CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 3(b) **CX/AMR 17/5/4 Add.1**
November 2017

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

***AD HOC* CODEX INTERGOVERNMENTAL TASK FORCE ON ANTIMICROBIAL RESISTANCE**

Fifth Session

INFORMATION ON THE WORK OF OTHER RELEVANT INTERNATIONAL ACTIVITIES ON ANTIMICROBIAL RESISTANCE

(Information of OIE and OECD)

WORLD ORGANISATION FOR ANIMAL HEALTH (OIE)

Introduction

1. In the capacity of an observer organisation, the OIE has a long-standing collaboration and regularly participates in meetings of the Codex Alimentarius Commission (CAC). The OIE also participated in the previous Task Force on Antimicrobial Resistance (AMR) that took place between 2007 and 2011.

2. The OIE addresses food safety-related issues in its standard-setting activities and works closely with CAC and its Committees, and with other international organisations in promoting safe international trade in animals and their products. AMR is of highest interest to the OIE and its 181 Member Countries and is also one of the priority topics for tripartite (FAO, OIE, WHO) collaboration.

3. The OIE's Fifth Strategic Plan (2011–2015) included actions such as good governance of Veterinary Services, the reinforcement of Veterinary Services capacities and infrastructure, including veterinary legislation, and, more generally, the linkages between animal health, food safety and food security. Veterinary medicinal products, in particular strengthened liaison with Codex and expansion of the programme on International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH), were included in the 5th Strategic Plan as they are considered to be essential tools for any effective animal health and welfare policy.

4. At the OIE General Session in 2015, the OIE's Sixth Strategic Plan (2016–2020) was adopted and sets out three major objectives leading to economic prosperity and social and environmental well-being.

- Objective 1: Securing animal health and welfare by appropriate risk management
- Objective 2: Establishing trust through transparency and communication
- Objective 3: Ensuring the capacity and sustainability of Veterinary Services

The OIE Sixth Strategic Plan is available at the following link: http://www.oie.int/fileadmin/Home/eng/About_us/docs/pdf/6thSP_ANG.pdf.

5. At the OIE's 84th General Session in 2016, the World Assembly unanimously adopted Resolution No. 36, which mandates that OIE compile AMR activities into a strategy. In November 2016, the OIE Strategy on Antimicrobial Resistance and the Prudent Use of Antimicrobials was published. Aligned with the Global Action Plan on AMR, the strategy recognises the importance of a "One Health" approach involving human and animal health as well as plant and environmental needs. It outlines the goals and projects the OIE has in place to support Member Countries in their fight against AMR, and to encourage the national ownership and implementation of international Standards. The document is available at the following link. http://www.oie.int/fileadmin/Home/eng/Media_Center/docs/pdf/PortailAMR/EN_OIE-AMRstrategy.pdf

Antimicrobial resistance

➢ Standards and guidelines related to AMR

6. The primary mandate of the OIE is to produce Codes and Manuals covering terrestrial and aquatic animals, which provide best practices to protect and promote animal health and welfare. Their development involves regular review and formal adoption at the annual General Session by the World Assembly, made up of Delegates designated by the governments of the 181 OIE Member Countries.

7. 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 OIE *ad hoc* Group provides expertise by updating the chapters relevant to AMR in the OIE T*errestrial Animal Health Code*[1], *Aquatic Animal Health Code*[2] and *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*[3].

8. Code chapters include:

- Harmonisation of national AMR surveillance and monitoring programmes
- Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals
- Responsible and prudent use of antimicrobial agents in veterinary medicine and
- Risk analysis for AMR arising from the use of antimicrobial agents in animals

9. The *Manual of Diagnostic Test and Vaccines for Terrestrial Animals* provides technical specifications for Laboratory methodologies for bacterial antimicrobial susceptibility testing.

10. Specific recommendations on the use of antimicrobial agents in animals are published in the OIE List of Antimicrobial Agents of Veterinary Importance. This List, developed as a draft list in May 2006 and refined in 2007, was submitted to the 75th International Committee and adopted unanimously by Resolution No. XXVIII. during the General Session in May 2007. The List identifies antimicrobial agents used in animals around the world, highlights where no or few alternatives for treatment of animal diseases exists, and provides guidance on use of antimicrobial agents that are of highest critical importance in human medicine. The List that was updated several times since 2007, will be reviewed by the *ad hoc* Group in January 2018 to take into account the latest update of the WHO List of Critically Important Antimicrobials, and following the recommendations of the OIE Resolution No. 38 (85 GS 2017) to define the purpose of ionophores. The current List is available at: http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/Eng_OIE_List_antimicrobials_May2015.pdf

11. The OIE standards and guidelines are published (online and in print) in the *Terrestrial Animal Health Code*, the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, the *Aquatic Animal Health Code* and the *Manual of Diagnostic Tests for Aquatic Animals* .and are available at: http://www.oie.int/fileadmin/home/eng/Media_Center/docs/pdf/PortailAMR/EN-book-AMR.PDF

12. The OIE *ad hoc* Group on AMR continues to work, with the participation of FAO and WHO, in support of the global efforts to prevent and combat AMR through updating Chapter 6.7. of the *Terrestrial Code*, Harmonisation of national antimicrobial resistance surveillance and monitoring programmes. The *ad hoc* Group also proposed definitions of “Therapeutic use” and “Growth promotion” for the Chapter 6.8. of the *Terrestrial Code*, Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals. The Group also supports the worldwide collection of data on the use of antimicrobial agents in animals.

13. 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 has taken the initiative, in line with the Global Action Plan, to build a global database on antimicrobial agents intended for use in animals.

➢ OIE Collection of data on antimicrobial agents intended for use in animals

14. 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. Since then, Member Country participation increased for the second phase of data collection. From October 2016 to May 2017, 146 Countries submitted completed questionnaires to the OIE Headquarters: 143 from OIE Member Countries and 3 non-Member 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.

[1] http://www.oie.int/en/international-standard-setting/terrestrial-code/access-online/
[2] http://www.oie.int/en/international-standard-setting/aquatic-code/access-online/
[3] http://www.oie.int/en/international-standard-setting/terrestrial-manual/access-online/

15. The OIE will publish annually a report on the worldwide distribution of antimicrobial agents intended for use in animals. The report of this second year of data collection, which will include for the first time an analysis of antimicrobial quantities reported by OIE Region, in the context of animal biomass, will be published on the OIE website by the end of 2017. Meanwhile, the OIE launched the third phase of data collection on 30 September 2017.

16. During the 85th General Session (May 2017), the World Assembly of Delegates was updated on the progress and future prospects of global action in combatting AMR under the Technical Item 1, and adopted Resolution No. 38 "Global action to alleviate the threat of antimicrobial resistance: progress and opportunities for future activities under the 'One Health' initiative" whereby the continued collection of global data on antimicrobial agents intended for use in animals was affirmed as a key effort in this goal.

17. The report of Technical Item 1 of the 2017 General Session can be found at: http://www.oie.int/fileadmin/home/eng/Media_Center/docs/pdf/85SG/TT1_AMR/A_85SG_9.pdf

Capacity building

18. Capacity building activities, including good governance of national veterinary services and veterinary medicinal products, are key elements for animal and public health.

- National Focal Points

19. The OIE encourages all Member Countries to nominate National Focal Points, under the authority of the OIE Delegate, for eight strategic issues, including for veterinary products.

20. The 4th cycle of specific training seminars for Focal Points for Veterinary Products has been completed in the Americas, Africa, Asia-Pacific, and in Europe. 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 will start with a training seminar for English-speaking African countries, held in Swaziland in December 2017.

21. The 5th cycle of seminars for the Focal Points for Veterinary Products aims to deepen understanding of key issues such as:

1) Tripartite activities related to AMR;

2) The quality and traceability of veterinary medicinal products (VMPs), 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;

3) Resistance to antiparasitic drugs and challenges relating to their use.

22. The seminars also allocate time for sharing of experience and lessons learnt between participants from the OIE Regions.

- The OIE PVS Pathway

23. The OIE PVS (Performance of Veterinary Services) Pathway is a global programme for the sustainable improvement of a country's Veterinary Services in compliance with OIE's internationally agreed standards on the quality of Veterinary Services. As a flagship programme of the OIE, it is central to the OIE's core mission of improving animal health and welfare around the world. At the specific request of a Member Country, the OIE conducts an independent and staged process of assessments and planning on the quality of Veterinary Services and Aquatic Animal Health Services including veterinary medicines and biologicals using the OIE PVS Tool. Subsequent steps in the PVS Pathway include PVS Gap Analysis, PVS Pathway Laboratory missions, Veterinary Legislation missions and PVS Evaluation Follow-Up missions, to help improve and monitor compliance of the veterinary infrastructure with the OIE quality standards set out in the OIE *Terrestrial* or *Aquatic Animal Health Code*. Further background on what the PVS Pathway is can be found on the OIE website at http://www.oie.int/support-to-oie-members/pvs-pathway/.

24. The programme has proven an unmitigated success over the last decade. To date (October 2017) 137 Member Countries have been actively engaged via national requests to conduct initial OIE PVS Evaluation missions. Relevant information may be found at: http://www.oie.int/en/support-to-oie-members/pvs-evaluations/status-of-missions/ .

25. In April 2017 the OIE organised a PVS Pathway Think Tank Forum as a platform to review, consult and plan for the evolution of the PVS Pathway, including AMR specific management relevant to Veterinary Services capacity, particularly in assessing the prudent and responsible use of antimicrobials in animal populations. This methodology is currently being finalised and the aim is to pilot it in candidate countries in 2018. The result should be that PVS mission findings and recommendations relevant to AMR are developed and presented in a more readily accessible and usable form for the country or its international partners to guide further AMR legislation, policies and/or activities to target the risks. The methodology will also be closely aligned with FAO-OIE-WHO Tripartite AMR initiatives, including the AMR national action plan self-assessment questionnaire, and the inclusion of AMR in IHR MEF[4] Joint External Evaluations.

➢ Veterinary Education

26. The OIE Recommendations on the competencies of graduating veterinarians ('Day 1 graduates') prepare the Day 1 veterinary graduate to promote global veterinary public health and provide a basis for advanced training and education for veterinarians in all OIE Member Countries. Further information is available at the following link: http://www.oie.int/fileadmin/Home/eng/Support_to_OIE_Members/Vet_Edu_AHG/DAY_1/DAYONE-B-ang-vC.pdf . Similar work on the education of veterinary paraprofessionals is ongoing.

International Collaboration

➢ Global Action Plan on AMR

27. The OIE closely collaborated with WHO and FAO (the Tripartite) on the Global Action Plan on AMR, which was developed based on the 'One Health' approach. OIE Member Countries are encouraged to follow the guidance of the Global Action Plan and the Tripartite developed a Manual for implementation of National Action Plans. An annual survey on the implementation of National Action Plans has also been developed and the questionnaire for the second survey will be sent in autumn 2017.

28. The OIE continues to collaborate with WHO and FAO on AMR, in particular through the development of tripartite frameworks on stewardship and on monitoring and evaluation of activities related to AMR.

➢ Interagency Coordination Group on Antimicrobial Resistance

29. Collaboration is also increasing at the highest political level and the three organisations hosted a High Level Dialogue on AMR in April 2016 at the United Nations in New York to raise awareness on AMR. On 21 September 2016, during the 71st Session of the United Nations General Assembly, Member States adopted the Political Declaration of the High-level Meeting on AMR contained in Resolution A/RES/71/3 and in March 2017 an *ad hoc* Interagency Coordination Group on AMR was established. The second face-to-face meeting of this UN Interagency Coordination Group on AMR took place at the OIE Headquarters in mid-October. The objective of the Group is to provide practical guidance for approaches needed to ensure sustained effective global action to address AMR, including options to improve coordination, taking into account the Global Action Plan on AMR. It will produce a report to the Secretary-General for the 73rd session of the UN General Assembly.

➢ OIE Reference Centres

30. The OIE's scientific work is supported by its worldwide network. In 2017, the OIE has a global network of 267 Reference Laboratories covering 118 diseases or topics in 38 countries, and 55 Collaborating Centres covering 49 topics in 29 countries. The complete list of Reference Centers is available at the following link: http://www.oie.int/en/our-scientific-expertise/collaborating-centres/list-of-centres/

31. Reference Centres with particular focus on AMR are:

Veterinary Medicinal Products

ANSES Fougères - Agence nationale du médicament vétérinaire (ANMV), B.P. 203 35302 Fougères Cedex FRANCE

Antimicrobial resistance

Animal and Plant Health Agency New Haw, Addlestone, Surrey KT15 3NB UNITED KINGDOM

Veterinary Drug Regulatory Programmes

Center for Veterinary Medicine, Food and Drug Administration (FDA), Department of Health and Human Services, 7519 Standish Place, HFV-1, Room 177, Rockville, Maryland 20855,
UNITED STATES OF AMERICA

[4] IHR MEF: International Health Regulations monitoring and evaluation framework

Diagnosis and Control of Animal Diseases and Related Veterinary Product Assessment in Asia

National Institute of Animal Health (NIAH) 3-1-‘5, Kannondai, Tsukuba, Ibaraki, 305-0856 and National Veterinary Assay Laboratory (NVAL) 1-15-1, Tokura, Kokubunji, Tokyo, 185-8511 JAPAN

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT (OECD)

Introduction

32. Anti-microbial resistance is one of the greatest challenges facing public health and animal health and welfare today. Several international studies have estimated the social and economic costs arising from AMR in human health and, to a lesser extent, in agriculture. The OECD’s work on AMR focuses on a comparative economic analysis of the potential economic impacts of AMR on human health, animal health and food production. In addition the OECD identifies best practices and prescribes policy recommendations that complement the technical work of the OIE and FAO, as well as the WHO.

33. A key concern for policymakers is the implications of AMR in animals, crops and aquaculture for long-term agricultural productivity and, hence food safety and food security. Another issue relates to the transmission of resistance bacteria and genes to humans, for example through direct contact with animals, consumption of products that have been treated with antibiotics and via the environment.

Agriculture and the food chain

34. There are specific concerns about the surge in consumption of antimicrobials in livestock agriculture. While data on the usage in agriculture are limited (but improving), in some countries agriculture accounts for the bulk of consumption. For example, the consumption of antibiotics in many OECD countries accounts for more than two-thirds of annual consumption. Moreover, the global consumption of antibiotics in agriculture is expected to increase by 70% by 2030, if the current trends in antibiotic consumption continue combined with the growth in demand for livestock products.

35. Analysing the economic impacts of AMR is extremely complex, as antibiotics are widely used in livestock production for therapeutic purposes, as well as for non-therapeutic purposes e.g. improving feed efficiency and growth promotion. The close interlinkage of these aspects makes it very difficult to decipher the prophylactic effects from the productivity effects at the farm level. A further complication relates to the fact that only a limited number of countries have comprehensive and reliable information and data on antimicrobial usage in food animal production. These deficiencies also include the lack of data by species (poultry, pigs, and cattle), stage of growth, type of production system, as well as by class of antibiotics used.

36. The OECD takes an integrated economic and policy approach to its AMR work on food animal production. More specifically, the current work focuses on quantifying the economic benefits and costs of antimicrobial use in food animal production, as well as the costs and benefits of transitioning to alternative interventions. The scope of this work covers the three major food animal species for the OECD countries, as well as for the BRIICS. This work is aimed at complementing the ongoing AMR technical work in other International Organisations. A key goal of this work is to identify best production practices and policy options to promote smart and sustainable systems for food animal production.

37. Some recent work in the Trade & Agriculture Directorate, OECD, has attempted to take stock of the usage of antibiotics in livestock production and in identifying alternative policy options and husbandry practices (Rushton et al. (2014)). A further study has analysed the economic costs of withdrawing antimicrobials growth promoters from livestock production (Laxminarayan et al. (2015)). The study noted those four countries; China, the US, Brazil and India account for almost 50% of global antibiotic consumption in agriculture. Moreover, consumption in the BRIICS is projected to double by 2030.

38. The current work in TAD is aimed at improving the understanding on the economic impacts of antimicrobials use in animal production, as well as the costs and benefit of alternative approached for OECD countries and the BRIICS. The specific objectives of this ongoing work are to:

- Estimate the economic benefits and costs of reducing the mass routine use of antibiotics in livestock production systems and transitioning to alternative approaches; and,
- Develop a list of best production practices and policy options to facilitate a move to a smart and economically sustainable approach to livestock production.

39. In the short term, livestock producers may “benefit” from the regular and systematic use of antibiotics, especially in high density livestock production systems. However, in the longer term with the emergence and spread of resistant microbes, in particular multi-drug resistant microbes, the private and social costs are likely to be enormous for food animal production, animal health and potentially public health.

Human health

40. OECD work on AMR in human health aims to close the evidence gap on three key issues. First, OECD produces evidence to make the economic case to invest in policies to tackle AMR. Second, OECD supports efforts to re-start the R&D development pipelines for new antimicrobials, vaccines and diagnostics. Third, OECD identifies and reviews best practices to support member countries in implementing innovative policy actions. More specifically, OECD is currently involved in the following activities:

1) Building on its modelling expertise, OECD has developed a tool to replicate historical trends of AMR rates and to project these trends into the future. The resulting model is used to gauge the health and economic burden of AMR and to evaluate the effectiveness and cost-effectiveness of innovative policy options to: i) promote prudent use of antimicrobials; and ii) prevent the spread of infections. Currently, the model covers 31 countries but future work aims to extend the geographical scope to 52 countries.

2) OECD is reviewing national action plans, national targets to reduce AMR and antimicrobial consumption and policies in place for a number of OECD countries. This work aims to identify best practices to promote prudent use of antimicrobials and to help countries implement these actions, given their national context. Through the series of Public Health Reviews, OECD also offers countries a 'tailor-made' analysis of the current policy landscape to identify gaps against international standards and to advise on innovative public health actions.

3) OECD produces evidence to inform global dialogue on potential strategies to ensure sustainable R&D. OECD has reviewed options to incentivize the various phases of the R&D pipeline, from basic research to market approval and commercialization. Together with WHO, FAO and OIE, OECD has produced the background paper conceptualizing a transnational incentive platform, based on downstream economic incentives and a delinkage of R&D investments from sales revenues, which was instrumental in the launch of the G20 'AMR R&D Collaboration Hub'. OECD is now working to support the establishment and the work of this hub.

Collaboration with other International Organisations

41. The work on AMR in OECD is aimed at complementing the ongoing technical and standards work in other International Organisations, including the Global Action Plan of the Tripartite Group (WHO/FAO/OIE), which calls for each country to develop its own plan to combat AMR, specific to its own needs and stage of economic development.

42. More specifically, the OECD has signed a Memorandum of Understanding (MoU) with the OIE (September 2016) which includes co-operation on all activities on antibiotic use and resistance in livestock agriculture. Also, the OECD has established an Expert Steering Group on AMR work in agriculture and food, with the FAO and OIE, as well as independent experts participating in this group. Moreover, as part of the programme of work on Public Health, OECD organizes an annual meeting of experts from member countries and other International Organizations, including WHO. Finally, there are regular meetings and sharing of information with the WHO, WB, EBRD and the ECDC on the progress on our ongoing work on AMR.

References:

Cecchini, M. and S. Lee (2017), "Low-value health care with high stakes: Promoting the rational use of antimicrobials", in Tackling Wasteful Spending on Health, OECD Publishing, Paris. http://dx.doi.org/10.1787/9789264266414-6-en

Laxminarayan, R., T. Van Boeckel and A. Teillant (2015), "The Economics Costs of Withdrawing Antimicrobial Growth Promoters from the Livestock Sector", OECD Food, Agriculture and Fisheries Papers No 78, OECD Publishing.

OECD (2015), "Antimicrobial resistance in G7 countries and beyond: economic issues, policies and options for action". OECD Publishing, Paris. http://www.oecd.org/els/health-systems/Antimicrobial-Resistance-in-G7-Countries-and-Beyond.pdf

OECD (2016), "Antimicrobial resistance policy insights". OECD Publishing, Paris. http://www.oecd.org/health/health-systems/AMR-Policy-Insights-November2016.pdf

OECD (2016), "OECD-FAO Agricultural Outlook 2016-25", OECD Publishing, Paris.

OECD, WHO, FAO and OIE (2017). "Tackling Antimicrobial resistance, ensuring sustainable R&D". http://www.oecd.org/els/health-systems/G20-AMR-Final-Paper-2017.pdf

Rushton, J., J. Pinto Ferreira and K.D. Stark (2014), "Antimicrobial Resistance: The Use of Antimicrobials in the Livestock Sector", OECD Food, Agriculture and Fisheries Papers No 68, OECD Publishing.