codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 5 **CX/RVDF 04/15/3, Add. 1**
August 2004

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Fifteenth Session

Washington, DC (metro area), United States of America, 26-29 October 2004

REPORT ON OIE ACTIVITIES, INCLUDING THE HARMONIZATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINAL PRODUCTS (VICH)

(updated information)

1. Cooperation between OIE and Codex

In order to strengthen the cooperation between OIE and the Codex Alimentarius Commission, the General Director of the OIE created a specific permanent OIE Working Group on Animal Production Food Safety (WGAPFS) following the adoption of a Resolution by the OIE Member Countries.

This Group aims to:

- Reduce food-borne risks to human health due to hazards arising from animals before slaughter or at the first stage in the production of products;
- Strengthen relationships with FAO and WHO, Codex Alimentarius Commission and expert groups regarding animal production food safety;
- Develop measures applicable at the farm level in order to prevent or reduce food-borne hazards. For example, the Working Group is developing ‘good farming practices’ to address food safety risks at the farm level.

2. International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH)

VICH focuses on harmonising registration requirements for veterinary medicinal products in the EU, USA and Japan. Countries not involved in VICH are kept informed of its progress through the OIE. Fundamental to the existence of VICH is the Steering Committee that is empowered to drive the harmonisation process. The Steering Committee comprises two delegates from each of the regulatory authorities and industry associations in the three regions. Australia/New Zealand (together) and Canada have observer status with one delegate representing government authorities and one representing industry associations. Consistent with its willingness to wider its work at the world-wide level, VICH welcomed a new interested party, Camevet, which represents Authorities and Industry Associations from Latin American Countries. IFAH (International Federation for Animal Health) coordinates the positions of the three regional industry federations. IFAH and the OIE signed an official agreement in order to improve the exchange of information between the two organisations.

As of the beginning of 2003, meetings of three Steering Committees and numerous ad hoc working groups were held within the scope of VICH activities.

As far as guidelines are concerned, the main outcomes may be summarised as follows:

- Guideline 27 (Guidance on pre-approval information for registration of new veterinary medicinal products for food-producing animals with respect to antimicrobial resistance) ready to be signed-off and presented to the steering committee;
- Guideline 36 (General approach to establish a microbiological ADI) signed off for implementation in 2005;
- Guideline 37 (Repeat dose (chronic) toxicity) signed off for implementation in 2005;
- Launch of review of guideline 28 (Studies to evaluate the safety of residues of veterinary drugs in human food: carcinogenicity testing).

Beyond the activities managed in the frame of the work plan, the Steering Committee discussed in depth the possible second phase of VICH for the period 2006–2010. The Steering Committee created a Task Force chaired by the OIE and composed of one representative from each member region and from the observers. The ongoing work of this task force will help the Steering Committee to evaluate needs and resources and to draw up proposals for remodelling the future VICH, including new ways of working.

The OIE, as an associated member, pays particular attention to all of these activities and does its utmost to help to contribute to the process of harmonisation of veterinary medicines at the world-wide level in order to strengthen the protection of public health and animal health and to help to harmonise international practices.

All these issues will be presented and discussed during the next VICH public conference (VICH 3), which will be organised by the United States of America in May 2005.

3. Antimicrobial resistance

In 1997, due to the growing importance of antimicrobial resistance at a world-wide level, the OIE Regional Commission for Europe requested that the OIE Collaborating Centre for Veterinary Medicinal Products, in Fougères, France, prepare a specific report with the view to deciding whether an action plan should be implemented. The report was presented to the OIE International Commission at its General Session in May 1998. On the basis of the report, and after a wide exchange of view and assessment of the challenges, the International Committee of OIE decided to:

- create an Ad hoc Group of internationally recognised experts on antimicrobial resistance;
- and defined the mandate and terms of reference to be followed by this Group.

This Group of international experts agreed to draft five guidelines on:

- Resistance surveillance programmes;
- Surveillance of antimicrobial consumption in animal husbandry;
- Responsible and prudent use of antimicrobial agents in veterinary medicine;
- Laboratories methodologies for bacterial antimicrobial susceptibility testing;
- Risk analysis and antimicrobial resistance.

Following the preparation of the five scientific documents, an international consultation was set up from 15 June to 15 September 2000 that enabled the final adoption by the Group in November 2000 of the scientific documents and recommendations.

The next milestone was the 2nd OIE International Conference on Antimicrobial Resistance organised from 2 to 4 October 2001 with the participation of WHO and FAO, aimed at:

- diffusing and promoting recommendations of the OIE expert group;
- developing international cooperation in the considered field;
- proposing new goals and meeting new challenges.

As a result of the efforts of the experts and the OIE Member Countries, four guidelines were adopted during the 71st General Session of the representatives of the 167 Member Countries of the OIE in May 2003. The fifth one was adopted during the 72nd General Session of OIE in May 2004. Through this adoption, the guidelines became OIE International Standards.

The Guidelines:

1. **Guidelines for the harmonisation of antimicrobial resistance surveillance and monitoring programmes (*Terrestrial Animal Health Code*, Appendix 3.9.1).**

   Purpose:

   - follow trends in antimicrobial resistance in bacteria;
   - detect the emergence of new antimicrobial resistance mechanisms;
   - provide the data necessary for conducting risk analysis with relevance for human and animal health;
   - provide a basis for policy recommendations for animal and public health;
   - provide information for prescribing practices and prudent use recommendations.

2. **Guidelines for the monitoring of the quantities of antimicrobials used in animal husbandry (*Terrestrial Animal Health Code*, Appendix 3.9.2).**

   Purpose:

   - to describe an approach for the monitoring of quantities of antimicrobial used in animal husbandry based on an objective and quantitative methodology.

3. **Guidelines for the responsible and prudent use of antimicrobial agents in veterinary medicine (*Terrestrial Animal Health Code*, Appendix 3.9.3).**

   Purpose:

   - these guidelines provide a guidance for the responsible and prudent use of antimicrobial agents in veterinary medicine with specific attention to public health and animal health;
   - responsibilities of all stakeholders are taken into consideration;
   - the main objectives of the guidelines are to maintain the efficacy of antimicrobials and limit or reduce the resistance phenomenon.

   Even though public health is of huge concern, it must be kept in mind that ethical and economic needs lead to keep animals in good health and welfare. Consequently the use of antimicrobial agents in veterinary medicine and rearing is essential.

4. **Laboratory methodologies for bacterial antimicrobial susceptibility testing (*Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, Chapter I.1.10)**

   Purpose:

   - the purpose of this guideline is to propose robust and reproductible criteria for antimicrobial susceptibility testing (AST).

5. **Guidelines on development of an appropriate risk analysis methodology for the potential impact on public health of antimicrobial resistant bacteria of animal origin (Terrestrial Animal Health Code, Appendix 3.9.4).**

   The purpose and objectives are mainly to conduct transparent consistent risk analysis and to identify the factors to be used in each of the following steps:

   - Risk assessment:
     - Hazard identification;

- Hazard characterization;
- Exposure assessment;
- Risk characterisation.

o Risk management:

- Risk management policy;
- Risk evaluation;
- Risk reduction strategy;
- Monitoring and review.

o Risk communication, essential between all stakeholders and decisions markers.

Perspectives and new goals

Antimicrobial resistance is a multidisciplinary and a worldwide issue.

Consistent with its rules, the OIE is willing to develop close contact with all organisations concerned, such as WHO and FAO, and governments of Member Countries (167 countries are currently members of OIE).

It is obvious that the OIE's goals can only be achieved in cooperation with the WHO and FAO, which are currently also working on the issue of antimicrobial resistance.

This close cooperation, which is actively being developed, will help to obtain the benefits of synergies amongst the different organisations.

In this spirit and following a suggestion of the WHO and Codex Alimentarius Commission, a world-wide consultation of experts has recently been launched in Geneva, Switzerland (2003) and Oslo, Norway (2004) by WHO, FAO and OIE with the view to gather all available scientific data and to prepare a common action plan for the future.

The 1st Workshop on Non-Human Antimicrobial Usage, held in December 2003 in Geneva, included a preliminary scientific assessment of 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, held in Oslo in February 2004, considered the broad range of possible risk management options for antimicrobial resistance from non-human use of antimicrobials. In particular, it focused on potential directions of future Codex, FAO, WHO and OIE work in this area, in order to prevent and minimise antimicrobial resistance at the global level. To ensure that the conclusions of the 2nd Workshop reflected the perspectives of interested parties, the major stakeholder groups (e.g. members of the pharmaceutical industry, farmers, food processors, consumers, regulatory agencies, and veterinarians) participated in the meeting.

The aim of these two workshops was to identify risk management options as far as antimicrobial resistance is concerned, for the attention of individuals from Member Countries who are in charge of the decision-making process in this field.

The workshops gathered a wide range of international experts, selected through an open call. That enabled the participants to reach a consensus on the possible ways forward.

The main important conclusions 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. Constitution of a Codex/OIE task force: Risk management options for antimicrobial resistance should be developed by a Codex/OIE task force. It 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 appendix to the existing Codex guideline for microbial risk assessment). Risk assessments can be shared, with the incorporation of national data, 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 being written, in an attempt to eliminate redundancies.
4. The concept of 'thresholds of resistance' should be pursued as a tool for risk management. For this purpose, concepts of establishing regulatory 'thresholds of resistance' that are specific for each antimicrobial/animal species/pathogen combination, should be considered. If these thresholds were exceeded, this would trigger a range of risk management actions.
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 the OIE. The overlap of critical lists for human and veterinary medicine can provide further information so that an appropriate balance may 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 use for antimicrobials in agriculture and aquaculture.
7. The meeting emphasised the need for rapid implementation of the principles in the WHO Global Principles and OIE Guidelines by governments and all stakeholders. WHO and OIE should keep the documents under continuous review in consultation with relevant stakeholders. Through this process, a common document may emerge in the future that will serve the purposes of both organisations 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 which may be developed.

There is a need for capacity building, networking and co-ordination to facilitate implementation of surveillance programmes in various countries.

Therefore, following the recommendations of the conference held in Oslo, the OIE accepted, during the 27th session of the Codex Alimentarius Commission, the creation of a joint Codex/OIE task force for assessing antimicrobial resistance caused by the non-human use of antimicrobials. As a result of discussion in the Commission, the secretariat has prepared a circular letter including terms of reference for this task force. In anticipation of the joint task force, the OIE, through its Working Group on Animal Production Food Safety and the specialised Ad hoc Groups of experts, will continue its work on OIE standards on antimicrobial resistance. High level official and experts from WHO, FAO and Codex Alimentarius Commission will be invited to participate in these meetings.