRx.pdf](http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en?lnk=1&url=https%3A%2F%2Fworkspace.fao.org%2Fsites%2Fcodex%2FMeetings%2FCX-804-08%2FCOMMENTS%2520COP%2520(CL%25202021-32-AMR)%2FCOP_CL2021-32-AMRx.pdf)

⁷ Information about the virtual meeting can be found on the Codex/TFAMR08 dedicated webpage (see Footnote 5)

Summary of the Main Points of Discussion of the Virtual Meeting of the Working Group on Revisions to the Code of Practice to Minimize and Contain Antimicrobial Resistance (CXC 61)

7. Following initial remarks providing the context for the revised COP, the Chairperson described the approach for reviewing the document from beginning to end. He then introduced each section providing an overview of the contents and opening the floor for discussion. Below are comments provided by delegations, which include input from Codex member countries and observer organizations.

1. Introduction

8. The Chairperson described key points in the Introduction and related them to the Terms of Reference of the Task Force. He also pointed out significant new risk management concepts and language describing the role of the COP with respect to AMR risk analysis and the relationship to other Codex texts and relevant AMR standards and guidelines.
9. There were no comments on this section from delegations.

2. Scope

10. The Chairperson reviewed important elements in the Scope including that the COP 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; and on relevant measures and practices along the food chain, including responsible and prudent use of antimicrobial agents in animal production (terrestrial and aquatic) and plant/crop production.
11. In addition, the Chairperson noted the Scope describes the range of interested parties who have a role to play; and that while most of the recommendations in the COP focus on antibacterials, 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. There were no comments on this section from delegations.

3. Definitions

13. The Chairperson described the need for the Task Force to elaborate new definitions to meet its mandate to expand the scope of the COP i.e. One Health Approach, plants/crops, plant/crop health professional, food production environment and medically important antimicrobials.
14. There was considerable discussion on the definition of “therapeutic use” as follows.
15. Delegations advocating for the deletion of the definition provided the following rationale.
- The term is redundant and therefore not needed.
 - The term includes preventive uses of antimicrobials along with uses for treatment and control and which could inadvertently encourage the use of antimicrobials.
 - The term would be in conflict with the term “veterinary medical use” in OIE which includes uses of antimicrobials for treatment, control and prevention of disease.
 - The term could be replaced with other terms where they arise in the document.
 - The terms “treatment” and “therapeutic use” are synonymous in the current COP (2005).
16. Other delegations supported the definition of “therapeutic use” and provided the following rationale for its retention:
- The term draws a clear distinction between responsible and prudent uses of medically important antimicrobials – that is for addressing conditions of disease and assuring the health of animals – as opposed to uses for improving animal production – that is for weight gain and feed efficiency.
 - The term aligns with the definition of “veterinary medical use” in OIE that includes treatment, control and prevention of disease.
 - A term is needed for this document to also address uses in plants/crops, “therapeutic use” is more appropriate than “veterinary medical use”.
 - A definition of “therapeutic use” is needed to provide clarity in the rest of the document where the term or related terms are used.
 - The term “therapeutic use” is widely encountered in practice and it would be helpful to define it here.
 - There was disagreement that the definition would inadvertently promote the use of antimicrobials.
 - “Therapeutic use” and “treatment of disease” are not synonyms and the definitions clarify that point.
 - The concept of distinguishing between uses of antimicrobials to assure animal health and production uses is being increasingly reflected in stewardship documents.

17. There was no consensus on deleting the definition of “therapeutic use”; therefore the definition, as amended by the EWG, was retained in square brackets for further discussion at TFAMR08.

4. General Principles

18. The Chairperson reviewed each of the General Principles, highlighting reordering and grouping within certain headers.
19. The European Union suggested replacing Principle 13 with the following text, as contained in their comments to CL 2021/32-AMR¹.
 - “Medically important antimicrobial agents should be used for treatment only when no other antimicrobial agent can be envisaged, following appropriate professional oversight, dose, and duration. Furthermore, medically important antimicrobial agents should be used for prevention/prophylaxis and control/metaphylaxis only exceptionally, and under the conditions laid down in Principles 14 and 15, respectively.”
20. There were delegations expressing support for the text offered by the EU while others expressed concerns including: the language is not well understood; the conditions described are not practical/feasible.
21. There was substantive discussion on Principles 12 and 13 with delegations offering similar rationales as stated above, exploring different possibilities for revision.
22. A delegation noted that a General Principle for treatment might be lacking, however relevant measures are covered later in the document.
23. Another delegation had a number of questions for the representative from IPPC with the aim to better understand any relevant definitions or principles for plants/crops that might be contained in IPPC texts.
24. Canada offered revised text for Principle 13 as follows.
 - “Medically important antimicrobials should only be used for disease treatment or prevention/prophylaxis and/or control/metaphylaxis purposes and only under the conditions laid down in Principles 7-10, and 14 and 15.”
25. Brazil offered revised text for Principle 13 as follows (combining with Principle 8).
 - “Medically important antimicrobial agents should only be used for therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease) and 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.”
26. There was substantive discussion of the three options offered as new text for Principle 13. Each option had their supporters as well as detractors. There was also support for retaining Principle 13 as written. In addition, concern was expressed about reopening principles that have already achieved a significant degree of consensus. A delegation expressed support for keeping Principles 8 and 13 separated and was concerned about options that refer to other principles.
27. In the absence of consensus, the Chairperson suggested that the discussion and proposals be captured in the WG report for further consideration at TFAMR08.

5. Responsible and prudent use of antimicrobial agents

28. The Chairperson reviewed key concepts involving the responsible and prudent use of antimicrobials by different participants along the food chain including new AMR risk management concepts that expand and augment the previous text.
29. Based on comments submitted to CL 2021/32-AMR¹, proposals for revisions were discussed. Certain comments relating to the previous debate on “therapeutic use” where additional consensus was not obtained were not discussed and were referred to TFAMR08. It was identified that the proposed edits are interrelated with the previous discussion and can be examined together with the relevant proposals.
30. Revisions that received consensus are described as follows and are to be reflected in the revised COP in Appendix I.
31. Paragraph 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
- ~~application intervals~~
- ~~duration of treatment~~
- ~~indications for use~~
- storage conditions

32. Paragraph 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 animals and dispose of dead or dying animals or plants/crops promptly under condition approved by competent authorities; 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;
 - 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;
 - To assist the relevant authorities in surveillance programs related to antimicrobial use and antimicrobial resistance, as appropriate.

33. Paragraph 64: There was a proposal from Jamaica for an additional bullet as follows:

“to address on-farm biosecurity measures and take infection prevention and control measures as appropriate and as provided in the International Plant Protection Convention (IPPC) and FAO”.

Questions arose about whether IPPC includes on-farm biosecurity measures whether the reference to FAO was appropriate given the organization is not a standards -setting body. In the absence of consensus, it was agreed to capture the discussion in the working group report for further consideration at TFAMR08.

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

34. This section of the COP was not discussed. Comments provided at Step 6 did not suggest any revisions.

7. Consumer practices and communication to consumers

35. This section of the COP was not discussed. Comments provided at Step 6 did not suggest any revisions.

Conclusions

36. Delegations in the Virtual Meeting of the Working Group on the revision to the Code of Practice to Minimize and Contain Antimicrobial Resistance (CXC 61-2005) acknowledged the significant advances in AMR risk management contained in the current revised COP, in particular the guidance expanding and augmented to cover the food chain.
37. There was general agreement to focus efforts to reach additional consensus on the text that remained in square brackets following TFAMR07. To that end additional proposals were developed with respect to General Principle 13 (see paragraphs 19, 24 and 25).
38. Delegations recognized that certain comments and suggested edits are interrelated with the discussion on “therapeutic use” and will need to be further considered in conjunction with the new proposals for Principle 13.
39. With a careful approach to not re-opening text that had already been extensively discussed, delegations reviewed the entire document for coherence and agreed on several additional edits and a few points for further reflection as summarized in this report.

Recommendations

40. Additional comments from Codex Members and Observers should be solicited by means of a circular letter taking into consideration the discussions of the virtual meeting of the WG as summarized in this report focusing on the remaining text in square brackets.
41. Members and Observers should be careful to not re-open text that has already been extensively discussed and where a significant amount of consensus has been obtained through numerous electronic, physical and virtual working groups, webinars, and plenary sessions of the Task Force.
42. Members and Observers should build on the agreed concepts, definitions, and principles in the revised Code of Practice to help promote consensus and advance the work on the Guidelines for Integrated Monitoring and Surveillance of Foodborne AMR.

**REVISION OF THE
CODE OF PRACTICE TO MINIMIZE AND CONTAIN FOODBORNE ANTIMICROBIAL RESISTANCE
(CXC 61-2005)
(For further comments at Step 6)**

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/crops¹ and recombinant DNA microorganisms²; 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 probiotics³; 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.

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.

¹ 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).

² 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).

³ 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).

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.

[Therapeutic use (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.

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 therapeutic purposes (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 organisations 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
- storage conditions

Monitoring 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 therapeutic regimens 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;
- 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
- 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 Veterinarians⁴ 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;
- 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 therapeutic 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.

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;

⁴ Under some circumstances, this may refer to a suitably trained person authorized in accordance with national legislation, for example an Aquatic Animal Health Professional.

- 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;
- 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 {therapeutic} regimen that is long enough to allow an effective treatment, but is short enough to limit the selection of resistance in foodborne and/or commensal microorganisms.

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 therapeutic 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;
- 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;
 - 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;
- 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.

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;
- 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 II**LIST OF PARTICIPANTS****Virtual Meeting of the Working Group
10, 11, 15, 16 and 18 June 2021****LIST OF PARTICIPANTS****LISTE DES PARTICIPANTS****LISTA DE PARTICIPANTES****CHAIRPERSON - PRÉSIDENT - PRESIDENTE**

Dr Donald A. Prater
Associate Commissioner for Imported Food Safety
U.S. Food and Drug Administration
Silver Spring, Maryland
United States of America

**ANTIGUA AND BARBUDA - ANTIGUA-ET-BARBUDA -
ANTIGUA Y BARBUDA**

Mrs Laël Bertide-Josiah
Microbiologist
Ministry of Agriculture Fisheries and Barbuda Affairs
St. John's

ARGENTINA - ARGENTINE

Ms Josefina Cabrera
DELEGATE
INAL

Mr Martin Colicigno
DELEGATE
MAGYP
CABA

Ms Mariaangeles Fernandez
DELEGATE
INAL

Mr Federico Luna
DELEGATE
magyp
CABA

Ms Noel Olivera
DELEGATE
inal

Mr Lisandro Ruiz
DELEGATE
SENASA

Ms Eleonora Tassara
DELEGATE
INAL

AUSTRALIA - AUSTRALIE

Dr Barbara Butow
Section Manager
Food Standards Australian and New Zealand

Dr Scott Crerar
General Manager
Food Standards Australia New Zealand
Kingston, ACT

Dr Leigh Nind
Principal Veterinary Officer
Department of Agriculture, Water and the
Environment

Dr Adele Yates
Food Scientist
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

BELGIUM - BELGIQUE - BÉLGICA

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

BRAZIL - BRÉSIL - BRASIL

Dr Guilherme Antonio Costa Junior
Chair of the Codex Alimentarius Commission
Ministry of Agriculture, Livestock and Food

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

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

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

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

Dr Clea Camargo
 Manager
 ABIQUIFI
 São Paulo

Ms Ivone Delazari
 Scientific Researcher
 SEARA/ABIA

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

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

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

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

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

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

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

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

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

CANADA - CANADÁ

Dr Manisha Mehrotra
 Director, Human Safety Division
 Health Canada
 Ottawa

Dr Reem Barakat
 Deputy Director, International Standards Setting
 Section
 Canadian Food Inspection Agency
 Ottawa

Dr Sujinder Bhachoo
 National Manager
 Canadian Food Inspection Agency
 Ottawa

Mr Jason Glencross
 International Policy Analyst
 Canadian Food Inspection Agency
 Ottawa

Ms Nancy Ing
 Regulatory Policy and Risk Management Specialist
 Health Canada
 Ottawa

Dr Pablo Romero-barrios
 Food epidemiologist
 Food Directorate
 Ottawa

Dr Carolee Carson
 Veterinary Epidemiologist
 Public Health Agency of Canada
 Guelph
 Canada

Mr Mark Reist
 Policy Analyst
 Health Products and Food Branch
 Ottawa
 Canada

CHILE - CHILI

Ms Constanza Vergara
 Asesor Técnico
 Ministerio de Agricultura
 Santiago

CHINA - CHINE

Prof Haihong Hao
 Professor
 Huazhong Agricultural University

Ms Hanyang Lyu
 Assistant Research
 China National Center for Food Safety Risk Assessment
 Beijing

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

Mrs Guyue Cheng
Associate Professor
Huazhong Agricultural University

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

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

Prof Yunchang Guo
Professor/Director of Risk Surveillance Division II
China National Center For Food Safety Risk
Assessment
Beijing

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

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

Prof Liping Wang
Professor
College of Nanjing Agricultural University

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

COLOMBIA - COLOMBIE

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

COSTA RICA

Dr Heilyn Fernández Carvajal
Programa Nacional de Residuos de Medicamentos
Veterinarios
Servicio Nacional de Salud Animal- SENASA
Heredia

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

CZECH REPUBLIC - TCHÈQUE, RÉPUBLIQUE - CHECA, REPÚBLICA

Dr Veronika Vlasakova
Senior Counsellor
State Veterinnary Administration
Prague

DENMARK - DANEMARK - DINAMARCA

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

Mrs Pia Jul
Veterinary Officer
Danish Veterinary and Food Administration
Glostrup

DOMINICAN REPUBLIC - DOMINICAINE, RÉPUBLIQUE - DOMINICANA, REPÚBLICA

Dr Luís Martínez
Encargado departamento de alimentos
Dirección General Medicamentos, Alimentos y
Productos Sanitarios, en Ministerio de Salud Pública
Santo Domingo, D.N.

Mr Modesto Buenaventura Blanco
Coordinador Normas Alimenticias
Ministerio de Salud Pública y Asistencia Social (MSP)
Santo Domingo

Dr Francelyn Pérez
Encargada División Análisis de Riesgo
Ministerio de Agricultura de la República Dominicana
Santo Domingo

Mrs Cesarina Reyes
Coord. División Microbiología
Ministerio de Agricultura

ECUADOR - ÉQUATEUR

Mrs Geovanna Del Pilar Amancha Vega
Analista de Vigilancia y Control de Contaminantes en
la Producción Primaria 3
Agencia de Regulación y Control Fito y Zoonosanitaria -
AGROCALIDAD
Quito

Mr Israel Vaca Jiménez
Analista de certificación de producción primaria y
buenas practicas
Ministerio de Agricultura y Ganadería - MAG
Quito

EGYPT - ÉGYPTE - EGIPTO

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

Dr Mona Botros
General Manager
General Organization for Veterinary Services
Giza

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

Eng Mohamed Yassien
Technical Specialist
Egyptian Chamber of Food Industries
Cairo

ESTONIA - ESTONIE

Mrs Piret Aasmäe
Chief Specialist
Ministry of Rural Affairs
Tallinn

Ms Svetlana Jankovenko
Codex Contact Point
Ministry of Rural Affairs

EUROPEAN UNION - UNION EUROPÉENNE - UNIÓN EUROPEA

Mr Risto Holma
Senior Administrator
European Commission
Brussels

Ms Barbara Freischem
Official
European Medicines Agency (EMA)
Amsterdam

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

FRANCE - FRANCIA

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

Mrs Claire Fuentes
Cheffe de bureau
Ministère de l'agriculture et de l'alimentation

Mrs Camille Pineau
Chef du bureau des négociations européennes et multilatérales (BNEM)
Ministère de l'agriculture et de l'alimentation
Paris

GERMANY - ALLEMAGNE - ALEMANIA

Dr Anke Schröder
Deputy Head of Division 326
Federal Ministry of Food and Agriculture
Bonn

Dr Heike Kaspar
Head of Unit 505
Federal Office of Consumer Protection and Food Safety (BVL)
Berlin

Prof Annemarie Käsbohrer
Head of unit Epidemiology, Zoonoses, antimicrobial resistance
German Federal Institute for Risk Assessment
Berlin

Dr Heike Priess
Scientist
BMEL
Berlin

GHANA

Mrs Harriet Ayebea Ofori-antwi
HEAD, FOOD MICROBIOLOGY
Food and Drugs Authority
Accra

GREECE - GRÈCE - GRECIA

Mr Christos Zafeiridis
Official Veterinarian - DVM, Msc
Ministry of Rural Development & Food
Athens

HONDURAS

Ms María Eugenia Sevilla
Gerente Técnico de Inocuidad Agroalimentaria
Servicio Nacional de Sanidad e Inocuidad Agroalimentaria
Tegucigalpa

INDIA - INDE

Dr Kiran Narayan Bhilegaonkar
Principal Scientist (Public Health)
Indian Veterinary Research Institute, India

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

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

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

INDONESIA - INDONÉSIE

Mrs Liys Desmayanti
Ministry of Agriculture
Ministry of Agriculture

Mr Apriyanto Dwi Nugroho
Ministry of Agriculture
Ministry of Agriculture

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

Mrs Ni Made Ria Isriyanthi
Ministry of Agriculture
Ministry of Agriculture

Ms Fauzul Muna
Researcher
Ministry of Health

Mrs Nelly Pusparani
Ministry of Agriculture
Ministry of Agriculture

Mr Imron Suandy
Ministry of Agriculture
Ministry of Agriculture

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

Mrs Nahid Rahimifard
member of national codex committee(AMR)
ministry of health
Tehran

IRELAND - IRLANDE - IRLANDA

Ms Caroline Garvan
Senior Veterinary Inspector
Department of Agriculture Food and the Marine
(DAFM)

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

ITALY - ITALIE - ITALIA

Mr Giulio Cardini
Senior Officer
Ministero Politiche Agricole Alimentari e Forestali e
del Turismo
Rome

JAMAICA - JAMAÏQUE

Dr Suzan McLennon-Miguel
Senior Veterinary Specialist (Public Health)
Ministry of Industry Commerce Agriculture & Fisheries
(Veterinary Services Division)

Dr Elton Burnett
Health Services/Research & Development Manager
Jamaica

Ms Tricia Fraser
Laboratory Quality
Minister of Agriculture and Fisheries

JAPAN - JAPON - JAPÓN

Dr Tomoko Ishibashi
Director, International Standards Office
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
Food Safety Commission Secretariat, Japan

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

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

KAZAKHSTAN - KAZAJSTÁN

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

KENYA

Mr Allan Azegele
Deputy Director
Ministry of Agriculture, Livestock & Fisheries

Mr Lawrence Aloo
Chief Biochemist
MINISTRY OF HEALTH
NAIROBI

Mr Leonard Kimtai
Food Safety Officer
Ministry of Health

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

Dr Kimutai William Maritim
Director- Regulatory affairs
Ministry of Agriculture, Livestock, Fisheries and
Irrigation
Nairobi

Dr Evans Ngunjiri Muthuma
Assistant Director of Veterinary
Ministry of Agriculture, Livestock and Fisheries
Nairobi

Mr Max Mutuku
Laboratory Analyst
Ministry of Health

Ms Lucy Namu
Head Analytical Chemistry Laboratory and Food Safety
Kenya Plant Health Inspectorate Services
Nairobi

Ms Josephine Simiyu
Deputy Director
Agriculture and Food Authority
Nairobi

KUWAIT - KOWEÏT

Mr Salah Al Bazzaz
Technical Advisor
Permanent Representation of Kuwait to FAO

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

Mr Ziad Ammar
Technical Support
Permanent Representation of Kuwait to FAO & WFP

Mr Yousef Juhail
Permanent Representative of Kuwait to FAO & WFP
Permanent Representation of Kuwait to FAO

LATVIA - LETTONIE - LETONIA

Mrs Inta Krauja
expert
Ministry of Agriculture Republic of Latvia
RIGA

LEBANON - LIBAN - LÍBANO

Dr Mariam Eid
Agro Industries Service
Ministry of Agriculture

Dr Rima El Hage
Director of Fanar Station Head of Food Microbiological
Laboratory
LARI

MALAYSIA - MALAISIE - MALASIA

Ms Nurhazwani Abd Rahman
Assistant Director
Ministry of Health Malaysia
Putrajaya

Mrs Nor Fasiah Abdullah Sani
Senior Research Officer
Veterinary Public Health Division

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

Dr Suraya Amir Husin
SENIOR PRINCIPAL ASSISTANT DIRECTOR
MINISTRY OF HEALTH MALAYSIA
PUTRAJAYA

Ms Sakhiah Md Yusof
Assistant Director
Ministry of Health, Malaysia
Wilayah Persekutuan Putrajaya

Dr Rohaya Mohd Ali
Senior Director
Ministry of Agriculture and Food Industry

Dr Yusniza Mohd Yusof
Chief Assistant Director
Ministry of Agriculture and Food Industry

Ms Ani Fadhlina Mustaffa
Senior Assistant Director
Ministry of Health Malaysia
Wilayah Persekutuan Putrajaya

Ms Kasumawaty Sudin
Principal Assistant Director
Ministry of Health Malaysia
Wilayah Persekutuan Putrajaya

Ms Nurul Hidayati Surawi
Principal Assistant Director
Ministry of Health Malaysia
Wilayah Persekutuan Putrajaya

MEXICO - MEXIQUE - MÉXICO

Ms Nidia Coyote Estrada
Directora Ejecutiva de Manejo de Riesgos Comisión de
Evidencia y Manejo de Riesgos
COFEPRIS

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

Mr Rogelio Estrada Rodriguez
Director del Centro Nacional de Servicios de
Diagnóstico en Salud Animal
SENASICA

Ms María Elena González Ruíz
Directora de Servicios y Certificación Pecuaria
SENASICA

Mrs Cindy Fabiola Hernández Pérez
Encargado 5 de Secuenciación y Bioinformática
Programa Operativo de Diagnóstico
SENASICA

Ms Mayra Morales Flores
Responsable 5
SENASICA

Ms Carolina Quiroz Santiago
Verificador o Dictaminador Especializado Comisión de
Evidencia y Manejo de Riesgos
COFEPRIS

Ms Lorena Reyes Guerra
Subdirectora de Regulación de Establecimientos y
Productos Veterinarios
SENASICA

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

Mrs Claudia Tzompantzi Hernandez
Verificadora especializada 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 Sami Darkaoui
Head of Pharmacy and veterinary Inputs
ONSSA
Rabat

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

Dr Sanae Ouazzani
Ingénieur en Chef
ONSSA - National Food Safety Office
Rabat

Dr Samah Tahri
Veterinarian
ONSSA

NETHERLANDS - PAYS-BAS - PAÍSES BAJOS

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

Mr Sam Verhagen
Policy Officer
Ministry of Health, Welfare and Sport
The Hague

Ms Ana Vilorio
Senior Advisor
Ministry of Health, Welfare and Sport
The Hague

Ms Rosa Peran Sala
Senior Advisor
Ministry of Health, Welfare and Sport
The Hague
Netherlands

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

Mr Allan Kinsella
Director
Ministry for Primary Industries

Dr Jennifer Doyle
Team Manager Assessments, ACVM, Assurance
Ministry for Primary Industries
Wellington
New Zealand

NIGERIA - NIGÉRIA

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

Dr Mairo Kachalla
Assistant Director
- Federal Ministry Of Agriculture & Rural Development

Ms Philomina Ngozi Nwobosi
Assistant Chief Scientific Officer
Federal Ministry of Health
Abuja

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

Mrs Gerda Ingrid Heglebäck
Senior Adviser
Norwegian Food Safety Authority
Oslo

Mrs Vigdis S. Veum Møllersen
Senior Adviser
Norwegian Food Safety Authority
Oslo

PHILIPPINES - FILIPINAS

Dr Alicia Layson
PH National Focal Point on AMR for OIE
Bureau of Animal Industry
Quezon City

Dr Alpha Mateo-Ilanuza
Senior Science Research Specialist
Bureau of Agriculture and Fisheries Standards
Quezon City

Ms Marissa Mojica
Food and Drug Regulatory Officer III
Food and Drug Administration-Common Services
Laboratory
Muntinlupa City

Dr January Nones
Chief Meat Control Officer
National Meat Inspection Service
Quezon City

POLAND - POLOGNE - POLONIA

Ms Magdalena Kowalska
Main expert
Agricultural and Food Quality Inspection
Warsaw

Prof Dariusz Wasyl
Head of Unit of Omics Analyses
National Veterinary Research Institute
Pulawy

PORTUGAL

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

Mr Miguel Cardo
Deputy Director-General
Directorate-General for Food and Veterinary (DGAV)
Lisboa

Ms Outi Tyni
Political administrator
EU Council Secretariat
Brussels

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

Ms Ji-won Han
Codex Researcher
Ministry of Food and Drug Safety

Mr Seokhwan Kim
Scientific officer
National Institute of Food and Drug Safety Evaluation

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

Ms Minji Kim
Codex Researcher
Ministry of Food and Drug Safety

Ms Yeonkyu Lee
Codex Researcher
Ministry of Food and Drug Safety

Ms Jieun Lee
Codex Researcher
Ministry of Food and Drug Safety

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

Dr Kwang Kyo Oh
 Researcher
 National Institute of Agricultural Science, Rural
 Development Administration
 Wanju-gun

Ms Ji Min Park
 Codex Researcher
 Ministry of Food and Drug Safety

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

Ms Jihye Yang
 SPS 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 Ioana Neghirla
 DVMPHD
 National Sanitary Veterinary and Food Safety
 Authority Romania
 Bucharest

SINGAPORE - SINGAPOUR - SINGAPUR

Dr Edmund Choo
 Assistant Director
 Singapore Food Agency

Ms Wei Ching Khor
 Scientist (Risk Assessment & Data Science Branch)
 Singapore Food Agency

Dr Li Kiang Tan
 Branch Head (Microbiology & Molecular Bio)
 Singapore Food Agency

SLOVAKIA - SLOVAQUIE - ESLOVAQUIA

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

SPAIN - ESPAGNE - ESPAÑA

Mrs Cristina Muñoz Madero
 Jefe de Servicio y Coordinadora del Plan Nacional
 Resistencia Antibióticos
 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

SWEDEN - SUÈDE - SUECIA

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

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

SWITZERLAND - SUISSE - SUIZA

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

THAILAND - THAÏLANDE - TAILANDIA

Dr Thanida Harintharanon
 Veterinarian, Expert Level
 Ministry of Agriculture and Cooperatives
 Bangkok

Dr Panisuan Jamnarnwej
 Vice Chairman of Committee on Fisheries and Related
 Industries
 Board of Trade of Thailand
 Bangkok

Dr Namaporn Attaviroj
 Senior Standards Officer
 Ministry of Agriculture and Cooperative
 Bangkok

Ms Nuttima Kositcharoenkul
 Plant Pathologist Senior Professional Level
 Ministry of Agriculture and Cooperatives
 Bangkok

Dr Sakranmanee Krajangwong
 Veterinarian, Professional level
 Ministry of Agriculture and Cooperative
 Bangkok

Mrs Thitiporn Laoprasert
Director of Aquatic Animal Health Research and
Development Division
Ministry of Agriculture and Cooperatives
Bangkok

Dr Mintra Lukkana
Veterinary officer
National Bureau of Agricultural Commodity and Food
Standards (ACFS)
Bangkok

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

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

Ms Jiraratana Thesasilpa
Food and Drug Technical Officer, Senior Professional
Level
Food and Drug Administration
Nonthaburi

Ms Supaporn Wongsrichai
Veterinarian, Senior professional level
Ministry of Agriculture and Cooperatives
Pathumthani

TURKMENISTAN - TURKMÉNISTAN - TURKMENISTÁN

Mrs Maya Ashirova
Chief Specialist
Ministry of health Turkmenistan

UGANDA - OUGANDA

Dr Sylvia Baluka
President
Uganda Veterinary Association
Kampala

Dr Vincent Magembe Kayizzi
Principal Regulatory Officer
National Drug Authority
Kampala

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

Dr Josephine Nyanzi
Principal Regulatory Officer - Vet Medicine
National Drug Authority
Kampala

UNITED KINGDOM - ROYAUME-UNI - REINO UNIDO

Mr Niloy Acharyya
Head of AMR policy
Veterinary Medicines Directorate

Dr Iulia Turiac
Senior Policy Advisor
Department for Environment, Food & Rural Affairs
(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

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

Mr Ally Hemedi Kingazi
STANDARDS OFFICER - FOOD
TANZANIA BUREAU OF STANDARDS
DAR ES SALAAM

UNITED STATES OF AMERICA - ÉTATS-UNIS D'AMÉRIQUE - ESTADOSUNIDOS DE AMÉRICA

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

Dr Donald Prater
Associate Commissioner for Foods and Veterinary
Medicine
United States Food and Drug Administration
Silver Spring, Maryland

Mr Robert Ahern
Director, WTO Agricultural Affairs
Office of the U.S. Trade Representative (USTR)
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 Julius Fajardo
Senior Plant Pathologist
USDA
Washington, DC

Ms Mallory Gaines
Manager, 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

Mrs Heidi Irrig
MRL Manager North America
Syngenta
Greensboro, NC

Ms Mary Frances Lowe
U.S. Manager for Codex Alimentarius
U.S. Codex Office
Washington, DC

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

URUGUAY

Dr Norman Bennett
Gerente de Inocuidad de la Dirección General Control
de Inocuidad Alimentaria
Ministerio de Ganadería, Agricultura y Pesca
Montevideo

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

Ms Joely Celis
Profesional
Servicio Autónomo Nacional de Normalización,
Calidad, Metrología y Reglamentos Técnicos
(SENCAMER)

Mrs Carolina Palomino
Jefe de Departamento de Tecnología de Alimentos
Universidad Central de Venezuela

Ms Jenitksa Salas
Sala Jefe de División de Análisis y Desarrollo de
Normas
Servicio Autónomo Nacional de Normalización,
Calidad, Metrología y Reglamentos Técnicos
(SENCAMER)

ORGANISATION MONDIALE DE LA SANTÉ ANIMALE (OIE)

Dr Elisabeth Erlacher-vindel
Head
World Organisation for Animal Health (OIE)
Paris

Dr Jorge Pinto Ferreira
Deputy Head
World Organisation for Animal Health (OIE)
Paris

ASSOCIATION OF AMERICAN FEED CONTROL OFFICIALS (AAFCO)

Mr Mike Stage
Division Manager
Arkansas Department of Agriculture
Champaign

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

CONSUMERS INTERNATIONAL (CI)

Mr Michael Hansen
Representative
Consumers International

Mr Steven Roach
Representative
Consumers International

CROPLIFE INTERNATIONAL (CROPLIFE)

Dr Manojit Basu
 Managing Director
 CropLife America
 Arlington

INTERNATIONAL CO-OPERATIVE ALLIANCE (ICA)

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

Mr Yuji Gejo
 Officer
 International Co-operative Alliance

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)

Mr Hsin Huang
 Secretary General
 International Meat Secretariat
 Paris

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

Mr Marc Henninger
 Market Access Manager France and MEA
 International Meat Secretariat
 Sèvres

Dr Kathy Simmons
 Chief Veterinarian
 International Meat Secretariat
 Washington, DC

Dr Liz Wagstrom
 Chief Veterinarian
 International Meat Secretariat
 Des Moines

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 Richard Coulter
 Senior Vice President
 HealthforAnimals
 Teaneck NJ

Dr Rachel Cumberbatch
 Director, International and Regulatory Affairs
 HealthforAnimals

Dr Olivier Espeisse
 Public Affairs 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.

FAO

Ms Daniela Battaglia
 Animal Production officer
 FAO

Mr Carmen Bullon
 Bullon
 Legal officer

Mr Alejandro Doradogarsia
 Animal Health Officer
 FAO

Ms Francesca Latronico
 AMR laboratory Specialist
 FAO

Dr Jeff Lejeune
 Food Safety Officer
 FAO

Ms Yu Qiu
Animal Health Officer
FAO

Mr Artur Shamilov
Agricultural Officer
FAO

Mr Teemu Viinikainen
Legal consultant
FAO

WHO

Dr Peter Beyer
Senior Advisor
World Health Organization
Geneva

Mr Jorge Matheu
Team Lead
World Health Organization
Geneva

TFAMR SECRETARIAT

Ms Sungmyung Bae
Deputy Director
Ministry of Food and Drug Safety

Ms Sungmyung Bae
Deputy Director
Ministry of Food and Drug Safety

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

Mr Sang-mok Lee
Assistant Director
Ministry of Food and Drug Safety

Mr Jaewoo Park
Deputy Director
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

Ms Sarah Cahill
Senior Food Standards Officer
Joint FAO/WHO Food Standards Programme

Mrs Myoengsin Choi
Food Standards Officer
Joint FAO/WHO Food Standards Programme

Ms Ilaria Tarquinio
Programme Assistant
Joint FAO/WHO Food Standards Programme

Ms Elaine Raheer
Office Assistant
Joint FAO/WHO Food Standards Programme