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

SUMMARY REPORT OF RESPONSES TO STDF GRP SURVEY

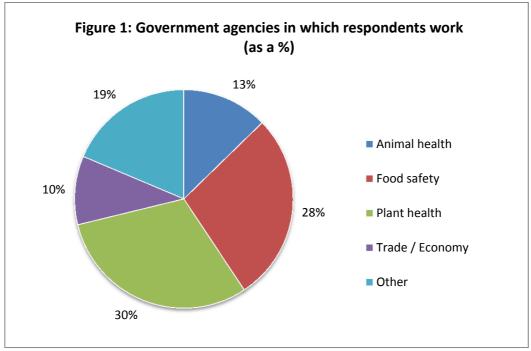
EXECUTIVE SUMMARY

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.

In March 2017, the STDF Working Group discussed possible work by the STDF on GRP (see STDF Concept Note). 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.

In October 2017, the STDF Secretariat conducted the online GRP survey in English (see Annex 2), 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.

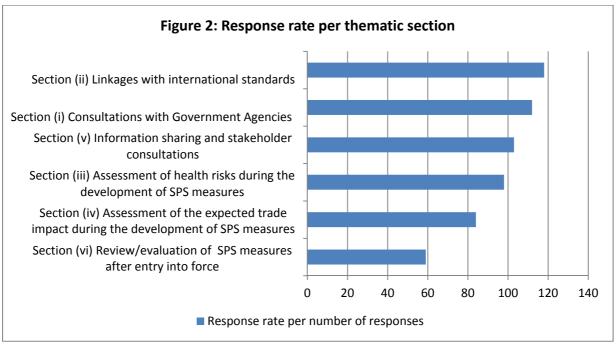
Information on the online STDF GRP survey was distributed widely by email, with the support of FAO (including the Codex and IPPC Secretariats), OIE and the WTO SPS Unit. In total, the online survey was completed by 118 officials in government ministries/agencies/departments based in 64 countries/territories. 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 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).



¹ See list in Annex 1. At the close of the survey, approximately 80 surveys on the online database were incomplete and are not included in this report.

This report provides a summary of the responses to the STDF GRP survey. Responses will be summarized in 6 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.

As illustrated in figure 2, 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 2).



Source: STDF GRP Survey

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) and SPS measures. 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 <u>information sharing and stakeholder consultations</u> (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 how SPS measures are being implemented 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.

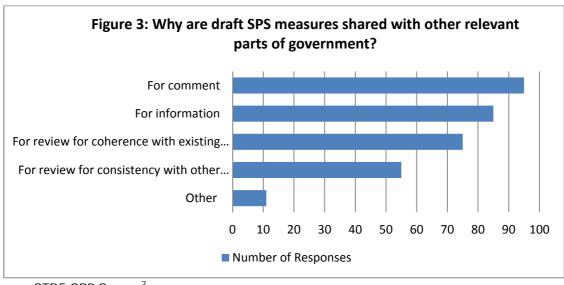
OVERVIEW OF RESPONSES

I. Consultations with Government Agencies

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.

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.

In another question, respondents were asked to indicate the purpose of sharing draft SPS measures with other parts of government, the ranking of results are illustrated in figure 3 below.



Source: STDF GRP Survey²

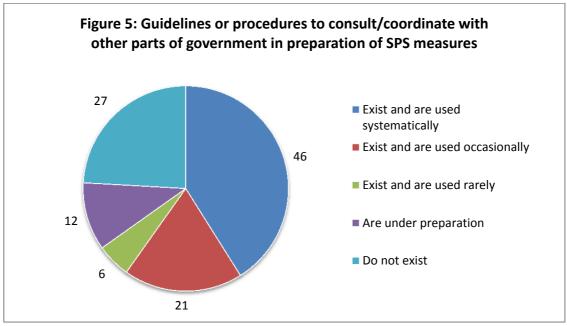
² This question allowed respondents to select as many answers as relevant.

Figure 4: Other government agencies consulted on the development of SPS measures Food safety Plant health Animal health Public health Economy / trade / industry SPS Unit Environment Justice Prime minister's office **Finance** Other 100 0 10 30 40 50 60 70 80 90 20 ■ Number of responses

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 4 below by ranking.

Source: STDF GRP Survey³

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 5 below provides an illustration of these findings.



Source: STDF GRP Survey, based on 112 responses.

³ This question allowed respondents to select as many answers as relevant.

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.

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)⁴

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)

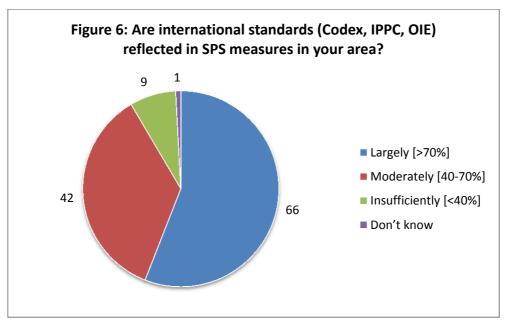
The consultation is often done through meetings, i.e. Codex committee meeting.

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

II. Linkages with International Standards

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 6).



Source: STDF GRP Survey, based on 118 responses.

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.

⁴ All translations by the STDF Secretariat.

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.

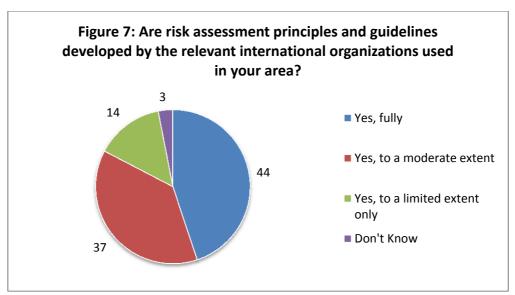
The challenges facing the institutions are very weak at technical level and the legislation are old not in line with modern practices. Lastly weak infrastructure of the institutions. At the policy level, low understanding of SPS agreement and other relevant information.

Source: STDF GRP Survey

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

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.

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 7 below.



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

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. 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.

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.

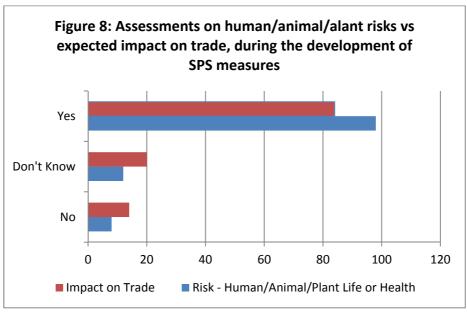
Use epidemiological data and laboratory reports.

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

IV. Assessment of the expected impact on trade during the development of SPS measures

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 8).



Source: STDF GRP Survey, based on 118 responses.

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.

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.

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.

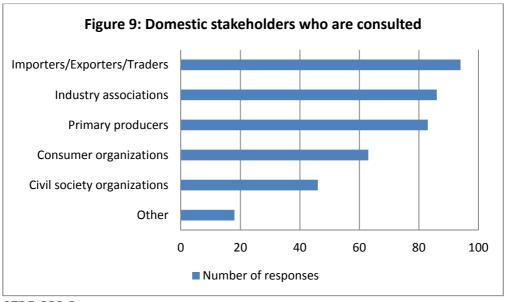
En reuniones de análisis del acto administrativo se analizan dichas repercusiones. Al interior del Ministerio de Comercio se cuenta con instrumentos y personal para dicho análisis. (In meetings for the analysis of the administrative act, these effects are analyzed. Within the Ministry of Trade, instruments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

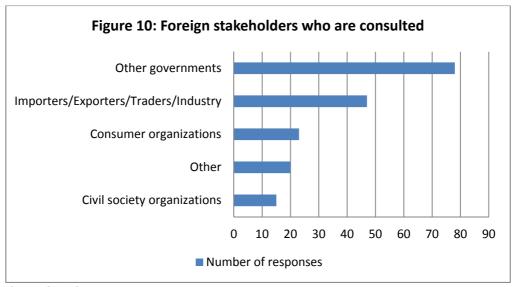
Source: STDF GRP Survey

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

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 9 and 10 provide an illustration of the domestic and foreign stakeholders who are consulted by ranking.⁵



⁵ These questions allowed respondents to select as many answers as relevant.



Source: STDF GRP Survey

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.

Another 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.

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.

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.

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

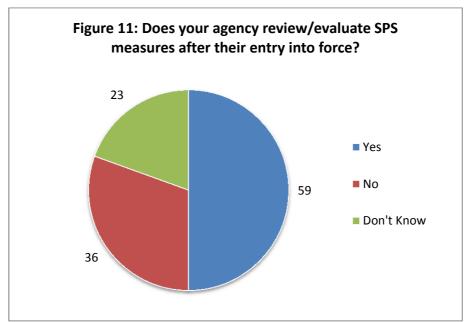
Avec le comité national SPS, des réunions se tiennent au moins 3 fois par année pour identifier les problèmes et chercher des solutions, etc. (With the SPS National Committee, meetings are held at least 3 times a year to identify problems and seek solutions, etc.)

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

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

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 do not know (see figure 11). 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.



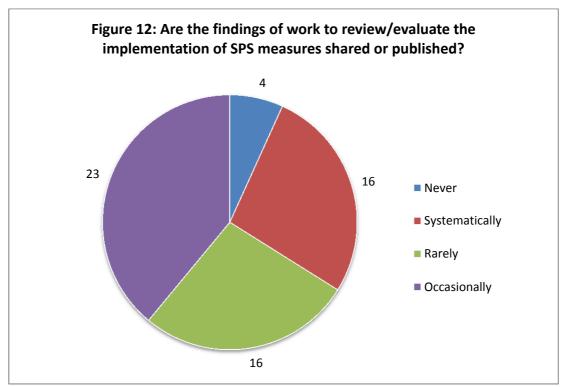
Source: STDF GRP Survey, based on 118 responses.

Among the 59 respondents to this section, the implementation of SPS measures is said to be reviewed and evaluated systematically according to 33 respondents, and occasionally 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.

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, such guidelines/procedures did not exist, while 4 respondents stated that such guidelines/procedures are under preparation.

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. Only 4 respondents stated that findings are never published (see figure 12 below).



Source: STDF GRP Survey, based on 59 responses.

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.

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)

Finally, 28 respondents provided additional information on how SPS measures are reviewed and whether stakeholders can request a review (see 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.)

ANNEX 1

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 Taipei⁶; Samoa; Senegal; Sierra Leone; Singapore; Sri Lanka; Tajikistan; East Timor; Togo; Tonga; Trinidad and Tobago; United Arab Emirates; United States of America; Uruguay; Yemen

⁶ 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.