



Agenda Item 5

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME
**AD HOC CODEX INTERGOVERNMENTAL TASK FORCE ON ANTIMICROBIAL
RESISTANCE**
Sixth Session
Busan, Republic of Korea, 10-14 December 2018
**PROPOSED DRAFT REVISION OF THE CODE OF PRACTICE TO MINIMIZE AND
CONTAIN FOODBORNE ANTIMICROBIAL RESISTANCE (CXC 61-2005)**

(Revised)

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

The Chair and Co-Chairs of the EWG on the Code of Practice would like to offer the following information to facilitate discussion on Sections 4-7 of the Proposed Draft Revised Code of Practice to Minimize and Contain Antimicrobial Resistance (CXC 61-2005)

Section 4. – General Principles

With respect to General Principles, the Chair and Co-Chairs request feedback from the TFAMR on which Principles may need further discussion (such as in a future EWG) and which Principles may have good agreement at this stage. Taking into account comments submitted in response to CL 2018/74-AMR, Co-Chairs offered the following assessment.

The following General Principles appear to have consensus and could be reviewed and adopted at Step 5.

[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 2: Biosecurity, appropriate nutrition, vaccination, animal and plant/crop best management practices, and alternatives to antimicrobial agents¹ where appropriate, and that have been proven to be efficacious and safe, should be considered to reduce the need for use of antimicrobial agents.]

[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.]

[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 8: Antimicrobial agents should be used as legally authorized and following all applicable label directions; except where specific legal exemptions apply.]

¹ [~~Could include ethnoveterinary and other approaches, e.g. herbal medicine, probiotics, competitive exclusion bacteriophages, immunomodulators, organic acids and tea sealants.~~]

[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 human and animal health of recommended risk management measures.]

[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 medically important antimicrobial agents in humans and food-producing animals, and transmission of pathogens and resistance genes between humans, food-producing animals, 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*.]

[Principle 13: Administration of antimicrobial agents should take into consideration sampling and 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 14: Administration of antimicrobial agents should be based on sound clinical judgement, experience, and treatment efficacy. Where feasible and appropriate the results of bacterial cultures and antimicrobial susceptibility testing and integrated resistance surveillance and monitoring can also be considered.]

The following General Principles should be referred to the EWG for further discussion.

[Principle 5: Responsible and prudent administration in food-producing animals does not include the use for growth promotion of antimicrobial agents that are considered medically important or are able to cause cross-resistance to other antimicrobial agents, or classes of antimicrobial agents, that are considered medically important, in the absence of a risk analysis. This risk analysis should:

- be undertaken by the appropriate national [regulatory competent](#) authority;
- be based on adequate scientific evidence; and
- include a publicly available summary.]

[Principle 6: Medically important antimicrobial agents should only be used for therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease); or in certain circumstances for research and conservation.]

[Principle 7: 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 duration.]

[Principle 11: 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 stepwise 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 barriers to trade.]

[Principle 12: Medically important antimicrobials should be administered, prescribed, or applied only by, or under the direction of, veterinarians, plant/crop advisors or consultants or other suitably trained persons authorized in accordance with national legislation.]

[Principle 16: On a continuous and stepwise 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.]

The following General Principle should be deleted as it is not well understood internationally.

[Principle 15: The reduce, replace and rethink (RRR) strategy on the use of antimicrobial agents in animals and on plants/crops should be actively promoted within all sectors.]

With respect to topics in **Section 5. - Responsible and prudent use of antimicrobial agents**, the Chair and Co-Chairs request feedback from the TFAMR on which topics may need further discussion (such as in a future EWG). Taking into account comments submitted in response to CL 2018/74-AMR, Co-Chairs identified the following possible topics.

Section 5. – Responsible and prudent use of antimicrobial agents

Q1: Given the fact that VICH is not a multi-lateral organization, should the reference in paragraph 11 be retained?

11. For more information on the data requirements for authorization of antimicrobial agents for food-producing animals see the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) guidelines.

Responsibilities of the regulatory authorities

Surveillance and monitoring programmes

Q2: Is this section needed, in whole or in part, given the development of Guidelines on Integrated Surveillance (GLIS)? Could this section be replaced with a reference to the GLIS?

21. Regulatory 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, taking into consideration relevant sections of Guidelines for risk analysis of foodborne antimicrobial resistance; WHO guidelines on integrated surveillance of antimicrobial resistance in foodborne bacteria, application of a One Health Approach; and OIE terrestrial animal health code Chapter 6.7 Harmonization of national antimicrobial resistance surveillance and monitoring programmes and Chapter 6.8 Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals, the OIE aquatic animal health code Chapter 6.3 Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals and Chapter 6.4 Development and harmonization of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals and section 8 of chapter 6.9.3 on post-marketing antimicrobial surveillance.

22. The surveillance and monitoring of antimicrobial resistant bacteria in different production sectors and in different food products and at different stages of the food chain, should be undertaken to understand the development and dissemination of antimicrobial resistance, provide relevant risk assessment data, and to assess the effectiveness of interventions. Surveillance and monitoring programmes may entail specific or continuous data collection, analysis and reporting that quantitatively monitors temporal trends in the occurrence and/or prevalence and distribution of resistance to antimicrobial agents; and also allow the identification of emerging or specific patterns of resistance. Surveillance and monitoring programmes should be prioritized based on the risk to public health, national priorities, should be practical and feasible, and may be implemented following a stepwise approach.

22bis. Regulatory authorities should have in place a pharmacovigilance program for the monitoring and reporting of adverse reactions to veterinary antimicrobial drugs, including lack of the expected efficacy

related to microbial resistance. The information collected through the pharmacovigilance program should form part of the comprehensive strategy to minimize microbial resistance.

22ter. In cases, where the assessment of data collected from pharmacovigilance and from other post-authorization surveillance including, if available, targeted surveillance of antimicrobial resistance, suggests that the conditions of use of the given veterinary antimicrobial drug should be reviewed, regulatory authorities shall endeavor to achieve this re-evaluation.

Control of advertising

Q3: Is this section necessary? Do we elaborate the section or do we make reference to the relevant Chapter in the OIE Code?

25. Regulatory authorities should assure that advertising of antimicrobial agents is done in accordance with national legislation.

26. Advertising of antimicrobial agents should be done in a manner consistent with prudent use guidelines and any other specific regulatory recommendations for the product.

27. All advertising of medically important antimicrobial agents should be controlled by the relevant authorities.

- *The authorities should ensure that advertising of antimicrobial agents:*
- *complies with the marketing authorization granted, in particular with the content of the summary of product characteristics; and*
- *complies with each country's national legislation.*

Responsibilities of Manufacturers and Marketing Authorization Holders

Advertising

Q4: Is this section necessary? Do we elaborate the section or do we make reference to the relevant Chapter in the OIE Code?

35. It is the responsibility of the marketing authorization holders to only advertise antimicrobial agents in accordance with the provisions of paragraphs 25-27 on the Responsibilities of the Regulatory Authorities, Control of Advertising and to not advertise medically important antimicrobials to producers.

36. Advertising should only be targeted to persons permitted to prescribe or supply antimicrobial agents. Promotional campaigns involving economic or material benefits for prescribers or suppliers of antimicrobials should be discouraged.

Off-label use

Q5: Are the following paragraphs agreeable as written?

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 approved 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. Off-label use of medically important antimicrobial agents should not be permitted for growth promotion.

52. Human health risk related to foodborne antimicrobial resistance should be an important factor when considering the off-label use of veterinary antimicrobial agents.

53. Medically important antimicrobials should not be used off-label for plants/crops.

Taking into account comments submitted in response to CL 2018/74-AMR the Section 6. - Practices during production, processing, storage, transport, and wholesale and retail distribution of food and Section 7 – Communications to Consumers: the following revisions have been made.

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

~~[60bis. Control of technological treatments in the industry: Technological treatments of food preservation based on the application of one or more bacteriostatic factors to prevent microbial growth (sub-lethal treatments) can increase the phenotypes of resistant bacteria, contrary to conventional bactericidal treatments. Modern conservation systems cause some bacteria to be only stressed and can increase resistance through phenotypic and / or genotypic adaptations. This adaptation is sometimes associated with an increase in resistance to different antibiotics.]~~

~~[60bis (a). Concerted efforts of all stakeholders within the entire food chain are required to minimize and contain foodborne AMR. While such efforts include focus 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.]~~

~~[60bis (b). The food processing industry and food retailers should follow the Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007).]~~

~~[60bis (c). Food should be produced and handled in such a way as to minimize the 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 Codex General Principles of Food Hygiene (CAC/RCP 1-1969. Rev. 4 - 2003) is a useful reference in this respect.]~~

~~[60ter. Control of post production contamination: Post production contamination should not be underestimated. It can occur in the different stages of the production and consumption chain, in which food handlers have an important responsibility to avoid contamination of food with microorganisms that can be carriers of resistance genes. Food contamination usually occurs at times of increased handling, in meat during slaughter or processing. In ready-to-eat foods, the real risk is presumed cross-contamination, directly between raw and processed foods or indirectly through contaminated hands, surfaces or utensils and vectors.]~~

~~[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 AMR infections.]~~

7. Consumer practices and communication to consumers

[61. Government, food industry and other stakeholders along the food chain should inform and educate

consumers on the risks of foodborne [illness, including AMR infections](#), 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 beliefs, traditions);
- Understanding the audience and testing messages to ensure they are culturally and demographically appropriate;
- [Ensuring that food product label claims relevant to use of antimicrobials \(e.g. “no antibiotics”\) are meaningfully defined/documentated, truthful and not misleading.](#)]

[62. For more information on risk communication refer to the *Guidelines for risk analysis of foodborne antimicrobial resistance*, the *WHO integrated surveillance of antimicrobial resistance in foodborne bacteria* and the *FAO/WHO risk communication applied to food safety handbook*.]

[63. The best way for consumers to prevent foodborne [illness, including AMR infections](#), is through proper food handling. The *WHO Five Keys to Safer Food Manual* can be used to teach consumers how to minimize foodborne bacteria in their food.]