CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 5, 6 **CRD15**

ORINGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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

Sixth Session

Comments of China

Agenda Item 5

China would like to thank the work of electronic working group, and provide following comments to the proposed draft document.

I. General Comments

China generally agree with the scope of RCP to the whole food chain, However, it is suggested that the sections of responsibility of crops health professionals and control of environment need to be further developed.

China also noticed statement on the biocide and probiotics in the scientific report of WHO. Due to the broad use of biocide and probiotic in food chain, It is suggested to consider the potential risks of biocides on co-selection of AMR and the potential risks of probiotics on transmission of AMR in food chain.

II. Comments for the main points

1. Point a: Definition of plants/crops

The scope of this COP includes all factors in the food chain.

However, it is better to harmonize this definition with other CODEX document, therefore, China agree with the definition of plants/crops which include the edible plant part.

2. Point b. Plant/crop health professional

China preferred to use the term of plant/crop health professional.

The term of plant/crop health professionals includes the regulators, experts, advisor and consultants who has knowledge and experience in crop production and protection practices on crop health or plant food safety.

3. Point c. Antimicrobials vs. antibacterials

The term of antimicrobials includes the antibacterial, antiviral, antifungal, antiparasitic agents. There are mechanisms of co-resistance and co-selection in a range of antimicrobial agents.

China agrees that antibacterials will be the focus of the code in paragraph 6 and some recommendations can be applicable to antiviral, antiparasitic, antiprotozoal and antifungal agents.

4. Point d. Medically important antimicrobials

China agrees with the definition of Medically important antimicrobials which included the WHO list of critically important antimicrobials and national list. However, it is inappropriate to give example of ionophores or other antimicrobial agents which are not for human therapeutic use.

It is recommended to highlight the list of medical important antimicrobials, which should be reviewed and updated when new scientific data is available on resistance patterns.

5. Point f. General principles

China considered that this section could be more concise.

Principle 1 focus on the one health.

Principle 2 focus on the alternative activities and alternative substance good health of human, animals and plants.

Principles 3, 4, 9 and 10 focus on the science-based risk analysis, risk assessment and risk management.

Principles 6, 7 and 12 focus on the prudent use of medical important antimicrobials.

Principles 13 and 14 focus on the administration of antimicrobial agents

Principles 11 and 16 focus on the step wise approach

China suggest to reorganize the sections, to be more tight and concise.

6. Point g. Stepwise approach

China agrees to consider national difference and capability to application of a stepwise approach. It is necessary to clarify that this stepwise approach should not be introduce barriers in international food trade.

7. Point h. Surveillance and monitoring programs

China prefers to replace the section on surveillance and monitoring programs with a reference to the GUIDELINES FOR INTEGRATED MONITORING AND SURVEILLANCE OF FOODBORNE ANTIMICROBIAL RESISTANCE

In addition, China would like to suggest this section to include the responsibility of the regulatory authorities, manufactures and health professionals on the surveillance and monitoring programs.

It is the responsibility of the Regulatory authorities to set up the national surveillance system or pharmacovigilance program. And it is the responsibility of the manufactures of antimicrobial resistance to keep record and submit the information of antimicrobial use. While it is the responsibility of the animal/crop professionals to give scientific advice.

8. Point i. Alternatives to antimicrobials

China would like to suggest to consider the potential risk of the development or co-selection of antimicrobial resistance by some alternative substances, like probiotic.

It is recommended that the efficiency and safety of the alternative substance be highlighted in the document, for instance, probiotics, prebiotics and competitive exclusion products.

9. Point j. Practices during production, processing, storage, transport, retail and distribution of Food

Since the purpose of this document is to provide guidance on containing AMR along the food chain. This section should be further developed.

For example, The food producer should do their best to reduce the contamination of AMR microorganisms in the raw and processing materials.

It is suggested to strengthen the monitoring and assess the risk of biocide on AMR when the technologies and enough data are available.

The slaughter house and processing industry should follow the GMP (good manufacturing practices) and HACCP (Hazard analysis and critical control points) principles in the codex general principles of food hygiene.

Additionally, it is suggested adding the following sentences at the end of 60ter: “It is necessary for food business operators to provide instructions and training on GHP (good hygienic practices) to avoid cross-contamination. The WHO Five Keys to Safer Food can be followed by food handlers to minimize the transmission of foodborne AMR.”

III. Specific comments of each chapter

1. Introduction (paragraph 1-6)

Para 2bis: AMR in environment should be addressed. China suggests to consider the occurrence/persistence of antimicrobials and their metabolites in the environment from anthropogenic sources and animal source.

Para 4: The national lists should be taken into consideration if they are available because they may be more applicable to local conditions.

Para 6: China agrees to focus on antibacterials in code.

2. Scope (paragraph 7-9)

Para 7: China suggests to provide advice on what can realistically be achieved and support recommendations made based on risk assessment.

Para 9： China agrees with most area of the exclusion. However, it can't be ignored that the potential risks of probiotics on the transmission of AMR. Risk analysis of the probiotics should be carried out. In addition, the guidelines of probiotics need to be updated.

In addition, China appreciated the sections of biocides in the scientific report of WHO. There is data gap on the contribution of biocide on the AMR, however, due to the broad use of biocide in food chain, the risk of biocide on the AMR should be assessed. The scope of the code should include the biocides used in the food chain.

3. Definition

It is better to put the definitions of three type of therapeutic use (prevention, treatment, metaphylaxis) together for comparison. Early treatment and the prevent treatment are very important for bacterial infectious diseases and for animal welfare.

Plant/crop: same with the comment for main point a

Plant/crop health professional: same with the comment for main point b.

Antimicrobial/antibacterial: same with the comment for main point c

Medically important antimicrobials: It is suggested to delete the last sentence in this definition. In addition, the lists of medically important antimicrobials should be regularly reviewed and updated as necessary when supported by scientific findings as new scientific data emerges on resistance patterns.

Pharmacovigilance: the definition of pharmacovigilance can be adapted from WHO, OIE and FDA standard.

4. Principles

Reorganize the principles following the comments for main point f.

principle 8: Consider the off-label use of AM under the supervision of professionals.

5. Responsibility for the use of antimicrobial agents.

it is suggested to modify the format of this chapter to make the structure of this chapter clearer.

5.1 Responsibility of authority regulation (paragraph 12-31)

surveillance and monitoring programs (para 21-22 bis):

China recommends to replace the section on surveillance and monitoring programs with a general reference to the GUIDELINES FOR INTEGRATED MONITORING AND SURVEILLANCE OF FOODBORNE ANTIMICROBIAL RESISTANCE. In addition, this section should state the responsibility of the regulatory authorities, manufactures and health professionals on the surveillance and monitoring programs. The Regulatory authorities has the responsibility to set up the national surveillance system or pharmacovigilance program. It is the responsibility of manufacturers to submit the information of antimicrobial use. The animal/crop health professionals have responsibility to keep the clinical data.

Para 22 bis: China would like to welcome the adoption of the definition of Pharmacovigilance and encourage the Pharmacovigilance program.

6 Responsibilities related to food production, processing and retail distribution

Same with the comments for main point j.

Since the purpose of this document is to provide guidance on containing AMR along the food chain, this section should be further developed.

The food producer should do their best to reduce the contamination of AMR microorganisms in the raw and processing materials.

It is suggested to monitor and assess the risk of biocide on ARM in the food processing.

The slaughter house and processing industry should follow the GMP (good manufacturing practices) and HACCP (Hazard analysis and critical control points) principles in the codex general principles of food hygiene.

It is suggested adding the following sentences at the end of 60ter: The WHO “Five Keys to Safer Food” is for promoting safe food handling behaviors and educate all food handlers, including consumers. It is suggested to incorporate “Five Keys to Safer Food” for food handlers along the food chain as well.It is necessary for food business operators to provide instructions and training on GHP (good hygienic practices) to avoid cross-contamination.

Agenda Item 6

China congratulates the work of the working group and would like to provide following comments.

General Comments:

China suggests using “foodborne” to limit the scope of AMR throughout the document, and the scope of monitoring and surveillance program include both foodborne AMR and AMU.

Specific Comments:

3. Definitions

Comment: China agrees with the concept that the definitions in GLIS need to be in line with the definitions in the COP (CXC 61-2005) and GL77. Especially, the use of crops/plants should be unified in the whole text. Some definitions, e.g. Antimicrobial resistance determinants, as it appears many times in the text, should also be included.

Crops/plants: A cultivated plant that is grown as food or feed, especially a grain, fruit, or vegetable.

7.3 Options for stepwise development of integrated monitoring and surveillance of foodborne AMR and AMU programs

Comment: China agrees that the stepwise approach should not create trade barriers, and each country could implement it according to its own national situation, capabilities and priority monitoring objectives. In this table, China suggests to add more details about the sampling sources and plans and target microorganisms for aquatic product, crops/plants and environment. The panel of antimicrobials tested should also include the national lists according to each country’s own situation.

8.3. Sample sources for the collection of isolates for AMR testing

Comment: Sample sources should include all stages along the food chain, including food production, food processing, storage, distribution and consumption. In addition, this chapter lacks sampling in the stage of food processing.

8.4. Target microorganisms and resistance/virulence determinants

Comment: Since it is the resistant pathogens which cause public health risks, foodborne pathogens should be the main target microorganisms to be monitored, and the indicator bacteria such as commensal bacteria should only be the supplement bacteria. Moreover, the antimicrobial resistance phenotypes of bacteria are the main objectives to be monitored, and antimicrobial resistance determinants e.g., resistant genes, are the supplement objectives.

For foods of animal origin, *Salmonella* is a key foodborne pathogen and should therefore be included in an integrated monitoring and surveillance program. Other foodborne pathogens like *Campylobacter* and pathogenic *E. coli* should also be strongly considered, as well as other pathogens depending on national or regional situation and risks (e.g. *Vibrio, Staphylococcus aureus*). For foods of plant origin, S*almonella* is also a key foodborne pathogen of great concern. Other foodborne pathogens like enteropathogenic *Escherichia coli* (such as *E. coli* O157:H7 and O104:H4) should also be strongly considered, as well as other pathogens depending on national or regional situation and risks (e.g. *Listeria*, *Shigella, Staphylococcus aureus, Campylobacter)*.

Indicator organisms of commensal intestinal bacteria may contaminate food and can harbor transferable resistance genes. Commensal bacteria such as *Escherichia coli* and *Enterococcus faecium/faecalis* should be considered as the indicators of Gram negative and Gram positive AMR microorganisms, respectively.

Whenever possible the monitoring and surveillance program should include genetic and/or phenotypic analysis of particular isolates that may be a public health concern such as extended spectrum β-lactamase (ESBL)- AmpC and/or carbapenemase-producing strains and MDR strains.

12. Risk communication

Comment: For risk communication, China suggests to further develop the roles and responsibility of risk assessors, risk managers and stakeholders in the risk communication.

13. Training

Comment: For training, China suggests to include all the stakeholders as the training objects.

Training involving all the relevant professional organizations, regulatory authorities, the antimicrobial and other relevant industries, research institutes, professional associations and other approved users is of importance to ensure consumer safety and, therefore, the protection of public health.