RESTRICTED

G/SPS/R/93

11 February 2019

(19-0772) Page: 1/38

Committee on Sanitary and Phytosanitary Measures

SUMMARY OF THE MEETING OF 1-2 NOVEMBER 2018

NOTE BY THE SECRETARIAT[1]

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

1 ADOPTION OF THE AGENDA

1.1. The Committee on Sanitary and Phytosanitary Measures (the "Committee") held its 73rd regular meeting on 1-2 November 2018. The proposed agenda for the meeting was adopted with amendments (WTO/AIR/SPS/24).

2 INFORMATION SHARING

2.1 Information from Members on relevant activities

2.1.1 Japan - Update on the situation surrounding Japanese food after the Fukushima Daiichi nuclear power plant accident

2.1. Japan thanked Brazil; France (New Caledonia); Hong Kong, China; and Singapore for lifting their import restrictions. Japan also provided an update on the most recent data from its food monitoring programme, and highlighted that Japanese standard limits had been set very conservatively taking into consideration the accident and the food intake of Japanese citizens. Foods exceeding the limits were not allowed to enter the food supply chain. The data showed that the situation regarding the safety of food, fishery and agricultural products continued to remain stable. All the test results of farm and fishery products, as well as harvests of wild plants and edible fungi (consumed in small quantities), had been within the Codex guidelines levels for more than five years, except those of specific game meat, which still exceeded the level by very low rates. Notably, the annual effective dose of radioactive caesium in food products had been estimated as far below the Codex intervention exemption level. Japan also recalled that the FAO and IAEA had acknowledged and evaluated the efforts made by Japan to ensure food safety, indicating that Japanese food supply chain was controlled effectively by the relevant authorities. Japan reported that 29 out of the 54 countries and regions who had introduced import restrictions on Japanese foods had completely lifted these restrictions. Japan urged Members to base their measures on scientific principles.

2.1.2 Japan – Current situation of Classical swine fever

2.2. Japan provided an update on the situation of Classical swine fever (CSF), indicating that it had notified the OIE on 9 September 2018 of the occurrence of the disease for the first time in 26 years, in Gifu prefecture. Japan underscored that it was now free from the disease and that it had shared information on the occurrence of the disease, control measures and surveillance with its trading partners. Various preventive measures had been implemented, which included stamping out procedures, establishment of a shipping and movement restriction zone, as well as monitoring of pig farms within the shipping restriction zone and farms with epidemiological links to the affected farm. Japan further explained that they had undertaken the testing of wild boars in Gifu and other prefectures, which had yielded positive results only in the Gifu prefecture, specifically within proximity of the affected farm (up to 12 km). Japan indicated its intention to apply for the recovery of its CSF-free status from the OIE, given that no additional cases of CSF in domestic pigs had been found. Japan thanked its trading partners for their prompt response to continue trade in porcine products.

2.1.3 Argentina – International statement on agricultural applications of precision biotechnology

2.3. Argentina drew the Committee's attention to a joint communication on precision biotechnology (G/SPS/GEN/1658/Rev.2) which had been submitted by Argentina, Australia, Brazil, Canada, Guatemala, Honduras, Paraguay and the United States.[2] Argentina highlighted that precision biotechnology techniques constitute an essential tool for agricultural innovation, as their use provided farmers with access to products that increase productivity while preserving environmental sustainability. Argentina informed the Committee of a "Seminar on Genome Editing for Regulators" which had been organized by IICA in April 2018, where participating countries had shared a draft statement on the applications of precision biotechnology. The primary objective was to coordinate efforts to ensure that the regulatory approaches for these techniques, which include gene editing,

[2] G/SPS/GEN/1658/Rev.3 was subsequently circulated on 1 November 2018 with the additional co-sponsors of the Dominican Republic and Uruguay.

are scientifically based and internationally harmonized. Argentina indicated that the final text of the international statement was non-binding on supporting countries, but provided the necessary guidelines for preventing regulatory asymmetries and, in turn, potential trade disruption. The text of the statement could be found in document G/SPS/GEN/1658/Rev.2.

2.4. Australia, Brazil, Canada, Colombia, the Dominican Republic, Guatemala, Honduras, Jordan, Paraguay, the United States, Uruguay and Viet Nam supported the International Statement, highlighting the importance of precision biotechnology techniques for the promotion of sustainable crop systems and food security by increasing crop yields, improving resistance to pests or diseases, and improving nutritional and food quality characteristics for consumers, among others. They supported the coordinated efforts to ensure that regulatory approaches to these techniques were based on scientific data and harmonized internationally. The Dominican Republic and Uruguay announced their intention to become co-sponsors of the document.

2.5. Brazil further underscored the need to have well-designed regulations, standards and policies which were necessary to support and guide innovative activities. Brazil called upon other WTO Members to take these factors into consideration when addressing the challenge of regulating precision biotechnology techniques, in order to guarantee the application of the fundamental principles of the SPS Agreement when pursuing technological approaches to agriculture.

2.6. Canada expressed concerns that differing domestic regulatory approaches for products derived from precision biotechnology could create unnecessary challenges for both importers and exporters. This could lead to international asynchronicity in approvals as well as asymmetric regulatory approaches, creating potential trade issues which threatened to impede innovation. Canada was also concerned about regulatory approaches that included arbitrary and unjustifiable distinctions between end products derived from precision biotechnology and similar end products obtained through other production methods. Canada encouraged interested Members to support the international statement and participate in cooperative and collaborative multilateral efforts to support open and fair trade of products of precision biotechnology.

2.7. Paraguay highlighted that the genetic improvement of plants had made it possible to substantially improve its production of principal crops such as soya, maize, wheat and rice, and further argued that the new products derived from biotechnology (e.g. precision or gene editing) should not be treated differently from products obtained through other production methods.

2.8. The United States underscored the potential of new biotechnology tools to significantly reduce the costs and timelines to bring new products to market, thereby enabling public researchers and small technology companies to provide new tools to support local needs and challenges, particularly in developing countries.

2.9. ECOWAS expressed support for the proposal, while highlighting some challenges for developing countries in responding to this advanced technology, particularly in relation to the lack of capacity to conduct appropriate risk assessments on products of precision biotechnology. ECOWAS called on donors and technical partners to provide support for capacity building in this area.

2.10. Argentina thanked Members and organizations for their support, and further underscored the importance of maintaining this issue on the Committee's agenda. Argentina also indicated its willingness to further revise the document, as well as to include additional co-sponsors.

2.1.4 Zambia - Update on emerging pests

2.11. Zambia reported on several emerging pests, indicating that the fall army worm was present and widespread in Zambia, but that government authorities and various stakeholders were working to control the pest. In relation to maize lethal necrosis, Zambia informed the Committee that surveys had been conducted, which had indicated that this disease was not present in Zambia. In addition, Zambia reported that the cassava brown streak disease had recently been detected but had been contained in the far northern part of Zambia. Finally, Zambia noted that further to surveys conducted, the potato cyst nematode was not present in areas where potato was produced.

2.1.5 Zambia – Change in the phytosanitary certificate of Zambia

2.12. Zambia announced that its phytosanitary certificate had been changed in order to enhance various security features. Zambia further indicated that it had informed most of its trading partners of the new features of its revised phytosanitary certificate.

2.1.6 Zambia – Market access for products of Zambian origin

2.13. Zambia informed the Committee that it had continued to gain access to new markets for new products, apart from traditional crops such as maize. These new crops included blueberries, grapes, passion fruit and stevia. In this regard, Zambia noted that its first shipment of blueberries had recently been sent to its new trading partners.

2.2 Information from CODEX, IPPC and OIE on relevant activities

2.2.1 Codex

2.14. Codex provided an outline of its activities, as detailed in G/SPS/GEN/1648, highlighting meetings held since the last SPS Committee meeting. Codex drew Members' attention to a number of standards which had been adopted at the 41st Codex Alimentarius Commission in July 2018. These standards included, among others: MRLs for different pesticides in various foods and feeds; maximum levels for methylmercury in certain fish species and for cadmium in chocolate; and MRLs for veterinary drugs used in food-producing animals and the Risk Management Recommendation for Gentian violet. The full report of the Commission meeting was available at: http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-701-41%252FReport%252FFINAL%252FREP18_CACe.pdf.

2.15. Codex also highlighted the recently held meeting of the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS), noting that the final report was not yet available, but that a draft version was available on the Codex website for consultation. Codex also drew the Committee's attention to the upcoming meeting of the Ad hoc Codex Intergovernmental Task Force on Antimicrobial Resistance (TFAMR) to be held in December 2018. Codex highlighted two main documents for this meeting which were available for public comments and consultation on the Codex website: (i) the proposed draft Revision of the Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005); and (ii) the proposed draft Guidelines on Integrated Surveillance of Antimicrobial Resistance.

2.2.2 IPPC

2.16. The IPPC provided an outline of its activities as detailed in G/SPS/GEN/1657. The IPPC highlighted that it had held consultations for various draft standards during the summer of 2018. These draft standards were now going through the standard-setting system. A consultation process had also been undertaken for the draft IPPC Strategic Framework (2020-2030), with comments compiled and considered at the Strategic Planning Group (SPG) meeting held in October 2018, leading to the subsequent revision of the Framework. This revised Framework would be submitted to CPM for endorsement, with the aim of seeking adoption in 2020 by Ministers at the Commission Meeting. The IPPC indicated that there was still an opportunity to make comments, and encouraged Members to do so.

2.17. The IPPC reported on several other topics which had been discussed at the SPG meeting, such as the safe trade facilitation action plan, the ePhyto five-year plan and e-commerce. In addition, the IPPC was also looking at how it could be involved in issues related to emerging pests, such as fall armyworm. The SPG was also considering to what extent the IPPC community should be involved in addressing antimicrobial resistance and had agreed to forward this issue to CPM-14 (2019) for discussion. In relation to commodity and pathway standards, a focus group meeting had been held in October and a report was available from the IPPC website. In addition, the IPPC reported on its efforts to have 2020 recognized as the International Year of Plant Health, highlighting that it was currently awaiting a final response on whether this proposal had been approved at the November 2018 UN General Assembly. Finally, IPPC noted that it had undertaken seven regional

workshops, and highlighted the importance of these activities in coordination and information sharing, as well as the need to secure funding for these activities.

2.2.3 OIE

2.18. The OIE outlined its report, as detailed in G/SPS/GEN/1652. The OIE highlighted the work undertaken by the four OIE Specialist Commissions in the development and review of OIE international standards, with high priority placed on the revision of the OIE standards related to the categorization of official BSE risk status, and infection with avian influenza viruses. The OIE drew the Committee's attention to the OIE Global Conference on Antimicrobial Resistance which had been held in October 2018, as well as the upcoming Global Conference on Aquatic Animal Health, scheduled to take place in Chile from 2-4 April 2019. The OIE also noted that it continued to work on the design of a new tool to monitor the implementation of OIE standards, with a view to identifying difficulties faced by countries in order to better propose solutions. In addition, the OIE continued to provide capacity building activities, which included seminars for recently appointed OIE delegates and regional seminars for OIE national focal points. In relation to vaccine banks, the OIE informed the Committee that it had released a policy paper (http://www.oie.int/solidarity/vaccine-banks/), which clarified the role and responsibility of the OIE, as well as countries benefiting from this mechanism. Finally, the OIE indicated that it continued to work on its Public-Private Progress Initiative, a strategic 3-year programme supported by the Bill and Melinda Gates Foundation and CIRAD, the French Agricultural Research and International Cooperation Organization (an OIE Collaborating Centre).

3 SPECIFIC TRADE CONCERNS (G/SPS/GEN/204/REV.18)

3.1 New issues

3.1.1 EU MRLs for buprofezin, diflubenzuron, ethoxysulfuron, ioxynil, molinate, picoxystrobin and tepraloxydim (G/SPS/N/EU/264) – Concerns of Colombia and India

3.1. India raised a concern regarding the lowering of EU MRL for buprofezin to default levels, as notified by the European Union in G/SPS/N/EU/264 on 19 July 2018. India noted that the measure was more trade restrictive than necessary to protect against risks to human health and argued that as per Article 5.7 of the SPS Agreement, the European Union should have taken into consideration the existing Codex MRLs, as well as the MRLs of other Members. Specifically, in relation to grapes, the Codex MRL for buprofezin was 1 ppm, and in the case of rice, the limits in the United States, China and Japan were 1.5 ppm, 0.3 ppm and 0.5 ppm respectively. India requested the European Union to provide the rationale for deviating from Codex standards, and for not considering MRLs set by other countries. India further observed that the modified measure did not provide an adequate transitional time period for commodities produced in accordance with the existing EU MRL, prior to its modification. India noted that in January 2011, the European Commission had amended the Council Directive to include buprofezin as an active substance from 1 February 2012 to 31 January 2021. Following which in April 2018, the expiration of the approval for buprofezin had been postponed until 31 January 2023 for use in fruits and vegetables at 0.5 ppm, and in cereals, including rice at 0.5 ppm. However, in July 2018, the European Union had proposed default levels for buprofezin. India argued that the EU decision was based on the perceived uncertainty around genotoxic potential, relating to the heat treatment of buprofezin and the production of aniline. India underscored that this chemical was normally present in many raw fruits and vegetables. India urged the European Union to conduct broad-based stakeholder consultations, as several countries, including India, would face substantial trade impacts due to the proposed measure. India hoped that the European Union would conduct a timely and objective science-based risk assessment consistent with its obligations under the SPS Agreement.

3.2. Colombia raised similar concerns in relation to EU MRLs for several pesticides, highlighting the importance of this issue for trade in cereals and food products of animal and plant origin, including fruits and vegetables. In particular, Colombia was concerned with the lowering of the MRLs for buprofezin to the default level of 0.1 ppm, as this substance was key in controlling quarantine pests for bananas, which for Colombia and other countries was done through the use of tree bag wrappings filled with buprofezin. This approach avoided damage to the fruit and allowed lower exposure to the product, when compared with insecticide spray. Colombia observed that there was no competitive substitute for the substance, which would make it more difficult to control pests for fruits, and

negatively affect Colombia's exports of banana to the European Union's market. Colombia further underscored the potential social impact due to the importance of employment in the regions where the crop was grown. Colombia highlighted the commitment of its banana producers to implementing international quality standards linked with good agricultural practices, such as GlobalGap, Rainforest Alliance and Fair Trade. Colombia noted that the EU measure had been based on the possible production of aniline, a sub-product which was carcinogenic, and could be present in foods treated with buprofezin when subject to high temperatures during processing. However, Colombia highlighted that the International Agency for Research on Cancer (IARC) had included aniline in Group 3 as non-carcinogenic for humans. In addition, the US Environmental Protection Agency and the European Union's Scientific Committee on Occupational Exposure Limit Values (SCOEL) had not given conclusive evidence regarding the carcinogenicity of aniline. Colombia requested the European Union to use a risk assessment approach in its decisions and to maintain the current MRL for buprofezin or establish a reference level of 0.3 ppm in line with Codex standards. Finally, Colombia requested the European Union to grant a transitional period sufficient for producers to adapt to the new measure.

3.3. Argentina, Brazil, Canada, Chile, Costa Rica, Ecuador, Guatemala, Honduras, Nicaragua, Panama, Paraguay, Peru, Turkey and the United States echoed the concerns raised by Colombia and India, underscoring the need for a risk-based approach to implementing SPS measures, in line with the SPS Agreement. Some Members requested an appropriate transitional period for producers to adapt to the measure, and also urged the European Union to maintain the EU MRL of 0.5 ppm or to at least apply the Codex MRL of 0.3 ppm for buprofezin in banana. Costa Rica highlighted the economic and social impact of the lowering of EU MRLs for buprofezin given the importance of its banana exports. Costa Rica had also carried out chemical risk assessments analyzing buprofezin on bananas, which had concluded that there was no sizable health risk for consumers of the fruit. Chile and Turkey indicated that they had already submitted comments to the European Union. In addition to buprofezin, Argentina noted similar concerns with ioxynil. Panama also specifically indicated its concerns with buprofezin, diflubenzuron, ethoxysulfuron and picoxystrobin.

3.4. Brazil recalled its previous comments in the TBT Committee on the Commission Implementing Regulation (EU) 2017/360, notified under the TBT Agreement, which authorized the use of buprofezin only as an insecticide and acaricide on non-edible crops. Brazil noted that the regulation had the objective of protecting human and animal health, characterized by the attention to operators' and workers' safety and the risk to aquatic organisms. In this regard, Brazil indicated that it had previously asked the European Union to clarify the reasons for not also notifying the measure to the SPS Committee. In addition, Brazil drew Members' attention to its trade concern on picoxystrobin, which had also been raised in the TBT Committee.

3.5. Canada indicated concerns with the EU proposal to lower the MRL for picoxystrobin to the limit of analytical detection. Canada sought to better understand EFSA's rationale for publishing an inconclusive peer review for picoxystrobin, citing a lack of information to complete the risk assessment. Canada was alarmed that a consumer health concern had been raised during the assessment without conclusive evidence of the risk to human health. Canada had conducted a scientific risk assessment on picoxystrobin and determined that the active substance would not be of concern to human health when used according to label directions. Canada highlighted the importance of picoxystrobin as a key active substance used in Canada's grain and oilseed production. Canada requested the European Union to conduct a fulsome risk assessment and establish import tolerances in order to minimize the impact on international trade.

3.6. The United States noted that these substances had been subject to multiple evaluations by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), which found that the available data was acceptable for the purposes of completing risk assessments and establishing Codex MRLs. In addition, the authorization holders for these pesticides had conducted and committed to supplying additional data that would address the European Union's concerns, however, the European Union had declined to review these data before withdrawing the authorizations for these chemicals and lowering their MRLs to default levels. The United States queried how an applicant might be expected to demonstrate the safety of substances, as required by EU legislation, when the European Union was not satisfied with data that had been evaluated and accepted by other scientific authorities. The United States had submitted several import MRL applications for these substances and hoped for a timely and objective science-based risk assessment to inform decisions on these requests, consistent with the European Union's obligations under the SPS Agreement.

3.7. The European Union explained that the proposed lowering of MRLs for buprofezin was necessary to protect consumers, as an assessment by the European Food Safety Authority (EFSA) had identified important consumer health concerns. Available information showed that under high-temperature processing conditions, buprofezin was degraded into several metabolites, including aniline. The European Union noted that aniline was a carcinogen for which a genotoxic mechanism could not be excluded and therefore no threshold for acceptable exposure could be assumed. As a result, the approval of the active substance buprofezin had been restricted to uses in non-edible crops only. In this regard, Commission Implementing Regulation (EU) 2017/360 had been notified under the TBT Agreement as G/TBT/N/EU/418. The European Union also provided responses to several issues raised by its trading partners in relation to aniline originating from different sources, IARC's conclusion that aniline was not carcinogenic for human beings, and alignment of EU MRLs with existing Codex standards. The European Union underscored that it aimed to minimize the exposure of consumers to aniline; it based its risk management measures on the evaluations carried out by its own risk assessment body; and that the EU policy was to implement Codex MRLs into EU MRL legislation where Codex MRLs were found to be sufficiently protective for European consumers. The European Union further clarified that it had not introduced a reservation at the 2013 CCPR meeting, because the establishment of the Codex MRL for buprofezin predated EFSA's identification of consumer health concerns. However, the European Union would be submitting a concern form to Codex mentioning the EFSA findings and conclusions in order to raise international awareness.

3.8. The European Union explained its concerns surrounding diflubenzuron, highlighting that EFSA had identified substantial safety concerns during its evaluation of the substance, due to the genotoxic carcinogenic metabolite 4-chloroaniline (PCA). Since toxicological reference values for PCA could not be set and consequently no safe residue levels could be identified, the approved use of the substance was restricted to non-edible crops only. In this regard, Commission Implementing Regulation (EU) 2017/855 had been notified as a draft to the TBT Committee, in document G/TBT/N/EU/447. The European Union further noted that since it had not been demonstrated that residues of diflubenzuron above the limit of analytical determination (LOD) were safe for EU consumers, it had been proposed to lower the MRLs to the LOD. The formal adoption of the draft legislative act was expected in January 2019, and the new MRLs were expected to be applicable from July 2019 onwards. The European Union invited interested parties, with information that, might in their view, allow the establishment of safe residue levels, to submit an application under the relevant EU legislative frameworks. The European Union indicated that it would also be submitting a concern form to Codex.

3.9. The European Union explained that during the evaluation and peer review of the substance picoxystrobin, a number of concerns had been identified and detailed in the relevant EFSA conclusion related to the clastogenic and aneugenic potential of metabolite IN-H8612 formed as a residue. The European Union indicated that, based on the data available in the dossier, it had not been possible to complete the assessment of genotoxicity for the substance. This led to the non-approval of the substance, which had been notified in G/TBT/N/EU/437, as the European Union considered that it had not been demonstrated that residues of the substance above LOD were safe for EU consumers. On this basis, it was proposed to lower the MRLs to the LOD. The formal adoption of the draft legislative act was expected in January 2019, and the new MRLs were expected to be applicable from July 2019 onwards. The European Union would also be submitting a concern form to Codex. The European Union invited interested parties, with information that might, in their view, allow the establishment of safe residue levels, to submit an application under the relevant EU legislative frameworks. The European Union also indicated that it had been made aware of the existence of an additional US study, however, this study had not been submitted in the context of a regulatory procedure provided for in the EU legislation. As such, it could not be taken into account for decision-making.

3.10. The European Union also provided information on iprodione, which had been classified as a carcinogen in line with the UN Global Harmonized System for Classification and Labelling (UNGHS). The 2016 EFSA assessment had also advised the classification of this substance as a carcinogen (Category 1B) and as toxic for reproduction (Category 2), based on concrete evidence from *in vitro* tests. Due to these results and several other concerns with this substance, the approval for use of this substance in the European Union had not been renewed. The draft regulation was notified to non-EU countries on 25 July 2017 under the TBT Agreement, and responses provided to comments received from the United States and Turkey. The European Union further explained that following the non-renewal decision, EU member States had to withdraw their authorizations for plant

protection products containing iprodione by 5 June 2018 at the latest. A draft regulation deleting iprodione MRLs was prepared by the Commission and notified to the SPS Agreement in July 2018. The European Union indicated that comments had been received from seven countries, mainly requesting transitional measures and referring to the EFSA opinion. These comments had been shared with EU member States, prior to the last meeting of the Standing Committee on Plant, Animals, Food and Feed on pesticide MRLs which took place in September 2018. Following discussions in that meeting, the draft regulation had received a unanimous favourable opinion from EU member States. In addition, due to the genotoxicity concerns for one metabolite, EU member States had decided that transitional measures could not be granted. The European Union noted that the regulation would come into force in summer 2019, highlighting that two years would have passed since the first notification of the measure in July 2017, which had provided sufficient time for trading partners to adapt to the measure. The European Union informed the Committee that it would send a concern form to Codex requesting a re-evaluation of the substance and a revision of the MRLs. Finally, the European Union indicated that import tolerances for iprodione could still be requested, but that it would have to address the genotoxicity concern for the metabolite.

3.1.2 The Russian Federation's bluetongue-related import restriction on ruminants – Concerns of the European Union

3.11. The European Union raised its concern regarding the Russian Federation's import restriction in relation to bluetongue. The European Union explained that several years ago, the Russian Federation had banned imports of all susceptible live animals and their genetic material from the areas affected by the disease, following the notification of outbreaks in limited areas of the European Union. In response to the Russian Federation's notification of these measures in 2014 and 2016, the European Union had expressed in writing, and through bilateral exchanges, its view that the measures were not in line with Chapter 8.3 of the OIE Terrestrial Code. The European Union underscored that the OIE recommendations indicated that the export of susceptible animals and their genetic material from areas affected by the disease should be allowed under certain conditions, such as vaccination, laboratory testing or protection of animals from vectors in vector-protected establishments. These conditions were also reflected in the relevant veterinary export certificates agreed between the European Union and the Russian Federation. However, this arrangement was not being respected, and despite its repeated requests, the Russian Federation had not provided the scientific justification for its measures. The European Union urged the Russian Federation to bring its measures in line with the international standards, and allow the resumption of trade in ruminants and their genetic material without further delay.

3.12. The Russian Federation explained that bluetongue was a wide-spread, dangerous viral disease of small ruminants and cattle, notifiable to the OIE, which had become established in Western Europe. Five Mediterranean countries had declared themselves as endemic. The Russian Federation underscored its interest in the regular import of breeding cattle and small ruminants, and maintaining trade links with its traditional partners in the European Union. In this regard, appropriate measures had been taken during the bluetongue outbreak in the European Union, in order not to completely stop the mutually beneficial trade in live animals. These measures had included the signing of the veterinary certificates agreed by the European Union and the Russian Federation, recognition and regular update of the bluetongue-free zone, as well as close contact between research institutes and veterinary services of the Russian Federation and the European Union, which had to date ensured safe supplies of live animals from individual farms. This approach had proven successful, as trade had been maintained at a high level, and the Russian Federation had also remained free from bluetongue. The Russian Federation further noted that from 1 October 2016 to 31 December 2020, import and marketing of breeding cattle, breeding pigs, sheep and goats, horses, poultry, eggs and semen, and embryos thereof were exempted from value-added tax in the Russian Federation. The Russian Federation indicated that it was taking the necessary steps to update its veterinary legislation in light of the current epidemic risks and economic interests of Russian importers. In this regard, the draft regulation from the Ministry of Agriculture on bluetongue spread, which was currently being reviewed, was destined to eliminate current contradictions between the veterinary certificate and the domestic legislation. The Russian Federation called for the European Union's understanding, and for continued constructive work in the prevention of the spread of bluetongue in Europe.

3.1.3 Viet Nam's import restrictions in the draft law of animal production – Concerns of the United States

3.13. The United States raised its concern regarding Viet Nam's draft Livestock Production Law, which could restrict US exports of livestock products, including meat and poultry to Viet Nam. The United States thanked Viet Nam for the extensive bilateral discussions on the issue, but highlighted that its concerns had not been fully addressed. The United States observed that the law could be debated and voted on by Viet Nam's National Assembly as early as November 2018, and further requested that Viet Nam provide an update on the status of the draft law. In particular, the United States drew attention to Article 12, clause 7 of the draft law which would ban the import of livestock products produced using chemicals prohibited for domestic production in Viet Nam, despite assurances from Viet Nam that it would harmonize its MRLs for imported goods to Codex standards. The United States reminded Viet Nam of its obligations under the SPS Agreement, in particular Articles 3 and 5, and sought clarification on how Viet Nam would ensure that the measures taken on chemicals prohibited for domestic production were based on science. The United States also queried the appropriate level of protection that Viet Nam was seeking through such bans on domestic chemical usage in animal production, considering existing scientific evidence, including by Codex, which showed that such chemicals were being used to produce safe food. The United States encouraged Viet Nam to adopt Codex MRLs of veterinary drugs in foods, and requested Viet Nam to delay adoption of this law, until Article 12, clause 7 had been revised to align with Viet Nam's SPS commitments, and had addressed the identified trade concerns.

3.14. Canada shared the concerns raised by the United States with respect to the latest version of Viet Nam's draft law of animal production. Canada thanked Viet Nam for productive bilateral meetings, but expressed its concern regarding the provision contained in Article 12.7 that banned imports of products containing residues of veterinary drugs which were prohibited domestically in Viet Nam. This provision would ban imports of meat products that contained residues of several veterinary drugs, including ractopamine, for which there were existing Codex standards for safe use. Canada noted that this provision was essentially the same proposed ban that the Vietnamese Ministry of Health had notified on 7 September 2016, under G/SPS/N/VNM/82. On 4 November 2016, Canada had submitted detailed comments on that proposal, including a request that Viet Nam maintain MRLs for ractopamine and other veterinary drugs based on Codex MRLs and provide the rationale and scientific justification for taking a zero-tolerance approach. To date Viet Nam had not responded to Canada's formal comments. Canada indicated that it had held several bilateral meetings, including at the highest levels, raising concerns about Viet Nam's proposed ban. However, despite these meetings and Viet Nam's indication that the concerns of trading partners were being taken into account, the latest version of the draft law of livestock production (draft 6) of August 2018 contained a provision which would legislate essentially the same ban which Canada had been objecting to since 2016. Canada noted that Viet Nam had notified this draft law on 30 October 2018 as G/SPS/N/VNM/95/Add.2, providing Members with a 60-day comment period ending 29 December 2018. Canada observed that Viet Nam's National Assembly would be reviewing the draft law on 7 November 2018, and voting on it on 20 November 2018, prior to the end of the notification's comment period. As such, Canada requested that Viet Nam delay the review and voting on this draft law until after the conclusion of the comment period of the WTO notification, so that Viet Nam could take into account the comments of trading partners. In addition, Canada continued to request that Viet Nam remove the provision that banned imports of products containing residues of ractopamine and other veterinary drugs for which there were existing Codex standards for safe use. Canada also requested that Viet Nam maintain MRLs for ractopamine and other veterinary drugs based on Codex MRLs. Canada looked forward to continue working with Viet Nam to resolve this issue.

3.15. Paraguay stated its interest in this trade concern and indicated that it would continue to closely follow developments on this issue.

3.16. Viet Nam underscored its commitment to ensuring transparency, highlighting that it had notified its draft law on livestock production as G/SPS/N/VNM/95 on 10 March 2018. Viet Nam welcomed comments and feedback from all WTO Members on the matter. Viet Nam informed the Committee that the drafting agency, the Department of Livestock Production in the Ministry of Agriculture and Rural Development, was still in the process of reviewing the draft law including comments from Members. Viet Nam noted that it had recently notified the final draft to the WTO on 30 October 2018 for further comments from Members. In relation to the ban on the chemicals, Viet Nam emphasized that its legislative system differed from that of other countries. Viet Nam explained that the three-step legislative process started with a more general law, which did not

provide details for each substance, followed by a decree related to the designation of the duty and responsibility of the government agency and the competent authorities responsible for developing the list of substances and chemicals subject to the ban. Lastly, a Circular was developed by the Ministry of Agriculture to regulate in detail the substances to be banned, especially as it related to the group of beta-agonists, including ractopamine.

3.17. Viet Nam noted Canada's concerns with Circular No. 24 which had been notified in 2016, and would be reviewed in the future. Viet Nam explained that the Circular still remained in effect, which meant that Viet Nam accepted the residue levels of ractopamine which had been adopted according to the existing Codex guidance. Viet Nam underscored that its measures were based on international guidelines and that they did not constitute a disguised restriction on international trade.

3.1.4 Thailand's import fees related to approval procedures for live animals and/or animal products (G/SPS/N/THA/243) – Concerns of the United States

3.18. The United States raised concerns regarding Thailand's food safety inspection fees, in the form of import permit fees on all shipments of uncooked meat, poultry and meat offal. The United States indicated that these fees, which had the same objective of preventing the spread of animal diseases as the corresponding domestic slaughtering fees for the same products, were significantly higher than the domestic fees, and appeared disproportionate to the cost of services rendered. The United States noted that despite several bilateral meetings held over a number of years, Thailand had still not provided a justification for the disparity between the two sets of fees. The United States underscored the obligation under Annex C, that any fees charged for the procedures on imported products be equitable in relation to those on like domestic products, and be no higher than the actual cost of the service. The United States argued that the higher fees acted as a disguised restriction on US exports, and requested Thailand to ensure that the fees levied on imported products were the same as those levied on domestic products.

3.19. Thailand highlighted the right of Members, as embodied in Article 2.1, to take SPS measures as necessary to protect human, animal or plant life or health. Thailand explained that, in order to protect human and animal health, it was necessary to charge import inspection fees for both animal products and live animals of all species. These fees were set at the rate defined in the Ministerial Regulation under the Animal Epidemic Act. Thailand clarified that the fees covered the operational expenses related to the cost of food safety and veterinary inspection services, which were necessary to ensure that the products were free from microbial, biological and chemical hazards, as well as animal pathogens. Thailand underscored that no special or differential treatment was granted to any individual trading partner. Unlike for imported animal products, the inspection service fees for domestic products were charged to domestic business operators along each step of the food production chain. This was done to ensure that the products complied with national legislation and were safe for consumers. Thailand argued that the combined cost of the fees charged at each step which domestic producers had to bear was higher than the import inspection fee. For this reason, Thailand indicated that its approach complied with Annex C(1)(f) of the SPS Agreement.

3.1.5 European Court of Justice Opinion 528/16 on organisms obtained by mutagenesis – Concerns of the United States

3.20. The United States raised its concerns about the European Court of Justice (ECJ) ruling regarding the forms of mutagenesis that qualified for the exemption contained in EU Directive 2001/18/EC on the Deliberate Release into the Environment of Genetically Modified Organisms. The United States noted that the ruling carried the effect that all products of genome editing were subject to the risk assessment and review requirements, labelling, and monitoring obligations, as well as traceability laws currently applied to products falling under the scope of Directive 2001/18/EC. The European Union was taking steps to now clarify how the Commission and the EU member States would implement this ruling. The United States was concerned that the implementation of this ruling would lead to unjustified barriers to trade in products of genome editing, as well as stifle the agricultural research and innovation necessary to prevent hunger and malnutrition in the coming decades, while ensuring environmental sustainability of agricultural activities. The United States invited the European Union to provide the scientific basis for the regulatory distinctions made across the products of mutagenesis, whereby products of random mutations induced by chemicals or radiation were exempted from any regulatory review, and products with precise mutations induced through biotechnology were subject to protracted premarket regulatory review. The United States also requested the European Union to inform the

Committee of its plans to implement the ECJ ruling, particularly with respect to how it was considering risk in assessing options related to import controls, detection and traceability. Finally, the United States noted its long experience with the European Union, in the context of the *EC Biotech* dispute settlement proceedings, and subsequent efforts to reach compliance. The United States urged the European Union to work with other countries that were taking science-based approaches to the oversight of products of genome editing.

3.21. Argentina and Paraguay shared the concerns raised by the United States, and requested the European Union to implement the ruling in a manner consistent with the provisions of the WTO, particularly those of the SPS Agreement.

3.22. The European Union explained that the ECJ had provided important clarification on the scope of application of the EU GMO legislation (Directive 2001/18/EC) in relation to organisms obtained by mutagenesis techniques. As a consequence, the GMO legislation was applicable to organisms obtained by new mutagenesis techniques. According to the Court judgement, organisms obtained by means of techniques or methods of mutagenesis, which had conventionally been used in a number of applications and had a long safety record, were exempted. The European Commission was currently analyzing the ruling together with EU member States to ensure its proper implementation. Operators in and outside the European Union remained responsible for ensuring that products which were placed on the market were safe and complied with all relevant regulatory requirements. The European Union further explained that the ruling had not extended the scope of the legislation, but had clarified how it should be read. The current EU legislation on GMOs was based on science and had been in place since the 1990s, following which it had been updated in 2001. In the European Union's view, this regulation was consistent with the WTO Agreements, and the European Commission had no plans to propose an amendment to the current legislation in the short term.

3.23. The European Union also addressed several concerns raised in other fora regarding the distinction between these products obtained by mutagenesis techniques and other products obtained by conventional techniques. The European Union noted that different scientific bodies and experts had acknowledged that identifying the techniques used to obtain certain products could be challenging. EU member States and the Commission were currently considering the issue. In addition, the joint research centre (JRC) was addressing the issue together with the European Network of GMO laboratories to support the competent authorities of member States in this task. The European Union recalled that the question of detection of certain GM products was already posed by some processed products in which no DNA was present, e.g. GM sugar. In this respect, the legislation included the need to ensure traceability throughout the chain, even when detection at a later stage was not possible. The European Union indicated that the Commission would carefully analyze the ruling from a legal perspective, including the status of products obtained from new techniques, and reflect on further action. The European Union also addressed comments related to the difference in its approach as compared to other parts of the world. In this regard, the European Union underscored its precautionary approach to the development of environmental and safety regulations, which was enshrined in its treaties, and reflected the high importance that EU citizens attached to safe food and environmental protection. The European Union remained open to continue discussing this issue on a bilateral basis within the framework of the regular dialogue on biotechnology with its trade partners.

3.2 Issues previously raised

3.2.1 EU revised proposal for categorization of compounds as endocrine disruptors – Concerns of Argentina, China, India and the United States (No. 382)

3.24. Argentina reiterated its concern over the European Union's policy on pesticides and the adoption of a hazard-based approach for identifying substances with endocrine disrupting properties. Argentina noted the adoption of Regulation (EU) No. 2018/605, modifying Annex II to Regulation (EC) No. 1107/2009, which would come into force as of 10 November 2018. Argentina expressed concern about the systemic and trade impact of the measure, which violated core provisions of the SPS Agreement, such as the obligation to undertake a risk assessment and to apply the least trade restrictive measure. Argentina requested again that the European Union continue applying the procedures for granting import tolerances under Regulation (EC) No. 396/2005. Argentina queried how the EU reliance on the precautionary principle would conform with the requirement in Regulation (EC) No. 396/2005 to conduct risk assessments in establishing import tolerances and recalled that

any precautionary measure would need to comply with Article 5.7 of the SPS Agreement. Argentina also queried when import tolerances guidance under discussion in the EU Standing Committee on Plants, Animals, Food and Feed would be published and applied. Argentina referred to the GMO case and emphasized the need to carry out assessment procedures for import tolerances without undue delay. Argentina asked the European Union to provide information on the approach that would finally be applied, and to examine the proposal on waivers in order to at least exempt the substances that represented a minimal risk to public health, due to low exposure levels. Finally, Argentina urged the European Union to reconsider its hazard-based regulatory approach to pesticides.

3.25. The United States reiterated its concern on the EU hazard-based approach to pesticide regulation, and the implementation of criteria for identifying and subsequently banning endocrine-active substances. The United States requested clarification on the appropriate level of protection that these actions would achieve, underscoring that the identification of hazards without identifying potential risks would likely be more trade-restrictive than necessary. Furthermore, the United States again requested an explanation of the "legitimate factors", other than risk, considered when evaluating import tolerances, and how these factors rationally related to achieving an appropriate level of protection. The United States also drew Members' attention to the EU notification (G/SPS/N/EU/263) of a proposal to lower the maximum residue limits (MRLs) for iprodione to trade-restrictive default levels, despite a final EFSA assessment which found no risks to consumers for a number of commodities, many of which also had Codex MRLs. Iprodione was an important crop protection tool for US agricultural producers, being highly effective against a number of fungal diseases. Finally, the United States noted that it remained unclear how the European Union would ensure consistency of its regulatory approach to pesticides with the SPS Agreement.

3.26. China reiterated its concerns over the European Union's process to define criteria to identify endocrine disrupting properties in Regulation (EU) No. 2018/605, which appeared to be based on a hazard assessment. China urged the European Union to consider the existing scientific evidence when assessing risks to life or health and to adopt Codex standards where they exist, to minimize the impact on international trade.

3.27. India echoed the concerns raised, in particular on the hazard-based regulation approach, which was highly trade restrictive.

3.28. Australia, Brazil, Canada, Chile, Colombia, Costa Rica, ECOWAS, El Salvador, Guatemala, Honduras, Korea, Malaysia, New Zealand, Panama, Paraguay, Peru, Chinese Taipei and Thailand indicated that they shared this concern and called upon the European Union to reconsider their measure, considering the significant negative impact that it would have on trade. They also called upon the European Union to base its measures on adequate scientific risk assessments and to consider Codex MRLs. Brazil reiterated the view that safe and modern plant protection products could be of the upmost importance for the protection of plants while promoting agricultural yield and productivity in tropical regions. Guatemala highlighted that certain products were necessary given the climate conditions in such regions, in particular as a consequence to climate change.

3.29. Canada reiterated its disappointment that the technical amendment for derogations based on negligible risk had not been included in the final regulatory amendment of Regulation (EU) No. 2018/605. Canada sought assurances from the European Union that once a substance was identified as an endocrine disruptor, import tolerances would continue to be based on complete risk assessments, as set out in Regulation (EC) No. 396/2005. Finally, Canada sought information on how the European Union planned to work with its trading partners to implement the measure in a manner consistent with its international obligations and without unnecessary disruptions to market access.

3.30. The European Union confirmed that new criteria to identify endocrine disruptors for biocides applied from 7 June 2018 (Delegated Regulation (EU) 2017/2100), whereas for pesticides they would apply as of 10 November 2018 (Regulation (EU) 2018/605). The criteria would also apply to ongoing renewal or approval procedures of active substances. The European Union also confirmed that the guidance document for the implementation of the adopted criteria had been published by EFSA and ECHA on 7 June 2018. The criteria were the same for biocides as for pesticides in order to ensure a harmonized approach. The criteria were based on the WHO definition, required consideration of all relevant scientific information and applied a weight of evidence approach. Regarding the proposals for derogation (i.e. the possible inclusion of the clause on negligible risk from exposure), discussions with member States had started, and a qualified majority in favour of the derogation was needed to

proceed with the inclusion. In relation to import tolerances, the European Union confirmed that the procedures of Regulation (EC) No. 396/2005 would apply, including a full risk assessment, followed by a case-by-case decision, taking into account all relevant factors, in accordance with risk analysis principles. In addition, the Regulation included transitional measures for products produced prior to the modification of MRLs to remain on the market until the end of their shelf life, even after the date of application of the new MRLs, six months after the date of entry into force. However, when a health concern was identified, such transition measures would not be provided. The European Union reminded that early warning was available. As an example, TBT notifications on the non-renewal of active substance approval were accompanied by a statement on possible impact on MRLs. Recent examples had shown that two years could elapse between such notifications and the application of the lowered MRLs. The procedure for import tolerances would be published on the Commission website.

3.2.2 EU maximum level of cadmium in foodstuffs - Concerns of Colombia, Côte d'Ivoire and Peru (No. 430) (G/SPS/GEN/1646)

3.31. Peru reiterated its concern over the maximum levels of cadmium in chocolates and other cocoa products proposed by Regulation (EU) No. 488/2014, and observed that the entry into force of the regulation on 1 January 2019 would have a negative impact on trade of cocoa beans with the European Union. According to Peru, the new maximum levels of cadmium were not justified by scientific evidence (G/SPS/GEN/1646). JECFA considered a food to represent a risk when it contributed 5% or more of the maximum tolerable intake of the contaminant, and since chocolate and cocoa products contributed only 4.3% to dietary cadmium exposure, there were no grounds for including them in the regulation. Peru also noted inconsistencies in the EU Regulation, which established the same maximum levels of cadmium, 0.10 mg/kg, for potatoes and chocolate with up to 30% cocoa, in spite of the fact that potatoes contributed a much higher percentage than chocolate (13.2%) to overall cadmium dietary exposure, and had a different consumption pattern. Therefore, the EU Regulation was in violation of articles 2.2, 2.3, 5.1 and 5.4 of the SPS Agreement, since it was not based on scientific principles, no proper risk assessment had been conducted, and the objective of minimizing the negative effects on trade when determining the appropriate level of sanitary protection had not been considered. The entry into force of the regulation would harm Peruvian cocoa bean producers, and many other WTO Members, as well as undermine Peru's joint efforts with the international community, including the United States and the European Union, to combat illicit drug trafficking within the framework of comprehensive and sustainable programmes for the development of alternatives to coca leaf production. Peru reiterated its request for the European Union to exclude chocolate and chocolate products from the scope of its regulation until there was updated scientific evidence on the level of risk to human health from cadmium, and Codex would finalize the adoption of maximum levels for cocoa. Peru concluded by requesting the European Union to postpone the entry into force of the regulation to 1 January 2022.

3.32. Côte d'Ivoire echoed Peru's concerns on this issue, and explained that efforts were being currently undertaken in the country to diversify exports and increase the production of higher value processed products. The entry into force of the EU Regulation, not based on a risk assessment, would negatively impact on exports of cocoa products, allowing trade in cocoa beans only, which was more sensitive to price fluctuations. While Côte d'Ivoire recognized the legitimate right of the European Union to take measures to protect its population, it urged the European Union to review its Regulation until the adoption of Codex maximum levels for cadmium in chocolate.

3.33. Colombia reiterated its concern over the proposed Regulation (EU) No. 488/2014, highlighting again the significant economic and social impact on the cocoa sector. Colombia recalled that its national agriculture policy aimed to replace illicit crops by incentivizing producers to change poppy and coca crops by seeding cacao. As a result, cultivation and exports of cocoa to the European Union had increased. Colombia remained concerned that the positive results obtained with the support of international cooperation initiatives, including the WTO through the STDF, and EU funding, would be affected by the application of the EU Regulation. In accordance with Article 10 of the SPS Agreement, Colombia requested the European Union to provide additional resources to continue research on cadmium in cocoa and to implement the necessary mitigation measures. Also, referring to JECFA's scientific opinion and Article 3 of the SPS Agreement, Colombia requested the exclusion of chocolate from the scope of the regulation. Finally, Colombia invited the European Union to consider notifying draft SPS legislation at an earlier stage, so as to allow sufficient time for comments to be considered.

3.34. The Plurinational State of Bolivia, Ecuador, Guatemala, Indonesia, Nicaragua, and Trinidad and Tobago shared the concerns, and requested that the European Union exclude chocolate and cocoa products from the scope of its regulation and/or to extend the entry into force of the regulation to 1 January 2022, pending the development of Codex standards on maximum levels of cadmium. Ecuador highlighted that certain trade operators applied the regulation before its entry into force and incorrectly, that is, not to the finished products as provided in the measure, but to the raw material (cocoa beans). This issue had resulted in the development of a national agenda for cadmium reduction, involving the public and private sectors, to implement mitigation activities, which would require additional resources and time. Trinidad and Tobago highlighted the negative impact of the proposed regulation on diversification initiatives in the cocoa sector.

3.35. El Salvador, Panama, the United States, and the Bolivarian Republic of Venezuela also echoed the concerns, emphasizing that the regulation created unnecessary barriers to trade. Furthermore, the United States urged the European Union to consider the objective of minimizing negative trade effects and to ensure that the level of protection achieved by its measure would be scientifically justified.

3.36. Costa Rica expressed its systemic interest in this concern, and reminded Members that cadmium, being present in the soil, was present naturally in cocoa. Costa Rica asked the European Union to take this element into consideration in its research on this matter.

3.37. The European Union recalled its previous interventions, highlighting that the limits in Regulation (EU) No. 488/2014 were not based on a hazard-based approach, but on risk assessments and scientific opinions from EFSA. Furthermore, the European Union noted that the EU limits for chocolate containing a high amount of cocoa (>50%) were consistent with adopted Codex maximum levels. The European Union reminded Members of its efforts to alleviate the difficulties of trading partners in complying with this measure, such as agreeing to a transitional period of five years. The European Union also pointed out that the ultimate goal of the European Union was to protect the health of EU consumers, and explained that EFSA's risk assessment showed that taking into account the EU Tolerable Weekly Intake (TWI) and consumption patterns, the mean dietary exposure to cadmium in EU countries was close to or slightly exceeded the TWI. The European Union further noted that certain subgroups of the population (mainly children) may even exceed the TWI by about two-fold. Furthermore, based on the risk assessment, it was considered necessary to limit the exposure of EU consumers to cadmium for all commodities, including chocolate. EU maximum levels were set on the basis of occurrence data at a level which was as low as reasonably achievable, and this was 0.10 mg/kg for potatoes and for milk chocolate containing less than 30% total dry cocoa solids. Finally, the European Union informed the Committee on future technical assistance projects on low cadmium and climate relevant innovation to promote sustainable cocoa production in Colombia, Ecuador and Peru.

3.2.3 EU review of legislation on veterinary medical products – Concerns of Argentina and the United States (No. 446)

3.38. Argentina reiterated its concern regarding the European Union's proposed regulation on veterinary medicinal products, stating that it was not based on a risk assessment nor in line with Codex guidelines and principles. Further, through this new regulation, the European Union would be applying *mutatis mutandis* 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. Argentina requested the European Union to consider the equivalence of third country regulations on the use of antimicrobial medicines based on rigorous scientific assessment vis-à-vis the level of sanitary protection set by the European Union.

3.39. Argentina noted that the issue of antimicrobial resistance had received greater attention in various international fora, such as the United Nations, G20, FAO, WHO as well as the OIE and Codex Alimentarius. Antimicrobial resistance was a complex topic that posed significant challenges, which required coordinated efforts based on science. Argentina further asked the European Union to develop the new regulation in compliance with the SPS Agreement and to avoid any barrier to trade. Finally, Argentina urged the European Union to provide the list of permitted antimicrobials for human and animal use, and encouraged the European Union to notify the revised measures to both the TBT and SPS Committees.

3.40. The United States also reiterated its concern, emphasizing that the measure would require foreign producers to abide by EU production standards regarding the use of antimicrobial veterinary drugs, without taking into consideration animal health conditions in their own territories. The United States further explained that the measure would ban the use of certain veterinary drugs based on approval in the exporting country and would not target residues of concern. Furthermore, the EU legislation prevented third countries from taking into account regional conditions and disease prevalence. The United States urged the European Union to consider the ongoing global effort undertaken in the Codex Task Force on Antimicrobial Resistance (TFAMR) to develop standards on antimicrobial resistance, and to delay implementation of its legislation until after the Task Force concluded its work. Finally, the United States asked the European Union to notify the revised legislation.

3.41. Colombia and Paraguay shared the concern raised by Argentina and the United States. Paraguay reiterated its support for the ongoing multilateral efforts to combat AMR, highlighting national initiatives currently under development.

3.42. Canada expressed its disappointment with the European Parliament's vote in favour of the new regulation on veterinary medical products to manage health risks from AMR. Canada recognized that AMR represented a serious public health issue that required high attention, but was concerned that the EU approach to managing such risks unnecessarily restricted trade and possibly undermined the ongoing multilateral efforts to combat AMR. Canada was of the view that AMR was a complex global issue and recognized the coordinated efforts undertaken by several international bodies to promote the prudent use of antimicrobials in animal and public health. Canada encouraged the European Union to support these ongoing efforts. Canada urged the European Union to notify the implementing measures given its significant potential impact on trade, to allow Members the opportunity to provide comments and to take these comments into account. Different conditions and diseases 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 and to provide the considerations that would be taken into account when preparing the list of medically important antimicrobials to be prohibited for veterinary use in the European Union and in third countries exporting to the European Union.

3.43. Brazil shared the concern, highlighting the ongoing multilateral efforts undertaken by international standard-setting organizations to address AMR. Brazil was of the view that AMR needed to be addressed multilaterally, and that unilateral decisions to ban the use of certain veterinary drugs and prohibit imports from countries where these products had been authorized was incompatible with Article 3 of the SPS Agreement and more trade-restrictive than necessary. Brazil emphasized the work of the Codex TFAMR and the "Code of Practice to Minimize and Contain Antimicrobial Resistance", supported by WHO, OIE, FAO and G20. Finally, Brazil requested the European Union to establish MRLs based on risk assessments.

3.44. Australia reiterated its support for 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 discouraged regional and individual countries' efforts to introduce AMR-related risk management measures that were inconsistent with agreed standards, not supported by science, and that could distort trade. Unilateral initiatives related to AMR trade policies outside the international standard-setting organizations had the potential to undermine collaborative global efforts and the integrity of these organizations. 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, welfare and biosecurity 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, efficient security measures to prevent the introduction of endemic and exotic diseases, and strong regulations governing the registration and 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.

3.45. The European Union noted that the revised regulation on veterinary medicinal products established a framework for the authorisation, distribution and use of veterinary drugs in the European Union. The European Union recalled that the original proposal, drafted in September 2014, had been notified under the TBT Committee in April 2015. Formal adoption, publication and entry into force was expected to take place in November 2018, and the new regulation would be applicable after three years. The European Union further explained that the key objectives of the new regulation aimed at addressing the global public health risk of AMR. The new regulation was based on a wide range of actions following the "One Health" approach internationally recognized as the most effective to tackle AMR. These actions included the strengthening of the principles behind the prudent and responsible use of antimicrobials, a ban on the preventive use of antibiotics in groups of animals, restrictions on metaphylactic use, the possibility to reserve certain antimicrobials for humans only, and compulsory data collection on sales and use of antimicrobials.

3.46. The European Union recalled that the ban on using antimicrobials for growth promotion was not new in the European Union, highlighting that the ban on using antibiotics as feed additives, in force since 2006, was based on a scientific opinion. Furthermore, the total ban was also in line with the growing international recognition of the need to phase out the use of antimicrobials as growth promoters, some of which were critically important for human medicine. The European Union recalled that AMR organisms and resistance determinants might spread to humans and animals through the consumption of food and feed originated in and outside the European Union. Therefore, certain non-discriminatory and proportionate provisions were introduced in the regulation to prevent operators in non-EU countries from using antimicrobials for growth promotion or antimicrobials designated in the European Union for human use only, insofar as relevant in respect of animals or products of animal origin exported to the European Union.

3.47. The European Union recalled that the new regulation would impose stricter requirements to operators in the European Union than to operators in non-EU countries, in particular for rules related to prophylaxis and metaphylaxis. The European Union noted that the new import requirements should be considered as part of the overall fight against the global spread of AMR, and not as trade barriers. The European Union reiterated its interest in the work carried out by WHO and OIE as well as the work of the UN Interagency Coordination Group (IACG) and the ad hoc Codex TFAMR.

3.2.4 Guatemala's restrictions on egg products – Concerns of Mexico (No. 413)

3.48. Mexico reiterated its concern over Guatemala's restrictions on egg products, highlighting that the measure in question violated fundamental principles of technical and scientific justification based on international standards. Mexico explained that these principles were enshrined in the SPS and TBT Agreements, as well as in the free trade agreement between Mexico and Central America. The continuous discussions held with Guatemala had not succeeded in resolving this matter, despite Mexico's self-declaration as an HPAI-free area. Mexico expressed concerns regarding undue delays in communications by Guatemala given discussions had been ongoing since 2010. Mexico further recalled that its egg products exports were significantly affected by the restrictions, and requested that Guatemala withdraw its measures, which had no scientific justification and were not based on any relevant international standard.

3.49. Guatemala replied that in October 2016, it had informed Mexico that it was reviewing the information provided. This issue had been further discussed in 2016 and 2017, and in June 2018, Guatemala had informed Mexico on the prohibition of imports of poultry products in response to an outbreak of H7N3 highly pathogenic avian influenza (HPAI) in two Mexican states. Guatemala noted that its measures were in line with the OIE standards, and was awaiting additional information from Mexico. Guatemala remained committed to continue bilateral discussions on this matter.

3.2.5 China's proposed amendments to the implementation regulations on safety assessment of agricultural GMOS – Concerns of the United States (No. 395)

3.50. The United States reiterated its concern over undue delays and the lack of predictability, transparency, and scientific basis for products approvals by China, highlighting the long-standing, robust and mutually beneficial trade of biotechnology products between their countries. The United States indicated that in March and July 2018 ten products remained poised for final adoption, most of which had been under review for five or more years. The United States asked China to provide precise and complete information to applicants on the processing periods, information requirements,

as well as to explain any delays in the process. The United States noted that no meeting of China's National Biosafety Committee (NBC) had been held thus far in 2018, whereas its domestic legislation on biotech approvals required that the NBC met at least twice a year. Finally, the United States urged China to take into account its SPS commitments in any revision of its biotech regulation.

3.51. China explained that the measure had been amended in 2016 on the basis of scientific assessment principles, and the approval procedures were open and transparent. China had notified to the WTO and trading partners a proposed amendment, taking into account other countries' practices and Members' comments. Finally, China remained open for further bilateral discussions with the United States on this matter.

3.2.6 EU Commission Decision 2002/994/EC on animal products – Concerns of China (No. 442)

3.52. China reiterated its concern over EU Commission Decision 2002/994/EC, highlighting that each consignment of poultry meat, casings, aquaculture fishery products and crayfish from China had to be tested for chloramphenicol, nitrofuran, malachite green, crystal violet and their metabolites before being exported to the EU market. China explained that in accordance with the "farm to table" concept it implemented strict inspection and quarantine procedures for animal products exported to the European Union. Moreover, the European Union had recognized China's food safety and residue regulatory systems, conducting several on-site reviews over the past years. On this basis, China urged the European Union to consider removing additional testing requirements on the above-mentioned substances, to reduce unnecessary costs and facilitate trade.

3.53. The European Union recalled that the measures contained in Decision 2002/994/EC had been introduced due to the detection of forbidden substances in products of animal origin. The European Union noted that exports were still allowed, with additional requirements for safety reasons. Since 2002, the measure had been repeatedly reviewed on the basis of information and guarantees provided by China, demonstrating progress made in residue controls. Finally, the European Union announced that the issue would be further discussed during the visit of the EU Agriculture Commissioner to China in November.

3.2.7 New EU definition of the fungicide folpet – Concerns of China (No. 447)

3.54. China again raised its concern with the new definition and MRL for folpet contained in Regulation (EU) No. 156/2016. The new regulation defined residues of folpet as the sum of folpet and phthalimide, whereas China stated that phthalimide was not only a metabolite of folpet as it could also metabolize from phosmet or bentazone insecticides, which meant that the presence of phthalimide might be irrelevant to folpet. Further, China argued that the regulation's residue definition for folpet did not comply with the Codex definition. China recalled that EFSA had published on its website an evaluation report on a folpet public consultation, recommending a revision of the residue definition for monitoring purposes. China encouraged the European Union to issue relevant regulations to review the definition as early as possible, in line with the Codex definition.

3.55. The European Union recalled its previous intervention, highlighting that the residue definition of the fungicide folpet would be considered during the on-ongoing renewal procedure of the approval of this active substance. The European Union explained that a significant part of this process was the EFSA peer review exercise, to be finalized early next year. Finally, the European Union expressed its commitment to keep China updated on further developments on this issue.

3.2.8 The Russian Federation's import restrictions on processed fishery products from Estonia – Concerns of the European Union (No. 390)

3.56. The European Union reiterated its concerns regarding import restrictions on fisheries products from Estonia, highlighting that these measures were inconsistent with several provisions of the SPS Agreement as well as with the Russian Federation's WTO accession commitments. Estonia had held several bilateral discussions with the Russian Federation, without much progress. The European Union welcomed the re-authorization for exports of one establishment, but regretted the continuous ban on every other establishment. The European Union welcomed the Russian Federation's acceptance earlier in the year to conduct another round of audits on Estonian establishments in 2018, but regretted that despite Estonian's efforts, no dates had been confirmed yet. The European

Union urged the Russian Federation to repeal the measure, which was inconsistent with several provisions of the SPS Agreement.

3.57. The Russian Federation provided information on progress made, highlighting that 500 tonnes of fishery products had been exported from one establishment in Estonia and another in Latvia in 2018. The Russian Federation further noted that it would discuss with Estonia conditions and dates of future inspection visits. Finally, the Russian Federation expressed its willingness to resolve this issue.

3.2.9 The Russian Federation's import restrictions on certain animal products from Germany – Concerns of the European Union (No. 411)

3.58. The European Union reiterated its concern over the Russian Federation's import restrictions on certain animal products from Germany imposed since 2013, highlighting that these measures were inconsistent with several provisions of the SPS Agreement. The European Union reported that six establishments had been re-authorized to export to the Russian Federation and hoped that the remaining plants would regain access to the Russian market soon. The European Union noted that interested establishments had already submitted relevant laboratory and inspection information to the Russian Federation. The European Union also clarified that several establishments, which had submitted relevant information, had renounced to export to the Russian Federation. Finally, the European Union urged the Russian Federation to repeal its measures without further delay.

3.59. The Russian Federation confirmed that six German dairy plants had regained access to the Russian market, and would be able to export as soon as mutual economic sanctions would be lifted. The Russian Federation continued to review the list of eligible establishments, based on the information provided by the German competent authorities. The Russian Federation expressed its willingness to continue its cooperation with Germany to resolve this issue.

3.2.10 Brazil's measures on shrimp – Concerns of Ecuador (No. 344)

3.60. Ecuador reiterated its concern over Brazil's Regulation 39, highlighting that since its adoption in 1999 Brazil had suspended imports of all species of crustaceans including fresh, frozen and cooked products from Ecuador. Ecuador recalled that SPS requirements for shrimps had been established in February 2017 and that in May 2017 Brazil had informed Ecuador of its equivalency for the inspection system for shellfish, and that enabled plants were authorized to export. However, a group of Brazilian producers had presented a court action which led to the suspension of the authorization to import shrimps from Ecuador. Ecuador further noted that the measure had been adopted for precautionary reasons, without taking into account sanitary requirements. Moreover, Ecuador contended that Brazil's measures were not in conformity with various provisions of the SPS Agreement and Article XI of the GATT. Finally, Ecuador regretted that despite various meetings with Brazil at the highest level, no official ruling had been made regarding the precautionary measure issued by the Supreme Federal Court of Brazil.

3.61. Brazil recalled its previous interventions, explaining that the approval process for shrimp imports considered all information received from Ecuador, including scientific evidence. Brazil explained that the animal health requirements for the importation of shrimps had been established in February 2017 under the regulation "Animal Health Requirements of Brazil for the importation of non-viable crustaceans and derivatives derived from extractive fisheries or aquaculture" (Circular Memorandum 6/2017/DSA.SDA/SDA/MAPA). In May 2017, the Brazilian market was opened for imports of shrimps from Ecuador, as reflected in letter No. 926/2017 informing Ecuador's sanitary authorities of the recognition of equivalence of their fisheries inspection system. Brazil explained that the recent suspension of exports by the Brazilian Supreme Court had only a preventive nature, highlighting that it had already established animal and health shrimp import requirements from Ecuador and had also recognized the equivalence of its fisheries inspection system. Brazilian Federal Executive authorities were providing all legal and technical information to guarantee fully informed judicial evaluations.

3.2.11 China's import restrictions due to highly pathogenic avian influenza – Concerns of the United States (No. 406)

3.62. The United Stated reiterated its concern on China's HPAI-related restrictions on US poultry products and requested China to follow OIE standards, particularly on regionalization. The United Sates regretted that despite being HPAI-free according to OIE guidelines, China still maintained restrictions. China had conducted an audit of the US avian influenza control system in July 2017, and had not requested further information to lift restrictions afterwards. The United States urged China to remove all HPAI-related import restrictions and indicated its commitment to continue maintaining its rigorous and effective surveillance for HPAI in compliance with OIE transparency obligations.

3.63. China expressed its preference for using compartmentalization rather than regionalization for poultry. China indicated that it would conduct consultations on the avian influenza epidemic management model based on the principles of reciprocity and synchronization to resolve this issue. Finally, China expressed its commitment to continue discussions on regionalization and compartmentalization with the United States to resolve these concerns as soon as possible.

3.64. The United States clarified that it had not received a formal compartmentalization proposal from China. Further, the United States noted that each country should be evaluated for recognition of regionalization or compartmentalization separately, following the procedure established by the importing country. The United States added that since both countries were in different stages of the process, it requested China to finalize the regionalization protocol that was provided following the July 2017 visit, and to remove all HPAI-related restrictions on imports from the United States, in line with its HPAI-free status, according to OIE standards.

3.2.12 General import restrictions due to BSE – Concerns of the European Union (No. 193)

3.65. The European Union reiterated its concern, noting unjustified undue delays in several Members regarding import approval procedures for safe commodities as defined by OIE. The European Union noted that longer approval procedures due to insufficient resources would constitute significant trade barriers in violation of Article 8 of the SPS Agreement. The European Union welcomed positive developments in China, Japan, and Chinese Taipei regarding certain EU member States applications, and hoped that they would proceed swiftly with all pending EU applications. The European Union urged Korea to finalize pending EU member States applications without any further delays. Finally, the European Union urged all Members to align their BSE requirements with OIE standards and to lift restrictions, particularly to allow trade in safe commodities (e.g. beef) regardless of the BSE country status.

3.2.13 South Africa's import restrictions on poultry due to highly pathogenic avian influenza – Concerns of the European Union (No. 431)

3.66. The European Union regretted to report that South Africa still did not apply regionalization, and maintained country-wide bans on imports of poultry products from several EU members States due to HPAI. The European Union stressed that these restricted and unjustified measures had been maintained by South Africa despite the fact that EU member States affected by the bans had been recognized as free from HPAI for months; that OIE standards stated that HPAI-related trade restrictive measures could be lifted three months after the whole country, or part of it, regained freedom of HPAI, following the application of a stamping-out policy; and that OIE requirements had been strictly applied by the European Union. The European Union considered these measures to be in contradiction to Article 6 of the SPS Agreement, which required recognition of the concept of disease free areas. The European Union reported that South Africa had audited three EU member States and was aware that the HPAI outbreak in the European Union had resulted from the movement of migratory birds, and not the result of international trade in poultry products. The European Union further had explained its control measures and regionalization system in bilateral discussions with South Africa. The European Union expressed its willingness to further discuss any necessary guarantee to minimize the disruption of trade in future outbreaks, in line with OIE Code. Finally, the European Union urged South Africa to respect its obligations and allow trade in all poultry products from the disease-free zones without any further delay.

3.67. South Africa repeated its concerns on the effectiveness of HPAI-related controls and preventive measures in the European Union. Preliminary inspections had been conducted in Hungary, Poland and Spain and reports would be sent. South Africa also reported that it had engaged in bilateral discussions with the European Commission in Johannesburg on 9-10 October 2018. South Africa highlighted that it had never doubted the EU legislation on the control of HPAI. However, the inspections had shown differences in the implementation of the legislation by EU members States. Furthermore, South Africa noted that in some parts the EU legislation was not equivalent to OIE guidelines. Finally, South Africa informed the Committee that it was considering different options to facilitate the evaluation of HPAI control implemented in the European Union, once freedom was declared.

3.2.14 New Zealand's draft import health standard for vehicles, machinery and equipment - Concerns of Japan (No. 440)

3.68. Japan reiterated its concern on New Zealand's SPS measures for vehicles, machinery and equipment from Japan notified on 30 May 2018. Japan recalled that a specific trade concern had been raised at the July 2018 Committee meeting, stressing that measures implemented by New Zealand should be based on sufficient scientific evidence, should not arbitrarily discriminate among Members, and should ensure sufficient time for comments. Despite the concern raised in July 2018, the new measures had entered into force on 1 September 2018. Japan highlighted that the measures put in place by New Zealand lacked scientific justification. Furthermore, the time-period between the notification and the entry into force of the measure had been insufficient. Japan encouraged New Zealand to base its measures on scientific principles, in accordance with Article 2.2 of the SPS Agreement, and reported that the scientific evidence provided by New Zealand had not included clarification on: (i) detection data of *Halyomorpha halys* (brown marmorated stink bug) from consignments, especially machinery exported to New Zealand from Japan; (ii) analysis of likelihood based on effective accumulated temperature on the introduction and establishment of *Halyomorpha halys* in New Zealand; and (iii) the rationale to establish on 1 September 2018 as entry into force of the regulation. Japan urged New Zealand to clarify these points and review the existing pest risk analysis. Japan also reminded New Zealand that SPS measures should not arbitrarily or unjustifiably discriminate among Members where identical or similar conditions prevailed. Finally, Japan highlighted that New Zealand had requested heat or fumigation treatment of used vehicles and used machinery for a certain period of time. However, Japan noted that this requirement had not been mandatory for other countries.

3.69. New Zealand considered the brown marmorated stink bug (BMSB) a very serious pest with potentially significant implications on agriculture, aquaculture, and New Zealand's environment. New Zealand underlined that BMSB had been intercepted in vehicles and machinery arriving from Japan, and noted that there were very limited options to manage BMSB. New Zealand was of the view that the measures put in place were consistent with SPS principles and New Zealand's appropriate level of protection. In addition, New Zealand expressed its appreciation for the collaborative work with Japan and hoped to continue to work together in resolving this matter.

3.2.15 India's fumigation requirements for grain and other products - Concerns of Ukraine (No. 427)

3.70. Ukraine reiterated its concern about India's fumigation requirements with methyl bromide on certain plant products, but expressed appreciation to India for providing temporary extensions to allow trade while alternative fumigation measures were under consideration. However, Ukraine looked forward to achieving a permanent resolution. Ukraine drew Members' attention on the IPPC "Recommendations on replacement or reduction of the use of Methyl Bromide as phytosanitary measure". Ukraine explained that *phosphine* was recommended as a replacement for grains, oil seeds, dried food stuff beverages including coffee, cocoa, herbs, tree nuts, fiber crops including cotton and others. In addition, Ukraine recalled that methyl bromide had not been listed under the State Register of Pesticides and Agrochemicals permitted for the used as fumigants for grains in Ukraine and could not be used for the export of grain shipment. Ukraine argued that according to Article 4 of the SPS Agreement exporting Members should recognize pest risk management measures that were alternatives to those initially required by importing Members. Ukraine added that in December 2016 it had submitted to India's National Plant Protection Organization the scientific information on the efficiency of application of alternative fumigants, including *phosphine*, and had provided further relevant scientific information during bilateral discussions held in July 2017 and 2018. Furthermore, Ukraine reported that India exempted some countries from the general

fumigation requirements and also allowed the use of phosphine instead of methyl bromide. Ukraine requested India clarify these provisions and emphasised that these alleged practices were contrary to WTO rules, including the MFN principle. Finally, Ukraine encouraged India to implement less trade restrictive and more predictable SPS measures, pointing out that the 2017 IPPC recommendations on plant health and environmental protection would represent a reasonable alternative to India's current requirement to use methyl bromide.

3.71. India recalled that until 31 December 2018, agricultural imports from other countries, whose products had not been fumigated with methyl bromide at the port of export, could be fumigated upon arrival in India, and indicated that more information could be found on the website http://agricoop.nic.in/. India also added that the Montreal Protocol allowed for the use of methyl bromide for quarantine purposes. India explained that the Indian authority had received from Ukraine the request for consideration of alternative methods of fumigation, and reported that in its response to Ukraine, India had requested clarifications and data to be able to conduct further examinations on this matter. Finally, India expressed its commitment to keep working at the technical level to resolve this concern as well as to maintain an appropriate level of protection in accordance with the principles of the SPS Agreement.

3.2.16 Thailand's import restriction on papaya seeds - Concerns of Chinese Taipei (No. 421)

3.72. Chinese Taipei reiterated its concern regarding Thailand's import restriction on papaya seeds imposed since 2008. Chinese Taipei expressed appreciation to Thailand for the proposal to submit the import protocol to the Committee on Plant Quarantine for approval. However, Chinese Taipei regretted that the final report had not been published and requested Thailand to adopt the final import protocol and ensure market access for its papaya seeds in Thailand.

3.73. Thailand welcomed the opportunity to provide clarifications on the concern raised by Chinese Taipei and stressed that the issue remained unsolved because Chinese Taipei failed to submit the request for export of papaya seeds under the transitory provision of the regulatory amendment. Thailand explained that during this transitory time all its trading partners, including Chinese Taipei, were informed to submit the request to apply the import exemption under the transitory provision. Thailand expressed its commitment to solve Chinese Taipei's concern.

3.2.17 US import restrictions on apples and pears - Concerns of the European Union (No. 439)

3.74. The European Union reiterated its concern regarding the US import restrictions on apples and pears under the systems approach and regretted that the United States had not provided a solution to this matter. The European Union recalled that since 2007 the European Union had been able to export apples and pears to the United States under the pre-clearance system. The European Union further explained that in practice, the US pre-clearance system hindered EU exports, as demonstrated by the limited volumes exported from the European Union to the United States. The quantity had even further decreased in recent years. As an alternative, in 2008 the European Union had applied to export apples and pears to the United States under a systems approach, to replace the pre-clearance system. The European Union noted that preparatory work had been finalized in a satisfactory manner, addressing phytosanitary concerns. However, the last administrative step towards the adoption of the final rule by the US Administration had been pending for over one year without scientific justification, which was inconsistent with the SPS Agreement, particularly in relation to avoiding undue delays in approval procedures. The European Union underscored that there were no phytosanitary justifications for postponing the publication of the final rule. Furthermore, the European Union noted that the United States had not provided details on the timing for the publication of this rule. The European Union requested the United States to respect its obligations and to allow trade in apples and pears to start immediately under the agreed systems approach conditions and to immediately publish the final rule. The European Union reiterated its willingness to continue to work with the United States to find a solution on this matter.

3.75. The United States highlighted the considerable progress made on several requests by the European Union to establish and expand access for EU apple and pear exports to the US market. The United States explained that the USDA Animal and Plant Health Inspection Service (APHIS) had published a proposed rule in 2016 to authorize imports of apples and pears from eight EU member

States (Italy, Spain, France, Germany, Netherlands, Portugal, Belgium and Poland) under a systems approach that minimized pest risk; and that in 2017, it had conducted a site visit to several of the EU members States included in the proposed rule. The United States had worked with the European Commission and interested member States to finalize the work plan to implement the regulatory changes in the proposed rule, and hoped that USDA APHIS would publish the final rule soon. The United States also reported that since 2013, exports of pears and apples from the United States to the European Union had continued to increase. Finally, the United States highlighted its commitment to transparency.

3.2.18 Lack of transparency and undue delays in Indonesia's approval procedures for animal products – Concerns of the European Union (No. 441)

3.76. The European Union raised a concern over the lack of transparency and undue delays in Indonesia's approval procedures for animal products, reporting that, for many years, European member States had not received feedback from Indonesia on their export applications, some of them filed in 2013. The European Union explained that in July 2018, Indonesia had provided information on questionnaires, but had not explained how to make progress on approval procedures for imports. According to the European Union, as Indonesian import approval procedures and standard processing periods were unknown, they were inconsistent with Article 8 and Annex C. Recalling previous interventions, the European Union stressed that WTO Members should ensure that approval procedures were undertaken without undue delays and in no less favourable manner for imported than for domestic products. Further, the European Union added that WTO Members should promptly examine the completeness of applications and provide the necessary feedback in case of any decision on the application and, upon request, provide information on the standard processing periods. The European Union expressed appreciation for preliminary meetings with Indonesia and Indonesia's commitment to provide feedback on EU member states' applications for dairy products. However, the European Union regretted that it had so far been unable to make progress. The European Union urged Indonesia to respect its obligations, be transparent about its approval procedure, and finalize the pending market applications from EU members states without further undue delays. Finally, the European Union looked forward to a more effective and regular dialogue with Indonesia.

3.77. Brazil and the Philippines shared the concern raised by the European Union and expressed their appreciation for bilateral discussions with Indonesia. The Philippines stressed difficulties related to the transparency and predictability of certain requirements, which affected the export not only of animal products but generally of all agriculture products exported to Indonesia.

3.78. Indonesia explained that the requirements for importing animal-based food products had been applied based on risk analysis and the applicable law. In relation to the legal basis, Indonesia listed several regulations for the implementation of the import policy, Law No. 18 of 2009 as amended by Law No. 41 of 2014 concerning animal husbandry and animal health; Government Regulation No. 95 of 2012 concerning Veterinary Public Health and Animal Welfare; Minister of Agriculture Regulation No. 34 of 2016 as amended by Minister of Agriculture Regulation No. 34 of 2016, as amended by Minister of Agriculture Regulation No. 23 of 2018, concerning imports of carcasses, meat, and offal; and Minister of Agriculture Regulation No. 17 of 2016, concerning the import of boneless meat originating from countries or zones in the country of origin. Indonesia clarified that these regulations were enacted to specify the requirements for imports of animals into Indonesia. Complimentary to the requirements set in these regulations, various procedures and permit approvals were foreseen. Indonesia reiterated that its procedures and permits were applied to all Members in a non-discriminatory way and in accordance with MFN treatment. In addition, Indonesia reported that the implementation of its import policy which included a detailed technical process was in line with Article 5.2 of the SPS Agreement.

3.79. Regarding the alleged lack of transparency, lack of responses from Indonesian authorities, and delays in approval procedures for imports, Indonesia drew Members' attention to the online system that could help monitor the process of filling an import approval for animal products. Indonesia also reported on a forum organized with several representatives from WTO Members and business associations in Jakarta to collect useful inputs to develop the online system. Furthermore, the forum was an occasion to inform relevant stakeholders about the implementation of changes in procedures. Finally, Indonesia expressed its willingness to continue to work with the European Union to find a solution to this issue.

3.3 Information on resolution of issues in G/SPS/GEN/204/Rev.18

3.80. The Chairperson drew Members' attention to the Annual Report on the Use of the Procedure to Encourage and Facilitate the Resolution of Specific SPS Issues (G/SPS/61). As required by the procedure, the Secretariat had prepared an annual report on the use of this procedure, contained in G/SPS/GEN/1642. The Chairperson noted that the report was very short since the procedure had never been used.

3.81. The Secretariat also informed Members of a new IT project in relation to online submission of STCs for inclusion in the Airgram. The project, supported by the IT Solution Division, would be jointly carried out for both the TBT and SPS Committees and would build on the success of the online notification system and the SPS and TBT Information and Management System (IMS). The project aimed to develop an online platform supporting Members in managing STCs ahead of SPS and TBT Committee meetings. The platform would be protected by personal passwords and would allow Members to submit and/or support STCs before the circulation of the SPS Airgram. The Secretariat highlighted that the system would improve transparency on STCs, and could enhance the efficiency of STCs discussions as well as enhancing the availability and coverage of information on STCs in the SPS IMS. The system was expected to be operative by the end of 2019. The Secretariat further explained that as a second stage, the project could allow Members to submit information on other agenda items online in addition to STCs. More detailed information on the system, in particular on the development of a pilot project, would be available at the March 2019 Committee meeting. The pilot project would enable a group of Members to test the platform.

3.82. Several Members expressed their appreciation for and interest in the project. Brazil looked forward to the implementation of the pilot project. Colombia thanked the Secretariat for its presentation and expressed its interest to be included in the pilot project.

3.83. The European Union requested more information on the impact that the online submission would have on raising STCs within the SPS Committee, and in particular whether the system would apply also to Members supporting a specific STC. The European Union queried whether this might be used to streamline meetings of the SPS Committee in the sense that not all Members supporting a given STC might need to take the floor.

3.84. Paraguay emphasised that every Member of the SPS Committee should continue to have the right to express its opinion regarding SPS measures in the SPS Committee.

3.85. Costa Rica expressed its interest in the pilot project. Furthermore, Costa Rica requested clarification on how the online platform would be integrated in other online tools such as ePing. Costa Rica also queried if the system would be similar to the Agriculture Information Management System (Ag-IMS), or whether it would follow a different scheme of implementation.

3.86. The Secretariat explained that the system would not change the way Members prepared SPS Committee meetings but aimed at helping Members to have more information ahead of time. Moreover, the Secretariat emphasised that the platform would improve transparency and efficiency in the formulation of the Airgram, and could be a supportive tool to tailor Members' interventions during Committee meetings. The Secretariat highlighted that the project was jointly developed with TBT colleagues and being developed in part due to the large number of STCs discussed in every meeting of the TBT Committee. The Secretariat indicated that the online platform would be integrated in the SPS IMS and explained that ePing was an alert system for SPS and TBT notifications, but did not contain information on STCs. Regarding the Ag-IMS, the Secretariat reported that the platform would follow a similar system, and clarified that the title and a brief description of the STC would be submitted ahead of time. However, statements of Members would not be included in advance.

4 OPERATION AND IMPLEMENTATION OF THE SPS AGREEMENT

4.1 Equivalence

4.1. No Member provided any information under this agenda item.

4.2 Pest-and disease-free areas (Regionalization)

4.2.1 Information from Members

4.2.1.1 Mexico – Self-declaration as a country historically free from African swine fever

4.2. Mexico informed the Committee about its self-declaration as a country historically free from African swine fever (G/SPS/GEN/1641). Mexico explained that the self-declaration contained information on African swine fever in Mexico; early detection systems; species susceptible to African swine fever in Mexico; and measures for maintaining ASF-free status. Mexico also reported that this communication had been submitted to the SPS Committee for purposes of transparency and in order to provide Members with further information on the current regulatory process in Mexico. Finally, Mexico informed Members that the document was available for consultation on the website of the World Organization for Animal Health.

4.2.1.2 Mexico – Declaration as an area free from Mediterranean fruit fly (*Ceratitis Capitata* (Wiedemann)

4.3. Mexico informed the Committee about its declaration as an area free of Mediterranean fruit fly (G/SPS/GEN/1644). Phytosanitary measures would be applied according to the national emergency and prevention system against exotic fruit fly (NOM-075-FITO-1997). Mexico further noted that the decisions declaring the free areas had entered into force on 7 September 2018, one day after their publication in the Official Journal, and were available for consultation on the website of the Federal Official Gazette.

4.2.1.3 Costa Rica – Official OIE recognition of Costa Rica as a country free from classical swine fever

4.4. Costa Rica informed the Committee of the official OIE recognition as a country free from classical swine fever (G/SPS/GEN/1638). For over 21 years, Costa Rica's National Animal Health Service (SENASA) had implemented a series of measures for the surveillance, control, prevention and eradication of the disease. Costa Rica further explained that during the 86th General Session of the OIE, held in May 2018, the Assembly had adopted Resolution No. 29, "Recognition of the Classical Swine Fever Status of Members", including Costa Rica in the list of members recognized as being free of classical swine fever, in accordance with the provisions of Chapter 15.2 of the Terrestrial Code. In the interests of transparency and in accordance with Article 6 of the SPS Agreement, Costa Rica encouraged Members to take note of this recognition, which reflected intensive efforts by both the public and private sectors to promote animal and public health both in Costa Rica and at the global level.

4.2.1.4 Canada – Experiences and approaches to regionalization relating to animal diseases

4.5. Canada recognised the importance of the SPS Agreement's obligations on adaptation to regional conditions, both for facilitating international trade and safeguarding animal and plant health. In document G/SPS/GEN/1650, Canada shared information about resources regarding recent experiences and approaches to regionalization. Canada further explained that information submitted on Canada's approach to zoning as an effective tool for animal disease control and to facilitate trade along with information on specific disease incidence, and Canada's risk management activities in response to avian influenza in British Columbia in 2014 and in Ontario in 2015, were available on the Canadian Food Inspection Agency website. Canada encouraged other Members to share information on their experiences with pest and disease-free areas.

4.6. The United States expressed its appreciation for the information provided in document G/SPS/GEN/1650. The United States reminded the Committee that in the context of Fifth Review Members' had emphasized the importance of sharing experiences on regionalization. The United States underscored that this agenda item represented an important opportunity where Members could share their experiences and information about procedures and processes related to various aspects of regionalization. Finally, the United States thanked Canada for its efforts to link regionalization to the Fifth Review.

4.7. Brazil and the European Union echoed the US comments and thanked Canada for sharing its experience. The European Union reminded Members that in 2012 it had submitted information on the EU regionalization system in document G/SPS/GEN/1159. The European Union also encouraged Members to provide information under this agenda item.

4.8. The Chairperson reminded the Committee that providing information on their pest or disease situation in the SPS Committee did not substitute for legal obligations to submit certain information to the IPPC or the OIE.

4.3 Operation of transparency provisions

4.9. The Secretariat drew Members' attention to its annual report on transparency (G/SPS/GEN/804/Rev.11). A corrigendum had been circulated mainly to correct some figures in Table 5 related to comment periods provided in regular notifications. In preparing this document, the Secretariat had largely relied on the SPS Information Management System (SPS IMS). The analysis contained in the report covered the period from 16 September 2017 to 15 September 2018.

4.10. Since 1995, a total of 23,525 notifications had been submitted to the WTO, of which 1,636 were notified during the period under review. The report included charts with the total number of notifications per year, the share of notifications submitted by developing country members and by geographical regions. As compared to the same period in the previous year, an increase in the number of notifications and share of notifications by developing countries could be observed. Tables 1 and 2 listed the Members which had submitted the greatest number of notifications since 1995 and during the last year. The report also provided an overview of the products most often covered by notifications, share of notifications that identified specific countries or regions affected by the notifications, as well as the most frequently cited objectives. The report contained statistics on the share of notifications which identified relevant international standards, and on conformity with those international standards. The report also included statistics on dates of adoption, publication and entry into force, and on final dates for comments. The 60-day period comment checkbox option had been selected in 56% of regular notifications. The report also highlighted the reasons for addenda to notifications. Section 4 some presented statistics regarding the most frequently assigned keywords.

4.11. In section 5, Members were reminded that the SPS Notification Submission System (SPS NSS) allowed National Notification Authorities to fill out and submit SPS notifications online, which improved accuracy and allowed the notifications to be circulated faster. The Secretariat stressed that 80 Members had requested access to the system, and 42 of these had submitted notifications via the SPS NSS. More than 50% of notifications were submitted via the SPS NSS. Paragraph 5.5 made reference to the practical manual on the operation of Enquiry Points and Notification Authorities. The revised 2018 edition of the manual, now named Practical Manual for SPS NNAs and SPS NEPs, was made available in English on the SPS gateway of the WTO website on 11 October 2018. Hard copies could be requested from the Secretariat. The Secretariat took the opportunity to thank Ms Sally Jennings from New Zealand, the original author of the manual, for her inputs as well as all those received from other Members, contributing to the successful finalization of this manual.

4.12. The Secretariat highlighted that paragraph 5.6 of the report made a reference to ePing. The Secretariat recalled that ePing was a publicly available notification alert system and covered both SPS and TBT notifications. Subscribers were able to receive email alerts regarding SPS and TBT notifications covering particular products and/or markets of interest to them. In addition, users could search and share notifications, upload additional information and related documents, as well as participate in discussion forums. ePing also offered an Enquiry Point management tool to facilitate domestic as well as international information sharing and discussion.

4.13. Finally, the Secretariat reminded all Members to inform the Secretariat on any change in the contact information of NNAs or NEPs to ensure that update information was available on the SPS IMS.

4.4 Special and Differential Treatment

4.14. No Member provided any information under this agenda item.

4.5 Monitoring of the use of International Standards

4.5.1 New issues

4.5.1.1 United States – Non-science factors in Codex standards

4.15. The United States drew Members' attention to document G/SPS/GEN/1656, stating that at the July 2018 SPS Committee meeting, the Codex secretariat had reported on the decision of the chairperson of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) not to move the MRL for the veterinary drug Zilpaterol to Step 5, despite consensus on the science and the safety of this veterinary drug. The United Stated explained that the CCRVDF chairperson cited a lack of consensus on moving the MRL due to factors outside the mandate of Codex. The United States noted the Codex representative had indicated that the real concern among some Codex members was related to the status of Codex standards under the SPS Agreement. Furthermore, the United States noted that the Codex secretariat had reported that the Legal Offices of WHO and FAO, the chairperson and vice chairpersons of Codex, and the Codex secretariat were preparing a report on issues related to the periodic blocking of Codex standards to be discussed at next year's Codex Executive Committee (CCEXEC) and next year's Codex Alimentarius Commission meeting.

4.16. Regarding the planned report to CCEXEC, the United States emphasised its support for the unique dual mandate of Codex to protect the health of consumers and ensure fair practices in the food trade. The United States added that the procedural and scientific foundation of Codex helped to ensure that the international standards developed in Codex were science-based, globally relevant, fit for purpose and reflected current best practices around the world. However, the United States stressed that the credibility and reliability of Codex was based on operating within its mandate, and taking decisions on the basis of considerations within its mandate. Clearly, opining on the WTO covered agreements, including on the implications of Codex MRLs or other food safety standards, guidelines, or recommendations under those agreements, would be outside the mandate of Codex.

4.17. The United States affirmed that in its view neither Codex nor the other drafting entities had the authority or the expertise to carry out a legal analysis of WTO implications. The Codex Alimentarius Commission must be grounded in the Codex *Procedural Manual*, not driven by WTO implications. The United States indicated that it would welcome a discussion in Codex about how to prevent WTO implications from influencing Codex decisions, but also highlighted that the appropriate forum for any exploration of the WTO implications of Codex decisions, including their implications under the WTO SPS Agreement, was the WTO. Regarding the intrusion of WTO considerations in the Codex MRL establishment process, the United States stated that scientific support was crucial in the context of Codex decision-making on MRLs. In this regard, the United States recalled the key principles of Article 2.2 and Article 5.1 of the SPS Agreement. The United States also pointed out that harmonization based on international standards, guidelines, and recommendations would be a significant tool for achieving these objectives, particularly for Members that lacked resources to perform their own risk assessments.

4.18. The United States further stated that Codex establishment of MRLs on the basis of considerations outside its mandate was contrary with assumptions underpinning the SPS Agreement and potentially undermined the value of those MRLs. The United States was particularly concerned about Codex allowing WTO implications of MRLs to drive its decision-making about whether, or at what levels, to set MRLs. The United Stated affirmed that the reliability of Codex decisions grounded on criteria outlined in the Codex Procedural Manual, and could not being driven by countries seeking to influence WTO outcomes to favour their country or region. The United States explained that Members would lose confidence in Codex standards if they had the perception that those standards were designed to achieve particular WTO outcomes, instead of being promulgated without regard to WTO implications. Loss of confidence in Codex would be damaging to countries at various development levels that may lack resources to set up and maintain complex food safety risk assessment programmes. In conclusion, the United States encouraged WTO Members to clarify in the context of Codex discussions and meetings that Codex should not be opining on WTO legal matters, and should remain laser-focused on establishing food safety standards, guidelines, and recommendations based on considerations within Codex's mandate.

4.19. The Russian Federation emphasised the importance of the scientific basis of Codex. Codex standards were recognized by the WTO and had two primary aims, namely to protect consumers'

health and to ensure fair practices in food trade. From the very beginning, Codex had developed food standards based on sound scientific principles and on data in relation to food safety and scientific risk assessment. The Russian Federation recalled that Codex standards covered a wide range of food issues, including pesticides, veterinary drug residues in food, environmental contaminants and pathogenic organisms in food, food additives, nutrition and standards for composition and identity for major food commodities. In relation to food safety, the protection of consumers implied a careful review of all scientific data. Although all food standards must be science-based, the Russian Federation pointed out that other legitimate factors were relevant for the protection of consumers and fair practices in food trade. However, the use of these different components should be clearly documented, including the rationale for integrating them in each case.

4.20. Argentina shared the concern raised by the United States and stressed that the scientific basis of the preliminary draft had been recognised by most members of the CCRVDF. However, it was not approved due to factors outside the mandate of the CCRVDF and the general principles of Codex. Argentina explained that the standard should be based on scientific principles and emphasised that the decision taken by the CCRVDF potentially affected the Codex system, and was against the basic principles contained in the Codex Procedural Manual. Argentina further indicated that Codex had established solid guidelines for the development of SPS measures based on scientific principles, and had adopted decisions to ensure that factors outside scientific principles were considered without any risk. Finally, Argentina emphasised the importance of Codex and the General Principles of Codex.

4.21. Chile, Costa Rica, Guatemala, Honduras and Paraguay shared the concern raised by the United States, emphasising the independent nature of Codex. Costa Rica recalled that Codex not only provided a scientific basis for SPS measures but represented one of pillars of the multilateral trade system. Costa Rica emphasised its willingness to continue to work with Codex to ensure the scientific principles underlying SPS measures. Guatemala expressed its concern regarding the issue of Zilpaterol and underlined the scientific basis of Codex. Guatemala emphasised the importance of the harmonization of SPS measures to Codex standards in the SPS as well TBT Committees. Furthermore, the interpretation of WTO rules was a prerogative of WTO Members.

4.22. ECOWAS recalled that international standards were based on science, and scientific advice bodies had been established within Codex, for instance the Joint FAO/WHO Expert Committee on Food Additives (JECFA). JECFA had conducted risk assessments on this compound and provided information on its safety during the last CCRVDF meeting. ECOWAS noted that the credibility of scientific advice bodies had been questioned in this case, underlining that the objective of these bodies was to provide scientific evidence and to facilitate the work of Codex and other standard setting bodies in developing international standards.

4.23. The European Union noted that it was open to discussions in the SPS Committee about the WTO implications of Codex standards, guidelines and recommendations. The European Union recalled the lessons learned during the thematic session held on 30 October 2018, and stressed that there was no hierarchical order among the SPS Committee, Codex, OIE or IPPC. The European Union added that, while the SPS Committee could invite Codex or other international standard-setting bodies to discuss topics of interest to the SPS Committee, in its view, the SPS Committee should not attempt to influence procedures or decision-making processes within Codex. The European Union noted that Members should raise their concerns in the competent fora.

4.24. Codex informed Members that the relevant document would be considered by CCEXEC. Codex also indicated that the composition of the commission responsible for preparing the document would follow instructions provided by the Codex Alimentarius Commission. Finally, Codex invited WTO Members to further considerations when the document would be distributed by the Codex Alimentarius Commission.

4.5.1.2 India – Use of the Codex definitions for milk and milk products

4.25. India drew the Committee's attention on the inconsistency in the application of the Codex standard relating to the definition of milk in some Members' regulations. India quoted the definition of milk developed by Codex and stressed that although the definition specified that milk could be obtained from any milking animals, some Members applied their own definition of milk and milk products which referred mainly to milk obtained from cows. India further explained the importance of taking into account that milk could be obtained not only from cows but also from other milking

animals such as buffalos, goats, camels etc. India also highlighted that there was no scientific justification for adopting such a restrictive definition, and that this misleading definition of milk and milk products had created unnecessary barriers to trade. Finally, India invited Members to consider Article 2.2 and 3.1 of the SPS Agreement and urged them adapt their regulations for milk and milk products to the definition provided by Codex.

4.26. Japan noted that the issue raised by India was not related to food safety, pointing out that it should be covered by the TBT Committee. Japan requested more clarifications from India in this regard.

4.5.2 Issues previously raised

4.5.2.1 United States – Use of the Codex international standard on glyphosate

4.27. The United States drew Members' attention to actions taken or under consideration to restrict the use to glyphosate that appeared to lack scientific justification. The United States pointed out that scientific and regulatory resources worldwide had re-evaluated and reconfirmed the safety of this crop protection tool, making it one of the most rigorously studied and evaluated. Furthermore, the United States recalled that in May 2016 the Joint FAO/WHO Meeting on Pesticides Residues (JMPR) had held a special session to re-evaluate glyphosate, at the recommendation of the WHO's Core Assessment Group on Pesticides Residues, due to concerns resulting from the 2015 International Agency for Research on Cancer (IARC) hazard report and availability of new toxicology and epidemiology studies.

4.28. After evaluating all previously reviewed data and new studies on genotoxicity, carcinogenicity, reproductive and developmental toxicity, and epidemiological studies on cancer outcomes, JMPR had concluded that neither short term nor long term dietary exposure to glyphosate presented a risk to consumers or a public health concern, and had reaffirmed the safety of all existing Codex MRLs for glyphosate. In addition, the United States highlighted that in December 2018 the US Environmental Protection Agency anticipated publishing the proposed interim registration review decision for glyphosate, reporting that glyphosate was one of the most widely used agricultural pesticides in the United States. The United States also noted that EPA's human health risk assessment concluded that glyphosate was not likely to be carcinogenic to humans and found no risks to human health when glyphosate products were used according to the label. Given the efforts and findings of Codex and competent authorities of several Members, including the US EPA, the United States reiterated that actions to restrict the use of glyphosate without a sound scientific basis appeared to unnecessarily restrict international agricultural trade, with no discernible benefits to public health. Finally, the United States urged Members to base their regulatory actions for glyphosate on sound scientific risk-based principles.

4.29. Brazil and Paraguay shared the concern raised by the United States and encouraged WTO Members to take into account the Codex standards on glyphosate.

4.30. Canada recognised the importance of Members basing their SPS measures to international standards, guidelines and recommendations. Concerning plant protection products, in particular glyphosate, the Codex Committee on Pesticides Residues (CCPR) and JMPR continued to provide useful guidance in this area. JMPR had re-evaluated glyphosate and found that glyphosate was unlikely to be genotoxic and unlikely to pose a carcinogenic risk to humans from exposure through the diet. Canada noted that similar reviews had been undertaken by Members, including Canada, which supported the continued registration and safe use of products containing glyphosate. Canada underscored the importance of timely, scientific, risk-based decision making with respect to plant protection products including glyphosate. Canada also encouraged Members to continue to base their regulations on scientific evidence and to take into account the advice of the international standard-setting bodies, in particular Codex.

4.31. Argentina reiterated the importance of respecting the basic principles of the SPS Agreement, which encouraged basing SPS measures on Codex international standards.

4.32. Costa Rica recalled the rigorous assessment conducted by Codex to establish pesticide MRLs and encouraged Members to adapt their measures for glyphosate on Codex recommendations.

4.33. Australia expressed its concern about the trade impact of Members applying glyphosate related restrictions based on non-science based assessments. Any regulation of this chemical should be based on WTO compliant risk assessments based on all available scientific evidence, and conducted in a transparent manner. Australia recalled that glyphosate was one of the most common crop protection chemicals and had been subjected to new re-evaluation by a number of countries chemical regulators to determine the safety of the chemical. Australia highlighted that the Australian Pesticides and Veterinary Medicines Authority (APVMA) had established that products containing glyphosate could be safely used according to label directions.

4.5.2.2 European Union – ASF restrictions not consistent with the OIE international standard

4.34. The European Union highlighted inconsistency in the application of the OIE international standard for African swine fever (ASF). The OIE Code contained clear ASF guidelines for the designation of containment and disease-free zones, and for identification, treatment and certification of tradable products. The European Union was gravely concerned when other Members ignored the Code's recommendations without sound scientific justification and timely decision making. The European Union further explained that ASF remained a very serious disease. However, experiences in the European Union showed that it could be efficiently managed to make sure that trade taking place in accordance with international standards did not cause any outbreaks.

4.35. The European Union further highlighted its transparent approach to disease control and regionalization measures, and remained open to provide all the necessary evidence demonstrating the efficiency of its policies to guarantee safe trade. Furthermore, this high level of transparency had also been acknowledged by the OIE. However, the European Union regretted to see that its trading partners were putting in place and maintaining unnecessary and unjustified trade restrictions. The European Union noted that its member States fully complied with international standards and urged other Members to evaluate import requests accordingly, and in line with the SPS Agreement. The European Union further explained that country-wide bans and excessive heat treatment requirements for each product were scientifically unjustified and should not be put in place. Finally, the European Union reiterated its willingness to cooperate with other WTO Members.

4.5.2.3 European Union – HPAI restrictions not consistent with the OIE international standard

4.36. The European Union reiterated its concerns regarding inconsistencies in the use of OIE standards on regionalization in relation to HPAI outbreaks. The European Union expressed regret that some Members applied country-wide bans whenever there was an outbreak, noting that this type of measure was not scientifically justified and that according to OIE standards there was no justification for maintaining such bans after EU member States had regained freedom from the disease. Moreover, the European Union regretted that its comprehensive surveillance programmes and transparent approach resulted in trading partners imposing unjustified restrictions. The European Union highlighted its strict and transparent system of control and acknowledged that many Members recognized EU regionalization measures for HPAI. The European Union also acknowledged OIE's ongoing work in distinguishing between HPAI and low pathogenic avian influenza (LPAI), to avoid unjustified barriers to trade due to LPAI outbreaks. The European Union applied the same policies and guarantees to its intra-EU trade as to its exports to third countries. In addition, regular audit reports were published on the European Commission website, which ensured that trading partners could be fully aware of the animal health situation in all EU member States. The European Union reiterated its call for Members to respect their regionalization obligations and to lift all existing unjustified bans and restrictions, as well as to refrain from imposing trade restrictions in cases where HPAI was detected in wild birds, and LPAI in poultry. The European Union looked forward to continuing discussion on the implementation of regionalization.

4.6 Fifth Review

4.6.1 Report on the Thematic Session on Equivalence (Part 1)

4.37. The Chairperson drew Members' attention to the report of the first part of the thematic session on Equivalence held on 30 October 2018. The Chairperson recalled that the thematic session was first proposed by Canada. Other Members had also submitted proposals recommending that the

Committee further discuss the concept of equivalence, including examining the existing guidance on the recognition of equivalence (G/SPS/19/Rev.2). The Chairperson explained that the first part of the two-part thematic session on equivalence provided an opportunity to lay out the international framework for the application of the concept of equivalence. The programme for the thematic session was circulated in document G/SPS/GEN/1640/Rev.1.

4.38. The Chairperson indicated that firstly, the Secretariat had provided an overview of the provisions of the SPS Agreement on equivalence (Article 4) and the relevant guidelines (G/SPS/19/Rev.2), as well as related jurisprudence. The Secretariat had highlighted that the existing body of relevant jurisprudence on equivalence was limited to one SPS dispute, which provided some general guidance on the relationship of Article 4 with the rest of the provisions in the SPS Agreement. The Secretariat had also presented information on SPS-related notifications and specific trade concerns on equivalence. In addition, based on the comments received from one Member, the thematic session had included a presentation from the Secretariat on equivalence from a TBT perspective. The Secretariat had stressed the provisions in the TBT Agreement which refer to equivalence, also noting the reference to the concept of mutual recognition in the TBT Agreement. The Secretariat had further presented information on the relevant work of the TBT Committee on equivalence and the notification of bilateral/plurilateral agreements, and had noted the lack of TBT-related jurisprudence in this area. The ensuing discussions had covered SPS topics related to the time-frame for expedited responses, the use of Committee guidelines in disputes, responding to equivalence requests, criteria for determining the appropriate level of protection, and the lack of equivalence notifications, among others. In addition, the discussions had focused on the differences in the coverage of equivalence in the SPS and TBT Agreements, and the lessons to be learned from discussions in the SPS and TBT Committees.

4.39. Secondly, the representatives of Codex, IPPC and OIE had explained how the concept of equivalence was applied in their respective areas, and had identified the relevant international standards and guidelines. In addition, the OIE had provided information on the level of implementation of equivalence and equivalence arrangements by its members, including the challenges faced in making an equivalence determination, as reported in a recent survey. Discussions had covered the need to ensure the consistency of the work being undertaken by the standard-setting bodies with the WTO Agreements; the challenges of having a common definition of equivalence; the lack of consistency in wording across organizations; the situations in which a systems approach should be used; and the link between recognition of disease-free areas and equivalence determinations. The Secretariat had also provided background information on the genesis of the equivalence guidelines and underscored the collaboration between the SPS Committee and the standard-setting organizations in the elaboration of guidance at the time.

4.40. The Chairperson stressed that the thematic session had proven to be informative and interesting, and that it had provided a useful opportunity to increase Members' awareness of equivalence, from the perspective of international rules and guidelines. Finally, she indicated that the presentations from the Thematic Session would be made available on the SPS Gateway page. In addition, she reminded Members that the second part of this thematic session would be held in March 2019, focusing on Members' experiences with the implementation of equivalence.

4.6.2 Report of the Informal Meeting

4.41. The Chairperson drew the Committee's attention to the draft report on the informal meeting held on 31 October 2018 (JOB/SPS/2 Rev.1), paper copies of which had been circulated to Members during the formal meeting. The Chairperson noted that the draft report would be made available electronically after the formal meeting and invited Members to make comments on the draft report either during the meeting, or to send them to the Secretariat by the deadline of Friday, 9 November 2018.

4.42. The Secretariat drew Members' attention to the new format for reporting informal Committee meetings adopted at the July 2018 Committee meeting. The Secretariat explained that the report had been updated maintaining the same structure and sequence of proposals as previously, starting with equivalence and adding any new proposal under each section as well as adding any new comments or views at the end of the list. The Secretariat further indicated that new subjects had been added at the end of the document.

4.43. The Chairperson reminded Members that, as indicated in the report on the informal meeting, there were no comments on the order of thematic sessions and workshops for 2019. The second part of the thematic session on equivalence, as well as the session on fall armyworm would be held at the next meeting in March. Finally, the Chairperson invited Members to submit suggestions for topics and speakers for both these sessions by 14 January 2019.

4.44. In addition, the Chairperson recalled that the proposal on fall armyworm contained in document G/SPSW/305 suggested the creation of a working group to discuss this topic. The Chairperson noted support for the creation this working group during the informal meeting, and invited Members to share their ideas on how the working group would function.

4.45. The United States noted that regarding the idea of the creation of a working group there had been expressions of interest during the informal meeting. The United States suggested to dedicate a specific time, perhaps at the end of the informal session to be held in March 2019, in the form an open-ended meeting for anyone interested in participating in a working group discussion. Furthermore, the United States proposed to structure the informal meeting in separate blocks of subjects. The United States also pointed out its interest, shared with Brazil and the European Union, to organize an informal session dedicated on regionalization. Finally, the United States explained that initial exchanges of ideas could be followed by electronic exchanges, depending on interest showed by Members.

4.46. Brazil expressed its support to the US proposal of having an open discussion of the working group following the informal meeting, on fall armyworm, and on equivalence. Brazil also stressed the importance having an in-depth discussion on regionalization during the informal meeting.

4.47. The Secretariat clarified that informal meetings or sessions on subjects of interest had been held in previous Committee meetings. For instance, dedicated informal meetings had focused on transparency and its procedures, and on equivalence, when the Committee was developing guidance in these areas. The Secretariat confirmed that is was possible to structure the March informal meeting in blocks of time dedicated to different subjects of interest. The Secretariat suggested that a first part of the informal meeting could be dedicated to discussing Review proposals. Depending on submissions received, a specific time could possibly be devoted to regionalization and/or equivalence, followed by an open-ended meeting of the working group on fall armyworm.

4.48. The Chairperson recalled next deadlines for the Fifth Review:

- **31 January 2019** for submitting additional proposals and papers on the issues under consideration;
- **8 February** for circulation by the Secretariat of a revised version of G/SPS/GEN/1625, which provided an overview of all papers/proposals submitted by Members;
- **22 February** for submission of comments by Members on proposed actions on the issues under consideration; and
- **28 February** for circulation by the Secretariat of a compilation of comments submitted by Members.

4.49. Finally, the Chairperson recalled that at the informal meeting Members had considered the updated version of the Secretariat's background note on the relationship between the Trade Facilitation Agreement and the SPS Agreement, circulated as document RD/SPS/3/Rev.2.

4.6.3 Chairperson's Annual Report to CTG

4.50. The Chairperson explained that she would submit a factual annual report on the activities of the SPS Committee for consideration by the Council for Trade in Goods (CTG). The report available to delegations for comments; it would be revised to reflect the Committee's work at the present meeting. The Chairperson further indicated that the report would be considered by the CTG at its meeting on 12 November 2018, and reminded Members to provide comments on the draft report by 6 November 2018, as announced at the start of the meeting.

5 CROSS-CUTTING ISSUES

5.1. No issue was raised under this agenda item.

6 TECHNICAL ASSISTANCE AND COOPERATION

6.1 Information from the Secretariat

6.1.1 WTO SPS activities

6.1. The Secretariat provided Members with an overview of the technical assistance activities held since the last SPS Committee meeting in July 2018. These activities had included a national seminar held from 6 to 8 August 2018 in Moldova, and a thematic session on Equivalence that took place on 30 October 2018. A regional workshop for Arab countries had been organized in collaboration with GSO; and training provided in the context of the WTO Regional Trade Policy Course for Asia-Pacific Members and Observers in Thailand.

6.2. The Secretariat also announced that national seminars would be held in Ecuador from 5 to 8 November; St Kitts y Nevis from 13 to 15 November; Chile from 20 to 22 November; Costa Rica from 3 to 5 November; and, Chinese Taipei from 4 to 6 December. The Secretariat further reported that was currently preparing a national seminar to be held in Côte d'Ivoire.

6.3. The Secretariat drew Members' attention on the Advanced Course on the SPS Agreement that had started on 22 October and would finish on 9 November 2018. The Secretariat reminded the Committee that the Advanced Course had been held for 14 years, and this year it was in Spanish. After a rigorous selection process, 25 government officials from 11 WTO Members had been selected to attend the course in Geneva. The Course had the objective to enhance the level of understanding of the rights and obligations arising from the SPS Agreement and the functioning of the SPS Committee. The Secretariat further explained that during the course, each participant would develop an action plan, which would address problems identified in their countries. Three coaches were assisting participants in developing their action plans. Participants would return after nine months to present on their experiences in implementing their action plans. The Secretariat highlighted that this year the course had benefitted from the co-operation with IICA, and thanked Mr Eric Bolanõs for his participation in the course as coach and speaker. The Secretariat also thanked WTO delegates that participated in the course as speakers and shared their experience with participants; Codex; IPPC; OIE; the Advisory Center on WTO Law; the International Chamber of Commerce (ICC) and FAO. Finally, the Secretariat reminded Members that the online course on the SPS Agreement was available online and encouraged Members to visit the SPS website to get more information on its technical assistance activities.

6.1.2 STDF (G/SPS/GEN/1653)

6.4. The STDF Secretariat provided a brief overview of its activities undertaken since July 2018, as detailed in document G/SPS/GEN/1653. At the outset, the Secretariat highlighted that the document included information on how to apply for project and project preparation grants. The Secretariat encouraged Members to visit the STDF website for information on STDF activities and projects and invited Members to subscribe to the STDF mailing list (http://www.standardsfacility.org/). At present, the STDF manages close to 50 innovative SPS projects at various stage of development, implementation or evaluation.

6.5. The Secretariat highlighted that the STDF Working Group had met on 29 and 30 October 2019 and agreed to fund four new projects focused on: (i) strengthening the spice value chain in India and improving market access through capacity building and innovative interventions; (ii) enhancing the capacity of Uganda's fruit and vegetable sector to comply with phytosanitary requirements for export to the European Union and other high-end and regional markets; (iii) enhancing capacity of Kyrgyz fruit and vegetable industry to implement Good Agriculture Practices (GAP) and Good Hygiene Practices (GHP); and (iv) reducing of aflatoxin contamination in maize from Burkina Faso.

6.6. The Secretariat also reported that two project preparation grants (PPGs) had been approved: (i) to study the feasibility of exports of live bees from Niue, in accordance with OIE standards; and (ii) to carry out studies and develop a regional project in Asia on the use of bio-pesticides as a way to mitigate conventional pesticide residues. In addition, the Working group had approved two PPGs benefiting countries in Central America and Africa to explore how developing countries can use Third Party Assurance (TAP) programmes in their national food control systems. Both PPGs were linked to

ongoing work in the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) on this topic.

6.7. The Secretariat also reported that the Working Group had also approved STDF's Work Plan for 2019[3]. The STDF will: (i) start updating its 2012 study on Public Private Partnerships to build SPS capacity; (ii) finalize and present a study on Good Regulatory Practice in the SPS area; and (iii) continue working on prioritizing SPS investment options for market access in developing countries sing the P-IMA framework. The Secretariat recalled STDF's participation in the July 2018 Workshop on Annex C, where it had shared experiences and lessons from its work on Facilitating Safe Trade, which are also summarized in STDF's Briefing Note on this topic. The STDF will continue to build bridges between the SPS and Trade Facilitation communities and reference was made to a series of forthcoming regional workshops that STDF helped organizing on Border Agency Cooperation, involving STDF partners, the standard-setting bodies and other relevant organizations such as the World Customs Organization (WCO). These workshops would be held for representatives from both customs authorities (training them on the importance of SPS controls) and SPS border agencies (training them on the role of customs at the border). Financial support for the workshops was kindly provided by the WTO Trade Facilitation Agreement Facility (TFAF) and the World Bank Group.

6.8. Finally, the Secretariat informed the Committee that the Facility was being reviewed by an independent evaluator. The final evaluation report was expected in early 2019, with recommendations to feed into the development of a new strategy for the STDF for 2020 and beyond.

6.2 Information from Members

6.2.1 Canada – Technical assistance to developing countries (G/SPS/GEN/1651)

6.9. Canada informed the Committee that it had provided 29 SPS-related technical assistance projects to various geographic regions, including Africa, Eastern Europe, Latin America and the Caribbean, Central Asia and the Asia-Pacific region amounting to approximately CDN $12.58 million. Canada's technical assistance to developing countries addressed three of the four broad categories listed in G/SPS/GEN/206: information; training; and "soft" infrastructure development (but not "hard" infrastructure development).

7 CONCERNS WITH PRIVATE AND COMMERCIAL STANDARDS

7.1. No Member took the floor under this agenda item.

8 OBSERVERS

8.1 Information from observer organizations

8.1.1 ECOWAS

8.1. ECOWAS reported on recent activities of its member States, detailed in document G/SPS/GEN/1643. ECOWAS informed the Committee about the joint monitoring mission FAO-CILSS which had the objective to anticipate the risk of food safety and to inform preparedness and response interventions to fall armyworm (FAW). The following countries have been involved in the joint mission: Togo, Burkina Faso, Guinea, Nigeria and Cape Verde. ECOWAS reported that it had conducted regional trainings on improving monitoring of FAW risk, prevalence and impact assessment at country level, and trained 31 qualified individual preventive controls and 17 lead instructors on food safety standards harmonization discussion and on the new US Food Safety Modernization Act (FSMA). Furthermore, ECOWAS provided technical assistance to members of the South Africa Development Community (SADC) on how to submit robust applications to the Codex Trust Fund. Recalling the intervention of the STDF secretariat, ECOWAS also informed Members on the recent approval of a project aiming at reducing aflatoxin levels across the maize value chain in Burkina Faso.

[3] See: http://standardsfacility.org/sites/default/files/STDF_Work_Plan_2019.pdf.

8.1.2 IICA

8.2. ICCA reported on recent activities of interest to the Committee, detailed in document G/SPS/GEN/1645. IICA indicated its continued support to build capacity in its member countries with activities related to the multilateral trade system. IICA thanked the United States for the technical and financial support provided, as well as the WTO Secretariat for the collaboration in the Advanced SPS Course currently taking place.

8.1.3 OIRSA

8.3. OIRSA reported on its main activities contained in G/SPS/GEN/1647. OIRSA recalled that its mandate aimed at supporting member countries in formulating national action plans and projects on animal and plant health. OIRSA emphasised that technical assistance had been provided to government officials and professionals on topics related to agricultural health. OIRSA indicated that as a part of their safety diploma training, officials from ministries of Agriculture in the OIRSA region took part in virtual tutored courses. Furthermore, OIRSA pointed out its work in supporting member countries in advancing their sanitary condition through disease control. Finally, OIRSA informed the Committee about its new internal structure that would enhance coordination among members and OIRSA's Technical Commission, in particular on animal and plant health, with the ultimate aim to be more effective at the national level.

8.1.4 IGAD

8.4. IGAD reported on its main activities of interest, detailed in document G/SPS/GEN/1649. As a regional economic community, IGAD stressed its commitment to enhance coordination among its members. In this regard, IGAD provided information on the cross-border Memorandum of Understanding (MoU) developed between Sudan and South Sudan, to increase harmonized animal disease surveillance, vaccination and reporting on harmonization matters. IGAD further reported that it was currently providing technical assistance to three member States to develop national SPS strategies aligned to the regional SPS strategy. Finally, IGAD indicated its contribution in the organization of six PPR regional control and eradication coordination meetings conducted to review progress of the implementation of the national PPR strategies and discussed key challenges. IGAD thanked USAID, the European Union and FAO for their collaboration and financial support.

8.1.5 OECD

8.5. OECD reported on recent activities, detailed in document G/SPS/GEN/1654. OECD drew Members' attention to the recent publication of a paper estimating ad valorem equivalents of non-tariff measures, including SPS and TBT measures. OECD underlined the new approach introduced by the study across 5000 traded goods and 80 countries and explicitly distinguished trade-cost effects associated with non-tariff measures from possible demand-enhancing effects that came from reducing information asymmetries and strengthening consumer confidence in imported products. In a number of cases, in particular in the SPS area, trade expanded, even though trade costs increased with the implementation of these measures. The OECD explained that this was likely explained by closer regulatory environments between the countries examined. However, OECD stressed the importance of further investigating these effects.

8.6. The OECD also provided information on a paper studying the implications of different IRC mechanisms within preferential trade agreements (PTAs), which was expected to be published at the beginning of 2019. The econometric assessment explicitly disentangled the effects of PTAs as such from those to be had from IRC mechanisms related to SPS and TBT measures, and also looked at the implications of their enforceability. The OECD reported that preliminary results suggested that TBT- and notably SPS-related IRC mechanisms generated the bulk of the positive trade effects to be gained from PTAs. However, the positive trade effects of SPS- and TBT-related IRC mechanisms remained small unless agreed mechanisms were backed by the relevant enforcement mechanisms.

8.1.6 WHO

8.7. WHO drew Members' attention to a Food Safety Conference jointly organized by the FAO and WHO which would take place in early 2019. The conference under the theme "The Future of Food Safety" would strengthen commitment at the highest political level to scale up food safety in the

2030 Agenda for Sustainable Development, and would identify key actions and strategies to address current and future challenges to food safety globally. The WHO explained that the conference would be held into two events. The opening event, in collaboration with the African Union, would be held at the African Union Commission in Addis Ababa from 12 to 13 February 2019; the closing event, the FAO/WHO/WTO International Forum on Food Safety and Trade, would take place at the WTO in Geneva from 23 to 24 April 2019. The conference would bring together ministers and high-level delegates from national governments, regulatory bodies, international organizations, development agencies, regional economic bodies as well representatives of academia, the private sector and civil society.

8.8. The WHO further explained that the conference had the objective to discuss the topic of foodborne diseases and the benefit of investing in food safety and sustainable food systems in an area of accelerate climate change, and identify key actions and strategies to address current and future challenges to food safety globally. The WHO stressed that the International Forum in Geneva would look more closely at trade-related issues related to this topic and invited Members to visit the website of FAO and WHO to get more information (https://www.who.int/food-safety/international-food-safety-conference).

8.9. The Secretariat thanked the WHO for the information provided and highlighted that initial discussions among FAO, WHO and WTO on the agenda for the second part of the conference had started. The Secretariat reminded Members that the conference would be held at the WTO in Geneva on 23-24 April 2019.

8.1.7 The African Union

8.10. The African Union African emphasized its commitment to work with FAO, WHO and WTO in organizing the First FAO/WHO/AU International Food Safety Conference. The African Union indicated that its work on SPS issues continued to be guided by the comprehensive African Agriculture Programme and reported that recently, African leaders had signed the Continental Free Trade Area Agreement. Trade Ministers at their meeting in December 2014 had requested the African Union Commission and the pan African quality infrastructure institutions to assess the quality of infrastructures in Africa, and added that the assessment was extended to SPS issues. The AU Commission had been requested to provide concrete information on SPS requirements of the African Free Continental Protocol on Trade in Services and Goods Annex on SPS measures and to undertake a study to assess the capacity of member States in various areas, especially covering legislative frameworks, capacity to conduct various risk assessments, audit and verification, transparency and inspections procedures. The African Union clarified that the SPS assessment would also provide information on the development of the EU continental SPS policy framework, as requested by ministers of agriculture in 2017. Recalling its previous interventions, the AU emphasized that fall armyworm affected many member countries; in particular, 44 countries had officially reported the presence of fall armyworm in their countries in February 2018. The AU stressed that currently there were no adequate early warning systems and pesticides were overused. The African Union was committed to work on this issue with different partners and would organize a conference on how to manage this pest.

8.2 Requests for observer status (G/SPS/W/78/Rev.14)

8.2.1 New requests

8.11. There were no new requests received by the Secretariat.

8.2.2 Outstanding requests

8.12. The Committee agreed to invite organizations with ad hoc observer status to participate in all of its meetings in 2019, with the exception of any closed meeting, and unless any Member raised an objection to the participation of any of these observers in advance of a meeting.

8.13. The Chairperson reminded Members that the Committee had agreed, in 2012, that if for any one-year period an ad hoc observer organization did not attend any meetings of the SPS Committee, the Committee would consider that its observer status has lapsed, but only after the Secretariat had contacted the observer organization and received confirmation that it was no longer interested in

maintaining its observer status. The Chairperson requested the Secretariat to verify if there were any ad hoc observer organizations that had not attended a single meeting of the SPS Committee during 2018. The Chairperson also requested the Secretariat to contact these organizations and to seek information regarding their continuing interest to participate as observers in the Committee.

8.14. The Chairperson noted that there was still no consensus on the six outstanding requests for observer status from the Convention on Biological Diversity (CBD); CABI International; the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES); the Organisation Internationale de la Vigne et du Vin (OIV); the Asian and Pacific Coconut Community (APCC); and the International Cocoa Organization (ICCO).

8.15. The Chairperson thanked the representatives of observer organizations for their contributions to the work of the Committee and for their assistance to Members. The Chairperson further encouraged observer organizations to provide written reports on their relevant activities in advance of the October 2018 meeting.

9 OTHER BUSINESS

9.1. No Member took the floor under this agenda item.

10 DATE AND AGENDA FOR NEXT MEETINGS

10.1. The Chairperson drew Members' attention to the proposed dates for the 2019 meetings of the SPS Committee, as circulated in document G/SPS/GEN/1619. The next regular meeting of the Committee was tentatively scheduled for the week of 18 March 2019, with an informal meeting on 20 March and two days of regular meetings on 21-22 March. In addition, thematic sessions would take place on 18 and 19 March. The Chairperson informed Members that a provisional agenda for the regular meeting would be circulated via e-mail.

10.2. The Secretariat reminded Members of the following deadlines:

- For comments on the Chairperson's annual report to the CTG: **Tuesday, 6 November 2018**;
- For inputs, including speakers, for the thematic sessions: **Monday, 14 January 2019**;
- For identifying new issues for consideration under the monitoring procedure and for requesting that items be included on the agenda: **Thursday, 28 February 2019**;
- For distribution of the Airgram: **Friday, 1 March 2019**.

10.3. In the context of the Fifth Review, Members were asked to take note of the following deadlines:

- For submission of specific proposals for actions on the issues under consideration: **Thursday, 31 January 2019**;
- For circulating a revised overview of papers/proposals submitted by Members (G/SPS/GEN/1625): **Friday, 8 February 2019**;
- For Members' comments on proposals: **Friday, 22 February 2019**;
- For circulation of a compilation of comments submitted by Members: **Thursday, 28 February 2019**.

10.4. All other deadlines related to the Fifth Review could be found in document G/SPS/W/296/Rev.1.

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