EXPLANATORY DOCUMENT ON INTERNATIONAL STANDARD FOR PHYTOSANITARY MEASURES No. 20 (*GUIDELINES FOR A PHYTOSANITARY IMPORT REGULATORY SYSTEM*)

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Note: Explanatory documents for International Standards for Phytosanitary Measures (ISPMs) are produced as a result of a decision of the Interim Commission on Phytosanitary Measures in 2004 (reported on paragraph 111 of the report of ICPM-6). They are written to provide supporting information to the standard they refer to and cannot be taken as an official legal interpretation of the IPPC or its related documents, and are produced for public information purposes only. Each document is written by an expert, reviewed by at least two peers (usually from the Expert Working Group concerned), then reviewed by the Standards Committee and the IPPC Secretariat. However, the material presented in explanatory documents remains the opinion of the writer and cannot be interpreted as a decision of the ICPM. It is hoped that most standards will have one or more explanatory documents associated with them.

The purpose of this Explanatory Document is to provide background information on ISPM No. 20, to explain the use of the standard, to clarify difficult issues and to assist with the implementation of the standard. The document must be read in conjunction with ISPM No. 20; it is not a replacement for the standard and does not cover every point of detail mentioned in the standard.

INTRODUCTION

ISPM No. 20 (*Guidelines for a phytosanitary import regulatory system*) was adopted by the Interim Commission on Phytosanitary Measures (ICPM) in April 2004. The scope and objectives of the standard are set out on pages 4 and 10 respectively of the standard. The standard provides guidance on the structure and operation of an import regulatory system with the aim of preventing the introduction of quarantine pests and limiting the entry of regulated non quarantine pests with imported commodities and other regulated articles.

This explanatory document provides guidance on:

- the purpose of ISPM No. 20 and relationships with other standards
- the general form of the standard
- the contents of the standard, including comments
- major points of concern
- references to additional explanatory material.

Any reference in this explanatory document to a section or page, unless otherwise indicated, is a reference to a section or page in ISPM No. 20.

PURPOSE AND RELATIONSHIPS WITH OTHER STANDARDS

All countries require a robust and effective phytosanitary import regulatory system for their territories. This is needed to protect their agriculture, other plant production systems and the plant environment from the risks posed by the introduction or spread of new pests (i.e. listed or potential quarantine pests) or to ensure the effective management of regulated non-quarantine pests (RNQPs). In addition, an exporting country needs an effective import regulatory system to ensure that it can accurately certify that exported consignments meet the requirements of an importing country. Without this there may be a lack of confidence on the part of the importing country, with commodities facing irritating delays at entry and even prohibition.

From the least developed to the most developed country, there can be a huge range in the detail of the import regulatory system. For some countries, systems to regulate imports for phytosanitary purposes can be particularly limited. However, even in countries with a well developed system, there can be lack of clarity with respect to at least a part of their system and this can lead to a lack of confidence and/or misunderstanding between trading partners.

The requirements set out in the International Plant Protection Convention (IPPC), the International Standards for Phytosanitary Measures (ISPMs) and other international agreements can be complex and the interaction of the various requirements adds further complexity. ISPM No. 20 aims to give clear guidance on good practice and clarify the complexity of international requirements.

In establishing the standard, it was considered important that the standard should:

- not impose new obligations beyond those already established either in the IPPC, other ISPMs or other relevant international agreements such as the World Trade Organisation Agreement on the Application of Sanitary and Phytosanitary Measures (the WTO-SPS Agreement),
- not require contracting parties to change their system where their procedures are already in compliance with the requirements of the standard, but
- provide clear, unambiguous guidance as to what a phytosanitary import regulatory system should achieve.

Thus this standard does not aim to force a uniform system on IPPC contracting parties. Rather it sets out to provide a framework or checklist of best practice that countries may use to establish a new import regulatory system, to modify or update their current system, or simply check that their system covers and, to the extent appropriate, complies with international agreements.

The standard is not a stand-alone document. It cross refers to the IPPC and to most other ISPMs as they are integral to and impact on the function, establishment and operation of an import regulatory system. In particular, the standard aims to set the respective rights, obligations, responsibilities and requirements in the context of the import regulatory system. In a few instances the standard explains and expands on the guidance of other standards.

GENERAL FORM OF THE STANDARD

The requirements sections of the standard begin with two short sections covering the objectives of an import regulatory system and its structure based on two components, a regulatory framework and the NPPO. The rights, obligations and responsibilities which must be taken into account in establishing and operating an import regulatory system are in Section 3.

The main requirements of the standard are in two parts:

- Section 4, the regulatory component, aimed mainly at regulators; that is, those who draft and/or establish regulations. It describes the regulations that must, may or may not be required by the system.
- Section 5, the operational component, aimed mainly at the NPPO and any associated agencies or personnel. It describes the implementation of the regulations, how they must, may or may not be applied and the resources required.

This reflects the suggested structure of an import regulatory system. Robust and unambiguous regulation and operational guidance is essential to enable effective operation of the system. Too often, plant health services

are faced with the need to carry out a particular task but do not have either the regulation (or the regulatory authority) to take such an action or the operational guidance or resources to fulfil the task within the regulation. By separating the components of regulation and operation, the two parts can be clearly identified and cross checked for compatibility.

The standard finishes with sections covering documentation, communication and review, elements that are common to most standards.

CONTENTS OF THE STANDARD

Objective (Section 1)

This short paragraph on the objective of the import regulatory system is self explanatory.

Structure of an Import Regulatory System (Section 2)

The structure consists of two components: a regulatory framework and an NPPO to operate the system.

Regulatory framework

Because the legal procedures of countries differ, the standard does not specify a particular legal system but provides general guidelines to be considered by the regulatory framework. In particular it notes that some countries require every detail of its procedures to be established in the regulations, whilst in other countries the law provides officials with the delegated authority to establish appropriate administrative procedures. Thus any legal structure is acceptable provided it enacts the requirements of the standard.

Official service

The standard states that the official service responsible for operating the import regulatory system should be the NPPO. This responsibility (see Section 5 first paragraph) arises from Article IV.2 of the IPPC, 1997. Although the import regulatory system is not mentioned specifically in the Convention, the responsibilities set out for the NPPO encompass most of those required for the operation of the import regulatory system. It is theoretically possible for a service other than the NPPO to operate the import regulatory system. However, the IPPC designates so many responsibilities for imports to the NPPO that designating any other service would result in at least considerable inefficiency and at worst conflicts of interest. This may lead to an operation not in compliance with international obligations. A recent example is a country in which officers of the Department of Trade had been given the responsibility for issuing Phytosanitary Certificates for consignments for export; this was in clear breach of the IPPC and had the potential for conflicts of interest to arise.

Although the NPPO should be operationally responsible for the system, it is not required that the officers of the NPPO carry out all the tasks. The NPPO may delegate tasks although they must remain responsible for overseeing these delegated tasks. In some cases delegation to others is, in practice, almost essential. The Customs Service in most countries has a pivotal role in the control of imports and certain tasks such as notification of arrival and certain aspects of documentary checking are often delegated to them. In other countries, particularly those with a federal structure, substantial aspects of the import regulatory system may be delegated to regional or state bodies which are not formally a part of the NPPO. However, wherever there is delegation it must be clearly defined and remain under the ultimate control of the NPPO.

Rights, Obligations and Responsibilities (Section 3)

In establishing this standard, it was considered essential to stress not just the obligations arising from international agreements such as the IPPC and the WTO-SPS Agreement but also the rights and responsibilities conveyed by such agreements. This is because the international community considers that such agreements are to be seen as beneficial to all trading partners. These agreements do not just convey obligations, which some see as negative, but also rights such as the right of a country to protect its producers and environment against phytosanitary threats. However, even where a country has the right to carry out a particular act, it has the obligation to respect another country's rights and to recognise responsibilities.

For example, a country has the right to restrict the entry of consignments which it has determined as presenting a phytosanitary risk but it also has the obligation to demonstrate the risk using scientific data and to publish the restriction in a freely available form.

In determining the exact elements of the many interacting aspects of these agreements it is necessary to consider each agreement in the light of the individual parts of the import regulatory system. Section 3.1 stresses in particular the most important principles affecting the import regulatory system set out in ISPM No. 1 (1993, *Principles of plant quarantine as related to international trade*). ISPM No. 20 does not explain these principles because to do so may result in an unintentional interpretation as their impact cuts across all aspects of the import regulatory system. Thus it is essential for both regulators and operators of the system to consult and comply with the individual agreements.

The Appendix to this Explanatory Document [published separately as ISPM No. 20/Explanatory document 1-Appendix] provides a checklist of the main rights, obligations and responsibilities of the IPPC, ISPMs and WTO-SPS Agreement. Its main purpose is to help regulators identify the individual elements of these international agreements relevant to the import regulatory system.

Economic and operational feasibility

The final paragraph of Section 3.1 notes the importance of ensuring that measures are feasible both economically and operationally. If a measure is not practicable (for example a treatment that destroys the use of the product such as a cold treatment for a cold sensitive tropical fruit) or not economic (such as a process that exceeds the value of the product), it is in practice a technical prohibition that may not be justified and thus open to challenge.

Regulatory Framework (Section 4)

This section provides detailed guidance as to what should be included in or covered by the regulatory component of the import regulatory system. There is advantage in the details being specified in the regulations, particularly with regard to transparency. However transparency can be provided by other means. Improved administrative efficiency or difficulties in amending regulations can mean that other systems, such as published administrative procedures based on legal authority, may be more appropriate.

Issuing and developing regulations

The first paragraph to Section 4 states that the contracting party (i.e. the government) is responsible for issuing regulations. This responsibility arises from the IPPC. However NPPOs, to the maximum extent possible, should be involved with the development of regulations as they normally have the relevant technical expertise (though generally not the legal expertise). This introductory paragraph also indicates the main areas for which regulation is required.

Regulated articles (Section 4.1)

This section explains and gives examples of regulated articles. In the footnote in section 4.1, there is the comment that pests *per se* and biological control agents do not fall formally under the IPPC definition of regulated article. Perhaps this was not intended but to change the IPPC definition is too complicated a process to be considered at this stage. However, as in the standard, countries could extend the use of the phrase “regulated article” in their regulations. If this is done, the term and revised definition must be written into the regulation to clearly indicate that the term covers pests and biological control agents. The final paragraph states that lists of regulated articles should be made publicly available; guidance on how this may be done is provided in Section 5.1.9.2.

Measures for consignments to be imported (Section 4.2.1)

This section provides a check-list of the types of measure that may be applied to imported consignments separating the measures into whether they would be applied in the exporting country, in transit, at entry or after entry. The footnote in section 4.2.1 states that, from the phytosanitary perspective, consignments entering free trade zones and detained illegal consignments should be considered as imported. This allows the NPPO to carry out inspections and other procedures within restricted zones to ensure consignments do not present a risk either to the zone itself or to areas adjacent to the zone. The exclusion of ‘consignments in

transit' is not to be taken as suggesting such consignments fall outside the import regulatory system but rather to recognise their special status; consignments in transit are covered in Section 4.3.

Phytosanitary certificates

There is no reference in this section of the standard to requirements for phytosanitary certificates. Perhaps it could be considered that this is an export matter and thus already provided for in ISPM no. 12 (*Guidelines for phytosanitary certificates*) although no mention is made in the references section of the standard. This is an oversight as commodities and other regulated articles for which the importing country requires a phytosanitary certificate as a condition of entry must be specified in the import regulations of that country or in equivalent publicly available documents.

Section 1.1 of ISPM No. 12 provides the following guidance regarding phytosanitary certificates which is particularly pertinent to this standard:

> *Importing countries should only require phytosanitary certificates for regulated articles. These include commodities such as plants, bulbs and tubers, or seeds for propagation, fruits and vegetables, cut flowers and branches, grain, and growing medium. Phytosanitary certificates may also be used for certain plant products that have been processed where such products, by their nature or that of their processing, have a potential for introducing regulated pests (e.g. wood, cotton). A phytosanitary certificate may also be required for other regulated articles where phytosanitary measures are technically justified (e.g. empty containers, vehicles, and organisms).*
>
> *Importing countries should not require phytosanitary certificates for plant products that have been processed in such a way that they have no potential for introducing regulated pests, or for other articles that do not require phytosanitary measures.*

In addition, the introductory paragraph to section 4.1 of this standard (ISPM No. 20) states:

> *All commodities can be regulated for quarantine pests. Products for consumption or processing cannot be regulated for regulated non-quarantine pests. Regulated non-quarantine pests can only be regulated with respect to plants for planting.*

Thus phytosanitary certificates may only be required for commodities and other regulated articles for which phytosanitary measures have been technically justified.

Evaluation of alternative measures

The final paragraph of section 4.2.1 makes the reference that:

> *The import regulatory system should make provision for the evaluation and possible acceptance of alternative measures proposed by exporting contracting parties as being equivalent.*

This is an important aspect of international cooperation and an obligation (see Principle 7 of ISPM No. 1 (1993) and Article 4 of the WTO-SPS Agreement). It is not covered elsewhere in this standard (ISPM No. 20) but is clearly one of the aspects that could be relevant for Sections 5.1.2, 5.1.5.1, 5.1.6.4 and 5.1.9.1.

Specified points of entry

For commodities or other regulated articles for which a phytosanitary certificate, inspection or treatment is required, entry may be restricted to particular ports where appropriate facilities are available. The relevant obligations are specified in Article VII.2d of the IPPC (1997).

Pest free areas, pest free places of production, etc. (Section 4.2.1.2)

Although often designed primarily to protect areas within the country or to assist with exports, it is essential that where appropriate these designations are recognised in the import regulatory system for two particular reasons.

With respect to pest free areas, areas of low pest prevalence and official control programmes, unless there is protection at the border, the designation may be jeopardised because of pest incursion through uncontrolled imports. However, measures must be technically justified and if the pest is already present in the country then import requirements may not be more stringent than those applied domestically (i.e. the principles of non-discrimination and equivalence must be respected). In the case of pest free places of production and pest

free production sites, the pest is present, often widespread and generally not subject to control outside the designated places of production. Import regulation may not be justified in these cases and therefore pest free places of production and pest free production sites are not mentioned in the first paragraph of Section 4.2.1.2. Where pest free areas, etc. are specified as a requirement for imported consignments, then the importing country may need to recognise such a designation made by the exporting country in their regulations although this is generally done through administrative procedures. Again to protect the designation and to support its export programme, the exporting country will probably wish to recognise the designations in its own import regulations. This will also provide further confidence to the importing country.

Import authorisation (Section 4.2.2)

This is a sensitive and complex issue. The standard recognises two forms of import authorisation: general authorisation and specific authorisation.

Some countries require import permits (sometimes referred to as licences) for virtually all imported consignments. Often each individual consignment requires a specific permit with the import requirements set out on the permit. In the standard, if a permit of any type is required, such authorisations for import are termed "specific authorisation". For phytosanitary purposes the standard recommends that wherever possible importing countries should avoid requiring a permit as a routine or general prerequisite to import. The standard thus 'encourages' countries to establish general authorisations "wherever specific authorisations become routine".

General authorisation

General authorisation to import is considered to cover the vast majority of situations and falls into two subcategories.

Most commodities do not pose an inherent pest risk. Inert materials, such as machine parts, minerals, computers, etc., and indeed the vast majority of trade, do not harbour plant pests and thus do not require specific phytosanitary measures. Authority to import without requiring a phytosanitary certificate or other specific measure should be established, although the ability to check such consignments at import should be provided (see Section 4.6) with such checks generally being on a random and occasional basis. This will enable the NPPO or its authorised agents to check for possible unexpected pest contamination or undeclared commodities.

A general authorisation to import should also be established for commodities where a pest risk has been identified and specific requirements established. The requirements should be set out in the regulations and entry permitted for consignments that comply with the requirements. Normally a phytosanitary certificate will be required (see paragraphs on "phytosanitary certificates" under comments on section 4.2.1 above) and compliance certified by the exporting country with the issue of the phytosanitary certificate. Entry without a specific authorisation should be allowed but again the ability to check at import should be provided.

Specific authorisation

The standard does not oppose the use of import permits. Rather, it encourages their restriction to situations where the risk has not or cannot be readily assessed or where appropriate phytosanitary measures applicable prior to entry cannot be established. Examples are provided under the heading "Specific authorisation" of Section 4.2.2. Some of the commonest uses of permits are for consignments for research or to assist with the development of a new trade (for example a new commodity or a new origin) when either there is insufficient data for the risks to be fully assessed or confidence in agreed measures or systems is yet to be established. When risks have been assessed and/or confidence in measures established then the regulations should be amended and a general authorisation to import given.

Consignments in transit (Section 4.3)

According to the definition in ISPM No. 5 (2004, *Glossary of phytosanitary terms*), 'consignments in transit' are not imported. However this section states that the import regulatory system may be extended to cover transit arrangements. This is to be encouraged as the procedures required for the effective operation of the system are ideally suited to counter possible risks from consignments in transit. The section provides guidance on appropriate measures.

Measures concerning non-compliance and emergency action (Section 4.4)

Such measures are some of the most important components of the import regulatory system. However, they are also some of the most common initiators of disputes between trading partners and thus require a sound legal base which respects international agreements. The section provides important guidance.

Other regulatory elements (Section 4.5)

Because legal systems and relationships between the legislature and administration differ the standard cannot cover all situations. This section deals essentially with administrative matters and provides a check list of operations which may need a legal base but which most commonly are covered by administrative procedures.

Legal authority for the NPPO (Section 4.6)

Operationally, this section of the regulatory component is perhaps the most important of the whole standard. Legal authority (legal power) is required for virtually all aspects of the operational component of the import regulatory system. It must be sufficient to enable NPPO officers or other authorised personnel to function effectively and efficiently. Resources are always limited and it is essential that they are utilised to the maximum benefit of the system. However it is also important that there is due balance between the needs of the NPPO and the rights of others.

The required authority/powers are listed in the section. It will be noted that they are mostly open in nature (i.e. not restricted to particular situations). This is important as it is not possible to define in advance all of the circumstances that may be encountered. The NPPO should have the authority to inspect any imported consignment. This authority should not be limited to certain specified imported consignments. For example it should not be limited to inspecting just those consignments for which a risk has been identified and for which a phytosanitary certificate is required. The reason is that situations are regularly encountered where risks change (such as a new host for a recognised pest) or new risks develop (such as a new commodity trade or origin). The authority to take samples, treat, refuse entry, etc. are equally important. However, although such powers should be as wide as possible it is equally imperative that all action is technically justified and its application is consistent with national and international obligations.

Operation of an import regulatory system (Section 5)

The introductory paragraph to Section 5, together with Sections 5.1 and 5.1.1 provide guidance on the management and administration of the operational component of the import regulatory system. The standard makes clear that the NPPO is responsible for the operation and/or oversight of the system and that it is a government obligation to provide the necessary resources. Later in Section 5, the standard identifies and provides guidance on the tasks to be done and the types of resource required. As in the case of regulatory procedures, the standard recognises that the operational structure will differ from country to country, some countries adopting a centralised system with others being highly decentralised, possibly including the authorisation of other agencies for much of the detailed work. Whatever operational structure is adopted, the standard stresses that the administration of the system should be coordinated at the national level. This is particularly important to facilitate effective international cooperation (see Section 5.1.8 and Section 7).

Regulatory development and revision (Section 5.1.2)

Although not specified in the IPPC as an NPPO responsibility, because of the technical nature of the subject the standard recommends that the NPPO should be involved with regulatory development and revision. The standard also recommends wide consultation with other agencies and interested parties such as industry, trade and producer groups (sometimes referred to as ‘stakeholders’). This can have considerable advantages for the NPPO, for example in enabling early inclusion of new developments in the regulations as well as increasing the acceptance of the regulations by the affected parties. By encouraging a feeling of ‘ownership’, if a particular group or organisation has had its concern acknowledged in a new or revised regulation, it is more likely to support its effective adoption.

Surveillance (Section 5.1.3)

This section appears to refer particularly to general surveillance (see ISPM No. 6). However information from any source should be available to the NPPO including that of specific surveys and that gathered during inspection of imports.

Pest risk analysis (Section 5.1.4)

Pest risk analysis (PRA) is the scientific bedrock of the import regulatory system. Not only is it necessary for the formulation and justification of regulations concerning measures for import, it is also required to help identify appropriate import inspection regimes and action in the case of non-compliance or an emergency situation. However it is a complex science and resources in the form of trained risk analysts and available data are invariably limited. This can result in either delays in the process or PRAs taking longer to complete than some envisage as necessary. The process can be further exacerbated by the requirements in some countries for extensive consultation with stakeholders. It is because of these concerns, the perceived uncertainty of the process and the resultant effect on trade that the standard urges countries to develop documented (i.e. transparent) processes, time frames for completion and guidance on prioritisation. There is considerable interest in international cooperation on the conduct of PRA, not just with respect to the sharing of information (which is an international obligation) but also with respect to the analysis itself. However there will always be a need for a strong national input because it is a national responsibility that measures are technically justified with respect to conditions in the specific area to which the regulations apply.

Audit and compliance checking (Section 5.1.5)

International agreements make detailed provisions regarding inspection because of the potential for disruption to trade flows. Thus the standard stresses the more important aspects and provides some guidance on how these provisions may be met.

Audit and compliance checking should not be regarded as the main element of the import regulatory system. Rather it should be regarded primarily as the monitoring element to determining the effectiveness of the regulations designed to exclude or control the entry of pests. The philosophy of the IPPC is international cooperation aimed at preventing or controlling the spread of pests. Thus the main responsibilities fall to:

- establishment by the NPPO of the importing country of effective import requirements based on pest risk analysis, and
- where required, effective certification of consignments for export by the NPPO of the exporting country to ensure compliance with the requirements of the importing country.

Audit and compliance checking by the NPPO of the country of import should thus be considered a verification process, confirming that procedures are appropriate, effective, and being properly applied. This should not necessitate 100% inspection either of individual consignments or of all consignments in a particular trade but rather some form of sampling process. As confidence grows in the procedures related to, for example, a particular trade the intensity of inspection should be reduced. This has the benefit of releasing scant resources for other tasks and encouraging greater responsibility and commitment by those involved with the trade and the export process in the country of origin.

Audit in the exporting country (Section 5.1.5.1)

In this section of the standard, the term ‘audit’ is used where the NPPO of the country of import wishes to check procedures in the country of export. Audit procedures in another country must be in cooperation with the NPPO of that country and the cooperation should encompass a clearly defined plan including the scope of the audit, a report of its findings and, if required, an agreed follow-up process.

This cooperative process can be beneficial to all parties. The importing country should gain a greater understanding of conditions in the exporting country and increased confidence in the exporting country’s procedures. The exporting country should be able to ensure that it is able to meet the requirements of the importing country with the minimum necessary effort and also should be reassured that its exports will not be rejected due to unanticipated occurrences. Both parties may identify issues which had not formerly been considered. However, as stated in the standard, such audits should not be regarded as permanent and should cease as soon as confidence is established (systems validated).

Compliance checking at import (Section 5.1.5.2)

For checks at import (which includes pre- and post-entry inspection) the standard uses the term "compliance checking". With respect to the words "audit" and "checking", such differentiation should not be considered definitive because each involves elements of the other and neither implies any particular levels of intensity. The words should thus be regarded as interchangeable. However the term "compliance procedure (for a consignment)" is defined as an "Official procedure used to verify that a consignment complies with stated phytosanitary requirements" (see ISPM No. 5, 2004, *Glossary of phytosanitary terms*).

This Glossary definition is narrower than the use of the term "compliance checking" in this standard. This is an important distinction. In addition to "determining compliance with phytosanitary regulations" (as per the Glossary), a fundamental aspect of the import regulatory system, as specified in Section 5.1.5.2, is that compliance checking may also be required:

- to check that the phytosanitary measures are effective, and
- to detect potential quarantine pests or quarantine pests not predicted as being associated with that commodity (i.e. new pests or new pathways).

These elements are critical to the effective operation of the import regulatory system. Compliance checking is the front line measure to assess efficacy and counter the unexpected. Any action taken resulting from these aspects would most likely be regarded as emergency action rather than non-compliance action because in both cases the strict requirements of the regulations could have been met (see Section 5.1.6). Checking normally involves the inspection of a sample and a 100% inspection of the commodity is not normally necessary Where a regular trade is established the likelihood of an unexpected occurrence is much less than in the case of novel trades and this should be factored into the determination of an appropriate level of checking.

Compliance checks should be done promptly and with the minimum interference with the flow of trade. Phytosanitary inspections should be done by, or under the authority, of the NPPO. Other types of checking, such as documentary checks or checking that the consignment consists solely of the commodities declared may be delegated to others and may be satisfactorily incorporated into other import checking procedures (such as those carried out by the Customs service). Functions and responsibilities must be clearly defined with the right of access to required data by the NPPO and prompt reporting to the NPPO of the results of such delegated tasks.

Place of inspection

Although there can be advantages in carrying out phytosanitary inspections at points of entry (cooperation with other services and ease of taking some types of action in the case of non-compliance), in practice phytosanitary inspection may be done wherever imported consignments can be identified and satisfactory facilities are available (see Section 5.1.5.2.1). This can include transhipment points, major markets and places of destination. It is of course essential that the phytosanitary integrity of consignments is maintained and that facilities are available for effective inspection and any other necessary procedures. An administrative system may be required to facilitate such procedures (for example to allow a delay in the final entry clearance process if this is considered necessary). Advantages in inspecting away from entry points include consignments moving quickly through ports thus reducing congestion and possible deterioration of perishable products; decentralisation of staffing; better access to the consignment; and the facility to check over a longer period without the formality of a post entry quarantine system (particularly useful for detecting possible latent infections such as in planting material).

Inspection intensity

Although often specified as a condition of entry, as confidence in export processes increases especially with regard to established trades, phytosanitary inspection is increasingly done as part of the import regulatory system monitoring programme (see above). In Section 5.1.5.2.1, it is stated that the level of inspection may be "established on the basis of predicted risk". The predicted risk will concern two components: the magnitude of the damage that may result from an event and the probability that the event will occur. This is an inexact science. NPPOs tend to err on the side of caution given the uncertainties of import inspection as a phytosanitary measure. Thus precise guidance is difficult although PRA will provide basic guidance which NPPOs then tend to fine tune on the basis of experience. Generally countries that operate import inspection

as a monitoring process tend to increase levels of inspection for consignments which may act as pathways for pests that threaten major production systems within their country and for consignments associated with trades for which confidence is yet to be established (e.g. new trades or trades where non-compliance has been a problem). Conversely they reduce the level of inspection on consignments where the pathway threat is considered low and for consignments where experience has resulted in a considerable body of confidence that the phytosanitary procedures are effective. In some cases phytosanitary inspection at import may be reduced virtually to zero where experience shows that the export certification process is wholly satisfactory.

Non-compliance and emergency action (Section 5.1.6)

Although this subject is already covered in ISPM No. 13 (*Guidelines on the notification of non-compliance and emergency action*), this standard provides considerable extra guidance on practical or operational aspects. This is necessary for a number of reasons:

- it is essential that action taken on imported consignments is fully in accordance with international agreements (i.e. the IPPC, ISPMs and the WTO-SPS Agreement);
- with respect to non-compliance and emergency action, these agreements are particularly complex and frequently misunderstood or misinterpreted; and, as a result,
- actions based on non-compliance or on emergency situations are some of the most frequent initiators of disputes between trading partners.

Type of action - non-compliance or emergency

An essential first step in communicating with other parties (both within your country and with other countries) is to clearly describe whether an action is taken as a result of non-compliance with your import requirements or on the basis of emergency action. Sections 5.1.6.1 and 5.1.6.2 provide detailed guidance as to the two types of action. For example, even if a listed quarantine pest is detected in an imported consignment, if it is detected in circumstances not covered by the import regulation, the exporting country could still have correctly certified the export. Thus although “in compliance”, action is justified on an emergency basis as the pest perhaps was not predicted as likely to be associated with that pathway. The exporting country would need to be informed of the action to avoid further disruption to trade but more importantly, changes to the import regulations may need to be considered.

The final paragraph in Section 5.1.6.1 contains the apparently unusual guidance that even where a regulated pest is detected or some incident of non-compliance is encountered, action does not always have to be taken. This is an important issue as action may only be taken where it is technically justified. It could be argued that if action is not justified then neither is the regulation that triggered the potential action. This is not correct. Normally action would be justified. However, this paragraph concerns somewhat exceptional circumstances. For example, a regulated pest is detected in a consignment destined for processing. The process is such that it eliminates all risk. The consignment is packaged and is to be managed in such a way that there is little risk of escape. Thus in this incident there is no risk and no justification for action. If such a situation is commonly encountered then amendment of the regulations would probably be justified.

Identification difficulties

One area that regularly results in disagreement or confusion is that related to situations where a pest is detected but it is not possible to provide an adequate or precise identification (see the last two paragraphs of Section 5.1.6.2). The detection of unidentified larvae associated with consignments of fresh fruit frequently fall into this category because of widespread concerns over fruit flies. Here the standard indicates that in such cases every effort should be made to ensure that action is taken only where an actual risk is identified. This is particularly the case where repeated interceptions are made. The NPPO of the exporting country should be contacted. If there are no fruit flies of quarantine concern known to occur in the country of origin then even if substantial numbers of larvae are detected, action should not be taken unless a positive diagnosis of a quarantine pest is obtained (i.e. at least some larvae raised to adult). However, if quarantine fruit flies are present in the country of export then, even in the absence of a definitive diagnosis, action may be justified. The NPPO of the exporting country should be informed but again every effort should be made to raise at least some of the interceptions to a diagnosable form.

Reporting action (Section 5.1.6.3)

In reporting an action it is essential to describe whether the action is based on a non-compliance with the import regulations or as a result of an emergency.

Amendment to regulations (Section 5.1.6.4)

If there are repeated incidents of non-compliance or repeated emergency actions triggered by the same type of interception, consideration should be given to changing the import regulations. No guidance is provided on "repeated" as this must be based on risk analysis.

In the case of emergency action, even a single incident could indicate that a new, changed or unanticipated risk has arisen requiring a change to the regulations. However it is often the case that an incident (or even a series of incidents) is considered an exception, unlikely to be repeated or that circumstances have already changed so that no change to the regulations is required.

With respect to non-compliance, single incidents should not trigger a need to change the regulations. Even in the case of several instances, before changes to the regulations are considered, contact should be made with the NPPO of the exporting country to determine why the non-compliance has occurred and what steps are being taken to avoid further incidents. If an importing country determines that it is facing a particularly severe threat then of course immediate action will be justified (perhaps in the form of temporary measures) but normally the exporting country should be given time to explain and enact procedures to avoid future incidents. If these are considered insufficient then changes to regulations may be necessary. Different types of measure are mentioned in Section 5.1.6.4.

Technical justification

Action taken in non-compliance and emergency situations must be technically justified and respect the principles of necessity, minimum impact and non-discrimination. For all situations, there must be evidence of phytosanitary risk. However, in new situations it may not always be possible for the risk to be fully evaluated (lack of data or lack of time to assemble and evaluate the data) so any analysis must be considered preliminary. In these circumstances it is an obligation that steps are taken to ensure that gaps in knowledge are filled and a full PRA completed as soon as possible.

Emergency measures and provisional measures

Where new or modified regulations are proposed, international obligations (in particular SPS Articles 5 and 7 plus SPS Annex B, 1-4) require

- technical justification (PRA) of the regulations, and
- pre-notification of the new or changed regulations allowing:
  - a reasonable time between publication and entry into force , and
  - where the regulation is not based on an international standard, reasonable time for comment and discussion.

However, in an emergency situation (where the threat is immediate) and/or in circumstances where it has not been possible to complete a full PRA, these requirements do not have to be applied. Although defined in ISPM No. 5, there is often confusion surrounding emergency and provisional measures but they may be differentiated as follows:

	Emergency measure	Provisional measure
Full PRA completed	Maybe done or not done	Not done
Immediate threat	Yes	Maybe
Seek further information	Maybe required	Required
Completion of full PRA	Maybe required	Required, as soon as possible
Review and/or modify the regulation	Required and modify if necessary	Required as soon as further information is available

Authorisation of non-NPPO personnel (Section 5.1.7)

The standard envisages that in many situations where the NPPO is responsible, tasks may be delegated to other organisations and non-NPPO personnel. However the responsibility for ensuring that actions are done

in accordance with international agreements remains with the NPPO. This section provides guidance on the elements to be considered to ensure effective dispensation and accountability. Most important are the accurate defining of functions, the procedures to authorise organisations and/or personnel to carry out those functions, reporting to the NPPO of actions taken under the delegated authority, audit of delegated procedures by the NPPO, procedures to correct systems which are not functioning correctly, and to withdraw authority.

National & international liaison; dissemination of information and regulations (Sections 5.1.8 - 5.1.10)

These sections provide a checklist of obligations and recommendations, many stemming from the WTO-SPS Agreement. In particular, where new or revised regulations are being developed, these should be made available at an early stage to trading partners and other interested parties including national contacts. This is so that they are aware of, and if appropriate can comment on and influence, proposed regulations. This has potential benefits for all parties. Producers, traders, exporters and other NPPOs can often identify factors of which the regulator may not be aware thus enabling correction to proposed rules to be made before they are enacted in law. They may also suggest alternative ideas leading to more efficient or effective procedures. For the exporter, etc. there is the advantage of ensuring procedures are practicable and having the time to put them into place prior to enactment thus avoiding possible delays or rejection.

NPPO resources (Section 5.2)

Ensuring that sufficient resources are available for an effective and efficient operation of the import regulatory system can present major difficulties for all countries and particularly for developing countries. This section provides a useful check list that governments and others may use to ensure adequate provision. However it also makes recommendations to NPPO managers as to what should be provided for or available to NPPO personnel or those to whom activities have been delegated. For example, it recommends that all should have access to their import regulations, to information on their regulated pests and to adequate training, equipment and facilities for their designated tasks.

Documentation, communication and review (Sections 6-8)

These sections provide guidance common to most standards. However it is essential that the many points both of a general nature and specific to the import regulatory system are applied with specific reference to the import regulatory system. Perhaps of paramount importance is Section 8, system and incident review.

System and incident review (Section 8)

The effectiveness of both the regulatory and operational components of the system must be regularly reviewed, perhaps at set intervals. These reviews should be conducted largely by the NPPO as they will have the expertise necessary to understand the issues concerned. However, a review undertaken by a completely independent person or organisation can often highlight issues not formerly considered by the NPPO personnel. Such reviews should consider not just changes in biological risk (such as a change in virulence) but also changes in trading patterns and practices. New trades can develop which were not even envisaged a year or so earlier whilst production or trading techniques can also affect phytosanitary security, generally reducing pest risk but sometimes having a negative effect.

Any significant incident or series of incidents should trigger a review which must include consideration of the necessity to amend the import regulations as well as consideration to changes in operational practices.

MAJOR POINTS OF CONCERN

There are no major points of concern. It is noted that there is little guidance regarding phytosanitary certificates. This and other issues of interest are discussed in the paragraphs above.

REFERENCES TO ADDITIONAL MATERIAL

References to the most important international agreements and standards are set out in the reference section of the standard (page 4). However, omission of the following appears to be an oversight.

Guidelines for phytosanitary certificates, 2001. ISPM No. 12, FAO, Rome.

Useful background information on phytosanitary import regulatory systems can be found in the following recent publications.

Ebbels D L (2003). *Principles of Plant Health and Quarantine.* CAB International, Wallingford, UK; 302 pages.

Elder A S, Duringhof H A, Vereecke M & Wenguo Y (1999). "The future role and position of National Plant Protection Organisations: the USA model; the Dutch model." In *Plants and Politics,* Meester G, Woittiez R D & de Zeeuw A. Wageningen Press, Wageningen, Netherlands; pp. 177-206.

APPENDIX - The Rights, Obligations and Responsibilities of the IPPC, ISPMs and WTO-SPS Agreement with particular reference to the Import Regulatory System.

The Appendix to this explanatory document (published separately, as ISPM No. 20/Explanatory document 1-Appendix) is a check-list of the main rights, obligations and responsibilities of the IPPC, ISPMs and WTO-SPS Agreement. Its main purpose is to help regulators identify the individual elements of these international agreements relevant to the import regulatory system. It should be noted that this check list is indicative, contains interpretations and assumptions and is not totally comprehensive.

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