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CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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

Sixth Session
Busan, Republic of Korea, 10-14 December 2018

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 Organization for Economic Cooperation and Development (OECD), World Bank, World Customs Organization and the World Trade Organization (WTO) is presented below.

I. ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT (OECD)[1]

Introduction

With increasing global concern over the rise in antimicrobial resistance (AMR) and the potential risks to human health and animal health, consumers and agriculture have been encouraged to reduce their use of antibiotics (WHO, 2015). The high consumption of antibiotics is considered as the single most important factor driving the emergence and spread of resistant pathogens. The OECD's work on AMR focuses on comparative economic analysis and policy recommendations and complements the technical work of the WHO, OIE and FAO-Codex. In essence, the OECD analyses are aimed 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

Evaluating the economic effects of antibiotics in animals is very complex. In animal production, antibiotics are used not only to treat sick animals, but also for sub-therapeutic purposes (to prevent disease and to promote growth). Moreover, the use, and in some cases overuse of antibiotics in animal agriculture, is often linked to the type of production system, with the highest usage often linked to production systems that have poor sanitary and management standards. In addition, the available evidence would suggest that there is increasing divergence in the use of antibiotics in between high income OECD countries and large emerging economies with the largest livestock populations, with a general decline in use in the former group and a continued rise in the latter.

A further concern relates to the fact that only a limited number of countries have reliable information on antimicrobial usage in animal production. These deficiencies extend to 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. Moreover, information on the transmission of resistance between animals and humans, and vice versa, is weak, but improving. To-date there have been few studies on evaluating the economic benefits and costs of antimicrobials in modern animal production, and on cost effective alternatives. There are major differences in the institutional and regulatory frameworks in countries that govern the availability and use of antibiotics in animal production. For policymakers, key concerns are the economic impact on the production of animal products, animal health and wellbeing, as well as the potential longer term effects on food security, food prices and the spread of resistance from animals to humans and vice versa.

Current work on AMR in agriculture focusses on clarifying the links between the use of antimicrobials in animal production and the emergence of AMR, as well as improving the information base on the farm level economic impacts of antimicrobial use in animal production. More specifically, this work has concentrated on:

[1] Dr. Michael Ryan, TAD, and Dr. Michelle Cecchini, ELS.

a) Evaluating the benefits and costs of antimicrobial use at farm level for food producing animals,

b) Identifying best production practices and policies to optimise the economic use of antimicrobials in animal production, while maintain high productivity and ensuring good animal health and animal well-being, and

c) Identifying alternative interventions to antibiotics in preventing disease in animal production.

While much of the work has focussed on European countries where the information is more robust and reliable, nevertheless, the work also involved gathering information on Brazil and China. In addition, a synthesis of the current state of knowledge on the transmission of antimicrobial resistance between species has been undertaken in order to better understand the interaction between humans, animals and the environment.

The proposed future work on AMR in animal agriculture will focus on a) estimating the cost effectiveness of alternative interventions to antimicrobials in animal production, and b) assessing the national implementation strategies through the "peer review process" with a view to identifying the best policy options and practices to combat the growth in AMR.

Human health

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 33 OECD and EU 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.

Findings from these two streams of work are going to be discussed in a forthcoming OECD publication to be released on the 7th of November 2018. The publication will make the health and economic case to invest in public health actions to tackle AMR and will present a set of 'best buys' to fight AMR. Future OECD work in this area aims to i) enlarge the geographical scope of the analyses with the inclusion of other low- and middle-income countries; and ii) to extend the number of assessed public health actions to identify other 'best buys'.

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.

Co-operation with other International Organisations

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.

To ensure that all technical aspects of the AMR work in agriculture are in line with the standard setting and technical guidance of Codex, the OIE and WHO, the Directorate for Trade and Agriculture, established an informal expert steering group in 2017 to guide the work on AMR in TAD. This ESG meets twice a year to review ongoing work and provides additional input and insights to the work. In addition to the project leaders in TAD and ELS, the ESG also includes academic experts in the analysis of AMU and AMR, national experts from government agencies, as well as the AMR experts from the OIE and the FAO.

Finally, we look forward to continued 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.

II. WORLD BANK

Report on the World Bank activities on antimicrobial resistance[2]

Introduction

- **Important and recognized development issue:** The World Bank (WB) recognizes antimicrobial resistance (AMR) as an important development issue, with the potential to disproportionately and significantly affect low- and middle- income countries. As a result, a range of activities is underway to engage the Bank and advance this issue.
- WB **mechanisms:** The Bank pursues its goals of improving shared prosperity and ending extreme poverty through five broad mechanisms, which are outlined in the Figure 1. These are: concessional funding for client countries; policy commitments within the funding package; advisory services and technical assistance directly for client countries; global knowledge generation and dissemination; voice and advocacy. However, it must also be recognized that the Bank provides concessional finance and pursues policy commitments, primarily through a non-earmarked model for low-income countries based on a country's performance-based allocation (PBA).

Fig. 1: Overview of WBG Mechanisms

- **Focus on relevant mechanisms:** This note presents AMR-related activities being undertaken by the WB in terms of these categories, with a focus on the three that are most relevant now (Concessional funding, global knowledge generation and dissemination, voice and advocacy). Activities in these streams are relevant to building momentum on this issue and laying the groundwork for building client demand for this issue, which is relevant given the non-earmarked funding model of the World Bank in International Development Association (IDA).
- **Consumer of knowledge:** While the Bank generates knowledge, it is also a consumer of knowledge in various specialist areas, such as antimicrobial resistance. The Bank plays a role in implementing research and evidence – and, therefore, access to knowledge on AMR is pivotal in strengthening the Bank's approach to AMR-related activities.
- **AMR specific versus AMR-sensitive:** the World Bank conceptualizes this issue in terms of activities that are AMR-specific (those with the primary purpose – in objective and design - to reduce AMR) and AMR-sensitive (those whose primary purpose is not AMR control, but which can be designed and delivered in such a way that they contribute co-benefits in combating AMR). Feedback from experts and internal discussions emphasize that the Bank can play a significant role by facilitating improvements through AMR-sensitive interventions. There is an on-going internal discussion on how to operationalize the recognition of AMR co-benefits across multiple diverse sectors.

AMR work at the World Bank

Many WB projects in health, nutrition, water, sanitation and agriculture have an impact on AMR. The projects listed below provide an illustration of on-going activities and this snapshot does not constitute a portfolio review. The financial values of projects are not provided because the entirety of a project would not necessarily correspond to AMR-specific activities, which on average are estimated to 5-8% of the projects listed below. Definition and determination of the financial value of AMR co-benefits is a work in progress.

[2] Franck Berthe, Naomi Rupasinghe, Jonathan Wadsworth, Enis Baris

Type of activity	Examples of activities
Concessional funding for client countries	• West Africa & the Regional Disease Surveillance Program (REDISSE) – aimed at building surveillance and laboratory capacity, including AMR, in the 12 participating countries of ECOWAS and Mauritania. REDISSE is a flagship One Health program for the Bank.
	• East Africa Public Health Laboratory Networking Project – addressing the spread of tuberculosis and establishing a network of laboratories.
	• Vietnam Livestock and Competitiveness and Food Safety Project (LIFSAP) – aimed at supporting good animal husbandry practices and food safety, including reducing the use of antimicrobials in livestock.
	• Sahel and Pastoralism and Access to Services Project (PRAPS) – aimed at supporting the disbursement of vaccines, and improving access to quality veterinary medicinal products in the region.
	• The Serbia Health project aims to improve the quality and efficiency of the public health system, including prescribing practices. The project has financed AMR-specific training activities to improve physician prescribing practices and, as a result, there has been a reduction in the consumption of antibiotics.
Global knowledge generation and dissemination	• In 2017 the World Bank published a report entitled, '*Drug Resistant Infections: A Threat to our Economic Future*', which made the economic case for AMR as a development issue that will disproportionately affect low income countries. • Another report is underway (funded by the Norwegian and Canadian governments) on the adaptive challenge of addressing AMR. The report will include a proposed re-framing of the AMR question and an analysis of existing interventions for addressing AMR, case studies to examine implementation and knowledge gaps.
Voice and advocacy	• Participation in conference activities, stewardship and global coordination, such as e.g. second OIE Global Conference on AMR, workshop of the National Academy of Medicine. • Participation to the Inter Agency Coordination Group (IACG) • Co-host of the second Call to Action on AMR, November 2018, with the Wellcome Trust, UN Foundation Ghana, Thailand and UK Governments. • Publications by senior figures within the public health and agriculture global practices.

Future possibilities for scaling up WBG support for resistance

Internal discussion, as well as feedback from experts and internal discussions has facilitated the recognition that the Bank could play a greater role and a comparative advantage in focusing on AMR-sensitive interventions to leverage greater AMR cobenefits. However, much more needs to be done from an advocacy perspective to develop sufficient support and client demand for this approach. Below are some options, which are currently in discussion.

Type of activity	Examples of potential activities
Concessional funding for client countries	• **Provision of increased concessionality to incentivize AMR-specific interventions or screening of AMR-sensitive interventions:** Given the challenges of creating client demand for AMR-related interventions in low- and middle-income countries, a financing facility could be used to provide clients with concessional financing / buydowns / increased concessionality to support including or establishing interventions that prevent the spread of resistance. This could include specific activities such as behavioural programming to improve infection control, or screening of large infrastructure projects to include approaches that limit exacerbating the problem. • **Development of an AMR-specific financing component to the Global Financing Facility:** One of the WBG's flagship commitments is to supporting Universal Health Coverage. The use of antibiotics has been referred to as a substitute for strong farming and health systems and strong hygiene and infection control systems. Incorporating additional financing mechanisms, within the WBG's UHC programming is also being considered. For example, the Global Financing Facility in support of Every Woman and Every Child could offer opportunities to address issues that are driving resistance. Antibiotics are often used in the treatment of sepsis so scaling up efforts to reduce sepsis in maternal and child health programming and, thereby reducing the use of antibiotics, could help limit resistance.
Advisory services and technical assistance for client countries	• **Project preparation facility for technical assistance:** The development of a project preparation facility that would support client countries with technical assistance in advance of a project. The first step would be to identify projects where there is likely to be a significant impact on AMR. The second step would be to provide technical assistance, through the facility, to support project teams and client countries in conducting diagnostics of how projects operations can be used to de-risk the spread of AMR. This type of intervention would be most relevant to client countries who have some awareness of AMR but who lack the technical know-how on how to prioritize and allocate financial and non-financial resources towards limiting the spread of AMR. Finally, this type of facility could support the design of country action plans, an approach that was helpful in with avian influenza preparedness.

III. WORLD CUSTOMS ORGANIZATION (WCO)

1. Overview of World Customs Organization (WCO) activities

The IPR, Health and safety Programme of WCO maintains its resolve to protect consumer health and safety, and continues to combat counterfeiting and piracy through a variety of activities. WCO's main activity is to raise awareness about Customs work in this area; either towards other international organisations or by promoting capacity building activities for our member Administrations. The Capacity Building consists of two main factors; training through workshops and education and training through operational activities.

The focus of our work is on health and safety and thus medicines come high on the our agenda, but WCO have so far not had any specific operation targeting antibiotics to curb antimicrobial resistance (AMR). This come partly because the issue is rather new and the knowledge of AMR within our members are limited, but also because the lack of focus from the health authorities. There is also an added challenge from the fact that in the area of veterinary medicine the there is little data, however the awareness of AMR has grown because of our cooperation with WHO and OiE.

For customs the approach would be to perform controls on legal imports and exports based on the request from the responsible national authority but also to try to curb illicit trade in antibiotics. It is in the latter where WCO will be able to give some information through our CEN- seizure database and the Illicit Trade Report[3]. So the efforts to curb AMR should be seen through the effort to stop all kinds of illicit trade in medicines and veterinary products, with an added focus on antibiotics.

(1) Statistics on counterfeits and illegal import of antibiotics

There is no sign of any significant decline in this crime area. WCO experience in this field are in line with the other international organisations enforcing IPR, but we are experiencing a shift towards the use of small consignments thus reducing the numbers of large seizures, to some degree, while the number of cases are going upwards.

WCO have through our CEN database access to the different seizure cases that our members have reported to us. When searching through all cases of illicit medicine from the start of the reporting in 2011 till today we find more than 35 thousand cases, and just above 1000 of then involve antibiotics:

Seizures of antibiotics 2011- 2018*

Anti-Infective Agents (e.g. anti-malarial; antibiotic)	Unit:
1050	Cases
1050	Pieces, pills and ampoules
658	blisters
11936	Boxes Cartons, packets
797.3	Grams
61120	Millilitres
1023.46	Litres
545322	Kgs

*(Please note that the units are dependent on each countries reports and that there have not been a conversion to a common unit. The numbers are not 100% accurate as the calculation have been performed on raw-data materials).

Although the number of seizures comes from several years, almost 260 million pills and pieces and more than 500 tonnes of illicit antibiotics and anti-bacterial products should give a good reason to worry about the risk of AMR and there is reason to believe that this represents only a small part of the actual illicit trade.

(2) Large-scale operations

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. Between October 2017 and September 2018, the WCO organized one large-scale operation in Africa; Operation Mirage and last year's Operation Pangea also contributes to an overall awareness on the health and safety issues related to illicit trade of medicines.

[3] http://www.wcoomd.org/en/topics/enforcement-and-compliance/resources/publications.aspx

Operation MIRAGE

From 10th to 19th September 2018 the WCO organized a major IPR, Health and Safety Operation on the African Mainland. The Operation was conducted under the codename MIRAGE, referring to the deception and delusion inherent to substandard and falsified medicines. 16 countries from West, East and Southern Africa participated in the operation. The close cooperation with the World Health Organization's (WHO) National Focal Points and the World Animal Health Organization (OiE) Focal Points led to a better follow up of cases and contact with Interpol's National Contact Bureaus were alerted in case of further investigations. The main focus of the Operation was counterfeit and illicit medicines; not losing attention to all other goods that could jeopardize the health and safety of the African citizens. Again around 200 million units of counterfeit or substandard medicines and products was seized. Exact number where not available at the time of print, but last year's operation ACIM 2 yielded 42 432 010 pieces/tablets of seized antibiotics.

Operation Pangea

In partnership Interpol and Europol and other Health Authorities WCO also co-organises the global operation PANGEA. An Operation aimed against pharmaceutical products sold online. Last year's 10th operation was held in September Involving 197 police, customs and health regulatory authorities from a record 123 countries, Operation Pangea X led to a record number of 25 million illicit and counterfeit medicines seized worldwide, but the number of antibiotics is not published.

(3) National/regional seminars

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. But the organisation 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 leads to a recommendation from WCO. Between October 2017 and September 2018, the WCO conducted several training seminars/workshops for officers from a number of WCO Member administrations. Although the question of AMR does not yet always fall naturally into the curriculum of the workshops, we try to cover as many aspect of health and safety issues and AMR should be a part of that.

(4) Counterfeit and Piracy Group (CAP) meeting

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. At its 14th Meeting from 15 to 16 November 2017, Members explored the challenges posed by the Internet and cyber investigations, e-commerce and small consignments but also food and plant varieties where discussed. During this meeting, Members also shared their experiences and exchanged practices on fighting counterfeits. And through the participation of both OiE and WHO we have spread some awareness of AMR.

Although this a fairly new area for Customs we will try continue our co-operation with OiE and WHO in the area of "One health" and the sharing of information on all aspects related to AMR and the illicit trade of antibiotics.

IV. WORLD TRADE ORGANIZATION (WTO)

Report by the WTO Secretariat[4]

1.1. This report to the 6th Session of the Codex *Ad Hoc* Intergovernmental Task Force on Antimicrobial Resistance (TFAMR6) has been prepared by the Secretariat of the World Trade Organization ("WTO Secretariat"). The topic of antimicrobial resistance has not been frequently discussed in the WTO Committee on Sanitary and Phytosanitary Measures (the "SPS Committee") in the past. However, in 2018, the issue was raised on a couple of occasions. In the July 2018 SPS Committee meeting, Members raised a specific trade concern related to antimicrobial resistance (AMR) for the first time. In addition, Members have occasionally provided information on AMR-related activities in the SPS Committee. This report provides an overview of these discussions within the SPS Committee of relevance to antimicrobial resistance: information from Members; specific trade concerns; and transparency.

1.1 Members' information related to antimicrobial resistance

1.2. During SPS Committee meetings, WTO Members provide information on their SPS-related activities. The following AMR-related information was shared in the SPS Committee:

- *European Union – Legislative measures on veterinary medicinal products*

1.3. During the July 2018 SPS Committee meeting, the European Union informed the Committee that EU co-legislators had agreed on the text of the new Regulation on Veterinary Medicinal Products, a new legal framework for the authorisation and use of veterinary drugs in the European Union. The European Union explained that the European Commission had issued a proposal for the Regulation in September 2014, which had been notified under the TBT Agreement in April 2015 as document G/TBT/N/EU/279. The Regulation would enter into force in November 2018, and would take effect at the end of 2021, three years after its entry into force. The European Union explained that one of the key objectives of the new Regulation was to address the public health risk of antimicrobial resistance (AMR), following the One Health approach. The European Union elaborated that the Regulation laid down several actions to fight AMR, including: strengthening the principles behind the prudent use of antimicrobials, for example by avoiding the routine prophylactic and metaphylactic use; reserving certain antimicrobials for treatment of infections in humans only; and banning the use of antimicrobials in animals for growth promotion or yield increase. The European Union noted that the new Regulation was part of a package which included a new regulation on medicated feed, which contained measures aimed at fighting the misuse of antimicrobials, including a ban on their use in medicated feed for prophylaxis, and limiting treatment duration.

1.4. The European Union recalled that in 1999 the EU Scientific Steering Committee had recommended phasing-out and ultimately abolishing the use of antimicrobials as growth promoters, and in 2006, a general ban on the use of antibiotics as feed additives for growth promotion had been introduced. The new Regulation would refuse the marketing authorization for antimicrobial products presented as growth promoters or to increase yield, regardless of the route of administration, and prohibited the use of such antimicrobial medicinal products in animals. The European Union added that the new Regulation would also envisage the possibility of reserving the use of certain antimicrobials for use on humans only, based on scientific risk assessments. To date, no antimicrobial had been so reserved in the European Union.

1.5. The European Union stressed the concern that AMR organisms and resistance determinants could spread to humans and animals through food and feed originating within or outside the European Union. Therefore, the new Regulation would require, in a non-discriminatory and proportional manner, that operators in non-EU countries refrain from using antimicrobials for growth promotion or antimicrobials designated in the European Union as reserved for human use only, in respect of animals or products of animal origin exported to the European Union. The European Union further explained that detailed rules on how to implement these provisions would be available in implementing acts, which would respect international agreements, including WTO obligations, and would be legally sound, proportionate, non-discriminatory and based on scientific evidence. The European Union expressed its intention to keep the Committee duly informed of new developments on its antimicrobial measures, in particular on delegated acts on measures concerning non-EU countries, and that draft acts would be notified in due course to the WTO. Finally, the European Union reinforced its commitment to engage with its trading partners and to promote and support effective strategies to prevent and contain the global threat of AMR.

1.6. Japan expressed its appreciation on the overview provided by the European Union, and looked forward to receiving more information on the implementation of the new Regulation in delegated and implementing acts.

[4] 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.

1.7. The United States requested clarification on the rationale for the notification as a TBT measure in 2015. In addition, the United States requested assurances that the measures in delegated and implementing acts would be notified to the SPS Committee.

1.8. The European Union explained that the original 2014 proposal had been notified under the TBT Agreement because, at that time, no SPS provisions had been regarded as potentially affecting international trade. The European Union clarified that the original proposal had changed, and assured the Committee that the new implementing measures would be notified to the WTO, and would be notified to the SPS Committee if it were concluded that they were SPS measures. In any case, the SPS Committee would be duly informed.

1.2 Specific Trade Concerns

1.9. 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.

1.10. A summary of the STCs raised in meetings of the SPS Committee is compiled on an annual basis by the WTO Secretariat.[5] Altogether, 439 STCs were raised between 1995 and the first quarter of 2018, of which 32% were related to food safety, and 39% were related to animal health and zoonoses.

1.11. The first AMR-related trade concern was raised in 2018 by Argentina and the United States regarding the EU legislation on veterinary medicinal products. Details on this trade concern are provided below:

- *EU review of legislation on veterinary medicinal products – Concerns of Argentina and the United States*[6]

1.12. In the July 2018 SPS Committee meeting, Argentina raised concerns regarding the European Union's proposed regulation on veterinary medicinal products, stating that the adoption of provisions regarding the use of antimicrobials in the veterinary sector would have a significant impact on international trade. Argentina reiterated its commitment to the fight against AMR; its active participation in Codex Alimentarius and OIE work; and its conviction that an appropriate solution should be reached by consensus within a multilateral setting in a manner compatible to the WTO SPS Agreement.

1.13. Argentina was concerned that the proposed text, which was to be formally adopted by the European Parliament and the Council of Europe, would require exporters of animals and animal products to meet EU standards concerning the use of certain antimicrobial medicinal products, as well as specific usage provisions, as a condition for maintaining access to the EU market, despite the differences in the prevailing sanitary conditions. Argentina further added that recommendations from international organizations such as Codex Alimentarius, did not suggest that measures of this type should be taken with regard to antimicrobials, which implied a lack of certainty as to the results that could be achieved through these measures, a lack of scientific basis and a disproportionate reaction to the risk.

1.14. Argentina contended that the provisions that the European Union deemed appropriate to resolve sanitary matters, specific to the European Union and its regions, could not be applied on an extraterritorial basis to countries that did not share the same sanitary conditions. Further, through this new regulation, the European Union would be applying a reciprocity approach that lacked scientific basis, preventing access to the EU market for animal products from third countries where antimicrobial medicinal products were subject to different usage authorization standards.

1.15. Argentina requested the European Union to consider the equivalence of third country regulations on the use of antimicrobial medicines in the veterinary sector based on rigorous scientific assessment vis-à-vis the level of sanitary protection set by the European Union; clarify the criteria used to list antimicrobial medicinal products to which this reciprocity policy would apply; and take appropriate steps to avoid undue restrictions on international trade of animals and foods of animal origin as a consequence of the application of new provisions on the use of antimicrobial medicinal products in the veterinary sector.

[5] The latest version of this summary can be found in document G/SPS/GEN/204/Rev.18. This document is a public document available from https://docs.wto.org/. Specific trade concerns can also be searched through the SPS Information Management System: http://spsims.wto.org.
[6] See G/SPS/R/92, paragraphs 4.18 to 4.29.

1.16. The United States shared this concern, emphasizing that the measure would require foreign producers to abide by EU production methodology requirements related to antibiotic use restrictions in livestock, and would not target residues of concern, or the presence of resistance genes. The United States also informed the Committee that it had joined several WTO Members in addressing concerns over this measure in a joint letter to EU Commission President Juncker. The EU restrictions would require other Members to adopt essentially the same comprehensive EU regulatory programme, without taking into consideration different conditions present in their territories. Applied extraterritorially, these restrictions would undermine multilateral efforts to combat AMR, such as those undertaken through the Codex Task Force on Antimicrobial Resistance, established to develop science-based guidelines on the management of foodborne AMR and to consider development of guidance on integrated surveillance of AMR, among others. In light of the ongoing multilateral efforts to develop standards on AMR, the United States urged the European Union to delay the adoption of new legislation until the guidelines were made available by Codex.

1.17. Colombia shared the concern and thanked the European Union for the information provided under the agenda item on information sharing.

1.18. Chile also expressed interest in this topic, given its potential consequences for international trade. Chile trusted that, through the comments from Members in this Committee, the European Union would take into consideration the work of the OIE and Codex Alimentarius in line with Article 3 of the SPS Agreement on harmonization, as well as science-based risk assessments, as per Article 5 of the SPS Agreement.

1.19. Canada expressed concerns that the EU proposed approach would likely have an unnecessary restrictive impact on international trade and that it would undermine the ongoing multilateral efforts to combat this problem. Canada was of the view that AMR was a complex global issue and that tackling AMR requires a coordinated international approach. Canada recognised the coordinated efforts taken by several international bodies, and supported the collaborative leadership of the WHO, OIE, the FAO and Codex to promote a prudent use of antimicrobials in animals and public health to address AMR. Canada was concerned that despite the significant potential impact on trade, the draft regulation had not been notified to the SPS Committee. Canada urged the European Union to notify this measure to allow Members the opportunity to provide comments and to take these comments into account. Different conditions and disease prevalence in third countries could result in approved usages of drugs that differed from those in the European Union. Canada requested that the European Union provide the rationale and scientific justification for prohibiting certain veterinary antimicrobial drugs in the European Union and imports from third countries; the considerations that would be taken into account when preparing the list of medically important antimicrobials to be prohibited for veterinary uses in the European Union and third countries exporting to the European Union; and that the list be shared with third countries at the earliest opportunity.

1.20. Brazil shared the concern, underlining that the proposed amendments to the EU legislation could significantly impact trade. Brazil had previously shared its concerns with the European Union, in coordination with other WTO Members. Brazil regretted that the European Union had moved forward with a proposal that might prohibit exporting companies to engage in trade with the European Union if their national governments authorized the use of certain veterinary antimicrobial drugs under different conditions than those permitted by the European Union, or if the exporters did not comply with certain EU requirements. The adoption of these measures could undermine the on-going work of international standard-setting organizations developing multilateral harmonized guidelines to deal with AMR. It was unclear how the EU proposed legislation would converge with the international criteria for maximum residue levels (MRLs) already established in accordance with a scientific risk assessment. Finally, Brazil requested the European Union to take into consideration the multilateral efforts on AMR regulation, particularly the on-going work of international standard-setting organizations to establish international standards on the use of veterinary medicinal products.

1.21. Australia expressed its support to the joint work of WHO, OIE and FAO in setting international standards for AMR. The application of risk measures to prevent and reduce AMR should be based on internationally agreed standards, and supported by scientific data. Australia also stressed the importance of retaining access to effective antimicrobials to protect animal health and to avoid adverse animal welfare outcomes. Australia strongly discouraged regional and individual countries' efforts to introduce AMR-related risk management measures inconsistent with agreed standards and not supported by science that could distort trade. Australia encouraged all countries to adhere to their international obligations, stressing that unilateral procedures related to AMR trade policies outside the international standard-setting organizations had the potential to undermine collaborative global efforts. Australia emphasized its commitment to an effective and robust system for the prevention and containment of AMR, and explained that it had adopted one of the most conservative approaches to the use of antimicrobials in livestock production in the world. However, Australia stressed that antimicrobials were important for animal health and welfare, biosecurity and production, and that it was critical for the Australian livestock sector to retain access to these antimicrobials to treat, prevent and control diseases.

Australia underlined its low rate of AMR in food animals due to its favourable animal health status, extensive farming systems, stringent border controls, good biosecurity measures to prevent the introduction, establishment and spread of endemic and exotic diseases, and strong regulations governing the registration and the use of antimicrobials. Finally, Australia expressed its concern that any measures to restrict access to the prophylactic use of antimicrobials in food animals would have significant adverse impact on exports of Australian and other livestock animal products.

1.22. The European Union recalled the information provided under agenda item 3 (a)(iii), and expressed appreciation for Members' shared recognition of the importance of AMR for global health. The European Union stressed that it promoted prudent and responsible use of antimicrobials worldwide and highlighted the growing international consensus on the need to phase out the use of antimicrobials as growth promoters. The European Union reiterated that the original proposal had been notified under the TBT Agreement because at that time it did not include SPS elements relevant to international trade. In addition, the European Union explained that it had not had the opportunity to notify the current version of the Regulation under any WTO Agreements because the EU co-legislators had introduced import-related AMR measures in the draft Regulation at the latest stage of the legislative process. The European Union emphasized that the measure would be notified. Concerning the criteria for antimicrobials reserved for humans, the European Union observed that no decision had been taken yet. However, the European Union emphasised that any implementation would be based on risk assessments provided by the European Medicine Agency, the European Food Safety Authority and other relevant EU agencies, taking into account relevant recommendations from international organizations.

1.23. Regarding the impact and the consistency with WTO requirements, the European Union reiterated that detailed rules on how to apply these measures would be available in delegated acts meeting all the relevant requirements, compatible with all the international agreements, including WTO obligations, and would be legally sound, proportionate, non-discriminatory and based on science. The European Union expressed its willingness to continue its engagement with Codex, WHO, FAO and OIE on the development of a consistent international framework and standards related to AMR. Finally, the European Union stated that this Regulation would contribute to the fight against the global spread of AMR.

1.3 Transparency

1.24. 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.[7] Although this recommendation does not change the legal obligations of WTO Members, it may enhance transparency regarding the application of international standards.

1.25. A total of 17,885 notifications, that is 15,787 proposed new or revised SPS measures and 2,098 emergency ones, have been submitted to the WTO between 1995 and 31 August 2018. In relation to antimicrobial resistance, few SPS notifications have been submitted to the WTO.[8] Information is provided below in Table 1 on the relevant regular SPS notifications submitted by Members, while Table 2 indicates the relevant emergency SPS notifications.

[7] G/SPS/7/Rev.3.

[8] It is important to note that in searching for these 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.

Table 1. Members that have submitted regular SPS notifications related to antimicrobial/antibiotic resistance between 1995 and 31 August 2018

Antimicrobial Resistance Regular Notifications			Antibiotic Resistance Regular Notifications		
Member	**Number of notifications**	**Products**	**Member**	**Number of notifications**	**Products**
United States	2	Animal drugs	Korea, Republic of	1	Food products
Colombia	1	Additives	European Union	1	Feed additives included in HS code 2309
Canada	1	Veterinary health products	Uruguay	1	Feed for bovine animals and sheep containing antibiotics for growth promotion purposes.
Uruguay	1	Feed for bovine animals and sheep containing antibiotics for growth promotion purposes	United States of America	1	Rhizobium inoculants applied to leguminous food commodities
Turkey	1	Control of Salmonella and other specific food-borne zoonotic agents	**TOTAL**	**4**	
Montenegro	1	Live animals			
Korea, Republic of	1	Foods and food additives			
TOTAL	**8**				

Table 2. Members that have submitted emergency SPS notifications related to antimicrobial/antibiotic resistance[9] between 1995 and 31 August 2018

Antimicrobial Resistance - Emergency Notifications		
Member	**Number of notifications**	**Products**
European Union	1	Pediococcus pentosaceus (NCIMB 30068) and Pediococcus pentosaceus (NCIMB 30044)

1.26. Similarly, very few AMR-related notifications have been submitted to the Committee on Technical Barriers to Trade (TBT).[10] Please see Table 3 below.

Table 3. Members that have submitted regular TBT notifications related to antimicrobial/antibiotic resistance[11] between 1995 and 31 August 2018

Antimicrobial/Antibiotic Resistance - Regular Notifications		
Member	**Number of notifications**	**Products**
Canada	2	Veterinary drugs
Argentina	1	Medicinal preparations for human use
European Union	1	Veterinary medicinal products
TOTAL	**4**	

[9] The following notification was retrieved using the search criteria of "antimicrobial resistance", as well as "antibiotic resistance".

[10] It is important to note that in searching for these 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.

[11] All four notifications indicated in the table were retrieved using the search criteria of "antimicrobial resistance". One of Canada's notifications (G/TBT/N/CAN/444) also appeared using the search criteria of "antibiotic resistance".