CODEX ALIMENTARIUS COMMISSION



Food and Agriculture Organization of the United Nations



CRD2

#### Agenda Item 5

ORINGINAL LANGUAGE ONLY

# JOINT FAO/WHO FOOD STANDARDS PROGRAMME

# AD HOC CODEX INTERGOVERNMENTAL TASK FORCE ON ANTIMICROBIAL RESISTANCE

#### **Seventh Session**

# Report of the Physical Working Group (PWG) on the Revision of the Recommended Code of Practice to Minimize and Contain Antimicrobial Resistance (CXC 61)

The purpose of the PWG meeting was to discuss areas requiring consensus in the Draft Code of Practice to Minimize and Contain Antimicrobial Resistance. The PWG used as the basis for the discussion Appendix 1 of the Report of the Electronic Working Group (EWG), CX/AMR 19/7/5.

Key issues discussed and decisions of the PWG are as follows. Where consensus was not reached, square brackets were added to highlight areas for further discussion.

#### Introduction:

Para 1: Agreed with the revisions proposed by the EWG by inserting "plant/crop" and deleting "food of plant origin".

Para 2: Recommended for adoption as previously agreed at TFAMR6.

Para 3: Recommended for adoption as previously agreed at TFAMR6.

Para 4: Agreed with the revisions proposed by the EWG to insert reference to CXG 71.

Para 5: Recommended for adoption as previously agreed at TFAMR6.

Para 6, bullet 2: Removed the square brackets without revision.

Para 6, bullet 4: Deleted "Regional".

Para 7: Recommended for adoption as agreed at TFAMR6.

Para 8: Revisions to the following phrase were offered, ["and should not be used <u>inappropriately</u> to generate <u>unjustified</u> barriers to trade"]. There was no consensus and the phrase was placed in square brackets.

## Scope:

Para 9: Agreed with the revisions proposed by the EWG to replace "food of plant origin" with "plant/crop production" and delete "feed". Deleted the last sentence.

Para 10: Recommended for adoption as agreed as TFAMR6.

Para 11: Deleted the introductory phrase. Removed the square brackets and accepted the additional text as proposed by the EWG.

Para 12: Inserted "biocides" and agreed with the revisions of the EWG to add "non-food plants/crops". Suggested to check the reference for footnote 3.

## **Definitions:**

An introductory statement was offered for the section and placed in square brackets.

Adverse health effect: Deleted.

Competent authority: An alternate definition was proposed, based on text under review in CCFH, and was placed in square brackets.

Food production environment: An alternate definition was proposed and placed in square brackets.

Food of plant origin: Deleted.

Plant/crop health professional: Agreed with revision from the PWG.

Prevention of disease/prophylaxis: Modified by adding "plants/crops or". The PWG noted that similar changes could also be applied to the definitions for "control of disease/metaphylaxis" and "treatment of disease".

Therapeutic use: Some delegations requested deletion stating that prevention of disease/prophylaxis should be not considered a therapeutic use. Several delegations did not agree explaining that all conditions of use (treatment, control, and prevention) related to disease are considered therapeutic uses. The term was retained in square brackets.

#### General principles to minimize and contain antimicrobial resistance:

Discussion was limited to Principles 5, 6, and 7.

General Principles 1-4, 8-11, and 13-14 were agreed at TFAMR06.

Principle 5: Some delegations requested deletion of the term "medically important" and proposed alternate text. Several delegations did not agree with removal of "medically important". The entire principle was retained in square brackets.

Principle 6: Some delegations requested deletion of the term "medically important" and "therapeutic use". Several delegations did not agree with removal of "medically important" and "therapeutic use". The terms "medically important" and "therapeutic use" were placed in square brackets. The phrase "or in certain circumstances for research and conservation" was deleted.

Principle 7: Some delegations requested deletion of the term "medically important" and insertion of the term "and exceptional". Several delegations did not agree with deletion of the term "medically important". The entire principle was retained in square brackets.

Some delegations requested the deletion of "medically important" throughout the entire text of the Code of Practice and indicated that the risk management measures in the text should apply to all antimicrobials, as described in paragraph 11.

Because the term "medically important" is used in numerous places throughout text to distinguish risk management measures for a subset of antimicrobials defined as important for therapeutic use in humans, it was agreed not to repeat the request for deletion in all subsequent sessions, in order to progress the text.

Principles 7bis and 7ter were not discussed.

## 5. Responsible and prudent use of antimicrobial agents

Para 13: Agreed with the revisions proposed by the EWG to add "the OIE list of antimicrobial agents of veterinary importance".

Para 14: Agreed with the revisions proposed by the EWG to delete the reference to VICH.

#### 5.1 Responsibilities of the competent authorities

Para 15: Agreed with the revisions proposed by the EWG to move the first sentence of Para 16 to the end of Para 15.

Para 16: Agreed with the revisions proposed by the EWG including to move the first sentence of Para 16 to the end of Para 15.

Para 16bis: The PWG agreed to revise and move the second sentence from Para 50 to this section creating a new 16bis because this sentence is more relevant for Competent Authorities.

Para 17: Agreed with the proposed revisions of the EWG along with additional edits.

Para 18: Agreed with the proposed revisions of the EWG. Deleted the last sentence.

The PWG agreed with the EWG proposal to delete the previous Para 14.

Para 19: Agreed with deletion of "including with regard to ensuring quality and purity in manufacture, storage, and when mixed with feed, water, or other ingredients."

Para 20: Agreed with the revisions proposed by the EWG. Deleted the last sentence.

Para 21: Agreed with the revisions proposed by the EWG. Added the phrase "used along the food chain".

Para 22: Revisions were proposed and the entire paragraph was placed into square brackets.

A proposal to was made to modify the heading of the section based on proposed changes, also placed into square brackets.

Some delegations indicated support for the previous Para 18, proposed to be deleted. Previous Para 18, proposed for deletion was retained pending discussion on Para 22.

Para 23: The paragraph was revised and placed into square brackets.

Para 24: Agreed with the revisions proposed by the EWG.

Para 25: Agreed with the revisions proposed by the EWG and made minor revisions.

Para 26: Agreed with the revisions proposed by the EWG.

Para 27: Agreed with the revisions proposed by the EWG and made minor revisions.

Para 28: Agreed with the revisions proposed by the EWG.

Para 29: Deleted, redundant.

Para 30: Agreed with the revisions proposed by the EWG.

Para 31: Agreed with the revisions proposed by the EWG.

The PWG agreed with the proposal of the EWG to delete previous Para 27.

Para 32: The PWG made further revisions and agreed with the revisions proposed by the EWG.

Para 33: The PWG made further revisions and agreed with the revisions proposed by the EWG.

Para 34: Deleted, redundant.

Para 35: Agreed with the revisions proposed by the EWG and made minor revisions. The heading of the section was revised to reflect the changes to the para.

Para 36: Agreed.

Para 37: Agreed.

Para 38: The paragraphs was revised, but retained in square brackets.

Para 39: The PWG agreed with additional revisions to the paragraph.

Para 40: Agreed.

Para 41: The PWG agreed with the revision made to the paragraph.

Para 42: The first sentence was deleted. The revisions of the EWG in the second sentence were agreed, however the paragraph was placed in square brackets pending further discussion on the term "medically important".

Para 43: Agreed with the revisions proposed by the EWG.

Para 44: Agreed with the revisions proposed by the EWG.

Para 45: Agreed with the revisions proposed by the EWG.

Para 46: Agreed with the revisions proposed by the EWG. The term "medically important" was bracketed.

Para 47: Agreed with the revisions proposed by the EWG and made additional revisions.

Para 48: Agreed with the revisions proposed by the EWG and made additional revisions, however the paragraph was retained in square brackets.

Para 49: Agreed the revisions proposed by the EWG and made additional revisions.

Para 50: Agreed with the revisions proposed by the EWG to the first sentence. Moved the second sentence to create new 16bis.

Para 51: Agreed with the revisions proposed by the EWG and made additional revisions. Bracketed the term "medically important".

Para 52: Additional revisions were suggested by the PWG, however time expired and the paragraph was not agreed.

The revised text can be found in Appendix 1.

# Appendix 1

# PROPOSED DRAFT REVISION OF THE CODE OF PRACTICE TO MINIMIZE AND CONTAIN FOODBORNE ANTIMICROBIAL RESISTANCE (CXC 61-2005)

## (Revised by the Physical Working Group)

## 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 in the food chain. It is recognized that the use of antimicrobial agents in 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 strategy 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 proportionate to 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 region and determining how best to reduce risk and to introduce levels of protection appropriate for circumstances.

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 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 approach may be utilized by some countries to properly implement applicable elements in this document proportionate to the foodborne AMR risk [and should not be used inappropriately to generate <u>unjustified</u> 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 and feed 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 will focus on antibacterials, however some recommendations may also be applicable to antiviral, antiparasitic, antiprotozoal, and antifungal agents, where scientific evidence supports foodborne AMR risk to human health.

12. As there are existing Codex or internationally recognized guidelines, the following areas related to antimicrobial agents or AMR are outside the scope of this document: residues of antimicrobial agents in food; AMR marker genes in recombinant-DNA plants/crops<sup>1</sup> and recombinant DNA microorganisms<sup>2</sup>; non-genetically modified microorganisms (for example, starter cultures) intentionally added to food with a technological purpose<sup>3</sup>; biocides; and certain food ingredients, which could potentially carry antimicrobial resistance determinants, such as probiotics<sup>4</sup>. 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 following definitions are included to establish a common understanding of the terms used in this document. The definitions presented in the *Codex Procedural Manual*, *Guidelines for risk analysis of foodborne antimicrobial resistance*, *General Principles of Food Hygiene* and the *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CAC/GL 30-1999) are applicable to 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.

[Competent Authority(ies): The official government organization/agency(ies) having jurisdiction.] [The government authority or official body authorized by the government that is responsible for the setting of regulatory food safety requirements and/or for the organisation of official controls including enforcement.]

Control of disease/metaphylaxis: Administration of antimicrobial agents to a group of animals containing

<sup>&</sup>lt;sup>1</sup> The food safety assessment on the use of antimicrobial resistance marker genes in recombinant-DNA plants is addressed in the *Guidelines for the conduct of food safety assessment of foods derived from recombinant-DNA plants* (CXG 45-2003).

<sup>&</sup>lt;sup>2</sup> The food safety assessment on the use of antimicrobial resistance marker genes in recombinant-DNA microorganisms is addressed in the *Guideline for the conduct of food safety assessment of foods produced using recombinant-DNA microorganisms* (CXG 46-2003).

<sup>&</sup>lt;sup>3</sup> The food safety assessment on the use of antimicrobial resistance marker genes in recombinant-DNA microorganisms is addressed in the *Guideline for the conduct of food safety assessment of foods produced using recombinant-DNA microorganisms* (CXG 46-2003). **CHECK REFERENCE** 

<sup>&</sup>lt;sup>4</sup> The food safety assessment on the use of probiotics in foods is addressed in the Report of the *Joint FAO/WHO* working group on drafting guidelines for the evaluation of probiotics in foods (FAO/WHO, 2002).

sick and healthy individuals (presumed to be infected), to minimize or resolve clinical signs and to prevent further spread of the disease.

**Co-resistance:** The ability of a microorganism to multiply or persist in the presence of different classes of antimicrobial agents due to possession of various resistance mechanisms.

**Cross-resistance:** The ability of a microorganism to multiply or persist in the presence of other members of a particular class of antimicrobial agents or across different classes due to a shared mechanism of resistance.

**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), <u>feed</u>, harvest/slaughter, packing, processing, storage, transport, and retail 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 food to be harvested or processed that has reasonable probability to contribute to foodborne AMR.]

[The immediate vicinity of food, feed, plant/crops, animals to be harvested or processed where scientific evidence / risk characterization indicates a reasonable probability to 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 those described in the *WHO list of critically important antimicrobials* and categorized according to specified criteria as important, highly important, and critically important for human medicine or equivalent criteria established in national lists, where available. It does not include ionophores or other antimicrobial agents not important for human therapeutic use, such as ionophores.

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

Pharmaceutical industry: Manufacturers and marketing authorization holders of antimicrobial agents.

**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 (or part thereof) 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 of antimicrobial agents to an individual or a group of plant/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.

[Therapeutic use: Administration/<u>Application</u> of antimicrobial agents for the treatment, control/metaphylaxis or and prevention/prophylaxis of disease.]

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

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

## Principles on AMR Risk Management (generally)

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

**Principle 9:** 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. When considering animal or plant health aspects risk managers should take into account relevant OIE and IPPC standards.

**Principle 4:** The WHO list of critically important antimicrobials, the OIE list of antimicrobials 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 15:** 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 2:** 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 13:** 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 12: Medically important antimicrobials should be administered, prescribed, 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 8:** Antimicrobial agents should be used as legally authorized and following all applicable label directions; except where specific legal exemptions apply.

**Principle 14:** The choice of which antimicrobial agent to use should take into consideration relevant professional guidelines, where available, results of <u>antimicrobial</u> 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 3:** 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 5:** 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 CXG 77-2011.:

## • considered medically important; or

• able to cause cross- or co-resistance to antimicrobial agents that are considered medically important.

Antimicrobial agents, others than those referred to above should not be used for growth promotion in the absence of risk analysis in accordance with CXG77.]

**Principle 6:** [Medically important antimicrobial agents should only be used for therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease).

[Principle 7: When used for prevention/prophylaxis of a specific disease risk, medically important antimicrobials should only be administered in well-defined <u>and exceptional</u> circumstances, based on epidemiological and clinical knowledge, and follow appropriate professional oversight, dose, and duration. <u>Medically important antimicrobial agents should only be used in well-defined circumstances for the prevention/prophylaxis of a specific disease risk and follow appropriate professional oversight, dose, and <del>duration.]</del></u>

[Principle 7bis: 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 7ter: When used for plant/crop protection, medically important antimicrobial agents should only be used to the extent necessary for a specific disease and follow appropriate professional oversight, dose, and duration.]

## Principle on surveillance of antimicrobial resistance and use

**Principle 10:** 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, <u>plants/crops</u>, 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.

16bis National action plans may include recommendations to relevant professional organisations to develop species or sector-specific guidelines.

17. 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.

18. 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

19. 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

20. 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

21. 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 *Guidelines for risk analysis of foodborne antimicrobial resistance*, the WHO list of critically important antimicrobials, the OIE list of antimicrobial agents

of veterinary importance, or national lists, where available.

## [Assessment of the environmental impact on the food production environment]

18. Competent authorities should assess the impact of proposed antimicrobial agent use on the environment in accordance with national guidelines or recognized international guidelines.

[22. In accordance with their national guidelines, <u>Ccompetent</u> authorities should consider <u>results of</u> foodborne AMR risk assessment <u>risk characterization from of environmental sources that contribute to the food production</u> <u>environment, such as e.g. pollution from pharmaceutical manufacture</u>, reuse of waste water for irrigation, and <u>use of manure</u>, and other waste-based fertilizers <u>and/or municipal wastes</u> for soil fertilization. the environmental aspects on foodborne AMR e.g. pollution from pharmaceutical manufacture, impacts of reusing waste water for irrigation, and using manure, and other waste-based fertilizers and/or municipal wastes for soil fertilization from pharmaceutical manufacture, impacts of reusing waste water for irrigation, and using manure, and other waste-based fertilizers and/or municipal wastes for soil fertilization. When <u>a</u> foodborne AMR risk is determined through the *Guidelines for risk analysis of foodborne antimicrobial resistance* the need for monitoring and proportionate risk management measures <del>can</del> <u>should</u> be considered.]

#### Establishment of a summary of product characteristics for each antimicrobial agent

[23. <del>20</del>. Competent authorities should establish a Summary of Product Characteristics <u>or similar document for</u> <u>each authorized antimicrobial veterinary medicinal product</u>. The information in <u>these documents</u> the summary of product characteristics can be utilized in labelling and as a package insert. Such information may include:

- brand/chemical/drug name;
- <u>drug product description;</u>
- dosage forms/strengths;
- contraindications; warnings;
- <u>adverse reactions;</u>
- <u>drug</u> product interactions and uses in specific populations for each authorized antimicrobial veterinary medicinal product, when available;
- <u>withdrawal periods;</u>
- application intervals;
- duration of treatment.]

#### Surveillance and monitoring programs

24. Competent authorities should establish systems for the surveillance and monitoring of antimicrobial resistance and antimicrobial use following the *Guidelines on integrated monitoring and surveillance of foodborne antimicrobial resistance* as developed by Codex.

25. 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.

26. 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 endeavor to achieve this re-evaluation.

#### **Distribution of antimicrobial agents**

27. Competent authorities should make sure antimicrobial agents are distributed through licensed/authorized distribution systems and prescribed or ordered in accordance with national legislation by credentialed/registered veterinarians, plant/crop health professionals, or other suitably trained persons authorized in accordance with national legislation.

28. 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 agents is done in accordance with national legislation.

31. Advertising and promotion of antimicrobial agents should be done in a manner consistent with specific regulatory recommendations for the product.

## Training on topics related to antimicrobial resistance and the responsible 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 constituencies, including awareness campaigns for consumers.

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; the OIE List of antimicrobials 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
- on the collection and reporting of AMR monitoring and surveillance data.

## Knowledge gaps and research

33. 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 [medically important] antimicrobials at the farm, regional,

and national levels, and the effectiveness of different interventions to change behavior and reduce the need to use [medically important] 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 and 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 <u>and safety</u> standards of the importing country should be exported from a country in which the products were produced.]

39. The amount of antimicrobial agents marketed should be provided to the national competent authority 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. Promotional campaigns involving economic or material benefits for prescribers or suppliers of antimicrobials should not be used.]

## 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.

#### 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 all antimicrobials supplied according to the national regulations and may include, for example:

- date of supply
- name of <u>responsible</u> 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.]

# 5.4 Responsibilities of Veterinarians<sup>5</sup> and Plant/Crop Health Professionals

49. Veterinarians and plant/crop health professionals should identify new or recurrent disease problems and develop strategies in conjunction with competent authority to prevent, control, or treat infectious disease. 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 foodproducing 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 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 and local expertise of the prescribing veterinarian, and epidemiological and clinical knowledge and, <u>if available</u>, <u>based on adequate diagnostic procedures</u> the accurate diagnosis, based on adequate diagnostic procedures. There will be occasions When a group of food-producing animals, which may have been exposed to pathogens, they may need to be treated without recourse to an accurate laboratory confirmed diagnosis based on and antimicrobial susceptibility testing to prevent the development and spread of clinical disease. and for reasons of animal welfare.

----- STOP PWG DISCUSSION ------

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<sup>&</sup>lt;sup>5</sup> Under some circumstances, this may refer to a suitably trained person authorized in accordance with national legislation, for example an Aquatic Animal Health Professional.

53 49. 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.

[49alt1: For food-producing plants/crops, the appropriate use of antimicrobial agents to manage disease/pests should be based on historical knowledge of the disease/pest situation, undertake monitoring on the current disease/pest status and input from a plant/crop health professional who has experience and local expertise.]

[49alt2: The monitoring and diagnostic of crop diseases allows farmers to know the phytosanitary situation and therefore to target and choose the appropriate treatment methods. It is done by the publication of phytosanitary alerts.

The plant protection against diseases should be based on the principles of integrated pest management

- <u>Assess the situation, environmental conditions, abundance of harmful and beneficial organisms and</u> <u>crop stage;</u>
- <u>Use of intervention thresholds allows not only to use a pesticide or other control at the right time, with</u> maximum efficiency, but also to achieve significant savings by not intervening when it is not justified;
- <u>Combining the different control methods curative, biological, mechanical, cultural, genetic and chemical ensures a more sustainable and effective reduction in pest populations and helps to reduce the risks associated with the exclusive use of pesticides;</u>
- <u>Use of registered pesticides as a last resort and combine active ingredients with different modes of</u> action to reduce the risk of resistance;
- <u>Evaluation of the process by assessing whether the intervention was effective, whether it produced</u> <u>unacceptable side effects, whether to continue, revise or abandon the program.</u>]

[49alt3: "For plant/crop, when the disease of plant/crop is identified as a new problematic disease or regulatory quarantine disease in accordance with the appropriate diagnostic procedure, plant/crop protection professional can prescribe or treat with medically important antimicrobial agents to prevent the development and spread of disease without recourse to an accurate diagnosis and antimicrobial susceptibility testing.]

54 <del>50</del>. Determination of the choice of an antimicrobial agent should be based on:

- The expected efficacy of the administration based on:
  - the <u>expertise and</u> experience of the veterinarian, plant/crop health professional or suitably trained and authorized person;
  - the spectrum of the antimicrobial activity towards the pathogens involved;
  - the history of the production unit particularly in regard to the antimicrobial susceptibility profiles of the pathogens involved. Whenever possible, the antimicrobial susceptibility profiles should be established before the commencement of the administration. If this is not possible, it is desirable for samples to be taken before the start of the administration to allow, if necessary, for adjustment of therapy based on susceptibility testing. Should a first antimicrobial administration fail, or should the disease recur, the use of a second antimicrobial agent should ideally be based on the results of microbiological susceptibility tests derived from relevant samples;
  - the appropriate route of administration;
  - results of initial administration;
  - previous published scientific information on the treatment of the specific disease <u>and available</u> scientific knowledge on antimicrobial use and resistance;
  - <u>evidence-based therapeutic treatment</u> 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 <u>whenever</u> <u>possible</u>;
- o optimized dosing regimens;
- o 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.
- the route of administration
- If the label conditions allow for flexibility, the veterinarian or plant/crop health professional should consider a dosage 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 51. 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 appropriate and/or use of approved or appropriate withdrawal periods to be used. 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.

51bis: Off-label use of medically important antimicrobial agents should not be permitted for growth promotion. <u>Fluoroquinolones, colistin and third and fourth generations of cephalosporins should be urgently prohibited for</u> <u>use as growth promotors.</u>

56 <del>52</del>. 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 53. Medically important Antimicrobials should not be used off-label for plants/crops.

## Record keeping and recording

58 54. For food-producing animals and plants/crops, records on antimicrobial agent prescription or administration application should be kept in conformity with national legislation or best management practice guidelines.

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 and genomic information, when available;
- record the antimicrobial used, the dosage regimen 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).

59 <del>55</del>. Veterinarians and plant/crop health professionals should also periodically review farm records on the use of antimicrobial agents to ensure compliance with their directions.

# Training

60 56. Professional or other organizations should participate in support the development and/or delivery of training on issues related to antimicrobial resistance and the responsible users of antimicrobial agents as defined described in paragraph 3228.

# 5.5 Responsibilities of food animal and plant/crop producers

61 <del>57</del>. Producers are responsible for implementing health programmes on their farms to prevent and manage disease outbreaks. They should call on the <u>with</u> 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 <u>to reduce reducing the need to use antimicrobials</u> ensuring the responsible and prudent use of antimicrobial agents to minimize risk of foodborne AMR.

62 58. 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 in a manner to minimize foodborne AMR under conditions approved by relevant authorities;
- to comply with the storage conditions of antimicrobial agents according to the approved product labelling;
- to address infection prevention and control measures regarding contacts between people, veterinarians, plant/crop health professional, breeders, owners, children, pets, wildlife and the foodproducing animals or plants/crops treated;
- to comply with the recommended withdrawal periods or pre-harvest intervals to ensure that residue levels in or on the food do not present a foodborne AMR risk for the consumer;
- 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 failures of suspected lack of efficacy of antimicrobial applications;
- to 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:
  - o copy of the prescription, order for application or other documentation, when available;
  - o name of the antimicrobial agent/active substance and batch number;
  - o name of supplier;
  - o date of administration; species and number of animals or plants/crops;
  - identification of the production unit (animal age, numbers, weights) to which the antimicrobial agent was administered;
  - o disease treated, prevented, or controlled;
  - o number of relevant information on animals or plants/crops treated (number, age, weight);
  - o daily dose and number of treatment days;
  - o quantity and duration of the antimicrobial agent administered;
  - withdrawal periods;
  - o 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 basic infection prevention and control measures as appropriate and as provided in the OIE terrestrial and aquatic animal health codes;

- <u>To participate in training on issues related to antimicrobial resistance and the responsible use of antimicrobial agents as described in paragraph 32, as appropriate;</u>
- To assist the relevant authorities in surveillance programs related to antimicrobial use and antimicrobial resistance, as appropriate.

63 <del>59</del>. The responsible and prudent use of antimicrobial agents should be supported by continuous efforts in disease prevention to minimize infection during production. <del>and decrease exposure to antimicrobial agents.</del> Efforts should aim to improve health, thereby reducing the need for <del>antibiotics</del> <u>antimicrobial agents</u>. This can be achieved by, <u>for example</u>, improving hygiene, biosecurity, <del>and</del> 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.

Disease prevention through the use of vaccines, integrated pest management, and other measures that have been clinically proven to be safe and efficacious for supporting animal health, such as adequate nutrition and feed additives, such as probiotics (beneficial bacteria found in various foods), prebiotics (non-digestible foods that help probiotic bacteria grow and flourish) or competitive exclusion products (intestinal bacterial flora that limit the colonization of some bacterial pathogens) may should/can be considered and applied wherever when appropriate and available. Disease prevention through the use of vaccines and other appropriate measures aimed at supporting animal health (such as adequate nutrition and whenever available feed additives such as prebiotics, probiotics) should be considered.

Prevention and reduction of the incidence and severity of plant pests and diseases should be implemented by applying best 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 and pest impact reduction strategies using host resistance, induced resistance, integrated pest management strategies and biological controls when appropriate and available.

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

[64 60bis (a). Concerted efforts of all stakeholders within the entire along the food chain are required to minimize and contain foodborne illness, including illness related to foodborne AMR. While this Code such efforts include 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.]

[65 60bis (b). The food processing industry and food retailers should follow refer to the Principles and Guidelines for the Conduct of Microbiological Risk Management (CXG 63-2007).]

[66 60bis (c). Food should be produced and handled in such a way as to minimize <u>the introduction, the</u> 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 (CXC 1-1969) is a useful reference in this respect.]

[67 60ter. 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 <u>AMR resistant</u> infections.]

## 7. Consumer practices and communication to consumers

68 64. 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.

Some aspects to consider when communicating to consumers are:

- Identifying all the stakeholders and having a common message;
- Providing information that is clear, accessible, and targeted to a non-scientific audience;
- Considering local characteristics that affect how risks are perceived (e.g. religious belief, traditions).;

The WHO Five Keys to Safer Food Manual can be used as a tool to assist in awareness raising for consumers on how to minimize foodborne bacteria in their food.]69 62. 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.

[63. The best way for consumers to minimize foodborne illness, including infections with resistant

microorganisms, is through proper food handling and personal hygiene. The WHO Five Keys to Safer Food Manual can be used as a tool to assist in awareness raising for consumers on how to minimize foodborne bacteria in their food.]