

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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Agenda Item 4

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

Fourteenth Session

Washington, DC, 4 - 7 March 2003

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

1. NEW DIRECTIONS FOR O.I.E.

In view of the growing consumer demand for improvement of the sanitary safety of food the world over, O.I.E., the world animal health organization which also monitors zoonosis and animal wellbeing, has received the assignment to extend its normative and scientific activities to the "sanitary safety of foods of animal origin during the production phase" (meat, milk, eggs, honey...), as well as to collaborate with other competent organizations in the study and prevention of risks associated with these foods from production to consumption ("from stable to table").

At its 70th General Session from 26 to 31 May 2002, the International Committee of the O.I.E. adopted a resolution (No XV) regarding the O.I.E. mandate for the sanitary safety of food.

The following recommendations were adopted:

- The goal of the O.I.E. with regard to the sanitary safety of foods of animal production is the reduction, in collaboration with the pertinent international agencies, of public health risks associated with foods due to dangers (biological, chemical or physical agents present in a food or the condition of the food that might exert a harmful effect on health) linked to their animal origin.
- The O.I.E. is to establish and/or reinforce formal and informal relations regarding the sanitary safety of foods of animal origin with the pertinent international agencies, especially FAO and WHO and the organizations under their umbrella (viz. CAC), as well as pertinent groups of experts.
- In order to assure the safety of foods of animal origin, the Director General of the O.I.E. is to establish a permanent work group on the sanitary safety of foods that will ensure coordination and follow-up of the Office's activities relative to sanitary measures to be practiced prior to animal slaughter and primary product transformation. The group will have multidisciplinary resources and balanced regional distribution with appropriate consideration of the needs of developing countries.

The task of the Working Group is as follows:

- Review all food risks associated with animals prior to slaughter or at the time of product transformation.
- Concentrate on sanitary safety measures for food at the farm level.
- Review food safety measures in other sectors, e.g. during animal transportation and in the selection of wild animals intended for human consumption.
- Establish criteria and priorities which take into account world priorities relative to food sanitary safety as well as work programmes in pertinent international organizations, particularly the CAC.

- Record existing food safety norms and those under discussion by the pertinent international organizations, particularly the CAC.
- Support the work of specialized commissions on measures pertaining to the sanitary safety of foods of animal origin that are to be utilized prior to slaughter.
- Advise the Director General of the O.I.E. on implementation of O.I.E. strategies by:
 - Setting up ad hoc groups and assigning them specific tasks;
 - Serving as the technical liaison with CAC, FAO and WHO;
 - Reviewing O.I.E. work so that matters regarding safety of foods of animal production will be integrated in the activities of the specialized commissions and ad hoc groups;
 - Supplying technical data for revision of O.I.E. criteria for reporting of diseases;
 - Improving communication, exchange of information and consultation in the above areas.

The permanent Working Group on the sanitary safety of foods of animal origin met in Paris 18 - 20 November 2002 and recommended that its work programme encompass the following:

- Review by the CAC and O.I.E. of the current standards of the two organizations and identification of areas that are not covered or redundant.
- Establishment of a priority order for work on the standards identified in the review process.
- Preparation of a communication plan including the organization of a public meeting in order to disseminate the new cooperation strategy and the activities of the work group.
- Establishment of procedures for developing common or linked standards on subjects of interest, using as an example the current CAC work on general principles for meat and poultry hygiene.
- Review of specific current chapters of the international animal health code on tuberculosis and brucellosis in order to focus more on risk management for the safety of foods of animal origin.

The Working Group identified the following points which will be put on the agenda in the future and which will benefit from a coordinated approach:

- Improvement of recognition of problems regarding foods of animal origin by breeders and veterinarians.
- Antibiotic resistance
- Animals derived from biotechnology
- Code of Good Animal Husbandry Practices

The projects planned in this area will reinforce the productive collaboration started many years ago with the Codex Alimentarius and contribute to safer food for humans all over the world.

The collaboration will make it possible to avoid the risk of developing contradictory international norms and to include the most recent normative areas that are not yet encompassed by the Codex and the O.I.E.

2. INTERNATIONAL HARMONIZATION RELATIVE TO VETERINARY DRUGS (VICH)

The international harmonization of technical requirements for registration of veterinary drugs continues to progress thanks to the work of the VICH, which was set up with the support of the O.I.E.

The steering committee of the VICH held its 10th meeting in April 2002, followed by the 11th meeting and the VICH 2 conference in Tokyo in October 2002.

Various guidelines were adopted during these meetings.

The following guidelines were implemented between July 2001 and the present time:

July 2001

- GL 6 Evaluation of the environmental impact of veterinary drugs (phase 1)
- GL 9 Good Clinical Practices
- GL 17 Stability test for new immunological/biotechnological drugs
- GL 18 Impurities: Solvent residues in new veterinary products, active substances and excipients.

July 2002

- GL 15 Effectiveness of anthelmintics: Specific recommendations for horses
- GL 16 Effectiveness of anthelmintics: Specific recommendations for hogs
- GL 19 Effectiveness of anthelmintics: Specific recommendations for dogs
- GL 20 Effectiveness of anthelmintics: Specific recommendations for cats
- GL 21 Effectiveness of anthelmintics: Specific recommendations for poultry

August 2002

- GL 22 Studies to evaluate the safety of veterinary drug residues in human food: reproduction studies
- GL 23 Studies to evaluate the safety of veterinary drug residues in human food: genotoxicity studies

The following guidelines will be applicable in:

May 2003

- GL 25 Test for formaldehyde (formic aldehyde) residues
- GL 26 Test for residual moisture

October 2003

Studies to evaluate the safety of veterinary drug residues in human food:

- GL 28 Tests on carcinogenic effects
- GL 31 Test for toxicity of repeated doses
- GL 32 Test for development of toxicity
- GL 33 General approach

In addition, one directive was submitted in **April 2002** for a 12-month public consultation period:

- D 34 Tests for detection of mycoplasma contamination

Report on the 2nd VICH conference:

- Approximately 200 delegates met in Tokyo at the second VICH conference in October 2002.
- It was reported that, since the establishment of the VICH in 1996, 25 guidelines have been adopted and most of these have been implemented in Europe, Japan and the US. Five others are at the end of the consultation period and four are in consultation.
- The VICH 2 conference provided the participants an opportunity to meet numerous experts and to discuss the scope and requirements of the VICH guidelines in areas such as quality, safety, ecotoxicity, tracking the quality of immunological drugs, effectiveness of anthelmintics, drug supervision, antimicrobial resistance and safety in the end species.
- Participants agreed that the VICH has never been as important as it is now for facilitation of global registration of veterinary drugs, establishment and maintenance of consumer confidence in the quality, safety and effectiveness of products. Animal wellbeing and consumer safety are of prime importance for modern society at the beginning of the 21st century.

For the future, O.I.E. must emphasize how important it is to focus diligently on harmonization in the area of veterinary drug registration. This is a major project and a challenge for the improvement of food safety the world over, and of animal health and animal wellbeing.

The next VICH 3 conference will be held in the US in the spring of 2005.

3. GUIDELINES ON ANTIBIOTIC RESISTANCE

In response to the recommendation adopted by its international committee in May 1999, the O.I.E. set up a panel of experts with representatives of FAO and WHO who were charged with the development of guidelines on the following subjects:

1. Harmonization of monitoring plans for antibiotic-resistant animal bacteria.
2. Standardization and harmonization of laboratory methods used to characterize the antibiotic resistance of animal bacteria.
3. Monitoring of the antibiotic quantities used in animal husbandry.
4. Prudent use of antibiotics in animal husbandry.
5. Utilization of antibiotics in animal husbandry and analysis of risks for public health.

These guidelines were submitted for worldwide public consultation and the guideline texts were published in 2001 as technical texts in the O.I.E. scientific review.

These texts were rendered into international normative form by an ad hoc O.I.E. group and submitted to the O.I.E. Norms Commission which endorsed them.

Guidelines 1, 3 and 4 will be submitted for adoption to the International Committee of the O.I.E. in May 2003 for inclusion in the O.I.E. *Code Zoosanitaire International*.

Guideline No 2 was incorporated in a draft chapter of the O.I.E. *Manual*.

Guideline No 5 was submitted to the Code Committee for review at its next meeting and possible incorporation in the O.I.E. *Code Zoosanitaire International* in 2004.

The O.I.E. is pleased that the Codex Alimentarius has developed complementary views on antibiotic resistance in its sphere of activity. Moreover, the O.I.E. has ascertained that the work documents of the Codex Alimentarius that are now available are entirely in accord with the O.I.E. guidelines in their final adoption phase. This confirms the merits of the new directions. It will facilitate future joint projects for coherent global monitoring of the entire food chain from production to consumption.