

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

AD HOC CODEX INTERGOVERNMENTAL TASK FORCE ON ANTIMICROBIAL RESISTANCE

Eighth Session

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MATTERS ARISING FROM OTHER RELEVANT INTERNATIONAL ORGANIZATIONS

Information relevant to the work of the *Ad Hoc* Intergovernmental Task Force on Antimicrobial Resistance carried out by the OECD, WB, WCO and WTO is presented below.

ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT (OECD)¹

Introduction

1. The OECD's work on antimicrobial resistance (AMR) focuses on comparative economic and policy analysis and policy recommendations. The OECD programme on AMR is designed to complement the technical work of the World Health Organization (WHO), Organization for Animal Health (OIE) and the Food and Agriculture Organization (FAO)-Codex. In essence, the OECD analyses are aimed at identifying policy gaps in the fight against AMR and at calculating the economic return on investment with a view to identifying the most effective and efficient policies to combat the rise in AMR in both the livestock and human sectors.

AMR work in the OECD

Agriculture – Trade and Agriculture Directorate (TAD)

2. In March 2021, the OECD released a publication on AMR – “Assessing National Action Plans on Antimicrobial Resistance in Animal Production: What Lessons can be Drawn?” (OECD Food, Agriculture and Fisheries Paper No 153, March 2021). Global efforts to contain the risks posed by AMR depend on the effective implementation of national action plans. This report summarises the findings of the implementation of national action plans on AMR in livestock agriculture across six OECD countries, as well as in Brazil, China and the Russian Federation. The report highlight the enormous challenge countries face to combat the risks posed by AMR in livestock agriculture and the need for greater attention (and investment) to the prevention, mitigation and containment actions to tackling AMR, under the auspices of the One Health approach.
3. Most countries have adopted a mix of policies to tackle AMR, including the use of integrated surveillance and monitoring systems, updating regulations on the availability and use of antibiotics in food animal production, and promoting efforts to enhance farm biosecurity practices. For example, good farm management practices such as strict sanitary measures, nutrition, housing, and ventilation have an important role to play in the prevention and transmission of disease. In addition, the selective use of vaccines under veterinary supervision is also an important part of the tool-kit to tackle AMR in animal agriculture.
4. While good progress is been made to raise public awareness to the dangers posed by AMR, governments should commit to providing stable and adequate long term funding to implement activities under the national action plans. This continues to be a formidable challenge in most countries.

Human Health – Directorate for Employment, Labour and Social Affairs (ELS)

5. Building on the success of the 2018 publication “Stemming the Superbug Tide - Just A Few Dollars More” (<https://oe.cd/amr-report>), the OECD is working a series of projects on the economics of AMR in a one-health framework. The projects aim to extend the analyses in a number of high-priority directions. Specifically, the OECD is working on the following projects:

¹ Dr. Michael Ryan, TAD; and Dr. Michele Cecchini, ELS.

6. First, a new edition of “Stemming the Superbug Tide” that extends the breadth and the scope of the analyses to identify ‘best buys’ to tackle AMR. If scaled up at the national level, these ‘best buys’ would provide an efficient and cost-effective instrument to promote prudent use of antibiotics and prevent the spread of infections. The project uses a ‘one-health’ framework by considering infections with an animal reservoir as well as use of antibiotics in livestock and agriculture. The project also assesses a comprehensive number of policies across different sectors (including, for example, food safety policies) and identifies policy gaps in the national action plans. Finally, the geographical scope of the analyses will be extended to key non-OECD member countries such as G20 countries.
7. Second, the OECD and WHO have recently started a new joint project to make the economic case to upscale implementation of actions part of the WHO infection prevention and control (IPC) core components. As part of this project, the two Organizations will use OECD expertise on economic modelling to understand what would be the cost of scaling up IPC core components and the potential impact of this investment. For the first time, these analyses will have a global scope, covering countries at all levels of income and in all the WHO Regions.
8. Third, the OECD is carrying out work on AMR in long-term care (LTC) facilities. LTC facilities are increasingly considered one of the key environments for the development of new resistant infections and as a spreader of resistant infections to other healthcare settings, such as hospitals. The project aims to understand the health and economic impact of imprudent use of antibiotics and of suboptimal prevention policies in LTC facilities. The project will also look at the policies currently in place among OECD countries to tackle AMR in LTC settings and will compare targets (e.g. in terms of reduction in antibiotic use) and objectives. Outputs from this project aim to help support the 2022 French Presidency of the European Union.
9. Finally, OECD produces evidence to inform global dialogue on potential strategies to ensure sustainable research and development (R&D). The OECD has carried out analyses on policy options to ensure sufficient incentives throughout the various phases of the R&D pipeline, from basic research to market approval and commercialization. Together with WHO, FAO and OIE, the OECD has produced the background paper conceptualizing a transnational incentive platform, based on downstream economic incentives and the 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 work of the Hub. More recently, the OECD has supported activities on revitalizing the R&D pipeline that were carried out as part of the UK G7 Presidency.

Co-operation with other Intergovernmental Organizations

10. The work on AMR in OECD is aimed at complementing the ongoing technical and standards work in other International Organizations, including the Global Action Plan of the Tripartite Group (WHO, FAO and OIE), which calls for each country to develop and implement its own plan to combat AMR, specific to its own needs and stage of economic development.
11. The work on AMR in the Trade and Agriculture Directorate (TAD) is done in close co-operation with several intergovernmental organizations, including the OIE, FAO and the WB, as well as experts from Member countries under an informal steering group (ESG), which meets twice a year. This ESG guides the AMR work in agriculture and ensures coherence with the work on AMR in other IOs. Similarly, the work on AMR on human health – managed by ELS – is carried out in close collaboration with relevant intergovernmental organizations, both at the global and regional level, as relevant. Work on one-health-related issues is also carried out in close communication with TAD and is normally presented at the TAD’s ESG.
12. Finally, the OECD looks forward to continuing close co-operation with Codex and the sharing of information of our studies on all aspects related to AMR in human health, animal health and food production.

WORLD BANK (WB)

Introduction

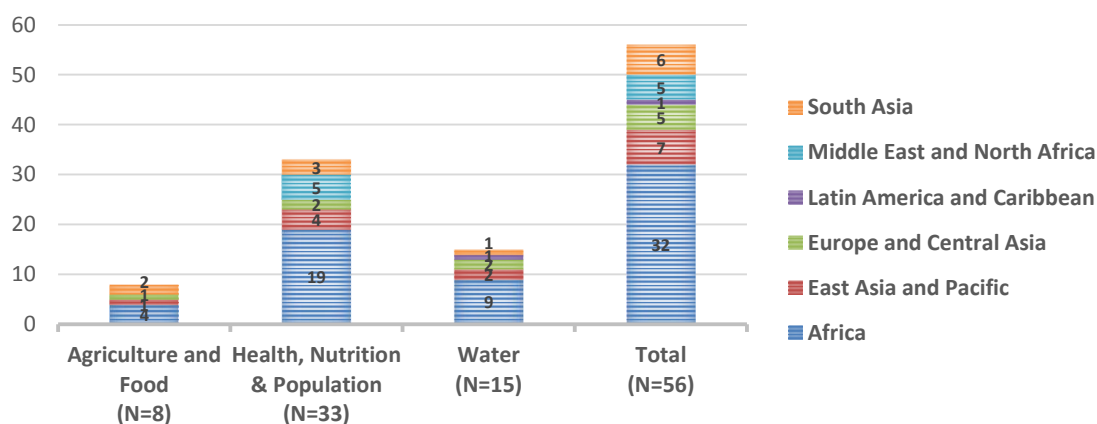
13. **Antimicrobial Resistance (AMR) is a development challenge that stands to disproportionately affect low- and middle-income countries (LMICs).** In 2017, World Bank (WB) analysis identified that, left unaddressed, AMR could cost as much as 3.8 percent of annual gross domestic product (GDP), with LMICs bearing the brunt of this impact. In addition, failure to address AMR stands to limit progress towards the Sustainable Development Goals (SDGs). Therefore, in collaboration with the Tripartite of the World Health Organization (WHO), Organization for Animal Health (OIE) and the Food and Agriculture Organization (FAO), the WB is committed to supporting countries in mobilizing investments to address AMR across multiple sectors, including health, agriculture, water and sanitation and other relevant fields.

14. **The WB’s AMR Program focuses on enabling client countries to finance interventions to address AMR through lending operations, as well as analytical and advisory work.** As of July 2021, the WB’s lending portfolio addressing AMR includes 56 projects across 35 countries. These projects are aimed at strengthening and developing agriculture, health, and water and sanitation systems to prevent the emergence of diseases and reduce the emergence and spread of AMR. In addition, the WB has an analytical and advocacy program to support clients in understanding how to mobilize investments and ensuring that AMR is better understood in national and international forums.

Lending Portfolio

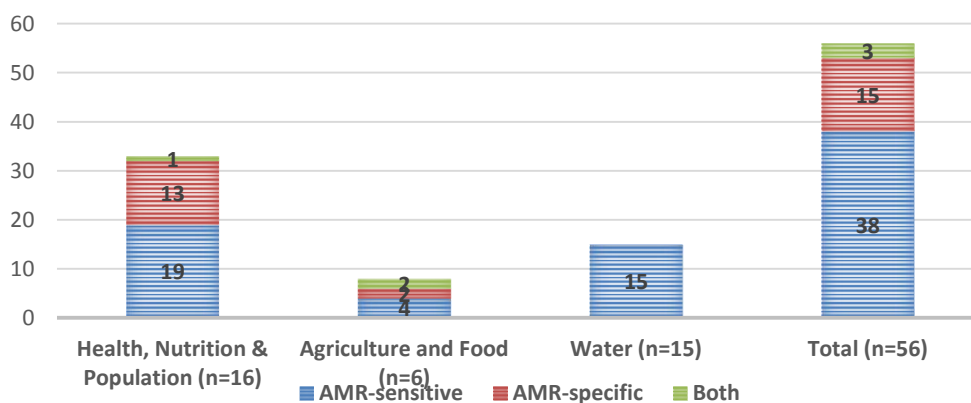
15. **A recent analysis of the WB’s lending portfolio identified 56 projects across 35 countries** (see figure 1). Of the 56 projects, 42 projects (75 percent) include investments in human health, 6 projects include investments in animal health (11 percent) and 8 projects include both (14 percent) (see figure 2). The AMR portfolio follows a One Health approach, cutting across the Health, Nutrition, and Population (HNP); Agriculture and Food (AGF); and Water Global Practices.

Figure 1. Projects by Region and Lead GP



16. **WB financing is currently supporting AMR-sensitive and AMR-specific interventions² in health, agriculture and water projects across the world.** Of the 56 projects, 15 projects (27 percent) addresses AMR-specific interventions (13 in HNP and 2 in AGF) while 38 projects (68 percent) addresses AMR-sensitive interventions (19 in HNP, 15 in Water, and 4 in AGF). 5 percent of the projects have been identified as addressing both types of interventions (1 project in HNP and 2 projects in AGF) (see figure 2). Box 1 provides two project examples.

Figure 2. Projects by Lead GP and Intervention Type (Source: WB operations portal)



² AMR-specific interventions are primarily intended to reduce the emergence and spread of AMR. AMR-sensitive interventions indirectly contribute to addressing emergence and spread of AMR.

Box 1: Project Examples

- **The Africa Centers for Disease Control and Prevention Regional Investment Financing Project (ACDCP).** This \$200m operation has a strong focus on AMR-sensitive and AMR-specific interventions in the health sector across the African continent. It will strengthen disease surveillance, prevention, and emergency-response systems across the African continent. The project will finance the establishment of laboratories, transnational surveillance networks, emergency-response mechanisms, and other public health assets designed to manage diseases on a regional and continental scale. It will support the development of guidelines and standards to improve coordination between the Africa Centers for Disease Control and Prevention (Africa CDC) Secretariat and national public health institutions across the continent and facilitate the sharing of public health assets and the exchange of vital data on infectious diseases.
- **The Second Serbia Health Project.** This \$70m operation has a focus on improving rational prescription practices, which resulted in a reduction in the consumption of antibiotics in 2016. Data from the Agency for Medicines and Medical Devices data, the systemic use of antibiotics in Serbia, defined daily dose (DDD) per one thousand inhabitants decreased from 36.5 in 2015 to 30.03 in 2016. Serbia has achieved this with strong support from the WB - through the Second Serbia Health Project, the Ministry of Health launched a concerted campaign for the rational use of antibiotics³.

Interventions Analysis

17. **Building on the foundation of the Tripartite, the WB is currently conducting a review of evidence with a view to selecting a priority list of interventions for WB financing.** Through a review of global literature sources on AMR and in consultation with relevant stakeholders, such as FAO and WHO, 16 interventions have undergone a detailed evidence review. For example, interventions have been reviewed in terms of the strength of evidence and the feasibility of their successful implementation in a range of diverse contexts. The identified interventions will be part of a 'Multi-Sectoral Interventions Framework' to advise operational teams and clients on good practice options for addressing AMR. By articulating what each sector can do to address AMR it is hoped that the framework will facilitate leadership and collaboration across different sectors, both in WB lending operations and further afield.

Developing the Operational Framework to address AMR

18. **Building on the Operational Framework for One Health⁴, which underpinned the WB's COVID-19 response programming, we are currently developing an Operational Framework for AMR.** The Operational Framework is intended to support clients and operational teams in designing and developing lending projects to address AMR. It will provide practical guidance on developing multisectoral approaches to prevent, detect, respond, and mitigate the emergence and spread of AMR in low- and middle-income settings. In addition to setting out a series of interventions it will also describe approaches to institutional arrangements to support multi-sectoral implementation, present existing and new tools that can be drawn upon to support successful implementation.

19. **Earlier this year the WB released a Landscape Analysis of Tools to Address AMR⁵, which identified 90 tools and approaches to support programming and policy implementation to address AMR.** This report was the first step in the Operational Framework work program and included an extensive desk review of existing tools and resources and a program of interviews and consultations with key stakeholders.

Country engagement

20. **To support policymakers in building their technical and adaptive skills for the benefit of addressing AMR, the WB facilitates training and workshops.** Most recently, as part of the HNP Global Flagship Course on Health Systems Strengthening, a self-paced training module on Addressing AMR was developed. It was intended to focus on technical and senior staff from Ministries of Health, who are participants of the annual training program. In addition, the WB is currently developing an online training on the operationalization of One Health, aimed at task teams implementing projects containing One Health components and activities. One module will focus on how a One Health approach can be used to address AMR in WB operations.

³ <https://blogs.worldbank.org/health/serbia-successfully-tackles-antimicrobial-resistance>

⁴ **World Bank. 2018.** Operational Framework for Strengthening Human, Animal, and Environmental Public Health Systems at their Interface. Final version. Washington, DC: World Bank Group.
<http://documents.worldbank.org/curated/en/703711517234402168/Operational-framework-for-strengthening-human-animal-and-environmental-public-health-systems-at-their-interface>.

⁵ <https://thedocs.worldbank.org/en/doc/e9d15ce04da6b28e0013dfca2cd2426f-0140012021/original/Landscape-Analysis-of-Tools-to-Address-AMR-Circulation-Copy-May-13-2021.pdf>

Global communications and advocacy strategy

21. In partnership with the Tripartite, Wellcome Trust, and others, the WB is committed to support global advocacy and communication on AMR. The WB recognizes that AMR faces a prioritization and awareness challenge and, particularly in the context of COVID-19, there is all the more need to ensure that the issue remains in the spotlight. As a result, the WB is examining ways in which global advocacy and awareness programming can engage new audiences and draw on new and emerging forms of communication. In addition, the WB's leadership and technical teams continue to advocate for action on AMR in high-level forums. Most recently, the WB's Global Director articulate the WB's commitment to addressing AMR in a High Level UN Dialogue⁶.

WORLD CUSTOMS ORGANIZATION (WCO)

Overview of the WCO activities

22. The Intellectual Property Rights (IPR), Health and Safety Program of the WCO maintains its resolve to protect consumer health and safety and continues to combat counterfeiting and piracy through a variety of activities. The WCO's main activity is to raise awareness about Customs work in this area with towards other international organizations and by promoting capacity building activities for our Member administrations. The capacity building consists of two main components; training through workshops and education and training through operational activities.

Statistics on counterfeits and illegal import of antibiotics

23. From September 1, 2019 September to September 1, 2020, the Customs Enforcement Network (CEN) database provided the information below of anti-infective agent seizures:

Unit	Anti-infective Agents
Kg	7,599
Pieces	45,005,757
Liters	907
Cartons	509

Operation STOP I: the WCO response to illicit trafficking linked to COVID-19

24. The WCO organizes simultaneous enforcement activities with multiple Customs administrations. These operations are aimed at gauging the scale of global counterfeiting whilst providing participating Customs officers with hands-on experience.
25. Operation STOP is the immediate and urgent response of the WCO, 99 of its Members and its RILOs, with the support of the WHO, UNODC, INTERPOL, Europol and OLAF, to the resurgence in the illegal trafficking of medicines and medical supplies linked to the COVID-19 pandemic.
26. For 63 days, participating Members simultaneously carried out targeted inspections of consignments that were likely to contain certain types of counterfeit, substandard and/or illicit pharmaceutical products and other medical supplies.
27. In the course of Operation STOP, 307,215,524 items of miscellaneous medicines were intercepted by Members. Antibacterials/antibiotics are among the medical products most often reported, with a total of **193,348,114** items seized or detained.

PANGEA

28. In partnership with Interpol and other partners, WCO also co-organizes the global operation PANGEA. Operation Pangea XIV was organized from 18 to 25 May 2021.

⁶ <https://www.un.org/pga/75/antimicrobial-resistance/#:~:text=The%20General%20Assembly%20High%2DLevel,tackling%20AMR%20as%20part%20of>

National/regional seminars

29. The WCO delivers extensive capacity building activities, mainly in the form of legislative training, document targeting training and product identification training, with private sector cooperation. The organization also performs diagnostic missions. In the diagnostic missions, WCO experts visit the country and assess the Customs administrations capabilities in the domain of fighting counterfeits. The evaluation includes both the legal base and practical and procedural arrangements and results in recommendations from the WCO.
30. Since December 2020, the WCO has been providing online training with the IPR, Health and Safety Programme. The online workshop is aimed at informing participants about effective enforcement strategies on how Customs could prevent counterfeit products from entering Members' national territories, with a specific focus on the illegal trafficking of medicines and medical supplies linked to the COVID-19 pandemic.
31. Currently, the WCO is developing an e-learning module on "Combatting illicit medicines and counterfeit or substandard medical supplies related to COVID-19 and other pandemics" to be made available on the Organization's CLiKC! platform. The aim of this online training material is to give frontline Customs officers greater tactical insight, through risk profiling and targeting training, when carrying out focused controls on suspicious consignments and/or searching for counterfeit/illicit medicines and COVID-19-related goods.

Counterfeit and Piracy Group (CAP) Meeting

32. The annual WCO Counterfeiting and Piracy (CAP) Group meeting provides a forum for Customs and related law enforcement agencies to exchange information, experiences and practices on combating counterfeiting and piracy.
33. At its 16th Meeting from 30 September to 1st October 2019, the CAP meeting Terms of Reference (ToR) was revised and approved during December 2020 Council session. The revised ToR will make it possible to create new tools and instruments to deal with emerging risks and meet Members' expectations in terms of combating counterfeiting and piracy.

WORLD TRADE ORGANIZATION (WTO)

ACTIVITIES OF THE WTO SPS COMMITTEE AND OTHER RELEVANT WTO ACTIVITIES

Report by the WTO Secretariat⁷

34. This report to the 8th Session of the Codex *Ad Hoc* Intergovernmental Task Force on Antimicrobial Resistance (TFAMR8) has been prepared by the Secretariat of the World Trade Organization ("WTO Secretariat"). Since 2018, the topic of antimicrobial resistance (AMR) has been more frequently discussed in the WTO Committee on Sanitary and Phytosanitary Measures (the "SPS Committee").⁸ This report provides an overview of the recent discussions within the SPS Committee, during the period 2020 and the first quarter of 2021, of relevance to antimicrobial resistance: information from Members; specific trade concerns; and transparency.

Members' information related to antimicrobial resistance

35. During SPS Committee meetings, WTO Members provide information on their SPS-related activities under the agenda item "*Information from Members on relevant activities*". No Member provided AMR-related information under this agenda item during the period 2020 to 30 April 2021.

Specific trade concerns

36. The SPS Committee devotes a large portion of each regular meeting to the consideration of specific trade concerns (STCs). Any WTO Member can raise specific concerns about the food safety, plant or animal health requirements imposed by another WTO Member that are affecting trade. Issues raised in this context are often related to the notification of a new or changed measure, or based on the experience of exporters. Frequently, other WTO Members will share the same concerns. At the SPS Committee meetings, WTO Members usually commit to exchange information and hold bilateral consultations to resolve the identified concern.

⁷ This report has been prepared under the WTO Secretariat's own responsibility and is without prejudice to the positions of WTO Members or to their rights and obligations under the WTO.

⁸ The first AMR-related trade concern was raised in the July 2018 SPS Committee meeting by Argentina and the United States regarding the EU legislation on veterinary medicinal products ([STC 446](#)).

37. A summary of the STCs raised in meetings of the SPS Committee is compiled on an annual basis by the WTO Secretariat.⁹ Altogether, 516 STCs were raised between 1995 and the first quarter of 2021, of which 34% were related to food safety, and 34% were related to animal health and zoonoses.

New specific trade concerns

38. In 2020 and the first quarter of 2021, 47 new specific trade concerns were raised for the first time in the SPS Committee, including the following AMR-related trade concern of relevance to Codex:

- *EU proposal requiring residue testing of casings (STC 500) - Concerns of Australia*¹⁰

39. In the November 2020 SPS Committee meeting, Australia indicated that it looked forward to receiving formal answers from the European Union to comments provided in response to notification [G/SPS/N/EU/401](#) regarding changes to export certificates for animal products and to an EU letter regarding requirements for the import of casings into the European Union. Australia considered that a separate residues plan for casings could not be justified as a risk management measure and that it would set a precedent for similar trade-limiting actions on other processed animal products. In Australia's view, the European Union had not provided the relevant scientific evidence and the measures were arbitrary and unjustified. Australia noted the lack of provisions for countries with EU approved residues monitoring plans for the species of animal from which the casings may be derived, the lack of justification for imposing the requirements on countries with controls over establishments preventing the use of antimicrobials in the production of casings, and the lack of relevance of the list of compounds proposed for testing to the concerns.

40. Ukraine expressed interest in staying informed on bilateral developments on this issue.

41. The European Union clarified that the establishments authorized to export casings to the European Union were listed in the Trade Control and Expert System (TRACES) at the request of the national authorities of 39 third countries. Regulation (EU) 2016/429 established that the entry of products of animal origin into the European Union was subject to listing of the third countries, territories, or zones of origin; the current requirements on production and entry into the European Union of casings would change as of 21 April 2021. Regulation (EU) 2017/625 required that products of animal origin enter the European Union only from listed third countries.

42. The European Union stated that the main risks of residues from pharmacologically active substances were linked to treatment of casings to avoid spoilage by bacteria. In order to mitigate the risk posed by the presence of antimicrobial residues in casings, the Commission required guarantees on the residue status of casings as a condition for importation, focusing on those antimicrobial substances which were prohibited from use in food-producing animals in the European Union. Batches of casings would have to be accompanied by a specific import certificate including attestations on animal health, public health and residues. EU stakeholders and trading partners had been informed of the new requirements through an SPS notification and by letter and a specific information session had also been organized.

43. In the March 2021 SPS Committee meeting, Australia reiterated its concerns regarding changes to the model health certificate for casings set out in Commission Implementing Regulation (EU) 2020/2235, referenced in notification [G/SPS/N/EU/401](#). Australia considered the measures to be arbitrary, unjustified and more trade-restrictive than necessary, and that they would set a precedent for similar trade-limiting actions on other processed animal products. The EU concerns over the possible use of antimicrobial substances during the production of animal casings did not justify the imposition of a separate residues testing system for casings for countries such as Australia, where controls were in place to prevent establishments from using antimicrobials in the production of casings. The measures did not include any provision for countries with EU-approved residues monitoring plans for each species of animal from which the casings may be derived. Australia encouraged the European Union to notify the requirements, provide an opportunity for comments and take them into account before implementing the measure.

44. The European Union said that the new requirements had been presented to trading partners through an SPS notification ([G/SPS/N/EU/401](#)) and by letter. The European Union clarified that imports of casings were subject to the animal health rules, and were authorized from the establishments listed in the TRACES system. The risks of residues of veterinary medicinal products following treatment of animals were very low in casings, the main risk being linked to treatment to avoid spoilage by bacteria. Guarantees on the residues status of casings were being required to mitigate the risk posed by the presence of antimicrobial residues in casings, with a focus on antimicrobial substances prohibited from use in food-producing animals in the European Union.

⁹ The latest version of this summary can be found in document [G/SPS/GEN/204/Rev.21](#) (and Corrigendum). This document is publicly available from <https://docs.wto.org/>. Specific trade concerns can also be searched through the SPS Information Management System: <http://spsims.wto.org>; and the Trade Concerns Database (beta version): <https://tradeconcerns.wto.org/en>.

¹⁰ November 2020 ([G/SPS/R/100](#), paras. 3.42-3.45) and March 2021 ([G/SPS/R/101](#), paras. 3.81-3.82).

As of 21 April 2021, the animal health requirements in place would change, and requirements to mitigate the risk posed by the presence of residues in casings during production and new requirements on residue testing of casings intended for importation into the European Union would apply. Regulation (EU) 2016/429 established that the entry of products of animal origin into the European Union was subject to listing of the third countries, territories or zones of origin. Regulation (EU) 2017/625 required that products of animal origin entered the European Union only from listed third countries. A specific import certificate including attestations on animal health, public health and residues would have to accompany the batches of casings destined to the European Union. The European Union remained open to continuing the dialogue with Australia.

Previously raised specific trade concern

45. One other AMR-related trade concern, that had been previously raised in the SPS Committee, was discussed again during 2020 and the first quarter of 2021:

- *EU review of legislation on veterinary medicinal products (STC 446) – Concerns of the United States¹¹*

46. In the June 2020 SPS Committee meeting, the United States provided its statement in document [G/SPS/GEN/1811](#).

47. Brazil, Canada, Colombia, Japan and Paraguay supported this concern.

48. Brazil provided the following statement: Brazil would like to thank the United States for maintaining this important concern on the agenda. While reiterating our previous statements delivered in previous meetings, we would like to reinforce the request to the European Commission to hold consultations with stakeholders and third countries on the delegated act of the criteria to designate antimicrobials to be reserved for human treatment.

49. Canada provided the following statement: Canada agrees with the European Union and many other Members that anti-microbial resistance is a major global threat of increasing concern to human, animal and environmental health. Canada recognizes the important contributions of both global and country-led efforts in the fight against antimicrobial resistance. Canada appreciates the EU's commitment to ensure that trading partners can participate in the consultation process for the secondary legislation related to the Veterinary Medicinal Products Regulation which will come into force in January 2022. We look forward to contributing to this process for the remaining pieces of secondary legislation, and particularly those that impact third countries, before the Regulation comes into force. We hope that the European Union will provide sufficient time for trading partners to comment, and have those comments taken into consideration in the finalization of secondary legislation.

50. Japan provided the following statement: Japan appreciates the European Union for holding the Briefing Session on the EU new regulations on Veterinary Medicinal Products in January 2020. However, Japan is still concerned that the European Union leaves critical points of the new regulation unclear, for instance, the list of antimicrobials to be banned for use in the European Union, regulated products, transition period and so on. Japan understands that the European Union will finalize details of the regulations in the near future. Depending on the details, Japanese producers exporting to the European Union will be impacted significantly. Therefore, Japan requests the European Union to provide the information swiftly and the timing of a notification to this Committee.

51. Paraguay provided the following statement: My delegation would like to thank the delegation of the United States for including this concern, which is shared by the Republic of Paraguay, in today's agenda. We are particularly concerned about the possible implications that the delegated acts of Regulation (EU) 2019/06 could have in third countries, specifically under Article 118 of this basic legislation. We will be monitoring the criteria that will be followed for the allocation of medicines for human use only, including the definition of risk analysis, provided for in Article 37.4 of this legislation. We understand that, although the EU had begun a consultation process in Brussels, this was suspended by the pandemic, despite the fact that the legislative process is still ongoing. In this connection, we urge the EU to resume consultations as soon as possible and to address the concerns of its trading partners at this early stage, to avoid further complications in the future.

52. The European Union provided the following response: The European Union would like to take this opportunity to recall explanations and information presented to WTO Members in previous Committee meetings and to provide an update on the state of play on the preparatory work for the implementation of the new legislation. The new Regulation on Veterinary Medicines (Regulation (EU) 2019/6) will strengthen the European Union action in fighting antimicrobial resistance (AMR), which is a global threat to public health and animal health. It lays down a wide range of measures to fight AMR and to promote the prudent and responsible use of antimicrobials, following the approach of the European One Health Action Plan against AMR. The measures to fight AMR following the "One Health" approach are internationally recognised as the only effective means to tackle AMR and as such endorsed by the WHO, the OIE and the FAO as well as by other international bodies.

¹¹ June 2020 ([G/SPS/R/99](#) paras. 3.239-3.253) and March 2021 ([G/SPS/R/101](#) paras. 3.70-3.80).

53. The European Union published the new EU Regulation on Veterinary Medicinal products (VMP) in January 2019, together with a new regulation on Medicated Feed. The objectives of these combined measures are: provide for a modern, innovative and fit for purpose legal framework on VMPs; give incentives to stimulate innovation for VMPs; increase the availability of VMPs; ensure economically viable production of safe medicated feed throughout the European Union; foster innovation in the oral routes of VMP administration, particularly medicated pet food; strengthen the European Union action to fight antimicrobial resistance. The new Regulation on VMP will start to apply as of 28 January 2022. A number of implementing measures are currently under preparation as follows:
54. (a) Delegated Act under Article 37(4) (Criteria for the designation of antimicrobials to be reserved for treatment of certain infections in humans): The European Commission received at the end of 2019 the scientific advice from the European Medicines Agency (EMA) as a basis for its preparatory work. It has consulted EU member States as well as targeted stakeholders. The scientific advice report is publicly available on the relevant European Commission webpage. The European Commission is currently working on the drafting of the delegated act. The deadline for its adoption is 27 September 2021.
55. (b) Implementing Act under Article 37(5) (List of antimicrobials reserved for human use): At the request of the European Commission, EMA set up an expert group at the end of 2019 to start preparing its scientific advice. The European Commission expects to receive it towards the end of the year. The deadline for adoption of the implementing act is 27 January 2022.
56. (c) Delegated Act under Article 118 (Rules on imports of animals and products of animal origin from third countries): The European Commission is moving forward in its reflections on the best approach for the application of Article 118. In this light, the questions raised by some of the Members in the context of the WTO SPS Committee are particularly relevant, as they highlight some of the specific elements of concern of other countries. It is extremely useful for the European Commission to be aware of such issues, as it draws its attention to those elements as it starts to shape the detailed rules of the delegated act under Article 118. The deadline for adoption is 27 January 2022
57. In terms of transparency, the European Union recalls that it regularly provides information to its trading partners not only at WTO SPS Committee meetings, but also through targeted information sessions and stakeholder consultations. The European Commission intends to organise another information session in the autumn. In accordance with WTO obligations, the European Union will notify for comments all relevant implementing measures under the relevant WTO Agreements.
58. Finally, the European Union would like to state, once again, that collaboration at the international level is of the utmost importance to address this major public health issue. The European Union remains determined to continue working as a driving force on the fight against AMR and to engage with WTO Members, within multilateral international organisations and bilaterally, to promote and support effective strategies to prevent and contain the global threat of AMR.
59. In the March 2021 SPS Committee meeting, the United States reiterated its concern regarding the implementation of EU legislation on veterinary medicinal products (Regulation (EU) 2019/06). Concerning the list of antimicrobials reserved for human use, the United States noted that the European Union had not yet published the relevant EU implementing act, which it understood needed to be adopted no later than January 2022. The United States further noted that the European Union had not provided the scientific justification and risk assessments that would inform this list. The United States urged the European Union to consider the needs of agricultural producers and to recognize the level of protection provided by national regulatory systems. The United States provided its statement in document [G/SPS/GEN/1895](#).
60. Paraguay, Australia, Canada, Argentina, Japan, and Brazil supported this concern.
61. Paraguay requested the European Union to provide an update on the status of the legislation, given that it was foreseen for the beginning of 2022.
62. Australia requested the European Union to consider the conditions, availability of antimicrobials and disease prevalence in third countries before releasing its list of antimicrobials reserved for the treatment of human infections. Australia highlighted this list should be based on science and encouraged the European Union to hold early consultations with third countries.
63. Canada looked forward to the response of the European Union regarding its technical questions on the veterinary medicinal products and the EU secondary legislation. Canada urged the European Union to provide to trading partners the basis to be considered during the preparation of the list of antimicrobials reserved for human use and to share this list with third countries. Canada expressed its interest in working collaboratively with the European Union as it developed this secondary legislation to minimize any potential negative trade impacts.

64. Argentina expressed its concern regarding the final list of antimicrobials reserved for human use and the implementation by the European Union of Article 118 of Regulation 2019/06, following which third countries would have to demonstrate the non-use of those antimicrobials. Argentina urged the European Union to base its regulations on science and avoid unnecessary barriers to trade.
65. Japan urged the European Union to provide Members the opportunity to comment on the implementing rules, taking into account the potential burden on producers and exporters. Japan requested that (i) antimicrobials prohibited for use in animals and kept for human use only should be limited to antimicrobials that truly needed to be prohibited considering international consensus; (ii) since management systems for antimicrobials differed from country to country, the details of the verification be limited as necessary, and the method of certification should be flexible; and (iii) appropriate grace periods should be established considering the production period for each type of animal and the preparation period of the producers.
66. Brazil noted that the EU regulation had the potential to impose a heavy burden on producers by limiting the use of currently available veterinary drugs and introducing sanitary requirements that were more trade-restrictive than necessary. Brazil considered that the unilateral ban of the use of several veterinary drugs and the prohibition of imports from countries where their use was authorized was inconsistent with the provisions of the SPS Agreement. Brazil urged the European Union to consider the ongoing global efforts undertaken by the WHO, OIE, FAO in setting international standards and guidelines for AMR, as well as the work of the Codex Task Force on Antimicrobial Resistance.
67. The European Union reiterated that its Regulation (EU) 2019/6 would strengthen EU action to fight AMR. The European Union indicated that the legislation had entered into force in January 2019 and would apply as of 28 January 2022. The European Union stressed that the new EU regulation would impose stricter rules on operators in the European Union than on those of non-EU countries, and should therefore not be seen as a trade barrier. The European Union provided information on the adoption timeline for its legislations: (i) the delegated act establishing the criteria to designate the antimicrobials to be reserved for human use was to be adopted by 27 September 2021; (ii) the implementing act establishing the list of antimicrobials reserved for human use was to be adopted by 27 January 2022; and (iii) the delegated act detailing the rules for the importation for animals and products of animal origin was to be adopted by 27 January 2022.
68. Referring to the delegated act establishing criteria to designate the antimicrobials to be reserved for human use, the European Union stated the draft had been discussed with member States and would soon be open for public consultation under the EU feedback mechanism, and notified for comments to the SPS Committee. Concerning the implementing act establishing the list of antimicrobials reserved for human use, the European Union noted that the European Medicines Agency had set up an expert group in 2019 to prepare the scientific advice, which would be finalized once sufficient certainty on the criteria to designate antimicrobials reserved for human use would be available. Regarding the last delegated act detailing the rules on imports from third countries, the European Union indicated that information on the current discussion concerning its preparation had been provided to third countries in December 2020, and that the EU Commission had adopted on 9 March 2021 a proposal notified in [G/SPS/N/EU/464](#) to amend the Official Controls Regulation to allow the official control system for imports of animals and products of animal origin to apply to verification of compliance with Article 118(1) of Regulation (EU) 2019/6.
69. The European Union highlighted the regulation had been notified under the TBT and SPS Agreements, and that implementing measures would be notified for comments under the SPS Agreement. The proposal to amend the Official Controls Regulation was notified under the SPS Agreement ([G/SPS/N/EU/464](#)) and the draft delegated act on the criteria to designate antimicrobials reserved for human use would soon be notified. The European Union reassured Members that non-EU countries would have the opportunity to provide inputs during the EU feedback mechanism, and after the notification of the draft acts to the SPS Committee. The European Union reiterated its commitment to fight AMR and to engage with Members.

Transparency

70. The legal obligation of WTO Members is to notify new or modified SPS measures when these deviate from the relevant international standards, including Codex standards. The recommendations of the SPS Committee however, now encourage the notification of all new or modified measures even when these conform to international standards.¹² Although this recommendation does not change the legal obligations of WTO Members, it may enhance transparency regarding the application of international standards.

¹² [G/SPS/7/Rev.4](#).

71. A total of 2,017 notifications, that is 1,641 proposed new or revised SPS measures and 376 emergency ones, have been submitted to the WTO during the period 2020 to 30 April 2021. In relation to antimicrobial resistance, only one regular SPS notification was submitted to the WTO during the period 2020 to 30 April 2021 (see information provided below in Table 1).¹³

Table 1. Members that have submitted regular SPS notifications related to antimicrobial/antibiotic resistance during the period 2020 to 30 April 2021

Antimicrobial/Antibiotic Resistance		
Regular Notifications		
Member	Number of notifications	Products
Ukraine	1	Veterinary drugs, animals, animal feed, animal by-products

72. No Member submitted emergency SPS notifications related to antimicrobial resistance or antibiotic resistance during the period 2020 to 30 April 2021.

73. For the same period, no AMR-related notifications have been submitted to the Committee on Technical Barriers to Trade (TBT).¹⁴

¹³ It is important to note that in searching for notifications in the WTO SPS Information Management System (spsims.wto.org), the search criteria of "antimicrobial resistance" and "antibiotic resistance" were used. As such, it is possible that not all relevant notifications have been captured, to the extent that the specific wording of "antimicrobial resistance" or "antibiotic resistance" was not included by Members in the actual text of the notification.

¹⁴ It is important to note that in searching for notifications in the WTO TBT Information Management System (tbtims.wto.org), the search criteria of "antimicrobial resistance" and "antibiotic resistance" were used. As such, it is possible that not all relevant notifications have been captured, to the extent that the specific wording of "antimicrobial resistance" or "antibiotic resistance" was not included by Members in the actual text of the notification.