

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 5

CRD04 REV

ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

AD HOC CODEX INTERGOVERNMENTAL TASK FORCE ON ANTIMICROBIAL RESISTANCE

Seventh Session

Proposed draft revision of the Code of practice to minimize and contain foodborne antimicrobial resistance

Comments of EU, Norway, Thailand, GSFI(Global Food Safety Initiative)

EU

General comment

The scope of a number of provisions in the draft document is limited to medically important antimicrobial agents. The EUMS note that the new text in paragraph 11 clarifies that the CoP covers antimicrobials other than antibacterials where scientific evidence supports foodborne AMR risk to human health. The EUMS are of the view that this clarification allows the extension of prudent use recommendations to cover all antimicrobial agents within the scope of the CoP.

Specific comments

Paragraph 1

The EUMS support using the term "plant/crop production". This is because the definition of the term "plants/crops" reads "a plant or crop that is cultivated or harvested as food or feed" which makes it clear that only plants/crops grown for food are covered by the CoP.

Paragraph 6

The EUMS support the 2nd bullet of paragraph 6 as currently drafted. It is important to refer to the entire WHO document although the emphasis is on the Annex.

Paragraph 11

The EUMS support the introduction of the new phrase "where scientific evidence supports foodborne AMR risk to human health" as it usefully clarifies the scope of the CoP as regards antiviral, antiparasitic, antiprotozoal and antifungal agents.

Definitions

Adverse health effects

The EUMS would prefer retaining the terms "of animal/crop origin" in the definition as the suggested definition is copied from the Guidelines for Risk Analysis of Foodborne AMR (CAC/GL 77-2011).

Competent authority(ies)

The EUMS are not in favour of having a definition for competent authorities. The term is self-explanatory while developing an all-encompassing definition for it would be very difficult. CCGP tried to develop such definition in the past but failed.

Food chain

The EUMS support adding "feed" in the definition of the food chain.

Food production environment

The term "immediate" is not clear and would need a definition of its own. Therefore, the EUMS support the definition for food production environment as currently written in the proposed draft guidelines for AMR monitoring and surveillance, i.e. "The vicinity of food, feed, plants/crops, animals to be harvested or processed that could contribute to foodborne AMR".

Food of plant origin

The EUMS reiterate their comment that there is no need for a definition for “food of plant origin” as it not used in the document. Moreover, the CoP does not make any difference on risk management measures applied to edible and non-edible parts of plants/crops.

Therapeutic use

There is no need for a definition for “therapeutic use”. It is only used in principle 6 but that principle can be deleted. The term “therapeutic” has been added to paragraphs 33 and 54 but there it can be replaced with the original wording.

Principle 1

The EUMS suggest rewording the principle as follows:

“A one health approach should be ~~considered~~ **applied** wherever possible and relevant, for identifying, evaluating, selecting and implementing foodborne AMR risk management options.”

Rationale: The present text of this principle suggests that the one health approach can be ruled out beforehand. The One health approach, however, is a universal principle that should always be considered. What should be expressed is that in identifying, evaluating, selecting and implementing foodborne AMR risk management options, the one health principle should be applied wherever relevant.

Principle 5

This principle should read as follows:

Antimicrobial agents should not be granted regulatory approval for growth promotion and their use for growth promotion should be phased out.

Rationale: There is a growing international consensus that the use of antimicrobials for growth promotion should be phased out. This was recently confirmed by the Interagency Coordination Group on Antimicrobial Resistance (IACG) which in its report of April 2019 calls UN Member States to phase out the use of antimicrobials for growth promotion and emphasises that this should be complemented by the adoption of global standards.

Principle 6

This principle could be deleted as it essentially repeats what is already said in principle 5.

Principle 7

Principle 7 should be modified as follows:

When used for prevention/prophylaxis of a specific disease risk, ~~medically important~~ antimicrobials should only be administered in well-defined **and exceptional** circumstances, based on epidemiological and clinical knowledge, and follow appropriate professional oversight, dose, and duration. **This use should not be systemic, nor routine, nor applied to compensate for poor hygiene or inadequate animal husbandry practices.**

Rationale: A clear principle is necessary to enshrine the conditions for preventive/prophylactic use of all antimicrobials, not only the medically important ones.

Principle 7bis

Principle 7bis should be modified as follows:

When used for the control of disease/metaphylaxis, ~~medically important~~ antimicrobial agents should only be used on the basis of epidemiological and clinical knowledge and a diagnosis of a specific disease and follow appropriate professional oversight, dose, and duration.

Rationale:

A clear principle is necessary to enshrine the conditions for control/metaphylactic use of all antimicrobials, not only the medically important ones.

Principle 7ter

Principle 7ter should be modified as follows:

When used for **in** plant/crop ~~protection~~ **production**, ~~medically important~~ antimicrobial agents should only be used to the extent necessary for a specific disease and follow appropriate professional oversight, dose, and duration.

Rationale:

A clear principle is necessary to enshrine the conditions for use of all antimicrobials, not only the medically important ones, when used in plant/crop production. The EUMS further suggest replacing "plant/crop protection" with "plant/crop production" to make it clear that antimicrobials should not be used prophylactically in plant/crop production.

Principle 12

The EUMS support retaining principle 12 and reiterate their comment that principle 12 should be modified as follows:

~~Medically important a~~Antimicrobials should be administered, prescribed, or applied only by, or under the direction of veterinarians, plant/crop health professionals or other suitably trained persons authorized in accordance with national legislation.

Rationale: The Codex guidance should be consistent with the corresponding OIE guidance. According to Article 6.10.3.(9) of the OIE Terrestrial Animal Health Code, all antimicrobial agents should be prescribed by a veterinarian or other suitably trained person in accordance with national legislation.

Paragraph 14

The EUMS support maintaining the reference to the VICH guidelines as this is useful information.

Paragraph 17

In order to promote responsible and prudent use of antimicrobial agents, it is important to encourage the use development, and availability, and use of validated, rapid, reliable diagnostic tools, where available, to support veterinarians and plant/crop health professionals **in diagnosing the disease and** in selecting the most appropriate antimicrobial, **if any**, to be administered/applied.

Rationale: To clarify that there is an alternative not to use antimicrobials. The diagnosis of a disease should also be covered as this is an essential step for prudent use of antimicrobials.

Paragraph 18

Following risk analysis, the competent authorities should determine appropriate labelling, including the conditions that will minimize the development of foodborne AMR while still maintaining efficacy and safety, ~~when this information is available~~. Furthermore, the professional judgement of the veterinarian or plant/crop health professional, who holds the responsibility of oversight, should be considered when competent authorities develop guidance for approved product labelling.

Rationale: When product specific information is not available, general information on the need to apply prudent use, and to follow national or regional guidance and guidelines can be given.

Paragraph 20

The EUMS suggest deleting the last sentence of this paragraph as the evaluation of good pharmacovigilance practices is not part of the assessment of efficacy.

Paragraph 22

The EUMS support retaining the former paragraph 18 reading:

“Competent authorities should assess the impact of proposed antimicrobial agent use on the environment in accordance with national guidelines or recognized international guidelines.”

Rationale: It is important to assess the impact of antimicrobial agent use on the environment. This also recommended in the Article 6.10.3(6) of the OIE Terrestrial Animal Health Code.

Paragraph 23

The EUMS support extending the scope of this paragraph to plant/crop protection products.

Paragraph 25

The EUMS suggest rewriting the last sentence of this paragraph as follows:

The information collected through the pharmacovigilance program can contribute to a comprehensive strategy to minimize antimicrobial resistance in feed **the food chain**.

Rationale: Also AMR occurring not (only) on food as a result of veterinary use can have significant impact on public health like LA-MRSA which is predominantly transferred to humans through contact with animals.

Paragraph 27

The EUMS reiterate their comment that paragraph 27 should be modified as follows:

Competent authorities should make sure approved antimicrobial agents are distributed through **licensed or authorised** appropriate distribution systems **and prescribed** in accordance with national legislation, ~~including that medically important antimicrobials are distributed to appropriately~~ **by** credentialed/registered veterinarians, plant/crop health professionals, or other suitably trained persons authorized in accordance with national legislation.

Rationale: The Codex guidance should be consistent with the corresponding OIE guidance. According to Article 6.10.3.(9) of the OIE Terrestrial Animal Health Code, the relevant authorities should ensure that all antimicrobial agents are supplied only through licensed or authorised distribution systems and all antimicrobial agents should be prescribed by a veterinarian or other suitably trained person in accordance with national legislation.

Paragraph 32

The EUMS support the revised text in paragraph 32. The EUMS also support retaining the list of examples as they provide useful and informative guidance.

Paragraph 33

The last bullet point of paragraph 33 should be modified as follows:

Determine the potential transfer to animals and plants/crops of resistant microorganism and resistance determinants due to agricultural chemical use, **including environmental effects.**

Rationale: To clarify that the use of antimicrobials could have environmental effects (which could lead to secondary effects for the human health such as shortage of food due to destroyed soil).

Paragraph 41

The EUMS reiterate their comment that paragraph 41 should be modified as follows:

It is the responsibility of the marketing authorization holders to only advertise antimicrobial agents in accordance with the provisions of paragraphs 30-31 on the Responsibilities of the Regulatory Authorities, Control of Advertising and to not advertise ~~medically important~~ antimicrobials to farmers or producers.

Rationale: The Codex guidance should be consistent with the corresponding OIE guidance. According to Article 6.10.4.(3) of the OIE Terrestrial Animal Health Code, the industry should not advertise any antimicrobial agent directly to the food animal producer.

Paragraph 46

The EUMS reiterate their comment that paragraph 46 should be modified as follows:

Wholesalers and retailers distributing ~~medically important~~ antimicrobial agents should only do so on the prescription of a veterinarian or order from a plant/crop health professional or other suitably trained person authorized in accordance with national legislation. All distributed products should be appropriately labelled.

Rationale: To bring the text in line with section 5 of CAC/RCP 61-2005. There is no justification to limit this provision only to medically important antimicrobial agents. The Codex guidance should also be consistent with the corresponding OIE guidance. According to Article 6.10.5.(1) of the OIE Terrestrial Animal Health Code, distributors of all antimicrobial agents should do so on the prescription of a veterinarian or other suitably trained person authorized in accordance with national legislation.

Paragraph 49

Paragraph 49 should be modified as follows:

Veterinarians and plant/crop health professionals should identify new recurrent disease problems and ~~work toward~~ developing strategies to prevent, control, or treat infectious disease. These may include, but are not limited to, biosecurity, improved production practices, and safe and effective alternatives to antimicrobial agents, including vaccination or integrated pest management practices__where applicable/available.

Rationale: To clarify that veterinarians and plant/crop health professionals should develop strategies.

Paragraph 51

The EUMS reiterate their comments on the bullets of paragraph 51:

The 1st bullet of paragraph 47 should be modified as follows:

“A prescription, order for application, or similar document for ~~medically important~~ antimicrobial agents should indicate the dose...”

The 3rd bullet of paragraph 47 should be modified as follows:

“All ~~medically important~~ antimicrobial agents should be prescribed...”

Rationale: To bring the text in line with section 6 of CAC/RCP 61-2005. There is no justification to limit these provisions only to medically important antimicrobial agents.

Paragraph 52

Paragraph 52 should be modified as follows:

For food-producing animals, the appropriate use of antimicrobial agents in practice is a clinical decision that should be based on the experience of the prescribing veterinarian and epidemiological and clinical knowledge and, if available, based on adequate diagnostic procedures. When a group of food-producing animals ~~may have been exposed to pathogens, they may need to be treated without recourse to a laboratory confirmed diagnosis based on antimicrobial susceptibility testing to prevent the development and spread of clinical disease and for reasons of animal welfare.~~

Rationale: To include a sentence on adequate diagnostic procedures which has been deleted. This is relevant as there are cases when diagnostics is part of good veterinary practice. However, it is also clarified that the clinical decision should be based on diagnostic procedures when available. Prevention should not be used if the food producing animals have not been exposed to pathogens.

Paragraph 53

The EUMS suggest modifying the paragraph as follows:

For plant/crop production, the appropriate use of ~~medically important~~ antimicrobial agents to manage disease/pests should be based on the principles of integrated pest management (IPM), consultation with a plant/crop health professional, historical and epidemiological knowledge of the disease/pest situation, and monitoring of the current disease/pest status. Only authorized products should be used following label directions. Alternatives to ~~medically important~~ antimicrobials should be considered when available and their safety and effectiveness has been determined. ~~Medically important antimicrobial agents should only be used to the extent necessary for a specific disease and follow appropriate professional oversight, dose, and duration.~~

Rationale: It is unclear why the provisions of this paragraph should be limited only to medically important antimicrobial agents. The last sentence repeats principle 7ter.

Paragraph 54

The last sentence of the 3rd sub bullet of the 1st bullet should be modified as follows:

Should a first antimicrobial administration fail, or should the disease recur, the use of a second antimicrobial agent should ~~ideally~~ be based on the results of microbiological susceptibility tests derived from relevant samples.

The last bullet of paragraph 54 should be modified as follows:

If the label conditions allow for flexibility, the veterinarian or plant/crop health professional should consider a dosage therapeutic regimen that is long enough to allow an effective treatment, ~~but is short enough to limit the selection of resistance in foodborne and/or commensal microorganisms.~~ and no longer than necessary so that selection of resistance is minimised.

Rationale: The selection for AMR occurs even if the dosage regimen is very short.

Paragraph 59bis

A new paragraph 59bis should be introduced:

Veterinarians and plant health professionals should assist the relevant authorities in surveillance programs related to antimicrobial use and antimicrobial resistance, as appropriate.

Rationale: This is an important duty/task of veterinarians and plant health professionals.

Paragraph 62

The 6th bullet point in paragraph 62 should be reintroduced with the following text:

to address farm biosecurity measures and take basic hygiene precautions as appropriate

Rationale: The argument to delete this bullet point is due to an overlap with OIE guidance. However, biosecurity is important to address and there are other parts as well in this document that overlap with

OIE. The bullet point could be amended to be more in line with the OIE guidance in order to be more readable:

The 8th sub bullet of the 11th bullet should be reintroduced as follows:

daily dose and number of treatment days in case of food producing animals

Rationale: This should remain in the text to ensure records of dose, quantity and duration. Quantity (sub bullet point below) could be the record of the total quantity for the treatment, and is not the same as the daily dose.

NORWAY

SECTION 1

Paragraph 6 second bullet point:

Comment: For clarity it is better to reference the entire WHO document.

SECTION 3

~~**Medically important antimicrobials:** Antimicrobial agents important for therapeutic use in humans taking into account those described in the *WHO list of critically important antimicrobials* and categorized according to specified criteria as important, highly important, and critically important for human medicine or equivalent criteria established in national lists, where available. It does not include ionophores or other antimicrobial agents not important for human therapeutic use, such as ionophores.~~

Reason: We suggest deleting this definition. We have suggested to delete the reference to only medically important antimicrobial agents where it is proposed in the document.

~~**[Therapeutic use:** Administration/Application of antimicrobial agents for the treatment, control/metaphylaxis or and prevention/prophylaxis of disease.]~~

Reason: This definition is redundant as it is only used Principle 6, and we suggest deleting Principle 6.

SECTION 4

Principle 5:

~~**[Principle 5:** Responsible and prudent use of antimicrobial agents does not include the use for growth promotion of antimicrobial agents that are considered medically important. Antimicrobial agents that are not considered medically important should not be used for growth promotion unless potential risks to human health have been evaluated through procedures consistent with the *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance CXG 77-2011*.:]~~

~~considered medically important; or~~

~~able to cause cross or co-resistance to antimicrobial agents that are considered medically important.~~

~~Antimicrobial agents, others than those referred to above should not be used for growth promotion in the absence of risk analysis in accordance with CXG77.]~~

Reason: The use of antimicrobial agents for growth promotion is not responsible and prudent use of antimicrobial agents, thus this practice should be phased out. The rationale being that there is significant risk of developing AMR when using antimicrobial agents for growth promotion in food producing animals. The use of antimicrobial agents as growth promoters, has been banned voluntarily by the stakeholders since 1995 in Norway. In 2006 we also implemented legislation banning the marked authorization for antimicrobial agents used as growth promoters.

Principle 6:

~~**[Principle 6:** Medically important antimicrobial agents should only be used for therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease); or in certain circumstances for research and conservation.]~~

Reason: This principle can be deleted because it repeats what is reflected in Principle 5.

Principle 7

~~**[Principle 7:** When used for prevention/prophylaxis of a specific disease risk, medically important antimicrobials **agents** should only be administered in well-defined **and exceptional** circumstances, based on epidemiological and clinical knowledge, and follow appropriate professional oversight, dose, and duration. Medically important antimicrobial agents should only be used in well-defined circumstances for the prevention/prophylaxis of a specific disease risk and follow appropriate professional oversight, dose, and duration.]~~

[**Principle 7bis:** When used for the control of disease/metaphylaxis, ~~medically important~~ antimicrobial agents should only be used on the basis of epidemiological and clinical knowledge and a diagnosis of a specific disease and follow appropriate professional oversight, dose, and duration.]

[**Principle 7ter:** When used for plant/crop protection, ~~medically important~~ antimicrobial agents should only be used to the extent necessary for a specific disease and follow appropriate professional oversight, dose, and duration.]

Principle 12:

[**Principle 12:** ~~Medically important~~ **Antimicrobials agents** should be administered, prescribed, or applied only by, or under the direction of, veterinarians, plant/crop health professionals, or other suitably trained persons authorized in accordance with national legislation.]

Reason: This principle should include all antimicrobial agents in order to be consistent with the OIE guidance. Reference is made to Article 6.10.3 of the OIE Terrestrial Animal Health Code.

Paragraph 15:

15 42. The competent authorities, including the authority responsible for granting the marketing authorization for antimicrobials for use along the food chain, have a significant role in specifying the terms of the authorization and in providing appropriate information to the veterinarian and plant/crop health professionals, or other suitably trained persons authorized in accordance with national legislation and producers through product labelling and/or by other means, in support of the responsible and prudent use of antimicrobial agents along the food chain. It is the responsibility of competent authorities to develop up-to-date guidelines on data requirements for evaluation of antimicrobial agent applications, as well as ensuring that antimicrobial agents used in the food chain are used in accordance with national legislation.

Reason: We do not support the inclusion of the last part of the sentence, because we are of the opinion that it is not only the responsibility of the competent authority to ensure that antimicrobial agents are used in accordance with national legislation.

Paragraph 17:

In order to promote responsible and prudent use of antimicrobial agents, it is important to encourage the use development, and availability, and use of validated, rapid, reliable diagnostic tools, where available, to support veterinarians and plant/crop health professionals in **diagnosing the disease and selecting the most appropriate antimicrobial agent to be administered/applied prescribed for treatment.**

Reason: We support the inclusion of this paragraph, with the suggested alteration.

Paragraph 27:

27 23. Competent authorities, ~~to the extent possible~~, should make sure approved antimicrobial agents are distributed through appropriate distribution systems in accordance with national legislation, including that ~~and medically important antimicrobials~~ **agents** are distributed to appropriately credentialed/registered veterinarians, plant/crop health professionals, or other suitably trained persons authorized in accordance with national legislation.

Paragraph 33:

33 29. The relevant authorities **should** ~~can~~ encourage public and private research to:

- improve the knowledge about the mechanisms of action, pharmacokinetics and pharmacodynamics of antimicrobial agents to optimize the **treatment dosage therapeutic** regimens and their efficacy;
- improve the knowledge about the mechanisms of transmission, selection, co-selection, emergence and dissemination of resistance determinants and AMR resistant microorganisms through food along the food chain;
- develop practical models for applying the concept of risk analysis to assess the public health concern precipitated by the development of resistance;
- further develop protocols to predict, during the authorization process, the impact of the proposed use of the antimicrobial agents on the rate and extent of resistance development and spread;
- develop and encourage good animal production and plant/crop production best management practices and alternative methods to prevent and treat infectious diseases that would to reduce the need to use antimicrobial agents

- assess the primary drivers leading to use of medically important antimicrobials at the farm, regional, and national levels, and the effectiveness of different interventions to change behavior and reduce the use of medically important antimicrobial agents in food production;
- improve the knowledge on behavior change and on cost-positive interventions to reduce the need of antimicrobial agents;
- develop safe and effective alternatives to antimicrobial agents, new antimicrobial agents, rapid diagnostics, and vaccines;
- determine the potential transfer to fresh produce and other plants/crops of resistant microorganisms and resistance determinants from animal manures or other biological materials used as fertilizer or selected for during the use of production practices, and if there is subsequent transfer through food to consumers;
- improve knowledge on the role of the environment on the persistence of antimicrobial agents, and the emergence, transfer and persistence of antimicrobial resistance determinants and resistant microorganisms;
- improve the knowledge and on the role of the environment on the emergence, transfer and persistence of antimicrobial agents, resistance determinants and AMR microorganisms;
- determine the potential transfer to animals and plants/crops of resistant microorganisms and resistance determinants due to agricultural chemical use.

Paragraph 41:

41 ~~35~~. It is the responsibility of the marketing authorization holders to only advertise antimicrobial agents in accordance with the provisions of paragraphs 30-31~~25-27~~ on the Responsibilities of the Competent Authorities, Control of Advertising. ~~and to not advertise medically important antimicrobials to producers.~~

Reason: This is covered by referencing paragraphs 30-31.

Paragraph 46:

46 ~~40~~. Wholesalers and retailers distributing ~~medically important~~ antimicrobial agents should only do so on the prescription of a veterinarian or order from a plant/crop health professional or other suitably trained person authorized in accordance with national legislation. All distributed products should be appropriately labelled.

Reason: We are of the opinion that this should apply to all antimicrobial agents in order to be consistent with the OIE guidance. Reference is made to Article 6.10.3 of the OIE Terrestrial Animal Health Code.

Paragraph 51:

51 ~~47~~. Antimicrobial agents should only be ~~used~~ prescribed or administered when necessary, as only as long as necessary, and in an appropriate manner:

- A prescription, or order for application, or similar document for ~~medically important~~ antimicrobial agents should indicate the dose, the dosage intervals, route and the duration of the administration, the withdrawal period, when appropriate, and the amount of antimicrobial agent to be delivered, depending on the dosage and the characteristics of the individual or population or plant/crops to be treated, in accordance with national legislation;
- The quantity of the antimicrobial provided to the end-user should, if feasible, be limited only for the administration concerned. Prescriptions or orders should also indicate the owner and the identification of the food-producing animals or plants/crops to which the antimicrobials are to be administered;
- All ~~medically important~~ antimicrobial agents should be prescribed or applied and used according to label directions and/or the direction advice of a veterinarian or plant/crop health professional, and the conditions stipulated in the national legislation.
- Protocols for monitoring use to allow for data collection or for quality assurance purposes should be considered as recommended in the Guidelines on Integrated Monitoring and Surveillance of Foodborne Antimicrobial Resistance.

Reason: This should apply to all antimicrobial agents in order to be consistent with the OIE guidance. Reference is made to Article 6.10.3 of the OIE Terrestrial Animal Health Code.

Paragraph 53:

53 ~~49~~. For plant/crop production, the appropriate use of ~~medically important~~ antimicrobial agents to manage disease/pests should be based on the principles of integrated pest management (IPM), consultation with a plant/crop health professional, historical and epidemiological knowledge of the disease/pest situation, and monitoring of the current disease/pest status. Only authorized products should be used following label directions. Alternatives to ~~medically important~~ antimicrobials should be considered when available and their

safety and effectiveness has been determined. ~~Medically important~~ Antimicrobial agents should only be used to the extent necessary for a specific disease and follow appropriate professional oversight, dose, and duration.

Reason: This should apply to all antimicrobial agents in order to be consistent with the responsibilities for the Veterinarians. This is also consistent with the OIE guidance. Reference is made to Article 6.10.3 of the OIE Terrestrial Animal Health Code.

THAILAND

We are of the view that it may be challenging to implement these recommendations in the parentheses under para 11 across all types of antimicrobials including antiviral, antiparasitic, antiprotozoal, and antifungal agents. However, we propose deleting this phrase for a coherence with a key feature of the COP that mostly describes the activities to minimize and contain foodborne antimicrobial resistance. The proposed amendment is shown below;

~~“11 8bis. Recognizing there are mechanisms of co-resistance or co-selection in a range of antimicrobial agents, most of the recommendations in this Code of Practice will focus on antibacterials, however some recommendations may also be applicable to antiviral, antiparasitic, antiprotozoal, and antifungal agents, where scientific evidence supports foodborne AMR risk to human health.”~~

3. Definitions

We have general comments for 3 definitions as follows:

(1) Food production environment:

To facilitate the implementation process, the definitions must be clear, narrow down and point out only the food production community under the scope of the draft COP. A clear definition shall enable Member countries to reach a common understanding to feasibly implement the National Action Plan which is suitable for their national priorities and contexts.

(2) Plants/crops and (3) Food of plant origin

Each term should be used appropriately in the relevant context of document.

4. General principles to minimize and contain antimicrobial resistance

Principle 5

To strengthen the responsible and prudent use of antimicrobials, the use of antimicrobial growth promoters in the food-producing animals should be phased out. Thailand, by the Department of Livestock Development (DLD), has prohibited antibiotics used for growth promotion under the Feed Quality Control Act 2015. Moreover, we have initiated the antibiotic-free livestock productions, e.g. pork, chicken and eggs to provide healthier choice for consumers and to draw public attention to combat against antimicrobial resistance.

5. Section 5.1 Responsibilities of the competent authorities

5.1 Subsection: Quality control of antimicrobial agents

Para 19, we propose the deletion of a phrase “when mixed with feed, water, or other ingredients.” because quality checking after antimicrobial agents incorporated to feed or water may not be feasible and it is considered costly. The proof of the GMP certification and following the manufacturing instructions should be sufficient to ensure the quality of antimicrobial agents. The proposed amendment is shown below;

~~“19 45. Competent authorities should ensure that quality controls are carried out in accordance with national or international guidance and in compliance with the provisions of good manufacturing practices, including with regard to ensuring quality and purity in manufacture, and storage, and when mixed with feed, water, or other ingredients.”~~

5.2 Subsection: Assessment of environmental impact

Title

For clarity, the title of this section “Assessment of environmental impact” should be amended to read “Assessment of food-production environment impact”

Para 22

The examples of sources for the dissemination AMR to the food-production environment might be outside the scope of Codex, and some of them may already be carried out by the other agencies. Therefore, we propose to delete such examples. The proposed amendment is shown below;

~~22 19. In accordance with their national guidelines, Competent authorities should consider foodborne AMR risk characterization from of environmental sources that contribute to the food production environment, such as pollution from pharmaceutical manufacture, reuse of waste water for irrigation, and use of manure, and other waste-based fertilizers and/or municipal wastes for soil fertilization the environmental aspects on foodborne AMR e.g. pollution from pharmaceutical manufacture, impacts of reusing waste water for irrigation, and using manure, and other waste-based fertilizers and/or municipal wastes for soil fertilization. When a foodborne AMR risk is determined through the Guidelines for risk analysis of foodborne antimicrobial resistance the need for monitoring and proportionate risk management measures can should be considered.~~

GFSI

→ Introduction

Paragraph 3: replace “best practices” with GMP (Good Manufacturing Practices) and/or GHP (Good Hygiene Practices).

→ Section 3, Definitions

As the term “agricultural chemical use” is being used throughout the document, we would propose to add a definition of this term.

→ 5.1 Responsibilities of the competent authorities

Editorial comment: the principles should be numbered sequentially.

Paragraph 16: Good animal production should be replaced with OIE definition: Good animal husbandry practice?

→ Assessment of efficacy:

Paragraph 20: Proposition to specify the wording in red:

Assessment of efficacy is important to assure adequate response to the administration of antimicrobial agents. As part of the marketing authorization process, the assessment should include the efficacy with optimal dosages and durations and **route(s) of administration** supported by clinical trials, microbiological data (including antimicrobial susceptibility testing) pharmacokinetic (PK) data, and pharmacodynamic (PD) data.

→ Establishment of a summary of product characteristics for each antimicrobial agent Paragraph 23:

GFSI would recommend some clarity on the paragraph, is it describing the establishment or approval of the summary of the product characteristics document?:

→ Distribution of antimicrobial agents

GFSI would recommend to delete paragraph 29 because the content is already covered in paragraph 27.

→ 5.3 Responsibilities of wholesale and retail distributors

Paragraph 47:

GFSI would recommend to change:

- “supplied” by “dispensed”
- “date of supply” with “dispensed date”
- GFSI would propose to insert the word “manufacturer” in the 4th bullet point

Distributors should keep records of all antimicrobials **supplied** according to the national regulations and may include including, for example:

- date of supply
- name of receiving prescribing veterinarian or plant/crop health professional or other suitably trained and authorized person
- name of user
- name of medicinal product, manufacturer, formulation, strength and package size
- batch number

- quantity supplied
- expiration dates

→ 5.4 Responsibilities of Veterinarians and Plant/Crop Health Professionals GFSI would recommend specification for “production unit”.

→ Consumer practices and communication to consumers Paragraph 68:

The food industry acknowledges their role to inform and educate consumers on the risks of foodborne illness in collaboration with other stakeholders.

Messaging associated with risks on AMR should be led by the public health authorities. We acknowledge that the industry should support the efforts of the public health officials.