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CODEX WORK ON ANTIMICROBIAL RESISTANCE¹

(Prepared by Codex Secretariat in collaboration with FAO and WHO)

Governments and interested international organizations are invited to submit comments on the recommendations regarding future work of Codex on Antimicrobial Resistance (see para. 48) to: the Secretariat of the Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme (E-mail: Codex@fao.org) **by 1 June 2016.**

1. Background

1. At the 70th Session of the Executive Committee (CCEXEC70) FAO and WHO presented a paper (CX/CAC 15/38/16 Add.1) on antimicrobial resistance (AMR), which highlighted relevant decisions of the FAO and WHO Governing bodies on AMR, including the WHO Global Action Plan on Antimicrobial Resistance², adopted by the 68th World Health Assembly (May 2015); and the FAO Resolution of Antimicrobial Resistance³, adopted by the FAO Conference (June 2015).

2. The FAO and WHO Representatives noted that these documents included a specific reference to Codex texts on antimicrobial resistance, i.e. *Code of Practice to Minimise and Contain Antimicrobial Resistance* (CAC/RCP 61-2005) and *Guidelines on Risk Analysis of Foodborne Antimicrobial Resistance* (CAC/GL 77-2011) and called on Members to review these texts and take urgent action to mitigate risks of inappropriate antimicrobial use and antimicrobial resistance.

3. Noting the need for countries to provide information on the way they were adopting and using Codex texts on AMR, identify gaps and evaluate the need for their update, CCEXEC70 supported the proposal that the Codex Secretariat issue a Circular Letter asking Members to: (i) Review the extent to which they are adopting and applying the existing Codex guidance and identify major capacity development gaps and any other challenges they face in adopting and applying these standards; (ii) Review the existing Codex texts (CAC/RCP 61-2005 and CAC/GL 77-2011) and evaluate the need for their update, taking into consideration the developments in the area over the past 10 years; and (iii) Consider the need to request FAO, WHO and OIE to convene expert meetings to review any new scientific evidence related to AMR in the food chain including risk management options for the containment of AMR in support of any revision of Codex texts.

4. CCEXEC70, requested the Codex Secretariat, in collaboration with FAO and WHO, to analyse the replies to [CL 2015/21-CAC](#) (issued in August 2015) and prepare proposals as appropriate for consideration at the next session of the Commission.

2. Summary of replies to CL 2015/21-CAC

5. Replies to CL 2015/21-CAC were received by twelve Member countries, one member organisation and three observers⁴, representing five of the six Codex regions and countries at different stages of development. A compilation of comments submitted is available on: ftp://ftp.fao.org/codex/meetings/CAC/cac39/replies-CL2015-21_compilation.pdf

¹ This document has been also included in the agenda of CAC39 as document CX/CAC 16/39/12

² http://apps.who.int/iris/bitstream/10665/193736/1/9789241509763_eng.pdf?ua=1

³ Resolution 4/2015 (<http://www.fao.org/3/a-mo153e.pdf>)

⁴ Australia, Bangladesh, Brazil, Canada, Costa Rica, European Union, Japan, Malaysia, New Zealand, Norway, Sudan, Thailand, United States of America, Consumer International (CI), International Dairy Federation (IDF), HealthforAnimals (IFAH)

General Comments

6. Respondents generally recognised the threat to human health posed by AMR and the need to have in place a structured and long term strategy to address this global issue. A number of members specified that they have already a national strategy or plan of action on antimicrobial resistance in place or plan to develop one in the near future. The plans of action already in place focus on the prevention, detection, monitoring and control of AMR across all sectors with the goal of reducing the total use of antimicrobials while securing their availability for the treatment of microbial infections. The status of the implementation of the plans varied among countries, with some already revising and evaluating their plans and others at the initial stage of development.

7. Most of the countries are in favour of the revision of the Codex texts on AMR, which should consider relevant resolutions of FAO, WHO and OIE.

a) Review the extent to which the *Code of Practice to Minimise and Contain Antimicrobial Resistance (CAC/RCP 61-2005)* and the *Guidelines on Risk Analysis of Foodborne Antimicrobial Resistance (CAC/GL 77-2011)* have been adopted and applied.

8. Many of the respondents indicated to have adopted and be applying all or parts of the recommendations of the *Code of Practice to Minimise and Contain Antimicrobial Resistance (CAC/RCP 61-2005)* and the *Guidelines on Risk Analysis of Foodborne Antimicrobial Resistance (CAC/GL 77-2011)*.

9. Other respondents explained that they are using the two texts as a reference in their AMR strategies and that the application should take into account the capacity development needs of various stakeholders. In contrast, a few respondents explained that they were not yet applying the documents because they didn't have the necessary legislation in place.

10. The responses show that members use the *Code of Practice* mainly in the development of strategies for the responsible use of antimicrobials in all sectors and for the reduction of antimicrobial use. The *Guidelines* are mainly used for the evaluation/assessment of veterinary antimicrobial drugs before their placement in the market or to draft a risk profile of AMR.

b) Identify major capacity development gaps and any other challenges faced in adopting and applying CAC/RCP 61-2005 and CAC/GL 77-2011.

11. The majority of respondents identified "monitor" and "control" of the use of antimicrobials (AM) and "surveillance" for antimicrobial resistant organisms, as the major development gaps and highlighted the lack of experience in implementing integrated monitoring and surveillance. Improved capacity to carry out systematic and integrated monitoring and surveillance would improve the quality and comparability of AMR data and facilitate the analysis of the impact of the measures taken.

12. Respondents also indicated the need for: (i) more guidance on the use of the *Guidelines* and suggested to provide practical examples, e.g. how to draw conclusions and make decisions from a risk profile; (ii) to develop the legislative framework; (iii) raising awareness among all involved in the distribution, use and marketing of AM; (iv) making the *Guidelines* simpler for policy makers; (v) detecting emerging risks in time; and (vi) guidance on the evaluation of risk factors and knowledge gaps on the source attribution of antimicrobial resistance.

c) Review the existing CAC/RCP 61-2005 and CAC/GL 77-2011 and evaluate the need for their update, taking into consideration the developments in the area over the past 10 years.

13. The majority of the respondents were in favour of reviewing the two documents to reflect developments in recent years and, in particular, to strengthen and further clarify the provisions in:

- CAC/RCP 61-2005: to take into consideration new evidence related to AMR; highlight the "One Health" approach in the prudent and responsible use of AM; broaden the scope to all foods (including those of plant origin) and stress the need for countries to develop and implement national action plans.
- CAC/GL 77-2011: to address a number of gaps related to (i) preliminary foodborne AMR risk management activities; (ii) risk profiles, i.e. pathways and extent of transmission of resistant organisms through foods of animals, identifying risk foods; (iii) identification, evaluation and selection of risk management options; and (iv) surveillance of use of antimicrobial agents and resistant microorganism and determinants.

14. Regarding CAC/RCP 61-2005 it was also noted that the revision should not duplicate OIE guidance but focus on the specificities of the Codex mandate. Regarding CAC/GL 77-2011, it was also noted that more experience on the use of CAC/GL 77-2011 might be necessary before considering its review.

15. A few respondents were of the view that the documents were adequate, and that at this time there was no need for their update and that further work could be considered at a later time when countries will have more experience in implementation of national action plans on AMR.

16. Some overarching considerations were also identified, e.g. the use of new technologies (e.g. genome sequencing) which could influence the direction of any revision.

d) Consider the need to request FAO, WHO and OIE to convene expert meetings to review any new scientific evidence related to AMR in the food chain including risk management options for the containment of AMR in support of any revision of Codex texts.

17. The majority of the respondents were in favour of requesting FAO, WHO and OIE to convene expert meetings, while others did not identify any specific need or were of the view that such request was premature as countries were still developing (or at the early stages of implementation of) their action plans on AMR.

18. Respondents in favour noted that the outcome of FAO, WHO and OIE expert meetings, bringing together experts from various sectors, would reinforce the scientific basis of Codex texts on AMR in line with the principles of the Codex Alimentarius.

19. In addition to the review of Codex texts and new scientific evidence related to AMR, respondents suggested that the scope of expert meetings could include:

- i. Advice on the role that new sequencing technologies could play in advocating for an integrated and coordinated surveillance and reporting framework;
- ii. Recommendations to support the national efforts against AMR risks in light of newly available information on foodborne AMR including epidemiological surveillance data;
- iii. Identification of AMR threats which create the greatest risks to public health for which Codex should develop specific recommendation;
- iv. Recommendations on a mechanism to house the findings from previous work;
- v. Development of a process for setting transparent national targets for AM use and AMR;
- vi. Setting thresholds for targeted reductions of AM use in animal production;
- vii. Identification of AM whose use should be restricted to human medicine.

3. Major developments on AMR

20. The high level recognition and political commitments of both FAO and WHO member countries to addressing AMR is reflected in the recent Resolutions agreed by their respective governing bodies and the adoption, in May 2015, of the WHO Global Action Plan on AMR which also recognized the role of FAO and OIE in addressing this issue. More details on these aspects are available in [CX/CAC 15/38/16 Add 1](#). Since then both FAO and WHO have been working independently, as well as jointly and with the OIE, to follow up on the implementation of the Resolutions and the WHO Global Action Plan in their respective areas. Due to the One Health nature of dealing with AMR, the tripartite of FAO, WHO and OIE have established an AMR working group, which works to ensure a coordinated, complementary and comprehensive global approach to addressing AMR. An example of this collaboration is the recent publication of a tripartite manual to support development of national action plans on AMR⁵. ()

a) FAO

21. To support the implementation of the FAO Resolution on AMR and contribute appropriately to the AMR Global Action Plan, FAO has developed a plan of action which defines its role and approach to supporting the food and agriculture sectors on the issue of AMR. This revolves around the four pillars of: (i) Awareness; (ii) Evidence; (iii) Governance; and (iv) Practices; and focuses on a cross cutting approach to ensure involvement of the relevant food and agriculture entities as well as the legislative and standard setting bodies. It places particular emphasis on an integrated and multidisciplinary approach along the food chain. Some of the aspects with particular relevance for food safety are highlighted here.

- i. There is limited information on antimicrobial resistance, antimicrobial use and the impact of AMR in the food and agriculture sectors, particularly in low and middle income countries. While it should not delay action this dearth of knowledge needs to be addressed in order to improve engagement with the food and agriculture sectors on AMR.

⁵ <http://www.who.int/entity/drugresistance/action-plans/manual/en/index.html>

- ii. Building on its existing activities on animal, plant health and food safety legislation, FAO has started working to identify the legal elements relevant for AMR and AMU and making recommendations on mainstreaming the related obligations and responsibilities into the relevant legislation.
- iii. FAO is supporting strengthening of capacities in this area of data collection and surveillance and monitoring in the food chain. For example, work is ongoing to expand on existing laboratory mapping tools that are used in the animal health sector to assess capacity in relation to resistance determination and in a manner that is consistent and complementary to other relevant assessment tools. Strengthening laboratory capacity for residue monitoring is an ongoing activity which has a particular importance in monitoring implementation of regulations with regard to use of veterinary drugs, including antimicrobials. In terms of new technologies FAO is working to increase awareness of countries on the use of whole genome sequencing in food safety management including antimicrobial resistance and a technical meeting on this will be convened in FAO in May 2016.⁶
- iv. Initial country work that FAO has recently engaged in highlights the many capacity development needs which need to be addressed ranging from basic awareness and knowledge amongst the food and agriculture sector to strengthening monitoring and surveillance capacity, and implementing good practices. In this context FAO is supporting better use of existing materials and tools to enhance good practices.
- v. FAO is working on the development of tools and instruments to support regulation and use of antimicrobial chemicals (e.g. pesticides and veterinary drugs) in the agriculture sector. For example, specific technical guidelines for registration and setting specifications for pesticides are under development as well as a toolkit to assist developing countries in assessment and registration of pesticides including those which are antimicrobials.
- vi. FAO is developing a Progressive Management Pathway to support countries in the process of their auto-assessments, development, implementation and evolution of national action plans on AMR, with emphasis on the factors addressing antimicrobial use and resistance in food and agriculture. This is based on successful experiences with the development, implementation and use of such pathways and stepwise approaches particularly in the animal health area.
- vii. FAO continues to engage strongly with the animal feed sector and the issue of AMR have been part of the discussions with that sector for the past two years with an initial focus on awareness raising with regard to AMR.

b) WHO

WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance (WHO-AGISAR)

22. WHO-AGISAR was established in 2008 to provide WHO with evidence supported expert advice on issues related to AMR from the food chain and to support WHO in strengthening laboratory capacity of its Member countries for integrated surveillance of AMR, taking a One Health approach. AGISAR has published a guidance document providing the basic information for establishing a programme for integrated surveillance of antimicrobial resistance, taking a step-by-step approach to designing the programme and using standardized and validated antimicrobial susceptibility testing methods and harmonized interpretative criteria⁷.

23. This document is being updated to include the use of new technologies such as the Whole Genome Sequencing for integrated surveillance of AMR, taking a “One Health” approach in support of the implementation of the Global Action Plan.

24. Since the adoption of the global action plan (GAP) on AMR in May 2015, WHO has actively started implementation, through whole-of-society engagement including a One Health approach. In June 2015, the WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR) developed a five-year strategic framework to support the GAP, and five thematic working groups were established to operationalize this framework with the ultimate aim to minimize the public health impact of AMR associated with the use of antimicrobials in the food chain.

25. Major planned activities include:

- i. Capacity building:
 - a. WHO has continued laboratory capacity strengthening activities for veterinarians, food microbiologists, epidemiologists and medical doctors, on integrated surveillance of AMR in foodborne and enteric pathogens

⁶ For more details see: <http://www.fao.org/about/meetings/wgs-on-food-safety-management/en/>

⁷ http://apps.who.int/iris/bitstream/10665/91778/1/9789241506311_eng.pdf?ua=1

- b. WHO has implemented AGISAR pilot projects in 20 developing countries with the aim to build capacity, generate data on antimicrobial usage and antimicrobial resistance in order to inform policy and at the same time foster cross-sectoral collaboration. Four of these pilot projects (Cambodia, India, Kenya and Vietnam) have been implemented with FAO.
 - c. WHO has developed a Global “One Health” Curriculum on the use of Whole Genome Sequencing for integrated surveillance of AMR with a first implementation in Bangkok Thailand in April 2016 with FAO and OIE participation.
- ii. WHO has developed, in collaboration with FAO and OIE, a Tripartite manual for development on National Action Plans on AMR taking a One Health approach. The three organisations are committed to joining forces in supporting their member states in the development of National Action plans to AMR taking a holistic, multisectoral approach
 - iii. WHO is implementing, jointly with the WHO Collaborating Center on Foodborne AMR and Genomics in Denmark, a Global Sewage Surveillance project. The project will serve as proof-of-concept for applying meta genomic approaches to sewage to detect, control, prevent and predict human infectious diseases, including foodborne diseases associated with resistant bacteria.

Critically Important Antimicrobials for Human Medicine

26. The World Health Organization (WHO) has developed criteria to rank antimicrobials according to their importance in human medicine. The WHO list of Critically Important Antimicrobials (CIA) was developed to provide a tool for developing risk management strategies related to antimicrobial use in food production animals. The list was first developed in Canberra in 2005 and then revised in Copenhagen in 2007 and 2009, in Oslo in 2011 and most recently in Bogota in 2013⁸.

27. At the WHO meeting in Bogota, it was recommended that WHO develop a Guideline on the use of antimicrobial agents in food animals that would take into account the WHO CIA List. A revision of the WHO CIA list that will feed into the development of such a Guideline is underway.

4. Conclusion

General conclusion

28. Consistent with decisions taken at the statutory bodies of FAO and WHO regarding AMR, Codex members have recognised the importance and urgency to address AMR and generally are supporting new work to address gaps and new developments in these areas.

29. Members have also recognised the need for an integrated and multidisciplinary approach to AMR and support FAO and WHO action plans to continue working in this area and assist countries to develop their capacity to address AMR at national level using an integrated and multidisciplinary approach, such as the One Health approach.

30. Countries have also emphasised the need for integrated surveillance of AMR and for monitoring the use of antimicrobials for updated scientific information to underpin Codex work.

Future work in Codex

31. Replies to the CL indicate that Members are generally using and have adopted the two Codex texts on AMR. It also appears that since CAC/GL 77-2011 is quite new, countries will need more time and experience to identify gaps or needs for its revision.

32. On the contrary for CAC/RCP 61-2005, which has been in use for a longer time, respondents have identified some gaps and needs for updating; in particular with regard to: the inclusion of references to the WHO and OIE lists of Critically Important Antimicrobials; the need to address the use of antimicrobials as growth promoters; the use of alternatives to AM (e.g. vaccines); guidance of monitoring the use of AM.

33. Comments have also highlighted the importance of the One Health approach and the need to broaden the text to consider all uses on antimicrobials in agriculture, i.e. not to limit to the use in animal production and to address the entire food chain.

⁸ http://www.who.int/foodsafety/areas_work/antimicrobial-resistance/cia/en

34. Many respondents identified integrated surveillance as an area, which might challenge future work. In this regard it should be noted that although CAC/GL 77-2011 emphasises the importance of programmes for surveillance of use and prevalence of foodborne AMR as important sources of information needed for risk analysis, the Guidelines do not provide specific guidance to countries on how to develop and implement such programmes. It should also be noted that WHO-AGISAR has developed guidance on integrated surveillance of AMR⁹ and that FAO and WHO are supporting countries to strengthening their capacities in this area (see para.25). A specific Codex text on this subject, using the One Health approach and based on AGISAR Guidance, would be a valuable support to FAO, WHO and countries activities and would underpin the importance of surveillance in combatting foodborne AMR.

35. Therefore, it is suggested that Codex considers starting new work in the following two areas:

- i. Revision of CAC/RCP 61-2005: update information and broaden the scope to include minimisation and containment of AMR in all foods;
- ii. Development of guidelines of surveillance of AMR microorganisms, based on WHO AGISAR guidance.

36. Respondents have also indicated other gaps in Codex texts, in particular the use of new technologies (e.g. genome sequencing) in risk assessment. While recognising the importance of these technologies, it seems necessary that an FAO, WHO and OIE experts meeting might better inform Codex in the identification of specific areas for new work.

37. As to the mechanism for carrying out this work, it has been recognised that AMR might fall within the mandate of different committees, such as the Committees on Food Hygiene (CCFH) for the aspects of hygiene (e.g. preventing the spread of AMR microorganisms through the food chain) and Residues of Veterinary Drugs (CCRVDF) and Pesticides Residues (CCPR) for the aspects related to residues derived from the use of antimicrobials in agriculture (animal and crop production). However, in view of the need to give a prompt reply to FAO and WHO resolutions on AMR, it seems that a dedicated Task Force would be the most appropriate mechanism. In particular because by grouping expertise to work exclusively on AMR under the same umbrella it would allow rapid progress and because such work would not interfere with the schedule of work of existing Committees.

38. It should be noted that the establishment of a dedicated Task Force is in line with Codex procedure which provides for these cases “to give first consideration to the establishment of an ad hoc Intergovernmental Task Force”. (Criteria for the Establishment of Subsidiary Bodies of the Codex Alimentarius Commission - Procedural Manual).

39. For such a Task Force to be created, it is first necessary to identify a host country, who will be responsible for all expenses associated with the operation of the Task Force. In this regard, consideration could also be given to sharing mechanisms, e.g. co-host the Task Force, co-host meetings of the Task Force, etc.

Need for FAO, WHO and OIE Expert Meetings

40. A number of respondents recalled the previous scientific advice that FAO, WHO and OIE had provided in relation to AMR and noted that given the time passed and the number of developments in this area there was a need to update recommendations to member countries.

41. Some of the areas identified for potential consideration by an FAO/WHO expert meeting included:

- i. Identify all potential sources/contributors to foodborne AMR;
- ii. Review any new scientific evidence related to AMR in the food chain, including on resistance transmission (e.g. plasmid borne resistance) and consider its importance for foodborne AMR and practices to mitigate resistance in the food chain;
- iii. Identify and evaluate risk management measure that countries have taken to address AMR and provide advice accordingly on effective risk management options;
- iv. Advise on how to bridge between those antimicrobials identified as critically important for human health and changing practices in the food and agriculture sector, which still require antimicrobials to remain effective.

42. Considering the challenge faced by the food and agriculture sector to change practices as well as meet the global food needs, consideration may also need to be given to providing advice on alternatives to antimicrobials in particular value chains which would support behaviour change and implementation of practices aimed at addressing AMR.

⁹ http://www.who.int/iris/bitstream/10665/91778/1/9789241506311_eng.pdf?ua=1

43. While FAO/WHO are the primary providers of scientific advice to Codex, in light of the tripartite FAO/WHO/OIE collaboration on antimicrobial resistance and the One Health approach, it would be appropriate that this expert advice is developed by FAO and WHO jointly with OIE.

44. Draft terms of reference for scientific advice are provided in Appendix 3. Given the evolving nature of the issue and the ongoing scientific work, such as the revision of the WHO CIA list, the mechanisms by which the scientific advice will be provided and key issues to be addressed should be refined accordingly.

Need for FAO and WHO activity on capacity development

45. A number of respondents indicated the critical need for capacity development to support implementation of the Codex texts but also highlighted the importance of country development of National Action Plans on AMR as a means of strengthening national efforts on AMR. At the global level there has been good coordination in relation to capacity development in this area which can be further built upon and strengthened. Following the publication of the tripartite Manual for developing national action plans on antimicrobial resistance¹⁰, FAO WHO and OIE are committed to joining forces in supporting their members in the development of National Action plans to AMR taking a holistic, multisectoral approach.

46. Considering the feedback from countries, there is a particular need to strengthen capacity in relation to risk analysis of Foodborne Antimicrobial Resistance. FAO and WHO have already developed some tools to support food safety risk analysis which can serve as a starting point. There may be a need to better promote their use as well as adapt some of the generic guidance to support specific AMR related needs and develop some new tools to support uptake at country level. Examples of focus areas which could be starting points for such work include risk profiles, dealing with uncertainty and communication/awareness of this issue.

47. Many respondents highlighted the importance of integrated surveillance systems for AMR. Work is already underway to support this through AGISAR and a number of initiatives underway to support laboratory capacity and surveillance relevant to AMR including the use of new technologies such as whole genome sequencing will aim to substantiate this. There is a need to further facilitate cross-sectoral collaboration to deliver truly integrated surveillance and intelligence based management of AMR.

48. Developing countries in particular also highlighted the need for improved legislative and regulatory frameworks to support efforts on AMR and in particular relative to antimicrobial use in the food and agriculture sector (registration, monitoring and control). Efforts are underway to develop a global database on AMR consumption in animals by OIE as well as in humans in WHO. Further efforts will be needed to ensure such efforts are complimented with data from all aspects of food and agriculture use.

5. Recommendations

49. The Commission is invited to consider the following recommendations:

- i. Start new work on:
 - a. The revision of the *Code of Practice to Minimise and Contain Antimicrobial Resistance* (CAC/RCP 61-2005) (attached project document: Appendix 1, Part 1); and
 - b. The development of *Guidance on Integrated Surveillance of Antimicrobial Resistance* (attached project document: Appendix 1, Part 2);
- ii. Establish a dedicated Task Force on AMR (attached draft TORs: Appendix 2) and identify a host country(ies);
- iii. Request FAO/WHO to provide scientific advice on AMR, in collaboration with OIE (attached draft TORs: Appendix 3).
- iv. Request FAO and WHO to develop a capacity development programme to respond to the need identified.

¹⁰ <http://www.who.int/entity/drugresistance/action-plans/manual/en/index.html>

Part 1**PROJECT DOCUMENT /1****Proposal for new work on the revision of the *Code of Practice to Minimise 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 Minimise and Contain Antimicrobial Resistance* by broadening its scope to address all uses on antimicrobials in agriculture products (i.e. animals and crops) and thus minimizing the potential development of foodborne antimicrobial resistance. The revision should also take into account new developments, including the establishment of Lists of Critically Important Antimicrobials, and the work of FAO, WHO and OIE in this area.

2. Scope

Guidance for the responsible and prudent use of antimicrobials in agriculture products is essential to minimize the potential adverse impact on public health in particular the development of antimicrobial resistance, which might result from the consumption of food. This work will define 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 antimicrobials.

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 68/20¹¹ 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 Nutrition¹², 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 Plan¹³, which was adopted by the World Health Assembly in May 2015 with WHA Resolution 68.7¹⁴.

The WHA Resolution urges WHO Member States to have in place, by May 2017, national action plans on antimicrobial resistance that are aligned with the Global Action Plan and with standards and guidelines established by relevant intergovernmental bodies, such as Codex. Furthermore, the GAP specifically 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.”

The importance of access to effective antimicrobials, the health and economic consequences of AMR and the need for a coherent comprehensive and balanced approach to address the issue was discussed by FAO at the 24th Session of the Committee on Agriculture¹⁵ (October 2014), the 151st Session of Council¹⁶ (March 2015) and the 39th Session of Conference (June 2015). The 39th Session of the Conference adopted Resolution 4/2015 on AMR, which is aligned with and complements the WHA Resolution, and underlines FAO support for the implementation of the GAP.

¹¹ http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_20-en.pdf

¹² <http://www.fao.org/3/a-ml542e.pdf>

¹³ http://apps.who.int/iris/bitstream/10665/193736/1/9789241509763_eng.pdf?ua=1

¹⁴ http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_R7-en.pdf

¹⁵ <http://www.fao.org/3/a-ML895e.pdf> (paras 8 and 12)

¹⁶ <http://www.fao.org/3/a-mn325e.pdf> (para. 35)

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 the Code of Practice will address all uses on antimicrobials in food and agriculture production and provide updated information, in particular with regard to: the inclusion of references to the lists of Critically Important Antimicrobials; the use of antimicrobials as growth promoters; the use of alternatives to AM (e.g. vaccines); and the inclusion of guidance on monitoring the use of antimicrobials.

The revision will also consider the outcomes and recommendations of the FAO, WHO and OIE Experts Meeting(s) on AMR (see Section 8).

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.*

Many countries have adopted and are applying all or parts of the recommendations of *Code of Practice to Minimise and Contain Antimicrobial Resistance* (CAC/RCP 61-2005), while others 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.

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 recognised by the recent resolutions of statutory bodies of FAO and WHO (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 ensure coherence with OIE texts.

10. Completion of the new work and other conditions

Subject to the Codex Alimentarius Commission approval at its 39th session in 2016, the identification of the subsidiary body responsible, it is expected that the work can be completed in three sessions.

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: 2016
- Discussion at Step 3: 2017/2018
- Adoption at Step 5: 2019
- Adoption at Step 8: 2020

Part 2

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 a programme for integrated surveillance of antimicrobial resistance (AMR) and thus promoting a harmonised approach among countries to AMR surveillance that will facilitate the exchange and analysis of data from different areas, countries and regions.

2. Scope

Integrated surveillance of AMR on foodborne bacteria is the coordinated sampling and testing of bacteria from food animals, foods and clinically ill humans and the subsequent evaluation of AMR trends throughout the food production and supply chain using harmonised methods. Global harmonisation of an integrated surveillance programme is needed so that surveillance data from different areas, countries or regions can be more easily compared.¹⁷

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 68/20¹⁸ 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 Nutrition¹⁹, which recognized that food systems need to contribute to preventing and addressing infectious diseases, including zoonotic diseases, and tackling antimicrobial resistance.

In 2015 FAO and OIE actively contributed to the development of the WHO led Global Action Plan²⁰, which was adopted by the World Health Assembly in May 2015 with WHA Resolution 68.7²¹.

The WHA Resolution urges WHO Member States to have in place, by May 2017, national action plans on antimicrobial resistance that are aligned with the Global Action Plan and with standards and guidelines established by relevant intergovernmental bodies, such as Codex. Furthermore, the GAP specifically 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.”

The importance of access to effective antimicrobials, the health and economic consequences of AMR and the need for a coherent comprehensive and balanced approach to address the issue was discussed by FAO at the 24th Session of the Committee on Agriculture²² (October 2014), the 151st Session of Council²³ (March 2015) and the 39th Session of Conference (June 2015). The 39th Session of the Conference adopted Resolution 4/2015 on AMR, which is aligned with and complements the WHA Resolution, and underlines FAO support for the implementation of the GAP.

¹⁷ Integrated surveillance of antimicrobial resistance, Guidance from a WHO Advisory Group, WHO 2013 : http://www.who.int/foodsafety/publications/agisar_guidance/en/

¹⁸ http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_20-en.pdf

¹⁹ <http://www.fao.org/3/a-ml542e.pdf>

²⁰ http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_20-en.pdf

²¹ http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_R7-en.pdf

²² <http://www.fao.org/3/a-ML895e.pdf> (paras 8 and 12)

²³ <http://www.fao.org/3/a-mn325e.pdf> (para. 35)

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 Guidelines will cover the following aspects:

- i. Approaches to integrated surveillance of AMR
- ii. Key components of integrated surveillance of AMR, including:
 - o sampling sources
 - o target microorganisms
 - o sampling design
 - o laboratory testing
 - o data analysis and reporting
- iii. Incorporation of information from integrated surveillance into management of AMR.

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

The following assessment has been made in accordance with the Criteria for 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 a programme for integrated surveillance of antimicrobial resistance will promote a harmonised approach among countries to AMR surveillance and will facilitate the 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 WHO AGISAR, in particular 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 recognised by the recent resolutions of statutory bodies of FAO and WHO (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 *Code of Practice to Minimise and Contain Antimicrobial Resistance* (CAC/RCP 61-2005); 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).

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.

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 ensure coherence with OIE texts.

10. Completion of the new work and other conditions

Subject to the Codex Alimentarius Commission approval at its 39th session in 2016, the identification of the subsidiary body responsible, it is expected that the work can be completed in three sessions.

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: 2016
- Discussion at Step 3: 2017/2018
- Adoption at Step 5: 2019
- Adoption at Step 8: 2020

Appendix 2**TERMS OF REFERENCE OF THE AD HOC CODEX INTERGOVERNMENTAL TASK FORCE ON
ANTIMICROBIAL RESISTANCE****Objectives**

To develop science based guidance on the prudent use of antimicrobials in agriculture and on integrated surveillance, taking full account of the work and standards of other relevant international organizations, such as FAO, WHO and OIE and the One-Health approach. The intent of these guidance documents is: (i) to ensure that measures are taken across the food chain to minimise the development and spread of AMR and (ii) to ensure a coordinated approach to surveillance of antimicrobial resistance.

Terms of reference

- (i) To revise the *Code of Practice to Minimise and Contain Antimicrobial Resistance* (CAC/RCP 61-2005) to address all uses on antimicrobials in agriculture products (i.e. animals and crops). The revision should also take into account new developments, including the establishment of Lists of Critically Important Antimicrobials, and the work of FAO, WHO and OIE in this area.
- (ii) To develop guidelines on integrated surveillance of Antimicrobial Resistance, taking into account the guidance developed by the WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR).

Time frame

The Task Force shall complete its work within three (max four sessions), starting in 2017.

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, that the scope appropriately reflects the role of the food and agriculture sector in minimizing the development of AMR 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 that need to be considered in the revision of existing codex texts and/or development of new Codex texts.

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

- i. Undertake a review of new data relevant to the development and transmission of 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
 - Identifying and evaluating risk management measures at different points in the food chain to address AMR and provide advice accordingly on the efficacy of such risk management options.
- ii. With particular reference to the WHO and OIE lists of Critically Important Antimicrobials, existing Codex MRLs and the most recent scientific information on 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 need to balance public health needs with animal health and food security needs.
- iii. Considering the challenge faced by the food and agriculture sector to change practices as well as meet the global food needs, provide advice on alternatives to antimicrobials, in particular value chains, which would support behaviour change and encourage the implementation of practices aimed at addressing AMR.