National Milk Producers Federation

2101 Wilson Blvd., Suite 400, Arlington, VA 22201 | (703) 243-6111 | www.nmpf.org

October 6, 2016

Dr. Neena Anandaraman
US Delegate

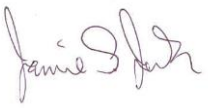
Dr. Ron Miller
US Alternate Delegate

Dr. Andre Ntamack
Executive Secretariat

Re: U.S. Draft Comments for the Pre-consultation of the Physical Working Group (PWG) on Antimicrobial Resistance (AMR)

On behalf of the National Milk Producers Federation (NMPF) we would like to provide the attached edits and comments on the draft US comments for the pre-consultation on Codex work on antimicrobial resistance (AMR). Please contact me at jjonker@nmpf.org or 703-243-6111 if you have any questions concerning these comments. Thank you for the opportunity and for your consideration.

Sincerely,



Jamie Jonker
Vice President
Sustainability & Scientific Affairs

Appendix 1

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* to assist in minimizing ~~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.

Commented [JJ1]: We believe that the scope should not be extended to crops at this point pending any scientific advice and involvement of International Plant Protection Convention.

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.~~

The Task Force will:

(a) Review CAC/RCP 61-2005 regarding use of veterinary antimicrobial agents and consider how distinguishable it is from work of other relevant organizations including OIE's Terrestrial Animal Health Code (Ch.6.9) to determine what gaps exist and what updates to language, references, or tools are necessary. After review, the Task Force will determine 1) what, if any, work is left that fits within the Codex mandate to address and update CAC/RCP 61-2005 or 2) what work should be referred to others working in the same area and refer such work.

(b) Document gaps identified regarding needs for capacity building to implement CAC/RCP 61-2005 and the OIE code with a view to informing FAO and WHO on needs for additional capacity building to complement existing efforts.

3. Relevance and timeliness

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.

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[1] 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[2], which recognized that food systems need to contribute to preventing and addressing infectious diseases, including zoonotic diseases, and to tackling antimicrobial resistance.

[1] http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_20-en.pdf
[2] http://www.fao.org/3/a-ml542e.pdf

In 2015 FAO and OIE actively contributed to the development of the WHO led Global Action Plan[3], which was adopted by the World Health Assembly in May 2015 with WHA Resolution 68.7[4].

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 Agriculture[5] (October 2014), the 151st Session of Council[6] (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.

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.~~

Consideration of the revision of the Code of Practice will address uses of antimicrobial agents in food-producing animals and provide updated information or inclusion of references to lists of Critically Important Antimicrobial agents; and will include an assessmfent of the various uses of antimicrobial agents in food producing animals and their potential to contribute to foodborne AMR; and guidance on monitoring the use of antimicrobial agents.

Commented [JJ2]: The main aspects should focus on the end-point of use of antimicrobials in animal agriculture (i.e. foodborne AMR) and not on the specific routes of exposure. Where specific examples of risk of foodborne AMR are identified via risk (not hazard) analysis they can be addressed.

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.

[3] http://apps.who.int/iris/bitstream/10665/193736/1/9789241509763_eng.pdf?ua=1
[4] http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_R7-en.pdf
[5] http://www.fao.org/3/a-ML895e.pdf (paras 8 and 12)
[6] http://www.fao.org/3/a-mn325e.pdf (para. 35)

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 including *OIE Chapter 6.7 Hamonisation of National Antimicrobial Resistance Surveillance and Monitoring Programmes.*

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) resulting from food consumption 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.

Commented [JJ3]: Need to stay within Codex mandate. Codex should not advise governments on surveillance of AMR not related to food consumption.

2. Scope

Integrated surveillance of AMR ~~on~~ of foodborne bacteria is the coordinated sampling and testing of bacteria from food animals, foods and clinically ill humans and the subsequent evaluation of the risk of foodborne AMR ~~AMR trends~~ throughout the food production system ~~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.[7]~~

Commented [JJ4]: "Supply Chain" is a unique term used in business-to-business relationships to identify specific commercial entities.

Commented [JJ5]: Moved to next section for clarity.

The Task Force will:

(a) Inventory and consider the work of other relevant international entities in the area of surveillance for foodborne antimicrobial resistance including WHO AGISAR, OIE [Terrestrial Animal Health Code (Ch.6.7)], the Transatlantic Task Force on Antimicrobial Resistance, and others as appropriate to determine any gaps and needs for development of guidance for integrated surveillance within the Codex mandate. If a need exists, develop guidance in collaboration with and complimentary to work of other international bodies.

(b) Document gaps identified regarding capacity building needs to implement existing surveillance activities with a view to informing FAO and WHO on needs for capacity building.

3. Relevance and timeliness

Global harmonisation of an integrated surveillance programme is needed so that trends derived from surveillance data from different areas, countries or regions can be more easily compared.[17] 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[8] 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[9], 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 Plan[10], which was adopted by the World Health Assembly in May 2015 with WHA Resolution 68.7[11].

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

[7] Integrated surveillance of antimicrobial resistance, Guidance from a WHO Advisory Group, WHO 2013 : http://www.who.int/foodsafety/publications/agisar_guidance/en/)
[8] http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_20-en.pdf
[9] http://www.fao.org/3/a-ml542e.pdf
[10] http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_20-en.pdf
[11] http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_R7-en.pdf

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 Agriculture[12] (October 2014), the 151st Session of Council[13] (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.

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 Task Force will determine what gaps exist in guidance as well as capacity building for implementation of integrated surveillance after review of existing work products of WHO AGISAR, OIE, TATFAR, and any other relevant international work. If gaps within the Codex mandate of ensuring food safety are found, the Task Force will develop guidance complimentary to and making reference to applicable, existing work products.

~~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).

[12] http://www.fao.org/3/a-ML895e.pdf (paras 8 and 12)
[13] http://www.fao.org/3/a-mn325e.pdf (para. 35)

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.

Commented [JJ6]: Superseded by Terms of Reference in REP16/CAC Appendix VII

Appendix 3

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:~~

The Task Force will address 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.~~

   - Identifying any new scientific data regarding the risk of acquiring AMR from plant and animal-based food.
   - 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 in regard to evidence-based public health outcomes such as a decrease in antimicrobial resistance exposure for human populations.
   - Identifying the hazards and relative risk foodborne AMR poses from 1) animal-based (to include aquaculture) food and 2) plant-based food compared to other sources to help address resource prioritization.
   -

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 contribute to the reduction in risk of foodborne AMR ~~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.~~

   - Clearly identify what challenges exist in the food and agriculture sector to contribute to the reduction in risk of foodborne AMR
   - Provide gaps, challenges, and resources necessary to support animal health infrastructure needs to reduce the risk of foodborne AMR.
   - Provide information on what capacity building efforts are in place or being planned to meet animal health infrastructure needs and existing gaps to address animal health infrastructure needs to reduce the risk of foodborne AMR.
   - Provide advice on alternatives to antimicrobials which would encourage the implementation of practices aimed at addressing AMR.

Commented [JJ7]: In general "animal health infrastructure" would be outside the scope of Codex so it is presented here in context of food safety. OIE is the competent authority for broader infrastructure discussions.