

STDF/Coord/588/Concept Note (Revised: 6 March 2018)

GOOD REGULATORY PRACTICE TO SUPPORT THE DEVELOPMENT AND IMPLEMENTATION OF SPS MEASURES

REVISED CONCEPT NOTE ON FUTURE STDF WORK FOR DISCUSSION BY THE STDF WORKING GROUP, 20-21 MARCH 2018

1 INTRODUCTION

1. In March 2017, the STDF Working Group discussed a concept note on future STDF thematic work on the use of Good Regulatory Practices (GRPs) to support the development and implementation of SPS measures. This discussion followed up on an initial exchange by the Working Group in October 2016 on future STDF work on GRP and/or the implementation of international standards in a public-private partnership context (with attention to private assurance schemes). Several members expressed support for work on GRPs. As an initial step, the Working Group requested the Secretariat to prepare and distribute an online survey to gather information on the use of GRP in developing countries to support the development and/or review of SPS measures.

2. The Secretariat developed this survey, in collaboration with STDF partners and the OECD. A link to the survey was distributed by email to Codex, IPPC, OIE and SPS contact points in September 2017, with the support of the Codex and IPPC Secretariats, OIE and the WTO. The survey gathered 118 responses from 64 countries/territories. Results generally indicated that GRPs (e.g. consultations with other parts of government as well as the private sector and other stakeholders, use of international standards, etc.) are being used to support the development of SPS measures, albeit with slightly more focus on assessing the risks to health, rather than the expected trade impacts. Responses suggest that less attention is given to reviewing or evaluating existing SPS measures to assess whether they are achieving the intended objectives. This conclusion is generally supported by the findings of recent OECD studies.

3. In October 2017, the Working Group discussed a report of the key findings of the survey. Members expressed satisfaction with the design of the survey questions, recognized the relatively high response rate and appreciated the findings. Some members advised for caution in interpreting the survey findings due to the nature of the questions and difficulty in providing clear feedback to complex issues. The WBG offered additional suggestions to enrich any future work/surveys, for instance to consider forward regulatory planning, the existence and use of e-registries of diverse regulations and how practices (e.g. on public consultations and regulatory impact assessment) are conducted and implemented. Going forward, the Working Group tasked the Secretariat to further disaggregate and analyse the data collected and, where possible, to cross-check against other relevant information. Annex 2 presents this expanded analysis of the survey findings.

4. During the Working Group discussions in March and October 2017, some members expressed support for further work on GRPs to improve the quality and effectiveness of SPS measures in order to ensure health protection and facilitate trade. As previously discussed, such work might include an STDF event, development of case stories, a checklist of good practices to improve the quality of SPS measures for capacity building purposes, and/or an STDF Briefing Note. Some Working Group members (e.g. WBG, WTO) noted their support the expected value of a checklist for their operational work on SPS capacity building, and proposed that it should include links to available resource materials and tools.

5. Building on these previous discussions in the Working Group, as well as the 2017 STDF GRP survey, this revised concept note outlines possible additional work on this topic. Background information, extracted and slightly updated from the previous STDF concept note (dated 28 February 2017, which benefitted from inputs from STDF partners), addressing the definition and purpose of GRPs, as well as linkages to other STDF activities and relevant work by STDF partners and others, is included in Annex 1.

2 STDF WORK ON GOOD REGULATORY PRACTICE

Applying GRP to improve the development and implementation of SPS measures, based on international standards and the SPS Agreement

6. As described in the STDF Medium-Term Strategy, the identification and dissemination of good practice to support SPS capacity building is an important component of the STDF's work, and contributes to output 2 of the STDF logical framework. Reflecting the STDF's mandate to strengthen SPS capacity to help gain and maintain market access, further STDF work on GRP would help to improve the quality and effectiveness of SPS measures to ensure health protection and facilitate trade. This work would be anchored on the SPS Agreement, with particular attention to principles and good practices to improve the development, implementation and review of SPS measures. Limiting the focus and scope of the STDF work in this way ensures that it targets and supports the STDF's core mandate, and complements the range of related activities led by STDF partners and others.

7. The purpose of future STDF work would be to identify good practices and recommendations to enhance the development and implementation of SPS measures in order to strengthen the effectiveness of regulatory interventions, improve compliance with international standards and the SPS Agreement, and ensure health protection while facilitating trade. This work would provide guidance to ensure that SPS regulations are "fit for purpose" and that they avoid the creation of non-tariff barriers. It would also address the use of GRP principles to take better account of complex and dynamic science and health status considerations affecting trade.

8. Wherever possible, this work would draw on and synthesize experiences in STDF projects that are related to the use of GRPs to improve the development, implementation and/or review of SPS measures. STDF projects have touched on GRPs in different ways. For instance:

- STDF/PG/345 (2014-18) promotes regulatory coherence in the animal feed sector in Latin America. This includes attention to strengthening cooperation between the public and private sectors in ten countries to achieve greater regional convergence in regulations affecting trade in animal feed. Implemented by industry association FeedLatina (Asociación de las Industrias de Alimentación Animal de América Latina y Caribe), the project established different channels to consult the private sector in the regulatory process.¹
- STDF/PG/358 (2013–15) aimed to strengthen the Official Veterinary Services of OIRSA member countries. It included work to develop harmonized regulatory criteria for veterinary services across eight OIRSA member countries, addressing gaps in secondary legislation as well as inconsistencies of national laws and regulations with OIE standards. The project built strong connections between public and private stakeholders, and resulted in 46 legal texts, which were expected to become mandatory Regional Technical Regulations following their review by the Central American Agricultural Council. As such, this project is an excellent example of effective regional harmonization through proper (inclusive, transparent, etc.) implementation of international standards.²
- STDF/PG/460 (2015-17) evaluated the impacts of the international wood packaging standard (ISPM 15) on the trade flows of four African countries. Under the project, four country reports were produced, analyzing all the national policies, laws, regulations and procedures relevant to ISPM 15 implementation. This work formed the basis for succinct policy briefs to enhance the participating countries' capacity to implement ISPM 15, and to disseminate lessons learned and best practices in implementation also to non-participating countries and international stakeholders. This included the identification of guidance and legislative tools to strengthen the implementation of ISPM 15.³

9. Building on the 2017 STDF GRP survey, follow-up STDF work on GRP would provide a way to bring this subject (in an easily understandable form) to the attention of policy-makers and staff of SPS regulatory authorities in developing countries, as well as the private sector. The outputs could be disseminated during future WTO national and regional SPS workshops.

¹ See: <u>www.standardsfacility.org/PG-345</u>

² See: <u>www.standardsfacility.org/PG-358</u>

³ See: www.standardsfacility.org/PG-460

- 10. In particular, STDF work on the topic of GRP would help to:
 - (i) increase awareness among SPS authorities about the meaning, role and value of GRP to improve the implementation of SPS measures in a way that ensures health protection and facilitates trade. The importance of meaningful engagement and consultation with relevant stakeholders, including the private sector and SMEs, would be a major element.
 - (ii) consider how to adapt existing principles and recommendations on GRP to support the development, implementation and periodic review of SPS regulatory frameworks.
 - (iii) identify and disseminate experiences, lessons learned and good practices on the use of GRP to improve the quality of SPS measures, as a means to strengthen SPS outcomes and reduce costs.
 - (iv) take stock of key capacity building needs to improve the quality of SPS measures.

11. In addition to generating benefits for governments and the private sector, this is likely to generate wider benefits for society as a whole. For instance, the application of GRP in the SPS area is likely to enhance and strengthen programmes focused on private sector development, which make a vital contribution to poverty reduction, growth and social inclusion. Engagement of the private sector in the design, review and monitoring of the implementation of SPS measures can help to strengthen the implementation of SPS measures in a way that is inclusive and participatory, and that also focuses on gender and empowering women to participate in market activity and trade.

12. Future STDF work on GRP would build on and learn from relevant existing work by STDF partners, other relevant organizations (notably the OECD) and any related initiatives at the regional or country level. While this work will focus on SPS measures linked to trade, the recommendations and good practices identified may be of value to enhance regulations in other areas not directly linked to trade.

3 OUTPUTS

13. The scope of future STDF work on this topic would comprise the following outputs, which would be made available on the STDF website and be further disseminated through the STDF's network. STDF partners and other Members of the Working Group are invited to provide additional guidance to further refine the expected outputs:

i. Document with compilation of short case stories describing experiences, results and lessons related to the use of GRP in the SPS area and including a checklist on the use of GRP to enhance the development and implementation of SPS measures

- A collection of short case stories (building where relevant and possible on the 0 STDF GRP survey responses, examples presented at the WTO/IICA regional SPS workshop in Costa Rica in June 2017, relevant experiences from STDF projects, and suggestions from Working Group members and other consultations/research) will be identified and documented on the use of GRPs to support the development, implementation and review of SPS measures. These case stories would address, for instance, experiences and tools to facilitate consultations on regulatory development, use of international standards, transparency on SPS measures, use of risk assessment, experiences in the evaluation of the expected trade impacts of SPS measures, use of Regulatory Impact Assessments, review / evaluation of the implementation of SPS measures.
- The purpose will be to share relevant experiences, outcomes and lessons of the use of GRP in the SPS area, particularly from developing countries, as well as tools and resources to support the use of GRPs in the development, implementation and review of SPS measures. Experiences related to private sector engagement and collaboration with regard to the design, implementation and review of SPS regulations will be an integral part of the case studies.

- These case stories, and available existing tools and resources, would be compiled in a short STDF document, distributed on the STDF website and shared with the STDF Working Group and other relevant audiences.
- Relevant experiences and good practices on GRP, identified through the case stories and additional consultations with STDF partners, could be distilled and synthesized into a practical checklist on the use of GRP to improve the development, implementation and review of SPS measures, based on the SPS Agreement, for capacity building purposes. Such a check-list would set out key pillars and principles of GRP including use of international standards, consultation with the private sector and other stakeholders, transparency, etc. It could build on the existing simple checklist, which the SPS Unit in WTO uses for training purposes to help regulators assess whether their SPS measures are consistent with the SPS Agreement.

ii. STDF Briefing Note on GRPs

- Development of an STDF Briefing Note (in English, French and Spanish) on the role and use of GRP in improving the development and implementation of SPS measures.
- This briefing note would provide information on available experiences, results and lessons related to the use of GRPs to improve the development and implementation of SPS measures, particularly in developing countries. It would also include examples of work in STDF projects related to the use of GRPs.

iii. STDF information seminar – targeted at SPS delegates – on the implementation of GRPs in the SPS area.

- Organization of a seminar (up to 2 days) on the use of GRP, possibly on the margins of an SPS Committee meeting at the WTO in 2019.
- Such a seminar would share experiences, practices and lessons in the use of GRP to improve the development, implementation and review of SPS measures. Representatives of SPS authorities in developing countries and the private sector would be invited to share experiences, as well as selected STDF partners, donors and other organizations.
- \circ $% \ensuremath{\mathsf{P}}$ Presentations and background documents would be shared on the STDF website.

Timeframe and budget

The STDF Work Plan for 2017-2018 included an estimated budget of US\$100,000 (US\$50,000 per year) for work on GRP, which has not yet been used. Building on the STDF GRP survey, the Working Group is invited to consider use of this already allocated budget for some or all of the activities outlined in the Table below.

Table: Possible outputs for further STDF work on GRPs

Possible Outputs	Delivery	Inputs	Estimated budget (US\$)
Online survey and draft report on the application of GRPs in SPS area	COMPLETED 2017	 Time of STDF Secretariat to draft, conduct and report on the survey Time of STDF partners to comment on and help distribute the draft survey, and review the findings 	-
Desk study to research and compile a collection of case stories describing experiences, results and lessons related to the use of GRP in the SPS area (building on examples identified in the STDF GRP survey findings, STDF projects and other sources), including a checklist on the use of GRP to enhance the development and implementation of SPS measures	End of 2018?	 Time of STDF Secretariat, STDF partners and other contributors External consultant, selected in consultation with STDF partners 	30,000
STDF Briefing Note	End of 2018?	 Time of STDF Secretariat to draft and finalize note Time of STDF partners to review and provide comments 	-
STDF seminar (up to 2 days, on the margins of an SPS Committee and STDF WG meeting) on the use of GRP to support the development, implementation and review of SPS measures	2019?	 Time of STDF Secretariat Costs related to participation of external speakers (including STDF partners) 	70,000

ANNEX 1: BACKGROUND INFORMATION ON THE USE OF GOOD REGULATORY PRACTICE TO SUPPORT THE DEVELOPMENT AND IMPLEMENTATION OF SPS MEASURES⁴

1 WHAT IS GOOD REGULATORY PRACTICE?

1. The OECD defines regulation as any instrument by which governments, their subsidiary bodies, and supranational bodies set requirements on citizens and businesses that have legal force. The term thus encompasses a wide range of instruments from primary laws and secondary regulations to implement primary laws, to subordinate rules, administrative formalities and decisions that give effect to higher-level regulations (e.g. the allocation of permits) and standards.⁵

2. Good regulatory practices are defined as internationally recognized processes, systems, tools and methods to improve the quality of regulations and ensure that regulatory outcomes are effective, transparent, inclusive and sustained (World Bank, 2015). Good regulatory practices provide governments with tools, processes and strategic approaches to make sure that regulations are "fit for purpose" and that they deliver what they set out to achieve.⁶ They can also help to identify and evaluate trade and other (intended or unintended) effects of regulatory action.⁷

3. Different approaches and practices can be used to support and enhance the development of regulations, evaluate their effectiveness and introduce changes or improvements, where needed. Public consultation and stakeholder engagement on new regulations at the drafting stage is a key pillar of regulatory development and a core principle of GRP. This includes consultation with the private sector (including small and medium sized enterprises), as well as with other parts of civil society (such as consumer groups). Other principles include coordination and cooperation on the development and implementation of regulations (for instance to avoid internal inconsistencies or repetition), transparency, *ex ante* and *ex post* evaluation of regulations, etc.

4. Many public authorities see a strong value in the use of GRP to consult more widely (with the private sector as well as civil society including consumer groups), achieve greater buy-in from relevant stakeholders, and increase confidence that regulations are feasible and appropriate to deliver the expected outcomes. Regulatory authorities applying GRP have made gains in the development of laws and regulations, which has important benefits for the implementation of legislation, which profits society in general. In addition, the application of GRP principles contributes to the process of improving transparency, which can support efforts to move towards electronic SPS certification and reduce trade costs. It also contributes to a stable and transparent environment that allows the private sector to flourish, which in turn helps to create employment, promote economic growth and reduce poverty.

2 LINKAGES TO WORK OF THE STDF, STDF PARTNERS AND OTHERS

GRP and links to previous STDF work

5. As highlighted during the Working Group meeting in October 2016, GRP is related to previous STDF work, particularly on the implementation of SPS measures to facilitate safe trade, and would be of considerable benefit to developing countries to support their SPS regulatory agencies. One of the recommendations of the STDF regional research work on implementing safe trade focused on the need to apply GRP in SPS legislation.8 The research findings highlighted how the application of GRP in the preparation, adoption and application of regulations to implement SPS measures, international standards and conformity assessment procedures helps to avoid unnecessary obstacles to trade. It noted that existing practice in the preparation and review of SPS legislation often falls short of OECD recommendations on GRP, and pointed to the need to regularly review and update SPS legislation (for instance due to changes in the economic environment, demands for health protection, new food safety, pest and disease risks, commercial challenges, compliance

www.oecd.org/regreform/policyconference/46270065.pdf

⁴ This annex is extracted and updated from the STDF Concept Note (dated 28 February 2017), which was prepared in collaboration with STDF partners and discussed by the Working Group in March 2017.

⁵ OECD. 2010. Regulatory Policy and the Road to Sustainable Growth. See:

 ⁶ See: <u>www.oecd.org/gov/regulatory-policy/grpn.htm</u>
 ⁷ Robert Basedow and Céline Kauffmann. International Trade and Good Regulatory Practices. Assessing the Trade Impacts of Regulation. OECD Regulatory Policy Working Paper. July 2016. See: <u>www.oecd-</u>

ilibrary.org/governance/international-trade-and-good-regulatory-practices_5jlv59hdgtf5-en;jsessionid=1km1c1y879l97.xoecd-live-03 ⁸ See:

www.standardsfacility.org/sites/default/files/Implementing SPS Measures to Facilitate Safe Trade SE Asia Aug-2014.pdf

with international requirements, etc.). This work concluded that the development of guidance for GRP would be useful to support the preparation and review of SPS legislation in general, and regulations for implementing SPS measures in particular.

6. The application of GRP provides a tool to support governments to review and streamline their SPS measures, simplify procedures and provide services in a more user-friendly way for businesses. In some cases, the review and update of SPS regulations lags behind new developments and changing needs, which creates concerns regarding obsolete legislation. Some STDF partners have further observed that, in some cases, regulatory frameworks are not sufficiently agile to keep pace with the dynamic international disease situation and the ongoing development of science. Work on GRP is therefore likely to assist governments to achieve an appropriate level of health protection while facilitating trade, which will have win-win impacts for both the government and the private sector, especially in cases where resources are limited.

7. In past STDF work related to public-private partnerships and implementing safe trade, representatives of the private sector have highlighted the importance of a regulatory framework that is as straightforward as possible, that makes it easier for businesses (particularly small and medium sized enterprises, which encounter the highest costs of an overly complex regulatory burden) to trade their food and agricultural products across borders. The private sector has also highlighted the value of a level playing field, transparency and predictability in the way in which SPS measures are implemented, as well as the benefits of meaningful consultation and engagement with business as part of the process of designing and implementing SPS-related regulations.

8. Several completed and ongoing STDF projects have components on legislation covering food safety, animal and/or plant health. FAO and OIE are collaborating on some STDF projects to support the development of new legislation on animal health. While the legislative elements of past STDF projects have not specifically focused on GRP as a stand-alone element, the experiences and recommendations are likely to be relevant.

GRP and the SPS Agreement

9. Regulation provides an important mechanism to recognize public and private roles and responsibilities in public-good related areas, including food safety, plant protection and animal health. It is also an important tool for preserving and advancing diverse public interests, including food safety, animal and plant health. Several provisions of the SPS Agreement encourage the use of GRPs, including use of international standards (Codex, IPPC, OIE), risk assessment, transparency, advance notifications on draft measures, etc.

10. The provisions of the SPS Agreement seek to address the quality of regulatory intervention by requiring that Members choose measures that, inter alia, are based on scientific evidence and an assessment of the risks, have the least impact on trade, avoid discrimination, and ensure transparency (including by notifying draft measures and providing an opportunity for comments). For instance:

- Article 3 encourages governments to establish national SPS measures consistent with international (i.e. Codex, OIE and IPPC) standards (often referred to as "harmonization"). Ensuring that SPS measures are based on international standards is the most effective way to ensure health protection and facilitate safe trade. The use of international standards provides a cost-effective and straightforward approach to support the development of better regulations. In cases where governments decide to regulate, it is essential to consider whether a relevant international standard exists that would support the regulation. GRP processes should be followed during the process of using international standards as a basis for national regulation and standards.
- Article 5 focuses on an assessment of risk and determination of the appropriate level of health protection. It encourages Members to ensure that their SPS measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations. In assessing risks, this article encourages Members to take into account, as relevant, economic factors. In addition, when determining the appropriate level of sanitary protection, Members are expected to "take into account the objective of minimizing negative trade effects" (para 4, Article 5).

Discussions on GRP in the SPS and TBT Committees

11. Good regulatory practice has been discussed briefly in the SPS Committee. During the Second Review of the SPS Agreement, Mexico proposed that the Committee consider developing guidelines that would promote practical implementation of the specific provisions of the SPS Agreement, including guidelines on good regulatory practice, to enable Members to check that the obligations of the SPS Agreement have been respected before adopting new SPS measures.⁹

12. In February 2018, the SPS Committee adopted a document entitled "Catalogue of Instruments to Manage SPS Issues". While not directly focused on GRP, this document includes some existing tools and resources that are available to WTO Members to support implementation of the SPS Agreement, including implementation of international standards (Codex, IPPC, OIE). Use of these tools and resources provides a practical way to support development, implementation and review of SPS measures, in line with GRPs.

13. The TBT Committee has recognized that "Good Regulatory Practice (GRP) can contribute to the improved and effective implementation of the substantive obligations under the TBT Agreement. Effective implementation through best practices is seen as an important means of avoiding unnecessary obstacles to trade. Institutionalizing the various mechanisms, processes and procedures of GRP through laws, regulations and guidance, as well as through the creation and designation of institutions within Member governments to oversee regulatory processes, is seen as a means of giving effect to GRP. Effective internal policy coordination, including among regulators, standardizing bodies and trade officials implementing the TBT Agreement, is stressed. Additionally, regulatory cooperation between Members is an effective means of disseminating GRP".¹⁰

14. The TBT Committee has organized a number of workshops on GRP since 2009. Most recently, the TBT Committee held a thematic session on GRP on 28 March 2017 (see below)¹¹. In 2012, with a view of furthering its work in this area, the TBT Committee agreed to identify a non-exhaustive list of voluntary mechanisms and related principles of GRP and to guide Members in the efficient and effective implementation of the TBT Agreement across the regulatory lifecycle in a number of areas. This work by the TBT Committee is also relevant for the SPS Committee and implementation of SPS measures.

Key messages from the TBT GRP Workshop (March 2017) of relevance to SPS measures

- GRP has several positive functions. It helps ensure the design of high quality and cost effective regulations that are also compatible with open trade. Further, GRP contributes to the establishment of a common and predictable framework for regulatory intervention which facilitates global regulatory cooperation and harmonization. Ms Ann C. Cabochan (Philippines).
- A "life-cycle" approach to regulation making and management helps to reduce the regulatory burden on businesses and make the regulatory system more predictable and transparent. Targeted iinitiatives can be used to reduce regulatory costs on small businesses, without compromising other important objectives. Ms Pirkko Penttila (Canada).
- Various categories of negative aspects of technical regulations exist: (i) excessive regulations; (ii) duplicative regulations; (iii) regulations that differ from international standards; and (iv) outdated regulations. Regulatory Information Systems can help to improve efficiency by decreasing time for information exchange between agencies. Mr. Myung-chul Shin (Republic of Korea).
- The EU's Better Regulation Agenda aims at delivering better rules for better results through • monitoring and evaluation, impact assessment and receiving stakeholders' inputs. Under the Better Regulation Agenda, the European Commission aims to further open up policy making and ensure high quality deliverables. Mr. Jeroen Casaer (European Union).

⁹ See G/SPS/W/166, 27 October 2004.

¹⁰ Note by the Secretariat. Decisions and recommendations adopted by the WTO Committee on Technical Barriers to Trade since 1 January 1995. G/TBT/1/Rev.12. 21 January 2015. ¹¹ See G/TBT/GEN/214 (5 April 2017): <u>www.wto.org/english/tratop_e/tbt_e/th_sess_gpr_280317_e.htm</u>

GRP and links to work of STDF partners

15. STDF partners (including the international standard-setting bodies) have extensive experience in the development and implementation of SPS-related legislation, including substantial capacity building and technical cooperation activities, which is highly relevant to GRP. They have developed considerable guidance to support member countries in developing legislation related to food safety, animal health and plant health, and implementing international standards and related texts. A number of publications, guidelines and other legal papers exist that address and support the use of GRP in the area of food, phytosanitary and veterinary legislation, as well as on biosafety, invasive alien species, risk analysis and other areas of relevance to the SPS Agreement.

16. FAO's Development Law Service helps member countries analyse and improve their laws governing agriculture, food and natural resources management, and has been involved in hundreds of advisory projects, supporting a wide variety of law reform activities in many different fields. FAO divisions are also involved in collaborative work with OIE on specific areas such as Anti-Microbial Resistance (AMR) and Peste des Petits Ruminants (PPR). In addition, FAO implements many technical cooperation projects and other activities to support food safety, such as work on strengthening food import controls, which includes guidance to countries on various aspects and principles of GRP. Reflecting this importance, the new FAO/WHO Food control assessment tool will include a section on the use of GRP.

17. Similarly, past and ongoing work of the IPPC is of relevance to the topic of GRP. One of the core modules of the IPPC/FAO Phytosanitary Capacity Evaluation (PCE) tool focuses on assistance to contracting parties to self-assess their capacity needs in the area of phytosanitary legislation. Specifically, this module helps to diagnose major gaps in the current national framework of phytosanitary law/act, regulations and standards, to identify improvements needed in the medium term for creating coherent and up-to-date phytosanitary legislation that protects plant health and support international safe trade of plants, plant products and other regulated articles. FAO has also developed "Guidelines for the revision of national phytosanitary capacity building activities. These guidelines discuss the many essential and desirable elements that should form part of a modern national phytosanitary legal framework. They also identify the issues that ought to be considered by governments in reviewing their existing regulatory frameworks on plant protection, especially in light of the new revised text of the IPPC and the SPS Agreement. Complementing its work on SPS legislation, the IPPC has also developed approaches to support engagement with stakeholders.¹²

18. OIE is also involved in a range of work of relevance to GRP. The development and efficient implementation of legislation is included among the 47 critical competencies in the OIE PVS Tool for the Evaluation of Performance of Veterinary Services. The Veterinary Legislation Support Programme (VLSP) of the PVS Pathway focuses on conducting veterinary legislation identification missions, at the request of OIE member countries, to identify gaps in legislation affecting the veterinary domain (including food safety, disease control, import/export, etc.). The VLSP also offers countries assistance in developing new or amended legislation to address gaps identified during identification missions. In 2010, the OIE organized a global conference on veterinary legislation.

19. In 2012, OIE members adopted new standards on veterinary legislation (Chapter 3.4. of the OIE Terrestrial Animal Health Code). Applicable worldwide, this new OIE standard provides "strong support for policies to enhance the effectiveness of national veterinary services, based on the adoption of standards of quality and the development and implementation of tools made available to Member Countries, such as the PVS Pathway". An OIE Editorial emphasizes that: "A notable innovation in the new standard is the inclusion of a definition of the quality of veterinary legislation, namely "the technical relevance, acceptability to society, sustainability in technical, financial and administrative terms and provision of a basis for effective implementation of laws."¹³ The OIE is developing an Observatory on the implementation of OIE standards. The Observatory is intended to serve as a tool to monitor progress and constraints faced by Members in the implementation of the OIE standards, in order to determine the effectiveness and practicability of

¹² For instance, the IPPC "Guide on Managing Relationships with Stakeholders" provides guidance on the establishment and maintenance of successful relationships with stakeholder, addressing aspects including communications and facilitating stakeholder input on phytosanitary policy.

¹³ New standard on veterinary legislation. Article on the OIE website (see: <u>www.oie.int/for-the-</u><u>media/editorials/detail/article/new-standard-on-veterinary-legislation/</u>).</u>

its standards and propose solutions. The Observatory is expected to support more effective implementation of OIE standards and enhance capacity building activities.¹⁴

20. In June 2017, the WTO and IICA held a workshop on Good Regulatory Practice, in which the STDF Secretariat participated. The workshop explored the application of GRP in Latin America and the Caribbean. Findings showed that transparency and stakeholder consultation were most widespread, but that regulations were not consistently reviewed once they entered into force. This workshop helped to inform the development of the STDF GRP survey and mobilize feedback. In October 2017, the WTO held a transparency workshop for SPS delegates focused on public consultations on SPS regulations.

21. Ongoing work by the World Bank to support selected countries to review their SPS legislation in the context of trade facilitation objectives is highly relevant to the planned STDF work. There are also synergies to the World Bank's work on Enabling the Business of Agriculture, the Global Indicators of Regulatory Governance project, and the four-year World Bank/USAID/UKAid programme on Good Regulatory Practice to improve regulatory quality in developing countries.¹⁵ This programme aims to help governments in transition and developing countries to enhance the quality of regulatory regimes and their outcomes. It will focus on a number of regulatory tools to enhance transparency, accountability and dialogue, and will collect and review lessons and experiences to enhance the impact of these tools and promote application of these tools in operational World Bank Group projects.

22. In addition, there may be linkages to work by WHO to adapt the general principles of GRP to the regulation of medical products to support its Member States to establish new regulatory systems for medical products and update existing ones.

Links to work by other international organizations, as well as relevant regional / country level initiatives

23. The OECD and others have recognized that regulations which are poorly-conceived and/or inadequately implemented can become an obstacle to achieving the very economic and social wellbeing for which they are intended. That is, regulatory arrangements can sometimes impede innovation and create unnecessary barriers to trade, investment and economic efficiency. They may involve duplication between regulatory authorities and different layers of government, and between governments of different economies. Similarly, regulations that are outdated or poorly designed to achieve their intended policy objectives contribute to inefficient regulatory arrangements.¹⁶ One recent study, which approaches regulatory cooperation as a sort of trade facilitation mechanism, cites various empirical studies which show how cooperation mechanisms such as harmonization and/or recognition can increase trade and facilitate efficiency.¹⁷

24. The need to improve the quality of regulations and ensure that standards promote so-called "better" trade to enhance the competitiveness of small and medium-sized enterprises (SMEs) is underlined in ITC's SME Competitiveness Outlook for 2016.¹⁸ The publication highlights that standards and regulations are an integral element in enabling companies to operate their businesses and trade, and that they play a critical role at each step in the value chain. At the same time, it emphasizes that standards and regulations, when poorly designed and implemented, are most likely to negatively affect SMEs (particularly in developing countries), which suffer the highest costs of compliance and largest impact of procedural obstacles. The report notes that "further progress in promoting good regulatory practices could be considered in the WTO."

- ¹⁴ See: <u>www.oie.int/en/standard-setting/overview/oie-observatory/</u>
- ¹⁵ See: <u>http://pubdocs.worldbank.org/en/57401456860309504/Good-Regulatory-Practice-Program-Overview-03-</u>

^{15.}pdf ¹⁶ ASEAN Good Regulatory Practice (GRP) Guide. Endorsed by the 2/40 SEOM Meeting, 2-4 February 2009, Bangkok, Thailand. See: <u>http://asean.org/wp-</u>

content/uploads/images/2012/Economic/sectoral_aem/standards_conformance/ASEAN%20Good%20Regulatory%20Practice% 20(GRP)%20Guide.pdf

¹⁷ Van Tongeren, Frank, Véronique Bastien, and Martin von Lampe. International Regulatory Cooperation, a Trade-Facilitating Mechanism. E15Initiative. Geneva: International Centre for Trade and Sustainable Development (ICTSD) and World Economic Forum, 2015. See: <u>http://e15initiative.org/publications/international-regulatory-cooperation-a-trade-facilitating-</u> <u>mechanism/</u>

mechanism/ ¹⁸ ITC. 2016. Meeting the standard for trade. SME Competitiveness Outlook. See: www.intracen.org/uploadedFiles/SMECO2016.pdf

25. Another paper for the E15 Initiative¹⁹ examines regulatory cooperation and regulatory coherence in the context of the world trading system, with some attention to good regulatory practice. The focus is on the TBT and SPS Agreements, described as "the most far-reaching examples of cooperation in the WTO".²⁰ This paper notes that the quality of a domestic regulatory process is enhanced through the use of good regulatory practices, transparency and stakeholder engagement. It makes a number of "substantive recommendations" and policy options, for instance to: (i) consolidate and strengthen the current transparency obligations (e.g. to consult the business community and other affected parties about new proposed legislation at an early stage, explain measures adopted including why alternative courses of action were rejected); (ii) assess the trade impact (*ex ante* and *ex post*) of regulations; and (iii) encourage the implementation of international standards. At the same time, this paper recognizes that "developing countries with a limited administrative apparatus may find some of the options difficult to implement, and thus underscores the need for capacity building".

26. Governments in OECD countries have spent considerable efforts developing approaches and tools to support the use of GRP in developing regulations, including in the SPS area. Examples include the Australian Government Office of Best Practice Regulation, which seeks better regulation not just more regulation. In the UK, the Better Regulation Executive works with government departments to measure regulatory burdens and coordinate their reduction, and to ensure that the regulation which remains is smarter, better targeted and less costly to business. The EU has implemented an ambitious programme of better regulation aimed at consolidating legal instruments, improving their quality and clarity, and ensuring the regulations deliver policy goals in the most efficient way. Several other examples exist. Many of these efforts reflect extensive work and guidance by the OECD to help governments pursue systemic regulatory reform to deliver regulations that meet public policy objectives and have a positive impact on the economy and society.²¹

27. Improving the quality of regulation is also increasingly a priority for governments in developing countries. For instance, the OECD and ASEAN have collaborated on good regulatory practice since 2010 in an effort to make the ASEAN region more dynamic and competitive. Good regulatory practice is considered as a cross-cutting theme for ASEAN connectivity, competitiveness and regulatory coherence, is closely linked to the ASEAN Agenda Post-2015, and supports ASEAN Member States' strategies to implement the United Nation's post-2015 Sustainable Development Goals. In 2005, the Asia-Pacific Economic Cooperation (APEC) and OECD developed an Integrated Checklist on Regulatory Reform, which sets out 11 criteria for better regulation, consistent with the OECD Principles. Experiences in Malaysia have highlighted that producing regulation through a more robust process of analysis and stakeholder engagement (including with the private sector) enhances efficiency and accountability, and also promotes greater participation, inclusiveness and ownership of the end solution of government intervention.²²

28. In the Pacific Region, governments have adopted a standard approach to developing legislation to ensure they follow GRP. Other countries in Asia are known to be doing work related to GRP. For instance, the Department of Agriculture in the Philippines is working with the government's "PROJECT REPEAL" (which aims at reducing the regulatory burden and cost of doing business across all government agencies) to identify ways to streamline agriculture-related regulations. The ASEAN Secretariat is launching new work with its Member States to "develop guidelines on how to formulate and apply SPS measures that follow international standards so as to maintain the sovereign right of ASEAN Member States to provide the level of health protection it

¹⁹ The E15Initiative was launched by the International Centre for Trade and Sustainable Development (ICTSD) in 2011. It convenes world-class experts and institutions to generate strategic analysis and recommendations for government, business and civil society geared towards strengthening the global trade and investment system for sustainable development. See: http://e15initiative.org/

http://e15initiative.org/ ²⁰ Mavroidis, Petros C. 2016. *Regulatory Cooperation: Lessons from the WTO and the World Trade Regime*. E15 Task Force on regulatory Systems Coherence – Policy Options P. E15 Initiative. ICTSD/WEF (available at:

www3.weforum.org/docs/E15/WEF Regulatory Cooperation Lessons WTO WTR report_2015_1401.pdf). ²¹ In March 1995, the OECD developed a Recommendation on Improving the Quality of Government Regulation, the first internationally accepted set of principles concerning regulatory quality (see www.oecd.org/gov/regulatorypolicy/35258511.pdf). In March 2012, the OECD adopted the Recommendation of the Council on Regulatory Policy and Governance, the first international instrument to address regulatory policy, management and governance as a whole-ofgovernment activity targeted at sectoral ministries, regulatory and competition agencies (see: www.oecd.org/gov/regulatorypolicy/2012-recommendation by the sectoral ministries and competition agencies (see: www.oecd.org/gov/regulatorypolicy/2012-recommendation by the sectoral ministries are sectoral ministries and competition agencies (see: www.oecd.org/gov/regulatorypolicy/2012-recommendation by the sectoral ministries are sectoral ministries and competition agencies (see: www.oecd.org/gov/regulatorypolicy/2012-recommendation by the sectoral ministries are sectoral ministries and competition agencies (sec: www.oecd.org/gov/regulatorypolicy/2012-recommendation by the sectoral ministries are sectoral ministries and competition agencies (sec: www.oecd.org/gov/regulatorypolicy/2012-recommendation by the sectoral ministries are sectoral ministries and sectoral sectoral ministries are sectoral ministries and sectoral ministries are sectoral ministries and sectoral ministries are sectoral ministries are sectoral ministries are sectoral ministries are sectoral ministries and sectoral ministries are sectoral minist

policy/2012-recommendation.htm). ²² See OECD 2015: http://www.keepeek.com/Digital-Asset-Management/oecd/governance/implementing-goodregulatory-practice-in-malaysia_9789264230620-en#.WIi5gNLR8dU#page5

deems appropriate, and ensure that these sovereign rights are not misused for protectionist purposes and do not result in unnecessary barriers to trade." 23

29. Dialogue, consultation and collaboration with diverse stakeholders – including the private sector and industry, as well as other parts of civil society (e.g. consumers groups) – are essential pillars of GRP. Governments in some countries are actively engaged in strengthening collaboration with the private sector and other civil society stakeholders to improve service delivery. This addresses various aspects of GRP. For instance: (i) consulting the private sector on new policy initiatives and legislation that impact their activities; (ii) publishing and making available draft legislation for comments and inputs by diverse stakeholders; (iii) leveraging the expertise, knowledge and experience of the private sector in further upgrading service delivery mechanisms; and (iv) considering feedback from the private sector and other stakeholders to enhance the efficiency and effectiveness of services.

30. For instance, in Asia, the food industry has been engaging ASEAN leaders and policy-makers on ways to enhance ASEAN's regional competitiveness including how to create effective and meaningful partnerships with relevant public and private sector stakeholders (including SMEs) across a range of areas, including in the area of GRP.²⁴ In APEC, the 2015 Cebu Food Safety Cooperation Forum (FSCF) PTIN Roundtable on Effective Industry/Regulator Cooperation emphasized the critical role of industry in the development of food safety regulation. In follow-up, the Grocery Manufacturers Association and Australian Food and Grocery Council developed the document: "Industry Associations: Their Role and Value in Policy & Regulation" as an information resource.²⁵

²³ Personal communication with ASEAN Secretariat

²⁴ Food Industry Asia. See: <u>foodindustry.asia/good-regulatory-practice-essential-in-the-implementation-of-the-aec</u> ²⁵ See: fscf-

ptin.apec.org/docs/2016/FOOD_INDUSTRY_ASSOCIATIONS_THEIR_ROLE_AND_VALUE_IN_POLICY_AND_REGULATION.pdf

ANNEX 2: GOOD REGULATORY PRACTICE TO SUPPORT THE DEVELOPMENT AND IMPLEMENTATION OF SPS MEASURES

SUMMARY REPORT OF RESPONSES TO STDF GRP SURVEY²⁶

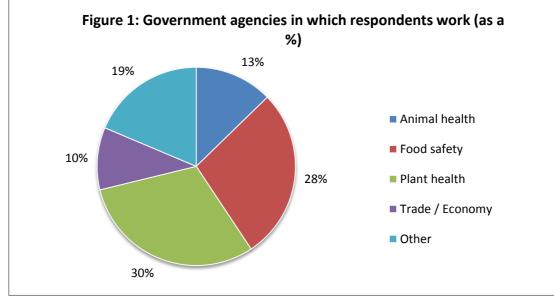
1 EXECUTIVE SUMMARY

1. Good Regulatory Practice (GRP) are defined as internationally recognized processes, systems, tools and methods to improve the quality of regulations and ensure that regulatory outcomes are effective, transparent, inclusive, and sustained (World Bank, 2015). They can be used to improve the quality and effectiveness of SPS measures in developing countries in order to ensure health protection and facilitate trade.

2. In March 2017, the STDF Working Group discussed possible work by the STDF on GRP (see <u>STDF Concept Note</u>). The Working Group agreed to begin with a survey to gather information on whether SPS agencies in developing countries are applying GRPs to strengthen the development, implementation and review of SPS measures, and how these were being applied. Based on the findings to the survey, and further discussion, the Working Group agreed that additional follow-up work by STDF on this topic may be considered.

3. In October 2017, the STDF Secretariat conducted the online GRP survey in English, French and Spanish. This survey was anchored on the WTO SPS Agreement, which includes several provisions related to GRP including the use of international standards (Codex, IPPC, OIE), risk assessment, transparency, etc. As requested during the discussion in the Working Group in March 2017, the draft survey was shared with selected, interested STDF partners and donors for comments prior to its finalization. Suggestions received from FAO, OIE, the United States, WTO and OECD were incorporated to the extent possible in the final version of the survey.

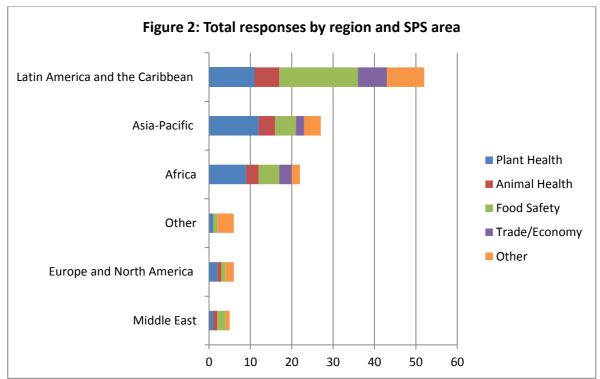
4. Information on the online STDF GRP survey was distributed widely by email, with the support of FAO (including the Codex and IPPC Secretariats), OIE and the WTO SPS Unit. In total, the online survey was completed by 118 officials in government ministries/agencies/departments based in 64 countries/territories.²⁷ As illustrated in figure 1, the majority of respondents work in government agencies responsible for plant health (36), followed by food safety (33), "other" agencies including those with multiple or cross-cutting SPS functions (22), animal health (15), and trade/economy (12). The majority of questionnaires were completed in English (74), followed by Spanish (36), and French (8).



Source: STDF GRP Survey

²⁶ Revised and expanded analysis based on the recommendation of the STDF Working Group meeting in October 2017.
²⁷ See list at the end of this report. At the close of the survey, approximately 80 surveys on the online database were incomplete and are not included in this report.

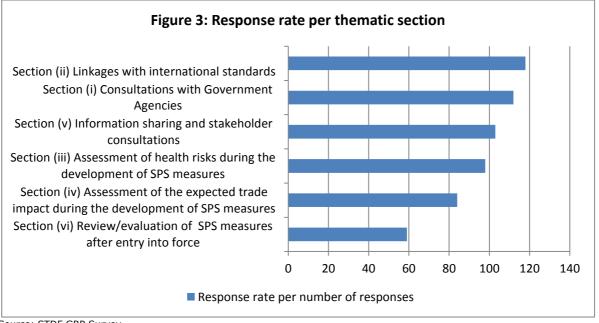
5. By region, the majority of responses came from Latin America and the Caribbean (52), followed by Asia-Pacific (27), then Africa (22), Europe and North America (6) and the Middle-East (5). An additional 6 respondents could not be identified and classified regionally. Overall, the highest number of responses came from plant health agencies. The breakdown of responses by SPS area and region is illustrated in figure 2 below. Some countries/territories also provided responses from several agencies i.e. plant health, animal health, food safety, trade/economy and others.



Source: STDF GRP Survey

6. This report provides a summary of the responses to the STDF GRP survey. Responses are summarized in six main sections: (i) consultations with government agencies; (ii) linkages with international (Codex, IPPC and OIE) standards; (iii) assessment of the risks to human, animal and/or plant life or health; (iv) assessment of the expected impact on trade; (v) information sharing and stakeholder consultations; and (vi) review/evaluation of the implementation of SPS measures after entry into force. The survey findings should be interpreted with some degree of caution, due to the nature of the questions and difficulty in providing clear feedback to complex issues.

7. As illustrated in figure 3, the response rate was highest for questions in section (ii) on linkages with international standards, with 118 responses, however it should be noted that most of the questions in this section were compulsory. The section with the second highest response rate was section (i) with 112 responses, followed by section (v) with 103 responses, section (iii) with 98 responses, section (iv) with 84 responses, and lastly, section (vi) with 59 responses (see figure 3).



Source: STDF GRP Survey

- 8. Some of the key findings of this survey were:
 - In section (i), 112 respondents noted their agency <u>consults with government agencies</u> within their country on the development of SPS measures, compared to only 6 respondents who stated that no such consultations take place. Furthermore, 65 respondents stated that draft SPS measures are shared systematically with other relevant parts of government; 34 said they are occasionally shared; while 13 respondents stated that draft SPS measures are rarely shared. Responses to this section also revealed that in some agencies, guidelines and procedures for consultations with other parts of government to prepare SPS measures do not exist (according to 27 respondents).
 - Section (ii) focused on the <u>linkages between international standards</u> (Codex, IPPC, OIE) <u>and SPS measures</u>. In their responses, 66 respondents stated that international standards are largely reflected in the SPS measures in their area. On whether any regulatory requirements exist to consider relevant international standards (Codex, IPPC, OIE) in the development of SPS measures, the majority of respondents (94) answered yes, that there were such requirements, 16 respondents stated no, and 8 respondents did not know.
 - In section (iii), 98 respondents stated that their government assessed the <u>risks to human</u>, <u>animal and plant life or health</u> when developing SPS measures, compared to 8 respondents who said these risks are not assessed, and 12 who did not know. In addition, according to 79 respondents, written guidelines to assess the risks to human, animal and plant life or health exist and are used to varying degrees. On the other hand, 13 respondents noted that written guidelines do not exist, while 6 stated that guidelines are under preparation.
 - Section (iv) focused on whether the <u>expected impact on trade</u> is assessed during the development of SPS measures. 84 out of 118 respondents stated that their government assesses the expected impact on trade in order to ensure that SPS measures are not more trade-restrictive than required to achieve the appropriate level of SPS protection. However, 20 respondents stated that the expected impact on trade is not considered, and 14 respondents did not know. As such, when compared with responses in section (iii), it seems that when developing SPS measures, there is slightly more focus on the assessment of risk to human, animal and plant health or life, than on expected trade impact.
 - Section (v) contained questions on information sharing and stakeholder consultations (e.g. private sector, industry groups, consumer groups, general public). A significant number of respondents (103) stated that their agency provides information and consults with stakeholders on SPS measures, while only 10 agencies do not inform or consult with stakeholders. Importers, exporters or traders are the most consulted domestic

stakeholders. Other governments are the most consulted foreign stakeholders. In total, 71 respondents stated that their agencies systematically consider stakeholder comments.

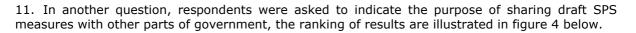
Section (vi) questioned whether reviews or evaluations are conducted to assess <u>how SPS</u> <u>measures are being implemented</u> and whether they are achieving their intended objective after entry into force. A total of 59 respondents stated that such reviews are conducted, with 33 among them noting that such reviews and evaluations are carried out systematically, while the remaining 26 respondents stated that reviews are occasionally conducted. However, only 16 respondents stated that findings from reviews and evaluations are systematically shared or published.

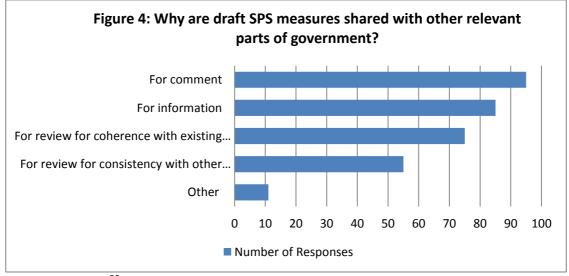
2 OVERVIEW OF RESPONSES

2.1 Consultations with Government Agencies

9. In total, 112 respondents stated that their agency consults with other government agencies within their country on the development of SPS measures, while only 6 respondents stated that their agencies do not. This includes consultations on both primary and/or secondary legislation, as well as diverse types of SPS measures, such as adoption of international (Codex, IPPC, OIE) standards, adoption of appropriate levels of protection (e.g. maximum residue levels for pesticides or veterinary drugs, maximum levels for chemical residues in food or feed), inspection or certification, setting administrative requirements and/or procedures domestically and/or the border, etc.

10. Among the 112 respondents to this section, 65 respondents stated that draft SPS measures are shared systematically with other relevant parts of government, 34 respondents said they are occasionally shared, while 13 respondents stated that their agencies rarely share draft SPS measures with other parts of government.

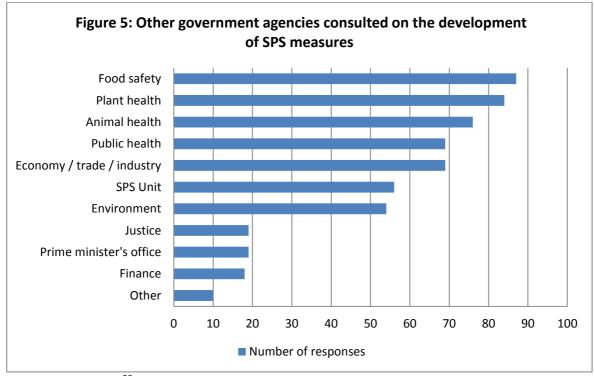




Source: STDF GRP Survey²⁸

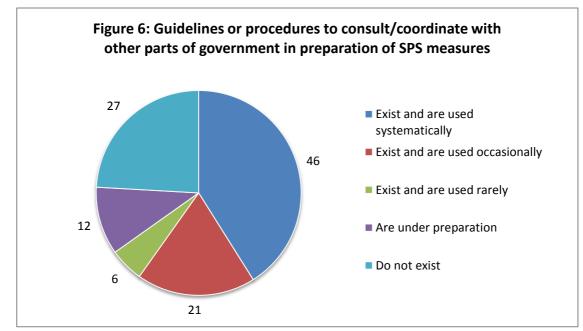
²⁸ This question allowed respondents to select as many answers as relevant.

12. Responses in this section also revealed that other relevant government agencies are consulted on the development of SPS measures. The results are presented in figure 5 below by ranking.



Source: STDF GRP Survey 29

13. In another question, 46 respondents stated that guidelines or procedures to consult and/or coordinate with other parts of government in preparation of SPS measures exist and are used systematically. Another 21 respondents stated that guidelines exist and are used occasionally, 6 said that they exist but are rarely used, while 12 respondents noted that such guidelines are under preparation. According to 27 respondents, such guidelines and procedures do not exist. Figure 6 below provides an illustration of these findings.



Source: STDF GRP Survey, based on 112 responses.

²⁹ This question allowed respondents to select as many answers as relevant.

14. Finally, 33 respondents provided additional examples on how their agencies consulted with government authorities on the preparation of SPS measures. Some examples are provided in Box 1 below.

15. Some African countries have set up committees to consult with other parts of government on the preparation of SPS measures. In Kenya for example, consultations to prepare animal health measures are said to be facilitated by a national SPS committee and national trade negotiation council, and a trade committee is used to support consultations for the preparation of plant health measures. In The Gambia, the respondent explained that the Ministry of Trade has set up a task force which includes all relevant stakeholders, to review and comment on all SPS Measures. This task force ensures that all relevant SPS institutions are consulted to ensure that measures are in line with current guidelines and legislations.

16. In Asia-Pacific, consultation methods reported in the survey tend to vary. For instance, the respondent from Papua New Guinea explained that Codex Standards, OIE & IPPC information are circulated to relevant stakeholders and private sector agencies. The respondent from Kiribati stated that consultations on food safety measures are often done through Codex Committee meetings. In Samoa, the respondent noted that relevant stakeholders are formally invited to consultations by the Chef Executive Officer. The respondent from India noted that consultations take place through an SPS/TBT cell established by the Government.

17. In Latin America and the Caribbean, consultation processes in some countries have been formally established. For example in Antigua and Barbuda, the Plant Protection Act No.8 of 2012 established a multi-sectoral board (including public and private sector stakeholder agencies) to recommend regulations to be made, to support the function of the NPPO. In El Salvador, consultations are said to be carried out systematically with representatives of the public sector, private sector, academia, consumers and NGOs. The procedure to prepare technical regulations (including SPS) in El Salvador is explained in a "Guía de Buenas Prácticas de Reglamentación Técnica" (available online).

Box 1: Examples of consultation with government authorities on the preparation of SPS Measures

Most often when such measures are being drafted, copies are sent to related ministries and agencies for their comments, which are incorporated before finally submitting it to cabinet/parliament for approval.

Au sujet des mesures SPS, un comité national SPS est créé par arrêté du premier ministre et regroupe tous les acteurs. (With regard to SPS measures, a national SPS committee has been created through a Prime Ministerial decree, bringing together all actors)³⁰

Se realizan reuniones en el marco de la mesa MSF, integradas por varios Ministerios y el Departamento Nacional de Planeación. (Meetings in the context of SPS coordination take place with the participation of various ministries and the national department for planning)

The consultation is often done through meetings, i.e. Codex committee meeting.

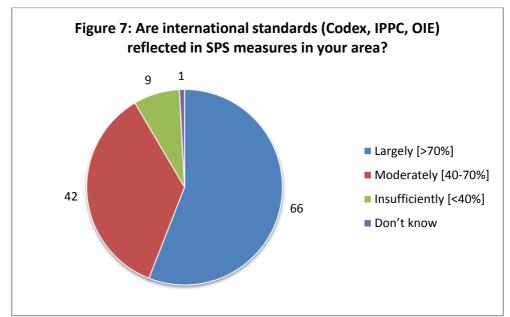
We have a National Codex Committee with regular meetings, and all these issues are discussed with all members of the Committee, private and public sector, NGO, other stakeholders.

Source: STDF GRP Survey

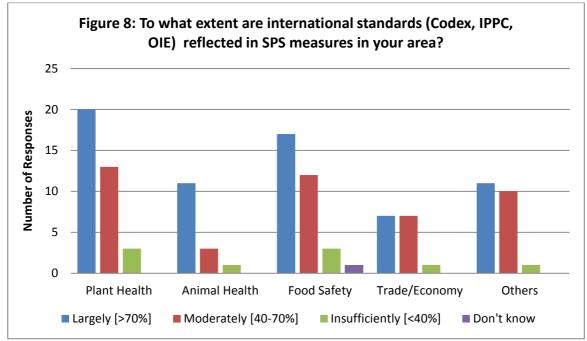
2.2 Linkages with International Standards

18. This section focused on the linkages between international standards (Codex, IPPC, OIE) and SPS measures. 66 out of 118 respondents stated that international standards are largely reflected (i.e. >70%) in SPS measures in their area of work. Another 42 respondents said that they are moderately reflected (40-70%), while 9 noted that they are insufficiently reflected (<40%), and 1 respondent was not sure (see figure 7). Figure 8 then demonstrates the extent to which international standards are reflected by SPS area.

³⁰ All translations by the STDF Secretariat.

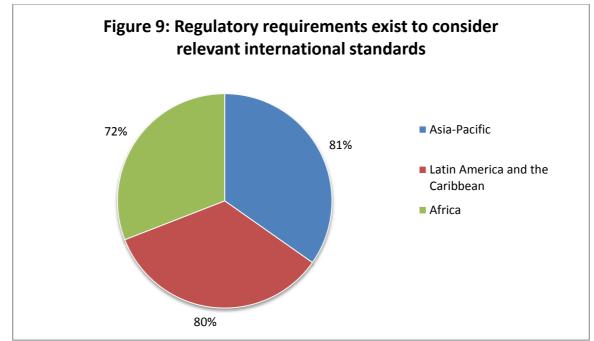


Source: STDF GRP Survey, based on 118 responses.



Source: STDF GRP Survey, based on 118 responses

19. In another question, respondents were asked whether any regulatory requirements exist to consider relevant international standards (Codex, IPPC, OIE) in the development of SPS measures. The majority of respondents (94) answered yes, that there are such regulatory requirements. 16 respondents stated no, and 8 respondents did not know. According to figure 9 below, 72% of respondents from Africa, 81% of the respondents from Asia-Pacific, and 80% of respondents from Latin America and the Caribbean, stated that regulatory requirements exist for the development of SPS measures. Across all three regions, guidelines exist in most respondent countries/territories to consider relevant international standards.



Source: STDF GRP Survey

20. In addition, 71 respondents provided further information on their experiences related to the adoption, adaptation and/or implementation of international standards. Some of these examples are included in Box 2 below.

Box 2: Experiences or challenges related to the adoption, adaptation and/or implementation of international standards

The OIE standards could be a challenge given the difficulty to implement, as it requires highly qualified human resource capacity which is a constraint to Small Island States.

Codex standards are adopted for enforcement as regulations but implementation can be difficult as the FBOs lack the required capacity to comply.

Compliance by smallholder farmers is a big challenge.

The implementation of national pest surveillance (ISPM 6) by African contracting parties are difficult due to limited and unqualified personnel; insufficient infrastructures and equipment; insufficient funds; and gap in knowledge sharing.

The challenges facing the institutions are very weak at technical level and the legislation are old not in line with modern practices. Lastly weak infrastructure of the institutions. At the policy level, low understanding of SPS agreement and other relevant information.

Source: STDF GRP Survey

21. In general, difficulties in understanding international standards (Codex, IPPC, OIE) seem to be one of the key barriers in adopting and implementing them. In the plant health area more specifically, some respondents mentioned challenges in the implementation of ISPMs 2, 3, 6, 7, 11, 12, 15, 26, 27, 31 and 36. In the animal health area, one respondent explained that OIE standards could be a challenge to implement as they require highly qualified human resource capacity. Another response made reference to the weak involvement of consumer associations and representatives of agri-food industries in the national SPS and Codex committees.

22. In the food safety area, experiences varied across regions. Several Latin America and Caribbean countries have formally adopted Codex standards, according to the responses. The Dominican Republic has so far harmonized national standards with over 150 Codex standards including those on the labeling of pre-packaged foods, MRLs for pesticides and veterinary drugs. In Costa Rica, the respondent states that national food safety standards are based on Codex

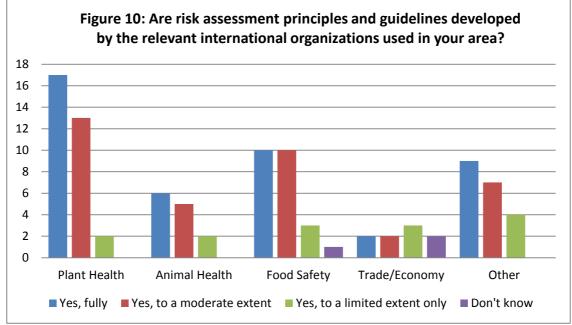
standards and by 2011, 53% of regulations were harmonized with Codex standards (of which 60.5% is total adoption and 39.5% is partial adoption). In Ecuador, authorities comply with pesticide MRLs set by Codex, and if Codex standards are unavailable, they comply with EU or US standards.

23. On the other hand, African countries have cited difficulties in implementing Codex standards related to limited operational structures and technical skills. One respondent from Asia-Pacific also mentioned challenges linked to variations between country specifications and proposed draft standards under Codex (for e.g. mycotoxins (aflatoxin) & pesticides in spices).

2.3 Assessment of risks to human, animal and plant life or health during the development of SPS measures

24. This section focused on the assessment of risks to human, animal, and plant life or health during the development of SPS measures. According to 98 respondents, these risks are assessed by their government during the development of SPS measures. On the other hand, 8 respondents stated their governments do not assess these risks, while 12 respondents did not know.

25. Among the 98 respondents who completed the remaining questions in this section, 59 stated that specific risks to human, animal, and plant life or health are assessed systematically, 27 noted that they are assessed occasionally, and according to 12 respondents, risks are rarely assessed. The extent to which risk assessment principles and guidelines developed by relevant international organizations are used, are illustrated in figure 10 below (grouped by number of responses per SPS area).



Source: STDF GRP Survey, based on a total of 98 responses.

26. Out of 98 respondents, 53 attributed responsibility for assessing the risks to human, animal and plant life or health to their own agency, while 45 stated that another government agency or specialized unit is responsible, including the ministry of agriculture, health and trade. Overall, the majority of respondents noted that assessments of risks to human/animal or plant health or life are done by various ministries and departments.

27. In another question, 48 respondents noted that written guidelines to assess the risks to human, animal and plant life or health exist and are used systematically. Another 28 respondents stated that such guidelines exist and are used occasionally, 6 stated that guidelines are under preparation, while 3 respondents said they exist but are rarely used. Finally, 13 respondents noted that written guidelines do not exist.

28. 50 respondents provided additional information on how risks to human, animal and plant health are assessed in the development of SPS measures. Some examples are provided in Box 3 below.

Box 3: Examples of how risks to human, animal and plant life or health are assessed in the development of SPS measures

Each Department has a risk assessment unit that deals with the specific issues at hand. Once the draft report is prepared, it is circulated to the Scientific Steering Committee for review and comments. Thereafter it is finalized. The reports are shared with the competent authorities of the respective country of export where applicable or with the relevant stakeholder.

Use IPPC PRA handbook, available legislation.

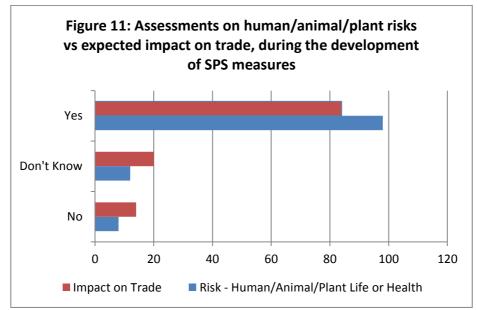
Use epidemiological data and laboratory reports.

The regulation defines the import conditions for animals and animal products. If importers want to import other goods, they have to provide sufficient information to allow a risk assessment.

Source: STDF GRP Survey

2.4 Assessment of the expected impact on trade during the development of SPS measures

29. During the development of SPS measures, 84 respondents stated that their government assesses the expected impact on trade in order to ensure that SPS measures are not more trade-restrictive than required to achieve the appropriate level of sanitary or phytosanitary protection. 20 respondents stated that the impact on trade is not considered, and 14 did not know. Interestingly, when comparing the results in sections (iii) and (iv), responses reveal that when developing SPS measures, there is slightly more focus on assessments of health risks than on trade impacts (see number of responses in figure 11).



Source: STDF GRP Survey, based on 118 responses.

30. Among the 84 respondents to this section, 57 noted that the potential impacts on trade are assessed systematically, 24 noted that they are occasionally assessed, and 3 said that they are rarely assessed. In another question on responsibility, 42 respondents stated that their agency is responsible for assessing the potential impacts of SPS measures on trade, while 42 respondents attributed this responsibility to another government agency or specialized unit, including ministries of agriculture, trade, health, or multi-agency approaches. In most cases, the ministries of trade or

economy were involved in the assessment of the expected impact on trade, either alone or in collaboration with other agencies.

31. According to 35 respondents, written guidelines/methodologies to assess the potential impacts of SPS measures on trade exist and are used systematically. Another 18 respondents said that they exist and are used occasionally, while 1 respondent stated that they exist but are rarely used. On the other hand, 22 respondents noted that such guidelines do not exist, and 8 noted that they were under preparation.

32. Finally, 40 respondents provided additional information on how expected trade impacts are assessed in the development of SPS measures (see Box 4).

Box 4: Examples of how expected trade impacts are assessed in the development of SPS measures

A trade representative as well as exporter/importer are members of the Plant Protection Board and hence would bring these concerns to the table when regulations are being developed.

En reuniones de análisis del acto administrativo se analizan dichas repercusiones. Al interior del Ministerio de Comercio se cuenta con instrumentos y personal para dicho análisis. (In meetings for the analysis of the administrative act, these effects are analyzed. Within the Ministry of Trade, instruments and personnel are available for this analysis)

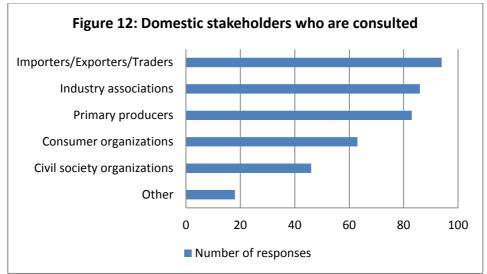
Des inspections phytosanitaires sont effectuées à l'importation comme à l'exportation: les produits agricoles non conformes à la réglementation subissent diverses situations allant du tri ou traitement à la destruction. On évalue les impacts commerciaux en se référant aux pertes subies, les interceptions... (Phytosanitary inspections are carried out both at import and export: agricultural products that do not comply with the regulations undergo various situations ranging from sorting or treatment to destruction. We evaluate the commercial impacts by referring to the losses suffered, the interceptions...)

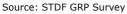
Source: STDF GRP Survey

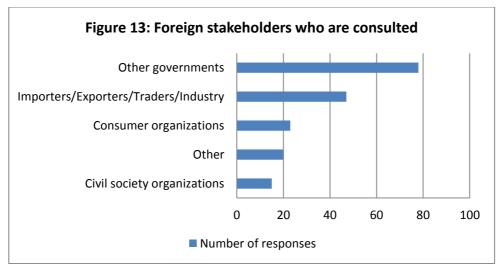
2.5 Information sharing and stakeholder consultations (private sector, industry groups, consumer groups, general public) on SPS measures

33. In total, 103 respondents stated that their agency provides information and consults with various stakeholders on SPS measures, 10 agencies did not inform or consult stakeholders, while 5 did not know whether consultations took place. Among the 103 respondents to this section, 42 stated that public consultation takes place systematically, 45 said it takes place occasionally, and 16 said that public consultation rarely takes place. Figures 12 and 13 provide an illustration of the domestic and foreign stakeholders who are consulted by ranking.³¹ In the animal health area, most additional responses explained that consultations with foreign stakeholders take place through WTO notifications.

³¹ These questions allowed respondents to select as many answers as relevant.







Source: STDF GRP Survey

34. In this same section, respondents were then asked four specific questions on how consultations functioned in practice and the use and publication of findings. The first question asked whether guidelines or procedures exist to consult stakeholders in their sector. 44 out of 103 respondents stated that such guidelines exist and are used systematically, 26 said that they exist but are used occasionally, 5 said they are under preparation, and 1 said they exist but are rarely used. Another 27 respondents stated that such guidelines/procedures do not exist.

35. The second question asked whether comments were received from stakeholders on draft SPS measures. 41 out of 103 respondents said that comments are systematically received, and 43 said that they are occasionally received. According to 15 respondents, comments are rarely received from stakeholders, and 2 respondents noted that comments are never received.

36. Respondents were also asked whether comments received from stakeholders on draft SPS measures were considered by their agency: 71 out of 103 respondents stated that comments are systematically considered; 28 respondents said that comments are occasionally considered; 3 stated that they are rarely considered. Only 1 respondent said that stakeholder comments are never considered.

37. The fourth question focused on whether responses to comments received from stakeholders on draft SPS measures were published. 29 out of 103 respondents stated that responses to stakeholder comments are systematically published; 25 others said that they are occasionally published; and another 25 respondents said that they are rarely published. 24 respondents stated that responses to stakeholder comments are never published.

38. Finally, 49 respondents provided additional relevant information on their experiences with consultations in practice, for instance on addressing methods, challenges, results. Some examples are included in Box 5 below.

Box 5: Experiences with consultations in practice

Les consultations se feront à travers des questionnaires sous forme d'enquête et à travers des groupements de producteurs ou d'agriculteurs existant dans les 570 sections communales du pays au moyen de téléphones portables. (Consultations take place via mobile phone surveys for groups of producers or farmers in the 570 communal sections of the country)

There are basically, no laid down procedures or guidelines for consultations in such matters. It is just a norm that my Ministry consults other stakeholders but due to financial constraints, there is that likelihood that not all stakeholders are consulted for their comments.

Consultations as per our regulation are limited to consulting with the competent authority of the country of export and the potential exporter for the risk assessment process. The draft report is sent to them for their review; they have 60 days in which to respond and thereafter the report is finalized. For regulations/legal instruments, national consultations are mandatory. No draft regulation will be considered by Parliament if it is not accompanied by evidence that consultations were held and the comments received during consultations.

Information about consultations is made public and can be checked at the legal department

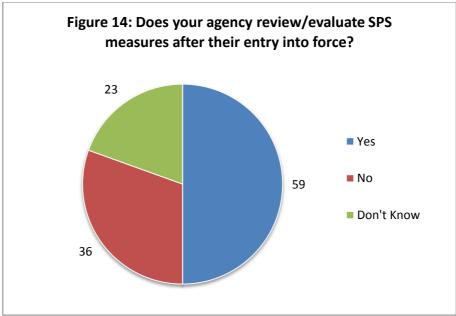
Avec le comité national SPS, des réunions se tiennent au moins 3 fois par année pour identifier les problèmes et chercher des solutions, etc. (With the SPS National Committee, meetings are held at least 3 times a year to identify problems and seek solutions, etc.)

La mayor dificultad viene en el poco conocimiento y diferenciación que existe en la comunidad en general respecto a una medida MSF y una establecida en virtud del Acuerdo sobre Obstáculos al Comercio - OTC. En el mismo sentido, las observaciones son realizadas de manera poco objetiva tendiendo a la protección de los intereses de un sector específico. (The greatest difficulty comes from the lack of awareness and differentiation that exists in the wider community with respect to an SPS measure and one established under the TBT Agreement. In the same sense, observations made are not very objective and lean towards the protection of interests of a specific sector)

Source: STDF GRP Survey

2.6 Review/evaluation of the implementation of SPS measures after entry into force

39. Out of 118 respondents, 59 stated that reviews/evaluations are carried out after an SPS measure enters into force, to assess how the measures (individually or as a group) are being implemented, and whether they are achieving the intended objective. Another 36 respondents stated that such evaluations are not carried out, and 23 respondents did not know (see figure 14). Among the 59 respondents, there were 19 from plant health agencies, 9 from animal health agencies, 16 from food safety agencies, 3 from trade/economy agencies and 12 from other agencies. With only 59 positive responses, the questions in section (vi) had the lowest overall response rate in this survey. This may suggest that respondents are less knowledgeable about whether or not a review of SPS measures is carried out, which may indicate that less attention is paid to this than to some of the other areas addressed in the survey.

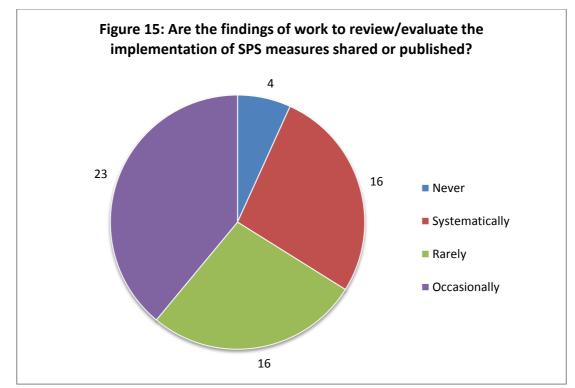


Source: STDF GRP Survey, based on 118 responses.

40. Among the 59 respondents to this section, the implementation of SPS measures is said to be reviewed and evaluated systematically according to 33 respondents (13 from plant health agencies, 7 from food safety agencies, 5 from animal health agencies, 3 from trade/economy agencies and 5 from others). Measures are occasionally reviewed according to 26 respondents. In another question, 38 respondents stated that their agency is responsible for reviewing or evaluating the implementation of SPS measures and whether they are achieving the intended objectives, while 21 stated that this is the responsibility of another government agency or specialized unit including the ministry of foreign affairs in collaboration with quarantine, ministry of economy, health, agriculture, trade and the NPPO.

41. According to 24 respondents, guidelines or procedures to review and/or evaluate the implementation of SPS measures exist and are used systematically. Another 18 respondents said they exist and are used occasionally while 3 responses indicated that they exist but are rarely used. According to another 10 respondents (mostly from food safety agencies), such guidelines/procedures did not exist, while 4 respondents stated that such guidelines/procedures are under preparation.

42. Respondents were then asked whether the findings of work to review and/or evaluate the implementation of SPS measures are shared or published. Among the 59 respondents, 23 noted that findings are occasionally published, 16 said that findings are published systematically, and another 16 stated that they are rarely published (see figure 15 below). Only 4 respondents (3 from Latin America and the Caribbean and 1 from Asia-Pacific) stated that findings are never published.



Source: STDF GRP Survey, based on 59 responses.

43. Some examples on how respondent agencies follow up on work to review and evaluate the implementation of SPS measures are provided in Box 6 below. Overall, responses show that in the animal health area, follow-up is done mainly through consultations and according to one respondent, by using the OIE Terrestrial Code for reference. In the food safety area, follow-up methods reported tend to vary (e.g. surveys, meetings, consultations). However, in the plant health area, most respondents note that their countries have monitoring mechanisms for follow-up.

Box 6: Examples of how agencies follow-up on work to review and/or evaluate the implementation of SPS measures

En se basant sur les normes du code sanitaire pour les animaux terrestres de l'OIE concernant les produits animaux et celle de la CIPV pour les produits végétaux comme cadre de référence. (Based on the standards of the OIE Terrestrial Animal Health Code and the IPPC Standard for plant products as a frame of reference.)

Our agency reviews the annual statistic import data and cases to determine the effect and evaluate the implementation.

Suivi des inspecteurs phytosanitaires dans les postes de contrôle frontaliers, la surveillance dans les parcelles de production, suivi auprès des autres acteurs impliqués. (Follow-up with phytosanitary inspectors at border control posts, surveillance in production plots, follow-up with other actors involved)

Durante la aplicación de la reglamentación por parte de las autoridades sanitarias, se realiza el seguimiento de la aplicación de las medidas. Los sectores y en general el público puede realizar las observaciones a dicha reglamentación. (During the implementation of the regulation by the health authorities, the implementation of measures is monitored. The sectors and the public in general can comment on said regulation)

44. Overall, most respondents in the animal and plant health areas indicate that stakeholders can request reviews of SPS measures. The respondent from Ecuador also shared an <u>online platform</u> through which consultations can take place. In total, some 28 respondents provided additional

Source: STDF GRP Survey

information on how SPS measures are reviewed and whether stakeholders can request a review (see examples in Box 7).

Box 7: Examples of how SPS measures are reviewed and whether stakeholders can request a review

By legislation measures should be reviewed every 3 years but in practices the agency tries to ensure it is done every 5 years. There is a back log and with limited human resources this will always be a challenge.

Always international counter-parts query some SPS issue through notification and allow for us to respond in remedial actions to resolve the SPS issue.

Los usuarios en general presentan demandas para conocer sobre la reglamentación vigente y su aplicación, donde realizan sus observaciones y mejoras a realizar. (Users in general present requests to find out about the current regulation and its application, and where observations and improvements are to be made)

Les parties prenantes ont toujours le droit de demander une contre-expertise si elles estiment être lésées par l'application des mesures SPS, particulièrement en ce qui concerne les analyses de laboratoire qui peuvent être réalisées tant sur les produits d'origine animale que sur les produits d'origine végétale. (Stakeholders always have the right to ask for a second opinion if they believe that it is prejudiced by the application of SPS measures, particularly with regard to laboratory analyses that can be carried out on both animal products and products of plant origin.)

Source: STDF GRP Survey

Countries/Territories in which survey respondents were based

Albania; Algeria; Antigua and Barbuda; Argentina; Azerbaijan; Bahrain; Belize; Bolivia; Burkina Faso; Cambodia; Cameroon; Chile; People's Republic of China; Colombia; Comoros; Costa Rica; Dominican Republic; Ecuador; Egypt; El Salvador; Ethiopia; Fiji; France; French Polynesia; Gambia; Georgia; Ghana; Grenada; Guatemala; Guyana; Haiti; Honduras; India; Kazakhstan; Kenya; Kiribati; Liberia; Madagascar; Malawi; Mauritius; Mexico; Moldova; Montenegro; Mozambique; Nepal; New Caledonia; New Zealand; Papua New Guinea; Philippines; Chinese Taipei³²; Samoa; Senegal; Sierra Leone; Singapore; Sri Lanka; Tajikistan; East Timor; Togo; Tonga; Trinidad and Tobago; United Arab Emirates; United States of America; Uruguay; Yemen

³² Chinese Taipei is a WTO Member in application of Article XII of the Marrakesh Agreement (1994). WTO membership has no implication regarding the sovereignty of the Member pursuant to international law.