

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
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World Health
Organization

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COMMENTS ON CODEX WORK ON ANTIMICROBIAL RESISTANCE¹

(Comments submitted by Argentina, Brazil, Costa Rica, Canada, Cuba, Dominican Republic, El Salvador, European Union, Ghana, Japan, Kenya, Malaysia, New Zealand, Norway, Republic of Korea, United States of America, Consumers International, International Poultry Council, Health for Animals)

ARGENTINA

(English)

BACKGROUND:

At the last session of the Codex Executive Committee (CCEXEC70), FAO and WHO presented a paper on antimicrobial resistance (AMR) and highlighted the recently agreed WHO Global Action Plan on AMR and the FAO Resolution of AMR 4/2015.

These documents refer to the *Code of Practice to Minimize and Contain Antimicrobial Resistance* (CAC/RCP 61-2005) and the *Guidelines on Risk Analysis of Foodborne Antimicrobial Resistance* (CAC/GL 77-2011).

In the Circular Letter CL 2015/21-CAC, Codex Members were asked to inform the extent to which they were adopting the said documents, to evaluate the need for their update, and to consider the need to request FAO and WHO to convene expert meetings to review any new scientific evidence.

Twelve countries (including Brazil and Costa Rica), one organization and three observers replied.

GENERAL CONCLUSIONS:

They agreed on the urgent need to address AMR, the need to provide it with an integrated and multidisciplinary approach like the ONE HEALTH approach, and the need for integrated surveillance and for monitoring the use of antimicrobials.

RECOMMENDATIONS:

1. Start new work on:
 - a. The REVISION of the *Code of Practice to Minimize 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);
2. Establish a dedicated Task Force on AMR (attached draft TORs: Appendix 2) and identify a host country (ies);
3. REQUEST FAO/WHO to provide scientific advice on AMR, in collaboration with OIE (attached draft TORs: Appendix 3);
4. REQUEST FAO and WHO to develop a capacity development program to respond to the need identified.

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

GENERAL COMMENTS:

As implementing agency, we find an overlap of reference documents to address the same issue. Such is the case of the "Prudent Use of Antimicrobials", which is addressed by Chapter 6.9 of the OIE Terrestrial Code and CAC/RCP 61-2005 of Codex Alimentarius. Duplication also occurs in the case of Risk Analysis for the Control of Antimicrobial Resistance, which is addressed by Guideline CAC/GL 77-2011 of the Codex Alimentarius and by Chapter 6.10 of the OIE Terrestrial Code.

The same could happen with future work on the development of a guideline for integrated monitoring of AMR, since the OIE Terrestrial Code already addresses surveillance in its Chapter 6.7, although it applies only to food animals and products of animal origin in consistency with the OIE mission.

It is important to pay attention to this situation and find a way to achieve articulation with the intergovernmental organizations involved (OIE, FAO and WHO) for the purposes of not duplicating work, optimizing the efforts of Member States, and mainly simplifying the work of national implementing agencies.

RECOMMENDATION 1a:

- A) The preparation of a homologous or complementary document addressing the use of antimicrobials in agricultural production (crops) is considered necessary instead of the opening of the CAC/RCP 61-2005 Code and the modification of its scope.

Rationale: This is for ease of reading, given the differences not only between animal and plant productions but also among the national agencies regulating them. **In many countries, these are individual agencies, so it is considered appropriate to have separate but complementary documents.**

Taking into account the regional situation, we believe that the weakness is not in the Code itself but in the failure of member countries to implement it.

Therefore, expert consultations are considered necessary for the development of the proposed annex to cover the use on crops.

- B) As regards the reference to the list of critically important antimicrobials, the use of the lists already published by the reference organizations WHO and OIE should be considered, i.e. just take them as reference because they are in constant review.
- C) The equivalence between the reference Code and Chapter 6.9 of the OIE Terrestrial Code (Prudent Use of Antimicrobials) is observed.

Rationale: It is necessary to simplify the work of national implementing agencies; therefore, reference should be made to the equivalent OIE standard in the CAC/RCP 61-2005 Code.

RECOMMENDATION 1b:

- We agree on the need for a guideline for the integrated surveillance of AMR that includes coordinated sampling and testing of bacteria **and resistance determinants** from food animals, foods and clinically ill humans and the monitoring of AMR trends throughout the food chain **and the health system** using harmonized methods. Integrating this into a global system of monitoring is also needed.

It should be stressed that the necessary aspects and actions for the surveillance and monitoring of AMR in food animals and foods of animal origin are **already described in Chapter 6.7 of the OIE Terrestrial Code.** It would be redundant to prepare a similar/equivalent document because these recommendations should be included literally in the future guide.

- On the other hand, the necessary aspects and actions for the surveillance and monitoring of AMR in foods of plant origin would require to be developed separately by Codex since the existence of a related standard/guideline is unknown.
- Another aspect of surveillance to cover is the ecological niches of humans as well as animals and crops, which are affected by effluents from these very systems, making it possible to play an additional role in the transmission of AMR and thus making their inclusion in this "integrated" approach of surveillance and monitoring of AMR necessary.

This issue is considered to be outside the scope of Codex.

- In the case of human health, the necessary aspects and actions for the surveillance and monitoring of AMR fall outside the scope of the Codex Alimentarius and **have already been addressed in the WHO Advisory Group Guidance on the Integrated Surveillance of Antimicrobial Resistance.**

- In conclusion, we consider that the proposed "Guideline on Integrated Surveillance of Antimicrobial Resistance" should be dealt with jointly by the Codex Alimentarius, OIE, FAO and WHO. In such a case, representatives of these intergovernmental organizations should at least be part of the working group to be created for its development.
- It is very important to point out that the breakpoints for determining antimicrobial susceptibility in humans are already established by internationally recognized and accepted standards, such as CLSI and EUCAST. However, the absence of breakpoints in veterinary medicine is a serious problem because it prevents rational prescription; this is due to the lack of sufficient samples for their determination and therefore a regional prospective strategy of sampling and analysis should be established. However, in order to perform integrated surveillance work in which the data obtained in both fields are comparable, we consider that breakpoints for humans should be used to perform integrated surveillance.
- Another important point to highlight is that the analysis and reporting of data (WHONET network) have also been developed by WHO and that they are implemented worldwide in order to ensure their harmonization and to allow for global conclusions, recommendations and actions.

Rationale: Given the implications of AMR on human health AND in order to control and reduce it, we find it necessary to develop the future guideline for integrated control. Considering the documents on surveillance and laboratory methods prepared by other intergovernmental organizations, we find it important not to duplicate work, to optimize the efforts of Member States, and mainly to simplify the work of national implementing agencies.

- Work done in this regard in Argentina is made available as reference.
 - Joint Resolutions of the Ministry of Health and the Ministry of Agriculture, Livestock and Fisheries No. 834/2015 and No. 391/15.
 - SENASA Resolution No. 591/15.

It should be noted that the actions proposed in the above rules are consistent with OIE Codes and WHO reference laboratory standards.

RECOMMENDATION 2:

We fully agree on the establishment of a dedicated task force to address the recommendations 1 and 2 and we propose to be part of it. However, interaction/articulation with the above-mentioned intergovernmental organizations WHO-OIE-FAO should be established.

RECOMMENDATIONS 3 AND 4:

We agree on requesting scientific advice and training from FAO and WHO. In the case of capacity development, it would be very necessary to establish training priorities and identify opportunities for cooperation among the systems with different degree of development accomplished by member countries and/or regions.

(Spanish)

ANTECEDENTES:

En la última reunión del Comité Ejecutivo del Codex (CCEXEC70) la FAO y la OMS presentaron un escrito sobre Resistencia a los Antimicrobianos (RAM) y destacaron el recientemente acordado Plan de Acción Global de la OMS sobre RAM y la Resolución sobre RAM de la FAO 4/2015.

En estos documentos se mencionan al Código de Prácticas para Minimizar y Contener la RAM (CAC/RCP 61-2005) y las Directrices para el Análisis de Riesgo de la RAM transmitida por Alimentos (CAC/GL 77-2011).

Se solicitó a los países miembros del Codex en la carta circular (CL 2015/21-CAC) que informaran el grado de adopción de los mencionados documentos del Codex, que indicaran si se necesitaba actualizarlos y si consideraban la necesidad de pedir a FAO y OMS realizar reuniones de expertos para revisar nueva evidencia científica.

Contestaron 12 países (entre los que están Brasil y Costa Rica), una organización y tres observadores.

CONCLUSIONES GENERALES:

Coincidieron en la necesidad de urgencia de tratar la RAM; la necesidad de darle un enfoque integral multidisciplinario tal como lo es el enfoque ONE HEALTH, y la necesidad de una vigilancia integrada y un monitoreo del uso de los antimicrobianos.

RECOMENDACIONES:

1. Iniciar una nueva labor sobre:
 - a. REVISIÓN del Código de Prácticas para reducir al mínimo y contener la resistencia a los antimicrobianos (CAC/RCP 61-2005) (documento de proyecto adjunto: Apéndice 1, parte 1)
 - b. Formulación de las Directrices sobre la Vigilancia Integrada de la resistencia a los antimicrobianos, (documento de proyecto adjunto: Apéndice 1, parte 2)
2. Crear un grupo de acción específico sobre resistencia a los antimicrobianos y determinar el país o los países anfitriones (Proyecto de mandato adjunto: apéndice 2).
3. SOLICITAR A FAO/OMS que presten asesoramiento científico sobre resistencia a los antimicrobianos, en colaboración con la OIE (Proyecto de mandato adjunto: apéndice 3)..
4. SOLICITAR A FAO/OMS que elaboren un programa de fomento de la capacidad para satisfacer la necesidad determinada.

COMENTARIOS:

GENERALES:

Como órgano de aplicación se detecta que existe una superposición de documentos de referencia para abarcar un mismo tema. Así ocurre con el "Uso Prudente de los Antimicrobianos" que es abordado por el capítulo 6.9 del Código Terrestre de la OIE y por el CAC/RCP 61-2005 del Codex Alimentarius. También se duplica en el caso del Análisis de Riesgo para el Control de la Resistencia a los Antimicrobianos que es abordado por la Directriz CAC/GL 77/2011 del Codex Alimentarius y por el Capítulo 6.10 del Código de Animales Terrestres de la OIE.

Podría ocurrir lo mismo con el futuro trabajo de desarrollo de una Directriz para la Vigilancia Integrada de la RAM ya que en el Código de Animales Terrestres la vigilancia ya es abordada en el Capítulo 6.7, si bien la misma sólo aplica a animales productores de alimentos y a productos de origen animal en congruencia con la misión de la OIE.

Se considera importante prestarle atención a esta situación y buscar la manera de lograr una articulación con las Organizaciones Intergubernamentales implicadas (OIE, FAO y OMS) a los fines de no duplicar trabajo, optimizar el esfuerzo de los países miembros y, por sobre todo, simplificar la labor de los órganos de aplicación a nivel nacional.

RECOMENDACIÓN 1a:

- A) Se considera que es necesaria más bien la redacción de un documento homólogo o complementario que aborde el uso de antimicrobianos para ser aplicado en producción agrícola (cultivos) y no la apertura del Código CAC/RCP 61-2005 y la modificación de su alcance.

Justificación: Esto se debe a los fines de una lectura ordenada, dadas las diferencias no solo entre las producciones animal y vegetal sino también entre los organismos nacionales que las regulan. En muchos países se trata de organismos separados, por ende, se considera apropiado contar con documentos separados pero complementarios.

Teniendo en cuenta la situación regional creemos que la debilidad no está en el Código en sí mismo sino en la falta de aplicación por parte de los países miembros.

Por lo dicho anteriormente se considera necesario la consulta a expertos para el desarrollo del anexo propuesto para cubrir el uso en cultivos.

- B) En cuanto a la referencia a la lista de antimicrobianos de importancia crítica, se debería contemplar el uso de las listas ya publicadas por los organismos de referencia, OMS y OIE, es decir, simplemente tomarlas como referencia, ya que las mismas se encuentran en constante revisión.
- C) Se observa la equivalencia entre el Código de la Referencia y el Capítulo 6.9 del Código de Animales Terrestres de la OIE (Uso Prudente de Antimicrobianos).

Justificación: Es necesario simplificar la labor por parte de los órganos de aplicación nacionales, por lo cual se estima conveniente referenciar la norma equivalente OIE en el mencionado Código CAC/RCP 61-2005.

RECOMENDACIÓN 1b:

- Se coincide con la necesidad de una Directriz para la Vigilancia Integrada de la RAM, que incluya el muestreo coordinado y testeo de bacterias y de determinantes de la resistencia provenientes de animales productores de alimentos, de alimentos y de personas enfermas, y el seguimiento de la tendencia de la RAM en toda la cadena alimentaria y el sistema de salud mediante métodos armonizados. También integrarlo a un sistema global de monitoreo.

Es necesario destacar que los aspectos y acciones necesarios para la vigilancia y seguimiento de la RAM en animales productores de alimentos y alimentos de origen animal ya se encuentran desarrollados en el Capítulo 6.7 del Código de Animales Terrestres. Sería redundante generar un documento similar/equivalente por cuanto se considera que deberían respetarse textualmente estas recomendaciones en el contenido de la futura guía.

- Por otro lado, los aspectos y acciones necesarios para la vigilancia y seguimiento de la RAM en alimentos de origen vegetal requerirían un desarrollo propio del Codex ya que se desconoce la existencia de norma/directriz en tal sentido.
- Otro aspecto a cubrir de la vigilancia son los nichos ecológicos en los que se encuentran tanto el ser humano como los animales y cultivos, que se ven afectados por efluentes provenientes de estos mismos sistemas pudiendo jugar un papel más en la transmisión de la RAM y por consiguiente ser necesaria su inclusión en este enfoque “integral” de la vigilancia y seguimiento de la RAM.

Se considera que este punto excede el ámbito de competencia del Codex.

- En el caso de la salud humana, los aspectos y acciones necesarios para la vigilancia y seguimiento de la RAM se escapan al área de competencia del Codex Alimentarius y ya han sido desarrollados en la Guía del Grupo Asesor de la OMS para la Vigilancia Integrada de la Resistencia a los Antimicrobianos.
- En conclusión, se considera que la propuesta “Directriz para la Vigilancia Integrada de la Resistencia a los Antimicrobianos” debería abordarse de una manera conjunta por Codex Alimentarius, OIE, FAO y OMS. En tal caso, al menos se debería contar con representantes de estas Organizaciones Intergubernamentales en el grupo de trabajo que se genere para su desarrollo.
- Es muy importante destacar que los puntos de corte para la determinación de sensibilidad bacteriana en humanos ya se encuentran establecidos por normas mundialmente reconocidas y aceptadas como los son las Normas CLSI y EUCAST. No obstante ello, la ausencia de puntos de corte en veterinaria es un gran problema porque impide la prescripción racional; esto se debe a la falta de muestreos suficientes para la determinación de los mismos, por lo cual se debería establecer una estrategia prospectiva regional de muestreo y análisis. Sin embargo, con el objeto de realizar un trabajo de vigilancia integrada donde los datos obtenidos en ambos campos sean comparables, consideramos que el uso de los puntos de corte de humanos deben utilizarse para realizar vigilancia integrada.
- Otro punto importante para destacar es que el análisis y la notificación de datos (RED WHONET) también han sido desarrollados por la OMS y que se están aplicando mundialmente de modo de garantizar la armonización de los mismos y permitir conclusiones, recomendaciones y acciones a nivel global.

Justificación: vistas las implicancias que tiene la RAM en salud humana Y con el fin de controlarla y reducirla se considera necesario el desarrollo de la futura directriz para el control integrado. vistos los documentos que abordan la vigilancia y los métodos de laboratorios redactados por otros Organismos Intergubernamentales se considera necesario no duplicar dicha labor con el fin de no duplicar trabajo, optimizar el esfuerzo de los países miembros, y por sobre todo simplificar la labor de los órganos de aplicación a nivel nacional

- Se pone a disposición las referencias del trabajo realizado en este sentido en Argentina.
 - Resolución Conjunta Ministerio de Salud y Ministerio de Agricultura, Ganadería y Pesca N° 834/2015 y 391/15
 - Resolución SENASA N° 591/15.

Se destaca que las acciones propuestas en las mencionadas normas se encuentran alineadas con los Códigos de la OIE y las normas de referencia para laboratorio de la OMS.

RECOMENDACIÓN 2:

Se está totalmente de acuerdo en establecer un grupo de acción específico para abordar las recomendaciones 1 y 2 y se propone integrar el mismo. No obstante, se debería establecer interacción/articulación con las mencionadas Organizaciones Intergubernamentales OMS-OIE-FAO.

RECOMENDACIÓN 3 y 4:

Se está de acuerdo con solicitar asesoramiento científico y capacitación a la FAO y a la OMS. En el caso del desarrollo de capacidades sería muy necesario establecer un orden de prioridades de capacitación e identificar las posibilidades de cooperación entre los sistemas con distinto grado de evolución logrados por los países miembros y/o regiones.

BRAZIL

Brazil would hereby like to submit its comments to CX/CAC 16/39/12, recognizing that antimicrobial resistance (AMR) is a global threat to human health and that there is a need for an integrated and multidisciplinary approach to address it. AMR is a priority for Brazilian relevant agencies and renewed efforts are under way to tackle AMR in a manner consistent with the *One Health* approach.

We thank the Codex Secretariat for drafting the proposals contained in CX/CAC 16/39/12, which reflect the importance of efforts being undertaken in the WHO, FAO and the OIE.

Brazil considers that any new work proposed in relation to AMR within the Codex should take into account the work already done in the relevant international organizations, such as the OIE and WHO.

Taking note that the comments previously submitted by Members in response to CL 2015/12-CAC do not allow us to state that there is a clear-cut consensus on how to structure the future work of the Codex on AMR, and considering that many countries are still implementing their National Action Plans on AMR, aligned with the WHO Global Action Plan, Brazil would like to suggest that, before establishing the dedicated Task Force, Codex members create a one-year electronic Working Group (eWG) to better define the main aspects to be covered and the scope of the new work proposed.

CANADA

Canada has previously provided comments on CL 2015/21-CAC for Codex work on antimicrobial resistance (AMR) and appreciates the opportunity to provide further input on this file. The summary of responses received from the member states to CL 2015/21-CAC continues to demonstrate the global AMR risk concern and the need for Codex contribution towards efforts against AMR. Canada would support Codex work in this area to address identified gaps and new developments as recommended in CX/CAC 16/39/12. Canada is of the opinion that, consistent with One Health Approach, it is important to make sure there is good coordination amongst the other organizations working on this file, namely FAO, WHO and OIE. Any new work on this file should take into account all existing relevant information and guidances and find the most effective way to fulfil the identified gaps and updates based on new developments, in a timely fashion, which could be fulfilled through an initial expert meeting among organizations with initiatives underway on this file.

COSTA RICA

Costa Rica agradece la oportunidad de expresar sus comentarios sobre la resistencia a los antimicrobianos. A continuación se desglosan los siguientes comentarios generales:

1. Costa Rica es conocedora de la problemática mundial sobre la resistencia antimicrobiana debido a múltiples causas y también es testigo del trabajo que el Codex ha venido realizando a lo largo de los años para establecer códigos de prácticas, entre ellos CAC/RCP 61-2005 (Código de prácticas para minimizar y contener el riesgo de la resistencia antimicrobiana) y el CAC/GL 77-2011 (Lineamientos de análisis de riesgo de la resistencia antimicrobiana en los alimentos), que mitigan el riesgo potencial de este problema. Asimismo, estos códigos de prácticas son documentos que actualmente son utilizados como referencia para las autoridades sanitarias de los países miembros del Codex. Dado lo anterior, Costa Rica considera que en lugar de enmendar el Código CAC/RCP 61-2005 y la modificación de su alcance, se debería redactar un documento complementario que aborde el uso de antimicrobianos para ser aplicado en producción agrícola (cultivos).

Paralelamente, lo que se debe reforzar es la generación de capacidad a los países para implementar el códigos y las directrices; considerando que en muchos países no existe una regulación actualizada que norme la implementación de estos documentos.

2. Costa Rica apoya la recomendación ii) de crear un grupo de acción específico sobre la resistencia a los antimicrobianos, porque de esta manera los países miembros del Codex, podrán elaborar un documento sobre vigilancia integrada que otorgue orientación a las autoridades de los países miembros; asimismo, los países miembros establecerán la interacción/articulación con las mencionadas Organizaciones Intergubernamentales OMS, OIE, FAO, con la finalidad de crear un sistema integral y complementario en los países.

3. Costa Rica apoya la recomendación iii) y iv) porque le parece fundamental que la FAO, OMS y OIE presten asesoramiento científico en materia de resistencia a los antimicrobianos, colaboren en la elaboración de un programa de fomento de capacidad y se pueda analizar en detalle cómo sensibilizar, mejorar y concientizar del uso de estas estrategias y herramientas con el fin de mitigar o controlar el riesgo de la resistencia a los antimicrobianos. Nos parece fundamental el asesoramiento en cuanto a las necesidades de concientizar y sensibilizar a los diferentes actores en la cadena alimenticia, determinar y evaluar las medidas de gestión de riesgos y su eficacia en los distintos puntos de la cadena alimentaria, proporcionar un asesoramiento basado en datos objetivos sobre el modo de orientar a los miembros del Codex en la utilización de estas listas de antimicrobianos de importancia crítica de OMS y OIE, gestionar la resistencia a los antimicrobianos transmitida por los alimentos, tomando en consideración la necesidad de buscar un equilibrio entre las necesidades de salud pública, salud animal, seguridad alimentaria y asesoramiento sobre alternativas a los antimicrobianos.

CUBA

Con referencia al documento CX/CAC 16/39/12, referido al Tema 11 de la 39 CAC, Cuba agradece la oportunidad de dar sus comentarios al respecto, y apoya las recomendaciones expuestas en el párrafo 48 del citado documento. Incluso nuestro país tiene adoptado como Norma Cubana El *Código de prácticas para reducir al mínimo y contener la resistencia a los antimicrobianos* (CAC/RCP 61-2005).

DOMINICAN REPUBLIC

República Dominicana, agradece la oportunidad de entregar los comentarios solicitados en el documento de trabajo CX/CAC 16/39/12, "Labor del Codex sobre la Resistencia a los Antimicrobianos", a ser debatido en la 39ª. CAC y a la vez felicita a la Secretaría del Codex por la elaboración del documento.

República Dominicana, se suma a los miembros que han reconocido la necesidad de ayudar a los países a fomentar su capacidad de afrontar la resistencia a los antimicrobianos a escala nacional utilizando un enfoque integrado y multidisciplinario, en colaboración tripartita de la FAO, la OMS y la OIE y a la nueva estrategia "Un Mundo, Una Salud".

República Dominicana apoya todas las recomendaciones planteadas en el párrafo 49 :

- i. Iniciar una nueva labor sobre:
 - a) La revisión del *Código de prácticas para reducir al mínimo y contener la resistencia a los antimicrobianos* (CAC/RCP 61-2005).
 - b) La formulación de las Directrices sobre la vigilancia integrada de la resistencia a los antimicrobianos.
- ii. Crear un grupo de acción específico sobre resistencia a los antimicrobianos (proyecto de mandato adjunto: Apéndice 2) y determinar el país o los países anfitriones;
- iii. Pedir a la FAO y la OMS que presten asesoramiento científico en materia de resistencia a los antimicrobianos en colaboración con la OIE (proyecto de mandato adjunto: Apéndice 3);
- iv. Pedir a la FAO y la OMS que elaboren un programa de fomento de la capacidad para satisfacer la necesidad determinada.

EL SALVADOR

El salvador apoya las recomendaciones hechas en el documento preparado por la Secretaría del Codex en colaboración con la FAO y la OMS)

- i. iniciar una nueva labor sobre:
 - a. la revisión del Código de prácticas para reducir al mínimo y contener la resistencia a los antimicrobianos (CAC/RCP 61-2005) (documento de proyecto adjunto: Apéndice 1, Parte 1);
 - b. la formulación de las Directrices sobre la vigilancia integrada de la resistencia a los antimicrobianos (documento de proyecto adjunto: Apéndice 1, Parte 2);
- ii. crear un grupo de acción específico sobre resistencia a los antimicrobianos (proyecto de mandato adjunto: Apéndice 2) y determinar el país o los países anfitriones;
- iii. pedir a la FAO y la OMS que presten asesoramiento científico en materia de resistencia a los antimicrobianos en colaboración con la OIE (proyecto de mandato adjunto: Apéndice 3);
- iv. pedir a la FAO y la OMS que elaboren un programa de fomento de la capacidad para satisfacer la necesidad determinada.

EUROPEAN UNION

The European Union and its Member States (EUMS) welcome document CX/CAC 16/39/12 and the opportunity to submit comments on the recommendations regarding future work of Codex on Antimicrobial Resistance (AMR). Fighting Antimicrobial Resistance (AMR) has long been and still is a high priority for the EUMS.

1. Start new work on the revision of the Code of Practice to minimise and contain AMR (CAC/RCP 61-2005) and on the development of Guidance on integrated surveillance of AMR

The EUMS fully support the revision of the Code of Practice (CAC/RCP 61-2005), which has been in use for a long time and needs to be updated in order to strengthen and broaden some of its provisions.

The EUMS also fully support the development of Guidance on Integrated Surveillance of AMR taking into account the work done by WHO AGISAR and other established multinational integrated surveillance systems.

An adequate and reliable surveillance and monitoring system of the use of antimicrobials and AMR in the food and feed chain is a crucial component of the strategy to combat AMR. It will help to better understand the role of food in spreading AMR and gather essential data for the development of future actions. The OIE data reporting tool on antibiotics used in animals is a helpful component of this system.

2. Establish a dedicated intergovernmental Task Force on AMR

The EUMS fully support the creation of such Task Force as an efficient mechanism for carrying out the work referred to in paragraph 1 above. In view of the experience gained in the monitoring and surveillance of the use of antimicrobials also within the context of the "One Health Approach", the EUMS will be pleased to contribute actively to the work of the Task Force.

3. Request FAO/WHO to provide scientific advice on AMR, in collaboration with OIE

The EUMS consider it important to convene WHO/FAO/OIE multidisciplinary expert meetings to, amongst others, review developments related to AMR in the food chain. In light of the complexity of AMR and considering the "One-Health approach" that needs to be implemented to combat its advance, the EUMS welcome the participation of experts in public health, human health, animal health and welfare, food safety and other fields deemed relevant to complete the task at hand.

4. Request FAO and WHO to develop a capacity development programme to respond to the need identified

Considering the critical need for capacity development to support the implementation of Codex texts and for effective national action plans against AMR, in particular in developing countries, the EUMS welcome this initiative. The EUMS consider that capacity development programmes should be jointly undertaken by FAO, WHO and OIE under the umbrella of their Tripartite agreement. The EUMS will be pleased to provide relevant expertise in this field as required.

GHANA

Ghana wishes to commend the FAO and WHO for the proactive resolutions and Global Action Plan adopted to address the threats of Antimicrobial resistance (AMR). Indeed AMR is a global health threat at the human–animal–environment interface and therefore requires a concerted effort by all interested parties at both national, regional and international level to prevent or mitigate the associated public health burden. It is in this regard that Ghana supports new work in the following areas to address gaps and new developments in the field of AMR.

- The revision of the *Code of Practice to Minimise and Contain Antimicrobial Resistance* (CAC/RCP 61-2005)
- The development of Guidance on Integrated Surveillance of Antimicrobial Resistance

CAC/RCP 61-2005 has been used as an important guidance document for drafting national strategies on foodborne Antimicrobial Resistance. Revision of the COP is necessary to ensure the standard remains relevant by widening the scope to cover the entire food chain whilst reflecting the "One Health Approach" in the phase of emerging developments in the area of AMR. Moreover, the development of guidance on integrated surveillance of AMR will serve as an important tool in monitoring implementation of regulations with regard to the use of veterinary drugs, including antimicrobials. In the light of the proposed revision of CAC/RCP 61-2005 and development of new guidance documents to address the threat of AMR, it is only appropriate that:

- The Ad hoc Intergovernmental Task Force which was dissolved by CAC in 2011 be established
- FAO/WHO are requested to provide scientific advice on AMR, in collaboration with OIE

- FAO and WHO to develop a capacity development programme to respond to the AMR needs

JAPAN

Japan would like to thank the Codex secretariat for preparing the documents and appreciate the opportunity to provide the following comment.

Japan notes that there have been several important developments with respect to the global fight against antimicrobial resistance (AMR), including the WHO Global Action Plan on AMR and the OIE resolution "Combating Antimicrobial Resistance through a One Health Approach: Actions and OIE Strategy (Resolution No.36 at 84th OIE General Assembly)". Japan considers these recent international initiatives should constitute the basis for the global actions against the challenge of AMR and if the CAC decides to launch new work on the revision of the Code of Practice to Minimise and Contain Antimicrobial Resistance (CAC/RCP 61-2005), due consideration should be given. Japan is ready to contribute to the new work by ensuring that the revision is based on the working principles of risk analysis.

With respect to the proposed new work on the Guidance on Integrated Surveillance of Antimicrobial Resistance, Japan would like to point out that the project document does not refer to the ongoing work of the OIE under 5 (c) of Project document 1: "*Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies).*" The OIE has developed international standards on AMR surveillance and monitoring. In addition, at its 84th General Session in May 2016, the OIE has just adopted a new resolution to combat AMR. Japan urges that the CAC give due consideration to, and ensure coordination with, the ongoing work of the OIE in order to prevent possible duplication of work in the two organizations.

KENYA

1. Kenya appreciates the work done by Codex Secretariat in collaboration with FAO and WHO and we are in agreement with the review of the CAC/RCP 61 taking into considerations the challenges posed by AMR.
2. We also support the development of guidelines of surveillance of AMR microorganisms, based on WHO AGISAR guidance.

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)

Part 1

2. Scope

Guidance for the responsible and prudent use of antimicrobials in agriculture products **and other production practices** 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.

COMMENT

Kenya has amended the scope and added "**and other production practices**" indicated in bold and underlined in the scope mentioned above

Justification: Production practices have the potential to contribute to AMR.

Part 2

PROJECT DOCUMENT/2

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

COMMENT

Kenya supports the new work item (project document/2) on Surveillance of Antimicrobial Resistance.

Appendix 2

TERMS OF REFERENCE OF THE AD HOC CODEX INTERGOVERNMENTAL TASK FORCE ON ANTIMICROBIAL RESISTANCE.

COMMENT

Kenya is in agreement with developing 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. We also acknowledge the intent of these guidance documents is to ensure that measures are taken across the food chain to minimize the development and spread of AMR and to ensure a coordinated approach to surveillance of antimicrobial resistance both in animal and human.

Therefore Kenya recommends establishing dedicated Task Force on AMR to come up with Guidelines and Surveillance of Antimicrobial Resistance

MALAYSIA

Malaysia supports the establishment of a dedicated Task Force on AMR to start new work on:

- Revision of “*Code of Practice to Minimise and Contain Antimicrobial Resistance (CAC/RCP 61-2005)*” and
- Developing “Guidance on Integrated Surveillance of Antimicrobial Resistance”.

Malaysia also supports the need to request FAO/WHO in collaboration with OIE to provide the scientific advice based on new scientific evidence to the Task Force undertaking the new work.

Malaysia acknowledges the need for some countries to be assisted in developing their capacity to address AMR at their national level. As such, Malaysia welcomes and supports the recommendation to request FAO and WHO to develop a capacity development programme to respond to the needs identified.

NEW ZEALAND

General Comments

New Zealand agrees and supports the need for concerted global efforts to address the issue of antimicrobial resistance. We welcomed and supported the resolutions of FAO and WHO in this area and see these as important instruments for promoting concerted actions by all parties to combat the growth of antimicrobial resistance.

New Zealand generally agrees that further efforts are needed by various entities to promote systematic actions to minimise and control antimicrobial resistance. New Zealand also agrees that concerted actions are needed particularly at the national level through the development and implementation of national action plans on antimicrobial resistance.

Specific comments

With regard to the specific recommendations contained set out in para 49 of document CX/EXEC 16/71/3 New Zealand would make the following comments:

- We are generally supportive of the proposal to initiate a review of the *Code of Practice to Minimise and Contain Antimicrobial Resistance (CAC/RCP 61-2005)*. Since this Code was established a decade ago, there have been important developments and initiatives and there is merit in a review and update of the current code. It is however important that any new work is clearly defined and falls within the mandate of Codex.
- As currently defined the scope of the proposed work, as set out in Appendix 1 Part 1 of CX/EXEC 16/71/3 has the potential to extend the Codex work to areas that may not fall within its mandate. In particular there may be need to review the practical implications of extending the scope of any new work to cover all agricultural products.
- New Zealand supports the development of guidance on integrated surveillance of antimicrobial resistance taking into account the work of WHO-AGISAR. However it considers the Purpose and Scope presently described in Appendix 1 Part 2 to be too general.
- Based on past experience with this work, New Zealand can support the suggestion to advance any future work through a dedicated task force. However before the establishment of such a body it considers it would be more appropriate to seek food specific scientific AMR advice from WHO/FAO in collaboration with OIE to assist in informing more specific Purpose and Scope for the proposed work.
- It is important that there is a strong science and evidence basis for decision making with respect to AMR.
- This is also important to ensure the work remains within the mandate of Codex and therefore avoids duplication of work by other international bodies.

NORWAY

Norway appreciates this second opportunity to submit comments upon future work of Codex on Antimicrobial Resistance. We would also like to refer to our more extensive comments submitted in reply to CL 2015/21 CAC.

We would initially like to highlight that fighting Antimicrobial Resistance is an important global issue and we strongly support the decisions of FAO and WHO in addressing this issue. We are also of the opinion that the "One Health" approach where public health, animal health, food safety and environmental authorities are working closely together is crucial to fight Antimicrobial Resistance.

When pathogens become resistant to antimicrobial agents, they can induce treatment failure, loss of treatment options and increased likelihood and severity of disease. The use of antimicrobial agents in food-producing animals/crops provides a potentially important risk factor for selection and dissemination of antimicrobial resistant microorganisms and antimicrobial resistance determinants from animals/crops to humans via food consumption. The current expansion of Antimicrobial Resistance is made even more serious by the stagnation in the development of new antimicrobial agents. Based on this we strongly support the proposed new work.

Specific response to the 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);**

We support the revision, and the proposed project document. This code is outdated and does not concur with the advance of development and knowledge in this area. We would like to add though, that the implementation of the code amongst members is highly important to be able to fight AMR.

We would also like to point out that Codex should make sure that the challenge of developing AMRs should be taken into consideration also when the use of antimicrobial agents is mentioned in other Codex work and adopted standards.

When revising the code, we are of the opinion that some of the provisions should be strengthened and further clarified. The attention on prudent and responsible use should be stressed. There is a need to reserve the use of critical important antimicrobials for human medicine. Off-label use of antimicrobial agents should only be allowed according to the cascade. It is also important to maintain a non-profit policy for prescription and distribution of antimicrobial agents in both the human health and the animal health sector and to maintain the prescriber's professional independence.

b. The development of Guidance on Integrated Surveillance of Antimicrobial Resistance (attached project document: Appendix 1, Part 2);

Norway supports the development of Guidance on Integrated Surveillance of Antimicrobial Resistance because there is a strong need for more data and welcomes the proposed project document. It is especially important to establish harmonized monitoring systems on the sales and use of antimicrobial agents and data on antimicrobial resistance in both humans and in relevant bacteria in targeted animals. Thus, it is important to include references to relevant OIE documents, and to continue the good cooperation between Codex and OIE in this area. Harmonized monitoring systems will enable the comparability and quality of antimicrobial resistance data within countries and animal species. This will make it possible to assess trends and analyze the impact of measures taken.

We find that due to significant data gaps and uncertainties regarding the risk factors together with knowledge gaps on the source attribution factors of antimicrobial resistance, it is challenging to make a precise risk analysis of foodborne antimicrobial resistance. If these data were available, it would be possible to give a more precise estimation of the overall risk.

Furthermore, the current monitoring systems do not detect emerging risks in due time. We also need more knowledge on how trade and movements of humans, animals, food and feed, will affect the development and spread of resistance in humans and animals globally.

ii. Establish a dedicated Task Force on AMR (attached draft TORs: Appendix 2) and identify a host country(ies);

Norway supports the establishing of a dedicated Task Force on AMR as described in Appendix 2 and the proposed terms of reference

The attention on prudent and responsible use and goals to reduce and contain antimicrobial resistance has to be equal in all sectors, in order to achieve the "One Health" approach.

iii. Request FAO/WHO to provide scientific advice on AMR, in collaboration with OIE (attached draft TORs: Appendix 3).

Norway supports to request FAO/WHO to provide scientific advice on AMR, in collaboration with OIE and the proposed terms of reference

In order to make full use of the available expertise and new scientific information, it would also be of great value to request FAO, WHO and OIE to convene expert meetings, bringing together participants representing public health area and from the entire food chain. We would prefer the mandate of these expert meetings to include the review of the scientific evidence and risk assessments.

REPUBLIC OF KOREA

The Republic of Korea supports recommendations prepared by Codex Secretariat on new work to revise the *Code of Practice to Minimize and Contain Antimicrobial Resistance* (CAC/RCP 61-2005) and develop Guidance on Integrated Surveillance of Antimicrobial Resistance.

For the revision of CAC/RCP 61-2005, the Republic of Korea believes that it is required to develop the program to determine not only the amount of selling antimicrobials, but also the amount actually used for livestock in regard to guidance on monitoring the use of antimicrobials. Also, we suggest to prepare specific management guidance for Critically Important Antimicrobials as a precaution, and for these reasons, we agree the recommendation to revise the relevant Code of Practice.

In regard to Guidance on integrated surveillance of AMR, specific and scope-expanded guidance on integrated surveillance is needed. For instance, concerning target microorganisms, the antimicrobial list for reviewing spread of foodborne bacteria and resistance, and breakpoint are needed. Also, most of the data are related to livestock (animals) in producing national AMR data, so that surveillance data for seafood may be needed since a large amount of antimicrobial is used in seafood as well. In addition, the Republic of Korea suggests to include international guidance for the environment.

In conclusion, the Republic of Korea believes that it is necessary to update *Code of Practice to Minimise and Contain Antimicrobial Resistance* in order to respond effectively to antimicrobial resistance. Also, the Republic of Korea is interested in the candidate for the possible host country if this new work is agreed by member countries at the 39th Commission. We would like to contribute to international society once again based on the experience as the former host country for Task Force on AMR during 2007-2010.

UNITED STATES OF AMERICA

The United States appreciates the opportunity to provide the following comments relative to Agenda Item 11 for the 39th Session of the Codex Alimentarius Commission meeting in June 2016.

General Comments

The United States notes the global importance of antimicrobial resistance and some of the activities taking place just last year:

- The World Health Assembly ratified the World Health Organization's (WHO) Global Action Plan (GAP) on AMR
- The Food and Agriculture Organization, (FAO) passed resolutions to address AMR
- The World Organization for Animal Health (OIE) passed resolutions on AMR and put out a call for information on antibiotic use data
- The FAO/OIE/WHO Tripartite committed to a One Health collaboration on AMR
- G7 countries committed to a One Health approach to address antimicrobial resistance
- Countries began implementing the Global Health Security Agenda (GHSA) which contains an AMR Action Package in 2015 with components to develop national action plans and conduct surveillance
- Members of the Transatlantic Task Force on Antimicrobial Resistance (TATFAR) began work to address technical gaps in agriculture on AMR including efforts to address surveillance and implementation of CAC/GL 77-2011

Countries are presently engaged in domestic activities to either develop or implement their national action plans by 2017 as called for in the WHO GAP with minimal additional resources in the agriculture sector. Before beginning new work or requesting expert consultations that will place additional strain on experts and may slow progress on existing domestic and global work, the United States suggests that a Codex working group (preferably electronic) review existing activities and needs, clearly delineate the scope of new work to be undertaken by Codex, and develop terms of reference for provision of consultative advice so that work products are non-redundant, relevant and useful. It is important to determine what gaps exist and what work within the mandate and scope of Codex could address these gaps and contribute constructively to the global effort. Establishing a Task Force prior to this scoping taking place would be an inefficient use of resources and may actually impede Codex from doing valuable work as the time of the Task Force would be taken up trying to decide what work is needed that would not duplicate effort or undermine work that has already been done or is currently taking place.

The issues around AMR are highly technical and require trained experts, experts who are currently involved in responding to and carrying out the domestic and international work referred to above. In scoping work to be undertaken by Codex, the Commission should ensure that multiple and potentially duplicative demands on countries do not impede ongoing work or divert scarce resources from existing efforts.

Specific Comments:

Paragraphs 35 and 49(i) and Appendix 1. Recommendations for new work

1. Revision of the *Code of Practice to Minimize and Contain Antimicrobial Resistance* (CAC/RCP 61-2005)

Project Document/1 states the scope of a revision should take into account “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 United States is concerned that the all-encompassing scope goes beyond the Codex mandate

The United States recognizes that Codex took on the task of drafting the Code over 10 years ago; at that time it was among the first documents of its kind with regard to practices minimizing risk of the development of antimicrobial resistance. Since then, the World Organization for Animal Health (OIE) has updated the information contained in the Terrestrial Animal Health Code and Aquatic Animal Health Code. These codes, modified as recently as last year, reflect specific language on risk analysis for antimicrobial resistance arising from the use of antimicrobial agents in terrestrial and aquatic animals.

2. Development of Guidance on Integrated Surveillance of AMR (Project Document/2)

Responses to the Circular Letter indicated that surveillance is a development gap and improved capacity is necessary to implement surveillance and improve the quality and comparability of data (para 11). Codex should determine what capacity development work WHO/FAO/OIE and others have done, including work for the GHSA AMR Action Package that calls for surveillance and evaluation of surveillance activities. Codex should also be informed by a WHO Advisory Group on Integrated Surveillance of AMR (WHO-AGISAR) meeting in October 2016 regarding pilot projects in developing countries to generate data on antimicrobial use and resistance. Before starting new work on surveillance, it would be helpful to determine what has been done, what structures already exist, where the gaps are, what is needed, and what entity would be best equipped to address the need. If respondents indicated that capacity is a problem, it may be premature to undertake guidelines without first being informed by what has been learned through WHO-AGISAR, development of national action plans for the WHO GAP for 2017, and GHSA implementation efforts.

Paragraphs 37 and 49 (ii) and Appendix 2. Dedicated Task Force

As outlined in our general comments, prior to expending valuable financial and technical resources, the United States believes it would be prudent for Codex to begin with a working group, preferably electronic, to enable participation of experts while being sensitive to strained resources. The electronic Working Group should determine what work is already occurring and define the scope for new work within the mandate of Codex, as well as define terms of reference for consultative advice prior to making a decision to establish a Task Force.

Paragraphs 40 and 49 (iii) and Appendix 3. Needs identified for expert meetings

The United States notes that some of the work identified is quite specific and the science regarding emerging resistance is constantly evolving. CAC/GL 77-2011 provides a framework to evaluate these constantly changing risks and risk management options. We also understand that many of the elements outlined in the proposal are already underway. The United States recommends that a Codex working group devoted to scoping work define the terms of reference for a consultative process with WHO, FAO, OIE, the International Plant Protection Convention, and others to understand what work has already been done or is planned. As part of the working group process, a more refined proposal for expert consultation could be developed.

Paragraphs 35 and 49(i) and Appendix 1. Recommendations for new work

1 Revision of the *Code of Practice to Minimize and Contain AMR* (CAC/RCP 61-2005)

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Thank you for the opportunity to submit these comments.

CONSUMERS INTERNATIONAL

Consumers International (CI) strongly supports the recommended new work including the project proposals, the creation of a new task force, and the request for scientific advice from WHO/FAO in collaboration with OIE. Consumers International is the world federation of consumer organisations with more than 240 Members in 120 countries. We do have some suggestions to strengthen the proposals that we ask you to take into consideration.

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)

CI supports the scope and terms of reference but is concerned that the aspects to be covered refers to growth promoters without reference to routine prophylactic use. There is strong evidence from several countries that routine prophylactic use can be substituted for growth promoter use if it is not controlled at the same time. CI recommends that the aspects to be modified to include “use of antimicrobials for growth promotion and prophylaxis.”

PROJECT DOCUMENT /2 Proposal for new work on the Guidance on Integrated Surveillance of Antimicrobial Resistance

CI is concerned that the goal of the document is to “facilitate the exchange and analysis of data from different areas, countries and regions” but risk communication is not included in the scope of the document. The exchange and analysis of data from different countries requires communication and this should be explicitly acknowledged. CI recommends that the scope include the following statement “This work will also include effective risk communication in promotion of integrated surveillance for antimicrobial resistance” which incorporates the title of a chapter in the AGISAR Integrated Surveillance Guidance.

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

It is inappropriate in the context of Codex Alimentarius, which has as its dual goals the protection of consumer health and the promotion of fair practices in food trade, to include language about balancing “public health needs with animal health and food security needs.” The term “balance” suggests that animal health and food security needs will be given equal weight to public health. While animal health and food security may be other legitimate factors, they are outside the scope of Codex. CI therefore recommends that the terms of reference be modified to read “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~~ where appropriate.

INTERNATIONAL POULTRY COUNCIL

The International Poultry Council (IPC) represents the global poultry meat sector. Its members include national poultry bodies in 24 countries responsible for 90% of world poultry meat production and trade, and 53 multinational companies as associate members engaged within the industry, supplying inputs, or as customers of the industry.

The IPC recognises the seriousness of antimicrobial resistance (AMR) and the threat it presents to both human and animal health. The IPC supports the necessity for coordinated actions across all sectors to ensure proper usage (human and agricultural) of antimicrobials thereby seeking to reduce and better manage the development of antimicrobial resistance. The IPC supports in general the recommendations regarding the future work of Codex on antimicrobial resistance as set out in the document Agenda Item 3 CX/EXEC 16/7/3 April 2016, noting that Codex should focus solely on that work within the mandate of Codex.

The Codex recommendations on future work appears to essentially mandate the continuation, review, and expansion of existing programmes and action plans of CODEX and of Codex in partnership with other international organisations (WHO, FAO and OIE). It is appropriate to ensure there is a robust system of monitoring and surveillance of AMR throughout the developed and developing world. The current focus appears to concentrate on characterising the extent of AMR as well as having the ability for early detection of emerging issues.

Recognizing that producers and country authorities have limited resources, there should be some assessment of actions taken to date and their impact on reducing AMR development. With little evidence to demonstrate the impact or benefit of the current measures that are being undertaken it is important to know how these measures influence and mitigate AMR impacts to human and animal medicine in order to improve further actions and to ensure future efforts are effective.

We therefore believe that greater attention now needs to be paid to the means of measuring the response of risk management interventions with respect to potential human AMR threats. Such strengthened activity is likely to yield multiple benefits including detection of those interventions that are most successful and early recognition of those that have unintended consequences. The most effective initiatives on AMR mitigation measures need to be described and key learnings disseminated worldwide.

The extended scope of the work proposed will have direct and potentially major impacts on most sectors of agriculture including the poultry meat sector. The IPC endorses the recognition by Codex that it is vital that all actions are scientifically informed and justified. It is also essential that the expertise and knowledge that the industry and industry technical specialists, including veterinarians, is able to be presented and considered in the discussions within the expert meetings on new scientific evidence related to AMR in the food chain and the various risk assessment, risk management and risk communication options. The IPC urges that industry be included in the integrated and multidisciplinary approach Codex is advocating in its document.

It is not appropriate for the IPC to attempt to comment on any specific aspects mentioned in the document as details have yet to be proposed. Rather we would wish to be involved throughout the process of developing the common positions on these aspects of direct impact on the industry. This way we believe new measures will be better informed and more likely to be understood and more readily and fully taken up by the industry across countries.

Antimicrobial usage monitoring initiatives and on-farm measures now being adopted by poultry industries within several IPC national member countries, often in collaboration with national authorities, are resulting in more accurate usage data, and significant overall reduction or cessation of use of certain categories of antimicrobials. The IPC is seeking to draw on these successes to develop industry guidance and case studies of practical techniques that poultry industries in all countries can take up in their own national programmes. We advocate the promotion of antimicrobial stewardship programmes to be considered as part of the global action plan.

However, strategies involving greater general use of vaccines in combatting animal diseases are hampered, in some cases severely, by manufacturing problems and supply shortages, and by a lack of development of new vaccines.

The IPC national country member organisations provide a powerful worldwide network, in addition to national authorities, for Codex/Industry collaborative communication, education, and confidence building aimed at poultry producers and processors at a local level, and for promulgating common, science-based stewardship programmes against AMR.

HEALTH FOR ANIMALS

HealthforAnimals thanks the Codex secretariat for drafting of document CX/CAC 16/39/12 “Future Work of Codex on Antimicrobial Resistance”.

General Comments

HealthforAnimals, its members and their national and regional associations have been active contributors to judicious/responsible use for over two decades. Significant thought and resource have been devoted to use, control and application of antimicrobials that has resulted in numerous actions toward better control of the issue.

- Regulatory review. All antibiotics proposed by animal health companies undergo thorough review by regulatory authorities, which includes an assessment of the risk of resistance from their use and food producing animals. This encompasses not only resistance of disease causing bacteria in animals but also in food-borne bacteria, as well as risk management of any potential change of the human gut flora. As regulated companies, they strictly apply good manufacturing practice ensuring that the medicines comply with all quality requirements.
- Monitoring, surveillance and usage studies. The industry has a longstanding commitment to monitoring and surveillance resistance since 1998. It supports the CEESA programme - a unique pan-European programme of monitoring resistance in foodborne and veterinary pathogens. To date, no other such programme exists. Industry has contributed to sales distribution and usage studies conducted by others, including the FDA (U.S.), ESVAC (EU) and OIE (global). In each case, companies have contributed to programme’s quality and have voluntarily submitted data.
- Responsible/prudent use standards. Animal medicines companies and associations have contributed proactively to the development of responsible use guidelines in Codex, OIE, WHO, as well as in many countries. Industry has a long commitment dating back to first prudent use guidelines, developed together with the WVA and the global farmers’ organisation. Industry has contributed in time, commitment and finance to numerous platforms, like the British platform RUMA or its European equivalent EPRUMA or global GPRUMA.
- Labelling and practices. In the U.S. all companies voluntarily contributed to the FDA plan of removing growth promotion and efficiency claims from medically important antibiotics. Companies follow requirements in terms of marketing and distribution, as prudent use guidelines are increasingly being included in labels.
- Research and development. The industry also contributes via R&D by bringing new solutions to infectious diseases, such as vaccines, immunostimulants, or other anti-infective solutions.
- Communicating appropriate use. Industry has communicated with users for many years regarding responsible/judicious use. Core has been that antibiotics should always be handled in such a way that limits their potential for stimulating the development of resistant bacterial strains. They should be “*used as little as possible, but as much as necessary*”. Antibiotics help fulfil the moral obligation we have to animals in our care. They help prevent suffering, waste and losses caused by disease

Regarding the terms of reference proposed, HealthforAnimals agrees that the current proposal is a good basis for future Codex work. We do concur with the revision of the Code of Practice CAC/RCP 61-2005 and appreciate the recommendation to let Member States get more experience in what regards guideline CAC/GL 77-2011. We do recommend, consistently with our previous comments that the revision of the Code of Practice CAC/RCP 61-2005 takes into account OIE Terrestrial Code Chapter 6.9 and other relevant OIE texts.

Regarding the discussion on Critically Important Antimicrobials, HealthforAnimals wants to attract the attention of delegates to the following point. HealthforAnimals considers that the WHO list of critically important antimicrobials is not, in any respect, a risk assessment of the concerned antimicrobial classes. The second criterion of the WHO list is based on possibility of transmission of AMR and not probability. Because probability of resistance development is not considered, this list is a more a hazard identification exercise than a risk assessment. Codex must stick with risk analysis principles as part of its decision-making and not entertain hazard-based concepts. In preparing terms of reference for the task force, the delegates should be mindful that the WHO Critically Important Antimicrobial list is no way a risk ranking or a risk assessment.

Therefore and in light of the tripartite FAO/WHO/OIE collaboration on antimicrobial resistance, the existence of also an OIE critically important list for veterinary medicine, and the One Health approach, it would be very appropriate that also expert advice and additional guidance on the substances listed in the WHO Critically Important Antimicrobial list is developed by FAO and WHO jointly with OIE i.e. by Codex.

Detailed Comments

- **Para. 36.**

HealthforAnimals recognizes the potential value of whole genome data sequencing as an additional tool to tackle AMR. However, we consider that this technology may not be at this stage the best tool to monitor foodborne AMR and in particular manage risks in a global context.

- **Para. 43**

We support the OIE participation in view of the Tripartite Agreement

- **Appendix 3**

Regarding the proposed terms of reference for the provision of scientific advice (appendix 3), HealthforAnimals considers that the third paragraph proposing expert advice on alternatives to antibiotics is not clear. Besides, we are not certain that an expert group is the best channel to elaborate on these issues. We would consider that this would be best addressed by a stakeholder group.

We would propose the following text to modify the TORs:

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 *the use of alternative technologies, the need for investment in infection prevention and the modification of value chains*, which would support behaviour change and encourage the implementation of practices conducive to decreasing ~~aimed at~~ addressing AMR.