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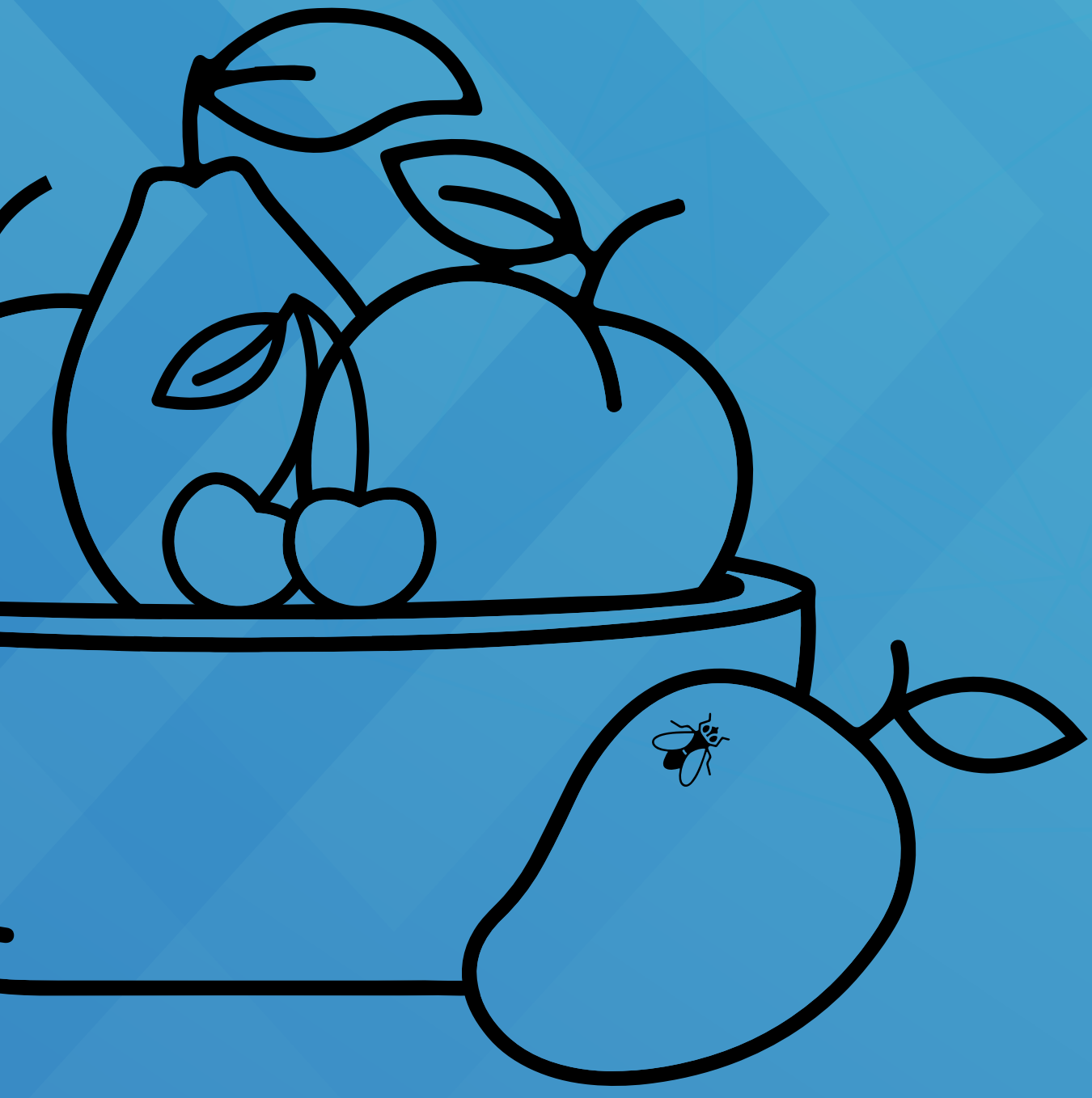
General guidelines

to facilitate the opening of international markets for fruits and vegetables that are fruit fly hosts based on International Standards for Phytosanitary Measures



General guidelines

to facilitate the opening of international markets for fruits and vegetables that are fruit fly hosts based on International Standards for Phytosanitary Measures

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Foreword

The key to opening markets in the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) and the International Plant Protection Convention (IPPC) framework, is to focus on the pest risk, and especially on all the factors contributing to risk and mitigating risk. There is often a tendency to begin with legacy concepts and requirements that were based on assumptions of high risk rather than begin with a fresh view of the evidence and an objective analysis of the risk. By breaking from the dogma of historical designs to embrace the opportunities for innovation created by the WTO-SPS-IPPC framework, researchers and regulators are able to create regulatory designs that more closely align with the concept of rational relationship and conform to relevant standards.

The purpose of the guide is to elaborate on the use of international standards to facilitate international trade of fresh fruit and vegetables known to be fruit fly hosts considering the regulatory framework of the WTO-SPS-IPPC with its associated International Standards for Phytosanitary Measures (ISPMs). Key aspects of this framework are identified and explained with emphasis on understanding their meaning and relationship to opening new markets and expanding existing markets. The guide aims for a better understanding of the factors that should be considered when establishing trade, and how to maximize the potential for international standards to facilitate safe trade.

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This document is for reference and guidance purposes and does not represent the policy directions of any government or organization. It is based on information available to the author and from first-hand experience. Recommendations and opinions are solely those of the author except where sources are indicated.

1. Introduction

The IPPC emerged in 1952 with the concept of phytosanitary certification. By placing some of the burden for preventing pest entry on the exporting country, the IPPC established that pest exclusion was a responsibility shared by both importing and exporting countries and the concept of phytosanitary measures was born.[1] By 1986, countries had identified measures put in place to protect "human, animal or plant life or health" as a key area for discipline in agricultural trade. This became a central issue in the General Agreement on Tariffs and Trade (GATT) Uruguay Round negotiations (1986-1994). The carefully crafted SPS Agreement resulted from this process. The Uruguay Round negotiations also resulted in the establishment of the WTO with a binding international dispute settlement mechanism.[2]

The intersection of the SPS Agreement with the IPPC and the initiation of associated standard setting processes created an evolving international regulatory framework that forms the background for the application of all phytosanitary measures in trade. The disciplines created by the SPS Agreement are designed to ensure that barriers to trade which have the objective of providing protection are not overly restrictive or politically motivated. It creates a regulatory focus on safe trade as a singular objective, recognizing that neither the extremes of exaggerated protection nor completely open trade are desirable.

Two central tenets of the SPS Agreement provide the foundation for discussions on the use of international standards. The first is the focus on international harmonization based on standards as described in Article 3 (Harmonization). The SPS Agreement specifically identifies the IPPC as the organization responsible for creating international standards for the phytosanitary community (Article 3.4). Further, the Agreement is clear that all SPS measures "shall" be based on the international standards (Article 3.1) or based on a risk assessment (Article 5) which is the other foundational element of the Agreement.[3] Phytosanitary measures that are not based on standards or exceed standards in their strength, must be scientifically justified with a risk assessment (Article 5. 1) and the measures must be the least restrictive for achieving the appropriate level of protection (Article 5.6). Simply having protection as an objective does not provide carte blanche for all possible measures or any strength of measures. This sharp departure from historical practice raises many significant challenges for national plant protection organizations (NPPOs) and has resulted in a strong focus on standard setting and risk assessment methodologies. The task now is establishing a risk-based orientation for the phytosanitary community and a strong background of standards that are consistent with the SPS-IPPC framework but may differ significantly from legacy decisions and designs.

2. Sources of harmonization

In the simplest terms, standards provide an agreed reference point. They are information that describes an example to be followed or a measure for comparison. The central source for harmonization in the SPS-IPPC framework are the International Standards for Phytosanitary Measures (ISPMs) created by the IPPC Commission on Phytosanitary Measures under Article XI.2 of the Convention.

The original version of the IPPC (1952) marked the beginning of harmonization for the phytosanitary community. By including the concept of phytosanitary certification, the Convention made a bold move to expand the responsibility for preventing pest introduction to the exporting country. In this way phytosanitary measures shifted from relying primarily on the importing country to protect itself, to a shared responsibility between trading partners. This design also established the IPPC as a reference point for international harmonization due to the high level of recognition enjoyed by the model phytosanitary certificate. The leadership role played by the IPPC for phytosanitary certification led the framers of the SPS Agreement to identify the IPPC as the organization responsible for phytosanitary standard setting. That single point of reference became the cornerstone for phytosanitary harmonization.

In the same way that the model phytosanitary certificate continues to be a point of harmonization from within the Convention, there are other sources of information outside ISPMs that support the harmonization of phytosanitary measures, including the agreements themselves and jurisprudence from dispute settlement. These three official sources of information work together to form the full basis for harmonization in the SPS-IPPC framework:

- harmonization based on the international agreements;
- harmonization based on international standards; and
- harmonization based on the results of disputes.

Each of these is evolving and has a dynamic relationship to the others. For example, the provisions and principles of the agreements are relatively static, but their interpretation in practice has a strong influence on standard-setting and disputes. Likewise, the results of disputes are important for clarifying the proper application of provisions and principles in the agreements and identifying areas where standards may be needed. Finally, standards reflect the priorities and concerns of the phytosanitary community and communicate agreement on important concepts with useful details that may not be described well in agreements but could be important for avoiding disputes.

2.1. The SPS Agreement and the IPPC

The agreements themselves enjoy treaty-level legal status and therefore translate to obligations for governments, but they also describe principles that provide the background for key features of the agreements. The IPPC has summarized these nicely in ISPM No. 1 (*Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade*).[4] The IPPC has also covered the terms and definitions from Article 2 of the Convention in ISPM No. 5 (Glossary of phytosanitary terms).[5] In addition, the agreements provide other important information that is not either an obligation or principle and may not be found in ISPMs. For instance, the IPPC links pest risk analysis with Technical Justification through its definitions in Article 2 and expands the concept to include "… another comparable examination and evaluation of available scientific information". The SPS Agreement has numerous provisions that offer important information which is not yet explained in standards or a topic of dispute. One good example is footnote 3 for paragraph 5.6 which explains how

to determine if a measure is more trade restrictive than required. The importance of the agreements as sources for harmonization will fade as the IPPC elaborates and updates standards with more detailed explanations on topics of interest or concern. In the meantime, there is substantial value to recalling the information in the agreements where standards are not available.

2.2. International Standards for Phytosanitary Measures

Despite the relatively short history of standard setting, the IPPC has developed ample background for harmonization, including many core references:

- **ISPM 1:** *Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade;*
- **ISPM 2:** *Framework for pest risk analysis;*
- **ISPM 4:** *Requirements for the establishment of pest free areas;*
- **ISPM 5:** *Glossary of phytosanitary terms;*
- **ISPM 11:** *Pest risk analysis for quarantine pests;*
- **ISPM 20:** *Guidelines for a phytosanitary import regulatory system;*
- **ISPM 23:** *Guidelines for inspection;*
- **ISPM 24:** *Guidelines for the determination and recognition of equivalence of phytosanitary measures;*
- **NIMF 45:** *Requirements for national plant protection organizations if authorizing entities to perform phytosanitary actions.*

Note: New ISPMs are adopted each year and existing ISPMs are amended, or in some cases deleted or replaced. It is strongly recommended that NPPOs frequently consult the IPPC website for the most recent information.[6]

There are two points that need to be understood about the legal status of ISPMs. The first is that although the IPPC has treaty status and the Convention itself represents obligations for Contracting Parties, the IPPC does not confer any legal force to ISPMs. However, under Article 3.1 of the SPS Agreement, WTO Members "… shall base their … phytosanitary measures on international standards". Article 3.4 goes on to name the IPPC as the organization responsible for phytosanitary standards. These provisions leave no doubt that IPPC standards are obligatory to WTO Members.

This awkward legal relationship is further complicated by the second point that needs to be understood: the ISPMs are a mix of requirements, guidance, and other information without clear distinctions about their intent. Even the titles are misleading. *Requirements for the establishment of pest free areas* (ISPM 4) does indeed include specifications for a pest free area that should be considered requirements, but it also provides information that is best considered guidance or recommendations. The differences are not clear. *Pest risk analysis for quarantine pests* (ISPM 11) is an especially important standard which is neither a requirement nor a guideline based on its title. It is rather a mix of both with many provisions that describe essential ingredients of risk analysis and others that are only recommendations or supplemental information. In the absence of greater specificity, the difference between requirements and guidance requires judgement. Great care is therefore needed to interpret the implementation of ISPMs in practice. Nevertheless, the ISPMs provide substantial background to support NPPOs with detailed information to assist in establishing requirements that meet their obligations in the SPS-IPPC framework.

2.3. Disputes

Disputes are arguably the least visible aspect of harmonization but an area that deserves much greater attention for two reasons. First, the issues emerge from actual trade disagreements. This means that two or more governments have different ideas about meeting their obligations, resulting in an exhausting debate the results in a final interpretation. Other countries have the benefit of following the arguments and studying the results to evaluate and adjust their own positions to avoid similar challenges. These "lessons learned" are not limited to phytosanitary topics but also include relevant issues in animal health and food safety.

The other reason disputes are important is because they can bring concepts into focus that might have been vague or completely misunderstood from interpreting the agreements.[7] For example, the idea of "rational relationship" is a point that has been a common theme in SPS disputes and deserves mention as an important concept that is not clearly described in the SPS or IPPC, or in ISPMs. Likewise, the concept of "strength of measures" is often overlooked and suffers from wide differences in interpretation that create friction. Both have emerged as central issues in SPS disputes but continue to be obscure in the agreements and standards. It is useful to discuss these concepts here precisely because they are vitally important to harmonization but not well understood from ISPMs.

2.3.1. Rational relationship and strength of measures

Every government has the sovereign authority to determine whether phytosanitary measures are required and the action necessary to provide the appropriate level of protection. In cases where phytosanitary measures are deemed to be necessary, there are usually a few to several options that can be evaluated for their efficacy. A high level of flexibility is needed for emergency measures applied in urgent, unanticipated situations. Emergency measures are generally conservative, i.e. deliberately over-restrictive to compensate for the lack of information or time to fully evaluate the situation. Other measures must be based on international standards or pest risk analysis and are subject to challenge for their appropriateness.

Strength of measures refers to the restrictiveness of phytosanitary measures based on a range of risk management options from most to least restrictive. This concept evolved from the SPS Agreement, but it is not expressly identified as such in the Agreement. The terminology comes from the IPPC definition of pest risk analysis (PRA) which is the basis for deciding whether phytosanitary measures are justified and "the appropriate strength of measures". The metaphor of a sliding scale is useful for visualizing the concept of strength of measures but in any regulatory situation there may not be such an extensive range of risk management options available for a precise match to the risk level. This means that in some cases, a risk which is found to be low may require a measure designed for higher risk because there is no other feasible measure. Begging clarity are the criteria and processes used for comparing and aligning measures with risk outside the odd instance where similar situations may be compared for consistency.

The term *rational relationship* is not used in either the SPS Agreement or the IPPC but emerged from WTO jurisprudence as a common issue at the core of nearly all WTO disputes on SPS measures. The rational relationship of a phytosanitary measure refers to two characteristics of its application. The first is that the measure has a demonstrated effect on mitigating the risk. The idea is simply that a measure is not justified if it has no mitigating effect on the identified hazard. Where treatments are concerned, this translates to the efficacy of the measure for reducing or eliminating the identified risk.

The second characteristic of rational relationship is that the strength of the measure is consistent with the level of risk. This point is especially important because it reinforces the IPPC principle of minimal

impact (Part 1.4 of ISPM No. 1).[7] It imagines a spectrum of possible measures ranging in strength from high to low that would align with risks likewise ranging from high to low. A high risk justifies stronger measures whereas the same measures would be unjustified for a lower risk.

The availability of phytosanitary measures can be a limiting factor in applying the concept of rational relationship. If only one measure is available, then the risk is either mitigated or not by the decision to apply that measure. In most cases, however there are options and opportunities to combine measures (e.g. systems approach) which provide the flexibility to adjust the strength of measures.

These concepts clearly overlap, and both have important implications that are not well understood or are often misunderstood in their phytosanitary context. Both concepts link to the same principles: that phytosanitary measures are limited to what is necessary to protect plant health (Necessity), consistent with the pest risk involved (Managed risk), represent the least restrictive measures (Minimal impact), based on conclusions reached using an appropriate risk analysis (Technical justification), and are promptly modified or removed as conditions change and new facts become available (Modification).[8] The underlying concept is both simple, logical and fair: measures are established and adjusted based on scientific evidence to be appropriate for the risk.

2.4. Fruit fly harmonization

Fruit flies occupy a pivotal place in phytosanitary harmonization because of their overall importance in phytosanitary regulations globally. The level of detail provided in ISPMs reflects a long history of regulatory and research efforts resulting in a high degree of agreement on key points for managing fruit fly risk. Two distinct strategies are evident: the first is to create fruit fly specific standards that follow from general reference standards, the other is to create technical standards offering details on fruit fly specific processes, procedures, methods and materials.

ISPM 26 (*Establishment of pest free areas for fruit flies (Tephritidae)*) builds on the pest free area concept outlined in ISPM 4 (*Requirements for the establishment of pest free areas*) by providing technical details specifically for fruit flies. Likewise, ISPM 35 (*Systems approach for pest risk management of fruit flies (Tephritidae)*) follows ISPM 14 (*The use of integrated measures in a systems approach for pest risk management*) and includes the material previously found in ISPM 30 (*Establishment of areas of low pest prevalence for fruit flies (Tephritidae)*) which was revoked in 2018. Curiously, the concept of host status has no general reference standard, thus making ISPM 37 (*Determination of host status of fruit to fruit flies (Tephritidae)*) the only ISPM directly addressing questions of host status. This makes it an important reference for both general concepts and terms as well as fruit fly specific information. In addition, two diagnostic protocols for fruit flies have been adopted under ISPM 27 (*Diagnostic protocols for regulated pests*): DP-9 for *Anastrepha* and DP-29 for *Bactrocera dorsalis* and ISPM 28 (*Phytosanitary treatments for regulated pests*) includes a long list of annexes for fruit fly treatments. The relationship between fruit fly ISPMs in support of safe international trade of fresh fruits and vegetables is presented and described in the following infographics.[i]

In sum, these standards provide greater scope and technical detail than what is available for any other pest or group of pests, demonstrating the high level of interest and attention given to fruit flies by the phytosanitary community. This does not mean that fruit fly standards are comprehensive but rather

[i] *https://**www.iaea.org**/newscenter/multimedia/videos/**fruit-fly-standards-can-help-gain-market-access***

that they complement the agreements, disputes, and other ISPMs with more extensive harmonization. The following simple example demonstrates this relationship from general to specific:

1. The SPS Agreement refers to the prevalence of specific pests as a factor to consider in risk assessment (Article 5.2). The IPPC defines "areas of low pest prevalence" in Article II.

2. SPS jurisprudence on Article 5.2 confirms that areas of low pest prevalence must be considered in the assessment of risk.

3. Areas of low prevalence are explained as an operational principle of ISPM 1. ISPM 22 provides the general requirements for the establishment of areas of low pest prevalence. ISPM 6 describes a monitoring survey as the type of specific surveillance needed for establishing and monitoring pest prevalence. ISPM 27 has the diagnostic protocols for the identification of certain fruit flies that would be the targets of specific surveillance. ISPM 29 describes the process for recognition of areas of low pest prevalence.

4. ISPM 14 talks about low pest prevalence as a pre-harvest element of systems approaches. ISPM 35 then provides a detailed explanation for the use of low prevalence in a systems approach for fruit flies.

The points described for harmonization in this example cover the main obligations, principles, concepts, policies, processes, and operations directly associated with using areas of low prevalence as part of a systems approach for fruit flies. Other standards provide indirect support and additional information. This background offers substantial risk management assistance to NPPOs, but it needs to be understood in the context of each government's unique circumstances. ISPMs are not a recipe. They provide information that has been internationally agreed upon (or settled in the case of disputes) as elements for the establishment of phytosanitary measures. It is not difficult to imagine how much more difficult and chaotic trade would be if every country invented their own interpretation of a systems approach based on low pest prevalence without this guidance.

2.5. Non-harmonization

When the SPS Agreement came into force in 1994, the IPPC had just started its standard setting program and the understanding of pest risk analysis was in its infancy. This placed the phytosanitary community at a distinct disadvantage for fully embracing implementation of the SPS Agreement. More than two decades later, the IPPC has put in place a wide range of concept, reference and specific standards, and pest risk analysis has become a settled practice. Despite this relatively rapid development, many current phytosanitary requirements continue to have legacy origins with no justification in either PRA or ISPMs and countries continue to negotiate trade arrangements for new requirements that ignore their SPS-IPPC obligations and ISPMs.

All governments have the sovereign right to enter into bilateral and multilateral agreements, and these may be inconsistent with their international obligations. They can also choose to ignore legacy requirements that do not conform with the international regulatory framework. All governments are culpable to some extent for undermining harmonization in favour of other arrangements. These practices exist and continue so long as they are not challenged. The WTO and IPPC have no enforcement mechanisms for ensuring conformity with the agreements. This means that member governments are responsible for identifying their own shortcomings and challenging those of others. This process is essential for advancing the implementation of the agreements and promoting harmonization.

3. Phytosanitary measures

Phytosanitary measures are broadly defined by the SPS and the IPPC to include laws, regulations, policies, procedures, methodologies, and much more. The key is their application by governments in trade to protect plant life and health. The aspects that are primarily concerned with risk management are those requirements that are intended to reduce or eliminate pest risk associated with consignments in commerce. These measures may be officially prescribed requirements, or they may be conditions that are characteristics of the product in question. For example, it is not necessary to require freezing for frozen strawberries but freezing may be required as a treatment for fresh strawberries. The key difference is how the product is defined for risk analysis purposes. It is important to be specific. Simply stating "strawberries" will raise many more pest concerns than "frozen strawberries".



ISPM 14 (*The use of integrated measures in a systems approach for pest risk management*) provides an extensive list of potential phytosanitary measures (Section 2, Characteristics of systems approaches).[9] The ISPM also makes important distinctions between mitigations (e.g. treatment), safeguards (e.g. pest-proof packaging) and procedures (e.g. inspection). The standard goes on to explain the critical relationship between pest risk assessment and pest risk management in the context of systems approaches. As a general point, PRA is not only essential for systems approaches but for all risk management designs because:

- It specifies the commodity, pathway and conditions proposed for trade.
- It identifies the pests of concern and the magnitude of the risk.
- It describes potential points and types of risk management.
- It explains the areas, types and significance of uncertainties.
- It illustrates the level of protection considered appropriate by the importing country.

All of these points represent vital information that weigh heavily on the potential for developing successful import programs and defendable regulatory requirements. This is especially true for fruit flies because there is general agreement on their status as pests requiring strong mitigation.

3.1. Emergency measures

Emergency measures (IPPC Article VII.6 and Principle 2.11 in ISPM No. 1) and ***"urgent circumstances"*** (SPS Annex B.6) are the same thing. Both offer the possibility for exceptions to the application of the concepts of *strength of measures and rational relationship* to the extent that overly restrictive measures may be temporarily applied in unanticipated circumstances where risk mitigation is deemed necessary, but time and information is not available for risk assessment. However, both the IPPC and the SPS Agreement also require the timely evaluation of these measures to justify or modify them as necessary to be appropriate for the risk.

No internationally agreed guidance or jurisprudence has emerged to describe when an emergency measure is no longer appropriate, so emergency measures often become the default action on an ongoing basis. This means that each application is treated like a distinct emergency no matter how many times the same situation has occurred in the past. It is easy to imagine the possibility for a dispute arising where emergency measures have been repeatedly applied over a long period without any effort to review their appropriateness for the risk involved.

The concept of emergency measures is significant for fruit flies primarily because most legacy requirements are based on worst-case assumptions that result in highly restrictive measures such as those used for emergency actions. This creates questions about the potential differences in risk and the technical justification for this equivalence.

3.2. Provisional measures

The SPS Agreement specifically describes another type of phytosanitary measure which may be provisionally adopted "where scientific evidence is insufficient" (Article 5.7). Unlike emergency measures, provisional measures are based on an analysis but provide for the adoption of stronger measures than might be necessary because of the absence of scientific evidence that might argue for reducing the strength of measures. The objective is to make trade possible until additional information is available to potentially reduce the strength of measures. The key point to remember with provisional measures is that they place the information burden entirely on the country imposing the measure.

Provisional measures can be an important factor with fruit fly regulations because so many requirements predate risk analysis. In many instances, trade can be facilitated by agreeing to adopt legacy requirements while endeavouring to develop evidence that would argue for reducing the strength of measures. For example, a country may want to export a fruit that is historically only accepted by its trading partner with a fruit fly treatment. The exporting country may initially accept the treatment requirement to gain access to the market with the proviso that alternative measures may be evaluated afterward that are more appropriate for the risk. The importing country then has the choice of establishing the requirement as a provisional measure or face a challenge on the technical justification for the treatment.

3.3. Precautionary approach

The precautionary approach (also referred to as the precautionary principle) is surrounded by significant rhetoric and diverse interpretations by governments as well as international and private organizations positing different claims about the application of the concept in practice and promoting regulatory systems that may not be consistent with existing phytosanitary mechanisms and international obligations. This has resulted in a growing impression that the precautionary approach is an alternative basis for regulatory decision-making to be used where there is judged to be insufficient

information to undertake a risk-based approach. The implication is that the process of risk analysis would not be undertaken or completed if the lack of information led to some level of uncertainty that was deemed to be unacceptable.

This interpretation indicates a fundamental misunderstanding regarding the nature of risk analysis and its role in the formulation of phytosanitary measures. It ignores the role of uncertainty as part of the risk analysis process. The adoption of such an interpretation is also inconsistent with the SPS Agreement and the IPPC.

The term "precautionary measures" is not explicitly used or described in either the IPPC or the SPS Agreement. However, it may be argued that phytosanitary measures are by their nature precautionary depending on the influence of uncertainty in the judgment regarding acceptable risk. The concept of precaution based on uncertainty is therefore implicit in the application of proper risk analysis; however, the role of scientific principles and evidence in risk analysis has historically been given greater prominence than the role of uncertainty. This sometimes results in a strong focus on "sufficient scientific evidence" without fully recognizing that uncertainty is inherent in all scientific evidence and a proper risk analysis should account for uncertainty.

If risk analysis is affected by different interpretations of the precautionary approach, then trade is also affected. The precautionary approach is overtly embedded in regulatory language underpinning phytosanitary guidance in many countries. It is often hidden in different regulatory processes without being identified as the underlying concept. For example, a country may state that large uncertainties associated with a given commodity (e.g. nothing is known about the pests in country X) justify indefinite prohibitions and preclude the consideration of risk analysis (and thus the usefulness of IPPC guidance) giving way to unjustified trade barriers which is against the principles of the WTO and the SPS Agreement.

In the WTO dispute cases of the US vs EC on hormones in beef and Japan vs. New Zealand on Fire blight of apples, arguments were made that potential hazards existed in the absence of evidence and a precautionary approach justified measures. In both cases, WTO dispute settlement panels agreed that uncertainty was not sufficient condition for prohibition and an evidence-based approach (= risk analysis) was necessary to justify measures.[10]

3.4. Equivalence

The concept of equivalence is well-described in SPS Article 4, ISPM 1 and ISPM 24 (*Guidelines for the determination and recognition of equivalence of phytosanitary measures*).[11] A key point that is not explicit in this guidance is that equivalent measures aim to achieve the same level of protection based on the assumption that the level of protection was based on risk analysis. Successful application of the concept cannot be done when comparing measures that have no basis in PRA from which to judge the risk and strength of measures. For example, it is often the case that a legacy treatment requirement was established without PRA or a specification for the required response, or the required response was set arbitrarily (generally much higher than needed). A review of the risk and the appropriate level of protection is needed to understand if the treatment is technically justified before considering the viability of an equivalent measure.

4. Risk management

The term "**risk management**" is not found in the SPS Agreement despite this being the focus of the agreement. The Agreement instead refers to phytosanitary measures in relation to harmonization (standards) and risk (risk assessment). The IPPC also only refers to phytosanitary measures, and although most of the ISPMs relate directly or indirectly to risk management, there is not yet a reference standard for risk management. Many of the elements and individual components of pest risk management are described in ISPM 2, ISPM 11 and ISPM 21. ISPM 11 (*Pest risk analysis for quarantine pests*) provides critical detail on the analysis for risk management in Stage 3 (Pest risk management), but many of the key aspects of risk management needed to create effective trade programs must be extracted from the range of ISPMs.[12] For instance, the concept of a "required response" in relation to treatment efficacy is found in ISPM 18 (*Guidelines for the use of irradiation as a phytosanitary measure*).[13] More complex relationships such as linking the concepts of low pest prevalence or host status with a systems approach are not explicit possibilities from the relevant ISPMs.

Plant health is uniquely disadvantaged among the disciplines covered by the SPS Agreement, and a relatively short history of standard setting compounds the challenges in standard setting for pest risk management. The phytosanitary community faces thousands of known pests, hundreds of potential host commodities, and dozens of pathways in comparison to the much smaller universes of concern in food safety and animal health. This disadvantage is made worse by a long history of relying on only a handful of risk management measures, primarily prohibition, inspection and treatment, all common requirements for fruit fly hosts. The limited number of risk management options combined with a historical focus on point mitigation for exclusion at the border has stifled the evolution of more sophisticated responses in the SPS-IPPC framework compared to other disciplines where risk management is a well-developed practice.[14]

The SPS Agreement has created possibilities for a more sophisticated view of pest risk management with a view to establishing measures that are justified by the level of risk and supported with scientific evidence or standards. Simply having protection as an objective no longer provides carte blanche for all possible measures or any level of restrictions. This brings into question a great many legacy requirements and points toward a needed shift from the focus on exclusion based on point mitigations at the border to new openness about the spectrum of measures and conditions that affect the risk of pest introduction anywhere in the supply chain. By recognizing that risk management can be viewed and practiced as a continuum that is overlayed on the supply chain, the possibilities for new risk management designs is exponentially increased. Opportunities and incentives for private sector contributions become natural extensions of this approach. By anchoring phytosanitary measures to a scientific justification and shifting the dialogue from pest presence at the point of import to the risk of pest establishment from a particular pathway, a broader and more realistic view of risk management emerges that invites the collaboration of trading partners and industry because they are drawn together in the risk management continuum by a shared purpose for achieving shared objectives. The bridge that makes this possible in the IPPC is the application and extension of the concept of systems approaches "A pest risk management option that integrates different measures, at least two of which act independently, with cumulative effect (ISPM 5)".

The metaphor of a bridge is appropriate because the concept of systems approaches links pre-SPS requirements to the future evolution of risk management in a post-SPS era. This forms a hierarchy of designs, from single point mitigation to holistic approaches, that helps to illustrate the opportunities for next-generation risk management.

4.1. Single point mitigation

These are traditional measures, usually applied at the point of import. The objective is pest exclusion based on pest absence. These measures typically rely on inspection or treatment and often have little or no consistency in their relationship to risk. Uncertainty is addressed through overkill. Single point mitigation is the prevalent form of phytosanitary practice for fruit flies around the world even though many of these measures are inconsistent with the SPS Agreement.

Inspection has a long history of service to the phytosanitary community and currently benefits from guidance provided by ISPM 23.[15] It is by far the most widely used phytosanitary measure for both import and export. Inspection is a comfortable measure because it provides tangible results linked to universally practiced policies. The reality of inspection as a risk management measure is however highly variable, poorly understood and inconsistently practiced. An important point to understand in the context of fruit flies is that inspection is far from being a highly effective measure.

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When a consignment is inspected, either before export or after import, or both, and no pests are found, the shipment is considered compliant. This is the century-old inspection paradigm that continues to misguide phytosanitary programs. The reality is that there is substantial uncertainty and variability around that inspection result, and unless the inspection was designed for a specific level of detection and confidence, the results do little to accurately characterize the phytosanitary status of the commodity. Additional haphazard inspections do not substantially improve our understanding of infestation rates from the statistical standpoint, and issues can easily arise where inspections are repeated. For instance, an inspection may be done in the country of export and another inspection done at the border in the destination country. Unless the trading partners have agreed in advance on the same methodology, the results cannot be compared. Furthermore, the technique may be a simple visual examination or involve destructive sampling (fruit cutting) and laboratory analyses. In all these cases, inspection does nothing to directly mitigate pest risk but rather provides information that can result in other actions being taken which change the phytosanitary status of a consignment.

Current inspection designs vary considerably, and many are not transparent regarding the risk management strategy and objectives. Routine inspection to detect **unanticipated pests**, or spikes in the prevalence of anticipated pests, provides a barometer on the overall phytosanitary state of the commodity and allows for potentially important changes to be observed and adjustments made before failures occur. It is important to understand that in this case, inspection is not being used as a phytosanitary measure (a requirement for trade) but rather to monitor the baseline effectiveness of measures applied by the country of origin to manage pest risk.

A key point to watch where fruit fly treatments are concerned is the historical reliance on a probit 9 response (99.9968 percent mortality). The "probit 9 mortality" standard is problematic from a policy standpoint because it fails to meet the test for rational relationship. It is a one-size-fits-all approach based on the assumption of high risk. It limits applications where less rigorous treatments are justified, and it is less defendable if challenged for its risk basis. Probit 9 mortality is problematic from a research standpoint because it is not always possible to work with the large number of fruit flies needed to meet the standard. A more reasonable approach is for countries to agree in advance on bilateral research protocols for specific tests that are practical, scientifically acceptable and appropriate for the risk.

4.2. Pest-free approaches

Designs around pest-free approaches were accepted and practiced for fruit flies before the SPS Agreement came into force but the SPS-IPPC framework has made it a central risk management strategy.[16] ISPM 4 (*Requirements for the establishment of pest free areas*) was one of the earliest standards and arguably one of the most impactful standards done by the IPPC because it validated these approaches and harmonized the requirements. Pest-free area measures rely on pest freedom in the production area and recognize different levels of application. Pest-free areas have been successfully established and maintained for several fruit flies. In addition to guidance found in the standards, it is important to note that the determination of pest freedom depends on the sensitivity of the tools and effectiveness of the design for detection and monitoring. This is a crucial factor for fruit flies because of the variability in fruit fly behaviour and the differences in the effectiveness of tools such as traps, lures and surveillance designs. ISPM 26 provides guidance for the establishment of pest free areas for fruit flies *(Tephritidae)* of economic importance, and for the maintenance of their pest free status (FAO, 2015).

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4.3. Policy measures

This is an unusual area of risk management that is not well addressed in standards but often found in fruit fly requirements. It involves designs such as harvesting and shipping windows which take advantage of seasons when pests are not present in the field or cannot establish at the destination. Another design restricts imports to specific ports and the distribution of imported commodities to areas where the risk of establishment is negligible. Policy measures are good options for provisional measures because they can be easily adjusted or eliminated based on experience.

4.4. Systems approaches

The integration of two or more measures in a systems approach is a design that offers a wide range of risk management opportunities and is well-supported by ISPMs. One great advantage of systems approaches is the ability to adjust the strength of measures by adding and removing measures. Another advantage is the increased range of risk management options that comes with the ability to combine different measures. Each systems approach can be uniquely designed for a specific application. The primary disadvantage of systems approaches is the increased complexity and uncertainty which varies greatly depending on the number and type of measures. Systems approaches have become popular options as mitigations for fruit flies, especially where the systems approach can be anchored to low prevalence or poor host status (ISPM 37 *"Determination of host status of fruit to fruit flies (Tephritidae)*"). The ultimate systems approach would mimic the Hazard Analysis Critical Control Point (HACCP) designs used in food safety. Phytosanitary approaches have not yet reached this level of sophistication. ISPM 35 provides guidance for the development, implementation and verification of integrated measures in a systems approach as an option for pest risk management of fruit flies *(Tephritidae)* of economic importance to facilitate trade of fruit fly host products or to minimize the spread of regulated fruit flies within an area (FAO, 2012).

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4.5. Continuum approaches

Recognizing that there are events and conditions in the supply chain that mitigate risk and including those in the risk management calculus is a continuum approach. It takes advantage of the entire spectrum of risk management inputs whether they are prescribed or not. For example, many fruits and vegetables are subjected to culling, washing, and other post-harvest handling that is primarily designed to ensure the quality of products. These processes also remove pests and can have a significant and measurable impact on pest risk. Likewise, cultivation methods, storage practices and shipping conditions can be important factors in managing pest risk. Continuum approaches extend the concept of systems approaches to include risk mitigation factors that are not prescribed but either define the commodity or are known to occur. For example, commercially produced bananas are almost universally grown under covers which has a substantial effect on pest susceptibility. Regulators recognize

this characteristic as a normal condition for commercial banana cultivation. By defining the commodity as "commercially produced banana" this condition is implied and does not need to be prescribed. A multitude of other events and conditions can be recognized in a continuum approach. This makes it important for producers and regulators to work together in closely reviewing the overall situation surrounding their production processes. The more data they can share about their specific situation, the greater the likelihood that some aspects will be included in the risk assessment and positively affect risk management. Ideally, a market access request will begin with such a complete scenario and evidence to support all aspects. Continuum approaches are rare but nonetheless legitimate and offer a wide field of possibilities for fruit fly hosts.

4.6. Holistic risk management

This is the ultimate form of risk management. It goes beyond measures and analysis to link the risk management communities of importers, exporters, researchers and industry with a common objective: safe trade. It begins with a willingness to collaborate based on shared interests and a desire to objectively evaluate all possibilities based on the available information. Although the concept is both practical and logical, the phytosanitary community suffers from reluctance to embrace this approach. This reluctance stems from a culture of distrust which is slowly eroding as harmonization begins to connect previously unconnected ideas and communities. As an example, researchers are able to gain enormous insight into priorities for regulatory research because of uncertainties identified by regulators through the process of risk analyses. This is especially true with fruit fly work where there is a long history of productive relationships between researchers and regulators.

5. Opening or expanding markets

A wide range of risk management strategies support international trade in fresh fruits and vegetables that are regulated for fruit flies. In many cases, these are legacy designs that pre-date the SPS Agreement. Others are simply bilateral agreements negotiated between trading partners. A few are risk-based designs that draw heavily from the background for harmonization. One additional group could be the risk management strategies that have not yet been created. This last category is arguable the most promising. Pest risk managers have yet to explore all the opportunities opened by the SPS Agreement for fruit fly regulations, especially in the concept of systems approaches and continuum approaches. Myriad opportunities exist to replace legacy designs or create new designs as legacy requirements are challenged and point mitigations are exhausted.

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The key to opening markets in the SPS-IPPC framework is to focus on the pest risk, and especially on all the factors contributing to risk and mitigating risk. There is often a tendency to begin with legacy concepts and requirements that were based on assumptions of high risk rather than begin with a fresh view of the evidence and an objective analysis of the risk. By breaking from the dogma of historical designs to embrace the opportunities for innovation created by the SPS-IPPC framework, researchers and regulators are able to create regulatory designs that more closely align with the concept of rational relationship and conform to relevant standards.

STEP 1
Consult the export industry

The objective in this step is to gain an objective understanding of the prevalence of fruit flies in the host and factors affecting prevalence. It begins with NPPO-industry collaboration to identify markets and to describe field, harvest, packing and shipping processes. Pay particular attention to data that may be available or can be collected on the prevalence of fruit flies. It is important to know the range of natural infestation levels and how measures taken or processes applied from the field to the time of export affect prevalence. The possibility for free areas is considered in this step. Likewise, the potential for identifying poor host status or low prevalence as anchors for a systems approach will be determined.

The effect of conditions such as weather, nearby alternative hosts (wild or cultivated), and differences in varieties and ripeness at harvest should be included in the analysis. Small observations can make a big difference. For instance, whether fruit pickers are paid for volume or quality will make a huge difference in the type of fruit arriving at the packing house and therefore the prevalence of fruit flies at that point in the supply chain. A higher prevalence translates to higher risk, which in turn means stronger measures. The point of the analysis is to gain a realistic view of the range of prevalence in contrast to beginning with worst-case assumptions.

This is the first point in the process where research is engaged, forming an alliance with regulators and industry to identify potential scientific inputs and opportunities to fill gaps. This is a crucial point because often a small amount of research that is easily done can provide immensely useful data for such analyses.

STEP 2
Identify all regulated pests

The NPPO of the exporting is always in the best position to know what pests affect its commodities but it may not know which are regulated and by what potential trading partners. In cases where the exporting country has already requested market access, a pest risk analysis (PRA) should have been produced by the importing country that identifies the pests, risk and regulatory position of the importing country. A full PRA may not be available if it is assumed that any fruit fly host commodities will be prohibited unless treated. It is nevertheless important to know if there are also other regulated pests which might require phytosanitary measures while also arguing that fruit fly risks can be managed.

STEP 3
Identify potential phytosanitary measures where they exist and gaps where measures are lacking

In this step, the NPPO is matching potential phytosanitary measures with pests to understand what measures are available and where there are no measures. The case for fruit flies is facilitated by the availability of highly effective treatments, and in the case of irradiation, a generic dose. Based on the analysis done in Step 1 above, consideration should be given to less rigorous options where prevalence is found to be far below worst-case assumptions.

This is again a point where research can provide critical support by identifying existing scientific information and the potential for covering shortcomings with new research.

STEP 4
Analyse options

Based on the above, the NPPO can determine:

- what measures are immediate prospects for risk management;
- what measures will require additional information or research; and
- what measures may be unfeasible under current circumstances.

Armed with this analysis, the NPPO is able to prepare a proposal (or proposals) that can be defended in negotiations with trading partners based on the SPS-IPPC framework. As noted above, it is important to focus on mitigating the risk of establishment, not the exclusion of fruit flies from the pathway. Irradiation treatment is useful to illustrate this point. Fruit may be infested and have any number of live larvae present after treatment. Although the presence of live quarantine pests may be alarming, it is not a risk because most of the larvae will eventually not survive the treatment and those few that might survive to adult stage will be sterile and therefore unable to establish.

STEP 5
Initiate programs

At this stage, the NPPO reconnects first with private sector stakeholders to develop strategies for implementation of a program. A critical aspect of this process is controls and accountability for ensuring the effectiveness and integrity of programs. Programs that fail will reflect poorly on the credibility of both the importing and exporting NPPOs. From this standpoint, it can be useful to add some redundancy to measures or put in place provisional measures that can be reduced or removed once a program has proven to be robust and consistently effective.

The process of negotiating with trading partners begins after the NPPO and its industry have agreed on their program proposal(s). The objective here is to establish requirements for a working program. This may be especially difficult if the trading partner has a hard policy of prohibition for fruit fly hosts. In many cases, the challenge is rooted in legacy decisions based on strong protectionist positions that are inconsistent with the SPS-IPPC framework. This point may need to be emphasized and the potential for a challenge may need to be raised to make progress.

6. Research

The importance of research has been highlighted many times here and is reinforced by the provisions of the SPS Agreement referring to scientific evidence as the basis for measures where international standards are not available or measures deviate from standards (Articles 3 and 5). Little specific guidance is provided in standards, with the exception of ISPM 18 (*Guidelines for the use of irradiation as a phytosanitary measure*) which includes a research protocol in Appendix 2. Although the protocol is directed specifically toward research for irradiation treatments, the design and many specific aspects are relevant for other treatments.

Where fruit flies are concerned, the research background is much broader than only treatments, including work on trapping, lures, field biology and behaviour, sterile insect technique, area-wide management, and biological control. A long history of research across the spectrum of questions associated with fruit flies has resulted in a broad foundation of information that is often directly relevant to regulatory programs. This greatly reduces the need for investments in basic research, but it does not mean that research is no longer needed. As the regulatory community is shifting from historic paradigms to more contemporary risk management designs that better align with the SPS-IPPC framework, the fruit fly research community is in an important position to facilitate this transformation.

Researchers play a major role in promoting the innovation needed to extend risk management from traditional to contemporary designs. Examples of areas for contemporary research that complements new regulatory directions for risk management include:

- methodologies to monitor pest prevalence in the supply chain;
- treatment metrics that focus on the risk of survivors rather than mortality;
- conditions for establishment;
- attrition of risk in the supply chain;
- equivalence of measures;
- designs for systems approaches;
- thresholds for low prevalence;
- more sensitive tools for monitoring field prevalence.

In sum, the researcher needs to take more initiative to offer new risk management options to regulators rather than only respond to specific requests from regulators. This needs to be a true partnership with regulators enjoying support on one side from harmonization and on the other from research.

7. Conclusion

The discussion herein crosses a range of issues associated with establishing trade programs for fresh fruits and vegetable within the context of the SPS-IPPC framework. One thread that follows all the discussion is the importance of being thoughtful about program objectives and the designs that achieve those objectives in a sound and defendable way. The central message is one of continued evolution, taking advantage of the new directions provided by the SPS Agreement and standards from the IPPC to move pest risk management into a new era. No group is in a better position to advance this agenda than the fruit fly community because of its long history, broad foundation and close relationship to the regulatory community.

Finally, it is important to note that the establishment or expansion of trade in fruit fly hosts requires more than only meeting SPS-IPPC obligations and following international standards. Close coordination with all relevant authorities, institutions and organizations, including the research sector, regulatory authorities, producer and export associations, investors, and international organizations is equally essential. **A holistic approach is ideal.**

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8. Notes

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General Guidelines to facilitate the opening of International Markets for Fruits and Vegetables that are Fruit Fly Hosts Based on International Standards for Phytosanitary Measures

The purpose of the guide is to elaborate on the use of international standards to facilitate international trade of fresh fruit and vegetables known to be fruit fly hosts considering the regulatory framework of the WTO-SPS-IPPC with its associated International Standards for Phytosanitary Measures (ISPMs). Key aspects of this framework are identified and explained with emphasis on understanding their meaning and relationship to opening new markets and expanding existing markets. The guide aims for a better understanding of the factors that should be considered when establishing trade, and how to maximize the potential for international standards to facilitate safe trade.

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