



JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

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MATTERS ARISING FROM THE REPORTS OF THE COMMISSION, THE EXECUTIVE COMMITTEE AND THE SUBSIDIARY BODIES

REPORT OF THE PHYSICAL WORKING GROUP ON ANTIMICROBIAL RESISTANCE (AMR)

London, United Kingdom

29 November – 2 December 2016

1. A physical working group, open to all Members and Observers, was held in London, United Kingdom, from 29 November to 2 December 2016 to undertake the tasks assigned to it at the 39th session of the Codex Alimentarius Commission. The working group was chaired by the United Kingdom and co-chaired by Australia and the United States of America and was attended by 110 people consisting of: 33 Member Countries, 1 Member Organisation, 13 Observers Organisations, FAO and WHO and the Codex Secretariat. The list of attendees is contained at Appendix 4.
2. Through a participatory process of extensive and lively discussion, and informed by the results of an electronic pre-consultation, the working group reviewed and revised the following project documents:
 - Proposal for new work on the revision of the *Code of Practice to Minimise and contain Antimicrobial Resistance* (CAC/RCP 61-2005); and
 - Proposal for new work on the Guidance on Integrated Surveillance of Antimicrobial Resistance.
3. The working group achieved consensus on the revised project documents (Appendices 1 and 2), which will be submitted to the 40th session of the Codex Alimentarius Commission for adoption.
4. Through a similar process, the working group also reviewed and revised the Terms of Reference for the Provision of Scientific Advice on Antimicrobial Resistance. The working group achieved consensus on this text (Appendix 3), which was received by WHO and FAO who will proceed to generate this advice to inform the work of the Task Force on Antimicrobial Resistance.
5. The working group considered the process by which draft texts may be elaborated for consideration by the first meeting of the Task Force, following adoption of the proposals for new work by the 40th session of the Codex Alimentarius Commission. The working group concluded that an electronic working group would be an appropriate mechanism for informing the elaboration of text in each of the two areas of new work, and agreed to recommend this to the 40th session of the Codex Alimentarius Commission.

PROJECT DOCUMENT /1

Proposal for new work on the revision of the *Code of Practice to Minimize and Contain Antimicrobial Resistance* (CAC/RCP 61-2005)

1. Purpose

The purpose of the proposed new work is to revise the *Code of Practice to Minimize and Contain Antimicrobial Resistance* by broadening its scope, and developing risk-based guidance on the management of foodborne antimicrobial resistance that addresses the entire food chain, in line with the mandate of Codex. The objective is to minimize the risk to public health from the development and spread of foodborne antimicrobial resistance.

The guidance should be scientifically supported and also take into account new developments, including the current and future revisions of Lists of Critically Important Antimicrobials, and the work of FAO, WHO and OIE in this area.

2. Scope

The revision should address the risk to human health associated with the presence in food and animal feed, and the transmission through food and animal feed, of AMR micro-organisms or determinants. It should provide guidance on relevant measures along the food chain to minimize the development and spread of foodborne antimicrobial resistance, including guidance on the responsible and prudent use of antimicrobial agents in agriculture and aquaculture.

3. Relevance and timeliness

The Codex Alimentarius Commission has actively been engaged in the fight against antimicrobial resistance (AMR) through standard setting, supported by the provision of scientific advice by FAO and WHO, with participation of OIE. The major achievements of the Commission are the adoption of *the Code of Practice to Minimize and Contain Antimicrobial Resistance* (CAC/RCP 61-2005) developed by CCRVDF; and the *Guidelines on Risk Analysis of Foodborne Antimicrobial Resistance* (CAC/GL 77-2011) developed by the TFAMR.

In May 2014, the World Health Assembly adopted Resolution 68/20 calling for the development of a Global Action Plan on Antimicrobial Resistance and for strengthened collaboration between the Food and Agriculture Organization of the United Nations (FAO), the World Organisation for Animal Health (OIE) and the World Health Organization (WHO) to address antimicrobial resistance (AMR) within the context of "One Health".

The Second FAO/WHO International Conference on Nutrition (ICN2), which met on 19-21 November 2014, adopted a Rome Declaration on Nutrition, which recognized that food systems need to contribute to preventing and addressing infectious diseases, including zoonotic diseases, and to tackling antimicrobial resistance. In 2015 FAO and OIE actively contributed to the development of the WHO led Global Action Plan, which was adopted by the World Health Assembly in May 2015 with WHA Resolution 68.7.

The UN General Assembly in September 2016 adopted a Declaration on AMR which commits member countries to develop multi-sectoral national action plans in line with a One Health approach that include development and strengthening of surveillance, monitoring and regulatory frameworks.

The proposed new work responds to the rising public health threat of antimicrobial resistance, including AMR from antimicrobial use in the food chain and the request for action in the Global Action Plan on AMR and is consistent with the commitment taken by FAO and WHO Membership at the statutory bodies of the two organisations.

4. The main aspects to be covered

The revision of the Code of Practice will address risk mitigation measures including all uses of antimicrobial agents along the food chain and provide updated information, in particular with regard to:

- determining and addressing the gaps¹ that exist in the Code and updates to language, references, or tools, that are necessary;
- strategies that prevent or reduce the need to use antimicrobial agents;

¹ Measures described in this guidance should be risk based to the extent possible and practical; recognizing that risk assessment for food borne illness due to AMR organisms or determinants in the food chain is currently limited in extent.

- the inclusion of references to the lists of Critically Important Antimicrobials;
- the respective responsibilities of all involved in the production of food along the food chain, from primary producers to end consumers, including those involved in the production, selling, distribution and application of antimicrobial agents and;
- the use of antimicrobials as growth promoters.

The revision will also consider the outcomes and recommendations of the FAO, WHO and OIE Experts Meeting(s) on AMR (see Section 8). The revised Code of Practice should be formulated to provide a framework that countries may implement in accordance with their capabilities but within a reasonable period of time. A stepwise approach may be appropriate to properly implement all elements of the revised Code of Practice.

5. An assessment against the criteria for the establishment of work priorities

General criterion

Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.

The proposed new work responds to the rising public health threat of antimicrobial resistance, including AMR from antimicrobial use in the food chain.

Criteria applicable to general subjects

(a) *Diversification of national legislations and apparent resultant or potential impediments to international trade.*

While a number of countries have adopted and are applying all or parts of the recommendations of *Code of Practice to Minimize and Contain Antimicrobial Resistance* (CAC/RCP 61-2005), utilising national legislation and other means, others have not, and do not yet have legislation on AMR.

(b) *Scope of work and establishment of priorities between the various sections of the work.*

Refer to Section 4.

(c) *Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies).*

This work will take into account work undertaken in this area by FAO, WHO and OIE, aiming to minimize duplication, avoid contradiction, and ensure coherence. This work is specifically mentioned in the WHO Global Action Plan on Antimicrobial Resistance, which states under Objective 2 of the Framework for Action: "FAO, with WHO, should review and update regularly the FAO/WHO Codex Alimentarius Code of Practice to minimize and contain antimicrobial resistance and the Codex Alimentarius guidelines for risk analysis of foodborne antimicrobial resistance".

(d) *Amenability of the subject of the proposal to standardization.*

Prior work on this subject was developed by CCRVDF in two sessions (CCRVDF14 and 15).

(e) *Consideration of the global magnitude of the problem or issue.*

The global magnitude of antimicrobial resistance is recognized by the recent resolutions of the United Nations and the governing bodies of FAO, WHO and OIE (refer to Section 3).

6. Relevance to Codex strategic objectives

The proposed work is directly related to the purpose of the Codex Alimentarius Commission, according to its *statutes*, to protect the health of the consumers and ensure fair practices in the food trade, as well as to the first Strategic Goal of the Codex Alimentarius Commission's Strategic Plan 2014-2019: "establish international food standards that address current and emerging food issues", and is consistent with Objective 1.2 "proactively identify emerging issues and member country needs and, where appropriate, develop relevant food standards". Further, it contributes to Activity 1.2.2 "develop and revise international and regional standards as needed, in response to needs identified by Members and in response to factors that affect food safety, nutrition and fair practices in the food trade". It is also consistent with Objective 1.3 "strengthen coordination and cooperation with other international standards-setting organizations seeking to avoid duplication of efforts and optimize opportunities."

7. Information on the relation between the proposal and other existing Codex documents

The work will take into consideration the *Guidelines on Risk Analysis of Foodborne Antimicrobial Resistance* (CAC/GL 77-2011); the *Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals* (CAC/GL 71-2009); the *Code of Practice on Good Animal Feeding* (CAC/RCP 54-2004); the *Code of Practice for Fish and Fishery Products* (CAC/RCP 53-2003); the *General Principles of Food Hygiene* (CAC/RCP 1-1969) as well as other Codes of Hygienic Practice for specific products.

8. Identification of any requirement for and availability of expert scientific advice

Scientific advice is required to expand the scope of the Code of Practice and provide advice on relevant practice and management options for the expanded scope.

9. Identification of any need for technical input to the standard from external bodies so that this can be planned for

Collaboration with OIE will be important to minimize duplication, avoid contradiction and ensure coherence between Codex and OIE texts. Cross-referencing to relevant OIE texts should be considered, when relevant (see REP14/CAC paragraph 104).

10. Completion of the new work and other conditions

The proposed timeline for completion of the new work includes the start date, the proposed date for adoption at Step 5 and the proposed date for adoption by the Commission.

- Approval of new work: 2017
- Discussion at Step 3: 2017
- Adoption at Step 5: 2019
- Adoption at Step 8: 2020

PROJECT DOCUMENT /2

Proposal for new work on the Guidance on Integrated Surveillance of Antimicrobial Resistance

1. Purpose

The purpose of the proposed new work is to provide Codex members with guidance on the design and implementation of integrated surveillance of foodborne antimicrobial resistance (AMR) along the food chain, and thus promoting a harmonised approach among countries to AMR surveillance that will facilitate the multi-sectoral exchange and analysis of data from different areas, countries and regions.

2. Scope

This work will develop guidance for integrated surveillance of foodborne AMR along the food chain.

Effective public health AMR surveillance systems aiming at prevention and control of AMR should include surveillance of both antimicrobial resistance and antimicrobial use. Effective AMR surveillance systems also need to be cross-sectoral, with surveillance conducted utilizing appropriate microbiological and epidemiological data from humans, animals, crops, and food, and data on antimicrobial use among humans, animals and crops; such an AMR surveillance system has been defined as an “integrated” AMR surveillance system.

3. Relevance and timeliness

The Codex Alimentarius Commission has actively been engaged in the fight against antimicrobial resistance (AMR) through standard setting, supported by the provision of scientific advice by FAO and WHO, often with participation of OIE. The major achievements of the Commission are the adoption of *the Code of Practice to Minimize and Contain Antimicrobial Resistance* (CAC/RCP 61-2005) developed by CCRVDF; and the *Guidelines on Risk Analysis of Foodborne Antimicrobial Resistance* (CAC/GL 77-2011) developed by the TFAMR.

In May 2014, the World Health Assembly adopted Resolution 68/20 calling for the development of a Global Action Plan on Antimicrobial Resistance and for strengthened collaboration between the Food and Agriculture Organization of the United Nations (FAO), the World Organisation for Animal Health (OIE) and the World Health Organization (WHO) to address antimicrobial resistance (AMR) within the context of “One Health”.

The Second FAO/WHO International Conference on Nutrition (ICN2), which met on 19-21 November 2014, adopted a Rome Declaration on Nutrition, which recognized that food systems need to contribute to preventing and addressing infectious diseases, including zoonotic diseases, and to tackling antimicrobial resistance. In 2015 FAO and OIE actively contributed to the development of the WHO led Global Action Plan, which was adopted by the World Health Assembly in May 2015 with WHA Resolution 68.7.

The UN General Assembly in September 2016 adopted a Declaration on AMR which commits member countries to develop multi-sectoral national action plans in line with a One Health approach that include development and strengthening of surveillance, monitoring and regulatory frameworks.

The proposed new work responds to the rising public health threat of antimicrobial resistance, including AMR from antimicrobial use in the food chain and the request for action in the Global Action Plan on AMR and is consistent with the commitment taken by FAO and WHO Membership at the statutory bodies of the two organisations.

4. The main aspects to be covered

The Guidance will cover the following aspects:

- (i) Approaches to integrated surveillance of AMR
- (ii) Key components of integrated surveillance of AMR, including:
 - sampling sources
 - target microorganisms
 - sampling design
 - laboratory testing
 - data management, analysis and reporting

(iii) Incorporation of information from integrated surveillance into risk analysis (see guideline 77).

The guidance should be formulated to provide a framework that countries may implement in accordance with their capabilities, but within a reasonable period of time. A stepwise approach may be appropriate to properly implement all elements of the guidance.

5. An assessment against the criteria for the establishment of work priorities

General criterion

Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.

The proposed new work responds to the rising public health threat of antimicrobial resistance, including AMR from antimicrobial use in the food chain.

Criteria applicable to general subjects

(a) *Diversification of national legislations and apparent resultant or potential impediments to international trade.*

International guidance on the design and implementation of integrated surveillance will promote a harmonised approach among countries to AMR surveillance and monitoring of antimicrobial use and will facilitate the multi-sectoral exchange and analysis of data from different areas, countries, and regions.

(b) *Scope of work and establishment of priorities between the various sections of the work.*

Refer to Section 4.

(c) *Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies).* This work will take into account work undertaken in this area by FAO, WHO and OIE, aiming to minimize duplication, avoid contradiction, and ensure coherence. In particular this work will take into account AGISAR Guidance on integrated surveillance of antimicrobial resistance:

http://www.who.int/foodsafety/publications/agisar_guidance/en/

(d) *Amenability of the subject of the proposal to standardization.*

Work on the development of the *Guidelines on Risk Analysis of Foodborne Antimicrobial Resistance* (CAC/GL 77-2011) was successfully completed by the ad hoc Intergovernmental Task Force on Antimicrobial Resistance (TFAMR), which was dissolved by CAC in 2011.

(e) *Consideration of the global magnitude of the problem or issue.*

The global magnitude of antimicrobial resistance is recognized by the recent resolutions of the United Nations and the governing bodies of FAO, WHO and OIE (refer to Section 3).

6. Relevance to Codex strategic objectives

The proposed work is directly related to the purpose of the Codex Alimentarius Commission, according to its *statutes*, to protect the health of the consumers and ensure fair practices in the food trade, as well as to the first Strategic Goal of the Codex Alimentarius Commission's Strategic Plan 2014-2019: "establish international food standards that address current and emerging food issues", and is consistent with Objective 1.2 "proactively identify emerging issues and member country needs and, where appropriate, develop relevant food standards". Further, it contributes to Activity 1.2.2 "develop and revise international and regional standards as needed, in response to needs identified by Members and in response to factors that affect food safety, nutrition and fair practices in the food trade". It is also consistent with Objective 1.3 "strengthen coordination and cooperation with other international standards-setting organizations seeking to avoid duplication of efforts and optimize opportunities."

7. Information on the relation between the proposal and other existing Codex documents

The work will take into consideration the *Guidelines on Risk Analysis of Foodborne Antimicrobial Resistance* (CAC/GL 77-2011); and the *Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals* (CAC/GL 71-2009).

The work will consider new work on the revision of the *Code of Practice to Minimize and Contain Antimicrobial Resistance* (CAC/RCP 61-2005).

8. Identification of any requirement for and availability of expert scientific advice

This work will take into account the Guidance on Integrated Surveillance of Antimicrobial Resistance, developed by the WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR). Therefore, AGISAR support will be important to ensure that the guidelines take into account the latest developments.

Scientific advice may be required to fill data gaps identified by the task force.

9. Identification of any need for technical input to the standard from external bodies so that this can be planned for

Collaboration with OIE will be important to minimize duplication, avoid contradiction and ensure coherence between Codex and OIE texts. Cross-referencing to relevant OIE texts should be considered, when relevant (see REP14/CAC paragraph 104).

10. Completion of the new work and other conditions

The proposed timeline for completion of the new work includes the start date, the proposed date for adoption at Step 5 and the proposed date for adoption by the Commission.

- Approval of new work: 2017
- Discussion at Step 3: 2017
- Adoption at Step 5: 2019
- Adoption at Step 8: 2020

TERMS OF REFERENCE FOR THE PROVISION OF SCIENTIFIC ADVICE ON ANTIMICROBIAL RESISTANCE

Objectives

To provide scientific advice to support the revision of the *Code of Practice to Minimise and Contain Antimicrobial Resistance* (CAC/RCP 61-2005) and ensure that it is based on the most recent evidence and scientific analysis regarding foodborne antimicrobial resistance (AMR), that the scope appropriately reflects the role of the food and agriculture sector in minimizing the risk to public health from the development and spread of foodborne antimicrobial resistance and that a range of risk management options are available for consideration by Codex. Furthermore, the scientific advice should seek to identify any further issues and specific gaps in current scientific knowledge that need to be considered in the revision of existing Codex texts and/or development of new Codex texts.

Some of the key issues to be addressed include the following:

- i) Undertake a review of current and new data relevant to the development and transmission of foodborne antimicrobial resistance through the food chain with the objective of:
 - Identifying all potential sources/contributors and practices related to the development and/or transmission of foodborne AMR.
 - Including scientific information on important factors influencing foodborne AMR, taking into consideration animals, crops¹, environment, and also manure, biocides, waste and packaging, production systems and practices (including animal husbandry of nomadic herds and ethno-veterinary use of plants), food processing, retail handling and consumption.
 - Provide information on examples of risk profiling and risk ranking and risk assessment for specific AMR organisms and/or determinants and their pathways, where available.
 - Identifying and evaluating risk management measures at different points in the food chain to address foodborne AMR and provide advice accordingly on the efficacy of such risk management options in achieving risk based public health outcomes.
- ii) With particular reference to the WHO and OIE lists of Critically Important Antimicrobials, existing Codex MRLs (veterinary drugs and pesticides) and the most recent scientific information on foodborne antimicrobial resistance and its occurrence in the food chain
 - Revisit the discussion of the 2007 expert meeting on this issue and update the advice based on current knowledge to provide evidence based advice on how to guide the Codex membership in the use of these lists in managing foodborne AMR, taking into consideration the interaction between public health, animal health, plant health, and food security needs.
- iii) Considering the challenge faced by the food and agriculture sector to change practices² as well as meet the global food needs, provide advice on alternatives to antimicrobials which would support behaviour change and encourage the implementation of practices aimed at addressing foodborne AMR.

¹ As a result of relatively limited information on the link between the use of antimicrobials on crops and foodborne AMR, strong emphasis should be placed on developing scientific advice in this area. For example, antimicrobial resistant organisms/determinants due to antimicrobial use in crops, and antimicrobial resistant organisms/determinants in the environment due to antimicrobial use in crops.

² Providing scientific advice regarding the impact on foodborne AMR as a result of current practices involving the administration of antimicrobials (e.g. growth promotion, therapeutic use, prophylaxis, metaphylaxis). Identify and evaluate risk management options that do not involve administration of antimicrobials.

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