

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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TO: Codex Contact Points
Interested International Organizations

FROM: Secretary, Joint FAO/WHO Food Standards Programme
00100 Rome, Italy

SUBJECT: **Request for comments on how to address the issue of antimicrobial resistance within Codex**

DEADLINE: **12 November 2004**

COMMENTS: To:
Secretary
Joint FAO/WHO Food Standards Programme
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BACKGROUND

The 27th Session of the Codex Alimentarius Commission (CAC) was informed of the two FAO/WHO/OIE workshops (see Annex I) that had been convened at the request of the 48th Session of the Executive Committee to advise the Commission on possible direction to be taken on antimicrobial resistance (ALINORM 04/27/41, paras 210-219). It was noted that there was unanimous support for cooperation with OIE in addressing the issue of containing antimicrobial resistance, but that financial implications and impact on country participation, especially for developing countries, should be carefully considered before a final decision towards establishing a new Task Force is taken. The Commission noted the willingness of the Delegation of the Republic of Korea to host an *ad hoc* Task Force on Antimicrobial resistance, if such a Task Force was to be established in future. The Commission also noted that OIE had already adopted sections on the containment of antimicrobial resistance in the OIE Code and noted its support to the conclusion of the Joint Workshops.

Many delegations supported the view of the Executive Committee (54th Session, June 2004) that there were several possible options for the Commission to deal with this matter, including the establishment of a Codex Task Force with active participation of the OIE, or the use of existing Codex subsidiary bodies such as the Committee on Food Hygiene, the Committee on Residues of Veterinary Drugs in Foods and the Task Force on Animal Feeding (see Annex II).

The Commission agreed that before deciding on the procedural mechanisms to further work, there should be a clear and common understanding of what should be achieved by Codex in regard to the question of antimicrobial resistance related to non-human use of antimicrobials (ALINORM 04/27/41, para. 216).

REQUEST FOR COMMENTS

In order to facilitate the discussion, the Secretariat, as requested by the Commission, is distributing this Circular Letter with the following two questions to be answered:

1. What should be achieved by Codex to address the issue of antimicrobial resistance related to non-human use of antimicrobials (e.g. risk assessment principles, risk management options); and
2. What mechanisms should be used by Codex to achieve the above outcome?

The Commission agreed that the comments received in reply to this Circular Letter would be considered at the 55th Session of the Executive Committee with the understanding that it would provide the advice to the next session of the Commission (ALINORM 04/27/41, para. 218). Therefore, Member governments and interested International Organizations are invited to provide comments on the above two questions, preferably by an email, to the address above and no later than 12 November 2004.

ANNEX I

Executive Summary of the Joint WHO/FAO/OIE Expert Workshop on Non-human Antimicrobial Usage and Antimicrobial Resistance, Geneva, 1 – 5 December 2003

Antimicrobial agents are essential drugs for human and animal health and welfare. Antimicrobial resistance is a global public health concern that is impacted by both human and non-human antimicrobial usage. Antimicrobial agents are used in food animals, including from aquaculture, companion animals and horticulture to treat or prevent disease. Antimicrobial agents are sometimes used in food animals to promote growth. The types of antimicrobials used are frequently the same as, or closely related to, antimicrobials used in humans.

Managing human health risks from non-human usage of antimicrobials and the resulting antimicrobial resistant bacteria requires national and international interdisciplinary cooperation. This consultation was convened by FAO, OIE and WHO to perform a scientific assessment of resistance risks arising from the usage of antimicrobials in animals (including aquaculture) and plants and to formulate recommendations and options for future risk management actions to be considered by the Codex Alimentarius Commission and OIE.

There is clear evidence of the human health consequences due to resistant organisms resulting from non-human usage of antimicrobials. These consequences include infections that would not have otherwise occurred, increased frequency of treatment failures (in some cases death) and increased severity of infections, as documented for instance by fluoroquinolones resistant human Salmonella infections. Evidence shows that the amount and pattern of non-human usage of antimicrobials impacts on resistant bacteria in animals and on food commodities and thereby human exposure to these resistant bacteria. The foodborne route is the major transmission pathway for resistant bacteria and resistance genes from food animals to humans, but other routes of transmission exist. There is much less data available on the public health impact of antimicrobial use in aquaculture, horticulture and companion animals.

The consequences of antimicrobial resistance are particularly severe when pathogens are resistant to antimicrobials critically important in humans. Therefore, the workshop recommends that an expert clinical medical group appointed by WHO define which antimicrobials are considered critically important in humans.

The expert workshop concluded that surveillance of non-human usage of antimicrobials and antimicrobial resistance in food and animals is important for the identification of resistance problems and as a basis for choosing interventions to limit the development and spread of resistance at all levels.

Several recent attempts to quantify the magnitude of related health impacts in the human population have been made. Estimates vary widely from small to large, depending on the organism and antimicrobial of interest, and are accompanied by considerable uncertainty.

The workshop concluded that residues of antimicrobials in foods, under present regulatory regimes, represents a significantly less important human health risk than the risk related to antimicrobial resistant bacteria in food.

Risk assessment approaches that adequately address the broad range of potential human health impacts need to be further developed with a view towards enabling efficient risk management of antimicrobial resistance in the international arena. OIE is invited to continue its work on risk analysis in coordination with FAO and WHO.

The Workshop recommended that the Codex Alimentarius Commission, where appropriate in collaboration with OIE, takes coordinated steps towards managing these risks focusing on the microbiological nature of the hazards.

¹² In the context of this report, farmers include individuals, groups and companies involved in primary food production.

Executive Summary of the Joint FAO/OIE/WHO 2nd Workshop on Non-human Antimicrobial Usage and Antimicrobial Resistance: Management Options, Oslo, Norway, 15-18 March 2004

Antimicrobial agents are essential drugs for human and animal health and welfare. Antimicrobial resistance is a global public and animal health concern that is impacted by both human and non-human antimicrobial usage. The human, animal and plant sectors all have a shared responsibility and role in efforts to prevent and minimize antimicrobial resistance selection pressures for both human and non human use of antimicrobials. Antimicrobial agents are used in food animals, aquaculture, companion animals and horticulture to treat or prevent disease. Antimicrobial agents are sometimes used in food animals to promote growth. The types of antimicrobials used are frequently the same as, or closely related to, antimicrobials used in humans.

Managing human health risks from non-human usage of antimicrobials and the resulting antimicrobial resistant bacteria requires national and international interdisciplinary cooperation. The 1st Workshop on Non-human Antimicrobial Usage, December 2003 in Geneva, conducted a preliminary scientific assessment considering all non-human uses of antimicrobials in animals (including aquaculture) and plants, and their role in antimicrobial resistance, based on the available scientific information. Based on the outcome of the 1st Workshop in Geneva, as well as other relevant input (e.g. reports of previous WHO and OIE workshops), the 2nd Workshop in Oslo considered the broad range of possible risk management options for antimicrobial resistance from non-human usage of antimicrobials. In particular, it focused on potential directions of future Codex, FAO, OIE and WHO work in this area, in order to prevent and minimize antimicrobial resistance at the global level. To ensure that the conclusions of the 2nd Workshop reflected the perspectives of affected parties, the major stakeholder groups (e.g., pharmaceutical industry, farmers², food processors, consumers, regulatory agencies, and veterinarians) participated in the meeting.

The workshop process has resulted in suggestions for a way forward in this area, for Codex, as well as for OIE, WHO and FAO. Among the important conclusions were:

1. The risks associated with non-human antimicrobial use and antimicrobial resistance should be part of the human safety assessment. The concept of “thresholds of resistance” should be pursued as a tool for risk management. If these thresholds are exceeded, this should trigger a range of risk management actions.
2. The concept of “critically important” classes of antimicrobials for people should be developed by WHO with a view to enabling specific resistance preventive actions for such antimicrobials related to non-human use. A similar list of “critically important” classes of antimicrobials for animals should be pursued by OIE.
3. Through stringent implementation of good agricultural practices including good animal husbandry and good veterinary practices it is possible to reduce the necessity for antimicrobials.
4. The need for rapid implementation by governments and all stakeholders of the WHO Global Principles for the Containment of Antimicrobial Resistance in Animals intended for Food and the OIE Guidelines on Antimicrobial Resistance is emphasised.
5. There is need for capacity building, networking and co-ordination to facilitate implementation of surveillance programmes in various countries, in particular developing countries. FAO, WHO and OIE should take a leading role in this.
6. A Codex/OIE Task Force should be established to develop risk management options for antimicrobial resistance related to non-human use of antimicrobials. Risk communication and transparency are critical to achieve effective risk management. Moreover, the International Code of Practice, General Principles of Food Hygiene should be reviewed to take account of antimicrobial resistance issues.

The outcome of this consultative process will be discussed in detail at the Codex Alimentarius Commission meeting in June 2004 in Geneva, based on the full publication and distribution of both reports to all Member States. Furthermore the outcome will be discussed in relevant OIE fora and will support future WHO work in this area.

ANNEX II

TERMS OF REFERENCE AND ONGOING WORK OF RELEVANT CODEX COMMITTEES IN RELATION TO ANTIMICROBIAL RESISTANCE***Codex Committee on Residues of Veterinary Drugs in Food (CCRVDF)***

The Terms of Reference for CCRVDF are:

- (a) to determine priorities for the consideration of residues of veterinary drugs in foods;
- (b) to recommend maximum levels of such substances;
- (c) to develop codes of practice as may be required;
- (d) to consider methods of sampling and analysis for the determination of veterinary drug residues in foods.

On-going work

Currently, the CCRVDF is developing a Code of Practice to Minimize and Contain Antimicrobial Resistance, at Step 2 of the Procedure. At its 14th Session (March 2003), the CCRVDF agreed that the proposed draft Code of Practice would be revised by the drafting group and, if possible, would consider the results of the Joint FAO/WHO/OIE expert consultation on antimicrobial resistance, for further consideration at the 15th Session (ALINORM 03/31A, para. 73-82).

Codex Committee on Food Hygiene (CCFH)

The Terms of Reference for CCFH are:

- (a) to draft basic provisions on food hygiene applicable to all food³;
- (b) to consider, amend if necessary and endorse provisions on hygiene prepared by Codex commodity committees and contained in Codex commodity standards, and
- (c) to consider, amend if necessary, and endorse provisions on hygiene prepared by Codex commodity committees and contained in Codex codes of practice unless, in specific cases, the Commission has decided otherwise, or
- (d) to draft provisions on hygiene applicable to specific food items or food groups, whether coming within the terms of reference of a Codex commodity committee or not;
- (e) to consider specific hygiene problems assigned to it by the Commission;
- (f) to suggest and prioritize areas where there is a need for microbiological risk assessment at the international level and to develop questions to be addressed by the risk assessors;
- (g) to consider microbiological risk management matters in relation to food hygiene and in relation to the risk assessment of FAO and WHO.

On-going work

In keeping with these terms, the CCFH, consisting of experts in food hygiene and food microbiology in particular, has the specific duty to propose any measures likely to reduce the burden of microorganisms, sensitive or resistant to antimicrobials, in food.

³ The term “hygiene” includes, where necessary, microbiological specifications for food and associated methodology.

A “Risk Profile on Antimicrobial-Resistant Bacteria in Food” was presented at the 34th Session of the CCFH (October 2001), which addressed the effects of non-human antimicrobial use on human health (ALINORM 03/13, para. 13). During its last Session (March 2004), the Committee noted the results of the Oslo workshops and supported the establishment of a Codex/OIE Task Force to develop broad risk management options for antimicrobial resistance related to non-human use of antimicrobials. The CCFH decided that efficient interaction between this Task Force, the CCFH, and other relevant Codex committees should be ensured (ALINORM 04/27/13, para. 159).

Ad Hoc Intergovernmental Task Force on Animal Feeding

The Terms of Reference for the Task Force are:

- (a) to complete and extend the work already done by relevant Codex Committees on the Draft Code of Practice for Good Animal Feeding;
- (b) to address other aspects which are important for food safety, such as problems related to toxic substances, pathogens, microbial resistance, new technologies, storage, control measures, traceability, etc.;
- (c) to take full account of and collaborate with, as appropriate, work carried out by relevant Codex Committees, and other relevant international bodies, including FAO, WHO, OIE and IPPC.

On-going work

The Task Force completed work on the Code of Practice on Good Animal Feeding, which acknowledges the need for safety assessments and the proper use of veterinary drugs in animal feed (ALINORM 04/27/38). The 27th CAC decided that at its next Session it will determine whether additional work should be required by Codex on animal feeding and if so what mechanisms would be most appropriate (ALINORM 04/27/41, para. 171).

Codex Committee on Pesticide Residues (CCPR)

The Terms of Reference for the Task Force are:

- (a) to establish maximum limits for pesticide residues in specific food items or in groups of food;
- (b) to establish maximum limits for pesticide residues in certain animal feeding stuffs moving in international trade where this is justified for reasons of protection of human health;
- (c) to prepare priority lists of pesticides for evaluation by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR);
- (d) to consider methods of sampling and analysis for the determination of pesticide residues in food and feed;
- (e) to consider other matters in relation to the safety of food and feed containing pesticide residues; and
- (f) to establish maximum limits for environmental and industrial contaminants showing chemical or other similarity to pesticides, in specific food items or groups of food.

On-going work

At the 32nd and 33rd Sessions of CCPR it was requested that *gentamicin* and *oxytetracycline* be added to the priority list for evaluation by JMPR in order to proceed with the establishment of Maximum Residue Limits (ALINORM 01/24A, para. 222), as it complied with the criteria for inclusion on the priority list. It was indicated that these agents are very effective and important for control of bacterial diseases on certain commodities, and that residue levels are very low when these substances are used according to Good Agricultural Practice (GAP). A number of delegations and observers did not support their inclusion on the priority list because they did not consider the use of these antibiotics as pesticides to be appropriate, which could lead to the development of antibiotic resistance in humans. Due to lack of consensus on this issue, the Committee asked advice from the Commission on how to proceed with this matter.