codex alimentarius commission E

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 6 **CX/AMR 08/2/6 Add.1**
October 2008

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

***AD HOC* CODEX INTERGOVERNMENTAL TASK FORCE ON ANTIMICROBIAL RESISTANCE**

Second Session

Seoul, Republic of Korea, 20-24 October 2008

PROPOSED DRAFT RISK MANAGEMENT GUIDANCE TO CONTAIN FOODBORNE ANTIMICROBIAL RESISTANT MICROORGANISMS (REPORT OF THE PHYSICAL WORKING GROUP) (NO2-2008)

(Comments at Step 3)

The following comments have been received from: Argentina, Australia, Brazil, Canada, Costa Rica, Iran, Kenya, Mexico, New Zealand, Norway, United States of America, Consumers International, IDF, IFAH

ARGENTINA

Argentina appreciates the opportunity to comment on this document.

General Comments;

The numbering from paragraph 22 onwards differs between the Spanish and English versions of the document. We suggest this difference be removed.

With regard to the term "bacterium" used, we believe it should be replaced with "microorganism" for the purpose of uniformity in all the dpcuments, in both English and Spanish.

Similarly, the translation "uso responsable" is inaccurate as international reference organizations have agreed on its translation as "uso prudente". This term involves sensible, appropriate and responsible use. We therefore suggest that "uso responsable" be replaced with "uso prudente".

Specific Comments;

Regarding III GENERAL PRINCIPLES, as recalled, theses principles would be harmonized between the three risk analysis papers being developed. In this sense, the work was carried out in conjunction with the principles contained in CX/AMR 08/2/5, paragraph 3, p. 7 (document in English) and p. 8 (document in Spanish).

In particular, in PRINCIPLE 2, p. 4, with regard to the clarification on the term "acquired from food", we believe the tern used should not be changed as there is no consensus on what terminology will be used, given that it is being discussed.

In PRINCIPLE 5, we believe the words "fully" and "openly" are relative, so they should be deleted from the text.

In PRINCIPLE 6, foot note 6, p. 6, we believe the order of interested parties should be changed as follows:

"For the purpose of the present document, the term "interested parties" refers to "risk assessors, risk managers, the academic community, industry, and, as appropriate, other relevant parties and their representative organizations."

As regards PRINCIPLE 10, the wording appearing in CX/AMR 08/2/5 should be the final choice. The wording would be as follows:

"Risk management activities should take into account recent work by internacional organizations on antimicrobial resistance."

Conceptually, the reference to the application of "additional mitigation steps" in PRINCIPLE 11 may be misleading as the only mitigation steps to be applied are those that are consistent with the model provided under risk analysis stages. We thus believe this principle should be deleted.

In IV. IDENTIFICATION OF THE AVAILABLE OPTIONS, paragraph 6, p. 4, clarification should be provided that the reference to antimicrobials should apply to "antimicrobials for use in animals intended for human consumption".

In paragraph 7, the term "bacteria" should be replaced with "antimicrobial resistant microorganisms and resistance determinants".

In A.- Pre-harvest options, A.1, p. 4, the section should adopt the changes below:

a) the word "all", bullet a) is not appropriate. Critically important antimicrobials should be stated, as defined by international reference organizations;

b) "bacteria" should be replaced with "microorganisms";

c) "dissemination" should be replaced with "prevalence";

d) add the words "in relevant animal species" after "AM".

In A.2- Food animal production, the Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61/2005) should be taken into account, particularly the provisions under paragraphs 50, 51 and 52.

The current wording of bullet point 5 is considered to be inappropriate. The wording may be changed as follows: "Prophylactic antimicrobial use should be circumscribed to situations where a risk of infection is considered to be present."

In bullet point 6, "bacteria" should be replaced with "microorganisms"; and "zoonotic AMR agents" with "foodborne AMR microorganisms"

Bullet point 7 should be deleted. Currently, there are no effective, applicable measures for use in the detection both of microorganisms and resistance determinants in live animal transit. Should the measure be applied, similar activities should be carried out on wild animal movement in the ecosystem.

Bullet point 8 may be merged with bullet point 1, by adding the following to the latter: "Use antimicrobials responsibly". The bullet point should be redrafted as follows:

"Use antimicrobials responsibly, restricting extra-label use, especially in Critically important antimicrobials (CIA) for human treatment."

Bullet point 9 is not consistent with this guidance and involves the attribution of intentionality in professional veterinary practice. This wording should not be retained.

In A.3- Plant production, p. 7, reference should be made to the Code of Hygienic Practices for Fresh Fruits and Vegetables being developed. We suggest the inclusion of this reference between brackets to indicate that the CCFFV is working on it. The reference should appear as follows:

"[See Code of Hygienic Practices for Fresh Fruits and Vegetables (CAC/RCP 53/2003)]"

In B.- Post-harvest options, the changes below should be made in each bullet point:

1. Replace "target […] towards" with "focus […] on"

2. and 3: Merge into a single bullet point as follows:

"Implement control measures that ensure an appropriate level of consumer protection"

4: The text should be redrafted as follows:

"Withdraw food containing an unacceptable level of AMR pathogenic microorganism from the market for destruction or, where possible, reprocessing as a risk mitigation measure"

In V.- EVALUATION OF RISK MANAGEMENT OPTIONS (RMO), paragraph 12, "assessed" should be replaced with "considered"; and "analysis", with "assessment".

In paragraph 13, "compliance" should be replaced with "compliability".

In VI.- SELECTION OF RISK MANAGEMENT (RM) OPTIONS, paragraph 16 should be redrafted deleting the word "various": The sentence should be redrafted as follows:

"16. Interested parties should be involved when developing regulatory programs".

In paragraph 18, it is important that this approach should take into account the cost/benefit of suppressing the use of some antimicrobials in veterinary medicine. In this sense, we believe the last sentence of the text should be redrafted as follows:

"The cost/benefit of adopting these measures and their effects on reduced antimicrobial resistance in animal health should be considered when evaluating the effects of reducing or suppressing pre-harvest use of some antimicrobials."

In paragraph 19, the last sentence should be deleted as it conveys doubt, thus making the paragraph less certain.

Paragraph 21 on the ALARA concept is not applicable. The term ALARA, "as low as reasonable available", was introduced for risk management for drug residues were MRL determination was not been possible, thus establishing a minimum possible detection level (instrument sensitivity level).

For antimicrobial resistance, antimicrobial residue transmission has proved not to create resistance, the real problem being resistant strains or their resistance determinants. Therefore, we believe the use of this term is not appropriate within risk management, as it focuses on antimicrobial drugs, not on microorganisms per se, so A.4 should be deleted.

This adds to the fact that the proposal by the Philippines concerning the inclusion of the term has not been received yet.

In paragraph 21 (22 in the Spanish version), further details should be requested on "legitimate factors" referred to.

In paragraph 26 (27 in the Spanish version), the words "as a minimum" should be deleted.

In paragraph 30 (31 in the Spanish version), the references to RCP 61 & GL63 and the words "between countries" should be deleted.

In paragraph 31 (32 in the Spanish version), the word "should" should be replaced with "could".

In paragraph 32 (33 in the Spanish version), the first sentence should be deleted. Only the second should remain.

In paragraph 33 (34 in the Spanish version), the words "be measured" should be replaced with "exist".

The IX.- RISK COMMUNICATION section should be harmonized with the Procedural Manual.

In Annex 1, p. 8, the following changes should be made: "frecuencia de presencia" should be replaced with "prevalencia" (Spanish version only), "bacteria" should be replaced with "microorganisms", and "bacterial" should be replaced with "microorganism" or "of microorganisms".

Bullet point e requires further comments on its meaning.

In bullet point k, the term "human" should be added before "treatment failures" for clarification purposes.

In bullet point n, the words "antimicrobial resistant bacterial infections" should be replaced with "infections caused by antimicrobial resistant microorganisms"

Bullet point o should be deleted. This sentence goes against the basic principles of risk analysis, as it includes subjective variables in the model, such as some stakeholders' "awareness" of the issue.

Another bullet point should be added: "s Technical and economic feasibility of the measures to be applied."

In Annex 2: step wise approach, p. 9, paragraph g, the words "compliance with" should be deleted as follows: "[…] to ensure quality product availability […]".

In bullet point l, the reference to the HAACP system should be deleted, namely "(i.e. HAACP)".

PROPOSED DRAFT GUIDELINES ON RISK MANAGEMENT TO CONTAIN FOODBORNE ANTIMICROBIAL RESISTANT MICROORGANISMS

(At step 3 of the elaboration procedure)

I.- INTRODUCTION

1. (to be harmonized)

II.- PURPOSE AND SCOPE

2. The purpose of the proposed work is to develop appropriate risk management guidance for national/ regional authorities that may be necessary following risk profiling and/or risk assessments, usually undertaken as described in the Risk Assessment and Risk Profile project documents prepared by the Task Force. Guidance will also be provided on how to measure and monitor the effectiveness of the selected risk management options, including establishing a baseline against which subsequent changes can be measured.

3. National/regional authorities, in implementing these guidelines, should consider a continuum of possible interventions along the entire food chain, each step of which can reduce risk by minimizing and containing antimicrobial resistant (AMR) microorganisms and resistance determinants.

4. This document should be read in conjunction with the Codex Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC-RCP 61-2005), the relevant sections of the OIE Terrestrial Animal Health Code (2007)[3] and the WHO documents/guidelines on containment of antimicrobial resistance in animals for food[4].

III.- GENERAL PRINCIPLES

PRINCIPLE 1: Protection of human health is the primary objective in antimicrobial resistance risk management.

PRINCIPLE 2: Antimicrobial resistance risk management activities should take into account the emergence and dissemination of both resistant foodborne pathogens and resistance determinants through the whole food chain. ~~("foodborne pathogens" to be modified based on harmonization of the WGs ("acquired from food"))~~

PRINCIPLE 3: Antimicrobial resistance risk management activities should focus on clearly defined combinations of food, antimicrobial drug (AM), antimicrobial use and the human pathogens and/or resistance determinants acquired from food.

PRINCIPLE 4: Antimicrobial resistance risk management activities should follow a structured approach[5].

PRINCIPLE 5: The activities conducted in all phases of antimicrobial resistance risk management should be transparent, timely, consistent, ~~fully~~ documented and ~~openly~~ communicated.

PRINCIPLE 6: Risk managers should ensure effective consultations with relevant interested parties[6].

PRINCIPLE 7: Risk managers and risk assessors should ensure effective interaction.

PRINCIPLE 8: Risk managers should take into account risks resulting from regional differences in human exposure to AMR microorganisms & determinants from the food chain and regional differences in available risk management options.

PRINCIPLE 9: Antimicrobial resistance risk management decisions should be subject to monitoring and review and, if necessary, revision.

PRINCIPLE 10: Risk management activities should take into account recent work by international organizations on antimicrobial resistance.

~~PRINCIPLE 10: Activities of risk management should take into account all work by Codex and work by international organizations on antimicrobial resistance and that Codex Guidelines (GL) and Recommended Code of Practice (RCP) should be fully implemented.~~

~~PRINCIPLE 11: Risk Managers should implement additional mitigation steps when Risk Analysis indicates it.~~

IV.- IDENTIFICATION OF THE AVAILABLE OPTIONS

5. Risk management options should consider the farm to table continuum and could be divided in pre-harvest

and post-harvest aspects. Pre-harvest would contain aspects such as responsible use guidelines and codes of practice documents specifically directed to antimicrobial agents and their use in food production, whereas postharvest would contain such aspects as food hygiene practices which are specifically directed to foodborne contamination.

6. As part of the pre-harvest activities, appropriate emphasis should be laid on evaluation prior to approval, taking due account of the resistance inducing properties of ~~antimicrobials~~ antimicrobials for use in animals intended for human consumption; emphasis should also be placed on defining use conditions of these antimicrobials. Countries should pay particular attention to the establishment of the necessary instruments for approval, registration and enforcement of regulations regarding usage.

7. With regard to post-harvest, the aim should be to monitor trends in antimicrobial resistance and prevalence of foodborne ~~bacteria~~ antimicrobial resistant microorganisms and resistance determinants and to apply targeted

[3] http://www.oie.int/eng/normes/Mcode/en_sommaire.htm
[4] http://www.who.int/foodborne_disease/resistance/en/index.html
[5] See para. 7 in GL 62-2007.: "The risk analysis should follow a structured approach comprising the three distinct but closely linked components of risk analysis (risk assessment, risk management and risk communication) as defined by the Codex Alimentarius Commission2, each component being integral to the overall risk analysis."
[6] For the purpose of the present document, the term "interested parties" refers to "risk assessors, risk managers, consumers, industry, the academic community and, as appropriate, other relevant parties and their representative organizations".

interventions aimed at reducing antimicrobial resistant microorganisms and resistance determinants of importance to human and animal health.

8. Risk management options described in the following section may be implemented, at the discretion of national/regional authorities and in a manner that is proportional to the level of risk, based upon the following considerations:

a). as a minimum, the existing Codes of Practice should be followed. These codes of practice describe the respective roles and responsibilities of authorities and groups to minimize and contain antimicrobial resistance:

o Codex Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005),

o Codex Recommended International Code of Hygiene Practice for Control of the Use of Veterinary Drugs (CAC/RCP 38-1993),

o Codex Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63- 2007), and

o Food Hygiene Basic Text – Recommended International Code of Practice General Principles of Food Hygiene (CAC/RCP 1-1969) and its annex on Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for Its Application.

b). Implementation of these options is subject to the resources, legislative, and other constraints of the country/ region;

c). The selection and implementation of the risk management options should be supported by scientific evidence, be feasible, and reviewable with respect to new scientific information;

d). They are intended to supplement the Codex Codes of Practice and related texts (above) and to provide additional risk management options to risk managers.

9. Examples of potential risk management (RM) options (used either alone or in combination) available for Codex or countries, as appropriate are listed below in the rest of this section:

A.- Pre-harvest options

A.1- General

o Monitoring and surveillance of the use of antimicrobials in animals and horticulture (this set of measures do not contribute to the reduction of foodborne antimicrobial resistance (AMR) risk – Monitoring is essential to establish a baseline for comparing the effectiveness of new MRM activities. It also may provide information which the manager may use to determine what steps may be taken to achieve further improvements in the extent or efficiency of risk mitigation {CAC/GL 63 – 2007, page 9})

a). monitoring should, to the extent possible, include ~~all~~ Critically important antimicrobials used in food production;

b). monitoring of usage in animals should be at species level and if possible also on category of animal within species & take into account drug/~~bacteria~~ microorganism/animal species relationship;

c). authorities should preferably plan in advance the collection and analysis of data on the ~~dissemination~~ prevalence of antimicrobial resistance and on antimicrobial usage.

d). AMR data should be analyzed with AM usage data in relevant animal species together with other relevant data to assess possible relationships

o Approval and licensing of antimicrobials used in animals and horticulture

a). Approval and licensing of an Antimicrobial may, whenever possible, be subjected to the monitoring of the use of this AM and of the AM resistance.

b). Approval and licensing of an Antimicrobial may, whenever possible, be subject to the review of existing

AMs.

c). AM product should not be authorized if risk assessment indicates unacceptable levels of risk

A.2- Food animal production

o ~~Restrict extra-label use, especially in Critically important antimicrobials (CIA) for human treatment o Perform a bacterial diagnosis and susceptibility testing prior to treatment for a given AM and bacterial infection.~~

o Use antimicrobials responsibly, restricting extra-label use, especially in Critically important antimicrobials (CIA) for human treatment

o Competent authorities and/or professional bodies should elaborate animal (plant & food processing) species- specific prudent use treatment guidelines in consultation with all relevant interested parties

o Recommend on different AM to be used, if several antimicrobials can be used for a given indication in an animal. (more comments required).

~~o Prophylactic use in healthy animals not considered to be at risk of infection or prior to the onset of clinical infectious disease, should be avoided. (more comments required)~~

o Prophylactic antimicrobial use should be circumscribed to situations where a risk of infection is considered to be present

o Prevent the presence and transmission of foodborne ~~bacteria~~ microorganism & determinants between animals and from animals to humans by implementing Animal health and infection control programs against the most important ~~zoonotic~~ foodborne AMR agents.

~~o Restrict movement of live animals, carrying a specific AMR foodborne pathogen or a bacteria carrying resistance determinant (more comments required : in/out of scope of Codex? OIE remit?).~~

~~o Responsible use in veterinary medicine of antimicrobials of particular importance for human treatment (more comments required : cf. OIE Terrestrial Animal Code).~~

~~o If sufficient evidence exists that profit from the sale of antimicrobials negatively impacts on prescribing practices, appropriate countermeasures should be taken to ensure prudent use. (more comments required :in/out of scope of mandate of Codex? but = WHO global principles on containment of AMR)~~

A.3- Plant production

[See Code of Hygienic Practices for Fresh Fruits and Vegetables (CAC/RCP 53/2003)]

~~Controlling the use of antimicrobial agents: more comments required~~

~~o Controlling the spread of AMR bacteria through other possible sources of contamination: direct use in agriculture of human and animal waste (manure) should be discontinued, if there is sufficient evidence of risk (practical, feasible and supported by science and to be revised in the light of further knowledge – more comments required).~~

B.- Post-harvest options

o ~~Target~~ Focus interventions ~~towards~~ on those ~~bacteria~~ microorganisms that are resistant to antimicrobials of critical importance to public and animal health

~~o Implement of control measures to the extent possible;~~

~~o Prevent the food containing an unacceptable level of AMR bacteria & AM determinants, reaching the consumer~~

o Implement control measures that ensure an appropriate level of consumer protection

o ~~Withdraw food containing an unacceptable level of AMR pathogenic bacteria from the market for reprocessing or destruction (commensals are not included here - to review the inclusion of commensals later on)~~

o Withdraw food containing an unacceptable level of AMR pathogenic microorganism from the market for destruction or, where possible, reprocessing as a risk mitigation measure.

V.- EVALUATION OF RISK MANAGEMENT OPTIONS (RMO)

10. Animal health should also be considered when evaluating risk management options, to the extent possible, consistent with the requirement of GENERAL PRINCIPLE 1.

11. Evaluation of the identified Risk management options should be performed at National/ Regional level.

12. Risk management options should be ~~assessed~~ considered in terms of the scope and purpose of risk ~~analysis~~ assessment and the level of consumer health protection they achieve. The option of not taking any action should also be considered.

13. Risk management options should be assessed taking into account the options' feasibility, effectiveness, economic implications, enforcement and compliability ~~compliance~~; they should be proportionate to the amount of risk. The level of control or reduction of risk that is necessary, should be specified, when feasible.

VI.- SELECTION OF RISK MANAGEMENT (RM) OPTIONS[7]

14. The selection of RM options should be based on their ability to mitigate the risks effectively and on the practical feasibility and consequences of the options. Where available, a risk assessment can often help in the evaluation and selection of RM options.

[7] CAC/GL 63 – 2007 provides general guidance on the selection of risk management options (sections 4 & 6).

15. The selection should be supported by mechanisms to evaluate success to contain and minimize AMR that may be transmitted through the food chain.

16. ~~The various~~ interested parties should be involved when developing regulatory programs.

A.- Identifying a appropriate level of consumer health protection[8]

17. Risk management decisions on appropriate options should be achieved by considering and integrating all evaluation information obtained from preliminary risk management activities and/or the risk assessment.

A.1- Benefit-risk approach

18. Because antimicrobials play a major role in animal health, animal health should be considered when evaluating risk management options, but this must be considered secondary to protecting consumers. When evaluating restrictions on the use of antimicrobial products it is necessary to consider substitutes or alternative practices that would reduce the need for the product. Substitutes could be other less important antimicrobials, non-antimicrobial products, or changes in livestock husbandry that promote animal health. ~~The impact of reduced antimicrobial resistance on animal health should also be considered when evaluating restrictions on antimicrobial use.~~ The cost/benefit of adopting these measures and their effects on reduced antimicrobial resistance in animal health should be considered when evaluating the effects of reducing or suppressing pre-harvest use of some antimicrobials

A.2- Threshold approach

19. Given the geographic variations in the levels of resistance and the increasing emergence of resistance, it may be necessary to explore the need to develop resistance thresholds for specific antimicrobial-species-pathogen combinations, above which any of a range of risk management options may be triggered. ~~However, this approach needs to be carefully assessed as it should be put in perspective with the current use of antimicrobials and the current level of resistance.~~

A.3- Precautionary approach:

20. When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, it may be appropriate for countries to select a provisional decision, while obtaining additional information that may inform and if necessary modify the provisional decision. In those instances, the nature of the provisional decision should be communicated to all interested parties and the timeframe or circumstances under which the provisional decision will be reconsidered (e.g. reconsideration after completion of a risk assessment) should be articulated when the decision is communicated initially.

~~A.4- ALARA approach~~

~~14. (Further comments to be submitted by Philippines)~~

B.- Reaching a decision on the preferred risk management options

21. The decisions should be based on risk assessment and taking into account, where appropriate, other legitimate factors relevant to health protection of consumers and for the promotion of fair practice in the food trade[9].

22. Cross-resistance, co-resistance issues should be considered.

23. control measures may be placed on the use of specific antimicrobial agent in some species or some route of administration or specific production processes (see GENERAL PRINCIPLE 3)

VII.- IMPLEMENTATION OF RISK MANAGEMENT OPTIONS

24. Risk managers should develop an implementation plan that describes how the options will be implemented, by whom, and when.

25. National/regional authorities should ensure an appropriate regulatory framework and infrastructure.

26. Prudent use guidelines, monitoring of antimicrobial usage and general food hygiene principles should be implemented ~~as a minimum~~; additional measures could be envisaged following a stepwise approach (see annex 2).

VIII.- MONITORING AND REVIEW OF RISK MANAGEMENT OPTIONS

[8] "Appropriate Level of Protection" (ALOP). ALOP is defined in the SPS Agreement as "the level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory". ALOPs may range from general to specific depending upon the level of information available with regards to the source of hazards and risks and will depend on the public health goals.

[9] WPRAC para 28, 2nd sentence

27. Governments should define an evaluation process to assess whether the risk management options have been properly implemented and an assessment whether or not an outcome has been successful (see also GENERAL PRINCIPLES).

28. Monitoring and surveillance should be supported by regulation and the enforcement of control measures

29. A minimum level of monitoring should be established in order to measure usage and risk management effects.

30. Monitoring schemes should be harmonized ~~(RCP 61 & GL 63) between countries~~, to the extent possible (in a general consideration about sharing info between countries; more comments are requested on this issue & review OIE Terrestrial Animal Code for existing wording).

31. risk management options ~~should~~ could be reviewed and evaluated, regularly, or at a predetermined moment in time, or whenever new relevant information becomes available

32. ~~A variety of endpoints (see Annex 1) may be measured with respect to antimicrobial resistance~~. Endpoints related to specifically implemented risk management options should be measured to assess the effectiveness and need for potential adjustment.

33. Additional endpoints may exist be measured to identify new information (e.g., emerging hazard, virulence of a pathogen, prevalence and concentration in foods, sensitivity of sub-populations, changes in dietary intake patterns,...).

IX.- RISK COMMUNICATION

15. (to be harmonized)

Annex 1: possible endpoints (exposure end points to be separated from adverse health effect end points)

(refers to section VIII – para 38)

In order to monitor variations in AM usages and AMR and the effects of risk management measures, possible endpoints include:

a. Nature and extent of antimicrobial resistance.

b. Nature and extent of antimicrobial resistance in animal-derived food products at retail level.

c. Prevalence of antimicrobial-resistant ~~bacteria~~ microorganisms on farm level.

d. Prevalence of antimicrobial-resistant ~~bacteria~~ microorganisms in animal-derived food products at retail level.

e. Prevalence of antimicrobial-resistant ~~bacteria~~ microorganisms or resistant genes in human clinical isolates of foodborne diseases.

f. Development of new ~~bacterial~~ resistance patterns of microorganisms.

g. Prevalence of foodborne pathogens on farms.

h. Prevalence of foodborne pathogens in food.

i. Prevalence of food borne disease in humans.

j. Number of deaths attributable to foodborne antimicrobial-resistant ~~bacteria~~ microorganisms.

k. Number of human treatment failures attributable to foodborne antimicrobial-resistant ~~bacteria~~ microorganisms.

l. Frequency of human infections attributable to foodborne antimicrobial-resistant ~~bacteria~~ microorganisms.

m. Frequency of adverse human health effects attributable to foodborne antimicrobial resistant ~~bacteria~~ microorganism.

n. Mortality due to foodborne infections caused by antimicrobial resistant microorganisms ~~antimicrobial resistant bacterial infections~~ in “vulnerable populations”.

~~o. Level of awareness of antimicrobial resistance risk (producers, consumers, industry and others).~~

p. Level of compliance with specific drug use restriction or compliance with prudent use guidelines.

q. Trends in usage of antimicrobials in food-producing animals.

r. Trends in usage of critically important antimicrobials (CIA) in food-producing animals.

s. Technical and economic feasibility of the measures to be applied

Annex 2: step wise approach

(refers to section VII – para 32)

Step 1

a). Ensure adequate veterinarian (or equivalent animal health professionals) coverage for the country, veterinarian training in judicious/appropriate/responsible antimicrobial use and animal production practices, and appropriate involvement in food production and food safety processes.

b). Ensure adequate infrastructure for food production/food hygiene with respect to existing Codex standards and guidelines.

c). National authorities should capitalize upon regulatory precedents and expertise of "peer" authorities in the region when capabilities are limited.

d). Communicate to the public the necessity of proper food preparation and hygiene.

Step 2

e). Implement responsible use guidelines via professional veterinary organizations.

f). Ensure reliable national food safety authority oversight of food safety activities consistent with Codex food hygiene guidance.

g). Implement adequate infrastructure and enforcement capacity to ensure ~~compliance with~~ quality product availability and veterinary involvement in antimicrobial usage.

h). Implement local/regional surveillance programs for foodborne disease.

Step 3

i). Implement national surveillance programs for foodborne disease.

j). Implement national resistance monitoring program, and where possible, usage monitoring.

k). Implement regulatory review of new antimicrobial agents prior to product approval.

l). Work in collaboration with food producing companies to maintain vigilance for implementation of food hygiene practices ~~(i.e. HAACP)~~ that safeguard against food contamination.

m). Work with professional associations (e.g. veterinary profession, species specific groups, etc.) to ensure compliance with responsible use guidelines by all members. Implement research programs to develop new research to fill data gaps that will improve antimicrobial use practices, or minimize the need for antimicrobial use by preventing disease, etc.

n). Encourage animal health companies to develop products that will avoid resistance selection of currently used human use antibiotic classes.

AUSTRALIA

Australia is pleased to provide the attached comments in response to Agenda Item 6:

General comments;

Australia commends the Working Group led by the Danish and French Codex delegations for developing the draft guidance broadly in line with the Codex guidelines on microbiological risk management. Australia considers that the draft document sets out a coordinated and balanced approach for the use of antimicrobials in food-producing animals and the management of foodborne antimicrobial resistant microorganisms.

- Risk Management is guided by Risk Assessment evaluation.
- Risk Management encompasses Codes of Practice for Antimicrobial Use and Food Hygiene.
- Risk Management Options that could be considered outside the scope of the working group include: clinical practice guidelines (page 2, #7). Environmental waste management is also beyond the mandate of Codex.
- Supplemental Risk Management Options are not considered mandatory (discretion of national authorities) and may be implemented only when certain conditions are met.
- Consolidating specific identified sections of the three documents would also benefit the risk management paper and would help harmonise language and provide focus.
- The document would benefit from examples and discussion specifically related to antimicrobial resistance (AMR) issues.
- The document should mention the aquaculture sector.
- Regulatory and non-regulatory approaches in managing the containment of AMR microorganisms in the food chain should be described.

- The document should include appropriate statements about the need to consider uncertainty in making risk management decisions.

Specific Comments;

Page	Section/Paragraph	Comment
3	Section II. PURPOSE AND SCOPE	Need to include Recommended International Code of Practice General Principles of Food Hygiene CAC/RCP 1-1969, Rev. 4 (2003) in this section as a key document.
4	Section III. GENERAL PRINCIPLES "PRINCIPLE 11: Risk Managers should implement additional mitigation steps when Risk Analysis indicates it."	Need to ensure alignment with Principles from other documents and within the risk management document (e.g. page 5, V. 10 animal health should be included in the PRINCIPLE). This principle is unique to this draft guidance (i.e. it does not appear in the document prepared for Agenda Item 5. It is not clear that this principle is necessary as it is already addressed by other principles, for example Principle 10 (Activities of risk management should take into account all work by Codex and work by international organizations on antimicrobial resistance and that Codex Guidelines (GL) and Recommended Code of Practice (RCP) should be fully implemented.)
4	Section IV. IDENTIFICATION OF THE AVAILABLE OPTIONS	There is reference to pre-harvest and post-harvest interventions. However, it is not stated where animal slaughter and processing sits. This section could be re-structured to conform to the areas of responsibility within the Codes of Practice (CAC/RCP 61, 2005; CAC/RCP 1-1969, Rev. 4 (2003)) to provide clarity as to what the available options are that should be implemented and then the new section on additional risk management options (RMO) that could be considered for implementation within each of the areas of responsibility. In other words, the Codes detail what regulatory authorities, veterinarians, animal producers, food producers, retail/distributors, and others should do. Some of these interventions span both pre- and post-harvest, so the continuum concept can be used to ensure that some activity is done at each step of the food chain.
4	"7. With regard to post-harvest, the aim should be to monitor trends in antimicrobial resistance and prevalence of foodborne bacteria and to apply targeted interventions aimed at reducing antimicrobial resistant bacteria of importance to human and animal health."	Monitoring of trends in AMR post-harvest should preferable be integrated into a combined pre and post harvest program in order that the continuum of risk management interventions can be assessed.
4	"8. Risk management options described in the following section may be implemented, at the discretion of national/regional authorities and in a manner that is proportional to the level of risk, based upon the following considerations:"	An additional consideration for choice of risk management options is the ability to measure the response (risk mitigation) to implementation.
4	IVA. Pre-harvest options	Include clear references to animal feed production and AMR determinants as these are included in the scope. Include a discussion of measures to prevent off-label use of antimicrobials in the food animal production section (IVA.2).

5	IVA.1-General "Approval and licensing of antimicrobials used in animals and horticulture b). Approval and licensing of an Antimicrobial may, whenever possible, be subject to the review of existing AMs."	It is not clear what is meant by "subject to the review of existing AMs."
5	IVA.2-Food animal production Restrict extra-label use, especially in Critically important antimicrobials (CIA) for human treatment Perform a bacterial diagnosis and susceptibility testing prior to treatment for a given AM and bacterial infection. Competent authorities and/or professional bodies should elaborate animal (plant & food processing) species-specific prudent use treatment guidelines in consultation with all relevant interested parties. Recommend on different AM to be used, if several antimicrobials can be used for a given indication in an animal. (more comments required). Prophylactic use in healthy animals not considered to be at risk of infection or prior to the onset of clinical infectious disease, should be avoided. (more comments required). Prevent the presence and transmission of foodborne bacteria & determinants between animals and from animals to humans by implementing Animal health and infection control programs against the most important zoonotic AMR agents. Restrict movement of live animals, carrying a specific AMR foodborne pathogen or a bacteria carrying resistance determinant (more comments required : in/out of scope of Codex? OIE remit?). Responsible use in veterinary medicine of antimicrobials of particular importance for human treatment (more comments required : cf. OIE Terrestrial Animal Code). If sufficient evidence exists that profit from the sale of antimicrobials negatively impacts on prescribing practices, appropriate countermeasures should be taken to ensure prudent use. (more comments required :in/out of scope of mandate of Codex? but = WHO global principles on containment of AMR)	A number of the potential risk management options set out in "A.2 Food Animal Production" carry the request for more comments. As a general principle, each risk management option should be supported by evidence that it is likely to be effective and if implemented its effectiveness in risk mitigation should be monitored. It does appear that a number of the presented options reflect belief or policy rather than fact. This is an important area for consideration and requires more time to prepare a detailed and thorough response.
5	IV B. Post-harvest options	Need further discussion/definitions of what is meant by 'control measures' and 'unacceptable level'. This section could include a discussion or mention of general measures to control foodborne bacteria and to prevent contamination as these will likely be the same as those required for AMR bacteria.
6	Section V. Evaluation of Risk Management Options (RMO) "12. Risk management options should be assessed in terms of the scope and purpose of risk analysis and the level of consumer health protection they achieve. The option of not taking any action should also be	The option of not taking any action should be evaluated.

	considered."	
6	"13. Risk management options should be assessed taking into account the options' feasibility, effectiveness, economic implications, enforcement and compliance; they should be proportionate to the amount of risk. The level of control or reduction of risk that is necessary, should be specified, when feasible."	This point could be expanded to include discussion relevant to AMR as these are important points for evaluating RMO. Some description of what is meant by "should be proportionate to the amount of risk" would be helpful.
7	Section VI. Selection of Risk Management Options	Part A of this section is really about risk management approaches and not ALOP. CAC/GL36 -2007 should be featured in this section. The contents of VI. A1-4 needs to be evaluated as to appropriateness for this section. For example, A-3, precautionary approach, is already contained in the Risk Profiling/Risk Prioritization section and, as written, is out of place in this section. Section VI B needs additional editing to better distinguish how it differs from Section VI A. Point 14 could be expanded to include discussion relevant to AMR as this is important discussion of how to select RMO. Point 15 is out of context and could be better placed in the monitoring and implementation section. Point 16 - Various interested parties should also be involved when developing non-regulatory programs. Point 17 is out of context and could be better placed in a different section. Point 18 - This is a good description of evaluation and should be moved to Section V. Point 19 needs more detail and maybe include discussion relevant to AMR. This could include discussion of selecting a mixture of approaches as approaches are not necessarily mutually exclusive. Point 20 - The impact of the measures that are implemented to mitigate the risk should be measured and the results should inform or guide ongoing actions. Point 21 could be expanded to include discussion relevant to AMR as this is important for reaching a decision. Point 21 - The assessment of risk changes associated with a risk management option should consider both reductions in risk as well as increases in risk (e.g. associated with the increased use of an alternative AM or the likelihood of increased incidence of disease). Point 22 and 23 - These points are perhaps better in the risk assessment paper or in the evaluating options section of this paper.
7	Section VII. Implementation of Risk Management Options	Need to coordinate this section with other sections, specifically with Section IV Identification of the

		Available Options. Point 26 - Rewrite this point to focus on having documents and programs that support implementation rather than implying that guidelines have to be followed anyway regardless of the RMO. Also needs expanding to justify the information in Annex 2. Point 29 - It is not clear what is meant here. Point 33 - Add in resistance of pathogens and multiple-resistance of pathogens.
7	Section VIII Monitoring and Review of Risk Management Options	A review of other Codex documents may reveal additional guidance that is appropriate. It is necessary to distinguish between the role of resistance monitoring programs and the monitoring of risk management intervention activities. A revised Risk Assessment may be considered.
8	Annex 1: Possible endpoints g. Prevalence of foodborne pathogens on farms. h. Prevalence of foodborne pathogens in food. i. Prevalence of food borne disease in humans.	In each of the listed endpoints, it is preferable that the foodborne pathogen carry AMR. It is quite possible that changes in foodborne pathogens that are susceptible to antimicrobial agents could greatly confound the results. Include reference to multiple-resistant pathogens.

BRAZIL

General comments;

1. Brazil supports the suggestion made by the Woorking Group regardind the unification of the three documents.

2. Brazil believes that the antimicrobial use in agriculture should be more emphasized in the document CX/AMR 08/02/06 jun.08. So, we consider that it may be necessary to ask to IPCC for some advice.

Specific Comments;

GENERAL PRINCIPLES

PRINCIPLE 10:

Brazil suggests redrafting this principle as follows:

Risk management activities should take into account relevant work by international organizations on antimicrobial resistance.

PRINCIPLE 11:

Brazil suggests deleting this principle.

~~Risk Managers should implement additional mitigation steps when Risk Analysis indicates it~~.

Justification: This is not a principle. It is not necessary at this point. Mitigation steps are part of the the risk management activities and there are provisions about it in all document.

IV- IDENTIFICATION OF THE AVAILABLE OPTIONS

Paragraph 7:

Brazil suggests the following wording for the paragraph 7:

With regard to post-harvest, the aim should be to monitor trends in antimicrobial resistance and prevalence of foodborne pathogens and commensals (in particular Salmonella spp., Campylobacter spp. and Escherichia coli) linked to potential resistance to critically important antimicrobials[1] to human and animal health.

[1] Pag viii *Report of the Joint FAO/WHO/OIE Expert Meeting on Critically Important Antimicrobials, 26–30 Nov. 2007*

Justification: It is necessary the adjustment of the text at the outset harmonized in Brussels and also to the document harmonized by the experts in Report of the Joint FAO/WHO/OIE Expert Meeting on Critically Important Antimicrobials, 26-30 Nov. 2007.

.Paragraph 8. c)

Brazil suggests replacing the verb "should" by the verb "must".

8 c) The selection and implementation of the risk management options must be supported by scientific evidence, be feasible, and reviewable with respect to new scientific information;

Justification: in order to eliminate any doubt on the obligation to take into account the science.

A - Pre- harvest options

A.1 - General

Brazil suggests specifying the acronym MRM or deleting the first M) in the first bullet point.

Brazil suggests the following changes:

a) To include the expression critically important:

Monitoring should, to the extent possible, include all critically important antimicrobials[2] to human and animal health used in food production.

b) To replace bacteria for pathogen:

…account drug/pathogen /animal species relationship;

d) To delete the expression "together with other relevant data"

AMR data should be analyzed with AM usage data to assess possible relationships

A.2 - Food animal production

Second bullet point:

Brazil suggests including, in the beginning of the text, the expression "to the extent possible", so it reads as follows:

- To the extent possible perform a bacterial diagnosis and susceptibility testing prior to treatment for a given AM and bacterial infection.

Third bullet point:

Brazil suggests deleting the word all in the sentence:

Competent authorities and/or professional bodies should elaborate animal (plant & food processing) species- specific prudent use treatment guidelines in consultation with all relevant interested parties.

Fourth bullet point:

Brazil suggests redrafting as follows:

If several antimicrobials can be used for a given indication in an animal, then the critically important antimicrobials should be the last choice.

Fifth bullet point:

Brazil suggests redrafting as follows:

Prophylactic use in healthy animals not considered to be at risk of infection should be avoided.

Sixth bullet point:

Brazil suggests redrafting as follows:

Prevent the presence and transmission of foodborne bacteria & determinants between animals and from animals to humans by implementing Animal health and infection control programs against foodborne pathogens and commensals (in particular Salmonella spp., Campylobacter spp. and Escherichia coli) linked to potential resistance to critically important antimicrobials3 to human and animal health.

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[2] Pag viii *Report of the Joint FAO/WHO/OIE Expert Meeting on Critically Important Antimicrobials, 26–30 Nov. 2007*

[3] Pag viii *Report of the Joint FAO/WHO/OIE Expert Meeting on Critically Important Antimicrobials, 26–30 Nov. 2007*

Seventh bullet point:

Brazil suggests deleting this bullet point since this issue is out of the mandate of Codex.

Eighth bullet point:

Brazil suggests including the expression “critically important antimicrobials”.

Responsible use in veterinary medicine of critically important antimicrobials for human treatment.

Ninth bullet point:

Brazil suggests deleting this bullet point.

~~If sufficient evidence exists that profit from the sale of antimicrobials negatively impacts on prescribing practices, appropriate countermeasures should be taken to ensure prudent use. (more comments required :in/out of scope of mandate of Codex? but = WHO global principles on containment of AMR)~~

Justification: It is necessary to exclude recommendations that are out of the Codex Alimentarius mandate, as for example: price control, profits and economic characterization of countries, as decided for the WG in Brussels meeting.

A.3 – Plant production

Brazil suggests inviting an IPCC representative to discuss this point during the Task Force session.

Bullet point

Brazil suggests to redraft as follows:

“The spread of AMR bacteria through other possible sources of contamination, such as direct use in agriculture of human and animal waste (manure), should be controlled, if there is sufficient evidence of risk and if practical, feasible and supported by science.”

B.- Post-harvesrt options

Third bullet point

Brazil suggests redrafting as follows:

“Avoid the consumption of food containing an unacceptable level of AMR bacteria & AM determinants characterized as a risk for consumers.”

Fourth bullet point

Brazil suggests including “characterized as a risk for consumers”.

Withdraw food containing an unacceptable level of AMR pathogenic bacteria characterized as a risk for consumers from the market for reprocessing or destruction.

V- EVALUATION OF RISK MANAGEMENT OPTIONS (RMO)

Paragraf 13

Brazil suggests replacing the expression “economical implication” by “cost-benefit analysis”.

Risk management options should be assessed taking into account the options’ feasibility, effectiveness, cost-benefit analysis (FAO/WHO/OIE ROME 2007), enforcement and compliance; they should be proportionate to the amount of risk. The level of control or reduction of risk that is necessary should be specified, when feasible.

VI – SELECTION OF RISK MANAGEMENT (RM) OPTIONS

Paragraf 14

Brazil suggests deleting the sentence “Where available, a risk assessment can often help in the evaluation and selection of RM options” and redraft it as follows:

The selection of RM options appointed in/by risk assessment process should be based on their ability to mitigate the risks effectively and on the practical feasibility and consequences of the options.

Paragraf 15

Brazil suggests including the expression “whenever possible” in the beginning of the sentence.

“Whenever possible, the selection should be supported by mechanisms to evaluate success to contain and minimize AMR that may be transmitted through the food chain.”

A. Identifying an appropriate level of consumer health protection

A.3 Replace precautionary for provisional

provisional approach

VIII. – MONITORING AND REVIEW OF RISK MANAGEMENT OPTIONS

Paragraf 30

Brazil suggests including the expression “considering coutries feasibity” in the beginning of the sentence

“Considering countries feasibility a minimum level of monitoring should be established in order to measure usage and risk management effects.”

ANNEX 1 (PAGE 8):

INITIAL SENTENCE

Brazil suggests redrafting as follows:

“In order to monitor the effects of risk management measures and variations in AMR, possible endpoints include:”

Brazil considers that the FAO/WHO/OIE ROME 2007 Meeting (page 28: information that could be used for monitoring the effects of risk management measures) should also be taken into account and incorporated to the annex whenever possible.

ANNEX 2 (PAGE 9)

Brazil suggests inserting the word “suggested” in the title, to read as follows:

“Suggested step wise approach”

CANADA

General Comments;

1. Canada would like to thank the delegation of Denmark and France for revising the draft Guidance on Risk Management to Contain Foodborne Antimicrobial Resistant Microorganisms in accordance with the recommendations of the Working Group which met in Brussels, May 29-30, 2008. Canada appreciates the opportunity to review and provide comments on the revised draft document.

2. Canada is of the view that the current draft has identified several risk management options that could be implemented depending on the legal and operational capacity of national/regional authorities.

3. Canada notes that the revised draft reflects a risk-based approach to the management of antimicrobial resistance (AMR) risks, as strongly emphasized at the Brussels meeting.

4. Canada is of the view that the Task Force should clarify the scope of this guidance document, particularly taking into consideration the content of the proposed draft guidance on risk profiling The Task Force should decide whether these guidelines are to focus on risk management activities after risk assessment is completed or should it entail the overall process of risk management which includes preliminary risk management activities.

5. Canada notes that risk management measures should be taken to achieve the appropriate level of protection. Therefore it is our view that the heading in Part VI; A – Identifying an appropriate level of consumer health protection should be deleted as management options are not intended to identify the appropriate level of protection but rather to achieve it.

Specific Comments;

Purpose and Scope:

6. Paragraph 2: Canada recommends that this paragraph should clearly specify that this guidance is specific for management of foodborne AMR arising from the non-human use of antimicrobials. This section should be consistent with the purpose and scope as discussed in the project document.

7. Paragraph 2: This paragraph indicates that risk management activities may be necessary following risk profiling or risk assessment. As indicated in paragraph 4 above, the Task Force needs to clarify the scope of the document. Should the Task Force decide to limit the scope of this guidance document to those risk management activities that occur after the completion of a risk assessment, then Canada suggests that the paragraph should be modified to reflect the fact that risk management process includes “preliminary risk management activities” and the guidance document on these activities would need to be referenced.

General Principles:

8. Canada is of the view that Principle 11 seems unnecessary and could be deleted.

Identification of Available Options:

9. Paragraph 5, second sentence: hygienic practices to minimize food contamination is also a pre-harvest practice and hence it is suggested to modify the text accordingly. It is also noted that hygienic practices are identified in this paragraph as an option to address post-harvest foodborne contamination but no such activities are actually described in the section under "B. post-harvest options".

10. Paragraph 6, second sentence: it is suggested deleting this sentence in this paragraph or moving it to another section, possibly under "Principles". A legislative basis for regulations and implementation powers is part of a functioning food safety control systems and not a specific pre-harvest risk management activity for AMR.

11. Paragraph 7: "applying targeted interventions for bacteria of animal health importance" is not within the Codex mandate. Hence, Canada suggests that paragraph 7 be revised to include only bacteria of importance to human health.

12. Paragraph 8: d). It is not clear what the word "they" is for: Are the identified risk management options to provide 'additional risk management options to risk managers"?

Pre-harvest options:

13. Monitoring and surveillance, first bullet under A.1: Canada recommends the removal of the description of "this set of measures do not contribute to the reduction of foodborne antimicrobial resistance risk", as it is unnecessary in this context..

14. Approval and licensing of antimicrobials used in animals and horticulture second bullet under A.1: Canada recommends replacing the word horticulture by "plant production".

15. Approval and licensing of antimicrobials, second bullet under A.1: sub-bullet c: Canada is of the view that emphasis should not be placed on only one possible outcome (i.e., "not be authorized") of pre-approval evaluation. This sub-bullet should be modified to include several other possible outcomes of pre-approval assessment; approval, rejection or approval with conditions/restrictions. There are several types of restrictions that can be imposed following approval of antimicrobials by the regulatory agencies (e.g., treatment of individual animals but not for mass medication or prophylactic use. Approval may also be granted only for a short duration treatment).

16. Food animal production, under A.2: First bullet: Restrict extra-label use of CIA: Canada is of the view that this bullet could be expanded to include not only the extra-label use restriction, but also to limit the use conditions for some of the critically important antimicrobials (e.g., restriction to individual treatment of sick animals as prescription-only drug to be used under veterinary supervision, but not for prophylaxis or mass medication).

17. Food animal production, under A.2: fourth bullet "Recommend different AM to be used, if several antimicrobials can be used for a given indication in an animal". Canada notes that this point could be better explained by highlighting the need for professional bodies to develop prudent use guidelines that are species- and disease condition-specific, and that lists the first, second or third line of antimicrobial treatment choices. It should also be mentioned that these specific guidelines should be regularly updated.

18. Food animal production, under A.2: seventh bullet "Restrict movement of live animals ……" maybe outside the scope of Codex and hence Canada suggests deleting this bullet.

19. Food animal production, under A.2: ninth bullet "If sufficient evidence exists that profit from sale of antimicrobials …". In many jurisdictions, there are likely to be regulatory limitations for federal governments to limit the sales of drugs going through the prescriber (e.g., veterinarians).

20. Plant production: It is suggest to include the following additional points in this section:

- Existence of alternatives (chemical and non-chemical)
- How antimicrobials will be used in combination with alternatives (e.g., sole replacement or in alteration);
- Preventative versus treatment purposes;
- Will applications be required at all developmental stages or only at specific stages?
- Restrict extra-label use of antimicrobials, especially of critically important antimicrobials for human treatment;
- A disease threshold at which applying an antimicrobial is considered necessary should be established.

Post harvest options:

21. Post-harvest risk management measures should also include a monitoring and surveillance program for important foodborne pathogens, both susceptible and resistant to specific antimicrobials. Post harvest risk management measures should also cover hygienic practices as they are identified as available options in paragraph 5 of the proposed draft guidelines but are not actually addressed under this section (please see our comments in Paragraph 9 above)

22. First bullet: "Target interventions towards those bacteria that are resistant to antimicrobials of critical importance to public and animal health". This sentence is more of a Principle than a risk management option. It is unclear about the specific risk management action in this sentence. In addition, the sentence can also be expanded to interventions

targeted not only to critically important antimicrobials but additionally to bacteria with multidrug resistance to several classes of antimicrobials.

23. Second bullet: “Implement of control measures to the extent possible”. This sentence appears not a specific post-harvest risk management option. It is suggested that this sentence be deleted. If anything, it should be a principle.

24. Third bullet “Prevent the food containing an unacceptable level of AMR bacteria and AM determinants, reaching the consumer” and the fourth bullet “Withdraw food containing an unacceptable level of AMR pathogenic bacteria from the market for reprocessing or destruction”: Criteria need to be defined to make the implementation of these measures practical, i.e., what constitutes an “unacceptable level”?

Evaluation of risk management options:

25. Paragraph 11. “at National/Regional level” can be deleted.

26. Paragraph 13: Most of this falls under the heading of selection of the risk management options. “Evaluation” and “Selection” sections could be combined.

Selection of risk management options:

27. Canada is of the view that it is necessary to specify in the document that selection of risk management options should be proportionate to the assessed risk, taking into consideration the outcome of the preliminary risk management activities and/or risk assessment, evaluation of available risk management options and social and economic considerations.

28. Paragraph 16 “… developing regulatory programs” should be replaced by “… selecting risk management options”.

29. Sub-heading A.- Identifying a appropriate level of consumer health protection- Canada is of the view that this heading should be deleted since the risk management options should be selected to achieve the ALOP and not the other way around.

30. Paragraph 18. Suggest adding additional description such as: Antimicrobials do not play as important a role in plant health as in animal health as alternatives are often available. Changes in cultural/crop practices that would reduce disease development should be encouraged and adopted.

31. VI sub-heading B. “Reaching a decision on the preferred risk management options” can be reworded as “Selection of preferred risk management options”. Alternatively, it is suggested to delete this subheading.

32. Reaching a decision on the preferred risk management options should also consider factors other than restricting antimicrobial use. Some of the important factors that may be considered include: hygienic food handling practices, reduction of prevalence of pathogens in animals or plant production, implementation of HACCP, etc.

33. Paragraph 23. This paragraph should be moved to pre-harvest options.

Implementation of risk management options:

34. Paragraph 26. For clarity, it is suggested that the sentence be revised to begin with “implementation could follow a stepwise approach’. The revised text would read as follows: Implementation could follow a stepwise approach by including, for example, prudent use guidelines, monitoring of antimicrobial usage and general food hygiene principles.

Annexes:

35. It is noted that Annex 2 is cited in the text before Annex 1.

36. Annex 1: point d should be deleted as it is a repetition of b

37. Canada recommends that Annex 1 should also include (preferably after bullet point k) other adverse health effects such as loss of treatment option and severity of infection (e.g., prolonged duration of illness, increased frequency of bloodstream infections, increased hospitalization, and increased mortality) associated with resistant infection. This Annex could benefit from subheadings.

38. Annex 2: Suggest including growers/grower groups in Step 1 as well as grower groups/grower industry organizations in Steps 2 and 3.

39. Annex 2, step 3 m: Canada suggests the deletion of the phrase “develop new research to” in the second sentence.

COSTA RICA

Costa Rica is grateful for the opportunity to express its comments and wishes to state the following:

1. Costa Rica considers that risk management should be based on existing Codex texts as discussed in the working groups.

2. Principle 5 should be supplemented to read as follows:

PRINCIPLE 5: The activities conducted in all phases of antimicrobial resistance risk management should be transparent, timely, consistent, fully documented, openly communicated, **and technically viable for Codex member countries.**

3. In paragraph 8 c), "debería" should be changed to "debe" to read "la selección e implementación de las opciones de gestión de riesgos **deben** apoyarse con pruebas científicas". *[T.N. This refers to Spanish text only]*

4. Paragraph 9. A.1 c) should read: Authorities should preferably plan in advance the collection* and analysis of data on the dissemination of antimicrobial resistance, antimicrobial usage **and type of animal production management, such as pasture grazing, stall feeding, etc.**

[T.N. Term in the Spanish text changed from "recogida" to "recolección", both translating as "collection"]*

5. Substitute "approval and licensing" with "registration".

6. Section A.2 bullet 2: As such tests are [not*] practical or possible in all countries, we suggest supplementing the text to read: Perform a bacterial diagnosis and susceptibility testing prior to treatment for a given AM and bacterial infection **within the possibilities of each country**. *[* T.N. 'not' seems to have been omitted)*

7. We suggest deleting bullet 5 of Section A.2.

8. We suggest deleting bullet 7 of A.2. as this is outside the scope of Codex.

9. In bullet 8 of Section A.2. we recommend adding **"responsible use in agricultural production"** instead of veterinary medicine, otherwise we would be omitting agriculture, a very important element.

10. We suggest deleting bullet 9 of Section A.9. as good manufacturing practices and good veterinary and agricultural practices should be considered when using medicinal drugs for both veterinary and agricultural purposes.

11. In Section A.3. on page 5, This text on plant production should involve a clear and concise study as animal waste management is very important in biodiversification.

12. On pages 4 and 5, Section A, Pre-harvest should read Pre-production and in Section B Post-harvest should read Post-production so the text reads:

A. – ***Pre-production options***

B. – ***Post-production options***

13. In B, "sanidad animal" should read "salud animal"

[T.N. This refers to Spanish text only: animal health in the English]

14. In Annex 2, Step 1 a. replace "judicious use" with "the use of medicinal drugs or antibiotics under the standards of good veterinary practices".

IRAN

The Iranian committee for Antimicrobial Resistance has reviewed the drafts and consensus has been made on the following comments:

General comments;

1. Antimicrobial resistance is not just a national problem and all of countries and national authorities should work together to solve the problem. An international agreement on antimicrobial usage that enforces the parties to work together and take their decisions and measures mutually under the agreement is a powerful tool. As a future plan, the Task Force may organize for preparing such a protocol in the international and regional levels.

2. Risk communication is one of the important steps in risk analysis. A data bank or a clearing house working under protocol or Task Force can facilitate the exchange of scientific, technical and legal information on antimicrobials and resistant microorganisms as well as the decisions and measures taken on risk assessments and risk managements. Such a bank serves as a means through which required information (including the national strategic plans for antimicrobial usage) is made available for the purpose of risk assessment and profiling process. If any database for antimicrobials exists, it can be improved and adopted for risk profiling and assessment as well.

3. Risk assessment and further actions for risk management on antimicrobial resistance are complex cases that need skilled and trained personnel. International or regional workshops or capacity building programs by FAO/WHO could help the countries which are less skilled in this field to implement legal actions. It is strongly recommended the Task Force coordinate for strengthening of human resources and institutional capacities for appropriate actions in developing

countries (e.g. developing the strategic plans, tracing antimicrobials in food by standard test methods and assessing risks of antimicrobials and resistant microorganisms in food).

4. It is recommended that the titles as well as the method of numbering and bulleting in the three documents to be harmonized.

5. Since in many cases the term of “pathogen” does not cover the meaning of the text, it is suggested “Foodborne pathogens” to be substituted by “Foodborne microorganisms”.

6. “Foodborne” is a more familiar term rather than “acquired from food” which contains all of microorganisms transmitted via food and has been used commonly in food microbiology texts.

7. “Organisms”, “bacteria”, or any other term that means microorganism, should be replaced with “microorganisms”, in order to make harmonization in the whole of the texts.

Specific Comments;

Page 3:

1. Purpose and scope:

The aim of measures of risk management can not be recognized through the structure of this part. It is suggested to add an expression that shows the aim of risk management actions and to make the scope more comprehensible and clear. Inserting an expression same as the title is suggested:

The purpose of the proposed work is to develop appropriate risk management guidance in order to contain and control foodborne antimicrobial resistant microorganisms for national/regional authorities that may be necessary following risk profiling and/or risk assessments.

Page 4:

Para 6:

It is recommended to focus on training as a powerful and important tool in establishing the required elements for risk management. Therefore such a following wording (in bold) is suggested to be included:

Countries should pay particular attention to the establishment of the necessary instruments for approval, registration and enforcement of regulations regarding usage. One of the most important instruments is training with the aim of building up the capacity of those who are involved in risk assessment and management.

Para 8:

In addition to the Codex Codes of Practice describing the role and responsibilities of authorities, it is suggested that other documents that may be useful in risk management options such as “critically important antimicrobial lists developed by national and international groups (e.g. FAO/WHO/OIE and IDF)” be considered.

A. – Pre Harvest options:

A-1. - General:

For making harmonization in results from assessing the efficacy and comparing the effectiveness of new antimicrobials, referring to a set of standard methods such as standards prepared by ISO/TC 212 or CEN/TC 140 is recommended, or at least it should be stated in the paragraph that standard and valid methods have to be used.

Page 5:

- Approval and licensing of an antimicrobial,

Since resistance is not a local problem and resistant microorganisms and resistance determinants could be transferred from one country to another, decisions for approval should be taken according to international or at least regional data, thus such a sentence (in bold) is recommended to be added:

An antimicrobial should be approving considering the international/regional data, especially whenever according to the existing data, resistant microorganisms have been identified the AM should not be authorized.

A-2.- food animal production:

"- Restrict movement of live animals, carrying a specific AMR foodborne pathogen or a bacteria carrying resistance determinant"

According to the GENERAL PRINCIPLES OF THE CODEX ALIMENTARIUS, SCOPE OF THE CODEX ALIMENTARIUS:

"The Codex Alimentarius includes standards for all the principle foods, whether processed, semi-processed or raw, for distribution to the consumer. Materials for further processing into foods should be included to the extent necessary to achieve the purposes of the Codex Alimentarius as defined."

Although "Live Animals" may be used as food it could not be regarded as food or even raw materials for food in itself. It seems that the item is out of the scope of Codex, and is suggested to be deleted from this part.

- The following items are suggested to be added:

- Use of antimicrobials other than treatment (growth promotion or as additive or preservative) should be considered.

- In the case of contamination during food animal production, control measures should be implemented.

Page 6:

B.- Post-harvest options:

Recalling by manufacturer can be an important option, thus it is suggested “recall” to be added to the last item of options as follows:

o Recall/Withdraw food containing an unacceptable level of AMR pathogenic bacteria from the market for reprocessing or destruction

An editing comment!

A. Identifying ~~a~~ an appropriate level of consumer health protection

KENYA

A.2- Food animal production

We would like to inform the committee that we have no objection on the 5th, 9th and 10th bullets stated below

o Prophylactic use in healthy animals not considered to be at risk of infection or prior to the onset of clinical infectious disease, should be avoided.

o Responsible use in veterinary medicine of antimicrobials of particular importance for human treatment (more comments required : cf. OIE Terrestrial Animal Code).

o If sufficient evidence exists that profit from the sale of antimicrobials negatively impacts on prescribing practices, appropriate countermeasures should be taken to ensure prudent use. (more comments required :in/out of scope of mandate of Codex? but = WHO global principles on containment of AMR) .

B.- Post-harvest options

Kenya proposes that the following statements remain without any change s or modification.

o Target interventions towards those bacteria that are resistant to antimicrobials of critical importance to public and animal health

o Implement of control measures to the extent possible;

o Prevent the food containing an unacceptable level of AMR bacteria & AM determinants, reaching the consumer

o Withdraw food containing an unacceptable level of AMR pathogenic bacteria from the market for reprocessing or destruction.

MEXICO

Mexico congratulates the Working Group on the structure and layout of the document.

In Section IV, Part B, Post-harvest options, more details are required on how to target interventions towards those bacteria that are resistant to antimicrobials of critical importance to public and animal health.

We suggest that Annex 1 specify that it also applies to plants or vegetables for human consumption.

In addition, and given that Annex 2 covers a step-wise approach, we suggest working on a priority list of microorganisms known to have developed antimicrobial resistance, in the world.

NEW ZEALAND New Zealand is pleased to offer the following comments in response to the above:

New Zealand acknowledges the endeavours of the physical Working Group and the co-chairs in producing a reworked proposed draft.

New Zealand has withheld its comments until the meeting of Task Force. This is because we support the working recommendation of one integrated guidance document. This approach will probably resolve some issues we have identified as regards risk management overall and the relationship of both risk profiles and risk assessment to it within am AMR risk management framework so we will reserve our comments until the Task Force's deliberation of and response to the recommendation.

Discussion is still required of the specifics of the document but it is now in a format which should facilitate the process. New Zealand would emphasise that the Task Force must keep within both its mandate and that of Codex. Some issues where it appears to be straying outside the mandate have been recognised by the Secretariat such as in A2.

Specific Comments;

While the options listed under 9 are cited as examples, the large number of these may result in this message being lost and subsequently being falsely recognised as having greater authority.

Sections VII and VIII could be, mistakenly in our view, read as relating to adoption of all risk management options rather than selected options.

Para 27 requires to be more in accord with 8a.

Annex 1

e from rather than of foodborne diseases

h consistency with b and d

I incidence rather than prevalence

Annex 2

h and i the ordering of these will be dependant on jurisdictional arrangements in the order in which they can be developed.

NORWAY

Norway takes the opportunity to thank the representatives from Canada, USA and Denmark/France (EC) for successful development of the draft guidance documents.

1. Terms and definition

In the title, objectives and terms of reference (TOR) for the TFAMR, the terms antimicrobial resistance, microorganisms and antimicrobials are applied. Furthermore, in CX/AMR 08/2/4 (Agenda Item 4), page 17, the following definition of antimicrobials (antimicrobial agents) is applied: *Any substance of natural, semi-synthetic, or synthetic origin that at in vivo concentrations kills or inhibits the growth of microorganism by interacting with a specific target.*

The term microorganisms includes bacteria, virus and fungi and the expression antimicrobial agents (consequently) includes antibacterial, antiviral and antifungal drugs. In modern text books in pharmacology the term antibacterial drugs is applied for natural, semi-synthetic and synthetic medicinal substances that kills or inhibits the growth of bacteria (see e.g. Rang and Dale's Pharmacology, 6th edition, 2007, Elsevier Limited). Unless antimicrobial agents in general are to be included in the TFAMR, the term antibacterial drugs should be applied throughout the document. However, when such substances are used for plant protection or as growth promoter, the term antibacterial agents have to be applied because such use is not included in the common definition of drugs. It should be noted that the expression antibacterial drug is applied by e.g. U.S. Food and Drug Administration and the European Medicine Evaluation Agency (EMEA). Furthermore, in the proposed draft guidance documents CX/AMR 08/2/4, CX/AMR 08/2/5 and CX/AMR 08/2/6 the term antimicrobial, leaving agent, is often applied. As antimicrobial (or antibacterial) is not a noun, but an adjective, the wording should be antibacterial drugs and antibacterial agents, respectively.

E.g. CX/AMR 08/2/4 includes a list of definitions. Norway is in favour of only including in this list terms/words that are defined differently in the literature, as those who are performing risk assessment or risk profiling in the field of antibacterial drug resistance should be expected to be familiar with terms such as cross-resistance and co-resistance.

UNITED STATES OF AMERICA

The United States of America is pleased to offer the following comments in response to the Proposed Draft Risk Management Guidance to contain Foodborne Antimicrobial Resistance Organisms (CX/AMR 08/2/6).

General Comments;

1. The United States is grateful to the delegations of Denmark and France for the careful revision of the draft Guidance on Risk Management to Contain Foodborne Antimicrobial Resistant Microorganisms. The draft contains the recommendations of the Working Group which met in Brussels, May 29-30, 2008. The United States appreciates the opportunity to review and provide further comments on the revised draft document.

2. Additional discussion is needed on the use of terminology "foodborne" vs. "acquired from food". "Food" and "food hygiene" have been defined by Codex as being intended for human consumption. Terminology used, either "foodborne" or "acquired from food" should take into account the potential for unrelated bacterial species to transfer resistance determinants while excluding non-food routes of exposure to resistant bacteria or resistance determinants from food to humans, such as zoonotic exposures.

3. Recognizing the consensus of the Working Group in Brussels as described in paragraph 7 under **Proceedings of the working groups**, it may still be necessary to discuss certain aspects of antimicrobial use and veterinary medical practice to adequately describe some risk management options (RMOs).

4. The document would benefit from further identification of supplemental RMOs. These RMOs would be used in addition or as alternatives to the RMOs contained in existing Codes of Practices when monitoring and review of existing RMOs indicates that consumer protection or food safety goals have not been satisfactorily met. Additional RMOs are described below.

5. The process for selecting options should apply either to provisional decisions or to decisions made after the completion of a risk assessment.

6. Risk management should be guided by risk assessment evaluation to the greatest extent possible.

7. Additional discussion would be beneficial to determine whether there is a need to identify risk management options to contain the transmission of AMR bacteria through feed and waste management.

8. The guidance should be clear that supplemental risk management options are not mandatory (discretion of national authorities) and may be implemented only when certain conditions are met.

Specific Comments;

Purpose and Scope:

Paragraph 2. The USA appreciates the relevance of the purpose and scope taken from the original project document. However, taking into account the consensus of the first session of the TF and the inter-session Working Group on certain key elements on the scope and direction of work, this paragraph could be augmented as follows.

Paragraph 2, suggested new first sentence. The purpose of this section of the guideline is to provide advice to national and regional authorities on risk management specific to the containment of foodborne antimicrobial resistant bacteria and resistance determinants arising from the non-human use of antimicrobials that may be necessary following risk profiling and/or risk assessment.

Paragraph 2, suggested new second sentence. Guidance on the identification, evaluation, and selection of risk management options will be provided. In addition, consideration will be given to the implementation of risk management options and how to measure and monitor the effectiveness of the selected risk management options, including establishing a baseline against which subsequent changes can be compared.

Paragraph 4. Recognizing the consensus of the Working Group that the guidance in this document build on existing Codex Codes of Practices and related texts in addition to relevant documents from WHO and OIE this paragraph seeks to make the point and identify the most important works without being an exhaustive list. The USA recommends that in addition to CAC-RCP 61-2005, the main text for pre-harvest, that the Codex Code for Food Hygiene CAC/RCP 1-1969, Rev. 4 (2003) be added representing a main text for post-harvest.

General Principles:

9. Principle 1. The USA recommends adding the following sentence after the first sentence.

Animal health should also be considered when evaluating risk management options to the greatest extent possible.

10. Principle 2. The USA interprets the first sentence "take into account the emergence and dissemination of both resistant foodborne pathogens and resistance determinants through the whole food chain" to follow from the section of the project document that describes "transmission through food and feed of antimicrobial resistant microorganisms and antimicrobial resistance genes" rather than to broaden the scope of exposures to non-foodborne routes of exposure such as zoonotic exposure.

11. The USA believes more discussion is needed before replacing "foodborne" with "acquired from food." It is noted that definitions for food, food hygiene, and foodborne illness accepted by most world bodies focus on consumption as the route of exposure to microorganisms. The following examples are offered.

Codex Procedural Manual, 17th edition. "Food means any substance, whether processed, semi-processed or raw, which is intended for human ***consumption***…"

Codex Procedural Manual, 17th edition. "Food hygiene comprises conditions and measures necessary for… product fit for human ***consumption***."

WHO Fact Sheet #237, March 2007. "Definition of foodborne illness: Foodborne illnesses are defined as diseases, usually either infectious or toxic in nature, caused by agents that enter the body through the ***ingestion*** of food."

CDC Foodborne Illness FAQ. "What is foodborne disease? Foodborne disease is caused by ***consuming*** contaminated foods or beverages."

FDA Food Protection Plan, November 2007. "Principles of the Food Protection Plan Focus on risks over a product's life cycle from production to ***consumption***."

12. Principle 3. The USA recommends deleting the words "acquired from food" for the reasons stated above in 16 and 17.

13. Principle 4. The USA recommends adding the following sentence.

Risk management should be guided by risk assessment evaluation to the greatest extent possible.

14. Principle 10. The USA believes that in order to prevent redundancy with Paragraph 4 in the Purpose and Scope and to focus on full implementation of existing Codes of Practice and other existing standards relevant to antimicrobial resistance the principle should be reworded as follows.

Full implementation of risk management options and interventions described in existing Codex Codes of Practice and relevant sections of the OIE Terrestrial Animal Health Code, such as Section 3.9 Antimicrobial Resistance, to the greatest extent possible should be the goal of national and regional authorities.

15. General Principle 11. The USA believes the principle would be strengthened by more specifically describing when additional risk management options should be implemented. The following replacement sentence is suggested.

Risk managers should consider implementing additional and/or alternative risk management options when monitoring and review of effectiveness indicates consumer protection or food safety goals are not being satisfactorily met.

Identification of the Available Options:

16. It has been suggested that this section of the document would be strengthened by organizing it by areas of responsibilities, similar to CAC-RCP 61. Because some interventions span the pre-harvest and post-harvest portions of the food chain, it has been suggested that this makes more sense and more closely aligns with existing Codex documents. The USA would be amenable to additional discussion on such a proposal.

17. Paragraph 5. The USA suggests minor edits to this paragraph as follows.

Risk management options should consider the production to consumption continuum and could be divided in pre-harvest and post-harvest aspects. Pre-harvest interventions include: Responsible Use Guidelines and Codes of Practice for antimicrobial agents used in food production. Post-harvest interventions include food hygiene practices which minimize foodborne contamination.

18. Paragraph 6. The USA suggests minor edits to this paragraph as follows.

As part of the pre-harvest activities, regulatory authorities should take into account the resistance selection properties of antimicrobials and define use conditions of antimicrobials as part of the approval process. National authorities should pay particular attention to the establishment of the necessary agencies for monitoring, registration and enforcement of regulations regarding antimicrobial usage.

19. Paragraph 7. The USA suggests minor edits to this paragraph as follows.

With regard to post-harvest, the aim should be to minimize and contain AMR bacteria on food. A system to monitor trends in antimicrobial resistance and prevalence of foodborne bacteria should be in place. Targeted interventions aimed at reducing antimicrobial resistant bacteria during food processing should be implemented.

20. Paragraph 8 a). The USA suggests minor edits to this paragraph as follows.

At a minimum, the existing Codes of Practice should be followed. These Codes of Practice describe the respective roles and responsibilities of authorities and groups to minimize and contain antimicrobial resistance:

21. Paragraph 8 a). The USA suggests adding a bullet with the reference to the following Codex Code of Practice related to risk management options for animal feed.

Codex Code of Practice on Good Animal Feeding (CAC/RCP 54-2004)

22. Paragraph 8 b). The USA suggests minor edits to this paragraph as follows.

Implementation of additional and/or alternative risk management options is subject to the needs, resources, legislative, and other constraints of the country/region;

23. Paragraph 8 c). The USA suggests minor edits to this paragraph as follows.

The selection and implementation of the additional and/or alternative risk management options should be supported by scientific evidence, be feasible, and reviewable with respect to new scientific information;

24. Paragraph 8 d). The USA suggests minor edits to this paragraph as follows.

Additional and/or alternative risk management options are intended to supplement the Codex Codes of Practice and related texts (above) and to provide additional risk management tools to risk managers.

25. Paragraph 9. The USA suggests revising this paragraph to emphasize that the RMOs to follow are not present in existing texts and describe when they should be considered.

The following are examples of supplemental risk management options (RMOs) that go beyond those described in existing texts and may be considered by various stakeholders when monitoring and review of effectiveness indicates consumer protection or food safety goals are not being satisfactorily met. These RMOs may be used as an alternative or in combination with RMOs already in place.

Pre-harvest options:

26. Section A.1 Monitoring. It is difficult to say where in the document is the best point to begin discussing the activity of monitoring. CAC/GL 63 in Section 8.1 describes the utility of monitoring with respect to establishing a baseline by which the effectiveness of RMOs may be measured and also points out the utility of monitoring in generating data for a risk profile and also in identifying potential RMOs.

The parenthetical comment acknowledges that this activity does not directly contribute to a reduction in risk, as a specific RMO would be expected to do. As such, it seems out of place under the heading of Identification of Available Options. The details described in a)-d) focus on a monitoring program for collecting antimicrobial use data.

The USA recommends including an expanded discussion about the utility of monitoring in the section on Monitoring and Review of Risk Management Options and retitling this bullet “Antimicrobial use monitoring”.

27. Section A.1 a). The USA recommends replacing “horticulture” with “plants”, “food crops” or other terminology and consistently referring to both food animals and food crops through the document where appropriate.

28. Section A.1 b). The USA recommends the following modification.

monitoring of usage in animals should be compatible with existing monitoring programs taking into account relevant aspects of the drug/bacteria/animal species/food relationship, approved label indications and if appropriate include data collection at the species level and/or category of animal within species.

The level of detail of data collection could be implemented in a stepwise fashion proportionate to the risk, as needed to obtain a consumer protection or food safety goal, or as needed to assess the effectiveness of risk management options.

29. Section A.1 c). The USA recommends the following modification.

authorities should have a statistically designed data collection system to ensure accurate statistical analysis and a means for the dissemination of information on antimicrobial resistance and on antimicrobial usage.

30. Section A.1 d). The USA suggests that the activity of analyzing the data in this section would best be done in the context of a risk assessment. Additional discussion may be needed.

31. Section A.1 Approval and licensing of antimicrobials. The USA recommends including plants or food crops in this section.

32. Section A.1 a). The USA suggests minor edits to this paragraph as follows.

Antimicrobial new animal drugs intended for use in food-producing animals may be subject to monitoring through a post-approval process, such as the National Antimicrobial Resistance Monitoring System (NARMS).

33. Section A.1 b). Approval and licensing of an antimicrobial subject to the review of existing antimicrobials could prove to be difficult. In these situations regulatory authorities may choose to convene an advisory committee to discuss the application. The USA recommends replacing the text with the following.

Advisory committee review: When making an approval decision regarding certain drugs regulatory authorities may choose to convene an advisory committee to discuss the application.

34. Section A.1 c). The USA suggests minor edits to this paragraph as follows.

35. An antimicrobial product should not be authorized if regulatory risk assessment indicates unacceptable levels of risk, as described in the OIE Terrestrial Animal Health Code or by national/regional regulations.

36. Additional risk management options in the approval and licensing of antimicrobials for food animals could include regulatory controls on conditions of use, such as marketing status limitation, extra-label prohibition, extent of use limitation. The level of control could be implemented in a stepwise fashion proportionate to the risk or as needed to obtain a consumer protection or food safety goal.

37. Section A.2 Food Animal Production, first bullet. Restrictions on extralabel use should be included in the previous section as a risk management option. The ranking of Critically Important Antimicrobials (CIA) should be considered as part of a pre-approval risk assessment. The USA recommends deleting this bullet as written.

38. Section A.2 Food Animal Production, second bullet. The USA recommends this bullet be deleted because it conflicts with Paragraph 51 of CAC/RCP 61 and the consensus of the WG in Brussels that the practice of veterinary medicine is outside the scope of the TFAMR. However, replacement points are suggested below that are consistent with portions of the idea in this bullet.

39. Section A.2 Food Animal Production, third bullet. The USA recommends a modification to this bullet as follows. Competent authorities and/or professional bodies should elaborate food animal and food crop species-specific Responsible Use Guidelines in consultation with all relevant interested parties. Responsible Use Guidelines should contain information such as use of culture and susceptibility, breakpoints, and interpretive criteria.

40. Section A.2 Food Animal Production, third bullet. Further, the USA offers an additional bullet to follow the third bullet. National authorities may support the development and dissemination of standards for establishing culture and susceptibility, breakpoints, and interpretive criteria for important pathogens and antimicrobials approved for use in food animals.

41. Section A.2 Food Animal Production, fourth bullet. While the USA does not support the development of national treatment guidelines consistent with the consensus of the WG in Brussels regarding the practice of veterinary medicine, there is recognition that under certain circumstances there could be situations where an extension of a Responsible Use Guideline might meet a national need.

When a specific AMR problem has been identified by a risk assessment/risk profile or through surveillance information, a national treatment guideline could be developed by national authorities in conjunction with national associations of veterinary medicine as a step prior to withdrawing a drug or making a significant label restriction.

42. Section A.2 Food Animal Production, fifth bullet. The USA recommends a modification to this bullet as follows. Prophylactic use in healthy animals should be discouraged. Preventative uses of antimicrobials in groups of food animals known to be “at risk” of developing disease (exposed to pathogens, unusual stress, trauma) are clinically acceptable.

43. Section A.2 Food Animal Production, sixth bullet. The USA recommends a modification to this bullet as follows. Minimize and contain the presence the transmission of foodborne resistant bacteria and resistance determinants from food animals to food and from food to humans by implementing biosecurity and infection control programs.

44. Section A.2 Food Animal Production, seventh bullet. The USA recommends deleting this bullet as it is outside the scope of the TFAMR. The situation described here could be addressed via the OIE Terrestrial Animal Health Code.

45. Section A.2 Food Animal Production, eighth bullet. The USA believes this bullet is redundant with CAC/RCP 61, Paragraph 52, 2nd bullet, 6th element and could be deleted. However, we are aware that some species-specific Responsible Use Guidelines contain such advice.

46. Section A.2 Food Animal Production, ninth bullet. The USA recommends this bullet be deleted because it is unlikely to be feasible and may be outside the remit of Codex.

47. Section A.3 Plant Production. The USA believes that it may be possible to develop some risk management option for plant or food crop production. Likely these would mirror some of those for food animal production, however this area is considerably less well developed than the veterinary applications. As a start, the USA would offer the following suggestions.

Competent authorities and/or professional bodies should elaborate crop species-specific prudent use treatment guidelines in consultation with all relevant interested parties. Prudent use guidelines should contain information such as use of culture and susceptibility, breakpoints, and interpretive criteria.

National authorities may support the development and dissemination of standards for establishing culture and susceptibility, breakpoints, and interpretive criteria for important pathogens and antimicrobials approved for use in crops.

Prophylactic use on healthy crops should be discouraged. Preventative uses of antimicrobials on crops known to be “at risk” of developing disease (exposed to pathogens, unusual stress, trauma) are acceptable.

Prevent the presence and transmission of foodborne resistant bacteria and resistance determinants between crops and from crops to humans by implementing biosecurity and infection control programs.

48. Section A.3 Plant Production, first bullet. The USA believes this RMO, as written, seems to go beyond the scope of Codex and could place a burden on resource-constrained countries or particular industry segments. More information needs to be developed to support this as a viable RMO and additional detail should be supplied to distinguish situations when it may be acceptable and safe to apply manure, etc. Furthermore, a better understanding of the risks should be developed, for example through a risk assessment, in order to establish endpoints for measuring and monitoring the effectiveness of the RMO toward obtaining a level of health protection. The USA would welcome further discussion on this area.

49. Feed contamination with AMR bacteria. The USA believes the Pre-harvest section could benefit from a reference related to risk management options for animal feed, such as the Codex Code of Practice on Good Animal Feeding (CAC/RCP 54-2004). We note that the original project document references "transmission through food and feed of antimicrobial resistant microorganisms and antimicrobial resistance genes".

Post-harvest options:

50. First bullet. The USA recommends a modification to this bullet as follows. Target interventions toward bacterial contamination of food, including bacteria that are resistant to antimicrobials.

51. First bullet. The USA offers an additional bullet to be placed after the first bullet as follows. In addition to the specific process steps (chilling, thermal processing, irradiation, drying, chemical preservation, vacuum or modified atmospheric packaging) described in CAC/RCP 1 5.2.2 national authorities may facilitate the development of novel interventions, such as bacteriophages.

52. Second and third bullets. The USA recommends deleting these bullets as they do not describe a specific risk management option.

53. Fourth bullet. As written, the USA believes this RMO is redundant with RCP1 5.8 which states in part: "Recalled products should be held under supervision until destroyed, used for purposes other than human consumption, determined to be safe for human consumption, or reprocessed in a manner to ensure their safety."

Evaluation of Risk Management Options (RMOs):

54. Paragraph 10. The USA suggests moving this to General Principle 1.

55. Paragraph 11. The USA suggests deleting this paragraph.

56. Paragraph 12 and 13. The USA suggests modifying these paragraphs as follows. Risk management options should be evaluated by risk managers, taking into account the options' feasibility, effectiveness, economic implications, enforcement and compliance; proportionality to the amount of risk, and consumer protection they are expected to provide; and as compared to the option of taking no action. The level of control or reduction of risk that is necessary, should be specified, when feasible.

57. The USA notes the following sections from the FAO Food Safety Risk Analysis #87 that may provide additional useful bullets. The USA would welcome additional comment on how to tailor these to risk management options to contain antimicrobial resistance.

58. In the ideal situation, the following information should be available for evaluating individual or groups of possible risk management options:

- A "menu" of estimates of risk that would result from application of potential risk management measures (either singly or in combination), expressed either qualitatively or quantitatively.
- Estimates of the relative impact of different potential risk management measures (either singly or in combination) on risk estimates.
- Technical information on the feasibility and practicality of implementing different options.
- Benefit-cost analysis of different potential measures, including both magnitude and distribution (i.e. who benefits, who pays the costs).
- WTO SPS implications of different options in international trade situations.

59. Risk managers should establish a process for evaluating risk management options. A desirable characteristic at all levels is an open process that provides opportunities for industry, consumers and other interested parties to provide information, to comment on proposals, and to suggest criteria for choosing preferred options.

60. When evaluating risk management options for microbial hazards in food, regulators should provide as much flexibility as possible in regulatory standards for the industry that is implementing them, as long as the outcome in terms of consumer protection is achieved.

61. Outcome-driven approaches, such as HACCP, include the concept of risk-based targets for control of hazards at particular steps in the food production chain. An ability to develop specific quantitative microbiological metrics – such as food safety objectives (FSOs), performance objectives (POs) and performance criteria (PCs) will assist in evaluating risk management options.

62. **Codex definitions of quantitative microbiological food safety metrics***

- **Food safety objective (FSO)**: The maximum frequency and/or concentration of a hazard in a food at the point of consumption that provides, or contributes to, achievement of the ALOP.

- **Performance objective (PO)**: The maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain that provides, or contributes to, achievement of the ALOP.

- **Performance criterion (PC)**: The effect in frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to provide or contribute to a performance objective.

Metrics are described as: "quantitative expressions that indicate a level of control at a specific step in a food safety risk management system. The term 'metric' can be used as a collective for the risk management terms of food safety objective, performance objective and performance criteria, but also can refer to existing microbiological criteria.

Selection of Risk Management Options:

63. Paragraph 15. The USA suggests modifying the paragraph as follows. The selection of risk management options should be supported by mechanisms to monitor and evaluate effectiveness to contain AMR bacteria that may be transmitted through the food chain.

64. Paragraph 16. The USA recommends deleting this paragraph.

65. The USA notes the following sections from the FAO Food Safety Risk Analysis #87 that may provide additional useful bullets. The USA would welcome additional comment on how to tailor these to risk management options to contain antimicrobial resistance.

66. Risk managers should focus on selecting those measures that have the greatest risk-reducing impact and weigh those impacts against other factors that influence decision-making, including the feasibility and practicality of potential measures, cost-benefit considerations, stakeholder equity, ethical considerations, and creation of countervailing risks such as decreases in the availability or nutritional quality of foods.

67. The concept of ALOP or similar future targets is essential in establishing the linkage between risk management actions and the level of consumer health protection achieved. A range of tools or approaches are available to the risk manager in bridging between practical control measures and level of consumer health protection.

Reaching a decision on the preferred risk management options

68. Paragraph 23. The USA suggests deleting this paragraph because these issues will be dealt with in the risk profiling and risk assessment sections of the document.

69. Paragraph 24. The USA recommends deleting this paragraph because it would be covered in the preapproval of antimicrobials or elsewhere among the identification of risk management options.

70. The USA notes the following sections from the FAO Food Safety Risk Analysis #87 that may provide additional useful bullets. The USA would welcome additional comment on how to tailor these to risk management options to contain antimicrobial resistance.

71. Where possible, risk management should consider the entire continuum from production to consumption, regardless of the number of authorities involved and their respective responsibilities, in order to develop the best management solutions. Any regulatory measures must be able to be enforced on the basis of the national framework of legal and regulatory authorities. However, in some countries, good results have been achieved by adopting measures that are voluntary rather than legally binding.

Implementation of Risk Management Options:

No additional comments.

Monitoring and Review of Risk Management Options:

72. Paragraph 29. The USA believes this paragraph is redundant with paragraph 26 above.

73. Paragraph 30. See comment 30 above related to monitoring antimicrobial usage.

74. Paragraph 31. Harmonization of national resistance monitoring programs is a challenging but important goal. Much work still remains to be done in this regard, however a comment should be developed that supports this goal. Existing Codex Codes of Practice RCP61 and GL63 contain additional information on existing programs and work.

National authorities undertaking new work in the development of such programs should carefully examine existing programs to ensure compatible data collection systems, endpoints, and reporting systems.

75. Paragraph 33. The specific endpoints measured for any given risk management option should relate to elements of the risk assessment and may serve as inputs for revising and updating the risk assessment as well as measuring the effectiveness of the risk management option toward attaining the food safety objective or the appropriate level of protection.

76. Paragraph 33. Note that the order of appearance of the Annexes is reversed.

Risk Communication:

To be harmonized.

Annex 1:

77. See comment 81 above.

Annex 2:

No additional comments.

CONSUMERS INTERNATIONAL

CI would like to thank the delegations of Denmark and France for the excellent job they have done in coordinating the working group for this very contentious part of the Task Force. CI believes that much progress was made at the working group meeting in Brussels, but that much more needs to be done. CI supports the decision in Brussels that this guidance not replace existing codes of practice, but instead should describe the procedure for choosing additional risk management steps needed to control specific identified antimicrobial resistance risks.

General comments:

CI believes that the current draft creates the correct framework for moving forward with the Risk Management Guidance document, but that it needs to be developed further. Many of the comments to the prior draft were not considered at the Brussels meeting and in some cases the current draft does not accurately reflect what was agreed upon in Brussels.

CI is particularly concerned that paragraph 7 under “Proceedings of the working groups” inaccurately describes the agreement made on the scope of the work. CI agrees that there was consensus that the scope of the work is limited to the risk for human health deriving from contamination of the food chain, but strongly disagree that this means that “guidelines on the use of antimicrobials or the regulation of the practice of veterinary medicine” are beyond the remit of the Task Force. The focus of this task force is on antimicrobial resistance arising from non-human antimicrobial use, so placing antimicrobial use or veterinary practice (a major way that antimicrobials are used) beyond the scope will greatly limit the utility of the draft. Where guidelines on antimicrobial use or the regulation of veterinary practice can impact human health related to resistance in the food chain then these are within the scope. The current document repeatedly states that existing codes of practice should be followed and these existing codes make numerous references to guidelines on antimicrobial use and on the regulation of veterinary practice.

At the same time, CI recognises that the aim of these guidelines is not to make risk management decisions on specific drugs or veterinary practices, but instead to lay out the process for making such a decision. The risk management options identified should refer to specific steps that could be taken when a specific drug use or veterinary practice is causing a problem. CI believes that once these guidelines are adopted by Codex then it would be within the remit of this task force or other Codex bodies to make such a recommendation.

CI believes that the codes of practice describe what all countries/regions should do and the identified risk management options in this draft should describe what could be done beyond that to address specific needs. Because of this CI recommends that the options identified should be expanded. In this context, CI recommends that at least a portion of the options be scaled in a stepwise approach to be consistent with paragraph 27 in the current draft. When considering a stepwise approach to implementation, resource limitations must be considered in the context of risk. A greater risk may warrant a greater use of resources to address the problem. Because of this, CI recommends that the stepwise approach be part of the selection of risk management options not just something done during the implementation phase of risk management.

CI recommends that categories of risk management options be placed in a stepwise fashion and that Annex 2 be dropped. Many of the items in Step 3 (the last items to be implemented) in Annex 2 are included in codes of practice, so should be considered Step 1. The stepwise approach in Annex 2 is also inconsistent with other parts of the draft document. For example, by including drug usage monitoring in Step 3, the current annex contradicts the recommendation in paragraph 27 which places drug use monitoring as a something to be implemented as a minimum (Step1).

CI recommends that the current draft be modified to be consistent with the decision in the risk assessment working group that the focus should be on pathogens and determinants acquired from food instead of foodborne pathogens to acknowledged the potential for bacteria to transfer genetic determinants between unrelated bacterial species including those not generally considered foodborne.

Summary of CI's main points:

- The guidance document should describe the process for selecting risk management steps when there is a recognized need for additional controls beyond those recommended in existing codes of practice.
- The scope of the Task Force is on the risk to human health from resistant bacteria and resistance determinants contaminating food, but guidelines on antimicrobial use or veterinary practice are within the remit of the Task Force to the extent that they impact this risk.
- The current identified risk management options are too limited and require further clarification.
- The stepwise approach should be included as part of the identification of risk management options with sub items under specific headings ranked to be commensurate with risk, not as a separate annex.
- The focus should not be on foodborne pathogens, but on resistant pathogens and determinants acquired from food to take account of the potential for unrelated bacterial species to transfer resistance determinants.

Specific recommendations (Tracked changes to draft document will be included in an attached Word Document)

Section II. Purpose and Scope

CI recommends that the purpose and scope be modified to better describe what the document contains. The purpose should be clarified to make it clear that this document describes how to make a decision on managing specific antimicrobial resistance risks, but its aim is not to provide advice about any specific antimicrobial resistance risk. The scope section should mention risk management option identification, evaluation, selection, implementation, and monitoring. The document should also make clear that it could be used by Codex as well as national/regional authorities.

CI recommends the inclusion of an additional sentence in paragraph 2 stating.

The purpose of this guidance document is to describe antimicrobial resistance risk management option identification, evaluation, selection, implementation, and monitoring for use by the Codex Alimentarius and by national/regional authorities.

Section III. General Principles

Foodborne can be deleted before pathogens in Principle 2 as it is included in the phrase food chain.

Section IV. Identification of the Available Options

Paragraph 8. Should be clarified to distinguish between codes of practice and additional options. See changes in draft text.

Paragraph 9. CI recommends that the step wise approach be included here under specific items. Examples of step wise implementation are given in the text. In developing the stepwise approach CI has combined many of the items in the current draft under single headings.

Background[4]:

1. During its First Session (Seoul, Republic of Korea, from 23 to 26 October 2007), the Codex ad hoc Intergovernmental Task Force on Antimicrobial Resistance agreed to undertake new work on the development of Risk Management Guidance to contain foodborne antimicrobial resistant microorganisms, subject to the approval by the 31st Session of the Commission (July 2008).

2. It further agreed to establish a physical Working Group, to be hosted by the European Community and co-chaired by Denmark and France, open to all delegations and observers and working in English, French and Spanish, which would prepare a proposed draft guidance document for circulation at Step 3 and further consideration at Step 4 at the Second Session of the Task Force.

3. The purpose of the proposed work is to develop appropriate risk management guidance for national/regional authorities that may be necessary following risk profiling and/or risk assessments, usually undertaken as described in the Risk Assessment and Risk Profile project documents prepared by the Task Force. Guidance will also be provided on how to measure and monitor the effectiveness of the selected risk management options, including establishing a baseline against which subsequent changes can be measured.

[4] See ALINORM 08/31/42 para. 44-47 & Appendix IV

Proceeding of the working groups

4. Written comments were received from several members (Australia, Brazil, Canada, European Community, Finland, Germany, Japan, United States of America) and observers organizations (FAO (Fishery), IFAH, CI, UECBV, IDF) and were used as the basis a first draft circulated by the end of March 2008.

5. The physical working group was held in Brussels from May 29th to 30th, at the kind invitation of the European Commission. It was attended by Australia, Belgium, Brazil, Canada, Czech Republic , Denmark, Estonia, European Community (Member Organization), Finland, France, Germany, Ireland, Japan, Netherlands, New Zealand, Norway, Philippines, Republic of Korea, Spain, Sweden, Thailand, United States of America, FAO, World Health Organization, Consumers International, International Federation For Animal Health (IFAH), European Livestock and Meat Trading Union (UECBV). The Group was co-chaired by Denmark and France and reviewed the initial draft on the basis of all the written comments received before the session.

6. The working group agreed that its work should build on existing texts, published by WHO, OIE and Codex, and, at this stage, did not support the suggestion in the para. 6 of the project document of revoking existing Codex texts upon the adoption of this Guidance[5]. The working group reviewed the draft in order to identify what additional guidance, beyond the existing framework, was provided and agreed to restructure the document to highlight them.

7. The working group also agreed that the scope of its work was limited to the consideration of the risk for human health deriving from the contamination of the food chain by antimicrobial-resistant bacteria and/or antimicrobial resistance determinants and that other issues, such as specific guidelines on the use of antimicrobials or the regulation of the practice of veterinary medicine, although relevant to some extent in this context, were beyond its remit and has already been adequately addressed by other international organizations with competence in these areas.

8. The working group noted that the scope of its work was not limited to food of animal origin, but should address food of plant origin and food processing; a section was inserted to this effect into the document; however, the working group noted that further comments would be required to cover these issues adequately.

9. The revised version of the proposed draft Guidelines has been prepared by the secretariat of the meeting (see Appendix 1); areas where further comments are required to progress in the elaboration of this paper have been highlighted in Appendix 1. In order to improve readability, the list of possible endpoints (section VIII – para 33) and the components of the stepwise approach (section VII – para 27) have been transferred to separate annexes.

10. References to the documents consulted during the drafting are included, for information, as Appendix 2.

Recommendations to the 2nd session of the Task Force

11. The recommendation of the 3 working groups to the Task Force is that the three working group documents (Guidance on creating a risk profile …, on risk assessment, on risk management options…) could be most usefully read by the intended audiences as an integrated guidance document. With this approach, certain sections such as introduction, definitions, documentation, and risk analysis general principles could be harmonized, resulting in a more consistent and readable guidance document. Furthermore, this approach would allow the inclusion of an overall flowchart that could guide the reader through a range of activities discussed in the three separate but overlapping working group documents. Finally, the integrated document would include a harmonized section on risk communication, which is critical to all activities addressed by the guidance.

12. The Task force may wish to consider the text of the proposed draft Guidelines on risk management to contain foodborne antimicrobial resistant microorganisms, presented in Appendix 1 and advance it through the step procedure of Codex.

Appendix 1

PROPOSED DRAFT GUIDELINES ON RISK MANAGEMENT TO CONTAIN FOODBORNE ANTIMICROBIAL RESISTANT MICROORGANISMS (At step 3 of the elaboration procedure)

I.- INTRODUCTION

1. (to be harmonized)

II.- PURPOSE AND SCOPE

2. The purpose of the proposed work is to develop appropriate risk management guidance for national/regional authorities that may be necessary following risk profiling and/or risk assessments, usually undertaken as described in the Risk Assessment and Risk Profile project documents prepared by the Task Force. The purpose of this guidance

[5] *"Upon adoption of the proposed document, the Codex Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005) and the Codex Recommended International Code of Hygiene Practice for Control of the Use of Veterinary Drugs (CAC/RCP 38-1993) should be revoked or amended as appropriate, to ensure consistency and avoid duplication within the Codex Alimentarius." (see ALINORM 08/31/42 Appendix IV – section 6).*

document is to describe antimicrobial resistance risk management option identification, evaluation, selection, and implementation for use by the Codex Alimentarius and by national/regional authorities. Guidance will also be provided on how to measure and monitor the effectiveness of the selected risk management options, including establishing a baseline against which subsequent changes can be measured.

3. National/regional authorities, in implementing these guidelines, should consider a continuum of possible interventions along the entire food chain, each step of which can reduce risk by minimizing and containing antimicrobial resistant (AMR) microorganisms and resistance determinants.

4. This document should be read in conjunction with the Codex Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC-RCP 61-2005), the relevant sections of the OIE Terrestrial Animal Health Code (2007)[6] and the WHO documents/guidelines on containment of antimicrobial resistance in animals for food[7].

III.- GENERAL PRINCIPLES

PRINCIPLE 1: Protection of human health is the primary objective in antimicrobial resistance risk management.

PRINCIPLE 2: Antimicrobial resistance risk management activities should take into account the emergence and dissemination of both resistant pathogens and resistance determinants through the whole food chain. ("foodborne pathogens" to be modified based on harmonization of the WGs ("acquired from food"))

PRINCIPLE 3: Antimicrobial resistance risk management activities should focus on clearly defined combinations of food, antimicrobial drug (AM), antimicrobial use and the human pathogens and/or resistance determinants acquired from food.

PRINCIPLE 4: Antimicrobial resistance risk management activities should follow a structured approach[8].

PRINCIPLE 5: The activities conducted in all phases of antimicrobial resistance risk management should be transparent, timely, consistent, fully documented and openly communicated.

PRINCIPLE 6: Risk managers should ensure effective consultations with relevant interested parties[9].

PRINCIPLE 7: Risk managers and risk assessors should ensure effective interaction.

PRINCIPLE 8: Risk managers should take into account risks resulting from regional differences in human exposure to AMR microorganisms & determinants from the food chain and regional differences in available risk management options.

PRINCIPLE 9: Antimicrobial resistance risk management decisions should be subject to monitoring and review and, if necessary, revision.

PRINCIPLE 10: Activities of risk management should take into account all work by Codex and work by international organizations on antimicrobial resistance and that Codex Guidelines (GL) and Recommended Code of Practice (RCP) should be fully implemented.

PRINCIPLE 11: Risk Managers should implement additional mitigation steps when Risk Analysis indicates a need.

IV.- IDENTIFICATION OF THE AVAILABLE OPTIONS

5. Risk management options should consider the farm to table continuum and could be divided in pre-harvest and post-harvest aspects. Pre-harvest would contain aspects such as responsible use guidelines and codes of practice documents specifically directed to antimicrobial agents and their use in food production, whereas post-harvest would contain such aspects as food hygiene practices which are specifically directed to foodborne contamination.

6. As part of the pre-harvest activities, appropriate emphasis should be laid on evaluation prior to approval, taking due account of the resistance inducing properties of antimicrobials; emphasis should also be placed on defining use conditions of antimicrobials. Countries should pay particular attention to the establishment of the necessary instruments for approval, registration and enforcement of regulations regarding usage.

7. With regard to post-harvest, the aim should be to monitor trends in antimicrobial resistance and prevalence of foodborne bacteria and to apply targeted interventions aimed at reducing antimicrobial resistant bacteria of importance to human and animal health.

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[6] http://www.oie.int/eng/normes/Mcode/en_sommaire.htm
[7] http://www.who.int/foodborne_disease/resistance/en/index.html
[8] See para. 7 in GL 62-2007.: "*The risk analysis should follow a structured approach comprising the three distinct but closely linked components of risk analysis (risk assessment, risk management and risk communication) as defined by the Codex Alimentarius Commission2, each component being integral to the overall risk analysis*."
[9] *For the purpose of the present document, the term "interested parties" refers to "risk assessors, risk managers, consumers, industry, the academic community and, as appropriate, other relevant parties and their representative organizations"*.

8. Risk management options described in the following section may be implemented, at the discretion of national/regional authorities and in a manner that is proportional to the level of risk, based upon the following considerations:

a). as a minimum, the existing Codes of Practice should be followed. These codes of practice describe the respective roles and responsibilities of authorities and groups to minimize and contain antimicrobial resistance:

- Codex Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005),
- Codex Recommended International Code of Hygiene Practice for Control of the Use of Veterinary Drugs (CAC/RCP 38-1993),
- Codex Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63- 2007), and
- Food Hygiene Basic Text – Recommended International Code of Practice General Principles of Food Hygiene (CAC/RCP 1-1969) and its annex on Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for Its Application.

b). Implementation of additional options is subject to the needs, resources, legislative, and other constraints of the country/region;

c). The selection and implementation of the additional risk management options should be supported by scientific evidence, be feasible, and reviewable with respect to new scientific information;

d). Additional risk management options are intended to supplement the Codex Codes of Practice and related texts (above).

e). Examples of potential risk management (RM) options (used either alone or in combination) available for Codex or regions/countries, as appropriate are listed below in the rest of this section. . In some cases options are described in a stepwise approach allowing for staged implementation as needed. Step 1 options may be easier to implement with Step 3 options requiring the most resources. Which steps to take will depend on resources and needs of country/region choosing this option.

A.- Pre-harvest options

A.1- General

- Monitoring and surveillance of the use of antimicrobials in animals and horticulture (this set of measures do not contribute to the reduction of foodborne antimicrobial resistance (AMR) risk – Monitoring is essential to establish a baseline for comparing the effectiveness of new MRM activities. It also may provide information which the manager may use to determine what steps may be taken to achieve further improvements in the extent or efficiency of risk mitigation {CAC/GL 63 – 2007, page 9})

a). monitoring should, to the extent possible, include all antimicrobials used in food production

b). monitoring of usage in animals should be at species level and if possible also on category of animal within species & take into account drug/bacteria/animal species relationship;

c). authorities should preferably plan in advance the collection and analysis of data on the dissemination of antimicrobial resistance and on antimicrobial usage.

d). AMR data should be analyzed with AM usage data together with other relevant data to assess possible relationships.

e). Steps in implementing drug use data collection

Step 1. Data collected through voluntary surveys and sentinel sites.

Step 2. National sales data collection.

Step 3. Data collected at farm level through mandatory prescription reporting.

- Approval and licensing of antimicrobials used in animals and horticulture

a). Approval and licensing of an Antimicrobial may, whenever possible, be subjected to the monitoring of the use of this AM and of the AM resistance.

b). Approval and licensing of an Antimicrobial may, whenever possible, be subject to the review of existing AMs.

c). Steps used in approval and licensing

Step 1.Unrestricted marketing status (OTC), Off-label therapeutic use allowed, Herd wide or farm wide use allowed

Step 2. Restricted marketing status, restrict off-label use, limit use to individual animals or plants, label requirement for bacterial diagnosis and susceptibility test before use, restrict prophylactic use.

Step 3. Refusal to approve or withdraw existing approvals.

A.2- Food animal production

- Development of prudent use and treatment guidelines

Step 1. Competent authorities and/or professional bodies should elaborate animal species-specific prudent use guidelines in consultation with all relevant interested parties.

Step 2. Competent authorities and/or professional bodies should elaborate animal species-specific and disease specific treatment guidelines.

Step 3. Regulatory authorities monitor veterinary practice and take action when guidelines not followed.

- Prevent the presence and transmission of foodborne bacteria & determinants between animals and from animals to humans by implementing Animal health and infection control programs against the most important zoonotic AMR agents.

Step 1. Producer education on management to reduce antibiotic use and the presence of resistant pathogens on farm. Competent authorities identify problems contributing to greatest antibiotic use.

Step 2. Create financial incentives for producers supplying animals with fewer pathogens and lower resistance at slaughter.

Step 3. Restrict movement of live animals, carrying a specific pathogen carrying specific resistance determinant known to create public health risk. Require pathogen reduction programs and reduced antibiotic use at farm level.

- Control advertising and profits from sale of antimicrobials when this negatively impacts on prescribing practices.

Step 1. Limit advertising for antimicrobials to labelled indications

Step 2. Create financial incentives for veterinarians to reduce antimicrobial use, Black box warnings on antimicrobial products.

Step 3. Prohibit profits from sales of antimicrobials by veterinarians.

A.3- Plant production

- Development of prudent use and treatment guidelines

Step 1. Competent authorities and/or professional bodies should elaborate species-specific prudent use guidelines in consultation with all relevant interested parties.

Step 2. Competent authorities and/or professional bodies should elaborate species/cultivar-specific and disease specific treatment guidelines.

Step 3. Regulatory authorities require licensed pesticide applicators follow guidelines and take action when guidelines not followed.

- Prevent the presence and transmission of foodborne bacteria & determinants between plants and from plants to humans by implementing plant health and infection control programs against the most important plant transmitted AMR agents.

Step 1. Research and producer education on management to reduce antibiotic use and the presence of resistant pathogens on farm. Develop disease resistant cultivars.

Step 2. Create financial incentives for reducing pathogens and resistance at slaughter.

Step 3. Restrict movement of plants, carrying a specific pathogen that also carries specific resistance determinant known to create public health risk.

A.4 Feed production

- Prevent the presence and transmission of AMR bacteria and determinants in feed intended for food animals.

Step 1. Voluntary feed contamination programs with monitoring of feed for AMR pathogens

Step 2. Mandatory process controls or HACCP for feed protection with AMR bacteria or determinants as hazard.

Step 3. Recall for further processing feed and feed ingredients known to be contaminated with specific pathogens containing specific resistance determinants of concern.

- A.5.Waste management

- Controlling the spread of AMR bacteria through manure and other agricultural wastes..

Step 1. Prohibit the use of raw manure as livestock feed or for fresh produce production. Require management plans to limit the contamination of water used for irrigation.

Step 2. Require HACCP plans for fresh produce production that includes monitoring for AMR pathogens in water and the production environment.

Step 3. Prohibit the use of manure containing specific AMR pathogens in food production without a pathogen reduction step.

B.- Post-harvest options

- Target interventions towards those bacteria that are resistant to antimicrobials of critical importance to public and animal health
- Implement of control measures to the extent possible;
- Prevent the food containing an unacceptable level of AMR bacteria & AM determinants from reaching the consumer

Step 1. Voluntary pathogen control measures in food production

Step 2. Require GMPs or HAACP plans include controls on specific resistant bacteria of concern

Step 3. Prohibit shipment of food or recall food known to be contaminated with specific pathogens containing specific resistance determinants of concern.

V.- EVALUATION OF RISK MANAGEMENT OPTIONS (RMO)

10. Animal health should also be considered when evaluating risk management options, to the extent possible, consistent with the requirement of GENERAL PRINCIPLE 1.

11. Evaluation of the identified Risk management options should be performed at National/ Regional level.

12. Risk management options should be assessed in terms of the scope and purpose of risk analysis and the level of consumer health protection they achieve. The option of not taking any action should also be considered.

13. Risk management options should be assessed taking into account the options' feasibility, effectiveness, economic implications, enforcement and compliance; they should be proportionate to the amount of risk. The level of control or reduction of risk that is necessary, should be specified, when feasible.

VI.- SELECTION OF RISK MANAGEMENT (RM) OPTIONS[10]

14. The selection of RM options should be based on their ability to mitigate the risks effectively and on the practical feasibility and consequences of the options. Where available, a risk assessment can often help in the evaluation and selection of RM options.

15. The selection should be supported by mechanisms to evaluate success to contain and minimize AMR that may be transmitted through the food chain.

16. The various interested parties should be involved when developing regulatory programs.

A.- Identifying a appropriate level of consumer health protection[11]

17. Risk management decisions on appropriate options should be achieved by considering and integrating all evaluation information obtained from preliminary risk management activities and/or the risk assessment.

A.1- Benefit-risk approach

18. Because antimicrobials play a major role in animal health, animal health should be considered when evaluating risk management options, but this must be considered secondary to protecting consumers. When evaluating restrictions on the use of antimicrobial products it is necessary to consider substitutes or alternative practices that would reduce the need for the product. Substitutes could be other less important antimicrobials, non-antimicrobial products, or changes in livestock husbandry that promote animal health. The impact of reduced antimicrobial resistance on animal health should also be considered when evaluating restrictions on antimicrobial use.

[10] CAC/GL 63 – 2007 provides general guidance on the selection of risk management options (sections 4 & 6).

[11] "Appropriate Level of Protection" (ALOP). ALOP is defined in the SPS Agreement as "the level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory". ALOPs may range from general to specific depending upon the level of information available with regards to the source of hazards and risks and will depend on the public health goals.

A.2- Threshold approach

19. Given the geographic variations in the levels of resistance and the increasing emergence of resistance, it may be necessary to explore the need to develop resistance thresholds for specific antimicrobial-species-pathogen combinations, above which any of a range of risk management options may be triggered. However, this approach needs to be carefully assessed as it should be put in perspective with the current use of antimicrobials and the current level of resistance.

A.3- Precautionary approach:

20. When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, it may be appropriate for countries to select a provisional decision, while obtaining additional information that may inform and if necessary modify the provisional decision. In those instances, the nature of the provisional decision should be communicated to all interested parties and the timeframe or circumstances under which the provisional decision will be reconsidered (e.g. reconsideration after completion of a risk assessment) should be articulated when the decision is communicated initially.

A.4- ALARA approach

21. (Further comments to be submitted by Philippines)

B.- Reaching a decision on the preferred risk management options

22. The decisions should be based on risk assessment and taking into account, where appropriate, other legitimate factors relevant to health protection of consumers and for the promotion of fair practice in the food trade[12].

23. Cross-resistance, co-resistance, and extended co-resistance issues should be considered.

24. control measures may be placed on the use of specific antimicrobial agent in some species or some route of administration or specific production processes (see GENERAL PRINCIPLE 3)

VII.- IMPLEMENTATION OF RISK MANAGEMENT OPTIONS

25. Risk managers should develop an implementation plan that describes how the options will be implemented, by whom, and when.

26. National/regional authorities should ensure an appropriate regulatory framework and infrastructure.

27. Prudent use guidelines, monitoring of antimicrobial usage and general food hygiene principles should be implemented as a minimum; additional measures could be envisaged following a stepwise approach commensurate with risks and resources available.

VIII.- MONITORING AND REVIEW OF RISK MANAGEMENT OPTIONS

28. Governments should define an evaluation process to assess whether the risk management options have been properly implemented and an assessment whether or not an outcome has been successful (see also GENERAL PRINCIPLES).

29. Monitoring and surveillance should be supported by regulation and the enforcement of control measures

30. A minimum level of monitoring should be established in order to measure usage and risk management effects.

31. Monitoring schemes should be harmonized (RCP 61 & GL 63) between countries, to the extent possible (in a general consideration about sharing info between countries; more comments are requested on this issue & review OIE Terrestrial Animal Code for existing wording).

32. risk management options should be reviewed and evaluated, regularly, or at a predetermined moment in time, or whenever new relevant information becomes available

33. A variety of endpoints (see Annex 1) may be measured with respect to antimicrobial resistance. Endpoints related to specifically implemented risk management options should be measured to assess the effectiveness and need for potential adjustment.

34. Additional endpoints may be measured to identify new information (e.g., emerging hazard, virulence of a pathogen, prevalence and concentration in foods, sensitivity of sub-populations, changes in dietary intake patterns,...).

IX.- RISK COMMUNICATION

35. (to be harmonized)

Annex 1: possible endpoints (exposure end points to be separated from adverse health effect end points)

(refers to section VIII – para 38)

[12] WPRAC para 28, 2nd sentence

In order to monitor variations in AM usages and AMR and the effects of risk management measures, possible endpoints include:

a. Nature and extent of antimicrobial resistance.

b. Nature and extent of antimicrobial resistance in animal-derived food products at retail level.

c. Prevalence of antimicrobial-resistant bacteria on farm level.

d. Prevalence of antimicrobial-resistant bacteria in animal-derived food products at retail level.

e. Prevalence of antimicrobial-resistant bacteria or resistant genes in human clinical isolates of foodborne diseases.

f. Development of new bacterial resistance patterns.

g. Prevalence of foodborne pathogens on farms.

h. Prevalence of foodborne pathogens in food.

i. Prevalence of food borne disease in humans.

j. Number of deaths attributable to foodborne antimicrobial-resistant bacteria.

k. Number of treatment failures attributable to foodborne antimicrobial-resistant bacteria.

l. Frequency of human infections attributable to foodborne antimicrobial-resistant bacteria.

m. Frequency of adverse human health effects attributable to foodborne antimicrobial resistant bacteria.

n. Mortality due to foodborne antimicrobial-resistant bacterial infections in “vulnerable populations”.

o. Level of awareness of antimicrobial resistance risk (producers, consumers, industry and others).

p. Level of compliance with specific drug use restriction or compliance with prudent use guidelines.

q. Trends in usage of antimicrobials in food-producing animals.

r. Trends in usage of critically important antimicrobials (CIA) in food-producing animals.

Annex 2

step wise approach

(refers to section VII – para 32)

Step 1

a). Ensure adequate veterinarian (or equivalent animal health professionals) coverage for the country, veterinarian training in judicious/appropriate/responsible antimicrobial use and animal production practices, and appropriate involvement in food production and food safety processes.

b). Ensure adequate infrastructure for food production/food hygiene with respect to existing Codex standards and guidelines.

c). National authorities should capitalize upon regulatory precedents and expertise of “peer” authorities in the region when capabilities are limited.

d). Communicate to the public the necessity of proper food preparation and hygiene.

Step 2

e). Implement responsible use guidelines via professional veterinary organizations.

f). Ensure reliable national food safety authority oversight of food safety activities consistent with Codex food hygiene guidance.

g). Implement adequate infrastructure and enforcement capacity to ensure compliance with quality product availability and veterinary involvement in antimicrobial usage.

h). Implement local/regional surveillance programs for foodborne disease.

Step 3

i). Implement national surveillance programs for foodborne disease.

j). Implement national resistance monitoring program, and where possible, usage monitoring.

k). Implement regulatory review of new antimicrobial agents prior to product approval.

l). Work in collaboration with food producing companies to maintain vigilance for implementation of food hygiene practices (i.e. HAACP) that safeguard against food contamination.

m). Work with professional associations (e.g. veterinary profession, species specific groups, etc.) to ensure compliance with responsible use guidelines by all members. Implement research programs to develop new research to fill data gaps that will improve antimicrobial use practices, or minimize the need for antimicrobial use by preventing disease, etc.

n). Encourage animal health companies to develop products that will avoid resistance selection of currently used human use antibiotic classes.

Appendix 2

REFERENCES

Codex. 1969. Recommended international code of practice general principles of food hygiene. CAC/RCP 1-1969, Rev. 4-2003.

Codex. 1993. Recommended international code of practice for control of the use of veterinary drugs. CAC/RCP 38-1993.

Codex. 2005. Code of practice to minimize and contain antimicrobial resistance. CAC/RCP 61-2005.

Codex. 2007. Report of the 1st session of the Codex ad hoc intergovernmental task force on antimicrobial resistance. Seoul, Republic of Korea. 23-26 October 2007.

FAO/OIE/WHO. 2008. Joint FAO/WHO/OIE Expert Meeting on Critically Important Antimicrobials Report of the FAO/WHO/OIE Expert meeting, FAO, Rome, Italy, 26–30 November 2007. http://www.fao.org/ag/agn/agns/files/Prepub_Report_CIA.pdf.

OIE. 2007. Terrestrial Animal Health Code (2007) Appendices 3.9.1-3.9.4. http://www.oie.int/eng/normes/mcode/en_titre_1.3.htm.

WHO. 2000. Global principles for the containment of antimicrobial resistance in animals intended for food. WHO/CDS/CSR/APH/2000.4

WHO. 2001. Global strategy for containment of antimicrobial resistance. WHO/CDS/CSR/DRS/2001.2

IDF

General comments;

IDF would like to congratulate to Chairs of the three TFAMR physical Working Groups for the excellent work done as is reflected in the resulting Codex documents CX/AMR 08/2/4, CX/AMR 08/2/5 and CX/AMR 08/2/06.

IDF supports the proposal to merge the 3 documents into one with the objective of providing coherent and harmonized Codex guidance on the risk analysis process with regard to foodborne antimicrobial resistant microorganisms. IDF would like to propose using the wording that can be found in CX/AMR 08/2/4, para. 3 (section “Background”) as a common introduction to explain the purpose and scope of the document.

Specific comments;

Page 4, IV.- IDENTIFICATION OF AVAILABLE OPTIONS, para., last sentence

IDF proposes to amend the last sentence as follows:

Preharvest would contain aspects such as responsible use guidelines and codes of practice documents specifically directed to antimicrobial agents and their use in food production ~~whereas.~~ Post-harvest would contain ~~such~~ aspects ~~as food hygiene practices which are~~ specifically ~~directed to foodborne contamination~~ contributing to the contamination of food by resistant bacteria such as food hygiene practices for handling and avoiding cross contamination.

Page 5, : A.2 Food animal production, first bullet point

“Restrict extra-label use, especially in critically important antimicrobials (CIA) for human treatment”

IDF would like to point out that the “Cascade system” provides a legal mechanism allowing veterinary surgeons to use their clinical experience and qualified judgement to prescribe a suitable medicine where no authorized medicine exists. In some cases, like for small ruminants such as sheep and goats, this may sometimes be the only option for correct treatment. Therefore, legal flexibility is necessary and should be available together with very strict guidance and rules and referring to the responsibility and supervision of the veterinarian.

IDF proposes to amend the respective bullet point to read:

~~Restrict extra-label us~~ Specific guidance should be provided for extra-label use, especially in critically important antimicrobials (CIA) for human treatment.

Page 5, A.2-Food animal production, 5th bullet point

"Prophylactic use in healthy animals not considered to be at risk of infection or prior to the onset of clinically infectious disease, should be avoided."

IDF would like to point out that in dairy animals, especially in case of dry cow treatment (prevention of mastitis), prophylactic use may avoid heavy treatment during lactation. IDF would like to re-emphasize that the dairy sector undertakes extensive testing of on-farm and ex-farm milk to ensure that unacceptable residues are not present. Raw milk that is detected positive with regard to the presence of antibiotics is not used for further processing and the respective dairy farmer will be subjected to a penalty payment. This practice is not only important with respect to food safety/human health but also in view of enabling the fermentation process to take place in the further processing of milk. The dairy sector works actively to reduce antimicrobial resistance and to keep it as low as possible in mastitis pathogens through on going active surveillance in many countries.

IDF proposes to amend the bullet point to read:

Prophylactic use of antimicrobials in healthy animals not considered to be at risk of infection or prior to the onset of clinical infectious disease, should be generally avoided. Prophylactic use may be considered on a case-by-case basis taking into account the specific production scenario and the availability and application of appropriate risk management strategies to minimize and contain antimicrobial resistant animal pathogens and other foodborne bacteria.

Page 7, **VI. – SELECTION OF RISK MANAGEMENT (RM) OPTIONS**, A.4 – ALARA approach

This paragraph is yet to be developed and is intended to provide guidance on the use of As Low As Reasonably Achievable (ALARA) approach in risk management. In doing so, it should be kept in mind that the standards should be established at levels that are adequate to address food safety concerns and at the same are not more stringent than necessary for this purpose.

The Codex Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC/GL 62-2007) indicate that (quote) When making a choice among different risk management options, which are equally effective in protecting the health of the consumer, the Commission and its subsidiary bodies should seek and take into consideration the potential impact of such measures on trade amongst its Member countries and select measures that are no more trade-restrictive than necessary.

Page 7, **VIII.-MONITORING AND REVIEW OF RISK MANAGEMENT OPTIONS**, para. 30

IDF would like to propose using the respective wording that can be found in the Principles and Guidelines for the Conduct of Microbiological Risk Management CAC/GL-63 (2007). Accordingly, the text should read:

Countries should work towards harmonisation of surveillance definitions and reporting rules, protocols, and data management systems, to facilitate comparison between countries of incidence and trends of the illnesses and microbiological data in the food chain.

Page 9, **Annex 2**, Step 1, bullet point b

There is a need to mention communication and training towards farmers. IDF proposes to introduce an additional bullet point c:

c). Ensure training, awareness and communication on prudent use of veterinary drugs for farmers and persons handling food animals.

IFAH

IFAH is pleased to provide the following suggestions for revision and comments on specific sections as requested by the Working Group on Risk Management. IFAH has used brackets [ ] to indicate a bullet point or section which has been edited or commented upon, and providing some rationale for the action.

GENERAL COMMENTS;

- Risk Management is guided by Risk Assessment evaluation
- Risk Management encompasses Codes of Practice for Antimicrobial Use and Food Hygiene
- Risk Management Options that are outside the scope of the WG include: clinical practice guidelines. Environmental waste management is also beyond the mandate of Codex.

- Supplemental Risk Management Options are not mandatory (discretion of national authorities) and may be implemented only when certain conditions are met.

IFAH is of the opinion that Section IV would be greatly improved if it were entirely revised as indicated

SPECIFIC CMMENTS;

I.- INTRODUCTION

9. (to be harmonized)

II.- PURPOSE AND SCOPE

10. [The changes in this section have been proposed to improve clarity]The purpose of the proposed work is to develop appropriate risk management guidance for national/regional authorities that may be necessary following risk profiling and/or risk assessments~~, usually undertaken as described in the Risk Assessment and Risk Profile project documents prepared by the Task Force~~. Guidance will also be provided on how to measure and monitor the effectiveness of the selected risk management options, including establishing a baseline against which subsequent changes can be compared ~~measured~~.

11. National/regional authorities, in implementing these guidelines, should consider a continuum of possible interventions along the entire food chain, each step of which can reduce risk by minimizing and containing antimicrobial resistant (AMR) microorganisms and resistance determinants.

12. [The changes in this section have been proposed to improve clarity and to add the Code of Food Hygiene document which was omitted]This document should be read in conjunction with the Codex Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC-RCP 61-2005), the Codex Code of Food Hygiene (CAC/RCP 1-1969, Rev. 4 (2003)), the relevant sections of the OIE Terrestrial Animal Health Code (2007)[13] and the WHO documents/guidelines on containment of antimicrobial resistance in animals for food[14].

III.- GENERAL PRINCIPLES

PRINCIPLE 1: [The changes in this section have been made to incorporate the added sentence from page 5, V. 10) that refers to this Principle. Balance is needed per Terms of Reference. Protection of human health is the primary objective in antimicrobial resistance risk management. Animal health should also be considered when evaluating risk management options, to the greatest extent possible.

PRINCIPLE 2: [IFAH suggests the following Principle be deleted for clarity because it is redundant with Principle 3 below] ~~Antimicrobial resistance risk management activities should take into account the emergence and dissemination of both resistant foodborne pathogens and resistance determinants through the whole food chain~~. ("foodborne pathogens" to be modified based on harmonization of the WGs ("acquired from food"))

[Comment: The matter of whether language should be adopted that reads food borne vs. acquired from foods requires additional comment. IFAH is of the opinion that food borne has a long history of acceptance within Codex Alimentarius and should remain the operative phrase to describe food as the vehicle for transmission by human consumption of contaminated food to the consumer. It is unclear why it is necessary to introduce new terminology since occupational exposure from handling of animals or food products is not within the scope of Codex. The Codex Procedure Manual, 17th ed., page 41definition for FOOD states "intended for human consumption" and the definition for FOOD HYGIENE is worded "…conditions and measures……to ensure a safe…..product fit for human consumption." The newly suggested phrase "acquired from food" could be interpreted broadly so as to mean food is a fomite (transmission to humans via direct contact with an inanimate object). In other words, mere physical contact with food (such as handling a carcass or possibly even a live animal or its environment, spoilage, etc.) would be included within this definition. The mandate of Codex, and the Task Force, is clear and that is to focus on consumption of food as a vehicle for transmission of AMR bacteria to the consumer. We recommend that the guidance clearly reinforce the route of exposure as food borne, as indeed the Title of the guidance indicates.]

PRINCIPLE 3: [The changes in this section have been proposed to improve clarity] Antimicrobial resistance risk management activities should focus on clearly defined combinations of food animal species, food, antimicrobial drug (AM), antimicrobial use and the human zoonotic pathogens and/or resistance determinants. ~~acquired from food.~~

PRINCIPLE 4: Antimicrobial resistance risk management activities should follow a structured approach[15].

PRINCIPLE 5: The activities conducted in all phases of antimicrobial resistance risk management should be transparent, timely, consistent, fully documented and openly communicated.

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[13] http://www.oie.int/eng/normes/Mcode/en_sommaire.htm
[14] http://www.who.int/foodborne_disease/resistance/en/index.html
[15] See para.7 in GL 62-2007.: "*The risk analysis should follow a structured approach comprising the three distinct but closely linked components of risk analysis (risk assessment, risk management and risk communication) as defined by the Codex Alimentarius Commission2, each component being integral to the overall risk analysis.*"

PRINCIPLE 6: Risk managers should ensure effective consultations with relevant interested parties[16].

PRINCIPLE 7: Risk managers and risk assessors should ensure effective interaction.

PRINCIPLE 8: Risk managers should take into account risks resulting from regional differences in human exposure to AMR microorganisms & determinants from the food chain and regional differences in available risk management options.

PRINCIPLE 9: Antimicrobial resistance risk management decisions should be subject to monitoring and review and, if necessary, revision.

[Note: Principle 10 is redundant with Section II, No. 4 which lists Codex, OIE, and WHO documents and may therefore be deleted for clarity; however, if it is needed as a Principle, the following wording is provided to improve clarity]

~~PRINCIPLE 10: Activities of risk management should take into account all work by Codex and work by international organizations on antimicrobial resistance and that Codex Guidelines (GL) and Recommended Code of Practice (RCP) should be fully implemented.~~

PRINCIPLE 10: National authorities should implement, as much as possible, the Codex Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC-RCP 61-2005), the relevant sections of the OIE Terrestrial Animal Health Code (2007)[17] , the Codex Code of Food Hygiene (CAC/RCP 1-1969, Rev. 4 (2003)) and relevant WHO documents/guidelines on containment of antimicrobial resistance in food animals[18].

PRINCIPLE 11: [The changes in this section have been proposed to improve clarity] Risk Managers should implement additional or alternative mitigation steps when monitoring and reviewing of effectiveness ~~Risk Analysis~~ indicates ~~it~~.that consumer protection or food safety goals have not been satisfactorily met

IV.- IDENTIFICATION OF THE AVAILABLE OPTIONS

[NOTE: IFAH proposes an Alternate Format for Section IV of the Risk Management document. After an extensive comparison to the main Codes of Practice (see below in section 3), it appears that the decision taken in Brussels to separate the risk management options on the basis of Pre-harvest and Post-harvest interventions is incompatible with the format already established in the Codes of Practice. In the existing Code of Practice documents, the convention has been to identify those stakeholders or groups that are responsible for implementing the intervention and providing further direction to them. While IFAH agrees that a continuum of risk management interventions extending from pre-harvest through post-harvest is desirable, the wording in the current Section IV is difficult to match to the existing Codes of Practice with regard to which group should perform what activity. Furthermore, as supplemental interventions are considered, it is difficult to separate some of the activities into pre- or post-harvest categories. There is no obvious reason why it is necessary to re-iterate the existing Codes of Practice when they can be referenced (and a URL provided), easily accessed online by anyone, easily distributed and read in their entirety, instead of being incompletely paraphrased as done at present. Thus, to eliminate confusion, IFAH proposes that Section IV can be streamlined to the four bullet points below to indicate those key documents which are to be implemented as a "minimum" intervention by national authorities and the organizations listed.

In addition, after deleting redundant interventions (i.e. those already contained within the Codes of Practice) from Section IV or those that were determined to be outside the remit of the TFAMR, it is apparent that relatively few supplemental interventions actually emerged in Brussels. In order to match the responsible organization in the existing Codes of Practice (bullet 4) with the supplemental activities that might be considered, Subsection A lists those risk management options that were listed in the draft Risk Management document..

IFAH thus proposes that all of Section IV be deleted and replaced with the new section below. IFAH believes this streamlined approach will improve understanding and bring clarity to the current draft yet maintain the content and intention of the Working Group. It will also foster more supplemental risk management options by the various stakeholders.

However, if this approach is not deemed acceptable by the TFAMR, then the revisions and comments following the new proposal are to be retained]

13. Risk management options should span the farm to table continuum. Since national authorities will need to rely upon various partners to implement risk management interventions, the responsibilities of the various partners are outlined, following the general outline in the Code of Practice CAC/RCP 61-2005.

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[16] *For the purpose of the present document, the term "interested parties" refers to "risk assessors, risk managers, consumers, industry, the academic community and, as appropriate, other relevant parties and their representative organizations"*.

[17] http://www.oie.int/eng/normes/Mcode/en_sommaire.htm

[18] http://www.who.int/foodborne_disease/resistance/en/index.html

14. The goal of risk management interventions is to minimize and contain the prevalence of bacteria on food. This is achieved by implementing targeted interventions along the food chain, as outlined in the key documents below.

15. Risk management options described in the following section may be implemented, at the discretion of national/regional authorities and in a step-wise manner that is proportional to the level of risk, based upon the following considerations:

f). At a minimum, the existing Codes of Practice should be implemented. These codes of practice describe the respective roles and responsibilities of authorities and groups to minimize and contain antimicrobial resistance:

o Codex Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005),

o Codex Recommended International Code of Hygiene Practice for Control of the Use of Veterinary Drugs (CAC/RCP 38-1993),

o Codex Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63- 2007), and

o Food Hygiene Basic Text – Recommended International Code of Practice General Principles of Food Hygiene (CAC/RCP 1-1969) and its annex on Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for Its Application.

16. Food Chain partners (below) described in Code of Practice and Food Hygiene (above) each have certain responsibilities which are to be implemented in cooperation with national authorities. These responsibilities are clearly outlined in the Code of Practice documents.

- Regulatory authorities
- Veterinary pharmaceutical industry
- Wholesale and retail distributors
- Veterinarians
- Food Animal Producers and Crop Growers
- Food Producers
- Food Distributors

A.- Suppplemental Risk Management Recommendations

The selection and implementation of these supplemental risk management options should be supported by scientific evidence, be feasible, and reviewable with respect to new scientific information. In addition to the specific responsibilities outlined in the Codes or Practice, cited above, national authorities may choose to include the following risk management options as supplemental interventions to be considered for implementation. Additional Codex, OIE, or WHO documents may also be referenced for supplemental risk management recommendations.

- Implementation of these options is subject to the resources, legislative, and other constraints of the country/region;
- They are intended to supplement the Codex Codes of Practice and related texts (above) and to provide additional risk management options to risk managers.
- Regulatory authorities
- Conduct regulatory-based risk assessment of currently approved products when evidence that consumer safety is at risk of food borne AMR bacteria associated with the use of a same-class antimicrobial agent. Based on the outcome, product labeling options available to regulatory authorities include: use restrictions or withdrawal of approval or no action. [Bullet not edited; carried over “as is” from the current draft]
- Veterinary pharmaceutical industry
- Wholesale and retail distributors
- Veterinarians
- Within Responsible Use Guidelines, a formulary approach may be established to rank antimicrobial products on the basis of first intention of use. [Bullet not edited; carried over “as is” from the current draft]
- Food Animal Producers and Crop Growers

- Restrict movement of live animals, carrying a specific AMR foodborne pathogen or a bacteria carrying resistance determinant (more comments required : in/out of scope of Codex? OIE remit?). [Bullet not edited; carried over "as is" from the current draft]

- Food Producers

- Food Distributors

- Withdraw food containing an unacceptable level of AMR pathogenic bacteria from the market for reprocessing or destruction [Bullet not edited; carried over "as is" from the current draft]

NOTE: The comments and revisions below are to be utilized if the above revision is not acceptable.

~~17.~~ [The changes in this section have been proposed to improve clarity] Risk management options should consider the farm to table continuum and could be divided in pre-harvest interventions that include ~~and~~ Codes of Practice for Antimicrobial Agents used in food animal production and Responsible Use Guidelines. ~~p~~Post-harvest interventions include food hygiene practices which minimize food borne contamination. ~~aspects. Pre-harvest would contain aspects such as responsible use guidelines and codes of practice documents specifically directed to antimicrobial agents and their use in food production, whereas post-harvest would contain such aspects as food hygiene practices which are specifically directed to foodborne contamination.~~

18. [The changes in this section have been proposed to improve clarity] As part of the pre-harvest activities, regulatory authorities should take into account ~~appropriate emphasis should be laid on evaluation prior to approval, taking due account of~~ the resistance selection ~~inducing~~ properties of antimicrobials and define use conditions as part of the approval process for antimicrobials. National authorities should pay particular attention to the establishment of the necessary agencies for approval, post-market monitoring ~~registration~~ and enforcement of regulations regarding antimicrobial usage.

19. [The changes in this section have been proposed to improve clarity] With regard to post-harvest, the aim should be to minimize and contain bacterial contamination, including AMR bacteria,on food. A system to monitor trends in antimicrobial resistance and prevalence of foodborne bacteria should be in place. ~~and to apply t~~Targeted interventions aimed at reducing all bacterial contamination, including antimicrobial resistant bacteria during food processing should be implemented. ~~of importance to human and animal health.~~

20. Risk management options described in the following section may be implemented, at the discretion of national/regional authorities and in a manner that is proportional to the level of risk, based upon the following considerations:

g). [The changes in this section have been proposed to improve clarity] ~~as~~ At a minimum, the existing Codes of Practice should be followed. These ~~c~~Codes of ~~p~~Practice describe the respective roles and responsibilities of authorities and groups to minimize and contain antimicrobial resistance:

o Codex Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005),

o Codex Recommended International Code of Hygiene Practice for Control of the Use of Veterinary Drugs (CAC/RCP 38-1993),

o Codex Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63- 2007), and

o Food Hygiene Basic Text – Recommended International Code of Practice General Principles of Food Hygiene (CAC/RCP 1-1969) and its annex on Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for Its Application.

h). Implementation of these options is subject to the resources, legislative, and other constraints of the country/region;

i). The selection and implementation of the risk management options should be supported by scientific evidence, be feasible, and reviewable with respect to new scientific information;

j). They are intended to supplement the Codex Codes of Practice and related texts (above) and to provide additional risk management options to risk managers.

~~21.~~ [The changes in this section have been proposed to improve clarity] Examples of potential risk management (RM) options (used either alone or in combination) available for implementation by various stakeholders are listed below in Sections A and B. ~~Codex or countries, as appropriate are listed below in the rest of this section:~~Supplemental risk management options are provided as noted below by an asterisk (*).

A.- Pre-harvest options

A.1- General

o [The changes in this section have been proposed to improve clarity. Note that there is a difference between monitoring and surveillance; it is best to consistently use the term monitoring because it fits into the concept of food safety. One definition is: To check, supervise, watch, or keep track of. In the context of an HACCP plan, the act of conducting a systematic and repeated sequence of measurements, or observations, of control parameters to assess whether a critical point is under control.. Surveillance is defined as: Ongoing close observation and collection of data or evidence, for a specified purpose or confined to a narrow sector. Horticulture definition is too narrow because it excludes commercial crop production : The science and art of growing fruit, flowers, ornamental plants, and vegetables in small gardens.] Monitoring ~~and surveillance~~ of the use of antimicrobials in food animals and food crops ~~horticulture~~ (this set of measures do not contribute to the reduction of foodborne antimicrobial resistance (AMR) risk – Monitoring is essential to establish a baseline for comparing the effectiveness of ~~new MRM~~ risk management interventions ~~activities~~. It also may provide information which the risk managers may use to determine what ~~steps~~additional or alternative interventions may be taken to achieve further improvements in the extent or efficiency of risk mitigation {CAC/GL 63 – 2007, page 9})

f). [The changes in this section have been proposed to improve clarity.] monitoring should, to the extent possible, include all antimicrobials used in food animal and crop production

g). [The changes in this section have been proposed to improve clarity. Also, the phrase requiring usage data at the species and category of animal is impractical to obtain. Neither prior the prior Joint consultation, WHO consultation on usage or the OIE Terrestrial Code require this level of detail, so it is best to delete it] .monitoring of antimicrobial usage in food animals and food crops should be at species ~~level and if possible also on category of animal within species & take into account drug/bacteria/animal species relationship;~~

h). [The changes in this section have been proposed to improve clarity. ~~] authorities should preferably plan in advance the collection and analysis of data on the dissemination of antimicrobial resistance and on antimicrobial usage~~. authorities should implement a statistically designed data collection system to ensure statistical analysis and a means for the dissemination of information on antimicrobial resistance and on antimicrobial usage.

i). [IFAH comments that « assessing possible relationships » and « other relevant data » may need further definition These informations will already have been used in Risk Assessment and in any Review of Effectiveness. A re-wording is proposed] .AMR data should be analyzed with AM usage data, together with other relevant data (to be determined), to assess possible relationships by means of Risk Assessment (see Risk Assessment section).

o [The changes in this section have been proposed to improve clarity.]Approval and licensing of antimicrobials used in food animals and food crops ~~horticulture~~

d). [The changes in this section have been proposed to improve clarity.]Approval and licensing of an ~~A~~antimicrobial by regulatory authorities may, whenever possible, be ~~subjected to~~ conditional with the monitoring of the use and relevant AMR bacteria~~of this AM and of the AM resistance~~.

e). [The changes in this section have been proposed to improve clarity.]~~Approval and licensing of an~~ Antimicrobials may~~, whenever possible,~~ be subject to the review ~~of existing AMs~~by regulatory authorities.

f). [The changes in this section have been proposed to improve clarity. Codex is not a drug approval agency so any regulatory activities must be appropriately directed to national authorities or the general OIE Terrestrial Code for Risk Assessment]]~~AM~~ An antimicrobial product should not be authorized if regulatory risk assessment indicates unacceptable levels of risk, as described in the OIE Terrestrial Code or by national/regional regulations.

A.2- Food animal production

~~o~~ [This bullet should be deleted because it is already covered in CAC/RCP 61-2005. Moreover, the association of Critically Important Antimicrobials with clinical use restrictions was not the intended application for the list; rather it was to guide prioritization]~~Restrict extra-label use, especially in Critically important antimicrobials (CIA) for human treatment~~

~~o~~ [This bullet should be deleted because it is already covered in CAC/RCP 61-2005 Moreover, the Brussels meeting attendees agreed that revisions to clinical practice guidelines were outside the remit of the TFAMR]. ~~Perform a bacterial diagnosis and susceptibility testing prior to treatment for a given AM and bacterial infection.~~

o [The changes in this section have been proposed to improve clarity. This bullet is similar to what is contained in CAC/RCP 61-2005, and could be cross-referenced instead of repeated. The only new feature is for food crops] *Competent authorities and/or professional ~~bodies~~ organizations should elaborate food animal and food crop ~~(plant & food processing)~~ species-specific ~~prudent use treatment~~ clinical practice guidelines in consultation with all relevant ~~interested~~ parties

o [This bullet should be deleted because it is already covered in CAC/RCP 61-2005 Moreover, the Brussels meeting attendees agreed that revisions to clinical practice guidelines were outside the remit of the TFAMR. IFAH is of the opinion that this is a matter for clinical veterinary practice and thus falls outside of the scope of the TFAMR. This exclusion was recorded in the Proceedings of the Brussels Working Group meeting on Risk Management in Point 7, which states "…that other issues, such as specific guidelines on the use of antimicrobials or the regulation of the practice of veterinary medicine, although relevant to some extent in this context, were beyond its remit and has already been adequately addressed…". Indeed, the matter of a formulary approach is one that is best left to national veterinary associations. As the OIE Critically Important List clear illustrates, there are so many factors in food animal production (geography, cultural preferences, livestock and poultry industries, animal drug availability, veterinary care, etc.) that it is neither practical nor realistic to develop a "one size fits all" list of antimicrobials within a Codex Code of Practice or within the TFAMR.] *~~Recommend on different AM to be used, if several antimicrobials can be used for a given indication in an animal. (more comments required).~~

o [The changes in this section have been proposed to improve clarity. This bullet is similar to what is contained in CAC/RCP 61-2005, and could be cross-referenced instead of repeated. Many veterinary medical organizations and national authorities include disease preventions (prophylactic use) within the overarching definition of treatment (i.e. treatment, control and prevention). Prevention is a legitimate administration of antimicrobial agents prior to an expected disease outbreak, when groups of animals have been exposed to stressful conditions or antecedent viral disease or other predisposing conditions. There is no medical or economic reason for a veterinarian or producer to administer antibiotics to prevent a disease that may be non-existent in the animal. This would amount to an unnecessary expense that most producers would clearly avoid incurring considering the need to control input costs in animal production. However, as stated above, if the animals are at risk and the use would prevent the onset of clinical infectious disease then the use of the drug is not only warranted but good for the health and welfare of the animal. As written, the bullet point is defining clinical practice, which the Brussels meeting participants agreed was outside the remit of the TFAMR. This bullet should be deleted, or if retained, alternative wording is proposed]. ~~Prophylactic use in healthy animals not considered to be at risk of infection or prior to the onset of clinical infectious disease, should be avoided. (more comments required)~~Preventive use of antimicrobials in groups of food animals exposed to pathogens, unusual stress or known to "break" with disease at certain timepoints (e.g. movement, weaning, etc) is clinically acceptable. Prevention use in food crops is subject to responsible use guidelines.

o [The changes in this section have been proposed to improve clarity.] ~~Prevent~~ Minimize and contain the ~~presence and~~ transmission of foodborne bacteria ~~&~~ and/or AMR determinants from ~~between~~ food animals or food crops ~~and from animals~~ to food to humans by implementing biosecurity, ~~A~~animal health and/or infection control programs ~~against~~ directed toward ~~most important~~ zoonotic AMR bacteria~~agents~~.

~~o~~ [This bullet should be deleted. IFAH views this recommendation as impractical and, if accepted, would compromise fair trade practices, which Codex is mandated to ensure. In essence, the restriction of live animals has been within the purview of the OIE for infectious agents such as transmissible spongiform encephalopathy agents, avian influenza, and other such diseases. The specific recommendation for AMR food borne pathogens implies that a national testing system, sampling scheme, holding period, compensation program and other infrastructure is already in place to accomplish the goal. Moreover, most food animals (and likely crops and feeds) will be found to contain some AMR bacteria, thus it may become nearly impossible to move animals or crops across geopolitical boundaries. A negatively tested group of animals or crops that leaves one country might test positive upon arrival due to stress, commingling, or external contamination; further complicating the value of this recommendation. IFAH views this recommendation as unsubstantiated and ill-advised because it has not been evaluated via a risk assessment process to determine whether animal movement restrictions would indeed help to minimize and contain AMR bacteria and protect consumer safety. Furthermore, susceptible food borne pathogens are already considered hazards and can cause food borne illness. To our knowledge, the Codex Committee on Food Hygiene has made no recommendations for national authorities to restrict movement of animals that may be carrying food borne pathogens let alone those that may carry certain antimicrobial resistance. ~~Restrict movement of live animals, carrying a specific AMR foodborne pathogen or a bacteria carrying resistance determinant (more comments required : in/out of scope of Codex? OIE remit?).~~

o [This bullet should be deleted. The use of the Critically Important Lists is already considered within the Risk Profiling section of the TFAMR document. There is no justification for linking the categorization of antimicrobials to responsible use, which has already been determined to be outside the scope of the TFAMR and the Working Group on Risk Management.] Responsible use in veterinary medicine of antimicrobials of particular importance for human treatment (more comments required : cf. OIE Terrestrial Animal Code).

o [This bullet should be deleted. The matter of clinical practice and or the ability of veterinarians to sell and dispense medicines is not within the remit of the TFAMR and the Working Group on Risk Management, as cited above. This matter is one that is best handled by national veterinary organizations and their membership and not by Codex.] ~~If sufficient evidence exists that profit from the sale of antimicrobials negatively impacts on prescribing practices, appropriate countermeasures should be taken to ensure prudent use. (more comments required :in/out of scope of mandate of Codex? but = WHO global principles on containment of AMR)~~

A.3- Plant production

Controlling the use of antimicrobial agents: more comments required

Although IFAH is concerned with antimicrobial use in animals, comments are provided on the use of antimicrobials in food crop production. The use of the term horticulture is inappropriate as this implies small gardens, ornamental plant use and does not cover large scale commercial growers; hence the term food crops seems more appropriate. There is not much information on the actual amounts of use of antimicrobials in crop production, even in the US. Tetracycline and streptomycin seem to be the two main antimicrobial agents used on certain fruit trees to combat particularly destructive bacterial diseases caused by non-human pathogens. So, far, the TFAMR has not received a list of Critically Important Antimicrobials for crop production, nor has a Code of Practice for Antimicrobial Use in Crop Production been prepared. As such, it seems premature to provide recommendations on antimicrobial use in crop production without first having sufficient information available to assess the matter. Certainly the TFMAR document can be written to encompass the potential for assessing a Food Safety Issue, conducting a Risk Profile and Risk Assessment, but the specific Risk Management actions remain ill-defined and should be stated as such within the current document.

o [This recommendation should be deleted as it first of all admits that there is not enough known about the matter. A "possible" source of contamination is insufficient to use as a basis for making a sweeping recommendation to discontinue "direct use" of human and animal waste in agriculture. Indeed, human sewage is processed and the sludge can be land-applied safely to minimize the need for fertilizers in resource-constrained countries. Animal waste can be processed in lagoons or other systems and land-applied. The recommendation cannot be supported because there has not been a risk assessment conducted to determine whether the intervention would indeed benefit consumer food safety more than current practices. Furthermore, this recommendation seems to be outside the scope of the TFAMR because it would likely be appropriate as a Good Agricultural Practice guidance.]~~Controlling the spread of AMR bacteria through other possible sources of contamination: direct use in agriculture of human and animal waste (manure) should be discontinued, if there is sufficient evidence of risk (practical, feasible and supported by science and to be revised in the light of further knowledge – more comments required).~~

B.- Post-harvest options

o [The changes in this section have been proposed to improve clarity.] ~~Target~~ Direct risk management interventions towards those bacteria that contaminate food, including those which are resistant to antimicrobials, with the goal of minimizing and containing contaminated food products that are consumed. ~~of critical importance to public and animal health~~

o [Delete this sentence fragment] ~~Implement of control measures to the extent possible;~~

~~o~~ [Delete this sentence fragment]. The concept is captured in the first bullet above.] ~~Prevent the food containing an unacceptable level of AMR bacteria & AM determinants, reaching the consumer~~

~~o~~ [IFAH supports food standards, as established by Codex and national authorities, which seek to limit consumer exposure to known bacterial (and other pathogenic microorganisms and infectious agents). However we are not aware that Codex has recommended that raw meats be routinely withheld from the market because of the presence of certain food borne bacteria like Salmonella. This particular recommendation to national authorities would imply that there is now another layer of testing that is necessary. For example, when salmonella is detected on meat, this recommendation implies that susceptibility testing would be needed, which can add another 1-2 days of holding time to a perishable, time-sensitive commodity. Moreover, since salmonella are not desirable on a meat product in the first place, it is unclear what additional value will be added by knowing that the salmonella is may also have AMR characteristics. As such, IFAH views this recommendation as unnecessary to ensure consumer protection; however, as with many of the other risk management options, it must be evaluated by risk assessment to determine whether it will achieve the desired goals. A revised bullet is provided] ~~Withdraw food containing an unacceptable level of AMR pathogenic bacteria from the market for reprocessing or destruction (commensals are not included here - to review the inclusion of commensals later on)~~*Although the goal is to minimize the amount of contaminated food from reaching consumers in the first instance, should it be determined that consumers will be or have been exposed to such a contaminated food product, national authorities should follow typical recall or re-processing or destruction procedures as appropriate to ensure consumer safety.

V.- EVALUATION OF RISK MANAGEMENT OPTIONS (RMO)

~~14.~~ [Moved to General Principle 1. Delete from this location] ~~Animal health should also be considered when evaluating risk management options, to the extent possible, consistent with the requirement of GENERAL PRINCIPLE 1.~~

~~15.~~ [This has already been specified in the RA and RP documents and can be deleted] ~~Evaluation of the identified Risk management options should be performed at National/ Regional level.~~

~~16.~~ [This bullet has been revised in combination with the bullet point below] ~~Risk management options should be assessed in terms of the scope and purpose of risk analysis and the level of consumer health protection they achieve. The option of not taking any action should also be considered.~~

17. [This bullet has been revised for clarity] Risk management options should be ~~assessed~~ evaluated by risk managers, taking into account the options' feasibility, effectiveness, economic implications, enforcement and compliance; ~~they should be~~ proportion~~ate~~ality to the amount of risk, and consumer health protection they are expected to provide; and as compared to the option of taking no action. The level of control or reduction of risk that is necessary, should be specified, when feasible.

VI.- SELECTION OF RISK MANAGEMENT (RM) OPTIONS[19]

36. [The bullet was excerpted to the bullet above where the evaluation criteria are a better fit] The selection of RM options should be based on their ability to mitigate the risks effectively and on the practical feasibility and consequences of the options.~~. Where available, a risk assessment can often help in the evaluation and selection of RM options. Risk management options should be assessed taking into account the options' feasibility, effectiveness, economic implications, enforcement and compliance; and they should be proportionate to the amount of risk. The level of control or reduction of risk that is desirable, should be specified, when feasible.~~

37. The selection of risk management options should be supported by mechanisms to monitor and evaluate success to contain and minimize AMR bacteria that may be transmitted through the food chain.

~~38.~~ [This bullet has nothing to do with selection or RM options and should be deleted] ~~The various interested parties should be involved when developing regulatory programs.~~

A.- Identifying an appropriate level of consumer health protection[20]

39. Risk management decisions on appropriate options should be achieved by considering and integrating all evaluation information obtained from preliminary risk management activities and/or the risk assessment.

A.1- Benefit-risk approach

40. Because antimicrobials play a major role in animal health, animal health should be considered when evaluating risk management options, but this must be considered secondary to protecting consumers. When evaluating restrictions on the use of antimicrobial products it is necessary to consider substitutes or alternative practices that would reduce the need for the product. Substitutes could be other less important antimicrobials, non-antimicrobial products, or changes in livestock husbandry that promote animal health. The impact of reduced antimicrobial resistance on animal health should also be considered when evaluating restrictions on antimicrobial use.

A.2- Threshold approach

41. Given the geographic variations in the levels of resistance and the increasing emergence of resistance, it may be necessary to explore the need to develop resistance thresholds for specific antimicrobial-species-pathogen combinations, above which any of a range of risk management options may be triggered. However, this approach needs to be carefully assessed as it should be put in perspective with the current use of antimicrobials and the current level of resistance.

A.3- Precautionary approach:

42. When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, it may be appropriate for countries to select a provisional decision, while obtaining additional information that may inform and if necessary modify the provisional decision. In those instances, the nature of the provisional decision should be communicated to all interested parties and the timeframe or circumstances under which the provisional decision will be reconsidered (e.g. reconsideration after completion of a risk assessment) should be articulated when the decision is communicated initially.

A.4- ALARA approach

43.

(Further comments to be submitted by Philippines)

B.- Reaching a decision on the preferred risk management options

44. The decisions should be based on risk assessment and taking into account, where appropriate, other legitimate factors relevant to health protection of consumers and for the promotion of fair practice in the food trade[21].

~~45.~~ [Delete this. It has been addressed in the RP and RA sections] ~~Cross resistance, co resistance issues should be considered.~~

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[19] CAC/GL 63 – 2007 provides general guidance on the selection of risk management options (sections 4 & 6).

[20] "Appropriate Level of Protection" (ALOP). ALOP is defined in the SPS Agreement as "the level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory". ALOPs may range from general to specific depending upon the level of information available with regards to the source of hazards and risks and will depend on the public health goals.

[21] WPRAC para 28, 2nd sentence

~~46.~~ [Delete this bullet because it is an action not an explanation of how to reach a decision. It is already covered in the Codex of Practice] ~~control measures may be placed on the use of specific antimicrobial agent in some species or some route of administration or specific production processes (see GENERAL PRINCIPLE 3)~~

VII.- IMPLEMENTATION OF RISK MANAGEMENT OPTIONS

47. Risk managers should develop an implementation plan that describes how the options will be implemented, by whom, and when.

~~48.~~ [Combined with the bullet below] ~~National/regional authorities should ensure an appropriate regulatory framework and infrastructure.~~

49. [This bullet has been revised for clarity] Prudent use guidelines, monitoring of antimicrobial usage and general food hygiene principles should be implemented as a minimum; additional measures could be ~~envisaged~~ implemented following a stepwise approach (see annex 2). National/regional authorities should ensure an appropriate regulatory framework and infrastructure.

VIII.- MONITORING AND REVIEW OF RISK MANAGEMENT OPTIONS

50. [This bullet has been revised for clarity] Governments should define an evaluation process to assess whether the risk management options have been properly implemented and ~~an assessment~~ make a decision whether or not an outcome has been successful (see also GENERAL PRINCIPLES). Generally this would follow the risk assessment process used initially by means of revising data inputs and considering other new data or endpoints.

51. [This bullet has been revised for clarity] Monitoring ~~and surveillance should be supported by regulation and the enforcement of control measures~~ is the ongoing collection of data for the purpose of determining whether the intervention is changing the endpoint as expected. The type of data collected may include usage data, resistance prevalence data, food contamination prevalence, food borne disease prevalence, etc.

~~52.~~ [This bullet is now contained in the bullet above and can be deleted] ~~A minimum level of monitoring should be established in order to measure usage and risk management effects.~~

53. [Both OIE and WHO have produced codes, meeting reports and various supporting documents that provide the means to harmonize resistance monitoring programs at the technical level. WHO has implemented the SalmSurv program in multiple nations and conducted training in many countries. Many nations have implemented their own national resistance monitoring programs as well. While the recommendation is well-intentioned, IFAH believes that it exceeds the scope of the TFAMR in that a risk management intervention should be one that is already available for implementation within a country and not one that requires substantial investment of resources across international boundaries. The visionary aspect of the recommendation is meritorious, but not practical and not feasible to be placed as a specific risk management option within a Codex guidance document.]Monitoring schemes should be harmonized (RCP 61 & GL 63) between countries, to the extent possible (in a general consideration about sharing info between countries; more comments are requested on this issue & review OIE Terrestrial Animal Code for existing wording).

54. risk management options should be reviewed and evaluated, regularly, or at a predetermined moment in time, or whenever new relevant information becomes available

55. A variety of endpoints (see Annex 1) may be measured with respect to antimicrobial resistance. Endpoints related to specifically implemented risk management options should be measured to assess the effectiveness and need for potential adjustment.

56. Additional endpoints may be measured to identify new information (e.g., emerging hazard, virulence of a pathogen, prevalence and concentration in foods, sensitivity of sub-populations, changes in dietary intake patterns,...).

IX.- RISK COMMUNICATION

57. (to be harmonized)

Annex 1

possible endpoints (exposure end points to be separated from adverse health effect end points)

- [IFAH views the list of endpoints as possibly useful, but they should be considered in conjunction with the Risk Assessors as possible outcomes of the Risk Assessment which will guide the selection of Risk Management options, or the review of implemented options. In other words, there is a need for the context where the data is generated (i.e. in what specific situations will these endpoints be useful?). At present, merely having this Annex I list does not seem to serve a particular role.]

(refers to section VIII – para 38)

In order to monitor variations in AM usages and AMR and the effects of risk management measures, possible endpoints include:

s. Nature and extent of antimicrobial resistance.

t. Nature and extent of antimicrobial resistance in animal-derived food products at retail level.

u. Prevalence of antimicrobial-resistant bacteria on farm level.

v. Prevalence of antimicrobial-resistant bacteria in animal-derived food products at retail level.

w. Prevalence of antimicrobial-resistant bacteria or resistant genes in human clinical isolates of foodborne diseases.

x. Development of new bacterial resistance patterns.

y. Prevalence of foodborne pathogens on farms.

z. Prevalence of foodborne pathogens in food.

aa. Prevalence of food borne disease in humans.

bb. Number of deaths attributable to foodborne antimicrobial-resistant bacteria.

cc. Number of treatment failures attributable to foodborne antimicrobial-resistant bacteria.

dd. Frequency of human infections attributable to foodborne antimicrobial-resistant bacteria.

ee. Frequency of adverse human health effects attributable to foodborne antimicrobial resistant bacteria.

ff. Mortality due to foodborne antimicrobial-resistant bacterial infections in “vulnerable populations”.

gg. Level of awareness of antimicrobial resistance risk (producers, consumers, industry and others).

hh. Level of compliance with specific drug use restriction or compliance with prudent use guidelines.

ii. Trends in usage of antimicrobials in food-producing animals.

jj. Trends in usage of critically important antimicrobials (CIA) in food-producing animals.

Annex 2:

step wise approach (refers to section VII – para 32)

Step 1

o). Ensure adequate veterinarian (or equivalent animal health professionals) coverage for the country, veterinarian training in judicious/appropriate/responsible antimicrobial use and animal production practices, and appropriate involvement in food production and food safety processes.

p). Ensure adequate infrastructure for food production/food hygiene with respect to existing Codex standards and guidelines.

q). National authorities should capitalize upon regulatory precedents and expertise of “peer” authorities in the region when capabilities are limited.

r). Communicate to the public the necessity of proper food preparation and hygiene.

Step 2

s). Implement responsible use guidelines via professional veterinary organizations.

t). Ensure reliable national food safety authority oversight of food safety activities consistent with Codex food hygiene guidance.

u). Implement adequate infrastructure and enforcement capacity to ensure compliance with quality product availability and veterinary involvement in antimicrobial usage.

v). Implement local/regional surveillance programs for foodborne disease.

Step 3

w). Implement national surveillance programs for foodborne disease.

x). Implement national resistance monitoring program, and where possible, usage monitoring.

y). Implement regulatory review of new antimicrobial agents prior to product approval.

z). Work in collaboration with food producing companies to maintain vigilance for implementation of food hygiene practices (i.e. HAACP) that safeguard against food contamination.

aa). Work with professional associations (e.g. veterinary profession, species specific groups, etc.) to ensure compliance with responsible use guidelines by all members. Implement research programs to develop new research to

fill data gaps that will improve antimicrobial use practices, or minimize the need for antimicrobial use by preventing disease, etc.

bb). Encourage animal health companies to develop products that will avoid resistance selection of currently used human use antibiotic classes.

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