codex alimentarius commission E

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 4 **CX/RVDF 09/18/4**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Eighteenth Session

Natal, Brazil, 11-15 May 2009

REPORT OF THE OIE ACTIVITIES, INCLUDING THE HARMONIZATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINAL PRODUCTS

1. Cooperation between the OIE and the Codex *Alimentarius* Commission

1. In order to strengthen the cooperation between the World Organisation for Animal Health (OIE) and the Codex *Alimentarius* Commission (CAC), the OIE Members gave the Director General the mandate to create a specific permanent OIE Animal Production Food Safety Working Group (APFSWG). The Working Group's membership includes internationally recognized experts from the Food and Agriculture Organization of the United Nations (FAO), the World Health Organization (WHO) and the Codex Alimentarius Commission (CAC), and reflects a broad geographical basis.

2. The 4th OIE Strategic Plan (2006-2010) supports the continuation of this mandate, recommending that the APFSWG "continues to work with other relevant organisations, especially the Codex Alimentarius Commission, in reducing food borne risks to human health due to hazards arising from animals".

3. The APFSWG has drawn up a detailed work programme for the development of standards relevant to animal production food safety, covering hazards that arise on-farm and at slaughter, with a primary focus on measures applicable at the animal production level. The APFSWG recognised that the goals of the OIE can only be achieved by working in collaboration with the WHO, the FAO and their subsidiary bodies, particularly the CAC. This is essential to avoid contradictory standards, to address gaps between current standards and to ensure the most effective use of available expertise. To this end, the OIE has strengthened formal and informal relationships with relevant international organisations and expert groups. The APFSWG identified as priorities an examination of the scope to develop joint OIE and Codex standards, to address gaps and duplication in standards, and to develop procedures for mutual recognition of standards where appropriate.

4. The Working Group met for the eighth time in November 2008.

Current work priorities:

5. In May 2008, the OIE International Committee adopted Resolution No. XXV, recommending that the APFSWG's 2008/2009 work programme guide the OIE's animal production food safety activities. This work programme includes the following topics:

- Development of additional text on the management of antimicrobial resistance
- Alternative approaches to risk management of zoonotic diseases
- Development of a new chapter on animal feeding for the Terrestrial Code

- Development of a new *Terrestrial Code* chapter addressing the safety of biotechnology derived vaccines in animal products
- Updating the *Terrestrial Code* Chapter on Brucellosis
- Development of new *Terrestrial Code* Chapter(s) on Salmonella.

2. Capacity building

6. The OIE and its Member Countries believe that the veterinary activities embrace a wide range of issues such as animal diseases, public health linked to zoonosis and safety of foodstuffs from animal origin, and also animal welfare.

7. In this respect, Veterinary Services are of major importance, constitute a Global Public Good and their bringing into line with international standards (legislation, structure, organisation, resources, capacities, role of private sector) is a public investment priority.

8. The OIE has undertaken a number of initiatives to support Veterinary Services all over the world, out of which the following are of importance as far as veterinary medicinal products are concerned:

- the training of trainers to support OIE National representatives (delegates) and National Veterinary Services;
- the implementation of a tool for the evaluation of Veterinary Services compliance with OIE international standards on quality (PVS = Performance, Vision, Strategy). This includes the assessment of the governance of veterinary medicinal products in the Member Countries;
- the creation of a network of specific focal points dealing with veterinary medicines issues in the regions;
- the development of the twinning concept launched by the OIE in December 2006 in order to strengthen the capacity and efficiency of the whole network of OIE Reference Laboratories and Collaborating Centres. That will help as well to pay particular attention to the best use of resources and assistance to developing countries. Optimisation and networking are key tools in this aim;
- the organisation of regional conferences specifically dedicated to Veterinary Medicinal products; the first took place in Africa in March 2008 (entitled “Towards the harmonization and improvement of registration and quality control” - Dakar / Senegal), the second will take place in the Middle East in December 2009.

9. These events are aiming at improving the whole governance related to veterinary medicinal products.

10. All the above mentioned tools are contributing to better governance of Veterinary Medicinal Products, at all stages from production to usage and including private and public areas.

3. Antimicrobial resistance

11. Since 1997, due to the growing importance of antimicrobial resistance at a world-wide level, the OIE implemented an action plan in this field.

12. The first milestone was to issue five guidelines:

- Guidelines for the harmonisation of antimicrobial resistance surveillance and monitoring programmes
- Guidelines for the monitoring of the quantities of antimicrobials used in animal husbandry
- Guidelines for the responsible and prudent use of antimicrobial agents in veterinary medicine
- Laboratory methodologies for bacterial antimicrobial susceptibility testing
- Risk assessment for antimicrobial resistance arising from the use of antimicrobials in animals

13. These guidelines were adopted respectively by the OIE general session of OIE in May 2003 for the four first mentioned and in 2004 for the fifth one. Through this adoption, the guidelines became OIE international standards.

14. A continuous follow up is performed by the OIE *ad hoc* Group on antimicrobial resistance enabling whenever needed their update. In particular, Appendix 3.9.4 of the OIE Terrestrial Animal Health Code on guidelines for the responsible and prudent use of antimicrobial agents in veterinary medicine was revised, taking into account the recommendations of the Codex Alimentarius – ALINORM 05/28/31, Appendix VIII 53 Proposed Draft Code of Practice to Minimize and Contain Antimicrobial Resistance. This revised guideline was adopted during the May 2005 OIE General Session.

15. Considering antimicrobial resistance is a multidisciplinary and a worldwide issue OIE is willing to permanently strengthen close contacts with WHO and FAO, and governments of Members (172 countries are currently members of OIE).

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

17. Several actions have already been conducted or are still ongoing.

18. A 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), a 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.

19. 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.

20. A third consultation specific to aquaculture was held in Seoul, Republic of Korea, in June 2006. It was a joint FAO/WHO/OIE Expert Consultation on antimicrobial use in aquaculture and antimicrobial resistance. The overall objective of this meeting was to discuss and to outline strategies and recommendations to minimize the risk related to antimicrobial use in aquaculture and its consequences for human public health and animal health, based on scientific assessment.

21. Following the two first Expert Workshops on Non-Human Antimicrobial Usage organised by FAO, OIE and WHO, two main ideas emerged: the concept of ‘critically important antimicrobials’ and the establishment of a task force on antimicrobial resistance.

- Critically important antimicrobials

22. During the above mentioned workshops, it was recommended that the concept of ‘critically important’ classes of antimicrobials for human and animal usage should be developed by WHO and OIE, respectively. The list of Critically Important Antibacterial Agents for Human Medicine was proposed in February 2005 at a WHO working group consultation meeting in Canberra, Australia and revised during a second WHO expert meeting on the subject held in May 2007 in Copenhagen, Denmark. In January 2005, the OIE *ad hoc* Group proposed to define and designate Veterinary Critically Important Antimicrobials (VCIA). This concept was adopted by the International Committee during the 73rd General Session in May 2005. After further work of the ad hoc Group and consultation of the OIE Members, a list of VCIA was adopted in May 2007, during the 75th General Session of the OIE International Committee.

23. The need and feasibility of a further joint FAO/OIE/WHO expert consultation meeting has been discussed among the 3 organisations. The joint FAO/WHO/OIE Expert Meeting on critically important antimicrobials was held in November 2007 in Rome, Italy. One of the aims of the meeting was to find an appropriate balance

between animal health needs and public health considerations taking into account the different risk management approaches and the possible overlaps of the two lists. The report gives particular attention to principles and approaches for prioritisation for risk assessment and the identification and characterisation of preliminary risk management activities for minimising the risk of antimicrobial resistance associated with food producing animals.

- Task Force

24. The conference held in Oslo endorsed by WHO, FAO, OIE and all participants recommended the creation of a joint Codex/OIE task force. This task force was established during the 29th session of the Codex *Alimentarius* committee, as a Codex *Ad Hoc* Intergovernmental Task Force on Antimicrobial resistance" with the participation of OIE. Keeping in mind that protection of human health and the prudent and responsible use of antimicrobials in animals or plant protection is the ultimate objective in antimicrobial resistance risk management, OIE has continuously supported the creation of this Task Force. Its objective, as defined in the terms of reference, is to provide guidance on how to assess the risks to human health associated with the presence in food and feed of resistance organism or resistance genes.

25. The ongoing work of this task force will be considered at the specific agenda item of this 18th CCRVDF session.

26. In developing Guidance on methodology and processes for risk analysis for antimicrobials, this Task Force will contribute to minimize the risk of antimicrobial resistance and will also help avoiding the duplication of existing guidelines.

4. OIE and VICH activities

27. Since its formal creation in April 1996, the VICH provides a forum for a constructive dialogue between Regulatory Authorities and the Animal Health Industry on the technical requirements for product registration in the EU, Japan and the USA.

28. VICH was established under the auspices of the OIE.

29. Australia, New Zealand and Canada participate in VICH as observers, with one delegate representing governmental Authorities and one representing Industry associations.

30. Since the last OIE reporting to the CCRVDF in September 2007 three VICH Steering Committee meetings were held: the 20th meeting in October 2007 in Yokohama (Japan), the 21st meeting in July 2008 hosted by the OIE in its headquarters in Paris (France) and the 22nd meeting in February 2009 in Ottawa (Canada). Good progress was achieved on a number of areas.

31. At the 20th meeting, in order to monitor and maintain the VICH guidelines implemented for more than 3 years, the Steering Committee adopted a methodology and an action plan for the review of the 27 concerned Guidelines until 2011.

32. At the 21st meeting, the Steering Committee systematically reviewed these 27 Guidelines and agreed that the majority of the Guidelines did not require updating for the time being. The Steering Committee decided however that 3 of these Guidelines needed further attention and will be reviewed in more detail at the next Steering Committee meeting.

33. Moreover, the following VICH Guidelines were revised since the last OIE reporting to the CCRVDF:

- GL3 Stability : Stability testing of new drug substances and products - Jan. 08
- GL10 Impurities substances : Impurities in new veterinary drug substances - Jan. 08
- GL11 Impurities substances : Impurities in new veterinary medicinal products - Jan. 08
- GL33 Safety – Studies to evaluate the safety of residues of veterinary drugs in human food: General Approach to Animal Testing. This revision concerns inserting a reference to the 3 R's Principle (Refine, Reduce and Replace), highlighting the VICH adherence to the goal of minimising animal testing – Feb. 09

34. The following new VICH Guidelines were adopted by the Steering Committee or implemented since the last OIE reporting to the CCRVDF:

- GL24 Pharmacovigilance : Pharmacovigilance of veterinary medicinal products: management of Adverse Event Reports (AERs) – adoption by SC Oct. 07
- GL41 Reversion to virulence : Examination of live Veterinary Vaccines in Target Animals for Absence of Reversion to Virulence – implementation date: July 08
- GL42 Pharmacovigilance: Data Elements for Submission of Adverse Events Reports – adoption by SC: Oct.07
- GL43 Pharmaceuticals : Target Animal Safety for Pharmaceuticals – Implementation date: July 09
- GL44 Biologicals : Target Animal Safety for Veterinary live and inactivated Vaccines - Implementation date: July 09

35. Among the developments of interest for CCRVDF discussed in the 22nd VICH meeting are:

36. The VICH Steering Committee agreed to re-establish the safety expert working group to draft a guideline on Studies to establish an acute reference dose.

37. The VICH Steering Committee also agreed to set up a specific expert working group to revise GL 36 – Studies to evaluate the safety of residues of veterinary drugs in human food: general approach to establish a microbiological ADI.

38. The Metabolism and Residue Kinetics Expert Working Group made significant progress in the development of four draft topic guidelines:

- Studies to identify the nature and quantity of residues;
- Comparative metabolism studies in laboratory species;
- Studies to determine the depletion of residues; and
- Analytical method validation.

39. OIE and VICH also reviewed together the ways of improving the outreach of VICH information and principles to other countries and regions wishing to benefit from VICH experience. In particular, good discussions occurred on the way VICH and OIE could achieve the objective to enhance the global outreach of VICH. It was decided to continue the discussions and to address a questionnaire to non VICH countries in order to better identify their expectations.

40. The 4th VICH Conference will be held at the OIE Paris headquarters on 24-25 June 2010. The conference program would be arranged for an important part with parallel sessions to be of interest for both VICH countries and non VICH countries representatives. It will comprise sessions discussing the ongoing work by the VICH expert working groups on the development of guidelines, as well as discussion sessions related to the new VICH global outreach initiative work

41. Considering the key role of a good governance of veterinary medicinal products within the OIE global strategy, the OIE will continue to provide its support to the VICH process and will continue to relay the information on VICH to the 173 OIE Members Countries.