



**Second Joint FAO/ OIE/WHO Expert Workshop on
Non-Human Antimicrobial Usage and
Antimicrobial Resistance:
Management options**

15–18 March 2004

Oslo, Norway



**World Health Organization
Geneva**



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Summary

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 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, and are sometimes used in food animals to promote growth. The types of antimicrobials used for such purposes are frequently the same as, or closely related to, the antimicrobials used in humans.

Managing human health risks arising from non-human usage of antimicrobials and the resulting antimicrobial-resistant bacteria requires national and international interdisciplinary cooperation. A preliminary scientific assessment was conducted by the first Joint Expert Workshop on Non-Human Antimicrobial Usage, held in December 2003 in Geneva; all non-human uses of antimicrobials in animals (including aquaculture) and plants, and their role in antimicrobial resistance were considered on the basis of available scientific information. The outcomes of that first workshop, plus other relevant input (e.g. reports of previous WHO and OIE workshops), formed the basis for consideration by the second Workshop, held in Oslo. This workshop considered the broad range of risk management options for antimicrobial resistance from non-human usage of antimicrobials and focused on possible directions for future Codex, FAO, WHO and OIE work in this area, with the aim of preventing and minimizing antimicrobial resistance at the global level. To ensure that the conclusions of the second Workshop reflected the perspectives of affected parties, the major stakeholder groups (e.g., members of the pharmaceutical industry, farmers,¹ 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 FAO, WHO and OIE. Among the important conclusions were the following:

- 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. A range of risk management actions should be triggered if these thresholds are exceeded.
- The concept of “critically important” classes of antimicrobials for humans should be developed by WHO with a view to enabling specific resistance-preventive actions for these antimicrobials in the context of non-human use. A similar list of “critically important” classes of antimicrobials for animals should be pursued by OIE.
- Through stringent implementation of good agricultural practices, including good animal husbandry and good veterinary practices, it is possible to reduce the necessity for antimicrobials.
- The need for governments and all stakeholders rapidly to implement the WHO Global Principles for the Containment of Antimicrobial Resistance in Animals Intended for Food and the OIE Guidelines on Antimicrobial Resistance is emphasized.

¹ In the context of this report, farmers include individuals, groups and companies involved in primary food production.

- There is need for capacity building, networking and coordination to facilitate the implementation of surveillance programmes in various countries, particularly developing countries. FAO, WHO and OIE should take a leading role in this.
- 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 the achievement of effective risk management. Moreover, both the International Code of Practice and General Principles of Food Hygiene should be reviewed to take antimicrobial resistance into account.

The outcome of this consultative process is to 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. It will also be discussed in relevant OIE fora and will support future WHO work in this area.

Preamble

A Joint FAO/WHO/OIE Workshop on Non-Human Antimicrobial Usage and Antimicrobial Resistance: Management Options was held from 15 to 18 March 2004 in Oslo, Norway. This workshop was part of a consultative process that began with the first Joint Workshop held from 1 to 5 December 2003 in Geneva, at which a preliminary scientific assessment of non-human uses of antimicrobials and their role in antimicrobial resistance was conducted.

After opening remarks by Mr Leif Helge Kongshaug, State Secretary, Ministry of Agriculture, Norway, Dr Gudrun Gallhoff was elected as Chairperson for the meeting and Dr Scott McEwen was appointed as Rapporteur.

Background

Antimicrobial agents are essential drugs for human and animal health and welfare. Antimicrobial resistance is a global public health and animal health concern that is impacted by both human and non-human antimicrobial usage with the resultant development and spread of antimicrobial resistance. International and interdisciplinary cooperation is essential and, since 1997, FAO, WHO and OIE have therefore organized a number of consultations to address issues related to the antimicrobial use at the different steps of the food chain, the emergence of resistant pathogens, and the associated human public health problems. To date, however, no common approach to dealing with the containment of antimicrobial resistance has been jointly designed by these three organizations.

At its 53rd session in 2001, the Executive Committee of the Codex Alimentarius Commission recommended that FAO, WHO and OIE should consider hosting a meeting to consider all issues of non-human antimicrobial use and antimicrobial resistance, including possible future directions. It was also agreed that the issues raised by several Codex Committees required a more general, multidisciplinary and multi-agency response.

In considering their response to this request, FAO, WHO and OIE took account of the following factors:

- the advice needed by the Codex Alimentarius Commission would include risk assessment issues as well as risk management implications, and,

- the outcome would have implications not only for Codex work but also for other standard-setting work in FAO, WHO and OIE.

In accordance with the Codex Alimentarius Commission risk analysis principles, it was decided to divide the considerations between two workshops, the first on scientific issues and the second on management options.

The first Workshop on Non-human Antimicrobial Usage, held in Geneva in December 2003, conducted a preliminary scientific assessment that considered all non-human uses of antimicrobials in animals (including aquaculture) and plants, and their role in antimicrobial resistance, on the basis of the available scientific information. It was important for the secretariats of FAO, WHO and OIE to have fully independent expert advice: the selection of experts therefore followed the corresponding requirements laid out by the Codex Alimentarius for advice on food safety issues. A call for experts went out, and areas of expertise to be covered and criteria for selection were agreed between the three organizations to ensure scientific excellence, independence, and participation of experts from developing countries. The curricula vitae that were subsequently submitted were evaluated for scientific competence by a panel composed of representatives from FAO, WHO and OIE plus independent external reviewers. Once this evaluation was completed, the three organizations selected the experts for the workshop.

The outcome of the first Workshop, plus other relevant input (e.g. reports of previous WHO and OIE workshops), provided a basis for the second Workshop to consider a broad range of risk management options for antimicrobial resistance from non-human usage of antimicrobials. The second Workshop focused particularly on potential directions to be taken in future Codex, FAO, OIE and WHO work in an effort to contain antimicrobial resistance at a global level.

To ensure that the conclusions of the second Workshop reflected the perspectives of affected parties, all major stakeholder groups (including the pharmaceutical industry, farmers, food processors, consumers, regulatory agencies, and veterinarians) participated in the meeting.

The strategic risk management actions for controlling antimicrobial resistance were discussed in four working groups:

I Regulation and distribution of veterinary drugs

Chair: Dr Stephen Sundlof *Rapporteur:* Dr Peter Collignon

II Prescription and usage at farm level

Chair: Dr Henrik Wegener *Rapporteur:* Dr Martin Holmes

III Food production and public health

Chair: Dr Roger Skinner *Rapporteur:* Dr Jorge Errecalde

IV Surveillance/monitoring, research, education

Chair: Dr Pascal Sanders *Rapporteur:* Dr Samuel Kariuki

The combined outcome of these two workshops represents the consultative effort by the three organizations involved, as requested by the Codex Alimentarius Commission, and should serve as relevant and timely input for the official standard-setting process of the Codex

Alimentarius. The outcome should also be of interest to FAO, WHO and OIE for planning their own future activities in dealing with this multisectoral issue.

Introduction

Foods that are safe and of high quality are essential to the promotion of public health. Antimicrobial resistance is a biological hazard to human and animal health. It crosses borders with the movement of people, food, and animals, and resistant strains can be transmitted through environmental pathways. Recognizing this, harmonized, global approaches can expedite the implementation of effective risk management options and would also provide support for building national capacities, especially in resource-limited countries. To achieve this, risk assessments should be shared, with national data being incorporated to enable and facilitate risk management at the national level.

Food safety is an issue that is relevant throughout the food chain and so includes on-farm antimicrobial usage. Antimicrobials are used in several areas of food production, such as animal production, aquaculture and horticulture, in order to maintain health and productivity. In these areas farmers and veterinarians have a key responsibility to prevent and minimize the antimicrobial resistance that may have an effect on human and animal health.

The usefulness of internationally established procedures and principles, such as good agricultural practices, good manufacturing practices, good veterinary practices, and the prudent use of antimicrobials and risk analysis to minimize the hazard of antimicrobial resistance at national and international levels, should be considered. Good standards contribute to consumer confidence and the success of the food and pharmaceutical industries. This is further enhanced by transparency and effective risk communication throughout all stages of risk assessment and risk management.

Governments have a clear role in minimizing the emergence and spread of resistance from the non-human use of antimicrobials. As part of this responsibility, risk management of antimicrobial resistance should be a continuing process applied both before and after the approval process. In the interests of food safety and public health, antimicrobial resistance is a critical aspect of the human safety evaluation of veterinary drugs. National governments are responsible for the registration of antimicrobials – a responsibility that includes setting conditions for use and distribution, evaluating safety (including antimicrobial resistance), labelling, and good manufacturing practices (including ensuring the integrity of the end-use product).

Cross-resistance – bacteria that are resistant to one antimicrobial are usually resistant to all other antimicrobials in the same class – and co-selection need to be addressed.

Surveillance systems can support good decision-making and, together with other information, can help to determine whether further risk management actions are needed to address public health risks (e.g. antimicrobial resistance in food-producing animals or at harvest that is above the level expected in the risk assessment).

Finally, environmental pathways and recycling of bacteria into the food chain (including non-animal products and drinking-water) are important in the consideration of risks.

Consideration of the recommendations from the December 2003 Workshop

The second Workshop considered the eight recommendations of the first Workshop held in Geneva in 2003, with a view to describing relevant risk management options as well as considering possible future steps for implementation.

1. Establish a national surveillance programme on the non-human usage of antimicrobial agents

It was concluded that data from surveillance of antimicrobial use are essential for risk assessment and risk management. The establishment of surveillance programmes on antimicrobial usage requires information on the classes and quality of antimicrobials that are available in a country. An international nomenclature of antimicrobials available on the market for non-human and human usage (classes, chemical form, and international unit) is essential if data are to be comparable. This nomenclature should be established by a WHO/OIE committee and should relate to more detailed classification systems, such as the Anatomical Therapeutic Chemical (ATC) and ATC Veterinary (ATCvet) Classifications. National regulatory bodies should adopt a system of control of products (antimicrobial classes and quality of product data) at the point of production and point of entry (customs), with reporting to regulatory bodies in charge of human and animal health. In addition, surveillance systems need to consider the different distribution channels for antimicrobial products – some of which are not necessarily through a regulatory system – as these may affect data.

Resource-limited countries may need to adopt periodic rather than continuous surveillance. Data may also be collected at farm level using sentinel studies, involving a number of farms, to produce reliable information about drug usage in the country – preferably by animal species and production system.

Surveillance data on usage should inform regulators, and be used to communicate with, educate and inform veterinarians, farmers and other stakeholders on the prudent use of antimicrobials. A stratified approach to collecting data on usage should therefore be used to determine where to determine the most appropriate animals and food to be considered in data collection to analyse the presence of resistant bacteria.

2. Establish a national surveillance programme on antimicrobial resistance in bacteria from food and animals

It was concluded that data from surveillance of antimicrobial resistance in bacteria are essential for risk assessment and risk management. These data should cover bacteria from plants, animals, foods, and humans.

Countries with minimal, if any, surveillance systems in place should start by establishing susceptibility testing of non-typhoid *Salmonella* that includes at least antimicrobials critically important for humans and animals. The sharing of laboratory capacity and professional experience between the veterinary and human health sector should be encouraged.

The structure of surveillance programmes (such as sampling regimes) should be based on country capability and characteristics and should follow OIE guidelines and WHO protocols. Whenever possible, countries should adopt a susceptibility testing and reporting system that

provides quantitative data (preferably minimum inhibitory concentrations (MICs) and disc zone diameters) and that uses quality assurance for ease of comparability.

Laboratory networking, especially involving developing countries, should be supported through training and the establishment of regional reference centres. The WHO Global SalmSurv programme is an example of successful regional capacity building and cooperation in surveillance. OIE and FAO should support such ventures, especially by providing training and materials in developing countries to support surveillance programmes. There is insufficient information on antimicrobial resistance in many areas, especially horticulture, aquaculture and companion animals. The methodology for sampling and susceptibility testing of bacteria in aquaculture and companion animals needs to be better defined, for example by determining suitable indicator bacterial species. In addition, there is a need to address data gaps with regard to design of surveillance programmes, and the methodologies to be applied for surveillance of water and food as well as animal by-products, manure, plants and feeds. Examples of surveillance in these areas are provided in OIE guidelines, but more detailed recommendations from an international body are needed. WHO has produced protocols on the isolation, identification and susceptibility testing of common human bacterial pathogens. Similar protocols for bacteriological techniques in food animals, companion animals, aquaculture and food should be developed by OIE in collaboration with WHO and FAO. OIE guidelines provide adequate analytical methods for detecting the emergence of antimicrobial resistance.

Specific surveillance programmes/studies that could contribute to an understanding of the presence and fate of resistant bacteria along the food chain could be the basis for developing specific measures for in-process control.

Data from surveillance programmes can be used for:

- risk assessment;
- determining the level of resistance relative to a threshold;
- detecting emergence of resistant bacteria, which triggers action;
- measuring the effect of risk management interventions.

Moreover, it is important to link resistance data and usage data to help risk managers in deciding, for example, at what point to intervene in the food chain.

3. Implement strategies to prevent the transmission of resistant bacteria from animals to humans through the food production chain

The range of options for implementation at the farm level that were elaborated at the first Workshop can be further developed. Specific meetings for farming stakeholders, farmers, veterinarians and consumers should be convened to explore their opinions and roles in more detail.

Adoption of good agricultural practices makes it possible to reduce the necessity for and use of antimicrobials in agriculture and aquaculture. Good Agricultural Practice, or GAP, as defined by Codex (*Recommended International Code of Practice – General Principles of*

Food Hygiene, CAC/RCP 1-1969, Rev. 4 (2003), with an annex on “Hazard Analysis Critical Control Point (HACCP) system and guidelines for its application”), covers animal husbandry, horticulture, agriculture and aquaculture. GAP is relevant to the reduction of antimicrobial resistance in the production of food. To reduce antimicrobial resistance, food businesses should emphasize to their suppliers that raw material should be produced under GAP and GVP (Good Veterinary Practice), and food legislation should include relevant requirements on primary production, thereby enforcing the implementation of GAP and GVP.

An important means of reducing human exposure to antimicrobial resistant organisms via the food chain is to ensure as far as possible that good hygienic practice and HACCP are being observed. The *Codex Recommended International Code of Practice – General Principles of Food Hygiene* appears to provide appropriate protection in this respect. However, the Code was drafted without regard to the hazard of antimicrobial resistance and it may therefore be worth considering its strengthening/modification in order to address this issue. This would be a matter for the Codex Committee on Food Hygiene (CCFH), which initially drafted the aforementioned guideline. The Workshop considered that antimicrobial resistance should be addressed as appropriate in new codes of hygienic practice.

Prevention and control strategies with regard to *Salmonella*, *Campylobacter* and other food-borne zoonoses in primary production should be developed and/or implemented. Control strategies should take due regard of the local epidemiological situation, and the size, type and species of livestock production system under consideration. In addition, control of food contamination may require attention to the water used in food processing and on the farm. To help reduce the bacterial burden in the food chain, information on whether a herd or flock is infected with an important pathogen such as *Salmonella* or *Campylobacter* before slaughter or harvest would enable specific action to be taken to reduce this risk (e.g. slaughtering specific herds or flocks on separate lines or on special days or at specified times of day, or setting restrictions related to final use, for instance heat treatment). Current protocols for national and international trade in live animals focus on prevention of the hazard of transmission of infectious and some zoonotic disease; they do not explicitly consider the issue of antimicrobial resistance.

The Workshop concluded that significant improvements would be achieved by stringent application of existing protocols and adherence to GAP. The benefit of developing microbiological standards with respect to antimicrobial resistance in live animals must be balanced against other management options.

4. Implement WHO Global Principles for the Containment of Antimicrobial Resistance in Animals intended for Foods and follow OIE Guidelines on Responsible and Prudent Antimicrobial Use

The OIE Guidelines and the WHO Global Principles offer valuable guidance for all stakeholders on the prudent use of antimicrobials in food animal production. The Workshop emphasised the need for governments and stakeholders to promote and ensure the rapid implementation of the principles set out in these documents; it was concluded that further work should be done to raise awareness of the documents and derive the maximum benefit from them. The Workshop stressed the need to train all stakeholders in the implementation of these guidelines. WHO and OIE should review the documents continually in workshops with

relevant stakeholders: through this process, a common document may emerge in the future that will serve the purposes of both organizations and Codex.

To assist with implementation of the WHO Global Principles the Workshop provided some clarification: an extra-label (off-label) use policy should ensure protection of human health, and should allow the extra-label use of specific drugs of critical importance to human health to be prohibited. Consideration should be given to the concept of establishing regulatory “thresholds of resistance” specific for each antimicrobial–animal species–pathogen combination. Exceeding these thresholds should trigger a range of risk management actions. Stakeholders, including consumer organizations and the pharmaceutical and food industries, should actively promote the implementation of the WHO and OIE Guidelines.

5. Implement specific management strategies to prevent the emergence and dissemination of bacteria resistant to critically important antimicrobial agents for people

WHO should convene an international expert group (including a broad range of clinical experts in infectious disease and microbiology), first to develop criteria for defining critically important antimicrobials for humans by class and/or subgroup, and then to propose a list of those antimicrobials. This list needs to take into account relevant bacteria – both pathogens and commensals – (or their genes) that are likely to transfer to people from animals, food products, or the environment.

This list and the criteria should be shared among WHO Member States and other organizations, such as FAO and OIE. Implementation of this concept at the national level will require that national considerations are taken into account. Consequently, lists may vary from country to country. These lists, which should be made publicly available, can be used for three purposes:

- to give guidance on resource allocation and prioritization of risk assessment and management processes for both new and existing drug applications;
- to estimate consequence (for harm to people) in risk assessment;
- to develop risk management options that involve restriction of use in a country. to here

Antimicrobials that are critically important in veterinary medicine should be identified and listed by OIE, to complement the identification of such antimicrobials used in human medicine. The overlap of critical lists for human and veterinary medicine can provide further information, allowing an appropriate balance to be struck between animal health needs and public health considerations. Criteria for identification of these antimicrobials of critical importance to animal health should be established by the OIE.

A range of risk management options is available to minimize the transmission of antimicrobial resistance. Outcomes are more important than process. In addition to regulatory options, non-regulatory risk management options (for example, development of codes of practice) should also be considered. Risk management decisions need to consider fully the effects of different options (restrictions, prohibitions, etc) for animal health and production or animal husbandry practices, all of which are different in different animal species and vary geographically.

Appropriate procedures should be developed to control specific resistant bacteria and resistance determinants. Appropriate and timely action should be taken to control the risk: this could include elimination of the risk, or adoption of one or more of the available options (such as recall of food or destruction of animals). The specific actions taken would depend on the assessment of the risk under the particular circumstances faced by the competent authorities. These actions would require a framework of food control and enforcement system that would include traceability. Appropriate public information and risk communication would also be essential.

6. Implement the risk assessment approaches that are needed to support selection of risk management options

I – Governments should view methods used for antimicrobial resistance risk assessment as a continuum from the purely qualitative to quantitative assessment. Both qualitative and quantitative approaches may be appropriate. However, risk assessments should address the range of potential human health impacts and the cumulative effects of resistance. The following risk assessment strategies could be considered:

- A tiered approach to the decision on whether to use qualitative or quantitative risk assessment.
- A qualitative approach for risk assessment as a basis for the pre-marketing or post-marketing decision. Depending on the outcome, the drug sponsor has the option to develop a quantitative risk assessment.
- Evaluation of currently marketed antimicrobials used in food-producing animals with respect to antimicrobial resistance (if such an evaluation has not already been conducted).
- In addition, regular re-examination of currently marketed antimicrobials with respect to antimicrobial resistance.
- On introduction of a new antimicrobial for human therapy with a chemical structure related to that of an antimicrobial approved for non-human uses, a qualitative risk assessment to assess the risk of the human drug being compromised by non-human uses.
- Peer review of risk assessments by appropriately qualified scientists. OIE is invited to continue its work on risk analysis in coordination with FAO and WHO.

II – When there is a high level of uncertainty, caution should be exercised in risk management. Extensive communication between risk managers and risk assessors is essential if the goals and objectives of the risk assessment are to be clearly defined and understood. A mechanism should be developed for sharing the results of risk assessments by governments.

Implications:

- Facilitation of risk-based evaluations of antimicrobials by resource-limited countries.
- Enhancement of the methods and practices of risk assessment.
- Current barriers to sharing the results of risk assessments include confidentiality and harmonization issues.

III – Governments should regularly review the effectiveness and adequacies of risk management strategies related to antimicrobial resistance and share this information.

Implications:

- Regulatory authorities would need to regularly review all available data, including experimental laboratory investigations, epidemiology studies or surveillance data.
- Ethical and economic considerations need to be included.
- When antimicrobial resistance reaches a level of concern for existing antimicrobials used for non-human purposes, then appropriate risk management should be conducted.

A Codex/OIE task force should define risk assessment policy and risk management options in relation to antimicrobial resistance. The task force should include a risk assessment policy for the Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA), introducing considerations related to antimicrobial resistance within the microbiological risk assessment framework. This could be done by means of an annex to the existing Codex guideline for microbiological risk assessment. JEMRA could help to develop appropriate risk assessment methodologies in relation to antimicrobial resistance, which could be available to national governments. Risk assessments can be shared, with national data being incorporated to enable and facilitate risk management at the national level. A task force should also review and consolidate existing documents on antimicrobial resistance, as well as documents in preparation, in an attempt to eliminate redundancies.

The Workshop considered that ethical and economic considerations should be taken into account in risk management decisions. Further work is needed in these areas.

7. Enhance the capacity of countries, particularly developing countries, to conduct surveillance of antimicrobial use and resistance, to implement intervention strategies to contain antimicrobial resistance and to implement risk assessment approaches to support selection of risk management options

Capacity building is needed to assist in risk analysis and surveillance in developing countries. There is also a need to improve technical expertise and training as well as infrastructure in developing countries in relation to the development of regulatory approval and control systems. For example, FAO, WHO and OIE offer technical assistance to developing countries on request, including Standards in Trade and Development Facility (STDF) and technical cooperation projects. Laboratory networking, especially in developing countries, should be supported through the establishment of regional reference centres. The WHO Global Salm-Surv programme is an example of successful regional cooperation in surveillance. OIE and FAO should support such ventures, especially by providing training and materials for surveillance programmes in developing countries.

Education and training for farmers, veterinarians and veterinary para-professionals (as defined by the OIE Code) are important, particularly in terms of their cooperation with each other, and especially in developing countries. Signatories to the World Trade Organization's SPS Agreement (Agreement on the Application of Sanitary and Phytosanitary Measures) are obliged to assist developing countries to achieve relevant international standards.

8. Risk Management of antimicrobial resistance in the international arena

It is important that any standards, codes and guidelines concerned with antimicrobial-resistant bacteria at the international level be developed through the risk analysis process as appropriate.

The Codex Alimentarius Commission (CAC) and OIE should consider setting up the task force referred to under Recommendation 6, which should also develop a framework to address the issue of antimicrobial resistance and indicate ways of implementation, on the basis of existing guidelines where these are appropriate.

Risk management options for antimicrobial resistance should be developed by the Codex/OIE task force on the basis of relevant risk assessments from JEMRA and OIE risk assessment outcomes. There is a need for alignment of risk management activities related to antimicrobial resistance within Codex and between Codex and OIE. When environmental issues arise, it may be appropriate to refer these to existing capacities within WHO.

Data gaps and areas for improvement

The Workshop concluded that the December 2003 list of data gaps is extensive, but could be supplemented as follows:

- to develop methods and data to identify foods (and food sources) of the highest risk in order to support better risk management decisions, for diseases and antimicrobial resistance (including resistance determinants in pathogens, commensals and the non-food environment).
- improvements in design and statistical analysis of surveillance programmes of usage and resistance.

Further considerations

The Workshop stressed that risk assessment and risk management need to take account of cross-resistance – when bacteria are resistant to one antimicrobial, there is usually resistance to all other antimicrobials in the same class. Co-selection is a separate issue that should also be addressed. For risk management, drugs should be reviewed by class and/or subgroup unless there are empirical data to show otherwise.

The Workshop confirmed that antimicrobial resistance in food production is not an issue that can be considered by any of the international organizations in isolation. It is clear that there are overlaps and linkages between the specialized concerns of FAO, WHO and OIE, and the Codex Alimentarius Commission.

The Workshop recognized that there are shared responsibilities and areas of consensus between different stakeholders and international organizations; these groups and Codex should take advantage of areas in which there is consensus to move forward rapidly. In the “farm-to-fork” production chain there should be through-chain linkages between all stakeholders in order to address the issues.

The Workshop emphasized that the use of antimicrobials in horticulture and their role in the dissemination of antimicrobial resistance has not been fully elucidated. The Workshop of December 2003 made no specific recommendations on this topic, although it mentioned

general concerns. It is clear that more focused scientific work is required in this area to collect data and assess the size of any potential problem. Nevertheless, the Workshop concluded that, when antimicrobials are used in horticulture, principles of prudent use should be followed – and specific guidelines should be developed. WHO and FAO should convene an expert consultation to examine the uses and potential public health implications of antimicrobials in horticulture.

The Workshop emphasized that antimicrobials should be used in a competent manner by trained users, in order to bring animals to the market that provide safe, wholesome food in a manner that protects animal welfare, animal health, public health and the environment. There should be transparency and traceability in the usage of antimicrobials in food-producing animals. Within international guidelines, individual member states can have the flexibility to reach their acceptable outcome in the manner that best suits their individual agricultural, stakeholder and legislative interests.

The Workshop supported the surveillance principles in reports of previous expert committee meetings, including WHO's *Global principles for the containment of antimicrobial resistance in animals intended for food* (WHO/CDS/CRS/APH/2000.4), *Monitoring antimicrobial usage in food animals for the protection of human health* (WHO/CDS/CSR/EPH/2002.11), OIE's *International standards on antimicrobial resistance* (2003), and the *Joint FAO/WHO/OIE expert workshop on non-human antimicrobial usage and antimicrobial resistance: scientific assessment* (WHO/CDS/CPE/ZFK/2004.7). The Workshop reiterated that, while surveillance data are currently focused on terrestrial animals, the general principles of prudent use with respect to animal hygiene and the environment relate equally to aquaculture. It recognized that surveillance programmes for antimicrobial usage and resistance are at various stages of development and implementation in various countries, and that there is need for coordination, networking and capacity building (especially for developing countries) under the auspices of FAO, WHO and OIE.

Final conclusions

The main conclusions of the workshop were as follows:

1. The risks associated with non-human antimicrobial use and antimicrobial resistance should be part of the human safety assessment for regulatory decisions in relation to veterinary antimicrobials.
2. Risk communication and transparency are critical to achieve effective risk management at both national and international levels.
3. Risk management options for antimicrobial resistance should be developed by a Codex/OIE task force. Risk management should include a risk assessment policy for JEMRA, introducing considerations related to antimicrobial resistance within the microbiological risk assessment framework. This could be done through an annex to the existing Codex guideline for microbial risk assessment. Risk assessments can be shared, with national data being incorporated to enable and facilitate risk management at the national level. The task force should also review and consolidate existing documents on antimicrobial resistance, as well as documents in preparation, in an attempt to eliminate redundancies.

4. The concept of “thresholds of resistance” should be pursued as a risk management tool. For this purpose, establishment of regulatory “thresholds of resistance” that are specific for each antimicrobial–animal species–pathogen combination, should be considered. A range of risk management actions would be triggered if these thresholds were exceeded.
5. The concept of “critically important” classes of antimicrobials for humans should be pursued by WHO. The Workshop concluded that antimicrobials that are critically important in veterinary medicine should be identified, to complement the identification of such antimicrobials used in human medicine. Criteria for identification of these antimicrobials of critical importance in animals should be established and listed by OIE. The overlap of critical lists for human and veterinary medicine can provide further information, allowing an appropriate balance to be struck between animal health needs and public health considerations.
6. Through adoption of GAP, including good animal husbandry and good veterinary practices, it is possible to reduce the necessity for antimicrobials in agriculture and aquaculture.
7. The Workshop emphasized the need for rapid implementation by governments and all stakeholders of the principles laid down in WHO and OIE guidelines. WHO and OIE should keep the documents under continuous review in consultation with relevant stakeholders. Through this process, a common document may emerge that will serve the purposes of both organizations and of the Codex Alimentarius. Moreover the *International Code of Practice: General Principles of Food Hygiene* should be reviewed to take account of antimicrobial resistance. In addition, antimicrobial resistance should be addressed as appropriate in any new codes of hygienic practice that may be developed.
8. Capacity building, networking and coordination are essential to facilitate implementation of surveillance programmes in various countries, particularly developing countries. FAO, WHO and OIE should take a leading role in this.

Annex 1. Glossary

antimicrobial agent

Any substance of natural, synthetic or semi-synthetic origin that, at low concentrations, kills or inhibits the growth of microorganisms but causes little or no host damage.

antimicrobial class

Antimicrobial agents with a related molecular structure, often with a similar mode of action. Variations in the properties of antimicrobials within a class often arise as a result of the presence of different molecular side-chains, which confer different patterns of pharmacokinetic and pharmacodynamic behaviour on the molecule.

antimicrobial growth promoter

Antimicrobial agents used for the purpose of increasing the daily weight gain or feed efficiency (feed–weight gain ratio) of food-producing animals.

antimicrobial resistance

The ability of a microorganism to continue to multiply or persist in the presence of therapeutic levels of an antimicrobial agent.

antimicrobial resistance genes

Genes in microorganisms that confer resistance to antimicrobials. These are often located on mobile genetic elements, thereby enabling transmission from resistant to susceptible strains.

containment of antimicrobial resistance

Infectious disease control measures that minimize the emergence and spread of antimicrobial-resistant microorganisms.

disease control

Activities aimed at preventing or curing disease in animals intended for food.

empirical therapy

Therapy that is initiated on the basis of observation of clinical symptoms and patient history only, without previous confirmation of diagnosis by laboratory or other methods.

food-producing animals

Animals raised for the purpose of providing food for humans. Most commonly this term refers to poultry, swine, cattle and sheep, but it does not exclude other domestically managed animals.

good management/farming/veterinary practices

Routine practices that minimize risk from harmful antimicrobial-resistant bacteria or resistance genes through good prescribing and farm management and hygiene practices (e.g. optimal housing conditions and feeding strategies) and other non-antimicrobial disease preventive strategies, while maximizing the productivity of food animal production.

Hazard Analysis and Critical Control Point (HACCP)

A science-based and systematic approach that identifies, evaluates, and controls hazards that are significant for food safety.

pharmacokinetics

The ways in which antimicrobials (principally drugs/medicines) are absorbed by, move within, and are finally eliminated from animals, humans, etc.

pharmacodynamics

The behaviour (e.g. quick, slow, short-term, long-term, etc.) of an antimicrobial at its receptor site (i.e. where it initiates its effect).

prescribing practices

The behaviour of licensed medical or veterinary practitioners with regard to prescription of medicines, including such aspects as readiness to prescribe such medicines, readiness to delegate decisions on repeat prescriptions and other routine demands to staff who are not medically qualified.

prescription-only medicines

Medicines that are legally available to the “end user” only if he/she obtains a prescription from a licensed professional (e.g. veterinarian, medical doctor, dentist).

prophylactic use

The administration of an antimicrobial to healthy animals in advance of an expected exposure to an infectious agent or following such an exposure but before onset of laboratory-confirmed clinical disease. Generally such usage is in a herd or flock situation and not in an individual animal.

prudent use of antimicrobials

Usage of antimicrobials that maximizes therapeutic effect and minimizes the development of antimicrobial resistance.

registration (licensing, authorization, approval)

The process of approving a drug for marketing in a country/region. Includes assessment based particularly on the criteria of safety, quality and efficacy. Because of inadequate local capacity, many developing countries rely on “third party certification”, i.e. granting market authorization to products already approved in certain developed countries.

regulatory authority

A government agency responsible for codifying and enforcing rules and regulations as mandated by law.

relevant authority

An authority with jurisdiction over relevant areas of concern in relation to use of antimicrobials in animals, including registration, licensing, sale, distribution, marketing and dispensing of antimicrobial agents.

risk

A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard.

risk-based evaluation

Evaluation of scientific and other relevant information with the aim of obtaining a qualitative and/or quantitative estimation of the probability of occurrence and severity of known or potential adverse public health effects.

stakeholder

A person or group of persons, or an industry, association, organization, etc. with an economic or professional interest in/responsibility for an area or (involuntarily) affected by the developments in that same area. In the field of antimicrobial usage in food animals, farmers, veterinarians, animal feed manufacturers, food processors and distributors, retailers, relevant government organizations, pharmaceutical companies, consumers, public health officials, academic and other related groups are recognized as stakeholders.

therapeutic use

Application of antimicrobials in curative doses in an adequate period of time to combat an established infection.

zoonotic bacteria

Bacteria that are present in animal reservoirs and can be transferred to, and cause infections in, humans.

Annex 2. Previous documents from the Organizations

WHO

The medical impact of the use of antimicrobials in food animals. Report of a WHO meeting, Berlin, Germany, 13–17 October 1997. Geneva, World Health Organization, 1997 (document WHO/ EMC/ ZOO/97.4; <http://www.who.int/emc/diseases/zoo/oct97.pdf>, accessed 13 May 2004).

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FAO/WHO

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Recommended International Code of Practice General Principles of Food Hygiene, including Annex on HACCP and Guidelines for its application. CAC/RCP 1-1969, Rev. 4-2003

OIE

Guideline on antimicrobial resistance. 1: Harmonisation of national antimicrobial resistance monitoring and surveillance programmes in animals and in animal-derived food.

Guideline on antimicrobial resistance. 2: Standardisation and harmonisation of laboratory methodologies for the detection and quantification of antimicrobial resistance.

Guideline on antimicrobial resistance. 3: Monitoring the quantities of antimicrobials used in animal husbandry.

Guideline on antimicrobial resistance. 4: Responsible and prudent use of antimicrobial agents in veterinary medicine.

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Annex 4. Agenda
Monday 15 March 2003

| Time | Item | Speaker |
|---|---|--|
| 09:30–1:00 | <ul style="list-style-type: none"> Opening | Mr Leif Helge Kongshaug State Secretary, Ministry of Agriculture, Norway |
| | <ul style="list-style-type: none"> Election of Chairperson and Vice-Chairperson Appointment of Rapporteur Adoption of the agenda | Jørgen Schlundt Chairperson |
| SESSION I: INTRODUCTORY PRESENTATIONS | | |
| 10:00–10:30 | <ul style="list-style-type: none"> Conclusions of Joint FAO/OIE/WHO 1st Expert Workshop (Geneva, 1–5 December 2003) | Scott McEwen (Chair 1st Workshop) |
| 10:30–11:00 | <i>Tea/Coffee break</i> | |
| 11:00–11:20 | <ul style="list-style-type: none"> Antimicrobial resistance risk management – general concepts and options | Stephen Sundloff (FDA/CVM) |
| 11:20–11:40 | <ul style="list-style-type: none"> Antimicrobial licensing, regulation and distribution | Liisa Kaartinen (EMEA/CVMP) |
| SESSION II: ROLE OF STAKEHOLDERS IN THE RISK MANAGEMENT OF ANTIMICROBIAL RESISTANCE | | |
| 11:40–12:00 | <ul style="list-style-type: none"> Pharmaceutical Industry | Jean Louis Delforge (IFAH) |
| 12:00–12:20 | <ul style="list-style-type: none"> Primary producers/Farmers (I) | Gunnela Stahle, Anne Touratier (COPA) |
| 12:20–13:30 | <i>Lunch</i> | |
| 13:30–13:50 | <ul style="list-style-type: none"> Primary producers/Farmers (II) | Bob Friesen (IFAP) |
| 13:50–14:00 | <ul style="list-style-type: none"> Consumers/environment | Ellen Silbergeld (ED) |
| 14:10–14:30 | <ul style="list-style-type: none"> Food industry | Manfred Noll (CIAA) |
| 14:30–15:00 | <ul style="list-style-type: none"> Animal feed industry | Alexander Döring (FEFAC) |
| 15:00–15:30 | <i>Coffee break</i> | |
| 15:30–15:50 | <ul style="list-style-type: none"> Veterinarians | Herbert Schneider (WVA) |
| 15:50–16:10 | DISCUSSION | |

| Time | Item | Speaker |
|-------------|--|---------|
| 16:10–17:30 | SESSION V: CONSTITUTION OF WORKING GROUPS <ul style="list-style-type: none"> • WG 1: Risk Management Strategic Actions for Controlling Antimicrobial Resistance : Regulation and Distribution of Veterinary Drugs • WG 2 : Risk Management Strategic Actions for Controlling Antimicrobial Resistance : Prescription and Usage at Farm Level • WG3 : Risk Management Strategic Actions for Controlling Antimicrobial Resistance : Food Production and Public Health • WG 4 : Risk Management Strategic Actions for Controlling Antimicrobial Resistance : Surveillance/Monitoring, Research and Education • | |
| 17:30–19:30 | <i>Reception</i> | |

Tuesday 16 March 2004

| Time | Item | Speaker |
|--------------|-------------------------------------|---------|
| 09:00–11:00 | SESSION V (continued) | |
| 11:0–11:30 | <i>Coffee break</i> | |
| 11:30–12:30 | SESSION V (continued) | |
| 12:30– 14:00 | <i>Lunch</i> | |
| 14:00–15:30 | Plenary: Restitution working groups | |
| 15:30–16:00 | <i>Coffee break</i> | |
| 16:00–18:00 | SESSION V (continued) | |
| 18:00 | Dinner | |

Wednesday 17 March 2004

| Time | Item |
|--------------------|--------------------------------------|
| 09:00–11:00 | SESSION V (continued) |
| <i>11:00–11:30</i> | <i>Coffee break</i> |
| 11.30 – 12.30 | Plenary : Restitution working groups |
| <i>12:30–14:00</i> | <i>Lunch</i> |
| 14:00–15:30 | Report |
| <i>15:30–16:00</i> | <i>Coffee break</i> |
| 16:00–18:00 | Report |

Thursday 18 March 2004

| Time | Item |
|--------------------|---------------------------------------|
| 09:00–10:30 | Report finalization |
| <i>10:30–11:00</i> | <i>Coffee break</i> |
| 11:00–12:30 | Adoption of report Closing remarks |
| <i>12:30–14:00</i> | <i>Lunch</i> |