



JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

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INFORMATION ON ACTIVITIES OF THE WORLD ORGANISATION FOR ANIMAL HEALTH (OIE)¹

The World Organisation for Animal Health (OIE) wishes to thank the Codex Alimentarius Commission for the opportunity to provide this update on relevant OIE activities.

The relationship between the OIE and the Codex is important because risks to human health and food safety may arise at the farm and any subsequent stage in the food production continuum. Therefore, risk management must be tailored to detect and address risks at the appropriate stage(s). The OIE is responsible for setting standards in the domains of animal health and veterinary public health, including animal production food safety, to manage risks arising from the farm level through to primary processing. The OIE and Codex must therefore continue to collaborate closely in the development of standards relevant to the whole food production continuum, taking care to avoid gaps, duplications and contradictions.

The OIE appreciated the opportunity to participate in meetings of the Codex Alimentarius Commission, Codex Committees and expert groups during the past year and to contribute to its standard development process. Since the 40th CAC Session, OIE representatives have contributed to, or attended the following Codex meetings:

- 24th Session of the Codex Committee on Residues of Veterinary Drugs in Foods (April 2018)
- 49th Session of the Codex Committee on Food Hygiene (November 2017)
- 5th Session of the Ad hoc Codex Intergovernmental Task Force on Antimicrobial Resistance (November 2017)

During this meeting, important knowledge gaps regarding “AMR and the environment” became apparent. To this end, the FAO and the WHO, in collaboration with the OIE agreed to convene an “Expert Consultation on food-borne AMR: role of the environment, crops and biocides” (to be held at FAO Headquarters, Rome from 11 to 15 June 2018). The OIE contributed to identifying suitable experts, and will also participate in the consultation meeting.

- Joint FAO/WHO expert meetings on Shiga toxin-Producing *E. coli* (STEC) (September 2017)

The OIE welcomed its participation in this meeting and will continue to monitor outcomes of relevant work underway by the CAC and the FAO/WHO expert consultation, and to consider undertaking relevant work when Codex commences new work.

¹ This document was prepared by, and under the responsibility of, the World Organisation for Animal Health (OIE).

- Codex Committee on Food Import & Export Inspection & Certification Systems (CCFICS) the OIE continues to play an active role in the work of this committee. Of particular relevance are the following items of work:
- Electronic working group on Development of Codex guidance for paperless electronic certification. This work is closely linked to the STDF project on e-veterinary certification which the OIE is implementing over three years (starting May 2018) and will take into account existing and ongoing work by Codex and the FAO.
 - Electronic and physical working group on guidance for competent authorities to assess third-party assurance and its potential to inform national food control system (NFCS) planning.
 - Electronic and physical working groups on guidance on recognition and maintenance of systems equivalence for national food control systems.

The OIE also appreciated the participation of representatives from the Codex in relevant OIE expert meetings and the OIE General Session in May 2018.

Regular participation in each other's standard setting work ensures the development of official standards by the two organisations across the food production continuum. The most recent example was the standards developed by both organisations on *Salmonella* in pigs and pork, and bovines and beef, which are aligned and address all recognised risks to animal health, human health and food safety in the farm to fork food production continuum.

Collaboration

At the 2017 OIE General Session, the World Assembly of Delegates agreed that the mandate for the OIE Animal Production Food Safety Working Group not be renewed considering that the OIE's work in animal production food safety was now well integrated into the work of the OIE. The World Assembly agreed that this work would continue to be addressed in other OIE forums including the FAO/OIE/WHO Tripartite Annual Executive Coordination Meetings.

In preparation for the 24th FAO/OIE/WHO Tripartite Annual Executive Coordination Meeting (held at OIE Headquarters, Paris, 21-22 February 2018), representatives from FAO, OIE, WHO and the Codex Secretariat met in Rome on 30 January 2018 to discuss Tripartite coordination and collaboration in food safety. Starting from lessons learned through past collaboration on food safety between OIE, FAO and WHO (including Codex), the participants discussed upcoming activities to identify where collaboration could be useful, and also discussed the appropriateness of the current practices for collaboration and if other mechanisms should be proposed for future collaborative work.

The Tripartite endorsed their recommendations, namely current mechanisms for Tripartite collaboration on standard setting and related scientific advice are adequate. The Tripartite also endorsed the recommendations related to capacity development in particular that will facilitate the use of each other's networks, identify contact points in each of the three organizations' on issues of agreed mutual interest related to animal production food safety as well as exploring the use of existing fora such as the STDF for opportunities for strategic alignment on capacity development issues. The Tripartite acknowledged that the Tripartite Food Safety Coordination Group will hold periodic meetings on a demand driven basis to deal with food safety issues as they arise.

In addition to collaboration at the international level, the OIE is taking steps to support collaboration at the national level, consistent with discussions within the SPS Committee. The OIE encourages its Delegates to coordinate their positions with their delegations to Codex to ensure, at the national level, alignment of their approach to standards developed by the OIE and Codex.

The list of OIE Permanent Delegates is available at: <http://www.oie.int/en/about-us/our-members/delegates/>. Contact details of OIE National Focal Points for animal production food safety and veterinary products are also available on the Regional Representatives websites at: <http://www.oie.int/en/about-us/wo/regional-representations/>

Another example of further strengthening of cross-sectoral coordination and cooperation at national and global levels was the recommendation from the FAO/OIE/WHO Tripartite annual meeting that the OIE encourage its Delegates to designate the national OIE Focal Points for animal production food safety as a INFOSAN Focal Point or, depending on national administrative arrangements, as an INFOSAN Emergency Contact Point. In response to this request the INFOSAN membership now includes OIE Focal Points for animal production food safety in more than 40 countries.

Relevant work in the OIE Terrestrial Animal Health Code

The role of Veterinary Services in food safety (Chapter 6.1.)

At the May 2018 OIE General Session, the World Assembly of Delegates adopted the revised chapter in the *Terrestrial Animal Health Code*, Chapter 6.1. 'The role of the Veterinary Services in food safety'. This chapter, first adopted in 2006, was revised to include all the food safety areas that veterinarians are now involved in, as well as incorporating a farm-to-fork approach to ensure food safety and suitability. The revised draft chapter also includes cross-references to relevant Codex standards. The revised draft chapter has been circulated for Member Country comments on a number of occasions and each time an extensive number of comments have been received and considered by the Terrestrial Animal Health Standards Commission.

OIE work on Antimicrobial Resistance

Standards related to AMR

Since 1997, in recognition of the growing importance of AMR at a global level, the OIE has developed standards and guidelines aimed at supporting responsible and prudent use of antimicrobial agents in animals and monitoring of AMR and use in animals. The OIE standard-setting process ensures that standards are updated, when relevant, in order to accommodate new findings and Member Country comments. This work is supported by the OIE *ad hoc* Group on AMR, which includes representatives from WHO, FAO, and, when relevant, the Codex secretariat.

The *Aquatic and Terrestrial Animal Health Codes* include chapters that address:

- Harmonisation of national AMR surveillance and monitoring programmes;
- Monitoring of the quantities and usage patterns of antimicrobial agents in animals;
- Responsible and prudent use of antimicrobial agents; and
- Risk analysis for AMR arising from the use of antimicrobial agents in animals.

During the OIE General Session in May 2018, the revised *Terrestrial Code* Chapter 6.7. Harmonisation of national antimicrobial resistance surveillance and monitoring programmes was adopted. This chapter, was revised in response to comments from OIE Member Countries and to define the criteria for selection of animal pathogens for antimicrobial resistance surveillance and develop a list of the most important animal pathogens for the different species, applicable worldwide.

Also adopted was the revised *Terrestrial Code* Chapter 6.8 Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals. Article 6.8.1. was revised to provide more detail on the definition of 'therapeutic use of antimicrobial agents' and to clarify what is expected for reporting in data collection and a new Article 6.8.1bis was introduced to include definitions for 'veterinary medical', 'non veterinary medical' and 'growth promotion'. During the OIE General Session in May 2018 a suggestion was made to delete the term 'therapeutic' to avoid problems of interpretation. After discussion, it was agreed that the proposed terms 'therapeutic' and 'nontherapeutic' be replaced by 'veterinary medical' and 'non veterinary medical', respectively. Growth promotion was adopted as proposed. In addition, as a consequential change, the terms 'therapeutic' and 'nontherapeutic' were amended accordingly in Article 6.8.3.

The OIE hopes that the Codex Ad hoc Intergovernmental Task Force will take these new definitions into account when developing their texts to clearly differentiate the use of antimicrobial agents for human and veterinary use.

These revised texts will be published in the 2018 edition of the *Terrestrial Code*, which will be available on the OIE website (<http://www.oie.int/en/standard-setting/terrestrial-code/access-online/>) in August 2018.

A revised version of Chapter 3.4. The role of official bodies in the international regulation of veterinary biologicals of the *Manual of Diagnostic Test and Vaccines for Terrestrial Animals* was adopted and will be published in the online version available in June at <http://www.oie.int/en/standard-setting/aquatic-manual/access-online/>

In view of the increasing importance of the work currently been undertaken in the field of antimicrobial resistance, it was agreed that the *Terrestrial Manual* Chapter 3.1. Laboratory methodologies for bacterial antimicrobial susceptibility testing would be reviewed in the coming year.

OIE List of Antimicrobial Agents of Veterinary Importance

Specific recommendations on the use of antimicrobial agents in animals are published in the OIE List of Antimicrobial Agents of Veterinary Importance. The list identifies antimicrobial agents used in animals around the world, highlights where no or few alternatives for treatment of animal diseases exist, and provides guidance on the use of antimicrobial agents that are of highest critical importance in human medicine. The list was reviewed to take into account the latest update of the WHO List of Critically Important Antimicrobials. The revised List was adopted unanimously by Resolution No. 21 at the 86th OIE General Session in May 2018 and is available at: <http://www.oie.int/en/about-us/key-texts/resolutions-and-recommendations/resolutions-adopted-by-the-world-assembly-of-delegates-of-the-oie/>

Based on the recommendations of the 2013 OIE Global Conference on the Responsible and Prudent Use of Antimicrobial Agents and the Tripartite (FAO, OIE, WHO), the OIE, in line with the Global Action Plan, agreed to build a global database on antimicrobial agents intended for use in animals. The first OIE Annual Report on Antimicrobial Agents Intended for Use in Animals, which described the results of the first phase of data collection, was published in December 2016; 104 countries had participated in the data collection. For the second phase of data collection (from October 2016 to May 2017), 39 new countries, including 143 from OIE Member Countries and 3 non-Member Countries, giving a total of 146 countries. Simultaneously, calculations of animal biomass to use as a denominator in the analysis of quantitative data on antimicrobials intended for use in animals was undertaken. The report of the second year of data collection, which included for the first time an analysis of antimicrobial quantities reported by OIE Region, in the context of animal biomass, was published in December 2017.

The third phase of data collection was completed in May 2018; 146 Member Countries and 1 non-Member Country had participated. The data are available on the OIE website at: <http://www.oie.int/en/scientific-expertise/veterinary-products/antimicrobials/>

OIE and the VICH activities

The OIE continues to be active in assisting 181 Member Countries to build and implement effective legislation to assure the quality, safety and efficacy of veterinary medicinal products, particularly antimicrobial agents. The OIE, as associate Member of the VICH provides support and encourages its Member Countries to take the VICH guidelines into consideration. The OIE considers that the international harmonisation of technical requirements for the pre- and post-marketing authorisation of veterinary medicines is a necessity for animal health, public health and the facilitation of international trade, and that VICH is one of the necessary tools for achieving these aims. In order to provide OIE Member Countries with the information about efforts to harmonise requirements, the OIE provides a brief summary after each VICH Outreach Forum (VOF) meeting via the Delegate and Focal Points for Veterinary Products and encourages their participation in the VOF meetings.

SPS Capacity Building for OIE Members

The OIE PVS Pathway

As a flagship programme of the OIE, the OIE PVS Pathway has been an unmitigated success over the last decade. A total of 139 Member Countries actively engaged via requesting an OIE PVS Evaluation mission, with 115 of those also requesting the next step, an OIE PVS Gap Analysis mission, and 63 requesting a second round through an OIE PVS Evaluation Follow-up mission. There has also been

strong engagement in the OIE PVS Pathway Targeted Support activities including 69 Veterinary legislation identification missions and 14 PVS Pathway Laboratory missions.

There is growing evidence of the OIE PVS Pathway's major global impact on strengthening national Veterinary Services in areas as diverse as improved government and donor resourcing, clearer governance structures and national coordination, improved inter-sectoral collaboration, and enhanced animal and veterinary public health surveillance, disease control, emergency response, border control, food safety, laboratory, educational, legislative and animal welfare systems.

Further to the OIE PVS Think Tank Forum in April 2017, and in consultation with numerous stakeholders, the OIE has further expanded the OIE PVS Pathway activities. Some new elements being developed as part of the OIE PVS Pathway Evolution include PVS Pathway trainings to support country self-evaluation, new specific content on priority topics (e.g. AMR) within PVS Evaluation missions, strategic planning support, and IHR/PVS National Bridging Workshops bringing together animal and public health sectors to identify areas for improved collaboration under the One Health approach.

OIE National Focal Points

The OIE encourages all Delegates to nominate National Focal Points in a range of subjects including Animal Production Food Safety (APFS) and Veterinary Products. Currently the OIE has 177 nominated Focal Points for APFS and 179 for Veterinary Products. The purpose of creating these OIE National Focal Points is to improve communication between the OIE, Delegates and all agencies responsible for food safety, veterinary products, and SPS matters at the national level. A series of training seminars for OIE Focal Points continues to be conducted worldwide, on a region-by-region basis.

National Focal Points for Veterinary Products

The 4th cycle of specific training seminars for Focal Points for Veterinary Products has been completed in Africa, Asia-Pacific, Europe and the Middle East Regions. In line with the 'One Health' concept, the FAO and WHO are regularly invited to participate in these seminar activities. The 5th cycle of seminars is ongoing. So far the first training was held in Ezulwini, Swaziland (6–8 December 2017) for English-speaking African countries; the second seminar was held in Abidjan, Côte d'Ivoire (16–18 Janvier 2018) for French-speaking African countries; the third seminar was held in March 2018 in Thailand for the Asia-Pacific Region; and the fourth Seminar will be held in August 2018 in Mexico for the Americas Region.

The 5th cycle of seminars for the Focal Points for Veterinary Products aims to deepen understanding of key issues such as: i) The Tripartite activities, results of the OIE data collection on antimicrobial agents used in animals, the OIE strategy on AMR and the prudent use of antimicrobials; ii) quality and traceability of veterinary medicinal products, including the issue of falsified and substandard veterinary medicines, the harmonisation/convergence of regional registration/authorisation systems for VMPs, and the implementation of VICH guidelines; and iii) resistance to antiparasitic drugs and challenges relating to their use. The seminars also allocate time for sharing of experience and lessons learnt among participants from the OIE Regions.

WTO Trade Facilitation Agreement

The OIE is working with OIE Member Countries to ensure they are aware of the critical role Veterinary Services play in the implementation of the Trade Facilitation Agreement (TFA). Veterinary Services are responsible for overseeing import and export processes (including veterinary health certification) relating to sanitary and zoosanitary controls of imports and exports of animals, animal products and other materials which may introduce animal diseases. In particular, obligations described in the TFA Articles 8: 'Border Agency Cooperation' and 10: 'Formalities and Documentation Requirements' will require closer collaboration between border agencies.

Monitoring the Implementation of OIE International Standards

The OIE has initiated the creation of an Observatory to monitor the implementation of its standards in order to identify the difficulties and constraints faced by Member Countries and therefore to propose solutions.

The OIE's international standards are based on science and adopted by its 181 Member Countries. Correctly applied, they protect animal health and welfare and veterinary public health during production, processing and transport and trade in animals and animal products.

The World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) recognises the OIE as the international standard setting body for matters relevant to animal health and zoonotic diseases. If countries apply OIE standards, they are complying with their WTO obligations.

The international standard setting process of the OIE is transparent and fully participatory. While the OIE works to ensure that Member Countries are aware of their international obligations, there are still significant problems in the consistent application of these standards by many countries, particularly when making decisions on the importation of animals and animal products. Concerns about the non-application of OIE standards are regularly raised at the WTO SPS Committee. OIE recommendations on foot and mouth disease, bovine spongiform encephalopathy, African swine fever and avian influenza have all been the subject of the formal dispute settlement process in the 20 years since the creation of the WTO. While the development of sanitary standards is a central mission of the OIE, the organisation must also look at how they are implemented. The Observatory is intended to serve as a tool to monitor progress and constraints faced by Member Countries in the implementation of the OIE standards. The Observatory is not intended as a tool for control or compliance. The Observatory demonstrates good management practice while remaining within the scope of the mandate provided to OIE by its Members.

Data collected by the Observatory will help the OIE to determine the relevance of its standards to Member Countries, in terms of effectiveness, practicability and impacts. Thus, the OIE will be better able to propose solutions to Member Countries and the expected outcomes would be more effective implementation of OIE standards.

Like other international standard setting organisations, the OIE faces the critical challenge to maintain the relevance and impact of its standards over time. The Observatory will be a new mechanism developed by the OIE to collect data providing a better understanding of constraints and challenges faced by Member Countries in the implementation of OIE standards. In this way, the OIE will be able to evaluate the use and impacts of its standards. The outcomes of the Observatory will help the OIE to prioritise its activities and work programme.
