CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 5, 6 **CRD16**

ORINGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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

Sixth Session

Comments of Russian Federation

Agenda Item 5

4. The *Principles and guidelines for the conduct of microbiological risk management* (CXG 63-2007) contains guidance for developing and implementing risk management measures. *WHO guidance on integrated surveillance of antimicrobial resistance in foodborne bacteria, application of a One Health Approach* and ~~*critically important antimicrobials for human medicine*~~ *WHO list of critically important antimicrobials for human medicine. 5th rev. Geneva, 2017* and relevant chapters of the *OIE terrestrial and aquatic animal health codes* and the *List of antimicrobials of veterinary importance* should also be referenced for setting priorities and identifying risk management measures.

3. Definitions

Antibiotic: A ~~naturally derived substance~~ chemical substance, produced by micro-organisms as well as their synthetic analogs, that acts against microorganisms, specifically bacteria.

Antibiotic resistance: The ability of a microorganism, specifically bacteria, to multiply or persist in the presence ~~of an increased level of an antimicrobial agent relative~~ of an antimicrobial in concentration that kills or inhibits the susceptible counterpart of the same species.

Prevention of disease/prophylaxis: Administration of antimicrobial agents to an individual or a population of sub-therapeutic doses at risk of acquiring a specific infection or in a specific situation when there is a high risk of developing an infectious disease.

Therapeutic use: Administration of therapeutic doses of antimicrobial agents for the treatment and control/metaphylaxis ~~and prevention/prophylaxis~~ of disease.

4. General principles to minimize and contain antimicrobial resistance

Principle 5: ~~Responsible and prudent administration in food-producing animals does not include the use for growth promotion of antimicrobial agents that are considered medically important or are able to cause cross-resistance to other antimicrobial agents, or classes of antimicrobial agents, that are considered medically important, in the absence of a risk analysis.~~

~~This risk analysis should:~~

- ~~be undertaken by the appropriate national regulatory authority;~~
- ~~be based on adequate scientific evidence; and~~
- ~~include a publicly available summary.~~

The use for growth promotion of antimicrobial agents that are considered medically important or are able to cause cross-resistance to other antimicrobial agents, or classes of antimicrobial agents, that are considered medically important should be prohibited.

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 (e.g. skeletal marking in fish).

RF We also propose to add subprincipal on necessity to minimise the use of antimicrobial agents of highest priority according to the WHO List of Critically Important Antimicrobials in food-producing animals.

Principle 8: ~~Only legally authorized antimicrobial agents should be used and all applicable label directions should be followed; except where specific legal exemptions apply.~~

Regulatory authorities should assure that only legally authorized antimicrobial agents are used and all applicable label directions are followed; except where specific legal exemptions apply

Principle 15: The reduce, replace and rethink (RRR) strategy on the use of antimicrobial agents in animals and on plants/crops should be actively promoted within all sectors.

RF we propose to give special reference for the definition of reduce, replace and rethink (RRR) strategy as it is done in One health approach.

5. Responsible and prudent use of antimicrobial agents

Control of advertising

RF We propose to add following provision: Advertising of medically important antimicrobial agents should be prohibited

Knowledge gaps and research

29. The relevant authorities should encourage public and private research to:

- improve the knowledge about the mechanisms of action, pharmacokinetics and pharmacodynamics of antimicrobial agents to optimize the dosage regimens and their efficacy;
- improve the knowledge about the mechanisms of transmission, selection, co-selection, emergence and dissemination of resistance determinants and AMR microorganisms through food;
- 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
- develop and encourage good animal production and plant/crop production best management practices and alternative methods to prevent and treat infectious diseases that would reduce the need to use antimicrobial agents
- develop safe and effective alternatives to antimicrobial agents, new antimicrobial agents, rapid diagnostics, and vaccines
- develop alternatives to antimicrobials, new antimicrobials, rapid diagnostics, and vaccines, including autogenous vaccines develop alternative methods to prevent and treat infectious diseases that would reduce the need to use antimicrobials, new antimicrobials, rapid diagnostics, and vaccines, including autogenous vaccines.

Responsibilities of wholesale and retail distributors

41. Distributors should encourage compliance with the national guidelines on the responsible use of medically important antimicrobial agents and should keep records of all antimicrobials supplied according to the national regulations including, for example:

- date of supply
- name of prescribing veterinarian or other suitably trained and authorized person
- name of user
- name of medicinal product, formulation, strength and package size
- trade and international nonproprietary name
- Name of producer
- batch number
- quantity supplied

42. Distributors should support the training of users of antimicrobial agents as defined in paragraph 28.

Responsibilities of Veterinarians[1] and Plant/Crop Advisors or Consultants

48. For food-producing animals, the appropriate use of medically important antimicrobial agents in practice is a clinical decision that should be based on the experience and local expertise of the prescribing veterinarian,

[1] Under some circumstances, this may refer to a suitably trained person authorized in accordance with national legislation.

and the accurate diagnosis, based on adequate diagnostic procedures. Such cases should be documented. Antibacterial drugs of highest priority (Highest priority) from WHO List of Critically Important Antimicrobials should not be used for treatment. There will be occasions when a group of food-producing animals, which may have been exposed to pathogens, may need to be treated without recourse to an accurate diagnosis and antimicrobial susceptibility testing to prevent the development and spread of clinical disease and for reasons of animal welfare.

Responsibilities of food producers

58. Producers have the following responsibilities:

- to use antimicrobial agents only when necessary and not as a replacement for good management and farm hygiene, or other disease prevention methods;
- to use antimicrobial agents only when necessary, under the supervision of a veterinarian or plant/crop advisor or consultant when required, and not as a replacement for good management and farm hygiene practices, or other disease treatment and prevention methods such as bacteriophage treatment vaccination;
- to implement a health plan in cooperation with the veterinarian, plant/crop advisors or consultants, or other suitably trained person authorized in accordance with national legislation that outlines measures to prevent disease;
- to use antimicrobial agents in the species, for the uses and at the doses on the approved labels and in accordance with the prescription, product label instructions or the advice of a veterinarian, plant/crop advisors or consultants or other suitably trained person authorized in accordance with national legislation familiar with the food-producing animals or the plant/crop production site;
- to isolate sick animals and dispose of dead or dying animals or plants/crops promptly under conditions approved by relevant authorities;
- to comply with the storage conditions of antimicrobial agents according to the approved product labelling;
- to address infection prevention and control measures regarding contacts between people, veterinarians, plant/crop advisor or consultants, breeders, owners, children and the food-producing animals or plants/crops treated;
- to comply with the recommended withdrawal periods or pre-harvest intervals to ensure that residue levels in or on the food do not present a foodborne AMR risk for the consumer;
- to not use out-of-date antimicrobial agents and to dispose of all unused or out-of-date antimicrobial agents in accordance with the provisions on the product labels and national legislation;
- to inform the veterinarian, plant/crop advisor or consultant, or other suitably trained person authorized in accordance with national legislation in charge of the production unit of recurrent disease problems or failures of antimicrobial applications;
- to maintain all clinical and laboratory records of microbiological diagnosis and susceptibility testing. These data should be made available to the professional in charge of the administration in order to optimize the use of antimicrobial agents.
- to keep adequate records of all antimicrobial agents used, including the following:
    - name of the antimicrobial agent/active substance and batch number expiry date, producer;
    - name of supplier;
    - date of administration; species and number of animals;
    - identification of the production unit (animal age, numbers, weights) to which the antimicrobial agent was administered;
    - disease treated, prevented, or controlled;
    - number of animals treated;
    - daily dose and number of treatment days;
    - quantity and duration of the antimicrobial agent administered;
    - withdrawal periods;
    - result of treatment;

- name of the prescribing veterinarian, plant/crop advisor or consultant or other suitably trained person authorized in accordance with national legislation.

- To ensure sound management of wastes and other materials to minimize dissemination of excreted antimicrobial agents, resistant microorganisms and resistance determinants into the environment where they may contaminate food;
- To address on-farm biosecurity measures and take basic infection prevention and control measures as appropriate and as provided in the *OIE terrestrial and aquatic animal health code*;
- To assist the relevant authorities in surveillance programs related to antimicrobial use and antimicrobial resistance, as appropriate.

59. The responsible and prudent use of antimicrobial agents should be supported by continuous efforts in disease prevention to minimise infection during production and decrease exposure to antimicrobial agents. Efforts should aim to improve health, thereby reducing the need for antibiotics. This can be achieved by improving hygiene, biosecurity and health management on farms, improving animal and plant/crop genetics, and implementing national or international good animal production (terrestrial and aquatic), and plant/crop production practices. Disease prevention through the use of vaccines, integrated pest management, and other measures that have been clinically proven to be safe and efficacious, such as probiotics (beneficial bacteria found in various foods), bacteriophages prebiotics (non-digestible foods that help probiotic bacteria grow and flourish) or competitive exclusion products (intestinal bacterial flora that limit the colonization of some bacterial pathogens) may be considered and applied wherever appropriate and available. Disease prevention through the use of vaccines and other appropriate measures aimed at supporting animal health (such as adequate nutrition and whenever available feed additives such as prebiotics, probiotics) should be considered.

6. Practices during production, processing, storage, transport, retail and distribution of food

RF

This section should address the risk management measures related to the practices during production, processing, storage, transport, retail and distribution of food that impact in preventing, minimizing and containing foodborne AMR and **this measures efficiency assessment.**

Some aspects that also could be covered are: measures regarding the food processing and handling environment that impact food.

While developing this section cross-reference to General Principles of Food Hygiene (CAC/RCP 1-1969) and other relevant Codes of Food Hygiene Practices (to be identified) should be made, where appropriate, aiming to minimize duplication, avoid contradiction and ensure coherence.

Moreover we propose to include provisions on responsibility of producers of new antibiotics intended for agriculture use to inform food producers about risks of possible antimicrobial resistance.

Agenda Item 6

7.2 Initiating monitoring and surveillance activities

The design of a stepwise monitoring and surveillance system should consider the following principles:

Antimicrobial resistance:

- Targeting the highest priority microorganisms, panels of antimicrobials and commodities (see section 10 of these guidelines) based on country data or international recommendations;
- Identifying the food production and distribution chain, points in the food chain and sampling frequency to undertake sampling to meet monitoring and surveillance objectives;
- Establishing sampling methods, laboratory analysis and reporting protocols; building capacity where required;
- Establishing standardized and harmonized methodologies (e.g., laboratory testing for AST) and best practices with those used in other sectors
- Conducting epidemiological studies of microorganisms resistant to antimicrobials in humans.

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

For Sampling plans of PROGRAM B we propose the following version of provision: Sampling broaden to be more representative of the national population of interest (e.g., surveillance of farms according to total number of livestock,of abattoirs according to slaughter volume).

For Target microorganisms, bacteria isolated of PROGRAM B we propose the following version of provision:

- Phenotypic testing of a broader range of pathogens and indicator bacteria for resistance
- Addition of testing for genetic determinants of transferable resistance.