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Committee on Sanitary and Phytosanitary Measures

COLLECTION OF AVAILABLE TOOLS AND RESOURCES IN RELATION TO SPS APPROVAL PROCEDURES

NOTE BY THE SECRETARIAT¹

The Report of the Fifth Review of the Operation and Implementation of the SPS Agreement included several recommendations on various topics, including a recommendation that the SPS Committee create a working group open to the participation of all Members and Observers to continue to examine the topic of approval procedures.² The Working Group on Approval Procedures was set up in November 2020 and concluded its work in March 2023.

Participants in the Working Group on Approval Procedures identified existing available tools and resources as they apply to approval procedures.³ These tools and resources are indicated in the table below, organized by key themes. The identified tools and resources may be applicable to more than one theme; however each tool or best practice has only been included once for simplicity.⁴

This is not an exhaustive list of tools and resources. It does not represent a legal interpretation of the rights and obligations under the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and does not in any way exemplify a legal definition.

The SPS Committee will keep this Collection up to date with the assistance of the Secretariat.

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

² G/SPS/64, para. 3.12.

³ <u>G/SPS/GEN/2098</u>

⁴ The order in which these tools and resources have been included in the table below does not reflect any hierarchy among them or any particular level of importance.

Tool or resource	What is it?	Where to find it?
1. General		
WTO Thematic Session on Approval Procedures, 5 November 2019	Presentations from and webcasting of the Thematic Session.	https://www.wto.org/english/tratop_e/sps_e/ workshop05112019_e.htm
SPS Committee Thematic Workshop on Control, Inspection and Approval Procedures (Annex C), 9-10 July 2018	Presentations from the Workshop.	https://www.wto.org/english/tratop_e/sps_e/ workshop910718_e.htm
SPS Committee Events, Workshops and Training	Events and resources listed on this page range from special information sessions of the SPS Committee to workshops, training sessions and training material, some organized in conjunction with other organizations, including the Standards and Trade Development Facility (STDF).	https://www.wto.org/english/tratop_e/sps_e/ events_e.htm
2. Timing and Undue Delays		
Global Low-Level Presence Initiative (GLI) Communiqué on Approaches to Reduce Asynchronous Authorizations in Food and Feed Derived From Recombinant-DNA (rDNA) Plant	Communiqué with the objective of offering a broad range of potential approaches for governments, technology developers, and other stakeholders to consider to minimize occurrences of asynchronous authorizations of food and feed derived from rDNA plants.	https://llp-gli.org/llp-communique.html
GLI Principles, Criteria and Practical Approaches for Addressing Low-Level Presence (LLP) of Food in International Food and Feed Trade of Plant Material	Document suggesting tools for addressing trade disruptions due to LLP, setting out guiding principles for the development of practical approaches to addressing LLP by governments and for bolstering continued industry stewardship efforts, supporting and encouraging essential elements of a given approach or approaches for addressing LLP, and supporting consideration of the possible approaches by governments and industry as practical means to address LLP.	https://llp-gli.org/llp-principles.html
GLI Information and Resources	Collection of resources offering approaches and principles for members, observers, international organizations, and individuals to consider to minimize asynchronous approvals and manage LLP.	https://llp-gli.org/llp-resources.html

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Tool or resource	What is it?	Where to find it?
3. Transparency		
ePing SPS&TBT Platform	The new <u>ePing SPS&TBT Platform</u> integrates all SPS and TBT transparency tools into a single platform. It includes various functions related to notifications, STCs, and information exchange. Through the ePing SPS&TBT Platform, users can browse notifications on new and updated product regulations and sign up to receive daily or weekly email alerts and to follow notifications on products and/or markets of interest. Users can also find information on trade concerns discussed in the WTO SPS and TBT committees. Information on enquiry points and notification authorities can also be located in the Platform. The ePing SPS&TBT Platform enables Members to submit notifications online. This improved functionality allows Members to fill in all types of notification templates, improve national coordination with regulatory agencies, provide more accurate and complete data, prepare notifications submitted.	https://eping.wto.org/en/
Thematic SPS Workshop on Transparency, 20 June 2022	Presentations from the Workshop, to serve as a reference for Members looking to strengthen their internal capacities to align with the SPS Agreement's transparency provisions.	https://www.wto.org/english/tratop_e/sps_e/ workshop_transparency_20jun22_e.htm
Thematic SPS Workshop on Transparency and Coordination, 15-16 July 2019	Presentations from the Workshop, to serve as a reference for Members looking to strengthen their internal capacities to align with the SPS Agreement's transparency provisions.	https://www.wto.org/english/tratop_e/sps_e/ workshop15072019_e.htm
SPS Workshop on Transparency, 30-31 October 2017	Presentations from the Workshop, to serve as a reference regarding implementation of the SPS Agreement's transparency provisions.	https://www.wto.org/english/tratop_e/sps_e/ wkshopttranparency_oct17_e.htm
Workshop on Transparency, 12-13 October 2015	Presentations from the Workshop.	https://www.wto.org/english/tratop_e/sps_e/ wkshop_oct15_e/wkshop_oct15_e.htm
Workshop on the Transparency Provisions of the SPS Agreement, 18 and 22 October 2010	Presentations from the Workshop.	https://www.wto.org/english/tratop_e/sps_e/ wkshop_oct10_e/wkshop_oct10_e.htm
Workshop on Transparency, 15-16 October 2007	Materials from the Workshop.	https://www.wto.org/english/tratop_e/sps_e/ wkshop_oct07_e.htm

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Tool or resource	What is it?	Where to find it?	
4. Communication or Information Exchange			
OECD Guidance for Country Data Review Reports on Plant Protection Products and their Active Substances (Monograph Guidance)	Guidance as to the format and presentation of the documentation to be prepared by the regulatory authorities in the context of applications for the approval of particular active substances made to them, for the registration of plant protection products, for the establishment of maximum residue limits (MRLs), or for the establishment of import tolerances.	https://www.oecd.org/env/ehs/pesticides- biocides/38588738.pdf	
GLI Memorandum on Improving Access to Data and Information for Food and Feed Safety Assessment in Situations of Low- Level Presence (LLP) of Recombinant-DNA (rDNA) Plant Material	Memorandum expressing the common understanding among GLI member countries that governments should be encouraged to share data and information about completed food and feed safety assessments of rDNA plant material with importing country governments in instances of LLP in imported food and feed.	https://llp-gli.org/llp-memorandum.html	
5. Justification			
Guidance for Risk Management Options in Light of Different Risk Assessment Outcomes	Information document.	http://www.fao.org/fileadmin/user_upload/co dexalimentarius/committee/docs/INF_CCCF e.pdf	
International Seed Testing Association (ISTA) Rules for Seed Testing	Standard procedures for sampling and testing of seeds, including genetically modified (GM) seeds for detection of approved/unapproved events present in imported consignments and also GM seeds for export to countries which require GM seed testing. It ensures seed quality and accuracy of testing by uniformity in seed sampling and testing.	https://www.seedtest.org/en/publications/int ernational-rules-seed-testing.html	
FAO GM Foods Platform and Resources	Online platform to share information on safety assessment of foods derived from rDNA plants authorized in accordance with Codex Guidelines. This Platform also facilitates the decision- making process with regard to possible LLP situations, through the effective utilization of food safety assessment in situations of LLP of rDNA plant materials in food.	http://www.fao.org/food/food-safety- guality/gm-foods-platform/en/	
	Resources section providing access to Codex documents, databases of safety assessments, training tools, and other relevant resources.	http://www.fao.org/food/food-safety- guality/gm-foods-platform/resources/en/	
OECD Work on Safety of Novel Foods and Feeds and on the Harmonisation of Regulatory Oversight in Biotechnology	OECD work on biosafety and food/feed safety assessment, which aims to assist countries evaluating the potential risks of transgenic products, ensure high safety standards, and foster mutual understanding of relevant regulations.	https://www.oecd.org/chemicalsafety/biotrac k/oecdandrisksafetyassessmentinmodernbiot echnology.htm	

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Tool or resource	What is it?	Where to find it?	
	Repository of science-based consensus documents which are mutually acceptable among member countries and contain technical information for use during the regulatory assessment of products of biotechnology.		
6. Harmonization with Internation	6. Harmonization with International Standards		
Codex Procedural Manual, 26 th edition	Manual to help Members participate effectively in the work of the joint FAO/WHO Food Standards Programme. Its sets out the basic rules of procedures, procedures for the elaboration of Codex standards and related texts, basic definitions, and guidelines for the operation of Codex committees.	http://www.fao.org/documents/card/en/c/I86 08EN/	
Codex Principles for Food Import and Export Inspection and Certification	Codex guidance related to certification.	CAC/GL 20-1995	
Codex Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems	Codex guidance related to certification.	<u>CAC/GL 26-1997</u>	
Codex Principles and Guidelines for the Exchange of Information between Importing and Exporting Countries to Support the Trade in Food	Codex guidance related to certification.	<u>CAC/GL 89-2016</u>	
Codex Guidelines for Food Import Control Systems	Codex guidance related to certification.	CAC/GL 47-2003	
Codex Guidelines for Design, Production, Issuance and Use of Generic Official Certificates	Codex guidance related to certification.	CAC/GL 38-2001	
Codex Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations	Codex guidance related to certification.	<u>CAC/GL 19-1995</u>	
Codex Principles and Guidelines for National Food Control Systems	Codex guidance related to certification.	CAC/GL 82-2013	
Codex Guidelines for the Exchange of Information between Countries on Rejections of Imported Foods	Codex guidance related to certification.	CAC/GL 25-1997	
Codex Principles and Guidelines for Monitoring the Performance of National Food Control Systems	Codex guidance related to certification.	<u>CXG 91-2017</u>	

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Tool or resource	What is it?	Where to find it?
Codex Principles for Traceability/Product Tracing as a Tool Within a Food Inspection and Certification System	Codex guidance related to certification.	CAC/GL 60-2006
Codex Guidelines for the Development of Equivalence Agreements Regarding Food Imports and Export Inspection and Certification Systems	Codex guidance related to certification.	<u>CAC/GL 34-1999</u>
Codex Working Principles for Risk Analysis for Food Safety for Application by Governments	Codex guidance related to risk assessments.	<u>CAC/GL 62-2007</u>
Codex Principles for the Risk Analysis of Foods Derived from Modern Biotechnology	Codex guidance related to biotechnology.	CAC/GL 44-2003
Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants	Codex guidance related to biotechnology.	CAC/GL 45-2003
Codex Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms	Codex guidance related to biotechnology.	<u>CAC/GL 46-2003</u>
Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals	Codex guidance related to biotechnology.	<u>CAC/GL 68-2008</u>
Codex Guidelines on Performance Criteria and Validation of Methods for Detection, Identification and Quantification of Specific DNA Sequences and Specific Proteins in Foods	Codex guidance related to biotechnology.	<u>CAC/GL 74-2010</u>
Codex Guidelines on the Judgement of Equivalence of Sanitary Measures associated with Food Inspection and Certification Systems	Codex guidance related to equivalence.	<u>CAC/GL 53-2003</u>
Codex Food Control Laboratory Management: Recommendations	Codex guidance related to methods of analysis.	<u>CAC/GL 28-1995</u>
Codex Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and Export Control of Food	Codex guidance related to methods of analysis.	CAC/GL 27-1997
Codex Harmonized Guidelines for Internal Quality Control in Analytical Chemistry Laboratories	Codex guidance related to methods of analysis.	<u>CAC/GL 65-1997</u>

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Tool or resource	What is it?	Where to find it?
Codex Guidelines for Settling Disputes over Analytical (Test) Results	Codex guidance related to methods of analysis.	CAC/GL 70-2009
Codex Principles for the Use of Sampling and Testing in International Food Trade	Codex guidance related to methods of analysis.	CAC/GL 83-2013
Codex Guidelines on Performance Criteria for Methods of Analysis for the Determination of Pesticide Residues in Food and Feed	Codex guidance related to pesticide residues.	<u>CXG 90-2017</u>
WOAH Handbook on Import Risk Analysis for Animals and Animal Products, Introduction and Qualitative Risk Analysis	WOAH handbook.	<u>https://rr-africa.woah.org/wp-</u> <u>content/uploads/2018/03/handbook on impo</u> <u>rt risk analysis - oie - vol i.pdf</u>
WOAH Terrestrial Animal Health Code - Chapter 2.1 - Import Risk Analysis	WOAH standards.	https://www.woah.org/fileadmin/Home/eng/ Health standards/tahc/2018/en chapitre im port risk analysis.htm
WOAH Aquatic Animal Health Code - Chapter 2.2 - Import Risk Analysis	WOAH standards.	https://www.woah.org/fileadmin/Home/eng/ Health standards/aahc/2009/en chapitre 1. 2.2.htm#chapitre 1.2.2
World Animal Health Information System (WAHIS)	WOAH database, which provides access to details of countries' current animal health situation, as well as their notification record over the years and other relevant animal health information.	https://wahis.woah.org/#/home
WOAH Official Disease Status	WOAH official recognition of the animal health status of countries or zones for six diseases: foot and mouth disease (FMD), African horse sickness (AHS), classical swine fever (CSF), contagious bovine pleuropneumonia (CBPP), peste des petits ruminants (PPR), and bovine spongiform encephalopathy (BSE).	https://www.woah.org/en/what-we- do/animal-health-and-welfare/official- disease-status/
WOAH Self-declared Disease Status	WOAH system to allow countries to communicate self-declaration of disease freedom for diseases (excluding the six diseases subject to official recognition by WOAH). This is an open mechanism, under the responsibility of each WOAH Member, which decides to share the information supporting a claim of freedom from a given WOAH-listed disease, based on the relevant WOAH standards.	https://www.woah.org/en/what-we- offer/self-declared-disease-status/
WOAH Performance of Veterinary Services (PVS) Pathway	Reports and relevant information relating to the PVS Pathway, WOAH's capacity-building programme for the sustainable improvement of national Veterinary Services. The PVS Pathway provides an external perspective that analyses the structure, functioning and performance of a country's Veterinary Services, highlights strengths, and identifies gaps and opportunities for improvements.	https://www.woah.org/en/what-we- offer/improving-veterinary-services/pvs- pathway/

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Tool or resource	What is it?	Where to find it?
	Available reports include: PVS Evaluation reports assessing the extent to which a country's Veterinary Services comply with WOAH standards; Veterinary Legislation Identification Mission reports analysing the current state of veterinary legislations; and PVS Gap Analysis reports identifying priority goals, as well as strategies, activities and a rough estimate of the investments required to achieve these objectives.	https://www.woah.org/en/what-we- offer/improving-veterinary-services/pvs- pathway/pvs-pathway-state-of-play-and- mission-reports/
WOAH Compartmentalisation Guidelines – African Swine Fever – Biosecurity checklist	WOAH outcome-based biosecurity checklist for ASF-free compartments.	https://www.woah.org/en/document/compart mentalisation-guidelines-african-swine-fever- biosecurity-checklist/
WOAH Expertise Network	Network of WOAH Collaborating Centres and WOAH Reference Laboratories, which contribute to the work of WOAH to ensure that standards, guidelines, and recommendations are scientifically sound and up to date.	https://www.woah.org/en/what-we- offer/expertise-network/
WOAH Register of Diagnostic Kits	WOAH register of diagnostic kits certified as validated as fit for purpose, which means that the kit has to be validated to such a level to show that the kit's results can be interpreted to have a defined meaning in terms of diagnosis or another biological property being examined.	https://www.woah.org/en/what-we- offer/veterinary-products/diagnostic-kits/the- register-of-diagnostic-kits/
International Standard for Phytosanitary Measures 2: Framework for Pest Risk Analysis	IPPC standards.	https://assets.ippc.int/static/media/files/publi cation/en/2019/05/ISPM 02 2007 En Fram ework PRA 2019-04- 30 PostCPM14 InkAm.pdf
International Standard for Phytosanitary Measures 3: Guidelines for the Export, Shipment, Import and Release of Biological Control Agents and other Beneficial Organisms	IPPC standards.	http://www.fao.org/3/j5365e/j5365e.pdf
International Standard for Phytosanitary Measures 20: Guidelines for a Phytosanitary Import Regulatory System	IPPC standards.	http://www.fao.org/3/y5721e/y5721e.pdf
International Standard for Phytosanitary Measures 21: Pest Risk Analysis for Regulated Non-Quarantine Pests	IPPC standards.	https://assets.ippc.int/static/media/files/publi cation/en/2019/05/ISPM 21 2004 En PRA RNQPs 2019-04-30 PostCPM14 InkAm.pdf
International Standard for Phytosanitary Measures 11: Pest Risk Analysis for Quarantine Pests	IPPC standards.	https://assets.ippc.int/static/media/files/publi cation/en/2019/05/ISPM 11 2013 En PRA <u>QPs 2019-04-30 PostCPM14 InkAm.pdf</u>

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Tool or resource	What is it?	Where to find it?
International Standard for Phytosanitary Measures 32: Categorization of Commodities According to their Pest Risk	IPPC standards.	https://assets.ippc.int/static/media/files/publi cation/en/2016/01/ISPM 32 2009 En 2015- 12-22 PostCPM10 InkAmReformatted.pdf
7. Regulatory Cooperation		
Enabling Access to Tools and Technologies: Towards Safer and More Sustainable Agriculture Through Regulatory Collaboration, Submission from Brazil, Kenya, Paraguay, and the United States of America	Compilation of concepts that can be employed, on a voluntary basis, to improve and streamline regulatory processes, while safeguarding human, plant, and animal health. This compilation serves as a resource, in particular for authorities with capacity constraints to help identify regulatory efficiencies that can lead to greater and faster market access. This compilation refers to tools and technologies, although the general concepts are applicable to a variety of market access requests. These concepts include common application requirements, joint risk assessments, data portability, adaptation to regional conditions, unilateral recognition, mutual recognition, familiarity, history of safe use, equivalence, and harmonization.	<u>G/SPS/W/317</u>
APEC, A Trade Facilitative Approach to Pesticide MRL Compliance Crop Life's Regulatory Harmonization Webpage	Brochure providing an overview of the benefits to trade associated with harmonized MRLs. Example of regulated community's contribution to promoting and advancing regulatory harmonization.	http://mddb.apec.org/Documents/2018/SCS C/WKSP8/18 scsc wksp8 003.pdf https://croplife.org/plant- biotechnology/regulatory-2/regulatory- harmonization/
Update of the APEC Baseline Study: Regulations of Products Derived from Innovative Agricultural Technologies and Identification of Ways to Promote Greater Efficiencies and Alignment	Report outlining APEC economies' decision frameworks for products of biotechnology and providing foundational information to be able to identify economies with regulatory regimes compatible with regulatory cooperation and collaboration through, for example, the sharing of food safety assessments and/or the mutual recognition of safety assessments.	https://www.apec.org/Publications/2019/06/ Update-of-the-APEC-Baseline-Study

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