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Good regulatory practices to improve SPS measures: A practical guide

Food and Agriculture Organization of the United Nations | WORLD ORGANISATION FOR ANIMAL HEALTH *Protecting animals, preserving our future* | WORLD BANK GROUP | World Health Organization | WORLD TRADE ORGANIZATION

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Snapshot of the GRP guide

Why a Guide on Good Regulatory Practices in the SPS area?

All countries maintain sanitary and phytosanitary (SPS) measures to ensure that food is safe for consumers and to prevent the spread of pests or diseases among animals and plants. Good Regulatory Practices (GRPs) are processes and tools to help improve the quality and effectiveness of SPS measures so that they achieve the expected policy outcome(s). This Guide aims to help SPS regulators in developing countries use GRPs to improve SPS measures and facilitate safe trade.

Who should use this Guide?

The Guide is targeted at government officials responsible for the development, oversight and/or implementation of sanitary and phytosanitary measures in developing countries. Users may also include officials in ministries, legislatures, oversight bodies tasked with GRPs, or other stakeholders supporting the development, review and/or implementation of SPS measures.

Why do GRPs matter for SPS authorities?

GRPs offer practical tools and processes to improve SPS measures and ensure they are fit for purpose. GRPs help ensure that SPS measures facilitate trade while ensuring adequate health protection, strengthening compliance with international standards (Codex, IPPC and OIE) and SPS requirements in line with the WTO SPS Agreement.

What are the benefits of GRPs for the public and private sector?

- Better designed SPS measures based on international standards.
- Improved understanding of, and greater compliance with, SPS measures.
- Reduced cost and administrative burden of SPS measures.
- Increased trust of the private sector and consumers in regulatory processes.
- Enhanced confidence of trading partners and investors.

What kinds of GRPs exist?

- *Tools to take stock of SPS measures* to check if new/revised SPS measures are required and ensure that SPS requirements fit well in the overall regulatory framework, are not duplicative or contradict existing SPS measures.
- *Forward-looking regulatory agendas* to plan ahead, allocate resources where they are most needed, and link new/revised SPS measures to broader policy initiatives.
- *Regulatory impact assessments (RIAs)* to assess regulatory and non-regulatory alternatives based on robust quantitative and qualitative analysis, and select the option that yields the greatest net benefit.
- *Coordination and cooperation mechanisms* to foster multi-sectoral responses to SPS risks in support of One Health, consider the impacts of SPS measures beyond domestic borders, ensure quality control of regulatory processes, base SPS measures on relevant SPS international standards, as well as take into account relevant regional SPS obligations and standards.
- *Transparency and stakeholder engagement* to promote trust and confidence in SPS regulatory processes, enhance understanding of and compliance with SPS measures and ensure that SPS measures adequately reflect the particular context and needs.
- *Monitoring and evaluation* to keep track of the implementation and performance of SPS measures, assess their effectiveness and efficiency, and make adjustments as needed.

Which GRPs are right for your context?

Various GRP tools and processes can be used, depending on the national context and resources available.

Are current SPS measures adequate?	• Taking stock of existing SPS measures based on international standards • Transparency, stakeholder engagement • Inter-agency cooperation • International regulatory cooperation
How to plan for SPS regulatory changes?	• Forward-looking agenda • Transparency, stakeholder engagement • Inter-agency cooperation
What SPS regulatory options exist?	• RIA • International standards • Transparency, stakeholder engagement • Inter-agency cooperation • International regulatory cooperation
How to develop new SPS measures?	• Stocktaking and RIA • Transparency, stakeholder engagement, information dissemination
Does the new/ revised SPS measure achieve its objective?	• Monitoring and evaluation • Transparency, stakeholder engagement • Intenational standards • International regulatory cooperation • Inter-agency cooperation

How can you use this Guide?

1

Learn about GRPs and how they can be used to improve the development and implementation of SPS measures and facilitate safe trade.

2

Understand how GRPs have been applied in the SPS area, as well as results and experiences.

3

Select GRPs that could fit your needs and follow the steps to roll them out.

4

Find links to other useful resources, tools and manuals.

Introduction

Good Regulatory Practices (GRPs) are internationally recognized processes, systems, tools, and methods used to improve the quality of regulatory measures and ensure that regulatory outcomes are effective, transparent, inclusive, and sustained. GRPs support better policy making by allowing trade, economic, health, and other possible impacts of regulation to be properly considered. GRPs ensure that regulations are fit for purpose, do not impose unnecessary costs or administrative burden, and are more easily enforced. Beyond improving policy outcomes, GRPs encourage good governance and have the potential of increasing public trust as well as investor and trading partners' confidence in the long run.

GRPs can improve and strengthen the design, development, and review of SPS measures. In a nutshell, SPS regulators can rely on GRPs to assist them in selecting the *most appropriate* SPS measure so that the expected policy objective(s) can be achieved. GRPs do not add an additional layer of substantive requirements for SPS regulators. Rather, they offer process-based tools to ensure that SPS measures are "fit for purpose" so that they protect human, animal, or plant life or health, without creating unnecessary barriers to trade.

Using GRPs improves compliance with the WTO Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures (WTO SPS Agreement)[1], including greater alignment with international standards for food safety, animal and plant health (see Box 2). GRPs are also relevant for other international and regional trade agreements, which increasingly include specific GRPs as binding SPS obligations.[2]

There is no single, ideal GRP implementation model for countries to replicate. GRPs incorporate internal coordination of regulation ("whole-of-government" approach), international regulatory cooperation, consultations and other forms of stakeholder engagement, mechanisms to take stock of existing regulatory measures, forward-looking regulatory agendas, regulatory impact assessments (RIAs), and monitoring or evaluation tools.

[1] The WTO SPS Agreement sets out the basic rules and disciplines for SPS measures. It aims to achieve a balance between the right of WTO Members to implement legitimate health protection policies and the goal of allowing the smooth flow of goods across international borders without unnecessary restrictions.

[2] For example, through transparency or consultation requirements. See Kauffmann, C. and C. Saffirio (2021), "Good regulatory practices and co-operation in trade agreements: A historical perspective and stocktaking", *OECD Regulatory Policy Working Papers*, No. 14, OECD Publishing, Paris.

BOX 1.

SPS measures

In the WTO, sanitary (human and animal health) and phytosanitary (plant health) measures refer to measures whose purpose is to protect:

- human or animal health from foodborne risks;
- human health from animal- or plant-carried diseases;
- animals and plants from pests or diseases; or
- the territory of a country from damage caused by pest.

SPS measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.

SPS measures typically deal with:

- additives, contaminants, poisonous substances, or residues of veterinary drugs or pesticides in food or drink
- certification: food safety, animal or plant health
- processing methods with implications for food safety
- labelling requirements directly related to food safety
- plant/animal quarantine
- declaring areas free from pests or disease
- preventing disease or pests spreading to a country
- other sanitary requirements for imports, e.g. imported pallets used to transport animals

Source: The WTO Agreements Series, Sanitary and Phytosanitary Measures

BOX 2.

GRPs and the WTO SPS Agreement

Through the WTO SPS Agreement, the WTO defines the rights and responsibilities of WTO Members with respect to food safety and plant and animal health measures that impact trade. The WTO SPS Agreement promotes GRPs through mechanisms for cooperation on regulation, such as harmonization, strongly encouraging WTO Members to use relevant international standards as a basis for SPS measures. These are the international standards of FAO/WHO Codex Alimentarius Commission (Codex) for food safety, the World Organisation for Animal Health (OIE) for animal health and zoonoses, and the International Plant Protection Convention (IPPC) for plant health. The WTO SPS Agreement also promotes GRPs through transparency and notification requirements, in particular the requirement to notify proposed measures and provide an opportunity to comment.

See Annex 4 on how GRPs support key disciplines of the WTO SPS Agreement

Although extensive literature exists on GRPs, tailored information on GRPs in the SPS context is missing. The Standards and Trade Development Facility (STDF) has developed this Guide to address this gap, as part of its knowledge workstream linked to the STDF Strategy for 2020-2024. Drawing on the technical expertise of STDF members, STDF knowledge work aims to identify and promote good practices to influence and support SPS capacity development and facilitate safe trade.

The Guide draws upon the experiences of several developed and developing countries and the work of STDF partners (including the Food and Agriculture Organization of the United Nations (FAO), the World Trade Organization (WTO), and the World Bank Group) as well as other stakeholders, such as the Organisation for Economic Co-operation and Development (OECD), the Inter-American Institute for Cooperation on Agriculture (IICA), and the Asia-Pacific Economic Cooperation (APEC).

The Guide is targeted primarily at country-level SPS regulators in developing countries, specifically officials responsible for the development, oversight and/or implementation of food safety, animal and/or plant health measures that are relevant for trade. It is a handbook to navigate and use GRPs when designing, developing, and reviewing SPS measures. It may also be used to support the development and/or implementation of capacity development projects at the national or regional level, supported by the STDF[3] or other partners.

This Guide provides practical guidance on:

- Where to start with GRPs in the SPS context, even when resources are limited;
- Step-by-step suggestions for SPS regulators to use GRPs when designing, developing, and reviewing SPS measures; and
- Where to find key resource materials to assist SPS regulators in the implementation of GRPs.

Real-life examples of the use of GRPs in developed and developing countries are referred to throughout this Guide. In addition, a case study describes how GRPs may help in the SPS area in a fictitious developing country (Pluto). This case study offers a simple illustration of the context, challenges, and issues that SPS regulators face in many developing countries.

This Guide is complemented by a list of acronyms (Annex 1), an explanation of key terms as used in this Guide (Annex 2), a list of useful resources on GRPs (Annex 3), as well as further details on how GRPs support key disciplines of the WTO SPS Agreement (Annex 4).

1

Part 1 provides guidance to get started with GRPs in the SPS area. It highlights the benefits of using GRPs and suggests a step-by-step approach depending on country context. The aim is to help SPS regulators understand how GRPs may improve their regulatory processes and help them achieve better SPS results.

2

Part 2 provides practical information on how key GRPs work in the SPS context, how they can be adjusted depending on capacity constraints, and where to find additional resources and guidance to develop their use. It includes a roadmap to help SPS regulators navigate GRPs in the SPS area (Figure 3) and focuses on selected GRPs with step-by-step suggestions on how to use them.

[3] For more on how to access STDF funding opportunities, see http://www.standardsfacility.org/funding.

1 Getting started with GRPs in the SPS area

SPS regulators in developing countries may wish to consider certain key steps to get started with or develop their use of GRPs (Figure 1). The suggested starting point is to understand the value of GRPs in the SPS context. Next, the existing GRP framework can be assessed to identify GRPs that SPS regulators may be required or encouraged to use. This would allow SPS regulators to consider how best to roll out GRPs and raise awareness within their governments and among private sector stakeholders to ensure proper implementation of GRPs going forward.

Figure 1. Getting started with GRPs in the SPS area

BOX 3.

What are GRPs?

Good Regulatory Practices (GRPs) are internationally recognized processes, systems, tools, and methods used to improve the quality of regulatory measures and ensure that regulatory outcomes are effective, transparent, inclusive, and sustained. GRPs ensure that regulations are fit for purpose and meet the intended policy objective(s).

A variety of different terms may be used to refer to GRPs, including: Regulatory principles, Regulatory quality, Better regulation, Smart regulation, Paperwork reduction, Regulatory management, Regulatory improvement, Simplification, etc.

International frameworks on GRPs include:

- OECD 2012 Recommendation on Regulatory Policy and Governance
- APEC-OECD Integrated Checklist on Regulatory Reform

1

Understand how GRPs may help in the SPS context

GRPs improve processes associated with the design, development, and review of SPS measures, with various benefits for governments and the private sector. Benefits include ensuring that the adopted SPS measure achieves the intended policy objective(s) without creating unnecessary barriers to trade. GRPs play an important role in promoting effective and efficient SPS systems while mitigating costs. They also generally support better policy making by allowing for various factors to be properly considered when SPS measures are developed and implemented. This includes trade, economic, and health factors, but may also incorporate environmental, social, gender and other factors, as appropriate.

Use of GRPs contributes to greater alignment with international standards and compliance with the WTO SPS Agreement (Annex 4). This helps countries provide effective responses to SPS issues. GRPs also support international regulatory cooperation by promoting transparency, dialogue and harmonization of SPS measures based on international standards. In the same vein, GRPs contribute to greater alignment with SPS-related obligations in trade agreements and support regional SPS cooperation.

GRPs also encourage greater public/private sector cooperation. Appropriate private sector engagement can assist in identifying emerging issues as well as challenges and opportunities of SPS measures. It also fosters a better understanding of SPS measures among those who will need to comply with the SPS requirements. Engaging particular groups that may be affected by the SPS measure (such as Micro, Small and Medium Enterprises (MSMEs)[4]) helps identify the challenges that they face at an early stage. These challenges can then be addressed in the design or implementation of the SPS measure. Regulatory burdens can be minimized and greater compliance with SPS measures can be achieved by identifying challenges early on, sharing information, and adjusting SPS requirements or implementation efforts. One-stop shops / single-entry points or digital tools to obtain information or permits are popular examples of how regulatory burden can be minimized. Enforcement challenges can be minimized by allowing for longer compliance periods and more time for stakeholders to adapt to SPS requirements or providing institutional support to certain stakeholders.

Proper application of GRPs in the SPS area is likely to have important additional benefits, such as enhancing good governance including transparency, predictability, and accountability of regulatory decision-making. Other important positive knock-on effects include facilitating safe trade and encouraging inclusive trade. This is likely to contribute to improving generally the regulatory and investment climate in developing countries, thereby stimulating private sector investment, sustainable economic growth, and poverty reduction.

Key success factors to implement GRPs in the SPS area include: strong political support, adopting a whole-of-government approach by considering how GRPs are used in other sectors, getting the support of an oversight body that may be tasked with GRPs, and relying on international cooperation at a bilateral, regional, or multilateral level.

BOX 4.

How can GRPs help SPS regulators?

Select the *most appropriate* SPS measure	GRPs help SPS regulators assess regulatory options to choose the most appropriate and least-trade restrictive SPS measure.
Understand diverse (intended and unintended) impacts of SPS measures	GRPs help SPS regulators critically assess trade, economic, and health aspects of SPS measures, as well as environmental, social, gender and other aspects, as relevant. For instance, to consider how an SPS measure may influence value-addition, agriculture-based livelihoods, or women's participation in value chains.
Increase efficiency and effectiveness of SPS systems	GRPs help to identify and address overlaps and gaps in SPS regulatory frameworks, which also reduces the administrative burden of SPS systems.
Improve compliance with SPS measures	GRPs provide opportunities for public and private sector stakeholders to comment on SPS requirements, which helps to improve understanding and compliance.
Use international standards and align with international SPS provisions	GRPs foster greater alignment with international standards, reinforce compliance with and benefit from the WTO SPS Agreement (Annex 4) and trade agreements.
Mitigate costs	GRPs help to assess the costs associated with SPS requirements and select the most cost-efficient SPS measure. GRPs also help to assess risks early on and plan contingency strategies. By fostering better compliance with SPS measures, they contribute to reducing enforcement costs.
Encourage inclusive SPS policies and inclusive trade	GRPs allow for the consideration of cross-cutting issues, taking into account the interests of MSMEs, youth, small farmers, women and other groups.
Enhance good governance and inter-agency cooperation	GRPs contribute to data-driven and evidence-based policy making based on the domestic legal tradition and institutional framework. This encourages synergies between SPS measures and broader regulatory systems and initiatives, from a whole-of-government perspective.

[4] For more information on how GRPs can support MSMEs, see OECD. 2018. Good Regulatory Practices to Support Small and Medium Enterprises in Southeast Asia.

BOX 5.

Pluto case study: Which GRPs are right for Pluto's needs?

Pluto is a low-income country facing several SPS challenges. The agri-food sector is important for regional trade, poverty reduction and economic growth. However, SPS capacity is weak. The SPS authorities have heard that GRPs can help them reform and streamline their SPS measures to improve compliance, and are trying to figure out which GRPs could be used.

SITUATION/CHALLENGE IN PLUTO	WHICH GRPs COULD HELP?
SPS agencies would like to impress on the decision makers the importance of investing in SPS capacity.	• Coordination and cooperation • Forward-looking regulatory agenda • Transparency and stakeholder engagement
Pluto developed and implemented many SPS measures over the years. It is unclear if all of them are still needed.	• Taking stock of SPS measures • Monitoring and evaluation • Coordination and cooperation
SPS regulators in Pluto are preparing to revise certain SPS measures. They do not know who to involve as there are many public and private sector actors, with different needs and objectives. Private sector actors often complain that they do not know what/when regulatory changes are made.	• Forward-looking regulatory agenda • Transparency and stakeholder engagement • Coordination and cooperation
Some of Pluto's development partners are focused on non-tariff measures (NTMs) affecting trade. SPS measures account for a large percentage of Pluto's NTMs. The Prime Minister's Office has asked several SPS agencies to fix the problem, but they do not know where to start.	• Taking stock of SPS measures • Forward-looking regulatory agenda • Monitoring and evaluation • Transparency and stakeholder engagement • Coordination and cooperation
Key private sector actors raised issues of lack of transparency of Pluto's regulatory process in the media. It was said that certain SPS measures are not in the form of written rules, and it is difficult to know if they need to be complied with.	• Taking stock of SPS measures • Transparency and stakeholder engagement • Coordination and cooperation
The Prime Minister's Office asked certain SPS agencies to identify all implementing regulations and manuals relevant to import permits.	• Taking stock of SPS measures • Coordination and cooperation
Pluto identified several possible regulatory options to address a given health risk. Pluto does not know which option to use and the one that may offer the best protection may be too costly.	• RIAs • Transparency and stakeholder engagement • Coordination and cooperation
Pluto promised legislative changes linked to trade facilitation. The SPS agency in charge of SPS border control systems was asked to prepare an annual plan for regulatory review, indicating which regulatory instruments will be removed or amended. They don't know where to start.	• Taking stock of SPS measures • Forward-looking regulatory agenda
A plant health emergency triggered the need for new SPS measures. The National Plant Protection Organization in Pluto was asked to ensure that the new SPS measures will not have any unexpected consequences on MSMEs.	• RIAs • Monitoring and evaluation • Transparency and stakeholder engagement
Several agencies are involved in SPS management, resulting in regulatory overlaps. Pluto is getting ready to sign a new regional trade agreement. All agencies tasked with regulating in the SPS area were asked to review existing SPS measures and ensure consistency among SPS agencies.	• Taking stock of SPS measures • Transparency and stakeholder engagement • Coordination and cooperation
Trading partners complained at the WTO that SPS measures in Pluto are not transparent and are not communicated in advance of becoming law.	• Transparency • Coordination and cooperation

2

Identify the existing framework for GRPs

SPS regulators should have a good understanding of the scope, range, and quality of GRP mechanisms used in their countries and the flexibility they have to use different GRPs. SPS regulators may be required or encouraged to use certain GRPs when developing or reviewing SPS measures based on domestic legal requirements applying to all types of regulatory activities or specific to the SPS area. GRPs may also be foreseen or overlap with international obligations contained in trade agreements, SPS-related international standards, or international commitments under the WTO SPS Agreement. There is benefit in understanding the various sources (domestic, bilateral, regional, and international) for GRPs and how they complement each other. This will help identify options available to SPS regulators in adapting GRPs.

Am I required to use certain GRPs?

Using certain GRPs may be mandated by law or otherwise formally required, e.g. in administrative procedures. GRPs may be required at country-level in all areas of regulatory activity or specifically in the SPS area. Using certain GRP mechanisms may also be required in international trade agreements (e.g. consultation or notification requirements). Alternatively, using GRP mechanisms may be the result of a practice or may be merely encouraged at the domestic, bilateral, regional, or international level. SPS regulators should first identify GRPs that are *mandatory* to give those GRPs priority.

Are there national/regional GRP policies?

Some countries have a national GRP policy or an agenda for regulatory initiatives and the mainstreaming of GRPs across all sectors. SPS regulators should consider such national initiatives and how that may impact their use of GRPs. Such initiatives can take the form of guidelines for the implementation of GRPs across all sectors. They may also take the form of: (i) administrative simplification programmes seeking to reduce the burden of regulations and requiring SPS regulators to re-examine the steps and procedures involved in issuing permits; (ii) legal simplification programmes seeking to clarify existing legislation and requiring an examination of the degree of complexity of the legal framework and its accessibility; and (iii) trade facilitation programmes, requiring streamlined border procedures, improved implementation of risk-based inspections, and replacing certain border controls with post-clearance audits or market surveillance. GRP policies and guidelines at a regional level may also exist, such as the ASEAN Good Regulatory Practice Core Principles (2018).

Spotlight 1.

Simplification and Trade Facilitation

The SPS measures that importing countries apply to agricultural products can lead to lengthy and costly inspection and certification procedures. Improving the efficiency of these processes cuts the time and cost of trade, which reduces the burden on businesses and encourages trade. The WTO Trade Facilitation Agreement (TFA), which came into force in 2017, contains provisions for expediting the movement, release and clearance of goods, including goods in transit. It also sets out measures for effective cooperation between customs and other agencies, including SPS agencies. Many of the TFA provisions are relevant to the SPS area as they deal with border controls, including SPS controls.[5]

"A number of countries have taken steps to streamline regulatory processes affecting the production and sale of agricultural products. For example, Côte d'Ivoire, the Dominican Republic and Rwanda introduced electronic applications for the submission of phytosanitary certificates. Peru introduced a new "ePhyto" system, which includes applications for phytosanitary certificates as well as their issuance and exchange with certain trading partners. Such digital processes facilitate the timely exchange of information. Several other countries improved border control procedures. In Brazil and Burundi, for instance, the law now allows phytosanitary import inspections to be risk-based, which helps target consignments that are more likely to be either harmful to plant health or non-compliant with local regulation, increasing border efficiencies and improving resource allocation.

In Kenya and Tanzania, the seed registration process is shortened when results from tests performed in pre-approved countries in the region are available. Tanzania improved its fertilizer registration process, removing the time limit formerly applied to the registration of fertilizer products. Some countries also took steps to increase the transparency of fees related to agricultural activities. Bangladesh published fee schedules for obtaining a phytosanitary certificate. ... Niger began to publicize costs associated with seed certification."

Source: World Bank (2019)[6]

[5] More information on the WTO Trade Facilitation Agreement: https://www.wto.org/english/tratop_e/tradfa_e/tradfa_e.htm.

[6] World Bank, Enabling the Business of Agriculture 2019, openknowledge.worldbank.org/bitstream/handle/10986/31804/9781464813870.pdf.

Are GRPs required or encouraged to be used in the SPS area specifically?

SPS regulators should review the domestic legal framework as well as existing bilateral and regional trade agreements to identify SPS-related provisions pertaining to GRPs. Domestic SPS-related policies or SPS-related provisions in bilateral or regional trade agreements can explicitly call for GRPs, or implicitly encourage their use. For example, effective food safety coordination may be highlighted as a backbone of the food safety system, encouraging consultations with private sector stakeholders, consumers, and civil society. GRPs may also overlap with certain international standards and international obligations in the WTO SPS Agreement, such as those pertaining to transparency and notifications. Endorsing GRPs, e.g. pertaining to transparency, can thus lead to greater compliance with international commitments and international standards (Annex 4).

Spotlight 2.

Attention to GRPs in cooperation between East Africa and the United States

Partner States of the East African Community (EAC) and the United States have signed a cooperation agreement on trade facilitation, SPS measures, and technical barriers to trade. On SPS, this agreement specifies, *inter alia*, that the "parties shall work together to enhance the technical capacity in the EAC Partner States for the consistent implementation of science-based SPS measures, including by promoting greater use of ... good regulatory practices, including: (i) transparency in the preparation, adoption, and application of SPS measures; (ii) evidence-based decision-making; and (iii) mechanisms and methods for periodic review of SPS measures."

Source: Cooperation Agreement on Trade Facilitation, Sanitary and Phytosanitary Measures, and Technical Barriers to Trade, Article 2, Sanitary and Phytosanitary Measures

Is there a regulatory oversight body tasked with GRPs in my country?

Certain countries have tasked an oversight body to promote, facilitate, and monitor regulatory initiatives and GRPs. Some countries have a single central oversight body, as is for example the case in Cambodia (Economic, Social and Cultural Council). Others have multiple bodies operating under the supervision of a coordination body, as is the case of Malaysia's Productivity Corporation (MPC). Oversight bodies are generally responsible for coordinating the use of GRPs and enhancing the quality of regulatory processes across government agencies, including SPS. They can promote and provide guidance on GRPs, coordinate and supervise GRP efforts, making sure that regulatory reform meets quality standards and that evaluation tools are used appropriately, and provide support to regulators to instil cultural changes in how regulations are developed. They can also have an important quality control function, for example through the review of RIAs and recommended systemic improvements for the future, or by challenging regulations. SPS regulators should get acquainted with the work of any such oversight body at country-level and any guidance that they may provide on GRPs.

Spotlight 3.

Mexico's oversight body and GRPs

The National Commission for Regulatory Improvement (CONAMER) is the federal body tasked with ensuring effective regulations and a transparent rulemaking process. CONAMER is hosted in the Ministry of Economy, with technical and operational autonomy. It has authority over regulatory measures at all levels of government, including state and municipal regulations. It promotes the improvement of regulatory processes, simplification, regulatory impact assessments, ex-post evaluation tools, and transparency in the elaboration of regulations; issues guidance documents; has the authority to review regulatory measures developed at the federal level; and performs coordination activities with respect to state and municipal regulatory activities. CONAMER has an online portal listing all draft regulatory proposals with their regulatory impact assessments. Once documents are published, citizens have at least 30 days to submit comments through the portal, by email, or by letter. The agency sponsoring the regulation is required to provide responses to all comments received.

Source: CONAMER

Which GRPs are used successfully in other government agencies and how?

SPS regulators should inform themselves about how different GRPs are used in their country and/or region, including by other agencies responsible for food safety, animal and plant health, as well as other parts of government agencies. Learning about what works well (and less well) is likely to be useful and can help to identify practices that could be replicated, not least when resources are limited.

3

Consider a stepwise approach to roll out GRPs

There is no one-size-fits-all approach to GRPs, nor is there a single, ideal GRP implementation model for SPS regulators to replicate. Different GRPs have different levels of complexity as well as different resource and knowledge requirements. How GRPs are rolled out will largely depend on country capacity and coordination and cooperation efforts at country-level. SPS regulators are strongly encouraged to analyse, at the outset, the capacity of SPS agencies in developing and implementing GRPs, as well as their capacity building needs.

Depending on capacity constraints, complex GRPs can be adapted or used strategically and replaced by more straightforward tools. For example, RIAs can be used in simplified forms or their use can be reserved for SPS measures that are expected to have a significant impact on trade. In other words, not all the elements of a single GRP tool or the complete set of available GRPs need to be used; good results can be achieved by applying selected GRPs or elements thereof.

Where SPS regulators already use some GRP elements, this can be expanded progressively towards a more comprehensive application of the GRP tool. Small-scale piloting and progressive implementation enable SPS regulators to build capacity for more complex aspects of GRPs over time; gather practical evidence of the benefits of specific GRP tools; and improve their understanding of factors that affect the design, development, and review of SPS measures.

4

Raise awareness on GRPs and build capacity to use GRPs

SPS regulators should be cognizant of the benefits of applying GRPs and should know which GRPs to apply depending on the context. Raising awareness on GRPs among SPS agencies and other regulating agencies is key to improving the effectiveness of SPS systems in the long run. If possible, GRPs should be applied consistently in all SPS areas to maximize their potential to improve the quality of SPS regulatory systems overall. Tailored information brochures or communication briefing notes can support this exercise. For example, under a trade facilitation initiative, information materials could address how using GRPs can help mitigate trade disruptions or transaction costs linked to the choice of an SPS measure over another.

Raising awareness on GRPs among private stakeholders is also important. It improves their participation in the context of consultations and allows them to gain a better understanding of SPS measures. This in turn fosters better compliance with SPS measures. Disseminating information on GRPs also enhances public trust and confidence in regulatory processes. Information on the processes to design, develop, and review SPS measures should be clear and easy to find.

Raising awareness efforts will also help garner necessary political support in the long run to implement and develop the use of GRPs in the SPS area. They should be complemented with a strategy to develop and build capacity of SPS regulators in using appropriate GRPs. Learning and development interventions should ideally be coordinated across agencies or monitored by an oversight body.

Spotlight 4.

STDF PPG: GRPs in the agriculture and fisheries sectors in the Philippines

An STDF Project Preparation Grant (PPG) benefiting the Philippines deals with GRPs in the agriculture and fisheries sectors. The PPG application was submitted by the Bureau of Agriculture and Fisheries Standards to provide support towards the implementation of GRPs, including RIAs, within relevant agencies.

The purpose of this PPG is to develop a project proposal to operationalize GRPs in agencies regulating in the agriculture and fisheries sectors in the Philippines in view of improving the development, implementation, and review of SPS-related regulations and other measures. The PPG will take stock of how SPS regulations and measures are developed and implemented, analyse constraints and challenges faced, and identify opportunities and needs to use GRPs. Work under the PPG, and resulting project, will contribute to improved coordination across government agencies, as well as a reduced regulatory burden for the private sector and lower trade costs.

Source: STDF/PPG/722

2 How to use GRPs to design, develop, and review SPS measures

This section provides step-by-step guidance to use GRPs to improve the design, development, and review of SPS measures and ensure that SPS measures are fit for purpose.

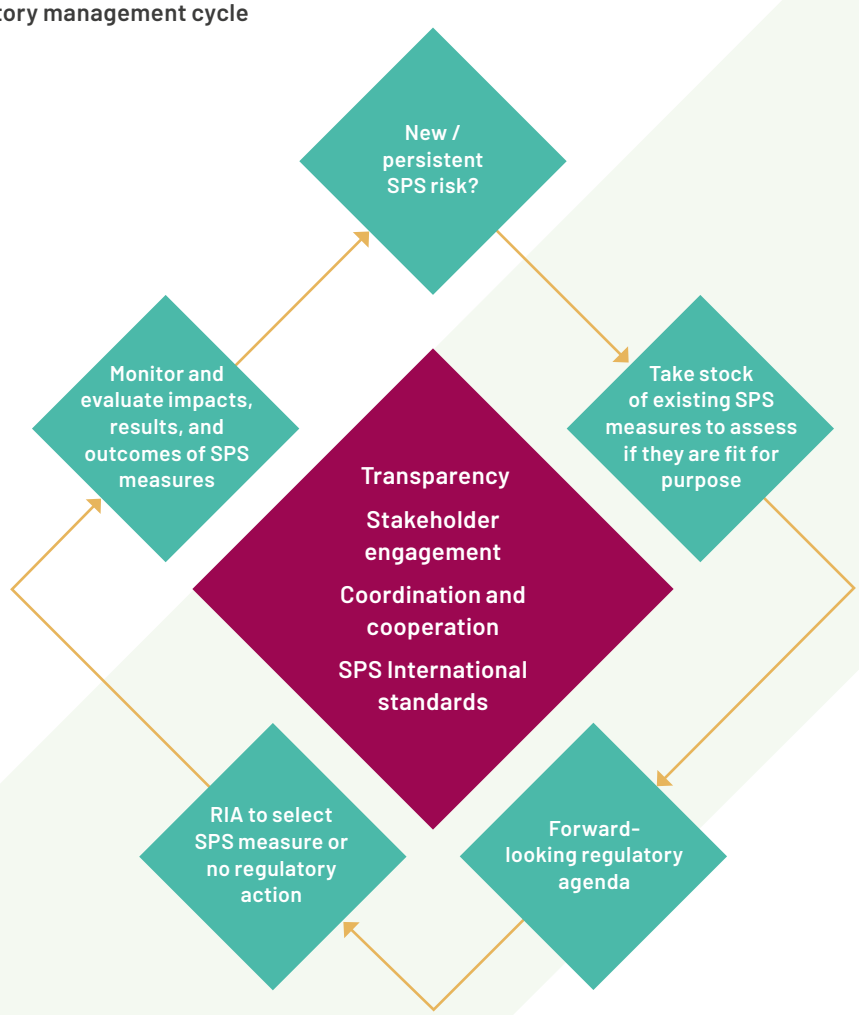
GRPs are presented according to the *regulatory management cycle* of SPS measures (Figure 2). Many of these good practices are interlinked and do not need to be applied sequentially. For example, an assessment of SPS measures may be conducted as part of taking stock of existing SPS measures, RIAs, or monitoring and evaluation efforts. Stakeholder engagement and cooperation/coordination is encouraged throughout the regulatory management cycle of SPS measures.

The review of existing SPS measures or the need to design new ones can be triggered by an emerging SPS risk or challenge, persistent SPS issues, or periodic review efforts. A preventive approach is encouraged to improve SPS systems. In this context, SPS regulators can use various forward-looking (*ex ante*) techniques, including horizon scanning and foresight[7], to identify and explore novel and unexpected SPS issues as well as persistent problems or trends. For example, climate change, new technologies, scientific progress, or urbanization can be drivers of change in the SPS area. Early identification and evaluation of SPS risks improves strategic planning of SPS review efforts and helps develop and implement effective SPS actions.

The GRP mechanisms presented in this Guide are:

- Stocktaking of SPS measures (section 2.1)
- Forward-looking regulatory agendas (section 2.2)
- RIAs (section 2.3)
- Monitoring and evaluation (section 2.4)
- Cross-cutting GRP mechanisms dealing with transparency and stakeholder engagement (section 2.5), including consultations as well as information dissemination, publication, and notification
- Coordination and cooperation at national and international level, including international regulatory cooperation based on SPS international standards (section 2.6)

Figure 2. SPS regulatory management cycle



[7] Horizon Scanning and Foresight: An overview of approaches and possible applications in Food Safety, Background paper 2: FAO Early Warning/Rapid Alert and Horizon Scanning, Food Safety Technical Workshop, Rome, 22-25 October 2013 http://www.fao.org/3/I4061E/i4061e.pdf.

When using GRPs to design, develop, and review SPS measures, keep in mind the following:

- **There is no one-size-fits-all:** GRP mechanisms are adaptable to country-specific institutional and cultural contexts, legal traditions, and capacity constraints. They can be applied in simplified forms, progressively, or strategically for SPS measures that are expected to have an important impact on trade.
- **Use of web-based tools supports the use of GRPs:** SPS regulators should make use of available technologies in applying GRPs (online consultations for wider engagement), keeping in mind associated challenges (online consultations may raise concerns related to data privacy).
- **Whole-of-government perspective adds value:** GRPs benefit from being applied from a whole-of-government perspective. Mechanisms for managing and coordinating within a government can be developed by oversight bodies to ensure cooperation among different regulating agencies, experience sharing, and adequate GRP implementation.
- **Quality control is essential:** The effectiveness of GRPs as implemented should be monitored and evaluated to identify and address systemic issues across government agencies, including SPS, and ensure proper GRP implementation over time.

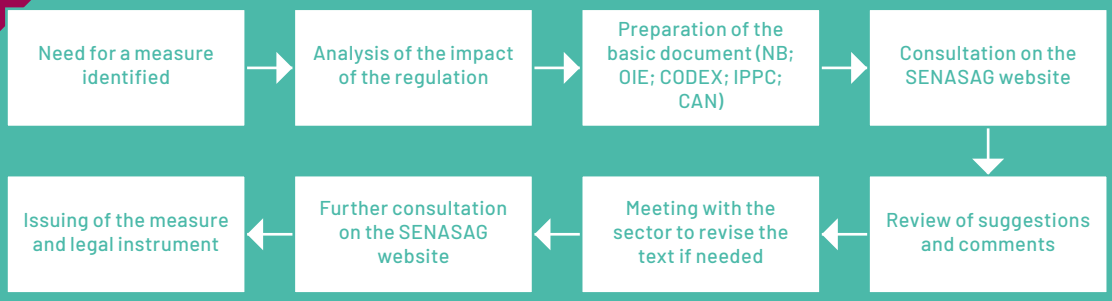
Additional resources on country experiences:

- OECD Regulatory Policy Outlook 2018
- Final Report on Good Regulatory Practices in APEC Economies (APEC, 2017)

Spotlight 5.

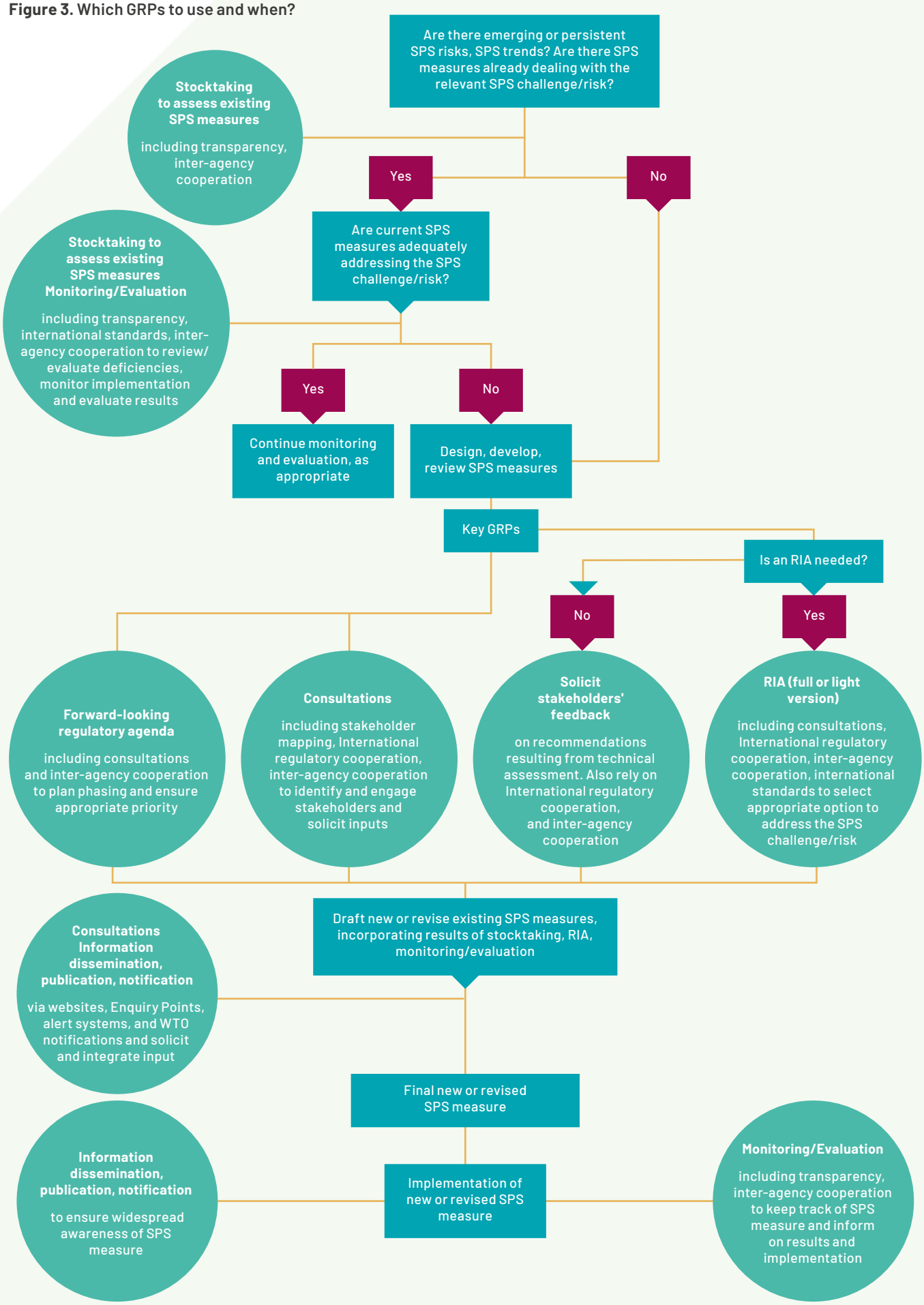
Developing SPS measures in Bolivia

The following chart illustrates the steps Bolivian authorities use to develop SPS measures.



Source: Trade Policy Review Report for Bolivia 2017, WT/TPR/S/363, Chart 3.10 Preparation of a phytosanitary or animal health measure

Figure 3. Which GRPs to use and when?



BOX 6.

Using GRPs to help mainstream gender in SPS measures

Gender equality makes sense from an economic perspective, as well as being important for human rights. The Joint WTO Buenos Aires Declaration on Trade and Women's Economic Empowerment recognizes that "inclusive trade policies can contribute to advancing gender equality and women's economic empowerment, which has a positive impact on economic growth and helps to reduce poverty". Trade and economic growth achieve greater poverty-reducing impacts, when there is more gender equality.[8] This is recognized in increased attention to gender in trade agreements.[9]

Compliance with SPS measures may not be gender neutral, particularly in value chains where women represent a large share of the workforce or are substantially involved in cross-border trade.[10] Women face constraints that may influence their ability to comply with SPS measures including care responsibilities, gendered social norms, labour market segregation, lower skills, restricted access to information and financing, etc. SPS measures may empower or disempower women and/or impact the burden they face on a day-to-day basis, their social position and overall welfare. SPS regulators are encouraged to consider and address the gendered nature of SPS measures as far as possible, including if and how SPS measures may disproportionately affect women's participation in trade. UNECE guidance can help to mainstream gender into the development and implementation of SPS measures.[11]

Use of GRPs provides a way for SPS regulators to consider the gender impacts of SPS measures, including the extent to which women and men are able to comply with these measures and/or are adversely impacted. Asking the following key questions can help to understand and assess these gender dimensions.

Key questions to promote a "gender lens" in SPS measures:

- To what extent are women employed by regulatory authorities responsible for SPS measures?
- What is the level of gender institutional capacity among SPS regulatory authorities?
- How are SMEs, women, civil society organizations and/or associations or networks of women producers and traders consulted on the development and implementation of SPS measures, and/or informed about changes to SPS measures?
- To what extent are the channels and processes used for consultation effective in reaching women, including women-operated businesses? Should specific outreach strategies be used for reaching female exporters/importers?
- Which SPS measures are likely to have more gender impacts (e.g. value chains that employ a significant share of women or in which women are more vulnerable or lack access to resources required for compliance)?
- How to increase access to gender-disaggregated data-related to trade and SPS measures?
- What particular constraints and/or opportunities are there for women and men in cross border trade including compliance with SPS measures?
- What are the options to minimize the potential negative impacts of SPS measures on women?
- What can be done to enable women to access the resources (technical, productive, financial, etc.) needed to comply with SPS measures?

[8] https://cdn.sida.se/publications/files/sida62217en-gender-equality-and-trade.pdf.

[9] For example, Chile-Uruguay Free Trade Agreement (2016); Chile-Canada Free Trade Agreement (2017).

[10] https://standardsfacility.org/sites/default/files/Gender_SPS_measures_in_the_context_of_trade_Henson_ICTSD_Nov_18.pdf.

[11] See UNECE Paper on Gender Responsive Standards, in particular Chapter 3 on Empowering Women to Comply with Trade-Related SPS Measures. See also UNECE Declaration for Gender Responsive Standards and Standards Development. Numerous initiatives on gender and international standards have emerged. For example, see www.fao.org/3/cb1583en/cb1583en.pdf, www.iso.org/files/live/sites/isoorg/files/store/en/PUB100440.pdf, and the WTO TBT workshop on the role of gender in the development of standards.

2.1 Take stock of existing SPS measures

2.1.1 Stocktaking in a nutshell

When an SPS challenge/risk or an SPS area gap is identified, SPS regulators may be tempted to reflect on possible additional SPS measures without first evaluating existing SPS measures. However, not all SPS challenges require government intervention. It is key first to take stock of and assess existing SPS measures to decide whether other measures or updated measures are needed. SPS measures that are developed on a piecemeal basis over time can result in inconsistencies, unnecessary complexities, redundancies, and increased costs relating to the enforcement of these measures. The associated costs of an existing SPS regulatory framework can sometimes be greater than is necessary to achieve a policy objective. Taking stock of existing SPS measures helps regulators identify whether certain SPS measures may be outdated or need to be amended and whether to simplify the SPS framework overall.

Taking stock of existing SPS measures is not only useful when a new SPS challenge/risk emerges. Many countries review existing measures when new regulations are being considered. For example, some implement a "one-in, two-out" rule in regulatory management. Stocktaking may also be the result of periodic management efforts. SPS regulations or parts thereof may by law, be due to expire at a set date (sunset clauses). SPS measures can be assessed as part of a comprehensive review of the regulatory regime (scrap and build), or set criteria may be applied in broad regulatory simplification efforts to eliminate regulations that are no longer needed (regulatory guillotine). Ideally, regulatory management efforts should be done on a regular basis (for instance annually or every few years), as considered necessary and useful in a particular country context.

It is important to take stock of existing SPS measures to:

- Improve transparency of the SPS regulatory framework;
- Reduce inconsistencies, gaps, and overlaps in existing SPS measures;
- Identify technically weak, outdated, inefficient, or ineffective SPS measures;
- Check compliance with SPS-related international obligations as well as possible harmonization with international standards and follow possible developments/evolutions of international standards;
- Update SPS measures to take account of changes in SPS issues, emerging trends, new technologies, etc.; and
- Facilitate implementation and enforcement of SPS measures through regulatory framework simplification.

BOX 7.

How can stocktaking help SPS regulators?

Examples of challenges that SPS regulators may face and how stocktaking may help:

SPS measures are enforced by different government agencies. This sometimes gives rise to confusion, e.g. Food Business Operators, traders and others are not clear which requirements they should conform to.	Taking stock of existing measures can help to map out what is required, including sequencing and conflicting requirements, and to clarify and streamline SPS measures.
SPS measures are applied but not necessarily enshrined in legal texts. For example, fees charged for SPS services are applied based on rates contained in draft texts that are not yet final legislations.	Taking stock of existing SPS measures will help identify such instances and where there is a need for rules to be formalized.
The rules applicable to certain commodities are not clear. They are also too numerous and hard to find. It is difficult to know which measures apply and when.	Taking stock of existing SPS measures will help identify all the relevant rules and possible overlaps or inconsistencies.
SPS measures were developed over time. Certain requirements may now be outdated.	Taking stock of existing SPS measures will help identify all existing requirements pertaining to food safety, animal or plant health and assess which ones are outdated and could be removed.

OECD, Reviewing the Stock of Regulation, OECD Best Practice Principles for Regulatory Policy (Draft for Public Consultations)

2.1.2 Key steps to take stock of SPS measures

STEP 1:

Regulatory mapping

SPS regulators should know the full spectrum of SPS measures within their respective areas, keeping in mind possible overlaps. Existing SPS measures (see Box 1 above for an explanation of SPS measures) should be identified and inventoried, whether they take the form of written or published measures or whether they are applied in practice but not officially recognized. Regulators should also be aware of non-SPS regulations (such as trade facilitation rules, environmental regulations or general legislation setting out cost-recovery mechanisms for service fees) that may impact the implementation of SPS measures.

Regulatory mapping is the process of identifying all the regulations and practices, procedures, and processes applicable in a certain area. *Regulatory mapping* may also include identifying which division within an SPS agency is responsible for review and enforcement and which agencies are involved in SPS processes or in the granting of necessary authorisations.

In some countries, international organizations or development partners have carried out work that can support efforts to take stock of SPS regulations. For instance, as part of its programme on NTMs, the International Trade Centre (ITC) engaged in a regulatory mapping exercise to collect, review and classify national trade-related regulations (including SPS measures), resulting in a database of import/export regulations categorized by type, product and country. It is completed by monitoring and facilitating efforts, with surveys and online reporting systems to document businesses experiences.[12]

Spotlight 6.

Regulatory mapping in the Philippines

The Philippines is implementing the Modernizing Government Regulations (MGR) Program, which aims to reduce the burden of compliance for businesses, and lower the costs borne by the government in enforcement of regulations. In this context, reviews are undertaken of priority sectors to create inventories of regulations and develop recommendations for improvements.

Regulatory mapping efforts are carried out to: gather information on businesses' experience in complying with regulations; map out the steps involved in compliance, based on practical experiences; validate the information gathered from the industry dialogues and process mapping with regulatory agencies; and assess existing regulations based on the necessity and relevance of the requirements and the clarity of and consistency with the policy purpose.

Regulatory mapping may comprise:

- Regulations matrix. This covers the legal basis of the regulation, agency(s) responsible for enforcement, stakeholders affected, compliance procedures, documents required, taxes/fees/charges to be paid (if any). The information collected is verified through phone calls, key informant interviews, and focus group discussions with stakeholders.
- Value-stream mapping. This provides a graphical illustration of all the steps and processes to comply with regulations, including sequencing activities undertaken by businesses or citizens and time expected to complete these activities.
- Analysis matrix. This identifies and plots linkages between regulations, in order to help identify priorities and develop recommendations.

Source: author based on consultations with the Development Academy of the Philippines

[12] For more information, see www.intracen.org/itc/market-info-tools/non-tariff-measures/, ntmsurvey.intracen.org/home/ (country surveys) and www.macmap.org/ (Market Access Map with information on SPS regulations for import and export).

STEP 2:

Define the scope and carry out the assessment

The SPS measures identified in Step 1 should be reviewed and evaluated for gaps, conflicts, or other technical, policy, or legislative deficiencies. The actions to be taken to address deficiencies will inform the forward-looking regulatory agenda (section 2.2). Evaluating the existing framework is also part of the RIA process (section 2.3) as well as the monitoring and evaluation process (section 2.4).

BOX 8.

Identifying SPS performance and capacity needs

SPS regulators can review and assess their capacity on food safety, animal and plant health performance using the evaluation mechanisms developed by the ISSBs. These tools collect data on various aspects relating to SPS control systems in a systematic manner. The results of the evaluations can be used to assess SPS measures, set regulatory agendas and support RIA processes. These tools also assess capacity related to GRPs, for instance on legislation, consultation, and information dissemination

- The OIE tool for the evaluation of Performance of Veterinary Services (OIE PVS): including a Veterinary Legislation Support Programme to provide countries with the opportunity to have their legislation in the veterinary domain systematically reviewed, identify gaps and weaknesses, and develop new legislation.
- The IPPC Phytosanitary Capacity Evaluation (PCE) tool, including a module on legislation.
- The FAO/WHO Food Control System Assessment Tool: www.fao.org/3/ca5334en/CA5334EN.pdf and www.who.int/publications/i/item/9789241515719, which includes attention to the quality of policy and legislation drafting processes: www.fao.org/3/ca5336en/ca5336en.pdf and https://www.who.int/publications/i/item/9789241516600.[13]

Other diagnostic tools exist, such as the Performance, Vision, and Strategy tools developed by the Inter-American Institute for Cooperation on Agriculture (IICA) for food safety, animal and plant health and national SPS systems.

- For an overview of performance evaluation mechanisms for SPS systems, see https://www.standardsfacility.org/sites/default/files/STDF_Briefing_14.pdf (ISSB focus) and https://www.standardsfacility.org/sites/default/files/STDF_Capacity_Evaluation_Tools_Eng_1.pdf

Where resources do not permit a comprehensive SPS review, an assessment in planned phases can be made. This assessment may be based on a selection of subjects or subsectors of plant health, animal health, and/or food safety following policy imperatives or identified needs. Regulators can then expand outwards to encompass related issues, such as those pertaining to trade, economic development, investment, gender, climate change, and others.

A regulatory assessment that is of a *technical or substantive nature* employs a range of methodologies. The assessment should consider trade, economic, and health factors to ensure that existing SPS measures achieve the intended objective(s). This should involve benchmarking against the international standards of Codex, IPPC, and OIE or other possible standards, including at the regional level. The assessment may also incorporate competition, environmental, social, gender and other factors, as appropriate.

A regulatory assessment of a *purely legal nature* may also take place. A legal assessment is often initiated by the central regulatory oversight body and includes legislative simplification or codification efforts seeking to provide clarity, accuracy, and easier access to SPS regulations.

Transparency / continuous communication: In all cases, actions to take stock of and assess SPS regulations should be communicated to stakeholders to give them an opportunity to comment and provide feedback (see section 2.5).

[13] See also Dimension B on Control functions (www.fao.org/3/ca5346en/ca5346en.pdf and https://www.who.int/publications/i/item/9789241516617); Dimension C on Interactions with stakeholders (www.fao.org/3/ca5348en/ca5348en.pdf and https://www.who.int/publications/i/item/9789241516624); and Dimension D on Science knowledge base and continuous improvement (www.fao.org/3/ca5404en/ca5404en.pdf and https://www.who.int/publications/i/item/9789241516631).

BOX 9.

Pluto case study: Review of Pluto's SPS import permit system

Pluto decided to review its current rules pertaining to plant, animal, and food import permits and certificates.

To start, Pluto identified all implementing regulations and guidelines relevant to import permits and certificates, including the legal texts specific to plant health, animal health, and food safety, as well as other relevant legislation relating to customs, investment, and trade. Pluto was careful not to limit its identification exercise to rules embodied in laws or regulations (some of which are quite old), and has also identified existing practices affecting the import of plants, animals, and food, as well as the responsible agencies for different controls. To ensure that the identification exercise is complete, Pluto heavily relied on consultations and inter-agency cooperation. In the process, Pluto identified specific subcategories (e.g. types of animal products or food products) that may be excluded from import permit and certification requirements.

Pluto then proceeded to assess this body of SPS rules to understand when an import permit or certificate is required, the conditions for obtaining the permit or certificate, the procedures to apply for the permit or certificate, timelines, and associated fees. With this assessment, Pluto gained a better understanding of the permit and certificate requirements, the products subject to these requirements (and those that are excluded), and the authorities involved. Pluto also identified certain gaps, overlaps, and ambiguities, benchmarking against relevant ISSB standards. These ISSB standards include section 4.2 of ISPM 20 on when authorisations for import would typically be required, chapter 5.1. of the OIE Terrestrial Animal Health Code, defining general obligations related to certification for live animals and animal products, and Codex Guidelines on Food Import Control Systems. Also relevant to this assessment are the principles of the WTO Trade Facilitation Agreement that seek to streamline import clearance procedures.

Through this exercise, it became clear that foods of animal origin may be subject to permit and certification requirements by food safety authorities as well as by animal health authorities. It also became clear that while certain products are subject to permit or certificate requirements by law, for others a practice has emerged but is not consistently applied. Furthermore, some products are not subject to any permit or certification requirements without a clear rationale for this difference in treatment. Pluto will share the results of this assessment to ensure better agency coordination where this is needed and to help officials in processing permit and certificate requests.

BOX 10.

Pluto case study: Simplification of Pluto's phytosanitary regulatory framework

Pluto does not have a single law setting out its phytosanitary regulatory framework. Legal responsibilities/mandates are scattered across many legal texts in the form of primary legislation (laws) and secondary legislation (decrees and regulations). The situation is complex because the mandate for some aspects of phytosanitary control is carried out by decentralised authorities in Pluto. Moreover, revisions and updates conducted over the years make it more difficult to identify which provisions continue to apply. Legal simplification/codification processes in Pluto will contribute to a "cleaned up" framework made up of those provisions already in force.

Spotlight 7.

Taking stock of the food processing regulatory framework in Romania

Romania reviewed its regulatory framework for food processing using the OECD Competition Assessment Toolkit. This toolkit includes four key stages: (i) sector mapping; (ii) legislation screening and analysis (including a competition checklist to screen for laws and regulations that have the potential to unnecessarily restrain competition); (iii) in-depth qualitative and quantitative assessment of policy objectives; and (iv) recommendations and capacity building assistance.

This exercise identified and analysed the legal framework for food processing, including relevant laws and regulations, authorities responsible for authorisations, and harmonization with Codex standards. It identified instances in which laws and regulations could be considered to restrict competition and where revisions should be considered. These included, for instance:

- Inconsistencies in practices compared to other EU member states regarding food inspections at the border and storage requirements for food products: The recommendation was to ensure through internal instructions or guidelines that practices during border inspections and analysis are aligned with practices in other European Union member states and allow operators to store imported products in a more cost-efficient manner pending analysis of the imported food products.
- Ambiguities in rules related to the handling and selling of food products with unnecessarily ambiguous terms. Such ambiguities created uncertainty for operators, left unnecessary discretion to the authorities, could encourage corrupt practices, and increased the cost of compliance. The report recommended to clarify certain rules, include specific definitions, and clarify certain deadlines.
- Unnecessary requirements including overlapping responsibilities of authorities to control compliance with food safety norms in the marketing of bakery products, resulting in uncertainty for businesses, additional costs, and differences in treatments. The report benchmarked this against the pursued objective of ensuring compliance with food safety rules and concluded that a double control was not necessary. The report then made specific recommendations as to how control requirements could be streamlined.
- Discrimination based on nationality/origin of the product, which identified certain inequality of treatments and made recommendations to treat domestic and foreign producers alike in relation to costs for testing of animal feed.
- Outdated legislation including instances in which domestic rules related to food safety and hygiene were redundant in light of EU regulations with the same regulatory content. The report listed these domestic rules, recommending that they be abolished.

Sources: OECD Competition Assessment Toolkit and OECD (2016), OECD Competition Assessment Reviews: Romania (Chapter 4: Food Processing)

2.2 Forward-looking regulatory agenda

2.2.1 Forward-looking regulatory agenda in a nutshell

A forward-looking regulatory agenda can be used to give an overview of proposed regulatory actions and phases for the future. Ideally, it is developed following systematic planning across the government to facilitate the setting of priorities, sequencing of activities, and quality control. It can also be set at the level of a Ministry, be SPS specific, or deal with only certain types of planned SPS regulatory actions. Coordinating a forward-looking agenda at the government level or covering different regulatory agencies can be entrusted to a separate body with the necessary capacity and political support. In all cases, a forward-looking regulatory agenda should help understand how particular SPS regulatory actions fit into the broader national framework or broader initiatives and explore synergies with other initiatives (e.g. in the SPS, trade, environment areas).

A forward-looking regulatory agenda identifies and plans legal and regulatory initiatives that will be considered, situates these initiatives within the broader governmental agenda, identifies linkages between initiatives, and helps oversight bodies to anticipate proposals and work closely with regulators to address issues that may delay consideration of time-sensitive proposals. It is an important tool to:

- Improve inter-agency coordination on the development of SPS measures, policy and regulatory coherence, and encourage broader political support;
- Identify short-, medium-, and long-term SPS priorities and improve SPS planning (STDF's evidence-based P-IMA framework can support prioritization and decision-making in the SPS area, see Box 12);
- Understand how draft SPS regulations fit into the broader national legal framework, including cross-sectoral synergies (e.g. across agriculture, health, trade and/or environment);
- Improve transparency and the predictability of actions by SPS regulators;
- Enable greater international cooperation by making the forward-looking regulatory agenda accessible to trading partners; and
- Provide businesses and the community with ready access to information about past and planned changes to SPS measures, and make it easier for them to take part in the development of new or revised SPS measures.

BOX 11.

How can a regulatory agenda help SPS regulators?

Examples of challenges that SPS regulators may face and how a forward-looking regulatory agenda may help:

The Trade Ministry recommended trade-focused reforms that impact SPS measures, but some SPS regulatory changes are already in the pipeline.	A forward-looking regulatory agenda will help synchronize regulatory changes in various areas to ensure optimum timing and coordination. It will increase transparency on planned regulatory changes and make SPS actions more predictable for other departments and ministries.
Private sector actors complain that they are not kept informed of regulatory changes and are ill-prepared to provide input and accommodate SPS changes.	A forward-looking regulatory agenda will increase transparency and facilitate stakeholder participation in the development or review of SPS measures.
SPS regulators complain that SPS systems do not receive enough high-profile attention.	A forward-looking regulatory agenda will ensure that planned SPS regulatory changes are prioritized and fit in the broader regulatory agenda. A coordinated agenda, with identified priorities and synergies, will help garner support for SPS regulatory changes.
SPS regulators have difficulties developing regulatory plans that bring together all items recognized as priority issues (such as balancing trade facilitation recommendations and the results of ISSB evaluation tools).	A forward-looking regulatory agenda will help list planned regulatory actions, coordinating within SPS agencies, and set priority areas depending on context.

BOX 12.

STDF P-IMA framework – Prioritizing SPS investments for market access

Developing countries face many demands to improve SPS capacity to boost agri-food exports and support policy objectives. Yet, the resources available from government budgets and donors are usually insufficient to meet all the needs. Prioritizing SPS investments when resources are limited is not easy. Evidence helps to improve the effectiveness of SPS policy and investment decisions. The P-IMA framework uses multi-criteria decision analysis to set priorities, based on available information and data. The process engages all relevant public and private sector stakeholders to discuss the various SPS investment needs and identify decision criteria and weights to prioritize investments. By transparently documenting the findings, as well as all the data and information used, it ensures that the SPS priorities generated are open to scrutiny, and delivers impartial information to inform priority policy decisions.

The P-IMA framework generates data and evidence to:

- Improve SPS planning and decision-making processes;
- Raise high-level awareness about the value of investing in SPS capacity building;
- Promote stakeholder dialogue on SPS capacity building;
- Guide the development of capacity building projects, national SPS action plans, and support resource mobilization; and
- Integrate SPS priorities into agriculture, trade or other investment plans.

Source: STDF

2.2.2 How to establish, publish, and monitor a forward-looking regulatory agenda

Key principles for forward planning

To avoid becoming a platform for over-regulation, a forward-looking regulatory agenda should be inclusive, easily accessible, plan ahead, highlight synergies in regulatory efforts, and be consultative/participatory in its approach.

Content of a forward-looking regulatory agenda

A forward-looking regulatory agenda in the SPS area should be set to cover a defined period of time and be predicated on an assessment of existing SPS measures (see section 2.1). The regulatory agenda should contain information on the rationale and supporting justifications for the targeted areas and activities, describe the SPS challenge/risk, identify the officials in charge and how to communicate with them, and provide a schedule of *future* actions, e.g. assessments, evaluations, monitoring, and consultations. The forward-looking regulatory agenda can also include a plan for the systematic and regular identification of emerging SPS risks and challenges, based on available tools such as horizon scanning and foresight.[14]

Ideally, the agenda should already identify potentially affected stakeholder groups and consider priority areas, for example to focus on:

- SPS measures leveraging the most health impacts, SPS measures reducing the SPS risk to an appropriate level of protection;
- key problems identified by trading partners (e.g. rejected shipments, no application of international standards); or
- the findings and outcomes of trade policy reviews (TPRs), audits, or evaluations.

A forward-looking regulatory agenda could cover the SPS area as a whole or focus on specific areas (food safety, animal health or plant health) as appropriate. It should be consistent with any SPS action plans, where available, and any sector-specific plans on food safety, animal health or plant health. A forward-looking regulatory agenda specific to SPS should align with any broader regulatory agendas (e.g. relating to trade, administrative simplification etc.). Where a central regulatory oversight body coordinates a regulatory agenda, it is important that SPS regulators conduct a review within their respective areas to recommend such areas as part of any broader national regulatory agenda. With distinct agendas for plant health, animal health, and food safety, SPS regulators should keep in mind possible overlaps: inter-agency collaboration and coordination are key to promote a One Health approach and allow effective multi-sectoral responses to SPS risks, such as food safety hazards and risks from zoonoses.

[14] Horizon Scanning and Foresight: An overview of approaches and possible applications in Food Safety, Background paper 2: FAO Early Warning/Rapid Alert and Horizon Scanning, Food Safety Technical Workshop, Rome, 22-25 October 2013 http://www.fao.org/3/I4061E/i4061e.pdf.

Procedures relating to forward-looking regulatory agendas

Establishing a forward-looking regulatory agenda should involve broad and robust stakeholder consultations to establish priorities. The agenda should ideally be available online and easily accessible. It should also be reviewed periodically (for instance every one or two years, depending on needs and resources available) to address new issues and adjust actions.

Forward-looking regulatory agendas can be notified to the WTO to allow other WTO Members to become acquainted with planned regulatory changes. When the SPS measure is not to be based on an international standard and when it may have a significant effect on trade, the WTO SPS Agreement requires WTO Members to publish an "early notice" when there is a plan to develop a new regulation. This is to allow other WTO Members to become acquainted with proposals to introduce new regulation.[15]

Spotlight 8.

Forward-looking regulatory agendas in Malaysia

Regulators in Malaysia are required to notify each year the Malaysia Productivity Corporation (MPC) in the Regulatory Review Department about their plans to review existing regulations. MPC is a technical agency with formal regulatory oversight functions to support the coordination, awareness raising, capacity building, and monitoring related to the implementation of the Regulatory Policy and GRPs. Through forward planning, Malaysian regulators announce a public list of regulatory proposals to be prepared, modified, reformed, or repealed in the upcoming year. Regulators must communicate in January of each year to MPC regulations subject to review in the next 12 months, annual review schedules, and strategies. As a complement to forward planning, MPC is required to publish on an annual basis all regulatory activities undertaken by regulators during the previous year based on lists of all regulations made prepared by individual agencies. MCP will also review lists and regulations to assess progress.

Source: Malaysia, Best Practice Regulation Handbook (2013)

Spotlight 9.

Sharing information on forward-looking agendas, Mexico

Mexico has developed a forward planning tool made public through its official gazette. The national standardisation programme is the instrument for planning, coordination and information with regards to the development of technical regulations and standards stemming both from the public and the private sector. It includes the list of Mexican Official Standards ("technical regulations" and "sanitary and phytosanitary measures") and Mexican Standards (voluntary "standards") to be developed, updated, modified or cancelled. Every year, Mexico notifies the WTO SPS Committee its programme of the year in order to provide WTO Members with further information on the ongoing regulatory process and planned regulatory activities in Mexico.

Source: G/SPS/GEN/491/Add.28 for 2021 2.3 Regulatory impact assessments (RIAs)

[15] SPS Agreement, Annex B.5(a). See also Box 20 on Transparency in the WTO Agreement below.

2.3 Regulatory impact assessments (RIAs)

2.3.1 RIAs in a nutshell

A regulatory impact assessment (RIA) is a systemic approach to assessing critically the positive and negative effects of proposed and existing regulations and non-regulatory alternatives. An RIA can be used in the SPS area to examine options that achieve the desired SPS outcome while avoiding unnecessary barriers to trade. It provides evidence for the selection of the option that yields the greatest net benefit based on robust quantitative and qualitative analysis.

RIAs can be used: (i) *ex ante*, as a forward-looking tool to inform a new or revised measure based on forecasted scenarios; and (ii) *ex-post*, as an evaluation tool to consider how existing SPS measures are implemented and determine costs and benefits of the baseline scenario. RIA principles can therefore be extremely helpful when developing new SPS measures as well as when evaluating existing ones as part of stocktaking (see part 2.1 above) and monitoring/evaluation efforts (see part 2.4 below).

Some SPS objectives may not require regulatory action at all. An RIA helps identify when and which non-regulatory options may be appropriate depending on the circumstances. Non-regulatory options to SPS measures may take the form of voluntary agreements, education campaigns, insurance schemes, and self-regulation. For example, educating farmers on biosecurity measures for livestock premises to prevent the spread of diseases may be such non-regulatory option. If regulatory action is needed, an RIA will help SPS regulators select the most appropriate SPS measure. In all cases, SPS regulators can rely on RIAs to assist them in balancing considerations from a range of disciplines, looking at trade, economic, and health aspects, but also possible environmental, social, gender-related, and other aspects of SPS measures, as appropriate (see Box 6 on gender considerations).

BOX 13.

RIAs and SPS risk assessments

A *regulatory impact assessment* (RIA) refers to a systematic process of identification and quantification of benefits and costs likely to flow from regulatory or non-regulatory options for a policy under consideration. RIAs are also sometimes referred to as regulatory impact analysis. RIAs are not specific to SPS measures; they can be used to improve the development of all types of regulatory measures.

A *risk assessment* is a key notion of the WTO SPS Agreement: WTO Members are required to base their SPS measures on relevant international standards *or* an assessment of risk, as appropriate to the circumstances. In the WTO SPS Agreement, risk assessment is:

- the evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing WTO Member according to the SPS measures which might be applied, and of the associated potential biological and economic consequences; or
- the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs. (WTO SPS Agreement, Annex A.4)

In the WTO SPS Agreement, risk assessment essentially refers to the process of gathering scientific evidence and relevant economic factors on the SPS risks involved in allowing a particular import to enter a country. The WTO SPS Agreement contains further details on how a risk assessment is to be conducted (Article 5 of the WTO SPS Agreement).

In addition, the ISSBs have developed guidelines for performing risk assessment, as a part of risk analysis:

- Codex Working Principles for Risk Analysis for Food Safety for Application by Governments, CAC/GL 62-2007
- IPPC guidance: framework for pest risk analysis (ISPM 2), pest risk analysis for quarantine pests (ISPM 11), pest risk analysis for regulated non-quarantine pests (ISPM 21), and pest risk analysis for biological control agents and beneficial organisms (ISPM 3): https://www.ippc.int/en/core-activities/standards-setting/ispms/
- OIE guidance: Section 2. Risk Analysis. Terrestrial Animal Health Code, https://www.oie.int/index.php?id=169&L=0&htmfile=titre_1.2.htm and Section 2. Risk analysis. Aquatic Animal Health Code, https://www.oie.int/index.php?id=171&L=0&htmfile=titre_1.2.htm

An RIA is important to:

- Determine if an SPS regulation is needed and identify the best regulatory or non-regulatory option to address the SPS challenge/risk;
- Design cost-efficient SPS measures;
- Ensure that decisions are made based on the best available evidence;
- Enable the proper consideration of various factors as relevant to the SPS measure at issue (e.g. health protection, trade, economic, environmental, social, gender-related factors);
- Estimate and understand the impacts, particularly on trade, and other relevant implications (economic, environmental, feasibility, etc.) of envisaged options, and potentially revise drafts to limit those impacts and implications;
- Pay attention to implementation principles, human resources capacities (e.g. availability of inspectors), the structure of the administrative system, and implementation challenges associated with the SPS options under consideration;
- Take into consideration data protection needs in the process of the legal development and implementation of the SPS measure; and
- Enable adequate allocation of resources to optimize the intended outcome of a proposed SPS option.

Box

BOX 14.

How can RIAs help SPS regulators?

Examples of challenges that SPS regulators may face and how RIAs may help:

The plant health authority, the veterinary authority, and the food safety authority each have a budget within which to control their own regulatory domain. It is difficult to know how much an SPS measure that works well in another country is going to cost if implemented in this country.	RIAs help assess the benefits of and costs associated with the SPS options under consideration and how costs may be allocated.
Relevant stakeholders (health and customs operators, MSMEs, large operators, etc.) have competing interests.	RIAs help develop a methodology to identify, assess, and strike a balance between competing interests.
Understanding the costs, benefits, or risks of regulatory changes in an SPS area requires considerable time, data gathering, skills, expertise, and resources.	RIAs can be used in simplified form or used strategically, e.g. for priority SPS areas or for SPS measures that are expected to have an important impact on trade.
It is challenging to convince senior policy makers that voluntary standards and codes of conduct combined with education campaigns can be effective to encourage specific crop and livestock production practices.	RIAs help compare non-regulatory options with SPS regulatory options based on robust quantitative and qualitative analysis. The results of the analysis can be used to show the benefits of a preferred non-regulatory option.
There are cost implications and other barriers to the adoption of specific phytosanitary treatments.	RIAs help identify and assess alternative treatment options and cost implications.
Options all appear to achieve the required health protection.	RIAs help select the option that yields the greatest net benefit, looking at the health objective, but also taking into account a variety of other factors, e.g. trade, cost, environmental, gender-related, social factors, implementation challenges associated with and feasibility of options.

RIA challenges and realities

Despite the benefits of RIA, experience in shows that there are often practical challenges in implementing an effective functioning RIA process.[16] Challenges may include: institutional resistance to RIAs leading to low level of voluntary implementation; a perception that RIA is a costly and lengthy bureaucratic layer; capacity and resource constraints; high staff turnover among SPS regulators resulting in limited staff capacity to analyse SPS trends and challenges, and elaborate solutions; lobbying from interest groups that may not match broader community interests. Such challenges can be overcome with a proper understanding of and strong political support for RIAs, provided a clear and transparent process is put in place, with quality control mechanisms.

Adapting RIAs to the developing country context and taking a proportionate approach to RIAs

When resources are limited, it can be helpful to adapt RIA processes (RIA light[17]) or gradually introduce RIAs. This can be done in various ways, for instance a pilot phase followed by institutionalisation of RIAs or the restricted use of RIAs to certain SPS agencies, the most important regulatory changes, or a particular SPS priority area. Another option is to implement certain elements of RIAs first (simplified methodology to be expanded) or start with a simple single- or multi-criteria qualitative analysis based on a limited number of factors, and then gradually moving to integrate a quantitative analysis (e.g. cost-benefit analysis) and considering a wider-span of factors.[18] Adapting RIAs may be done based on the priorities that would have been set in a forward-looking regulatory agenda.

Not all SPS initiatives require the same type and depth of analysis: major SPS measures may necessitate a comprehensive RIA while a preliminary or a partial RIA may suffice for minor SPS measures or an RIA may not be necessary. Some countries use threshold tests to apply RIAs only to certain types of SPS regulations, instead of using it systematically for all SPS measures. SPS regulators may consider adopting a proportionate approach to conducting RIA depending on the scale of the SPS issue, the SPS measure, or the expected impact. Following this proportionate approach, RIAs may be preliminary, partial, or comprehensive, as appropriate.

Transparency and RIAs

A central aspect of RIAs is that it should be conducted in a transparent manner. SPS regulators should ensure that they sufficiently inform the public of the RIA process, provide details of the proposed course of action, explain why the chosen SPS option is more desirable than other alternatives, and communicate draft or final impact assessment results to the public.[19] RIAs also rely on effective stakeholder engagement and consultations, in particular in data collection and analysis efforts. Stakeholder engagement and consultations are key to understand constraints and issues early on and build on them when developing and selecting SPS options. Transparency ensures a better understanding of SPS measures and greater compliance in the long run.

RIA quality control

While RIAs are usually conducted by the regulating agencies, oversight bodies play an important role in the RIA context. Oversight bodies are often tasked with promoting the use of RIAs, providing guidance on RIAs as well as technical support, checking the quality of RIAs (e.g. approving RIA documents as meeting quality standards), encouraging regulators to publish the most complete and precise RIA reports, updating and maintaining a web portal, and helping to target groups potentially affected by newly proposed regulatory initiatives. To ensure that RIAs improve over time, RIA methodologies themselves can be periodically evaluated by an oversight body (or the SPS agency if there is no existing oversight body with this particular function). This involves reviewing the choice and variation of methodologies, criteria, checklists, and other tools used in RIAs. Evaluation tools typically used include indicators, case studies, and surveys.

[16] CUTS. Regulatory Impact Assessment Toolkit: a Practitioner's Guide in Developing Countries

[17] Ladegaard, Peter Farup; Rimmer, Stephen; Rodrigo Enriquez, Delia. 2009. Making it work: 'RIA light' for developing countries. World Bank Group

[18] Renda, A. (2015), Regulatory Policy in Perspective: A Reader's Companion to the OECD Regulatory Policy Outlook 2015

[19] World Bank Group, Global Indicators of Regulatory Governance: Worldwide Practices of Regulatory Impact Assessments (2018)

Additional resources on RIAs:

- For information on "RIA light" processes for developing countries: Ladegaard, Peter Farup; Rimmer, Stephen; Rodrigo Enriquez, Delia. 2009. Making it work: 'RIA light' for developing countries. World Bank Group
- For information on the proportionate approach: OECD Regulatory Policy Outlook 2015
- For an example of a development plan in relation to RIAs: Implementing Good Regulatory Practice in Malaysia (OECD 2015) (Chapter 2)
- OECD Regulatory Impact Assessment 2020, OECD Best Practice Principles for Regulatory Policy
- OECD Regulatory Policy Outlook 2018
- OECD Regulatory Impact Analysis 2009, A Tool for Policy Coherence.
- OECD Introductory Handbook for Undertaking Regulatory Impact Analysis (RIA), 2008
- World Bank Global Database for Regulatory Impact Assessment
- Ladegaard, Peter Farup; Rimmer, Stephen; Rodrigo Enriquez, Delia. 2009. Making it work: 'RIA light' for developing countries. World Bank Group
- Ladegaard, Peter Farup; Lundkvist, Petter; Kamkhaji, Jonathan Camillo. 2018. Giving Sisyphus a helping hand : pathways for sustainable RIA systems in developing countries, World Bank Group
- CUTS. Regulatory Impact Assessment Toolkit: a Practitioner's Guide in Developing Countries
- Final Report on Good Regulatory Practices in APEC Economies (APEC, 2017)
- Regulatory Impact Assessment in the Philippines (OECD 2021)
- For further information on how to evaluate RIAs and ensure progress over time, see OECD. 2003. Proceedings from the OECD Expert Meeting on Regulatory Performance: Ex-Post Evaluation of Regulatory Policies, www.oecd.org/regreform/regulatory-policy/30401951.pdf.

2.3.2 Key steps for RIAs

There are various approaches and methodologies to RIAs in the SPS area and RIAs can be adapted depending on available resources and capacity constraints. Irrespective of the methodology used, a key component of RIAs is robust stakeholder engagement efforts throughout the process. Incorporating consultations into RIAs enhances the transparency of regulatory processes and provides quality control for impact assessments. It also improves the information on which decisions are based and allows for a more complete and realistic capture of the range of negative and positive impacts of SPS options.

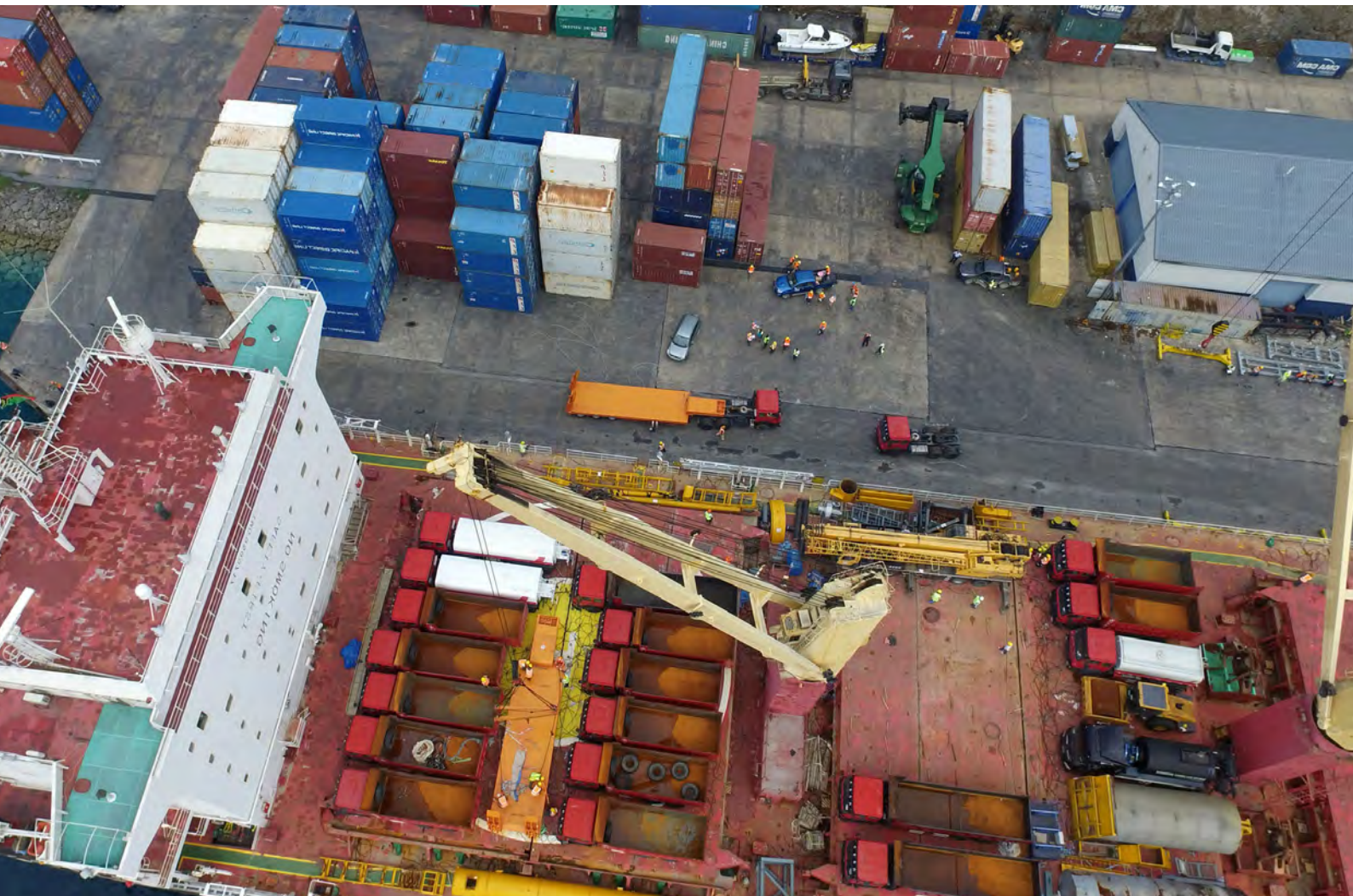
Many countries have developed legislation or guidelines on RIAs, or have given an oversight body the mandate to coordinate efforts on RIAs, promote their use, give guidance to regulating agencies, and assess the quality of RIA. RIA guidelines may also exist at the regional level. RIA guidelines are likely to provide details on:

- rules and RIA processes, such as how the RIA process operates;
- roles – who does what and when;
- when a RIA should be prepared;
- the steps involved in preparing RIA;
- when and how consultations should be conducted with private and public sector stakeholders;
- methodology, data, and indicators to analyse impacts with an emphasis on health, trade, and economic dimensions, and possibly others (social, environmental, gender dimensions);
- how each RIA will be assessed and against what criteria;
- quality scorecards for each stage of RIA preparation;
- reference materials and examples of real RIA provided to assist officials; and
- contact points.

SPS regulators should consider whether they may be required to use some form of RIA process by law. They are also encouraged to use the guidelines that may exist at country or regional level.

Additional resources on RIA guidelines:

- APEC-OECD Integrated Checklist on Regulatory Reform
- ASEAN Good Regulatory Practice Core Principles (2018)
- Circular A-4 providing guidance to US Federal agencies on the development of regulatory analysis and Guidelines for regulatory impact analysis for the US Department of Health and Human Services, HHS_RIAGuidance.pdf
- The Australian Government Guide to Regulation
- Manual on Regulatory Impact Assessment for use in the public service of the Republic of Armenia
- Malaysia, Best Practice Regulation Handbook (2013)
- See also World Bank Group, Global Database for Regulatory Impact Assessment (RIA), containing documents issued by or for national governments, or publications studying RIA as it is applied by governments worldwide.



STEP 1:

Determine degree of intervention in light of SPS issue and SPS objective

An RIA may be used to develop a new or revised SPS measure in the context of an emerging or unaddressed SPS risk. The RIA process may thus need to start with identifying and understanding the SPS issue that needs to be addressed and the SPS objective to be achieved. For that purpose, the SPS issue should be properly and clearly identified, and its underlying causes as well as baseline and future trends properly understood.

An RIA may also be useful to assess the impact of existing SPS measures in order to understand how well they are performing in light of the SPS risk they seek to address. In this case, the SPS issue and its underlying causes should be properly considered and understood as well as the SPS measure itself and its implementation.

As part of the RIA, SPS regulators should determine: (i) whether the situation will autocorrect over time and whether additional regulatory intervention is necessary; and (ii) the degree of regulatory intervention required. This mitigates the risk of over-regulation and ensures that the SPS measure is proportional to the SPS issue that has been identified.[20] Trends towards co-regulatory approaches and self-regulation also influence the nature of regulatory interventions. For instance, some food safety authorities are using the voluntary third-party assurance programme (vTPA) approach, set out guidance developed by the Codex Committee on Food Import and Export inspection and Certification Systems, to integrate industry controls and data into regulatory plans.

STEP 2:

Data collection

Accurate data that reflect the operational reality and are representative of the SPS challenge at issue are critical to the success of an RIA. Collecting relevant and reliable data can be expensive and time consuming. The choice of which data to collect and the data collection method are not isolated decisions. They influence the whole RIA process and its quality. Depending on country context, SPS regulators can start with relying on more easily identifiable quantitative data and develop incremental capacity on gathering and evaluating more complex data sets as well as qualitative data.

SPS regulators should identify in advance: what information exists; what information is needed, and how it can be obtained; and what data can be made available. ISSB evaluation tools help to gather strategic data for SPS regulators to review their systems.

In particular, data sources should be identified and data should be collected, referenced, and interpreted to facilitate the decision-making process. A variety of sources and methods for data collection to use quantifiable and qualitative data sets are available. A good starting point can be government statistics and databases, which often identify the number of businesses, size of particular sectors of the economy, features of the operation of markets, etc. Experts, academics, consultants and research organizations can also be consulted. Tools such as questionnaires, surveys, synthetic analysis (e.g., estimating impacts on a hypothetical business) and related tools can be used. RIA data collection methods may also include direct interviews and focus groups.

Data/information collection benefits from planning ahead, clearly identifying the specific needs to ensure resources are targeted wisely, developing good working relationships with stakeholders (including in the private sector) who may have relevant data or information to share; and using a variety of methods (e.g. surveys, interviews, focus groups or other stakeholder consultations, etc.). All data and information collected should be documented, including attention to quality, gaps and uncertainties, if any.

[20] New Zealand Government. 2012. Government Expectations for Good Regulatory Practice, treasury.govt.nz/sites/default/files/2015-09/good-reg-practice.pdf

STEP 3:

Analyse regulatory and non-regulatory options to address the SPS issue

Various regulatory and non-regulatory options to address the SPS issue should be identified and analysed based on robust quantitative and qualitative analysis and looking at impacts, costs and benefits, as well as feasibility. This stage looks at how well each SPS option will work to address the SPS issue identified, and at what costs. Typically, a scenario with no regulatory intervention should also be considered. Non-regulatory options may include "doing nothing". They may also involve raising public awareness, improving the enforcement of existing SPS measures, or reviewing and re-allocating government resources.

SPS regulators may wish to consider the following when identifying and analysing options to address the SPS issue.

Diverse impacts on the public and private sectors (including MSMEs, farmers, youth, women)

Impacts and factors to consider can include: (i) expected benefits from the SPS options, including whether they all achieve the SPS objective to the same or to a similar extent; (ii) costs associated with SPS options for the public and/or private sectors; (iii) implementation of proposed SPS options, considering implementation challenges (resources constraints, private sector capacity to comply with different types of SPS requirements based on realities) and possible strategies to ensure that SPS requirements are complied with; and (iv) other impacts on trade[21] and the domestic situation, including the environment, sustainable development, gender equality, etc.

Possible methodologies

Depending on the RIA's objective, the analysis may be based on: (i) quantitative data; (ii) qualitative data; (iii) an assessment of costs and benefits[22]; (iv) an assessment of cost effectiveness; (v) standard costs modelling; (vi) a multi-criteria assessment; (vii) an assessment of risk; or (viii) a combination of these options.[23] A quantification and systematic comparison of costs and benefits enables the assessor to determine if the costs outweigh the benefits of a given option or vice versa. While certain benefits and costs are tangible and visible up front, other costs and benefits may be hidden. A proper assessment of costs and benefits of all options is thus critical.[24]

SPS international obligations

An SPS principles and requirements checklist can be used as a filter to weed out options that are not aligned with a country's WTO obligations and its SPS obligations under regional or bilateral trade agreements. In that regard, the WTO Catalogue of instruments for managing SPS issues can be a useful tool.[25] See also Box 15 for a proposed checklist for SPS regulators to check an SPS measure's consistency with the WTO SPS Agreement.

SPS international standards

Under the WTO SPS Agreement, WTO Members are strongly encouraged to base their SPS measures on Codex, OIE, and IPPC international standards. SPS regulators should thus consider SPS options in light of the relevant standards and guidance that the Codex, OIE, and IPPC provide. Alternatively, SPS measures should be based on an assessment of risk, as appropriate to the circumstances. In the WTO SPS Agreement, risk assessment essentially refers to the process of gathering scientific evidence and relevant economic factors on the SPS risks involved in allowing a particular import to enter a country. (Box 13 on RIAs and SPS risk assessments).

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[21] SPS regulators may consider whether to establish a threshold to determine when an SPS measure has a significant impact on trade, triggering an additional trade component of the assessment. (Basedow, R. and Kaufman, C. 2016. International Trade and Good Regulatory Practices: Assessing the Trade Impacts of Regulation. OECD Regulatory Policy Working Papers. No. 4, OECD Publishing, Paris. www.oecd-ilibrary.org/governance/international-trade-and-good-regulatory-practices_5jlv59hdgtf5-en).

[22] See Reference Case Guidelines for Benefit-Cost Analysis in Global Health and Development, Review Draft (2019), https://cdn2.sph.harvard.edu/wp-content/uploads/sites/94/2019/02/BCA-Guidelines-Review-Draft.Feb-2019.pdf.

[23] For more information on some of these methods, see e.g. Manual on Regulatory Impact Assessment for use in the public service of the Republic of Armenia, http://www.valdeklaur.eu/RIA_Manual_Print_content_bleed3mm_FULL.pdf.

[24] See STDF, Use of Economic Analysis to Inform SPS-Related Decision-Making, https://www.standardsfacility.org/sites/default/files/STDF_Economic_Analysis_Nov-11_EN_0.pdf.

[25] G/SPS/63.

BOX 15.

Is my SPS measure consistent with the WTO SPS Agreement? A checklist for SPS regulators

1. Is this measure more stringent than the international standards of CODEX, IPPC or OIE?
   a. If the measure is not based on an international standard, can its scientific base be doubted?
   b. Is there scientific evidence supported by risk assessment suggesting that this measure is not necessary?
2. Does the measure impose stricter requirements to imported products than to national products or to imported products from certain countries compared to imported products from other countries? If so, could this be considered as discrimination, or as a response to different levels of risk?[26]
3. Are there other ways to fulfil the objective of this measure, imposing less restrictions on international trade[27]?
4. Are there exporting countries to which such regulation applies, which may objectively demonstrate that their own system meets our appropriate level of protection (ALOP)? Have we followed the SPS Committee's guidelines on equivalence (G/SPS/19/Rev.3)?
5. Is our ALOP applied consistently to avoid arbitrary or unjustifiable distinction in different situations? Have we followed the SPS Committee's guidelines on consistency (G/SPS/15)?
6. If a region of an exporting country was able to demonstrate that it is free of a pest or disease, does the measure impose that such information be ignored?
7. Is this a provisional measure? If so,
   a. Is the measure temporary?
   b. Is relevant scientific evidence sufficient to assess the health risks?
   c. Are we actively seeking to obtain additional evidence in order to complete a risk assessment?
8. Can this measure have a significant effect (positive or negative) on trade?
   a. Is it different from the relevant international standard?
   b. If so, was the draft measure notified to the WTO Secretariat (SPS Committee's document on transparency G/SPS/7/Rev.3)?
   c. If notified, were at least 60 days provided for comments by other countries?
   d. Were the comments taken into account in the final measure?
9. Was the measure published promptly upon its adoption[28]?

Source: author based on a document developed by the WTO Secretariat for training purposes

[26] SPS measures shall not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. (Article 2.3 of the WTO SPS Agreement).

[27] An acceptable level of risk can often be achieved in alternative ways. Among the alternatives – assuming they are technically and economically feasible and provide the same level of SPS protection – WTO Members should select the less-trade restrictive alternative to meet their health objective. (Articles 2.2 and 5.6 of the WTO SPS Agreement).

[28] Except in urgent circumstances, Members are to allow a reasonable interval between the publication of a SPS regulation and its entry into force. (Annex B.2 of the WTO SPS Agreement) This reasonable interval should normally be understood as a period of not less than six months. (Ministerial Decision on Implementation-Related Issues and Concerns (WT/MIN(01)/17)).

STEP 4:

Select option and develop implementation strategies based on evidence

Following the analysis under Step 3, a particular SPS measure may have emerged as a preferred option. This SPS measure may be subject to additional scrutiny, looking at risk factors and detrimental impacts more closely, for confirmation.

Appropriate compliance mechanisms and incentives as well as enforcement provisions should also be considered. In that context, the results of evaluations can be used to develop implementation strategies. Implementation strategies should address the resources required to meet the requirements of the selected SPS measure, whether on the side of the government or the private sector. This stage may reveal that the SPS measure under consideration is not necessarily effective on its own and that a combination of requirements is appropriate to ensure that the SPS objective is achieved. For example, if a phytosanitary treatment is mandatory for certain plants or plant products and requires a certificate, controls by the relevant SPS authority may be limited.

Regulatory contingency planning for any risks or disadvantages highlighted in Step 3 should equally be considered. This may mean increasing the periodicity of monitoring and having fall-back mechanisms where implementation is poor, or compliance is weak.

STEP 5:

Plan monitoring/evaluation of SPS measure

Processes to monitor the selected SPS measure as well as steps and time periods for the future evaluation of how the chosen SPS option performs over time need to be considered. Relevant indicators for monitoring and evaluation efforts can be considered at the RIA stage.

STEP 6:

Finalise and publish RIA (outcome)

The final step of the RIA process includes publishing the outcome of the RIA. The outcome of an RIA should be published in a Regulatory Impact Statement or Report, outlining the reasons for selecting a given SPS option and identifying how this SPS option impacts relevant stakeholders. An RIA Report should be prepared to include basic information on the data used, the conclusions of the RIA, information about public consultations that have taken place during the RIA process, as well as results of these consultation (do stakeholders support the proposed SPS option?).

Posting the results on a unified website for all proposed regulations is considered best practice. Communication can also take place through the website of the relevant SPS agency, public meetings, or targeted outreach to business associations or other stakeholder groups.[29]

BOX 16.

Reporting on RIAs

Source: author

[29] World Bank Group, Global Indicators of Regulatory Governance: Worldwide Practices of Regulatory Impact Assessments (2018).

BOX 17.

Pluto case study: Licensing Food Business Operators (FBOs) – RIA steps

SPS issue and objective	• Pluto starts by identifying the SPS issue and the SPS objective pursued. • Pluto wants to ensure that FBOs comply with food safety obligations to produce and distribute safe food in light of specific risks related to food quality.
Degree of intervention?	• There are regulatory and non-regulatory options to ensure FBOs comply with food safety obligations. • Options include: (i) registration requirements, supplemented with mandatory training on food handling and safety procedures; (ii) licensing requirements for FBOs with a given size/volume/sales and registration/training requirements for smaller FBOs; and (iii) universal licensing with differentiated requirements depending on the FBO's size/volume/sales.
Data	• Pluto's food safety authorities have initial data, estimating the current and future numbers and types of FBOs, their products and locations. This data is important for developing inspection systems, creating risk profiles, etc. • This data will be complemented by engaging with stakeholders.
Develop options	• Pluto's checklist covers: (i) whether the SPS options comply with the WTO SPS Agreement and international standards; (ii) the importance of the options in light of SPS objective; (iii) whether the options achieve the ALOP; (iv) implementation cost; (v) the cost for stakeholders to comply; and (vi) whether an alternative measure exists that is less restrictive of trade. • Pluto looks at impacts of options, in particular considering aspects such as administrative burdens for FBOs, its own ability to manage licensing schemes, costs (to the government and businesses), and positive effects on food safety. Consulting a wide range of FBOs offers insights into operational realities and feasibility of options.
Select option and plan strategies	• Pluto selects universal licensing with enforcement mechanisms, e.g.: (i) an inspectorate system to cover all the licensees on a risk basis with enough trained inspectors; and (ii) clear consequences if license terms are not complied with (suspension, cancellation) and corresponding enforcement resources. • If the inspectorate cannot carry out intensive inspections on FBOs, other options include allowing a greater degree of autonomy over different aspects of food safety processes, coupled with record-keeping obligations.
Plan monitoring evaluation	• Pluto plans the future evaluation of its FBO licensing requirements. Operation mechanisms for licences capture relevant data (types of FBO, locations, food safety incidents/risks). Pluto selects certain indicators, such as number of recalls, suspensions/cancellations of licenses, failed inspections.
Publish RIA	• Pluto publishes the results of the RIA in an RIA report.

CONSULTATIONS

Spotlight 10.

RIA and the EU Animal Health Law

The EU Regulation on transmissible animal diseases (EU Animal Health Law) was adopted in 2016. The following steps were part of the EU RIA.

1. **Identify the problem:** high complexity of current animal health policy, lack of an overall animal health strategy, insufficient focus on disease prevention, need for increased biosecurity, and other issues identified for intra-EU trade in live animals.
2. **Identify main policy objectives.** General objectives included: (i) ensure a high-level of public health and food safety by minimizing the incidence of biological and chemical risks to humans; (ii) promote animal health by preventing/reducing the incidence of animal diseases, and in this way to support farming and the rural economy; (iii) improve economic growth/cohesion/competitiveness assuring free circulation of goods and proportionate animal movements; and (iv) promote farming practices and animal welfare which prevent animal health related threats and minimize environmental impacts.

The goal was to build a simplified and more coherent legislative framework for animal health, based on good governance and compliant with international (e.g. OIE) standards.

3. **Identify policy options**

Option 1: Do nothing. Current animal health rules would remain, with technical updates and adaptations as necessary, without a horizontal framework establishing overall strategic objectives.

Option 2: Simplification of existing legislation with no major changes. Existing pieces of Animal Health legislation would be brought into one large piece of legislation. Changes would only be made as circumstances required.

Option 3: Existing legal framework with more self-regulation. This option would complement the current animal health policy and existing legislation with additional non-regulatory initiatives.

Option 4: A new simplified flexible general legislative framework, based on achieving certain animal health outcomes. The simplified legal framework would set out the principles and objectives for animal health policy required to achieve desired outcomes. The outcomes, such as certain animal health and linked public health standards, would be agreed at EU level. However, the framework would be flexible to allow EU member states to apply EU rules as appropriate in accordance with local circumstances to achieve the desired outcomes.

Option 5: A new prescriptive legislative framework, based on setting specific processes and standards for animal health policy. This framework would set specific standards for animal health rules and procedures which would be required across EU member states, with little flexibility for EU member states to adapt the rules to their differing circumstances.

4. **Assessing the impacts, using the "no change" option as baseline.** The benefits associated with option 2 are those of simplification of the legislation by bringing together existing legislation into one place. To put everything in one piece of legislation would lead to a long list, achieving very little in the way of genuine simplification, so the objectives will not be met. The assessment of the options 3-5 led to the comparison table in the next step.
5. **Comparing options.** Options were compared looking at effectiveness (likelihood to achieve its objective), efficiency (looking at factors related to costs, resource availability, administrative burden) and coherence with EU objectives.
6. **Planning monitoring and evaluation:** Simple and reliable performance indicators (i.e. hard indicators of animal health and softer indicators tracking the confidence, expectations and perceptions of European citizens) were considered helpful to measure progress. Examples of hard indicators of success identified included: (i) the proportion of EU veterinary expenditure for eradication and monitoring measures vs. emergency measures; (ii) restrictions (number of areas x length of restrictions) due to outbreaks of regulated notifiable diseases; (iii) the number of large scale disease outbreaks and of animals culled due to eradication measures; (iv) overall costs and losses for the EU, MS and farmers and other stakeholders due to animal disease outbreaks; (v) animal consignments moved across borders under the simplified regime; and (vi) the number of training sessions taken up by animal keepers, especially farmers. An evaluation was envisaged to take place around five years after the implementation of the Animal Health Law.

Source: SANCO/7221/2010-EN SIA Rev.1

2.4 Monitoring implementation and evaluation

2.4.1 Monitoring and evaluation in a nutshell

Monitoring is a regular and ongoing process to gain information on the use of SPS measures. It refers to the continuous review of an SPS measure and requires regularly keeping track of the SPS measure by collecting information/data on the measure's implementation and performance.

Monitoring efforts are typically complemented by evaluations. Evaluation is a periodic process using monitoring results to evaluate the impacts/effects of SPS measures. It assesses the effectiveness and efficiency of the SPS measure to learn about how well (or otherwise) an SPS intervention is performing, providing timely lessons to feed into decision-making for the future. Evaluation usually takes place towards the end of the regulatory management cycle because it involves looking at results. It also closes the loop of the cycle as it links the end results stages with the beginning stages of assessment and agenda-setting for new or updated SPS measures.

Monitoring implementation and evaluating outcomes is important to:

- Assess the various trade, economic, and health impacts of an SPS measure as relevant, including any unintended or unforeseen consequences that may only be properly evaluated once the SPS measure is implemented;
- Consider other possible cross-cutting implications, effects of an SPS measure e.g. covering environmental, social, and gender-related effects, as appropriate;
- Evaluate costs and benefits to assess the effectiveness, efficiency, and relevance to the intended policy and outcome;
- Monitor the use of international standards; and
- Demonstrate an efficient use of resources for regulators and provide guarantees to trading partners.

For example, monitoring and periodically evaluating SPS measures can help regulators understand better why an SPS measure is not achieving the expected level of SPS protection and what specific factors (e.g. geography, lack of skilled inspectors, or inadequate laboratories) are relevant in this context. Assessing how existing SPS measures affect trade can support reporting to senior government officials and development partners, and may help to secure additional resources to address some of the identified challenges. Monitoring SPS measures can also help identify whether scientific evidence underlying the SPS measure has evolved, new technologies or new Codex, IPPC, or OIE international standards were developed, which may warrant revisiting SPS measures.

The quality of monitoring and evaluation efforts can be ensured through robust stakeholder engagement. Communication of the purposes of monitoring/evaluation with all stakeholders can facilitate data collection (through monitoring bodies or surveys) and help make recommendations that are practical and user-centric (see section 2.5 on stakeholder engagement). In addition, when monitoring or evaluations are carried out by SPS regulators themselves, it might be worth considering an external evaluation of the process itself by a central regulatory oversight body or another external body. This ensures quality control and helps improve the quality of the monitoring/evaluation processes for the future.

BOX 18.

What do international standards say about monitoring and evaluation? A few examples

ISPM 7: Phytosanitary certification system

6.1 System Review. The NPPO should periodically review the effectiveness of all aspects of its export phytosanitary certification system and implement changes to the system if required.

ISPM 23: Guidelines for inspection

2.6 Review of inspection systems. NPPOs should conduct periodic reviews of import and export inspection systems to validate the appropriateness of their design and to determine any course of adjustments needed to ensure that they are technically sound.

Codex Guidelines: Principles and Guidelines for National Food Control Systems (CAC/GL 82-2013)

Principle 9. Self-assessment and Review Procedures

20. The national food control system should possess the capacity and capability to undergo continuous improvement and include mechanisms to evaluate whether the system is able to achieve its objective.

Section 4.4 Monitoring and System Review

82. The effectiveness and appropriateness of the national food control system should be regularly assessed against the objective of the system, effectiveness of control programs, as well as against legislative and other regulatory requirements. Criteria for assessment should be established, clearly defined and documented, and may also include cost benefits and efficiency.

90. The results of the evaluations, including the results of self-assessment and audits should also be taken into account in further improvement of the system, and corrective actions should be taken into account as appropriate.

91. Any review and continuous improvement of the national food control system should be communicated effectively and efficiently to ensure that clear exchange of information and engagement between all stakeholders in the national food control system occurs. Following any review, all related documentation, procedures and guidance should be reviewed and updated if necessary to reflect any changes.

92. Competent authorities should consider the resultsof monitoring and review processes and take preventive or corrective action or improve the system as appropriate.

Spotlight 11.

Use of monitoring and evaluation tools by countries

A 2018 study gives indication on the use of OIE standards when setting sanitary measures, including on the use of monitoring and evaluation tools by countries.

Proactive policies to evaluate and revise sanitary measures periodically as part of monitoring and evaluation efforts, e.g. to consider amendments to the OIE Codes, were reported by 52% of countries surveyed. 30% of African countries surveyed have such policies in place (and up to 60% of African countries surveyed will engage in such efforts if requested by a trading partner), while the figures were higher for Asia-Pacific countries and Middle East countries (40% of the countries surveyed in these regions have such policies in place and up to 90% engage in such efforts if requested by a trading partner).

Source: OIE (2018)[30]

Additional resources on monitoring and evaluation mechanisms:

- OECD Conference (2016), Measuring Regulatory Performance. Closing the regulatory cycle
- OECD (2014), OECD Framework for Regulatory Policy Evaluation
- UNCTAD project, assessing cost-effectiveness of non-tariff measures – a toolkit, October 2020

[30] Kahn, S; Bucher, K; Tellechea, D. 2018. Implementation of OIE standards by OIE member countries: state of play and specific capacity building needs. Descriptive analysis of questionnaire, https://www.oie.int/fileadmin/Home/eng/Publications_%26_Documentation/docs/pdf/TT/2018_A_86SG_9B.pdf

2.4.2 Key steps of monitoring and evaluation processes

STEP 1:

Identify objectives and what is to be monitored/evaluated

SPS regulators should identify the specific objectives of the monitoring/evaluation processes to determine the scope of what is to be monitored/evaluated. For this purpose, questions pertaining to the SPS measure's implementation/results, such as the following ones, may be useful:

- How effective is the animal health measure in achieving the appropriate level of protection while minimally inhibiting trade?
- How effective is the plant health measure in reducing risks from regulated non-quarantine pests?
- How effective are market surveillance inspections to prevent outbreaks of foodborne illnesses?

STEP 2:

Define monitoring/evaluation indicators

Monitoring exercises and evaluations do not need to cover everything. They can have a limited scope targeting critical issues that would leverage the most insight into the functioning of an SPS measure. In addition, evaluation criteria should be set considering the type of data that can be collected.

Various quantitative and qualitative indicators can help in monitoring and evaluation efforts. SPS regulators may want to consider whether: (i) private sector stakeholders and government officials fully understand the SPS measure and what is required to comply; (ii) the SPS measure is available in the public domain; (iii) the SPS measure can be implemented and how; (iv) the SPS measure achieves the expected outcome; (v) costs of implementing the SPS measures; and (vi) unintended consequences of implementation. Indicators used to monitor or evaluate SPS measures should ideally follow the SMART criteria: they should be Specific, Measurable, Achievable, Relevant, Timebound. See Spotlight 8 on RIA and the EU Animal Health Law for examples of indicators.

BOX 19.

Pluto case study: Monitoring and evaluating effectiveness of declarations for animal health emergencies

Defining the scope of monitoring/evaluation efforts

Animal health regulators in Pluto want to determine the effectiveness of using a declaration of an infected area to stop the spread of a notifiable disease in a manner that is quick and cost-efficient. Evaluations help them understand how declarations trigger the use of certain special powers that may be important for competent authorities to apply in their responses, allow for the deployment of special funds as well as enable the application of controls of people, vehicles and animals. Evaluations can assist regulators in tracking how well such declarations have worked, whether such declarations were necessary in the circumstances, whether other factors should be considered in the future, or whether a simpler, cheaper non-regulatory alternative could achieve better results.

Setting indicators for monitoring/evaluation

Pluto's objective is to stop disease spreading as quickly as possible. It decides to focus on the following indicators:

- Number of disease detections outside infected area while declaration was in effect;
- Actions taken within time prescribed in declaration/emergency response plan; and
- Instances of non-compliance with measures established in the declaration.

Additional resources on indicators for monitoring and evaluation of SPS measures:

- STDF working documents on indicators to measure SPS performance
- OECD Indicators of regulatory policy and governance
- OECD (2014), OECD Framework for Regulatory Policy Evaluation, OECD Publishing, Paris
- OECD Conference. 2016. Measuring Regulatory Performance. Closing the regulatory cycle: effective ex-post evaluation for improved policy outcomes.

STEP 3:

Identify methodologies

Monitoring is usually conducted by SPS agencies. Evaluation can equally be conducted by SPS agencies, in which case independent quality control may be recommended, or an independent body. In all cases, the entity in charge should clearly identify monitoring/evaluation methodologies to be applied, considering methodologies that may be promoted by central regulatory oversight bodies.

The following should be considered: how the monitoring and evaluation tasks are to be carried out; by whom; at what stage of the regulatory shelf-life of the SPS measure and during what time period; in what sequence; which stakeholders would need to be consulted; and how to ensure consistency in terms of criteria and measurement across different groups and technical areas. SPS regulators may wish to set up continuous monitoring mechanisms that do not require significant resources. This could be accomplished by being strategic in their choice of indicators. Expectations should be managed about what monitoring/evaluation efforts can deliver.[31]

Importantly, any evaluation of the impacts/effects of SPS measures should be considered in light of other types of evaluations, for example, findings of the OIE PVS Pathway or IPPC PCE Tool (see Box 8), or other evaluations or assessments prepared by central regulatory bodies.

STEP 4:

Data collection and analysis

SPS regulators should determine in advance: what information exists; what information is needed and how it can be obtained; and what data should be available for the monitoring and evaluation exercise.

Any survey questions and data to be collected should bear direct relevance to the main monitoring/evaluation issue so that the data can be succinct and manageable. Data should be from diverse sources and accurate to serve as base evidence for analysis and recommendations. Once collected, the data require appropriate sorting and analysis. Data-related recommendations for RIAs can be applied in the context of monitoring and evaluation efforts (see above section 2.3.2).

[31] EU Better Regulation Toolbox. 2017. ec.europa.eu/info/sites/info/files/better-regulation-toolbox_2.pdf.

2.5 Transparency and stakeholder engagement

2.5.1 Transparency and stakeholder engagement in a nutshell

Transparency is a cross-cutting principle of GRPs that is relevant throughout the regulatory lifecycle of SPS measures. It is embodied in various GRPs, such as stakeholder engagement (e.g. consultations), information dissemination, or cooperation and coordination mechanisms. Transparency is also a fundamental tenet of the WTO SPS Agreement and is reflected in many SPS related international standards issued by Codex, IPPC, and OIE, as well as in many bilateral and regional trade agreements (see e.g. Spotlight 3 on SPS-related GRPs in the EAC Partner States - US Cooperation Agreement).

In the WTO framework, transparency refers to the aim of achieving a greater degree of clarity, predictability and information exchange about trade policies, rules and regulations of WTO Members. The WTO SPS Agreement provides a unique multilateral transparency framework that contributes to cooperation among WTO Members. This SPS transparency framework includes notification of proposed regulatory measures with potentially significant trade effects and providing the opportunity for comment, Enquiry Points and National Notification Authorities (Box 20 on Transparency in the WTO SPS Agreement). In addition, the WTO SPS Committee serves as a platform for transparency, by providing public and centralized access to SPS measures notified and/or discussed by WTO Members. Exchanges on proposed SPS measures increases the chance that the right balance between trade facilitation and regulatory autonomy is struck. Awareness of regulatory trends in other markets can also assist regulators as they develop measures to address similar policy objectives.

The WTO Trade Facilitation Agreement also contains important transparency provisions, some of which go beyond the transparency requirements in the WTO SPS Agreement and may be relevant for SPS agencies (SPS-plus provisions).[32] These include the obligations: (i) to publish a wide range of information related to importation and exportation requirements and procedures, for instance on the required forms and documents, or on fees and charges; (ii) to make a description of importation, exportation and transit procedures available on the Internet and whenever practicable, in one of the WTO official languages; (iii) for enquiry points to reply to enquiries from the private sector (not only from other WTO Members); and (iv) to provide opportunities and an appropriate time period to traders and other interested parties to comment on the proposed introduction or amendment of laws and regulations related to the movement, release and clearance of goods and to provide for regular consultations between border agencies and traders or other stakeholders within their territory.[33]

BOX 20.

Transparency in the WTO SPS Agreement

Transparency obligations are at the heart of the SPS Agreement. They include:

- Notification of draft regulations, receive comments, discuss them upon request and take them into account (recommended minimum 60-day comment period[34]).
- Publication of regulations with a transition period (minimum 6 months before entry into force[35]).
- Establishment of National Enquiry Point responsible for the provisions of answers to all reasonable questions and well as the provision of relevant documents.
- Designation of National Notification Authority responsible for implementing the notification requirements of the WTO SPS Agreement.

More on transparency: WTO | Sanitary and Phytosanitary Measures – members' transparency toolkit.

[32] The WTO Trade Facilitation Agreement, which entered into force in 2017, aims to expedite the movement, release and clearance of goods and to reduce transaction costs in trade. While most provisions of the WTO Trade Facilitation Agreement are to be implemented by customs authorities, many also apply to other agencies that deal with international trade, including SPS agencies.

[33] On the relationship between the WTO Trade Facilitation Agreement and the WTO SPS Agreement, see https://www.wto.org/english/tratop_e/sps_e/tf_sps_e.pdf.

[34] Recommended Procedures for Implementing the Transparency Obligations of the SPS Agreement (G/SPS/7/Rev.4).

[35] Ministerial Decision on Implementation-Related Issues and Concerns (WT/MIN(01)/17).

Transparency goes hand-in-hand with stakeholder engagement in the regulatory process to ensure that SPS regulations serve the public interest and are informed by the legitimate needs of those interested in and affected by these regulations. This involves that all regulations are easily accessible by the public. It also involves providing meaningful opportunities for stakeholders to contribute to the regulatory process and to the quality of the supporting analysis.[36]

Broadly defined, stakeholders are: (i) individuals, groups, or organizations whose interests are affected by the SPS challenge or the contemplated SPS measure (this may include stakeholders from other SPS agencies or stakeholders from third countries); (ii) those who possess information, resources and expertise needed for the RIA or assessment, strategy formulation, and implementation; and (iii) those who control relevant implementation instruments.

SPS measures deal with a variety of disciplines and a wide range of stakeholders may need to be involved: other SPS agencies that may be dealing with overlapping or related SPS concerns as well as private sector stakeholders, such as food industry associations[37], traders, FBOs, exporters, importers, consumers. Stakeholders whose views and perspectives may otherwise be marginalized should be considered, such as MSMEs, lower income farmers, and women. The views, practical experience and data provided by a wide range of stakeholders will help deal effectively with various challenges (e.g. environmental or equality challenges), deliver higher quality and more credible SPS initiatives, ensure greater legitimacy of SPS measures, and contribute to their successful implementation.

Stakeholder engagement has many benefits, in particular that of ensuring that SPS measures adequately reflect the country's needs and realities. Stakeholder engagement is important to[38]:

- Consider meaningfully the perspectives of those who use, have access to, and are affected by SPS measures;
- Identify the full scope of needs and challenges of regulated parties and regulators;
- Allow for the consideration of the views of diverse groups, including MSMEs, lower income farmers, and women, and that their needs be addressed;
- Make it more likely that unintended impacts on operators are identified and factored-in;
- Address ambiguities and reduce overlaps (e.g. duplicate inspections) early on, thereby improving the effectiveness and quality of the decision-making process;
- Foster better understanding of SPS measures by (and garner support from) those who need to comply with them, which in turn may lead to better implementation;
- Identify and address vested interests; and
- Build the private sector's trust and confidence in the work of SPS authorities.

There are three typical forms of interactions with stakeholders, with varying degrees of engagement and interactivity[39]:

- Information dissemination, publication, and notification for the purposes of raising awareness among stakeholders;
- Consultations to seek the opinion and inputs of stakeholders; and
- Participation to seek the direct involvement of stakeholders, e.g. through legislative drafting committees or policy working groups.

Additional resources on stakeholder engagement mechanisms:

- OECD Regulatory Policy Outlook 2018
- OECD Pilot database on stakeholder engagement practices
- UN/CEFACT. 2015. Consultation approaches: best practices in trade and government consultation approaches on trade facilitation matters. Recommendation 40

[36] OECD 2012 Recommendation on Regulatory Policy and Governance, Principle 2.

[37] Food industry associations can serve as a trusted source of knowledge and help disseminate information. APEC. Food Industry Associations: Their Role and Value in Policy and Regulation. September 2016.

[38] UN/CEFACT. 2015. Consultation approaches: best practices in trade and government consultation approaches on trade facilitation matters. Recommendation

[39] OECD. 2010. OECD Review of Better Regulation in Sweden

BOX 21.

What do international standards say about transparency? A few examples

OIE Terrestrial Animal Health Code, Chapter 3.4 Veterinary Legislation, Article 3.4.3. General Principles

3. Transparency

Veterinary legislation should be inventoried and be readily accessible and intelligible for use, updating and modification, as appropriate. Competent Authorities should ensure communication of veterinary legislation and related documentation to stakeholders.

4. Consultation

The drafting of new and revised legislation relevant to the veterinary domain should be a consultative process involving competent authorities and legal experts to ensure that the resulting legislation is scientifically, technically and legally sound. To facilitate implementation of the veterinary legislation, competent authorities should establish relationships with stakeholders, including taking steps to ensure that they participate in the development of significant legislation and required follow-up.

ISPM 20: Guidelines on a phytosanitary import system

5.1.9.1 New or revised phytosanitary regulations

Proposals for new or revised phytosanitary regulations should be published and provided to interested parties on request, allowing reasonable time for comment and implementation.

5.1.9.2 Dissemination of established regulations

Established import regulations, or relevant sections of them, should be made available to interested and affected contracting parties as appropriate, to the IPPC Secretariat and to the RPPO(s) of which they are a member. Through appropriate procedures, they may also be made available to other interested parties (such as import and export industry organizations and their representatives). NPPOs are encouraged to make import regulatory information available by publication, whenever possible using electronic means including Internet websites and linkage to these via the IPPC International Phytosanitary Portal (IPP)(www.ippc.int).

Codex Principles and guidelines for national food control systems CAC/GL 82-2013

Principle 3 Transparency

10. All aspects of a national food control system should be transparent and open to scrutiny by all stakeholders, while respecting legal requirements to protect confidential information as appropriate. Transparency considerations apply to all participants in the food chain and this can be achieved through clear documentation and communication.

2.5.2 Transparency tools

There are many transparency tools available to help with consultations, information dissemination, publication, notifications, etc. The nature of the SPS issues at hand, resource constraints, the objective pursued (inform, raise awareness, seek input) and the types of stakeholders dictate the appropriate tools to be used. Tools should be designed to best engage the targeted groups. For example, while centralized or local working groups and in-person meetings are useful, they may be too burdensome, time consuming, or impractical. Online tools can be particularly useful when stakeholders are geographically scattered but may not be suitable if key stakeholders have limited Internet access. Governments should consider regular training and knowledge sharing activities on available transparency tools to ensure that public and private sector actors are adequately informed.

Enquiry Points/National Notification Authorities: Enquiry Points are mechanisms for sharing information on SPS measures. The WTO SPS Agreement provides that each WTO Member shall ensure that one enquiry point exists which is responsible for the provision of answers to all reasonable questions from interested WTO Members as well as for the provision of relevant documents.[40] Some WTO Members identified challenges with regard to the operation of Enquiry Points, such as poor coordination between state agencies resulting in a limited flow of information. Efforts should be made to ensure the operational capacity of Enquiry Points.

Under the WTO SPS Agreement, WTO Members are also required to designate a single central government authority as responsible for implementing, on a national level, the notification requirements of the Agreement. This is the National Notification Authority. It is responsible for ensuring proposed regulations are published early to allow for comments; notifying other WTO Members of proposed SPS regulations, using the appropriate notification forms; providing copies of proposed regulations on request; and ensuring that comments are handled correctly.

Challenges have been identified with respect to SPS notifications. For example, an APEC Study on SPS Notifications identifies particular challenges with SPS notifications, also from the private sector perspective. It concludes that a prioritized vision to define better the scope of products affected by a draft SPS measure, as well as a detailed summary of the notified SPS legislation in the description of the content could have a significant impact on trade in the short term.[41]

Spotlight 12.

National and regional guides to manage SPS notifications – Chile's experience

In 2019, Chile developed a good practice guide on SPS notification management. The guide supports Chile's National Notification Authority (NNA) and relevant public and private stakeholders and clarifies issues related to notification. The document assigns responsibilities and establishes procedures for the management of national notifications, thus encouraging compliance with notification requirements in the SPS area. It also defines responsibilities and establishes procedures regarding notifications from other WTO Members to review and comment on these notifications. The document aims to strengthen the engagement of interested stakeholders that might be affected by SPS measures.

Countries in the Pacific Alliance (Colombia, Mexico, and Peru) developed a guide to promote international cooperation and good practices in cooperation with IICA. Focused on notification and transparency provisions in the WTO SPS Agreement, the Guide offers SPS Notification Authorities a tool for knowledge management and training.

Source: WTO SPS Notification Management – Good practice guide for Chile and Good Practice Guide for WTO SPS National Notification Authorities (NNAs)

Additional resources on transparency:

- Procedural step-by-step manual for SPS national Notification Authorities and Enquiry Points
- WTO SPS Information Management System (IMS) to track information on SPS measures notified to the WTO

[40] Annex B of the WTO SPS Agreement.

[41] www.apec.org/Publications/2019/08/Study-of-APEC-Economies-SPS-Notifications.

Notification alert systems ePing, a joint initiative of the UN, WTO and ITC, is a global online tool that enables private and public stakeholders to access, keep track, and react to notifications of new/revised SPS (and TBT) measures.[42] This tool facilitates the browsing of SPS notifications by product, notifying member, date, objective, and keyword.[43] Alerts can be set to help policy makers, SPS focal points, exporters, importers, and others be informed of SPS notifications. Moreover, for each individual notification, there are discussion fora in the ePing system: the Discussion Forum for Enquiry Points and the National Discussion Forum.

Given the high volume and diversity of regulatory measures notified by WTO Members, it is a challenge for interested stakeholders to track and react to changing product requirements. ePing's alert system and search options can help address that challenge. In addition, ePing is an important tool for contacting foreign stakeholders and gathering insights from beyond the jurisdiction, for example on possible unintended trade impacts of regulations. ePing can assist National Enquiry Points in managing and reaching out to domestic stakeholders or other Enquiry Points to discuss specific notifications and/or provide complementary information (such as translations). These features can in turn facilitate the formulation of timely comments on notifications or the adaptation to new requirements.

Spotlight 13.

ePing promotion and implementation in Uganda

Uganda was one of the pilot countries for ePing. In 2018, the Enhanced Integrated Framework (EIF) reported on this pilot:

George Opiyo, Uganda's TBT focal point for the WTO, has been working with ePing since its inception. "Before we started using ePing, one of the challenges that was associated with the earlier mechanism of dissemination of notifications to people in our country was that the notifications were not reaching the final intended beneficiaries, who may be directly impacted," he said.

There were in-country trainings for Uganda's central and district government officials, the private sector and key industries like the National Organic Agricultural Movement and the Uganda Flowers Exporters Association.

With more than 280 registered ePing users in the country, according to Opiyo, one could say that the platform – and as a result communication about trade with the aim of increasing it, and thereby improving citizens' lives – is now flowering. ePing users can also talk notifications with interested parties. Opiyo said, "We are using ePing to discuss and get feedback on notifications. We are also using ePing for sharing any complementary information." This could include the full text of draft measures, translations and questions from members about the specifics of a new requirement. With a 60-day comment period, knowing that a draft has been notified immediately means more time for consideration and response.

Source: EIF News 2018, Information on new product requirements for LDCs – now direct to your inbox

[42] www.un.org/development/desa/dpad/wp-content/uploads/sites/45/publication/2016_eping_flyer_v4.pdf and www.epingalert.org/en.

[43] The WTO SPS Information Management System (IMS) also allows users to track, inter alia, information on SPS measures that were notified to the WTO. spsims.wto.org/.

In-person/virtual meetings: Public hearings or small-group meetings, focused group discussions, advisory groups, expert groups, workshops/conferences or other types of meetings can be organized in-person or virtually. This can be particularly useful when feedback has been received in writing but requires further exploration and discussion. Such meetings can be organized periodically or take the form of a single event to gather targeted feedback. Generally speaking, committees, working groups, or other types of meetings across different government agencies and involving the private sector play an important role to ensure effective stakeholder engagement.

Websites: Websites can be used to disseminate and gather information, via comments and feedback. One of the OECD recommendation includes that a complete and up-to-date legislative and regulatory database should be freely available to the public in a searchable format through a user-friendly interface over the Internet.[44] Practices range from providing basic information on main SPS measures to providing detailed guidance on SPS measures, access to forms, and updated information. SPS regulators may use a unified or central website, in particular where a central regulatory body exists. In the alternative or in addition, SPS regulators may use the website of their parent ministry or their own website (in which case it might be easier to exert control on the information shared). Website publication is quick, cost-efficient, and reaches a broad public. However, stakeholders may have limited Internet access or IT literacy. Therefore, depending on the stakeholders to engage, websites are not always the most appropriate medium.

Spotlight 14.

Transparency in the Philippines

Standard practices to disseminate information about a new regulation include letters or notices to affected parties, publications available on the web and in print, and press releases. Where agencies post draft legislation or administrative issuances online, the website can enable comments and recommendations. For primary legislation, after the comments have been considered an the draft finalised, stakeholders are provided with feedback through legislative hearings and consultations.

Other transparency initiatives include the Philippine Business Regulations Information System (PBRIS) of the Anti-Red Tape Authority (ARTA). This is a platform made to provide accessible information on business regulations issued by the Philippine government. The Philippines also put it place a transparency seal on government agencies' websites to contain information on: mandates and functions, names of officials, and contact information; annual reports; budgets and targets; major programs and projects and their beneficiaries; status of implementation as well as evaluation/assessment reports; and annual procurement plan.

Source: Anti-Red Tape Authority, Philippine Department of Agriculture and OECD (2018)[45]

[44] OECD 2012 Recommendation on Regulatory Policy and Governance, Principle 2, www.oecd.org/gov/regulatory-policy/2012-recommendation.htm.

[45] OECD. 2018. Good Regulatory Practices to Support Small and Medium Enterprises in Southeast Asia, OECD Publishing Paris, doi.org/10.1787/9789264305434-en.

Spotlight 15.

Lao People's Democratic Republic's Trade Portal

An online Trade Portal (in Lao and in English) was established in 2012 under the auspices of the Department for Import and Export of the Ministry of Commerce. This Portal fostered a culture of cooperation and collaboration in the exchange of information among key ministries as well as sensitized the public in the use of a website as a source of regulatory and trade information.

The core objective of this Trade Portal is to facilitate trade by increasing the transparency of trade-related regulatory information. The Trade Portal contains:

1. All laws, regulations, and other legal instruments;
2. All license and permit requirements, prohibitions, restrictions, technical standards, SPS measures;
3. Entire commodity classification and tariffs;
4. All procedures for license/permit application and clearance; and
5. Copies of all forms.

The Portal offers plain language information on existing rules as well as market access information. It offers news, announcements, events, and publications and contains features to contact specific agencies, receive information assistance, and access SPS Enquiry Points.

Source: https://www.laotradeportal.gov.la/

Spotlight 16.

Regulations.gov in the United States

Regulations.gov was launched in 2003. It is a government portal and document repository to allow members of the public to participate in the rulemaking processes of some government agencies. The aim is to enable public access to regulatory materials, increase rulemaking participation, and improve agencies' efficiency and effectiveness. In particular, the website allows users to search for publicly available regulatory materials, such as trending regulations, public comments, supporting analyses, Federal Register notices, etc. Users can also make public comments in response to notices of proposed rulemaking issued by participating agencies. Such comments become part of the public record and may be displayed on the site.

Source: www.regulations.gov

Social media: Social media platforms, such as Facebook and Twitter, are increasingly used by SPS regulators to raise awareness. Webinars and YouTube videos can also be used to share key information (e.g. relating to new SPS rules that will come into effect), offer free training (e.g. on food handling and hygiene), and disseminate information broadly (e.g. on plant import restrictions). Using social media is quick and cost-efficient but may not be suitable where stakeholders have limited Internet access or IT literacy. It can be particularly useful to disseminate information about outbreaks of foodborne illnesses, zoonoses, or pests, where public cooperation plays an important role in ensuring a coordinated and timely response.

Email lists: Email lists may be used to distribute newsletters or alerts. Emails are efficient and cost-effective but may not be suitable where stakeholders have limited Internet access or IT literacy.

Telephone lists: Telephone lists can be used for alerts or to convey brief information through text messages. This works well where the number of stakeholders is limited but is not suitable to convey complex information. Telephone calls are time consuming, and the lack of record may enable abuse (e.g. restrict information access to certain stakeholders or claim information was conveyed when it was not).

Video conferences/calls: Video conferences/calls are reliant on good Internet speed or good telecommunication networks and lines. Like other online tools, these may not be suitable where stakeholders have limited Internet access or IT literacy.

Official Gazettes: Official Gazettes publish legal notices and legislation, and sometimes draft legal instruments. In some countries, the Government and private parties may publish notices in Official Gazettes and include "non-legal" elements of information relating to specific products or producers.

Other media: Information may be disseminated via the radio, newspapers, and other media. These mechanisms are particularly useful in the case of pest or disease outbreaks, outbreaks of foodborne illnesses, and product recalls.

2.5.3 A focus on consultations

Consultations are one form of stakeholder engagement. Consultations should be an *ongoing* and interactive process, conducted at all stages of the regulatory management cycle, and before new or revised SPS measures are applied. Consultations can help identify inadequate SPS measures within the existing regulatory framework as part of stocktaking efforts, build a forward-looking agenda and set the right SPS priorities for future reforms, or ensure that assumptions made in the context of RIAs are correct and that the options explored are adequate. Consultations can also support international regulatory cooperation as well as coordination and cooperation at the domestic level to adequately address SPS issues.

Consultations are key to garner the support of the key stakeholders, in particular those that will need to comply with the SPS measures, thus ensuring better compliance with SPS measures. Support for even the most stringent SPS measures can be gained where stakeholders are managed effectively and understand why such measures are needed.

BOX 22.

Key consultation principles

- **Openness:** SPS regulators should be prepared to consider various views and perspectives (including those of groups that are sometimes marginalized, e.g. MSMEs, lower income farmers, women) and adjust their initial expectations and plans for the SPS measure.
- **Accountability:** The input and feedback from stakeholders is collated and assessed and used in the design, development, or review of the SPS measure. SPS regulators are accountable for the outcome of the consultations and for how stakeholder input has informed and helped shape the SPS measure.
- **Transparency:** The consultation process is transparent. Information is available to stakeholders about relevant aspects of the process, stakeholder engagement, stakeholder input, consultation outcomes, and how stakeholder input is used to design, develop, or review SPS measures.
- **Ongoing process:** Consultations and other forms of stakeholder engagement should be conducted at all stages of the regulatory management cycle of SPS measures. They are a key element for the successful implementation of other GRPs, such as RIAs and monitoring and evaluation processes.
- **Visibility:** All those who may be impacted by the SPS measure under consideration or are interested in participating in the consultations need to be made reasonably aware of the process. This means efforts to reach all relevant stakeholders.
- **Access to information:** Stakeholders need access to all relevant information to help them provide quality inputs on the SPS issue. Information provided should be clear and easy to comprehend.
- **Access to the process:** Stakeholders must have reasonable access to the process. The methods chosen for the consultation must be suitable for the intended stakeholders.

STEP 1:

Stakeholder mapping and establishing a consultation strategy

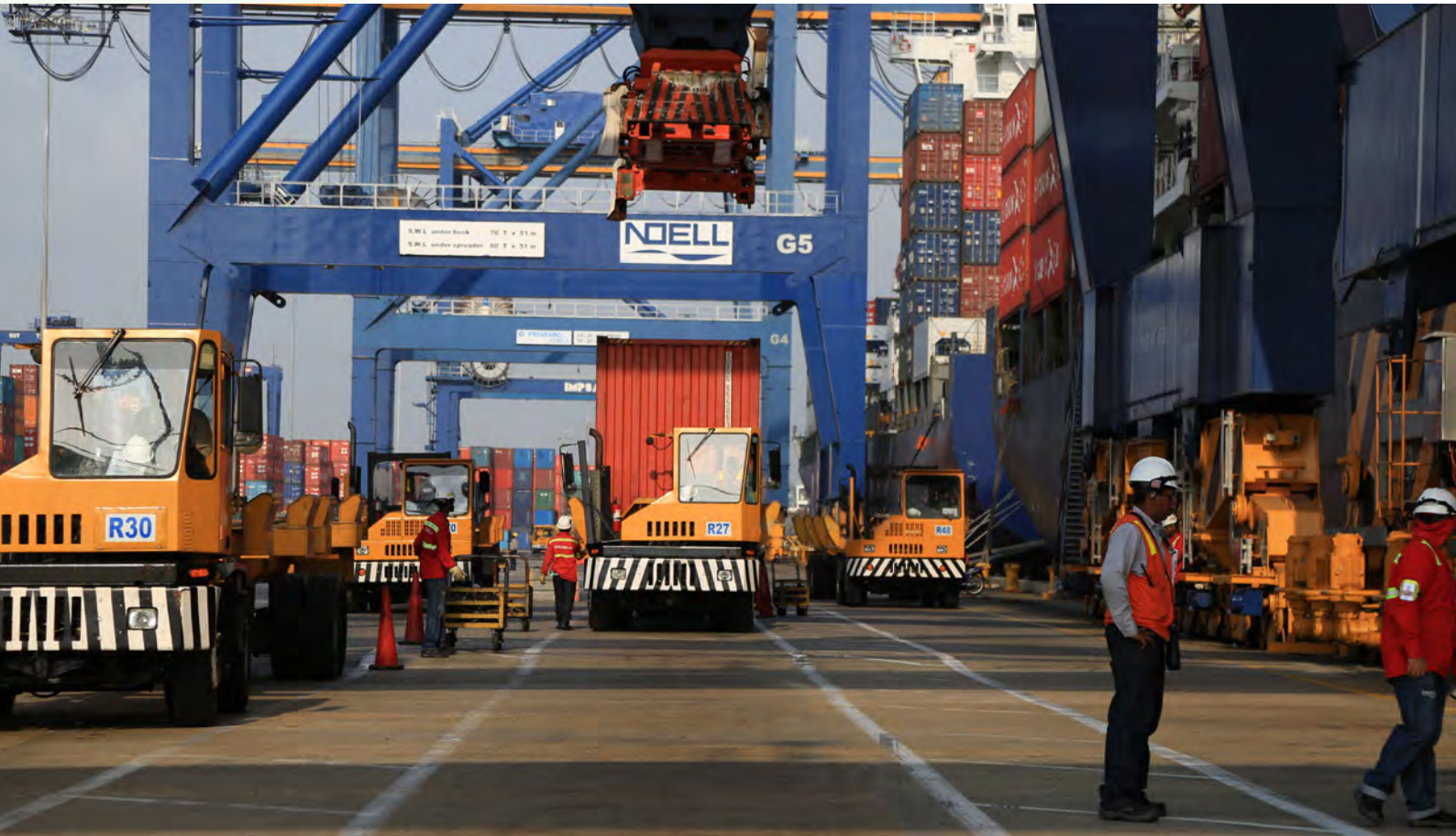
A first consideration for successful consultations is deciding which stakeholders to engage and understand their interests and their relationship to the SPS issue. Resource constraints may make it impossible to engage with all relevant stakeholders at the same level of intensity and certain stakeholders may need to be prioritized. The purpose of consultations is not to include the highest number of stakeholders, but to gather diverse viewpoints. It is thus also key to establish a consultation strategy to ensure that the objectives of the consultations are achieved. A consultation strategy can include information on: the level of influence and interest of the stakeholders; current and desired orientation of the stakeholders; risks if desired orientation will not be achieved; opportunities if desired orientation will be achieved; strategies to engage with the stakeholders; appropriate consultation tools to employ; and a timeline for the consultations.

Stakeholder mapping identifies stakeholder groups concerned with a given SPS measure and categorizes these stakeholder groups according to levels of interest and influence.

A list of possible stakeholders should be drawn up, identifying stakeholders currently affected by the SPS measure and those who could be affected in the future by a new/revised SPS measure. This list can be based on research and feedback through polls/surveys. Listed stakeholders should then be grouped by looking at how they may be impacted by the SPS measure, their relevance to the SPS measure, or their positions or views on the SPS measure. Relationships and linkages among and with other stakeholders should also be considered.

Once there is a preliminary list of grouped stakeholders, SPS regulators should assess: (i) the contribution value of stakeholders or their willingness to engage on issues; (ii) their needs, interests, and capacities; (iii) the influence they can exert; (iv) the risks they pose; and (v) what data they will require from various groups. SPS regulators should be cautious of asymmetries in stakeholders' power/influence and ensure that these asymmetries do not undermine the neutrality and fairness of the consultation mechanisms (or perception thereof). Large importers, exporters, food processors, or other types of businesses may be perceived to, or may in effect, leverage more influence over the esign of SPS measures than smaller enterprises. This is referred to as "policy capture" by powerful interest groups. Assessing stakeholders will help SPS regulators finetune the stakeholder list and groups as well as identify priority stakeholders.

The list and groups of stakeholders as well as priority stakeholders are likely to evolve over time as unforeseen information may surface when stakeholders are identified, assessed, and consulted. The process should be as thorough as possible from the start, but reassessment and updates may be necessary.



BOX 23.

Pluto case study: Establishing designated entry points for plants

Pluto is a country with large border areas and many checkpoints, but its financial, human, and infrastructure resources are limited, and the numerous checkpoints are not well managed. Pluto has decided to designate entry checkpoints for the import of plants and plant products. Pluto is aware that these designations should not impede trade and that it will need to consider factors pertaining to technical health and risk management; trade facilitation; informal trade, smuggling, and relations with neighbouring countries; and livelihoods and socio-economic impact. The Government in Pluto asked the national plant protection organization (NPPO) to map stakeholders engaged in the import and export of plants and plant products. This will help design a consultation strategy and ensure effective consultations.

NPPO's steps for stakeholder mapping:

List stakeholders	• Preliminary list to include: agencies and government units with a role in regulating trade of plants and plant products; relevant customs agencies and government units; local authorities in border regions; customs brokers and other border agents; importers; and trade associations.
Group stakeholders	• Preliminary grouping based on considerations pertaining to trade, livelihoods, and the nature (public/private) of the stakeholder.
Assess stakeholders	• Factors considered: (i) strategic access to key routes and distribution networks; (ii) types of goods traded through formal and informal channels, seasonal variations, local communities' reliance on informal trade; (iii) stakeholder relationships (larger importers use informal channels via intermediaries); (iv) available resources to control informal trade; and (v) ability to establish quarantine facilities at or nearby designated entry points. • Stakeholders exerting political or economic influence are identified.
Identify priority stakeholders	• Priority to stakeholders directly impacted by the SPS measure (traders) and those responsible for collaborating on implementation (e.g. customs officials).
Update list	• List, groups and identified priority stakeholders may need to be updated over time.

STEP 2:

Conducting consultations

To be effective, consultation mechanisms should be as straightforward as possible for stakeholders and rely on a consultation strategy plan that would have been developed ahead of time (see above step 1). For example, SPS regulators should ensure that participation is not made difficult owing to stringent deadlines or onerous feedback processes.

SPS regulators leading consultation efforts are encouraged to:

- Check if a consultation policy has already been put in place by a central regulatory oversight body, in other government agencies, or at the regional level;
- Provide guidance to stakeholders on how consultations will be carried out and scheduling;
- Provide stakeholders with all relevant information on the SPS measure under consideration;
- Adjust their request for input as appropriate, e.g. requesting targeted feedback via questionnaires if useful;
- Consult when there is still an opportunity for stakeholders to influence the outcome of the SPS measure under consideration, allowing stakeholders time to read and understand SPS measures and develop their positions;
- Analyse information received from stakeholders;
- Publish reports summarizing feedback, details on comments received and explaining the rationale for decisions taken; and
- Establish a mechanism for quality control, i.e. a means through which the stakeholder consultation mechanism itself is evaluated.[46]

Given the diverse pool of SPS-related stakeholders (e.g. SPS and customs agencies, trade associations, MSMEs, livestock and crop farmers, FBOs, importers/exporters, consumers), SPS regulators may use a consultation strategy to ensure that stakeholders understand the purpose, scope, and value of consultations and can provide quality inputs. A consultation strategy typically: (i) establishes consultation objectives, such as getting information to provide evidence base analysis or soliciting specific feedback on a policy issue or proposed SPS rule; (ii) sets out a range of options for methodologies; and (iii) provides practical indications regarding scheduling/phasing, timelines, language considerations, how to record/handle/analyse collected information, and the treatment of sensitive information.[47]

Spotlight 17.

Consultations in Thailand

The regulating agency arranges a public consultation to solicit inputs. Once the agency has a draft legislation, it must upload the draft to a central stakeholder consultation website for a minimum period of 15 days. The website lists ongoing public consultations, provides the proposed draft and a summary thereof, gives information on the comment period, and invites to share opinions. Substantive information is also to be shared, including on the problem, causes, justification of necessity, overview and key issues associated with the proposal. Once the consultations are carried out, the regulating agency is to prepare a report summarizing the consultations. The Cabinet Secretariat that receives the legislative proposal from the regulating agency is to receive the results of the consultations. At subsequent stages of approval, the Office of the Council of State may also review this summary report.

Source: OECD (2020), Regulatory Management and Oversight Reforms in Thailand: A Diagnostic Scan

Using a variety of methods for consultations can help to include different groups of stakeholders and widen access to the consultations. Consultation methods include: written submissions, public hearings or face-to-face meetings, focused group discussions with particular types of stakeholders, structured surveys (quantitative and/or qualitative), web-based consultations and interactions (surveys, questionnaire, comments, social media tools and channels, including web fora, blogs, twitter), and advisory groups and expert groups.

SPS regulators may invite experts to offer research or opinions on the SPS matters at issue and may establish/organize committees, networks, peer groups, advisory groups, working parties, or conferences/workshops for this purpose.[48] For example, key stakeholders may form a multidisciplinary committee that meets in-person or online, with periodic broader consultation occurring at periodic intervals. Technical discussions pertaining to specific standards, treatments to be applied, or inspections would likely be attended by technical level government staff while strategic discussions would be led by senior level officials. If such groups are established, it is important to ensure that appropriate stakeholders (with the necessary skills or expertise) are included.

[46] OECD. 2010. OECD Review of Better Regulation in Sweden

[47] EU Better Regulation Toolbox (2017)

[48] EU Better Regulation Toolbox (2017)

2.6 Coordination and cooperation mechanisms

Coordination and cooperation mechanisms should be put in place at national, regional, and international level to foster better SPS measures. Such mechanisms can take many forms, e.g. processes to share information across SPS agencies to ensure a coordinated response to a given SPS risk, quality control by oversight bodies of the use of RIAs or other GRPs including in the SPS area, harmonization of SPS measures with other countries on the basis of international standards and relevant regional standards, and processes to share information with trading partners. Coordination and cooperation at national and international (including regional) level support GRPs and may be relevant at all stages of the regulatory management cycle of SPS measures.

2.6.1 Coordination and cooperation at national level

SPS measures are, by nature, multidisciplinary. Where multiple agencies are responsible for overlapping SPS issues, this can lead to duplication of regulatory activities, confusion among stakeholders and gaps in coverage of SPS control activities. Coordination and cooperation are strongly encouraged among SPS agencies and other government agencies to ensure exchange of knowledge and experience on GRPs and on cross-cutting SPS regulatory issues. Coordination is particularly encouraged among SPS agencies since they are bound by the same principles in the WTO SPS Agreement and may be subject to the same SPS-related international obligations under bilateral or regional trade agreements.

Training and capacity building are key to ensure that public sector actors across different sectors are aware of current SPS issues and their relative importance, and to ensure a coordinated response where appropriate. Knowledge on SPS matters should be shared with relevant private sector actors to ensure compliance with SPS measures.

Inter-agency coordination and cooperation is an ongoing process with many benefits for SPS regulators. It is important to:

- Promote a One Health approach and provide multi-sectoral responses to SPS challenges that may be of the responsibility of several SPS agencies[49];
- Address fragmented legislation, reduce duplicate SPS requirements and related administrative burden, and deal with uneven implementation of SPS requirements;
- Strengthen and ensure coherence in SPS control systems with uniform application of the SPS measures across value chains and throughout the country;
- Deal more effectively with practical SPS aspects, such as the process of notifications or information sharing or the work of inspectors;
- Centralize information, raise awareness of certain key SPS issues, and share knowledge. For example, there is an increased interest for single window initiatives to integrate services on regulatory requirements normally handled by various SPS agencies, which rely on effective coordination among SPS agencies; and
- Mitigate costs and prioritize resources at national level.

Coordination and cooperation beyond SPS agencies support a whole-of-government approach to GRPs, ensure that GRPs are used effectively through quality controls by oversight bodies or other oversight mechanisms, and that SPS measures fit in the overall regulatory framework.

Coordination and cooperation efforts can take many forms, such as SPS working groups and coordination bodies or SPS committees, central online systems, outreach by oversight bodies, elaboration of policy documents or inter-agency strategies, or any process to facilitate information sharing, and the consultation of government agencies, e.g. as part of RIAs.

Additional resources on National SPS Coordination Mechanisms:

- WTO Collection of Resources to Facilitate Implementation of National SPS Coordination Mechanisms, Note by the Secretariat, G/SPS/GEN/1850/Rev.1
- STDF, National SPS Coordination Mechanisms: An African Perspective, January 2012, esp. Checklist to Assist the Establishment and Operation of National SPS Committees in Annex 1.

[49] One Health is an approach based on collaboration and coordination to designing and implementing programmes, policies, legislation and research in which multiple sectors communicate and work together to achieve better public health outcomes. For example, many of the same microbes infect animals and humans, and efforts by one SPS organization/sector on its own may not adequately address the complete SPS risks. Collaboration and coordination mechanisms across SPS agencies are necessary to ensure multi-sectoral approaches to SPS risks and adequate SPS measures. For more information, see for example https://www.oie.int/en/for-the-media/onehealth/oie-approach/.

Spotlight 18.

Korea's central online system

Since 2009, the Republic of Korea has a central management tool (Regulatory Information System (RIS)) to assist the government in managing a whole-of-government regulatory quality programme. It is an online system that covers the entire process of regulatory reform, ranging from regulatory review to registration, reform task management and access to regulatory information.

Through this new system, the whole process of regulatory review – from initial review request by each ministry, preparation of review report to notification of results by Regulatory Reform Committee – has been moved online. With a function that notifies unregistered regulations and termination date of sunset laws, the system offers a concrete management of regulations. Furthermore, for the regulatory reform management across the different administrative bodies, the system provides monitoring service on the current status of each ministry's regulatory reform process. In 2010, by linking the regulation register database of RIS to the current website of Regulatory Reform Committee, more upgraded and specified regulatory information search service and related statistics is provided to citizens.

Source: Korea Regulatory Reform Committee, Regulatory Reform Committee (RRC)

2.6.2 International regulatory cooperation (bilateral, regional, and multilateral cooperation)

International regulatory cooperation in the SPS area refers to approaches to promote some form of cooperation at the international level in the design, development, and review of SPS measures, including regulatory convergence at a bilateral, regional, or multilateral level, harmonization based on relevant international standards, equivalence, engagement of foreign stakeholders, and sharing of information and experience.

International regulatory cooperation is important to:

- Account for cross-border risks and contribute to preventing the development of cross-border SPS risks;
- Allow for the views of trading partners and international stakeholders, such as exporters that may be affected by the SPS measure, to be taken into account and facilitate their compliance or adaptation with the SPS measure;
- Foster evidence- and science-based rulemaking, helping reduce unnecessary barriers to trade while maintaining an appropriate SPS protection;
- Benefit from the experience of trading partners in addressing similar SPS risks;
- Reduce the prevalence of unnecessary differences in SPS measures between countries and lower trade barriers; and
- Reduce trade costs associated with regulatory heterogeneity in the SPS area.

International regulatory cooperation and GRPs are closely interlinked. For example, international regulatory cooperation goes hand-in-hand with transparency mechanisms, whereby SPS regulators publish information about their regulations, develop open and participatory policy making process, and exchange information with trading partners and foreign stakeholders. To develop good quality SPS measures, SPS regulators are encouraged to consider the impacts of SPS measures beyond their domestic borders, take into account the international environment, and cooperate with their foreign peers in bilateral, regional or multilateral contexts.

In this context, SPS regulators should explore processes to exchange information about current SPS regulations and new SPS regulatory initiatives with trading partners. This can take the form of notifications of draft SPS regulations, allowing for a comment period (recommended 60 days in the WTO (G/SPS/7/Rev.4)) and to discuss and take comments into account, or processes to provide answers to questions by other countries and relevant documents, e.g. through a national enquiry point, or through consultations. SPS regulators are also encouraged to monitor SPS measures adopted in other countries and requesting information

from trading partners to benefit from their experience. SPS regulators can use ePing, an online tool that enables stakeholders to access, keep track, and react to notifications of SPS measures.[50]

International regulatory cooperation also helps SPS regulators ensure that their measures comply with international commitments under the WTO SPS Agreement, other trade agreements, and SPS related international standards.

Within the WTO framework, obligations on transparency (see Box 20 on Transparency in the WTO SPS Agreement), international standards, and the principle of equivalence require regulators to embed international considerations within their domestic rulemaking procedures. WTO Members are required to base SPS measures on relevant international standards if they exist, except if the country has a scientific justification to deviate from the international standard or the international standard does not achieve the country's appropriate level of protection. They are also incentivized to fully harmonize measures with international standards and strongly encouraged to participate in the development of international standards. SPS regulators should thus pay attention to international standards developed by Codex, IPPC, and OIE. In addition, disciplines on equivalence help ensure that traders do not face duplicative requirements or procedures when regulations differ across markets.

Additional resources on international regulatory cooperation:

- OECD/WTO, Facilitating trade through regulatory cooperation, The case of the WTO's TBT/SPS Agreements and Committees
- OECD Best Practice Principles on International Regulatory Cooperation (final publication forthcoming)

BOX 24.

Monitoring the use of international standards

The OIE initiated an Observatory project on the implementation of OIE standards. The Observatory's objective is to provide a continuous and systematic mechanism to collect information and analyse the practices of Members' in implementing OIE international standards. The pilot was launched in 2020. For more information: https://www.oie.int/en/what-we-offer/safe-trade-and-movement-of-animals/observatory/.

Codex's Strategic Plan for 2020-2025 includes a goal that seeks to "increase impact through the recognition and use of Codex Standards" and identifies a number of actions it could take to promote uptake and use of its standards and guidelines. See http://www.fao.org/3/ca5645en/CA5645EN.pdf.

IPPC has the Implementation Review and Support System (IRSS), which undertakes activities that evaluate and identify countries' plant protection challenges and best practices. These activities generate national, regional and global information about the implementation of IPPC standards and emerging issues in plant health. It includes surveys on the use of IPPC standards. See https://www.ippc.int/en/irss/activities/.

Monitoring the use of international standards is a standing item on the agenda of the WTO SPS Committee. In 2020-2021, a proposal to improve the monitoring process was made and discussed in the SPS Committee. (G/SPS/GEN/1851 and G/SPS/GEN/1877).

[50] www.un.org/development/desa/dpad/wp-content/uploads/sites/45/publication/2016_eping_flyer_v4.pdf and www.epingalert.org/en.

Many trade agreements foster cooperation in the SPS area at a bilateral or regional level. Many such trade agreements encourage collaboration to achieve equivalence of SPS measures, for instance with dialogue starting from common work plans for SPS measures, or encourage harmonization of SPS measures based on international or regional standards. Regional coordination among partner countries in terms of harmonization and equivalence or mutual recognition arrangements helps countries to fully benefit from trade opportunities. Some trade agreements also contain specific cooperation provisions, such as the establishment of a specific SPS Committee in which government officials and regulatory agencies from both parties can meet to discuss respective draft regulations or trade restrictive measures.[51]

[51] Kauffmann, C. and C. Saffirio (2021), "Good regulatory practices and co-operation in trade agreements: A historical perspective and stocktaking", OECD Regulatory Policy Working Papers, No. 14, OECD Publishing, Paris.

Spotlight 19.

ECOWAS Food Safety Actors Network

ECOWAS' Network of Food Safety Actors was established in 2015 driving harmonization and convergence of science-based SPS measures, aligned with Codex standards, to advance SPS capacity building as part of African Member States' commitments in the African Continental Free Trade Agreement (AfCFTA). The network aims to harmonize SPS regulations in West Africa by facilitating dialogue and partnerships and promoting the development of policy guidelines for SPS measures aligned with the AfCFTA. The network also works on SPS capacity in the region by strengthening private sector capacity and improving food laboratory testing and data management capacities.

Source: ECOWAS implemented SPS activities July-October 2017 (G/SPS/GEN/1574) and March-June 2021 (G/SPS/GEN/1917)

Spotlight 20.

Bilateral and regional coordination efforts – Peru's experience

With the purpose of addressing ongoing SPS issues, Peru's National Agrarian Health Service (SENASA) regularly engages in bilateral meetings with its counterparts in neighbouring countries. The discussions, which are held in virtual and in-person format, cover a variety of challenges including those related to SPS requirements for market access, and technical cooperation for capacity building. Continuous exchanges contributed to the improvement of SENASA's institutional capacity and have had a positive impact on the international trade of agricultural products.

At the regional level, the SPS chapter of the Additional Protocol to the Pacific Alliance Framework Agreement aims to increase transparency in the application of SPS measures, strengthen the use of scientific information, and improve communication amongst the competent authorities of Colombia, Chile, Mexico, and Peru. The protocol also created a regional SPS committee to monitor and implement the provisions of the agreement and address trade issues when they arise.

Source: author based on consultations with SENASA Technical Secretariat and Additional Protocol to the Pacific Alliance Framework Agreement

Spotlight 21.

Chile-Thailand Free Trade Agreement – cooperation in the SPS area

The SPS Chapter of the Chile-Thailand Free Trade Agreement includes several provisions pertaining to cooperation. It identifies competent authorities and contact points. It also provides for the establishment of an SPS Committee with the objective of ensuring the implementation of the SPS Chapter and enhancing cooperation between the countries' respective SPS agencies. The Committee provides a forum to: enhance mutual understanding of each country's SPS measures and the regulatory processes related to those measures; discussing matters related to the development or application of SPS measures that may, directly or indirectly, affect human, animal and plant health and trade between Chile and Thailand; exchanging information on relevant laws and regulations, the occurrence and control of infectious diseases of animals and pests of plants, and notifying emerging situations; coordinating technical cooperation programmes on SPS measures; and consulting on issues relating to the meetings of the WTO SPS Committee, Codex, OIE and IPPC.

Source: Chile-Thailand Free Trade Agreement (2015), Chapter 6

Annexes

ANNEX 1:

Acronyms

ALOP	Appropriate level of protection
APEC	Asia-Pacific Economic Cooperation
Codex	Codex Alimentarius Commission
EAC	East African Community
FAO	Food and Agriculture Organization of the United Nations
FBOs	Food Business Operators
GRPs	Good Regulatory Practices
IICA	Inter-American Institute for Cooperation on Agriculture
IPPC	International Plant Protection Convention
ISSBs	International Standard Setting Bodies
ITC	International Trade Centre
NPPO	National Plant Protection Organization
NTMs	Non-tariff measures
OECD	Organisation for Economic Co-operation and Development
OIE	World Organisation for Animal Health
MSMEs	Micro, Small and Medium Enterprises
PCE	Phytosanitary Capacity Evaluation
PVS	Performance of Veterinary Services
RIA	Regulatory Impact Assessment
SPS	Sanitary and phytosanitary
STDF	Standards and Trade Development Facility
TBT	Technical barriers to trade
TPR	Trade Policy Review
USAID	United States Agency for International Development
USDA	United States Department of Agriculture
WHO	World Health Organization
WTO	World Trade Organization
WTO SPS Agreement	WTO Agreement on the Application of Sanitary and Phytosanitary Measures
WTO SPS Committee	WTO Committee on Sanitary and Phytosanitary Measures

ANNEX 2:

Key terms explained[52]

KEY TERM	WHAT IS IT ABOUT?
Ex-post evaluation	Periodic process to evaluate the impacts and effects of SPS measures and assess the effectiveness and efficiency of SPS measures. Ex-post evaluation provides insight on how well an SPS measure is performing.
Forward-looking regulatory agenda	Document published by a regulating agency outlining the planned/expected changes to regulation or new regulations to be implemented over a given period of time. A forward-looking regulatory agenda can have an SPS focus or be broad (i.e. encompass all types of planned regulatory changes, including SPS).
Good regulatory practices	Internationally recognized processes, systems, tools, and methods used to improve the quality of regulatory measures and ensure that regulatory outcomes are effective, transparent, inclusive, and sustained.
International regulatory cooperation	Approaches to promote some form of cooperation at the international level in the design, development, and review of SPS measures, including regulatory convergence at a bilateral, regional, or multilateral level, harmonization based on relevant international standards, equivalence, engagement of foreign stakeholders, sharing of information and experience.
International Standards	International standards, guidelines and recommendations developed by: • the Codex Alimentarius Commission for food safety, including standards, codes of practices, maximum residue levels; • the World Organisation for Animal Health (previously known as the Office International des Epizooties) for animal health and zoonoses, in particular the Terrestrial and Aquatic Animal Health Codes; and • the International Plant Protection Convention for plant health, i.e. the International Standards for Phytosanitary Measures (ISPMs).
Monitoring	Regular and ongoing review of SPS measures by collecting information and data on its implementation and performance.
Oversight body	Standing national level body to provide oversight of regulatory policy procedures and foster regulatory quality, including of SPS measures.
Regulatory impact assessment	Systematic approach to assessing critically the positive and negative effects of proposed and existing SPS regulations and non-regulatory alternatives.
Risk assessment	The process of gathering scientific evidence and relevant economic factors on the SPS risks involved in allowing a particular import to enter a country. In this Guide, risk assessment is used to refer to an assessment of the SPS risk at issue in the context of the obligation, in the WTO SPS Agreement, to base SPS measures on science. Under the WTO SPS Agreement, SPS measures shall be based on international standards or 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.

[52] As used in this Guide.

KEY TERM	WHAT IS IT ABOUT?
SPS measure	Any measure applied: a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms; b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs; c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests. SPS measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety. (Annex A of the WTO SPS Agreement)
SPS regulation	Diverse set of instruments by which governments set requirements on businesses and citizens in the SPS area.
Stakeholder engagement	Iterative process of allowing stakeholders (private and public sector, domestic and foreign, etc.) to be informed of and participate meaningfully in the design, development, and review of SPS measures.
Transparency	Multi-faceted term and cross-cutting GRP that entails the provision of information on SPS measures, including draft SPS measures, facilitating public access to SPS measures, stakeholder engagement, cooperation and coordination efforts, publication, and notification.

ANNEX 3:

Selected resources

GRPs

APEC-OECD Integrated Checklist on Regulatory Reform (2005), www.apec.org/Groups/Economic-Committee/Toolkit-for-Structural-Reform/APEC-OECD-Integrated-Checklist#:~:text=The%20APEC%2DOECD%20Integrated%20Checklist,competition%20and%20market%20openness%20policies

OECD Indicators of regulatory policy and governance, www.oecd.org/gov/regulatory-policy/indicators-regulatory-policy-and-governance.htm

OECD 2012 Recommendation on Regulatory Policy and Governance, www.oecd.org/gov/regulatory-policy/2012-recommendation.htm

OECD Regulatory Policy Outlook 2018, https://www.oecd.org/governance/oecd-regulatory-policy-outlook-2018-9789264303072-en.htm

SPS capacity evaluation tools

STDF, SPS-related Capacity Evaluation Tools An Overview of Tools Developed by International Organizations (2011), https://www.standardsfacility.org/sites/default/files/STDF_Capacity_Evaluation_Tools_Eng_1.pdf

WTO SPS Agreement and related sources

WTO SPS Agreement www.wto.org/english/tratop_e/sps_e/spsagr_e.htm

The WTO Agreements Series, Sanitary and Phytosanitary Measures, https://www.wto.org/english/res_e/booksp_e/agrmntseries4_sps_e.pdf

SPS Information Management System (IMS), a database of WTO SPS information containing notifications, concerns raised by WTO Members in the SPS Committee, enquiry points, and other documents: http://spsims.wto.org/

ePing SPS & TBT Notification Alert System for daily or weekly email alerts containing notifications covering products/markets of interest, an enquiry point management tool and discussion fora: https://www.epingalert.org/en

Regulatory Impact Assessments and evaluations

CUTS. Regulatory Impact Assessment Toolkit: a Practitioner's Guide in Developing Countries, cuts-ccier.org/pdf/Regulatory_Impact_Assessment_Toolkit.pdf

Ladegaard, Peter Farup; Rimmer, Stephen; Rodrigo Enriquez, Delia. 2009. Making it work: 'RIA light' for developing countries. World Bank Group, documents.worldbank.org/curated/en/184141468167049021/Making-it-work-Ria-light-for-developing-countries

OECD (2020) Regulatory Impact Assessment, OECD Best Practice Principles for Regulatory Policy, OECD Publishing, Paris, doi.org/10.1787/7a9638cb-en

World Bank Global Database for Regulatory Impact Assessment, rulemaking.worldbank.org/en/ria-documents

SPS cooperation mechanisms

OECD/WTO, Facilitating trade through regulatory cooperation, The case of the WTO's TBT/SPS Agreements and Committees, tbtsps19_e.pdf (wto.org)

WTO Collection of Resources to Facilitate Implementation of National SPS Coordination Mechanisms, Note by the Secretariat, G/SPS/GEN/1850/Rev.1

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ANNEX 4:

Selected GRP mechanisms and the WTO SPS Agreement

The WTO SPS Agreement enshrines the right of WTO Members to regulate in the SPS area. WTO Members have the right to prepare, adopt and apply SPS measures necessary to achieve SPS public policy objectives, such as protection of human health and safety, animal life and health, at levels of protection they consider appropriate. However, WTO Members have committed to be guided by certain principles, objectives and disciplines in their regulatory activities. These include, among others: non-discrimination; avoiding unnecessary trade barriers; ensuring a scientific basis for SPS measures; transparency (including notification of draft SPS measures); using relevant international standards as a basis for SPS measures or basing SPS measures on a risk assessment; and promoting equivalence.

Disciplines of the WTO SPS Agreement promote GRPs, including the principle of transparency and the strong encouragement for Members to use international standards. Proper application of GPRs in the SPS area fosters greater compliance with obligations in the WTO SPS Agreement. This table illustrates how GRPs support key disciplines of the WTO SPS Agreement.

GRP	RELATED OBLIGATION IN THE WTO SPS AGREEMENT
RIAs and consultations to select the most appropriate, efficient, and least-trade restrictive SPS measure	SPS measures should be applied only to the extent necessary to protect human, animal or plant life or health and should not discriminate. Where an acceptable level of risk can be achieved in alternative ways, among the alternatives that are technically and economically feasible, governments must select the SPS measure that does not restrict trade more than necessary to meet the health objective. See Articles 2.2, 2.3, 5.5, and 5.6 as well as Annex C, paragraph 1 of the WTO SPS Agreement.
Consultations and dissemination of information to enhance clarity and accessibility of SPS measures, promote regulatory cooperation and whole-of-government approach	The WTO SPS Agreement provides a unique multilateral transparency framework that contributes to cooperation, by setting notification requirements for proposed regulatory measures with potentially significant trade effects. Transparency requirements seek to ensure, inter alia, that SPS measures are accessible and that WTO Members have an opportunity to comment on draft SPS measures. The SPS requirements also contain obligations for WTO Members to set up a national enquiry point and a national notification authority. See Article 7 and Annex B of the WTO SPS Agreement.
RIAs, stocktaking, evaluation, and continuous review to ensure SPS measures are effective and appropriate	SPS measures are for the protection of human, animal or plant life or health and shall be based on scientific principles / not maintained without sufficient scientific evidence. SPS measures must be based on international standards or a risk assessment. In addition, in case of provisional SPS measures, these must be reviewed as additional scientific information becomes available. See Articles 2.2, 5.1, 5.2, 5.3, and 5.7 as well as Annex A, paragraph 4 of the WTO SPS Agreement.
RIAs, stocktaking, evaluation, continuous review, and regulatory cooperation to ensure SPS measures are efficient	WTO Members are strongly encouraged to base SPS measures on international standards (harmonization). These are the international standards of Codex for food safety, the OIE for animal health and zoonoses, and IPPC for plant health. See Articles 3.1-3.3 of the WTO SPS Agreement.
RIAs, evaluation, continuous review, and regulatory cooperation to ensure SPS measures are efficient	If an SPS measure applied by another country provides the same level of health protection, it should be accepted as equivalent. Typically, recognition of equivalence is achieved through bilateral consultations and the sharing of technical information. See Articles 4.1 and 4.2 of the WTO SPS Agreement.

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