IMPLEMENTATION REVIEW AND SUPPORT SYSTEM (IRSS)

Food and Agriculture Organization of the United Nations

International Plant Protection Convention
Protecting the world's plant resources from pests

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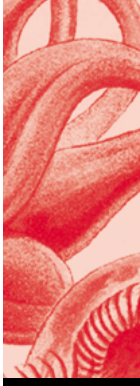
ENG

Equivalence

A Review of the Application of Equivalence Between Phytosanitary Measures Used to Manage Pest Risk in Trade



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This study was commissioned by the IPPC Secretariat under the work programme of the Implementation Review and Support System (IRSS). The document was drafted by Megan Quinlan in 2013 and reviewed by contracting parties, regional plant protection organizations and the IPPC Capacity Development Committee (including phytosanitary experts from seven FAO regions).

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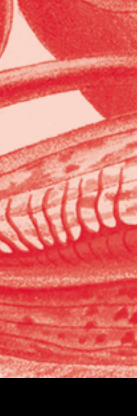


Abbreviations and acronyms

ALOP	appropriate level of protection
ANAO	Australian National Audit Office
APHIS	Animal and Plant Health Inspection Service (USDA)
APPPC	Asia and Pacific Plant Protection Commission
AusAID	Australian Agency for International Development
CAC	Codex Alimentarius Commission
CDC	Capacity Development Committee (of the IPPC)
CEPM	Committee of Experts on Phytosanitary Measures (predecessor of CPM)
COSAVE	Comité de Sanidad Vegetal del Cono Sur
CPM	Commission on Phytosanitary Measures
DG SANCO	Directorate-General for Health and Consumers (European Community)
DPIE	Department of Primary Industries and Energy (of Australia)
EC	European Commission
EDB	ethylene dibromide
EEC	European Economic Community
EFSA	European Food Safety Authority
EPPO	European and Mediterranean Plant Protection Organization
EU	European Union
EWG	expert working group
FAO	Food and Agriculture Organization of the United Nations
FCEC	Food Chain Evaluation Consortium
GATT	General Agreement on Tariffs and Trade
GISP	Global Invasive Species Programme
HACCP	Hazard Analysis and Critical Control Point
IAEA	International Atomic Energy Agency
ICPM	Interim Commission on Phytosanitary Measures (predecessor of CPM)
IDA	International Development Association
IICA	Inter-American Institute for Cooperation on Agriculture
IPPC	International Plant Protection Convention
IRSS	Implementation Review and Support System (of the IPPC)
ISPM	International Standard for Phytosanitary Measures

MB	methyl bromide
MERCOSUR	Mercado Común del Sur / Southern Common Market
MRA	mutual recognition agreement
NAPPO	North American Plant Protection Organization
NPPO	national plant protection organization
OIE	World Organisation for Animal Health
PFA	pest free area
PLH	Panel on Plant Health (EFSA)
PPPO	Pacific Plant Protection Organisation
PRA	pest risk analysis
PVS	Performance, Vision and Strategy (In this paper, refers to IICA's tool for evaluating national implementation of sanitary and phytosanitary norms. The OIE has produced a tool specific to animal health systems, using the same name.)
RPPO	regional plant protection organization
RSPM	regional standard for phytosanitary measures
SC	Standards Committee (of the IPPC)
SPC	Secretariat of the Pacific Community
SPS	sanitary and phytosanitary measures (as in the WTO Agreement on the application of ...)
STDF	Standards and Trade Development Facility (of the WTO)
TBT	Technical Barriers to Trade (as in the WTO Agreement on ...)
TPG	Technical Panel for the Glossary (of the IPPC)
TPPT	Technical Panel on Phytosanitary Treatments (of the IPPC)
UNEP	United Nations Environment Programme
USA	United States of America
USAID	United States Agency for International Development
USDA	United States Department of Agriculture
USEPA	United States Environmental Protection Agency
WTO	World Trade Organization

Glossary of terms[1]

efficacy (of a treatment): A defined, measurable and reproducible effect by a prescribed treatment (ISPM 18 – FAO, 2003)

entry (of a pest): Movement of a pest into an area where it is not yet present, or present but not widely distributed and being officially controlled (FAO, 1995a)

free from (of a consignment, field or place of production): Without pests (or a specific pest) in numbers or quantities that can be detected by the application of phytosanitary procedures [(AO, 1990; revised FAO, 1995a; CEPM, 1999)

interception (of a pest): The detection of a pest during inspection or testing of an imported consignment (FAO, 1990; revised CEPM, 1996)

pathwayAny means that allows the entry or spread of a pest (FAO, 1990; revised FAO, 1995a)

pest: Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products. Note: In the IPPC, plant pest is sometimes used for the term pest (FAO, 1990; revised FAO, 1995a; IPPC, 1997; revised CPM, 2012)

pest free area: An area in which a specific pest is absent as demonstrated by scientific evidence and in which, where appropriate, this condition is being officially maintained (FAO, 1995a; revised CPM, 2015)

pest free place of production: Place of production in which a specific pest is absent as demonstrated by scientific evidence and in which, where appropriate, this condition is being officially maintained for a defined period (ISPM 10 – FAO, 1999; revised CPM, 2015)

pest free production site: A production site in which a specific pest is absent, as demonstrated by scientific evidence, and in which, where appropriate, this condition is being officially maintained for a defined period (ISPM 10 – FAO, 1999; revised CPM, 2015)

pest risk (for **quarantine** pests): The probability of introduction and spread of a pest and the magnitude of the associated potential economic consequences (ISPM 2 – FAO, 2007a; revised CPM, 2013)

pest risk (for **regulated non-quarantine** pests): The probability that a pest in plants for planting affects the intended use of those plants with an economically unacceptable impact (ISPM 2 – FAO, 2007a)

pest risk analysis (**PRA**) (agreed interpretation): The process of evaluating biological or other scientific and economic evidence to determine whether an organism is a pest, whether it should be regulated, and the strength of any phytosanitary measures to be taken against it (FAO, 1995a; revised IPPC, 1997; ISPM 2 – FAO, 2007a)

1/ These terms are official definitions from the International Standard for Phytosanitary Measures (ISPM) 5 Glossary of phytosanitary terms (FAO, 2015). This list includes only the glossary terms that are used in this paper. The references cited within the definitions of terms, however, are annotated per those references in this paper, not always matching those in ISPM 5 (FAO, 2015), e.g. 2002a versus 2002b, because the order of appearance may vary in this paper. Therefore, if using these definitions, one should return to the original ISPM text for full citations. The IPPC Glossary is updated annually based on decisions taken by the Commission on Phytosanitary Measures. The complete and updated Glossary is maintained at: https://www.ippc.int/publications/glossary-phytosanitary-terms

pest risk assessment (for **quarantine** pests): Evaluation of the probability of the introduction and spread of a pest and the magnitude of the associated potential economic consequences (FAO, 1995a; revised ISPM 11 – FAO, 2001; ISPM 2 – FAO, 2007a; revised CPM, 2013)

pest risk assessment (for r**egulated non-quarantine** pests): Evaluation of the probability that a pest in plants for planting affects the intended use of those plants with an economically unacceptable impact (ICPM, 2005; revised CPM, 2013)

pest risk management (for **quarantine** pests): Evaluation and selection of options to reduce the risk of introduction and spread of a pest (FAO, 1995a; revised ISPM 11 – FAO, 2001)

pest risk management (for r**egulated non-quarantine** pests): Evaluation and selection of options to reduce the risk that a pest in plants for planting causes an economically unacceptable impact on the intended use of those plants (ICPM, 2005; revised CPM, 2013)

pest status (in an area): Presence or absence, at the present time, of a pest in an area, including where appropriate its distribution, as officially determined using expert judgement on the basis of current and historical pest records and other information (CEPM, 1997; revised ICPM, 1998)

place of production: Any premises or collection of fields operated as a single production or farming unit. (FAO, 1990; revised CEPM, 1999; revised CPM, 2015)

point of entry: Airport, seaport or land border point, or any other location officially designated for the importation of consignments, or entrance of persons (FAO, 1995a; revised CPM, 2015)

quarantine pest: A pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled (FAO, 1990; revised FAO, 1995a; IPPC, 1997)

required response: A specified level of effect for a treatment (ISPM 18 – FAO, 2003)

systems approach(es): A pest risk management option that integrates different measures, at least two of which act independently, with cumulative effect (ISPM 14 – FAO, 2002a; revised ICPM, 2005; revised CPM, 2015)

treatment: Official procedure for the killing, inactivation or removal of pests, or for rendering pests infertile or for devitalization (FAO, 1990, revised FAO, 1995a; ISPM 15 – FAO, 2002b; ISPM 18 – FAO, 2003; ICPM, 2005)

Executive summary

The possible introduction of new plant pests through agricultural trade and its associated pathways is a serious threat to crops, natural fauna and biodiversity in general. Yet, the demand for free trade, open travel and movement of goods increases. National and regional governments balance these competing objectives by regulating potential pathways for pest introductions, using a risk-based decision process.

An intergovernmental treaty, the International Plant Protection Convention (IPPC), was established over 60 years ago to coordinate such activities aimed at preventing the introduction and spread of economically significant plant pests. There are now over 180 countries that are contracting parties to this Convention. The IPPC rests on principles such as: national sovereignty for setting the level of protection of plant resources; non-discrimination in application of that level of protection; applying restrictions in trade only to the degree necessary to meet that level of protection, based on scientific evidence; and allowing alternative risk management measures when they can achieve the same level of protection (equivalence).

These same principles are central to the World Trade Organization's (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), which names the IPPC as the standard-setting body for plant health, thereby furthering the influence of the Convention. The principle of equivalence was included in the SPS Agreement to recognize that an acceptable level of risk from trade may be achieved using alternative risk management measures.

One impetus for negotiating equivalence of measures is when an existing pest risk management measure is no longer available, for example due to the loss of registration of a pesticide. Equivalence agreements can facilitate trade by allowing the use of a combination of pest risk management measures, referred to as systems approach (described in International Standard for Phytosanitary Measures[2] (ISPM) 14 *The use of integrated measures in a systems approach for pest risk management* (FAO, 2002a). This approach can be applied when the existing single measure is not appropriate, for example if it shortens the shelf life of the commodity. In other instances, there are new trade opportunities for an exporting contracting party that lacks the infrastructure or resource capacity to carry out the existing requirements for pest risk management, but which can apply alternative measures. The use of equivalence agreements can open new trade opportunities, maintain trade already underway and make trade arrangements more flexible and targeted.

Over the past decades, contracting parties to the IPPC have recognized equivalence of specific inspection regimes, commodity treatments and other risk management measures in order to facilitate trade while maintaining an *appropriate level of protection* (ALOP)[3]. This has been a common-sense approach, generally negotiated on an ad hoc, bilateral basis to accommodate existing capacity and conditions. The focus of development assistance in the 1980s and 1990s on trade as a source of economic development fuelled some of these negotiations. For the most part, this has been done with informal bilateral agreements, after gaining confidence in the exporting contracting party through extensive trade, and with strong collaboration between the national plant protection organizations (NPPOs) –

2/ Global Plant Protection Standards developed under the International Plant Protection Convention (IPPC) framework (www.ippc.int).
3/ This term is defined in the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization (WTO-SPS Agreement) as follows: Appropriate level of sanitary or phytosanitary protection – the level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory. Note: Many Members otherwise refer to this concept as the "acceptable level of risk". (Source: Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) – WTO, 1995).

the national authority designated by each contracting party of the exporting and importing countries.

When ISPMs were developed, these became de facto equivalence agreements in the cases in which risk management was described in sufficient detail, such as for pest free areas (PFAs) or places of production. The ISPM 15 *Regulation of wood packaging material in international trade* (FAO, 2002b), and ISPM 18 *Guidelines for the use of irradiation as a phytosanitary measure* (FAO, 2003), and its annexes, are prime examples of internationally recognized equivalent measures, which may be substituted for each other to achieve a recognized level of protection.

In 2005 the governance body of the IPPC, the Commission on Phytosanitary Measures (CPM), adopted ISPM 24 *Guidelines for the determination and recognition of equivalence of phytosanitary measures* (FAO, 2005a), which provides guidance for the process for determination and recognition of equivalence of phytosanitary measures. There is presently a growing trend to ask for its application, although, according to contracting party NPPOs surveyed, the standard itself may not be the primary reason. Many contracting party NPPOs remain challenged by the resources and time it takes to negotiate the case for alternative measures, the lack of transparency regarding what is required by the importing contracting party, and the lack of a common framework and difficulty in determining efficacy or defining what the ALOP should be. A clearer basis for determination of equivalence appears to be needed. There is also frustration when industry does not take advantage of the alternative measures after agreement is finally achieved.

The best approach for demonstrating equivalence will be experimentation with appropriate design and analysis. A statistical level of probit-9 efficacy is no longer considered the only valid pest risk management design objective. Other statistical approaches should be considered, according to the scenario. In point of fact, various initiatives are underway to introduce other approaches to a systematic, quantified analysis of the impact of measures, which will support the evaluation and determination of equivalency of alternative measures.

Some confusion may arise because of the difference between how equivalence is applied for plant health and other goals — particularly food safety and animal health, which are addressed by sister standard-setting bodies (Codex Alimentarius Commission (CAC) and the World Organisation for Animal Health (OIE)). In the area of food safety and animal health, equivalence will often be based on domestic risk management systems, which should produce the same level of safety in the exporting country as in the importing country; for example, the slaughterhouse system or a laboratory system for analysing pesticide residues. In plant health, the overwhelming majority of equivalence agreements have focused on the performance of individual measures, or combinations of measures, that are applied along the production chain and possibly all the way to the point of entry in the importing country. The emphasis then is on pest- or commodity-class-specific risk management measures rather than on overarching systems. This confusion could be compounded by the fact that virtually no contracting parties are reporting equivalence agreements as such, so that little documentation of the application is available.

Increased transparency through greater reporting on the application of equivalence for plant health agreements between contracting parties, or regions, would support opportunities for capacity enhancement. The Implementation Review and Support System (IRSS) of the IPPC may provide a mechanism for discussion of experiences and recommendations for improvements. Over the next few years, development and adoption of bespoke tools, models and frameworks may also support decision-making. Official guidance for estimating the efficacy of pest risk management measures and for the operational aspects of determination of equivalence appears to be a priority for follow-up. One could start with a harmonized set of information requirements for consideration of equivalence, drawing on the template for reviewing alternative phytosanitary treatments. A review of ISPM 24 (FAO, 2005a) could address some of these remaining issues. Also, consultation with regions, for example through the IRSS, may reveal experience in determining equivalence that are useful to share. Continuing efforts to enhance overall phytosanitary capacity also will address some of the challenges of implementing the ISPM with regard to equivalence.

1 Introduction

This study aims to provide some insight into the use of equivalence in plant health and to highlight where further clarity might enhance its application.

1.1 What is equivalence?

In plant health, when the estimated risk of introducing a new pest through particular trade is higher than the importing contracting party[4] finds acceptable, pest risk management measures may be applied to lower the risk to an appropriate level, thereby facilitating trade. The concept of equivalence of pest risk management measures has a long history as a common-sense approach to allow for alternative measures when the existing option is not ideal. This usually involves the national authority in plant health of the exporting contracting party proposing a different measure, or combination of measures, from that of the authority of the importing contracting party. If the measures are recognized by the importing contracting party in achieving or exceeding the same level of reduction in pest risk (or ALOP), the exporting contracting party may use the equivalent measures in place of what is already accepted for trade in the particular commodity or commodity class, either from that country or from other sources with the same pest status, when the principles of non-discrimination are practised (Box 1).

Most examples of the recognition of equivalence between pest risk management measures in plant health are bilateral and are negotiated at the operational rather than policy level. Therefore they are not documented in the public domain. The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement – WTO, 1995) has brought increased rigour to this concept and encourages greater transparency in its application.

Box 1

Equivalence of Phytosanitary Measures
The situation where, for a specified pest risk, different phytosanitary measures achieve a contracting party's appropriate level of protection (FAO, 1995a; revised CEPM, 1999; based on the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures; revised from ISPM 24 *Guidelines for the determination and recognition of equivalence of phytosanitary measures* – FAO, 2005a).

4/ The entity that has signed and ratified the convention, usually a national government, is the contracting party to the convention. For further discussion on this point, see https://www.ippc.int/about/convention-text. Most of the plant health activities are carried out by the national plant protection organization (NPPO) of the contracting party, which is the unit or division in the government given authority by the contracting party for this role. Most of the NPPOs are in the ministry of agriculture or equivalent. The authority often is stated in related plant-health legislation. However, in some government frameworks other entities are also involved in developing or approving international trade agreements. This may be the ministry of foreign affairs or simply a higher-level office in the same ministry of agriculture. While the NPPO carries out most activities in plant health, it is sometimes an external group that conducts a few of the activities, for example pest risk analysis or border control. To further complicate the terminology, generally it is the private sector doing the importing and exporting, although in this report importing country and exporting country are used to refer to the entire sector involved in the trade. For these reasons, various terms are used in this report, such as contracting party, market country, exporting or importing country, NPPO and national authority. This depends on the topic being addressed and favours the term relevant in the majority of situations, although exceptions may occur.

1.2 Plant health, standards and equivalence in world trade

Agricultural trade poses one of the greatest potential threats for moving plant pests[5] into new areas. History has shown that, despite the biological challenges, small populations of pests can establish in new locations. Pests can have a profound impact on crop production, conservation of native flora, biodiversity and people economically dependent on plants. This is why most countries of the world have agreed to collaborate in preventing the spread of such pests, especially across national borders. This agreement is in the form of an international treaty that came into force in 1952, with subsequent revisions, called the International Plant Protection Convention (IPPC, 1997).

Plant pests may be introduced not only through agricultural trade, but also through trade of non-agricultural products if the materials are susceptible to pest infestations (e.g. *dunnage*[6] such as pallets, handicrafts, household effects, etc.) or simply contain hitch-hiking or *contaminating pests*[7] (e.g. on military equipment, used cars and other goods, etc.). This transport of goods can take place through postal deliveries or the travelling public, or by natural means (e.g. wind and weather events, the pest's own mobility, etc.). Illegal or undocumented trade and smuggling are other pathways, and these can be significant in some cases. Globally, one of the primary pathways for the entry of a pest and its establishment in an area where it is not yet present (or present but not widely distributed), while being officially controlled, is believed to be agricultural trade, including planting material and the dunnage and freight containers related to trade (Hedley, 1990; *Nugent et al.*, 2001; Baskin, 2002; IPPC, 2010). Therefore, the regulation of trade has a significant impact on the risk from the spread of new pests[8].

Under the principles of the IPPC, contracting parties retain the sovereign right to protect domestic plant resources. The right to propose alternative pest risk management measures – when these achieve equivalence to what the importing contracting party already officially accepts in terms of risk – it is also one of the basic principles for cooperation among governments for protecting plant health (ISPM 1 *Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade* – FAO, 2006). The principle of equivalence simply acknowledges that there may be alternative options for reducing the phytosanitary or pest risk posed by trade.

Another global objective competing with preventing the spread of pests, is the demand for goods to flow among countries without unnecessary restrictions. This demand has been demonstrated through decades of negotiation under the process of the General Agreement on Tariffs and Trade (GATT)[9] (WTO, 1994) and the current high level of membership to the World Trade Organization (WTO). From the beginning, GATT noted the legitimacy of trade restrictions or regulations aimed at protecting human, animal and plant health. The tension is that non-tariff restrictions might be used to replace the tariff barriers of the past with the intention of trade protectionism rather than to make trade safe.

To ensure that plant health restrictions are not unwarranted trade barriers, therefore, they should be scientifically justified. This may be either by reference to standards developed through the IPPC pro-

5/ The term *pest* includes "any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products". Note that in the IPPC, *plant pest* is sometimes used for the term *pest* (FAO, 1990; revised FAO, 1995a; IPPC, 1997; revised CPM, 2012). If the pest would have potential economic importance in this new area, it is a *quarantine pest*. If it is in the area and not officially controlled, but would affect the intended use of plants (for example, when infesting planting material), it may be a *regulated non-quarantine pest*. Together these categories make up *regulated pests* (IPPC, 1997).

6/ *Dunnage* is defined as "wood packaging material used to secure or support a commodity but which does not remain associated with the commodity" (FAO, 1990; revised ISPM 15 *Regulation of wood packaging material in international trade* – FAO, 2002b). This includes pallets, for example.

7/ The term *hitch-hiker pest* was revised to be *contaminating pest*, and means "a pest that is carried by a commodity and, in the case of plants and plant products, does not infest those plants or plant products" (CEPM, 1996; revised CEPM, 1999).

8/ The threat of pest introductions through the travelling public is high, but cannot be managed in the same manner as trade. Risk management measures are applied by the importing country's NPPO for this pathway.

9/ The commitment to the GATT was also based on the belief that raising living standards through economic growth will contribute to peace (Devorshak, 2012).

cess (ISPMs), or on the basis of a pest risk analysis (PRA) conducted by the contracting party imposing the restrictions. All measures are based on the assessment of pest risk associated with trade in a specific commodity or commodity class. The pest risk management measures are selected commensurate to pest risk, meaning that the strength of the measures imposed is consistent with the level of risk.

Once an organism has been categorized as a pest for a particular *endangered area*[10], the pest risk assessment estimates risk based on the probability of entry, establishment and spread – and the projected impact or consequences of this introduction – to the endangered area. The process leads to a determination of whether the pest should be regulated, whether the risk requires some management measures or interventions, and the strength of any measures required for pest risk management. All together this is the PRA process conducted by the importing contracting party (see Figure 1, section III A). This is followed by the regulatory decision regarding which risk management options to employ. The choice of pest risk management measures is then communicated as new regulations, policy decisions, etc.

While there is no specific requirement for involving the exporting contracting party's national plant protection organization (NPPO) in the PRA process beyond provision of pest status and related information, it may be beneficial to engage the organization beyond these requirements for information (IPPC, 2013). The exporting contracting party NPPO can then share concerns about feasibility, for example, or any issues regarding the PRA early in the process to avoid wasting resources with risk-management plans that cannot be implemented (IPPC, 2013).

Another of the SPS Agreement principles upheld by the IPPC is that phytosanitary measures imposed by a contracting party should be limited to what is necessary, so that the restrictions are proportional to the estimated risk (ISPM 1 – FAO, 1993; revised FAO, 2006). If risk can be managed, then the objective of protection of plant resources can be met, while at the same time trade is facilitated. The managed risk (remaining risk after implementing management measures) must achieve a level accepted by the importing contracting party (WTO, 1995).

In the international movement of plants and plant products, there are alternative ways to manage pest risk. Equivalence is an important principle underlying both free trade and national sovereignty in protection of domestic plant resources. In general terms, equivalence (further defined below) means that exporting contracting parties may employ pest risk management measures that are alternative to those initially required by importing contracting parties, as long as equivalency in the outcome can be demonstrated.

The concept of equivalence will be increasingly important for opening and maintaining future trade based on the reasons for seeking equivalence, discussed below.

1.3 The reasons for seeking equivalence

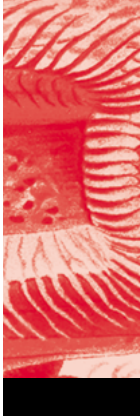
Triggers for seeking equivalence have been identified in various sources, including survey results (Dudley, 2012; personal communications with M. Quinlan, 2011-2012)[11] and interviews. Similar drivers were identified in a study on the application of the systems approach[12] (Quinlan and Ikin, 2009). Systems approach plans have frequently been used to achieve equivalence with existing phytosanitary measures.

The most commonly cited reason for seeking alternative, equivalent measures for pest risk management has been the loss of a chemical treatment such as a pesticide or post-harvest fumigant, meth-

10/ *Endangered area means* "an area where ecological factors favour the establishment of a pest whose presence in the area will result in economically important loss" (ISPM 5 Glossary of phytosanitary terms – FAO, 2015).

11/ A survey of NPPOs of contracting parties in 2011 and 2012 provided limited documentation of common practice. Although only 15 NPPOs responded, each of the FAO Regions (Africa, Near East, Europe, Asia, Pacific, Latin America and Caribbean, and North America) was represented by this response. The survey may not be representational in other ways (e.g. of the greatest volume of trade or of the range of experiences). Finally, individual interviews of government officials were conducted and are cited, where permitted.

12/ The systems approach(es) are discussed further in this report and were defined under the IPPC as "The integration of different risk management measures, at least two of which act independently, and which cumulatively achieve the appropriate level of protection against regulated pests [ISPM 14 The use of integrated measures in a systems approach for pest risk management – FAO, 2002a; revised ICPM, 2005]."



yl bromide (MB) being an obvious example (ICPM, 2003; IPPC, 2006a; CPM, 2008). The environmental impact of an existing option is also cited, even when the measure is still available. Environmental impact has become increasingly important on the global agenda, as well as in national priorities, at the same time that preventing the spread of pests across national borders also has become a more serious international consideration (Quinlan, 2004). A correlating reason for seeking equivalence is the issue of pesticide residues. Not surprisingly, if the number of detections of a pest in shipments rises, a common response is to apply more pesticides, sometimes beyond the recommended dosage. Detentions due to pesticide residues are not directly related to the IPPC, but may cause exporting private-sector entities to ask their NPPO to explore alternatives with an importing contracting party, in order to address pest risk management.

At times, constraints in financial, logistical or capacity resources are the motivation for requesting recognition of equivalence. This may be due to a heavy workload on a contracting party's NPPO employees; limited volume of a particular kind of trade, which cannot justify the existing measure; or lack of infrastructure, or availability of alternative infrastructure. Even highly developed contracting parties may not have the infrastructure in place for managing a new pest situation, so that treatment in transit or upon arrival is a useful emergency measure, to be replaced over time with equivalent measures to be carried out in the country of the export contracting party. If the existing measure requires financing of the inspection on site (or *preclearance*[13]) by the NPPO of the importing contracting party, for example, this may lead to petition for alternatives on site, or measures that may be carried out in transit or upon arrival at the port of entry, so as to avoid the associated cost.

Sometimes the existing pest risk management measure has negative impacts on quality of the commodity (e.g. as discussed in a review article, Pryke and Pringle, 2008). This has been noted with treatments that use extreme temperatures or high doses of radiation, which may shorten the shelf life of the commodity. In this case, an equivalent measure, often a systems approach that may include the treatment at a lower dosage, is sought for greater market acceptability. Another example of seeking equivalence for market quality concerns is the shipment of citrus from Uruguay to China, for which cold treatment was replaced with a combination of measures including registration of growers, fruit fly monitoring, inspection and suspension of trade with a single interception in order to avoid loss of quality (COSAVE, no date).

In general, the causes for seeking equivalence are on an upward trend. Most respondents to a survey expect more equivalence requests and negotiations in the future. The contracting party NPPOs that responded indicated the importance of equivalence agreements by noting these key benefits (Dudley, 2012; and personal communications with M. Quinlan, 2011-2012):

- opening trade that would otherwise be prohibited
- continuing trade when the existing measure is no longer available or is considered objectionable for other reasons (impact on the environment, quality impact on products, etc.)
- introducing a systems approach that allows flexibility (adjusting effectiveness by adding or removing measures, targeting noncompliance without stopping all trade, etc.)
- opening discussions on technical justification of an existing measure (without going to a formal dispute).

In conclusion, an important option for facilitating horticultural or other regulated agricultural trade is to use pest risk management measures that are equivalent to the initial measures. Although the volume or value of this trade is not known, this paper gives a sense of the widespread application of the general concept, even prior to the development of ISPM 24 *Guidelines for the determination and recognition of equivalence of phytosanitary measures (FAO, 2005a).*

13/ Pre-clearance, phytosanitary certification and/or clearance in the country of origin, performed by or under the regular supervision of the NPPO of the country of destination (ISPM 5 – FAO, 2012).

2 Conceptual context for equivalence

2.1 The advent of the SPS Agreement and relevant principles

The advent of the SPS Agreement had significant influence on the evolution of the IPPC and the concept of equivalence. The 1951 version of the convention (IPPC) text has an objective to "secure common and effective action to prevent the spread and introduction of pests of plants and plant products, and to promote measures for their control." The original convention language did not cover harmonization and equivalence (Van der Graaff, 1999).

Before the formation of a Secretariat for the IPPC (established in 1992 and operational in 1993), the Plant Production and Protection Division of the Food and Agriculture Organization of the United Nations (FAO) coordinated activities of the convention. Van der Graaff and Ikin (1993) describe how the parties in the GATT approached the FAO to seek stronger coordination of the objectives of the IPPC and to add specific trade-related objectives that emerged from the GATT negotiations. The need for a stronger unified voice on plant health necessitated a stronger IPPC, rather than a fragmented response from the regional plant protection organizations (RPPOs), which were the stronger of that period (Stanton, 1993).

The demand for safe free trade culminated in the SPS Agreement. However, the thrust of the agreement is to prevent the misuse of rights. It states that "Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary" (Article 2, paragraph 2). From this period, prohibition of trade was employed, and indeed tolerated, much less than previously, because of international commitment to free trade (for further history, see Mulders, 1977; MacLeod *et al.*, 2010; and Devorshak, 2012).

The concept of equivalence was made explicit in Article 4 of the SPS Agreement (Box 2). This reference emphasized that the fundamental objective of equivalence was to open and maintain trade that otherwise might be restricted by prohibition or lack of alternatives for pest risk management. The right of Members to protect their own plant resources was acknowledged, but this was not the primary objective under the trade-oriented framework of this reference.

At the time, equivalence also was presented as an added support to developing contracting parties that might not have the same technologies and infrastructure available for treating commodities (Thiermann, 1999). The ability to negotiate equivalence was not taken up as a capacity development objective for some years, during which the focus on capacity was first infrastructure and equipping contracting party NPPOs, and then became more procedural and legislative (Canale, 2005). It did not appear explicitly, for example, in the early versions of the Inter-American Institute for Cooperation on Agriculture (IICA)

Box 2

Article 4 of the SPS Agreement: Equivalence

1. Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.

2. Members shall, upon request, enter into consultations with the aim of achieving bilateral and multilateral agreements on recognition of the equivalence of specified sanitary or phytosanitary measures.

Performance, Vision and Strategy (PVS) capacity assessment tool (Bolaños Ledezna and Cordero Peña, 2008), although now it is specifically noted.

Other principles underlying plant health were added or clarified by the IPPC, with influence from the new environment of trade facilitation. The use of PRA was promulgated as a way to enhance transparency of national regulatory decisions, use of proportionality (necessity) in imposing measures and the scientific justification of any measures that would deviate from the existing and future ISPMs (NAPPO, 1993). Principles of non-discrimination and the formalized use of the term *equivalence* appear to arise during this period of transition to the 1997 version of the IPPC text. The contemporaneous version of the ISPM 1 includes equivalence as a general principle (Box 3).

Box 3

Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade

(ISPM 1 *Reference standard. Principles of plant quarantine as related to international trade* – FAO, 1993)

1.10 Equivalence of phytosanitary measures

Importing contracting parties should recognize alternative phytosanitary measures proposed by exporting contracting parties as equivalent when those measures are demonstrated to achieve the appropriate level of protection determined by the importing contracting party.

A revision of the IPPC text, to align it with SPS Agreement, also included equivalence as a general principle of the Convention (IPPC, 1997). The governance body of the IPPC, the CPM, later endorsed an ISPM providing guidelines for the determination and recognition of equivalence of phytosanitary measures (ISPM 24 – FAO, 2005a) in 2005, as reviewed below. While the IPPC and its international framework of contracting parties long preceded the SPS Agreement, the huge political influence of the WTO affected the implementation of the IPPC in various ways.

2.2 IPPC definitions and concepts related to equivalence

An early definition of equivalence was of measures that are "not identical but have the same effect" (FAO, 1995a), indicating that the outcome or impact of the measures in terms of the pest risk would need to be the same, while the measures themselves differed. The use of the word *effect* was more appropriate for a commodity treatment than for other forms of phytosanitary measures[14] (e.g. surveillance, pest free areas (PFAs), certification, inspection, etc.). Indeed many early cases of equivalence were for commodity treatments.

To address ambiguities and cover the range of situations, the definition of *equivalence (of phytosanitary measures*) evolved to be "the situation where, for a specified pest risk, different phytosanitary measures achieve a contracting party's appropriate level of protection (FAO, 1995a; revised CEPM, 1999; based on the SPS Agreement [WTO, 1995]; revised ISPM 24 – FAO, 2005a)". Therefore, a specified pest risk was indicating a particular pest species, area, and possibly period of time, and the ALOP ties in more closely to the WTO SPS concept of a defined tolerance of risk.

The current definition (see Box 1) captures much of the history of development of the concept, as laid out in this report.

The definition of equivalence immediately highlights the concept of ALOP. The ALOP is a key component of the IPPC definition of equivalence, as noted in both ISPM 1 (FAO, 1993, 2006) and ISPM 24 (FAO, 2005a), but has not been well defined. Each contracting party has the right to set the level of protection that reflects national tolerance of pest risk. This level may be achieved either (a) because the inherent risk of proposed trade is low or (b) because pest risk management measures reduce the risk to the required level. If this ALOP cannot be reached through the addition of pest risk management measures, then the importing contracting party may prohibit the trade.

14/ Although the term phytosanitary measures appears in the definition of equivalence, in general, in the context of equivalence agreements, it is phytosanitary procedures that are used. These are defined as: "any official method for implementing phytosanitary measures including the performance of inspections, tests, surveillance or treatments in connection with regulated pests [FAO, 1990; revised FAO, 1995a); CEPM, 1999; ICPM, 2001, 2005]". See Glossary of terms (ISPM 5) for this and pest risk management (for quarantine pests).

The ways to establish the ALOP vary from a defined economic threshold of potential impact to a more nebulous sense of matching the post-management measures risk level that has been accepted historically over years of trade. Anderson *et al.* (2001) provide one of several conceptual discussions on setting ALOP. At this stage, there is little documentation from governments of contracting parties on how the NPPO decides that measures are sufficient to meet this ALOP.

Griffin (2012a) describes practical approaches to considering ALOP, focusing on consistency and transparency. He considers ALOP not to be static, but advises that if the criteria for selecting a level of acceptable risk changes they should be consistent. One of the SPS Committee sessions (reported in WTO, 2000) focused heavily on interpretation and practical implementation of ALOP, although many of the recommended actions will not be achieved by NPPOs of contracting parties. It is not realistic for all NPPOs of contracting parties to clearly define ALOP in a quantitative manner in the immediate future, but the spirit of the IPPC would require more transparency than is currently the case.

In 2005, at the Interim Commission on Phytosanitary Measures (ICPM, 2005), the decision was taken to produce an ISPM or supplement to describe the concept of ALOP (IPPC, 2005, 2006b). A draft ISPM on ALOP was prepared by the related Expert Working Group (EWG) and discussed by the Standards Committee (SC)[15]. A definition was proposed for the Glossary (ISPM 5), as a supplement to ISPM 11 *Pest risk analysis for quarantine pests* (FAO, 2001) and in the revision of ISPM 1. Later, in the November 2008 meeting of the SC (IPPC, 2008), the decision was taken to remove the topic from the work programme. The topic proved to be challenging and "it remained the remit of the SPS Committee to define ALOP", as it arose as terminology from the SPS Agreement rather than the IPPC (IPPC, 2008). A discussion paper from the SPS Secretariat at that EWG discouraged pursuing the matter, most likely due to the politically charged disputes taking place over this concept at the time. Despite this, the term appears in ISPMs and remains central to the concept of equivalence.

Another important concept to support equivalence is efficacy. Pest risk management[16] reduces the risk from a pest by reducing the probability of entry, establishment or spread of the pest. Therefore, the impact of management measures on the pest risk relates to the level of threat (e.g. pest population or infestation) and the efficacy of the measures – both as designed (i.e. as they perform under laboratory conditions and in operational studies) and as implemented or applied. The need for further development of definitions was noted at the time (IPPC, 2002). But the difficulty in distinguishing efficacy, effectiveness and other related terms, particularly in translation to various languages, was a challenge left for the EWG convened on efficacy to address using description rather than through standalone definitions (IPPC, 2003a).

Thus even before the ISPM on equivalence was drafted, an EWG was convened by the IPPC Secretariat (in a unique collaboration with the Global Invasive Species Programme [GISP], which hosted this session) for the development of an ISPM on efficacy. The first gathering took place in November 2002, under a specification that was later revised. The revised specification noted that guidance on equivalence would be developed separately (IPPC, 2003a). The plan to develop two separate standards (equivalence and efficacy) was reported to the SPS Committee as well (WTO, 2004). After reviewing the initial draft, the SC working group (SC-7) recognized that several ISPMs could be developed on this topic. It was recommended that equivalence, the methodology for evaluating efficacy of treatments and the relationship of efficacy to PRAs be removed from the draft regarding efficacy. The purpose of this was

15/ For explanation of the standard-setting process and the role of the SC, EWG, Technical Panels, the CPM at large, etc., see IPPC, 2011.
16/ By definition, pest risk also could be reduced by limiting the potential consequences, for example by reducing the impact from pesticide use needed to control or eradicate a pest after introduction, or by using resistant varieties. In practice, however, the convention focuses on "Evaluation and selection of options to reduce the risk of introduction and spread of a pest [FAO, 1995a; revised ISPM 11 – FAO, 2001]", rather than interfering with the domestic policy regarding managing consequences. See section on issues for discussion of the difference between this and *pest risk management (regulated non-quarantine pests)*.

to simplify the document for the initial conceptual ISPM, with the understanding that these other topics would be taken up later (IPPC, 2003b).

A smaller group from the EWG on efficacy was selected to carry on under these revised instructions, and refined a definition that would refer to a *specified phytosanitary effect* as the indicated outcome that a phytosanitary measure or measures were designed to have, with the degree to which this effect was met being the efficacy of the measure (IPPC, 2004). Others in the first EWG meeting had argued that *efficacy* might be the outcome as designed, whereas *performance* would be the term for what effect actually occurs (personal communication with M. Quinlan). The distinction between concepts of the outcome as designed and what actually happens in each case of application is fundamental to understanding equivalence.

Parallel to that EWG, the group that developed the ISPM 18 *Guidelines for the use of irradiation as a phytosanitary measure* (FAO, 2003) proposed the term *efficacy (treatment)*, to be "a defined, measureable and reproducible effect by a prescribed treatment" (from ISPM 18 – FAO, 2003). The concept is used extensively in ISPM 28 *Phytosanitary treatments for regulated pests*, (FAO, 2007b) and by the Technical Panel for Phytosanitary Treatments (TPPT), which reviews treatments to be registered under the ISPM. Other than for treatments, the term *efficacy* is not defined in the IPPC Glossary (FAO, 2012) at this time, however, having been removed by the Technical Panel for the Glossary (TPG) in 2010 (TPG, 2010).

The TPG later stated that the term efficacy should be used only for situations in which the impact can be quantified, whereas for general performance of a measure under natural conditions the term *effectiveness* is more appropriate (TPG, 2009a). The challenge of distinguishing terms in translation was also noted by the TPG (2009a, b), which requested through the SC that the TPPT review use of these terms to ensure standardized meaning.

Amid all of these discussions, the drafting process for an ISPM on efficacy stalled, although the specification and mandate are still in place. The reports reveal the complexity of the issues. For example, there is still no harmonized method to quantify efficacy of systems approach (FAO and IAEA, 2011). NPPOs of contracting parties approach this either by estimating the risk reduction of the entire system or by calculating efficacy for the major components of the system and integrating these. Although the TPG determined that additional definitions were not required (TPG, 2007 in Appendix), the concept of equivalence may be more easily implemented with further clarifications.

2.3 What equivalence does not mean

When existing measures are not performing to the expected level, which might be discovered by increased interceptions, additional or alternative measures may be needed to achieve ALOP. In the discussions at the SPS Committee in 2002, Australia observed that the term *equivalence* had been used mistakenly for this situation, which they described as a *conformity determination*[17], or consideration of causes for non-compliance. The same text notes that additional measures may be imposed or trade may be suspended if existing measures are failing to meet the ALOP, even while equivalence negotiations are underway, but that this is not linked and cannot be interpreted as a reaction to those negotiations (WTO, 2002a).

When equivalent measures are sought in a situation of non-compliance, obviously it is the original intended level of protection with which the alternative proposal would need to be equivalent, not the system of measures that are in fact not delivering as designed. Frequently, non-compliance after applying one measure has led to the development of a combination of integrated measures, or systems approach, in order to address the failure of an individual pest risk management measure and to maintain trade (Quinlan and Ikin, 2009).

17/ This concept is described more fully under the WTO Technical Barriers to Trade (TBT) Agreement. See Annex A.

Equivalence also does not mean that all exporting contracting parties that are shipping consignments with the same estimated pest risk to the same importing contracting party may necessarily be allowed to use the same alternative measures. The ISPM 24 (FAO, 2005a) clearly states that the capacity of the exporting country's NPPO to apply the measure or measures may also be evaluated as an important component of the likelihood of achieving the ALOP of the importing contracting party. Implementation of measures forms part of the overall system, which must deliver an equivalent, intended outcome.

Equivalence is not the same as meeting the existing level of protection, if that level is higher than the ALOP set by (or implied by) the importing contracting party. This is a key reason for considering the ALOP of an importing contracting party rather than a set effect, as was suggested in the original definition. The requirement for similar end-point pest mortality levels from commodity treatments led to wide use of probit-9 statistics as the basis for acceptance of new treatments (as discussed below). There are many statistical approaches other than probit-9 that are equally valid and more appropriate for objectives other than pest mortality levels (e.g. Sgrillo, 2002; EFSA, 2012; Griffin, 2012b). It is possible for measures to achieve the ALOP of the importing contracting party without reaching an effect demonstrated to the level of probit-9.

Similarly, there are cases in which a combination of measures or a new measure or technology has allowed movement of plant products when previously there was a prohibition of trade. Clearly, the alternative pest risk management measures cannot meet the same effect as prohibition, which would essentially be zero risk. Because of this, in general, negotiations to gain market access previously prohibited would not be described as a request for equivalence.

Other examples exist in which trade was, and still is, initiated using a combination of measures that are duplicative or redundant in terms of pest risk reduction. Some redundancy may be used to compensate for uncertainty, be it from natural variability, lack of experience or for other purposes. Redundancy of measures is not in the spirit of the IPPC nor of the SPS Agreement when it does not reduce pest risk, is not necessary to achieve the ALOP or is introduced with more of a *just in case* attitude than scientific justification. Redundancy has occurred, however, if all parties agree (i.e. when the opportunity for trade still seems worthwhile to the exporters). When unjustified measures are imposed, this may allow exporters to proceed with trade, but it is not complying with the principle of necessity. Trying to match this level of protection with alternative measures is not a case of equivalence because it is not a legitimate ALOP.

2.4 The ISPM on equivalence

The ISPM 24 (FAO, 2005a) was adopted by the ICPM in 2005. Its development was fairly rapid, beginning with the drafting by an EWG in 2003 and contracting party consultation in 2004. Around 35 sets of comments were received during the consultation process (from contracting parties and RPPOs). Comments on the draft of ISPM 24 (FAO, 2005a), available on the IPPC website (http://www.ippc.int) provide a useful view of concerns and understanding, though many were not incorporated into the subsequent version of the draft.

The standard sets the context by explaining that,

- The process of recognizing equivalence is the objective examination of alternative phytosanitary measures proposed to determine if they achieve the appropriate level of protection of an importing country as indicated by existing measures of that country.

This allows for an ALOP to be implied by historical practice, rather than defined quantitatively, for instance. Section 1 of the ISPM on *General Considerations* also indicates that the focus of the standard is on bilateral negotiations, while recognizing that some contracting parties list alternative measures in regulations that are acceptable for entry, although not necessarily equivalent. Later, in section 3.1, the determination is limited to a specified export commodity and specified regulated pests as the most likely scenario, which suggests that the basis of decision-making is generally commodity or pathway PRAs.

The second section of the standard, *General Principles and Requirements*, changed considerably in text from the draft through to the final version, although only by shifting emphasis on particular principles. All of the principles are those already established under the Convention text and in ISPM 1 (FAO, 1993, 2006). Although section 3.6 introduces a term not previously used in the IPPC, that of *non-disruption of trade*, which reflects the language in the SPS Agreement (Zúñiga Schroder, 2011) but remains undefined by the IPPC. The instruction is that trade should not be disrupted only because a request for recognition of equivalence is made, as long as the current trade is meeting the importing contracting party's requirements.

The section on *Specific Requirements for the Application of Equivalence* acknowledges that the importing contracting party NPPO may participate in the development of proposals for alternative measures to replace their own existing measures, in a process of technical assistance. The need for technical assistance is echoed in section 2.6.

Although a PRA is not required, the importing contracting party is instructed to provide information, upon request, that describes "how its existing measures reduce the risk of the specified pest and how they achieve its appropriate level of protection". The same section also states that information may be quantitative or qualitative. Equivalence negotiations require agreement on the initial assessment of risk and conclusions regarding the need for pest risk management measures. The threshold level of accepted or tolerated risk must also be articulated sufficiently to allow consideration of pest risk management measures. This remains a difficult point, but allows for the comparison of the outcome rather than the effect of a measure (as discussed in sections IA and IIB).

In the longest section, 3.5 *Factors considered in determining equivalence*, the types of factors are listed as:

- the effect of the measure as demonstrated in laboratory or field conditions
- the examination of relevant literature on the effect of the measure
- the results of experience in the practical application of the measure
- the factors affecting the implementation of the measure (e.g. the policies and procedures of the contracting party).
- Various sections from the text of the draft standard were combined to appear in this section in the final version.

An entire section, 2.4 *Non-discrimination in the application of the equivalence of phytosanitary measures*, was added to the final text of ISPM 24 (FAO, 2005a) regarding non-discrimination. This reasserts the concept that implementation of a measure may affect the outcome, in contrast to the predicted effect, of a measure. It also indicates that experience in the application of a measure by other trading partners does not necessarily match what the contracting party NPPO of a different country will deliver. Nowhere in the ISPM does it explain how to determine the capacity for implementation of a measure, although there is mention of surveillance, certification and other systems as critical to success. Capacity evaluation tools do not address this particular issue, either (Day *et al.*, 2006), although the revised tools could link with this capacity if desired. On the other hand, the ISPM states that "the effect of phytosanitary measures implemented in a third country may be considered as reference."

The entire ISPM studiously avoids the use of the term *efficacy* but speaks of the effectiveness of measures. There is no guidance on how to determine effectiveness, although the use of extrapolation to a defined confidence level is mentioned, when measures are not directly comparable. The adopted version (FAO, 2005a) also eliminates use of the proposed new definition of *acceptable level of risk*[18], using instead the ALOP term.

18/ The proposed definition was the "level of risk above which a contracting party applies phytosanitary measures" (ICPM, 2005).

There was little mention of laboratory or field studies to provide new data to support the request (as endorsed by the European Food Safety Authority (EFSA, 2012), and others, and as relied upon for earlier cases of recognition of equivalence).

The ISPM was an important first step in setting down procedures for requesting and responding to requests to recognize equivalence. It introduced some vital concepts such as: assessment of risk, effectiveness for risk reduction (of measures, groups of measures or systems), capacity and resources for implementation, and trust. Contracting party NPPOs already using equivalence have not altered their practices nor increased requests or responses since ISPM 24 (FAO, 2005a) was adopted (Dudley, 2012; personal communication with M. Quinlan, 2011-2012). Yet those less familiar with the concept have benefited from the agreed steps and guidance provided.

Still left to be elaborated is more specific guidance on reaching a judgement of equivalence. Annex 1 of ISPM 24 (FAO, 2005a) describes the steps for the exporting and importing contracting parties (and their NPPOs) to take in the determination of equivalence, including the recommendation that if equivalence is recognized to "... immediately upon their adoption, publish and transmit phytosanitary requirements, restrictions and prohibitions to any contracting party or parties that they believe may be directly affected by such measures" (Article VII, IPPC, 1997). This establishes the importance of notification as an integral part of the ISPM, but the final language in section 3.4 only says: "Contracting parties should agree on a procedure to determine equivalence. This may be based on the procedure recommended in Annex 1 of this standard or another bilaterally agreed procedure."

The lack of specific guidance on methodology for determining effectiveness or efficacy has left a gap in clarity on how equivalence will be determined, as noted by survey respondents in 2011 (Dudley, 2012; and personal communications with M. Quinlan, 2011-2012). Additional guidance is required.

3 Approaches to equivalence

3.1 Determination of equivalence on a bilateral basis

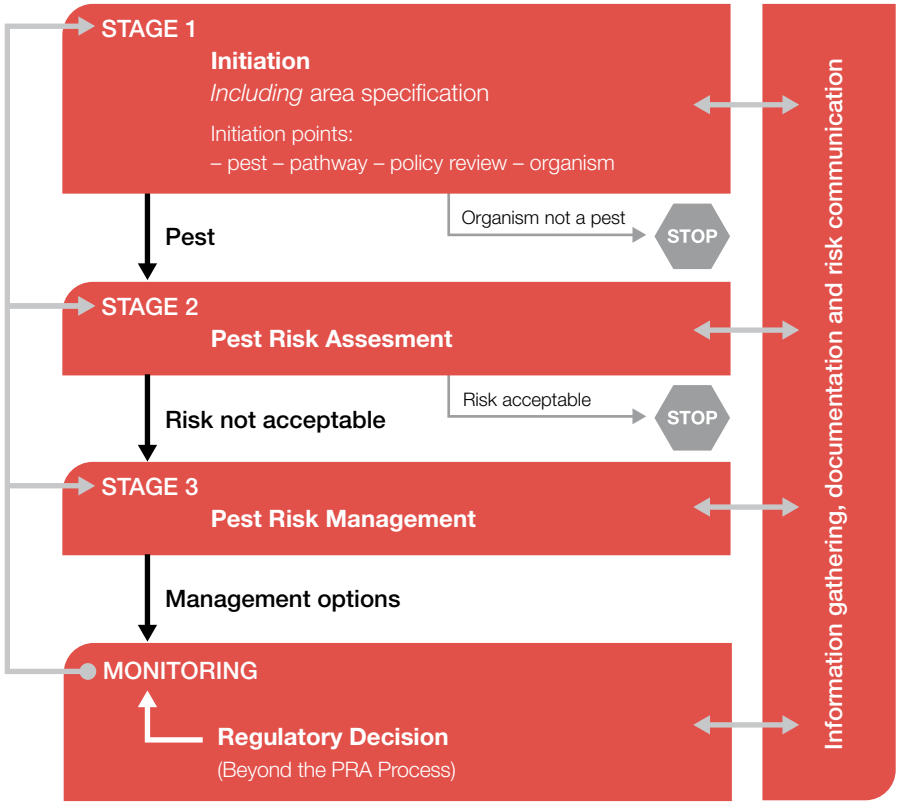
Once an organism has been categorized as a pest for a particular *endangered area*, the pest risk assessment estimates risk based on the probability of entry, establishment and spread, and on the projected impact or consequences of this introduction in the endangered area. The process leads to a determination of whether the pest should be regulated. All together this is the PRA process conducted by the importing contracting party, as shown in Figure 1.

If the estimated risk requires some management measures or interventions, the available options for pest risk management should be described. The best practice would be to describe and also somehow quantify the strength of the pest risk management measures required. In actuality, this is frequently done with qualitative terms such as high, medium and low risk. A description of the options is followed by the regulatory decision regarding which pest risk management options to employ.

The choice of pest risk management options may be negotiated with the exporting contracting party NPPO or other appropriate government entity, or presented in final form by the importing contracting party for implementation. While there is no specific requirement for involving the exporting contracting party NPPO in this process, it may be beneficial to engage the party beyond the requirements for information (IPPC, 2013).

This is the point when the exporting contracting party NPPO should ensure that the measures are feasible for implementation in their country con-

Figure 1. The process of pest risk analysis (based on ISPM 2 *Framework for pest risk analysis* – FAO, 2007a)



text, having considered fully the PRA presented by the importing contracting party NPPO (IPPC, 2013). The choice of pest risk management measures is then communicated as new regulations, policy decisions, operational or work plans for implementation in the field. It is not unusual, however, for the work plan or operational details to never be published for other contracting parties to see.

The exporting contracting party NPPO may request a determination of equivalence of measures, and request adoption of the proposed alternatives as regulations, at the time of opening new trade –

Figure 2. Procedure for the determination of equivalence (ISPM 24 *Guidelines for the determination and recognition of equivalence of phytosanitary measures*, Annex 1 – FAO, 2005a)

ECP = exporting contracting party; ICP = importing contracting party

which will consist of a specified commodity (or other pathway) and an identified regulated pest or pests. Or the exporting contracting party NPPO may request determination of equivalence when, for some reason, the existing regulations regarding entry to a market are no longer tenable. For example, if a single end-point measure such as fumigation is no longer available, then a combination of measures might be proposed. Other reasons for seeking agreement on equivalent measures are discussed earlier in this report (section I C).

The overall procedure for determination of equivalence is laid out in Figure 2. Any stages may be skipped if experience supports adoption of the proposed measures (Stage 7) without further deliberation.

As mentioned in the Introduction (section I), a request for determination of equivalence of measures should not be confused with either a challenge to the justification of the original measures, or with the need for additional measures to be added (if the initial measures are not delivering the level of protection required).

3.2 Approaches to equivalence under the IPPC

There are various commonly applied approaches to facilitating trade under plant health. The author attempts to describe them, although there are varying opinions on categorization of these approaches.

Table 1 suggests how one could categorize these approaches by outcome and the mechanism for reaching agreement (the titles of the approaches are terms not defined by the IPPC). As shown, each approach has some limitations; however each is being employed in current trade.

In general, the concept of equivalence in plant health is not limited to the approach of equivalence agreements. The suggestion that ISPMs for specific measures can serve to demonstrate equivalence, for example, is supported by the reference in ISPM 24 (FAO, 2005a) to ISPM 15 *Regulation of wood packaging material in international trade (FAO, 2002b (later revised as FAO, 2009a)):*

- Although equivalence is generally a bilateral process between importing and exporting contracting parties, multilateral arrangements for comparing alternative measures take place as part of the standard setting process of the IPPC. For example, there are alternative measures approved in ISPM 15:2002.

Others would class ISPMs under harmonization and as a separate process to equivalence determinations, which admittedly are influenced by a number of factors requiring case-by-case consideration. Adoption of pest- or commodity-specific measures in ISPMs implies acceptance of a global ALOP for that scenario.

Some of these approaches are specified in ISPM 24 (FAO, 2005a) and others may be considered trade facilitation, but not equivalence. It is an area that warrants more clarity for the plant health sector.

Table 1. Some approaches to facilitating *safe* trade and alignment in risk management

Approach	Outcome	Mechanisms	Limitations
Harmonization	Common approach to establishment of measures or procedures, assuming global (or regional) agreement on ALOP.	Development and endorsement of ISPMs (or Regional Standard on Phytosanitary Measures (RSPMs)), which are specific to a phytosanitary measure (and with sufficient detail to implement) aimed at risk management or monitoring of the outcome of implementation of the measure; agreed interpretations or common terminology.	Assumes interpretation and implementation of guidance are largely uniform, once adopted. Requires years of technical consultation and negotiation, e.g. within the CPM.
Equivalence agreements	Level of risk remaining after management (level of protection) is perceived to be or measured to be the same, both meeting the importing contracting party's ALOP.	Recognition by the importing contracting party of equivalence of alternative measures with those already approved for similar pest risk. This is done on a case-by-case basis, upon request of the exporting contracting party, through either bilateral or regional negotiations.	Not applied to other trading partners or contracting parties automatically, but this allows for variation in pest risk and implementation of measures. Requires consultation between parties, often taking years.
Provision of alternative measures by the importing contracting party	Regulatory objectives of the importing contracting party are met and options provided. Alternatives may have varying levels of protection but at a minimum meeting the ALOP.	Alternative measures provided in importing country or region legislation or regulation, e.g. the EU. Any may be employed, under conditions specified, without individual negotiation.	May provide different levels of protection, even surpassing the ALOP. Assumes a level of capacity and responsibility on the part of the exporting contracting party NPPO to interpret and implement the measures without the interaction that an equivalence negotiation would entail.
Mutual recognition-type agreements	Compliance assessment procedures are evaluated, audited and recognized as equivalent.	Recognition of equivalent systems such as for inspection, certification of production sites or facilities (e.g. for treatments), registration of growers, etc. PFAs is an example that might fall under this category, as well as under harmonization.	Often based on historical trade, and other confidence building technical cooperation, and review between contracting party NPPOs, over the course of years. Development of new agreements may be resource intensive, yet save resources in the longer term.
Market trading blocs with specific agreement on plant health	Trading partner plant health systems are recognized as equivalent.	Trading blocs with agreements, including plant health, agree to accept products from sister countries as if produced domestically in terms of plant health (e.g. within EU single market, MERCOSUR).	Can be more difficult to challenge when one country considers others in the bloc not to be complying at the same level, or if one has a different interpretation of rules.

3.3 Guidance from the standard setting bodies recognized under the SPS Agreement

The OIE and CAC, the other standard setting bodies recognized by the SPS Agreement, each has its own guidance for determination of equivalence. The OIE has included a section on reaching a judgement of equivalence of sanitary measures (Chapter 1.3.7) in its Terrestrial Animal Health Code since 2003 (also see Chapter 5.3 (OIE, 2012)). Animal Health determinations might focus on equivalent infrastructure, laboratory methods, documentation and legislative provisions. Equivalency with the sectors in exporting countries in meat processing and slaughterhouses is required by some countries before allowing import of meat. The concept of equivalence also falls under responsiveness, as stated in the health codes: "Legislation and regulations should be suitably flexible to allow for judgments of equivalence and efficient responses to changing situations."

The CAC developed general guidance for evaluation and recognition of equivalence, to be used in conjunction with other relevant parts of the Code (CAC, 1999, 2003). The purpose of the original guidance was specifically to determine "the capability of different inspection and certification systems to meet the same objectives." Mutual recognition agreements (MRAs) are widely used for food safety systems, guidance on determining equivalence of food import and export inspection and certification systems developed under other guidance from the CAC.

The role of the authority for the importing country and the exporting country (in the case of plant health, the NPPO) was defined in discussions at the SPS Committee (WTO, 2004). The steps for agreement seem clear and are covered in Annex 1 of ISPM 24 (FAO, 2005a).

The process for determination of equivalence (expressed in a simplified flow chart in CAC, 2003), includes the need for establishing an objective basis for comparison. This was explained further with the footnote:

- The objective basis for comparison of sanitary measures categorized as "Infrastructure" is likely to be of a qualitative nature, e.g., the ability of food control legislation to achieve broad food safety goals. The objective basis of comparison of sanitary measures categorized as "Specific Requirements" is likely to be quantitative in nature e.g., a comparison of levels of hazard control achieved by the measure. The objective basis of comparison of sanitary measures categorized as "Programme" is likely to contain a mixture of qualitative and quantitative elements e.g., correct application of principles, and establishment of appropriate critical limits, in HACCP food control systems.

As with plant health, the challenge of identifying quantifiable units of efficacy arose with food safety.

The CAC recognized the value of harmonization of best practice as a way to facilitate recognition of equivalence (Gascoine, 1999), including for inspection and certification systems. In the same forum, however, the issue of capacity to carry out the measures and *performance* was discussed. The need for building trust before negotiating equivalence was also noted. A recommendation at that time was to link training and capacity building with the capacity to evaluate and demonstrate equivalence. Specifically mentioned were: "training on the process of undertaking the judgement of equivalence, assessment of needs in regards to obtaining equivalence, and assistance in establishing enhanced capabilities in areas required for undertaking equivalence determinations" (Gascoine, 1999).

In the application of the WTO Technical Barriers to Trade Agreement (TBT), discussion of approaches to fair trade (e.g. by Veggeland and Elvestad, 2004) implies that harmonization will result in uniformity of measures, equivalence will result in uniformity of the level of estimated risk (effect produced after risk-reduction measures are applied), and mutual recognition of entire systems will result in the regulatory objective being met – although possibly not in the same manner or even to the exact same level of managed risk. The TBT Agreement

distinguishes equivalence in conformity assessments from equivalence of technical regulations (Zúñiga Schroder, 2011). The IPPC does not define this distinction among approaches so clearly, nor is there consistent interpretation by all parties of what equivalence encompasses.

The description in Table 1 may provide a basis for further discussion with the plant health sector.

3.4 The role of notification

Notification of equivalence agreements is not obligatory under the SPS Agreement, although a later decision by the SPS Committee specifically encouraged it (WTO, 2004) and provided a format for reporting (WTO, 2002b). Transparency includes the notification of equivalence agreements to the SPS Committee (WTO, 2008a). Further, in the second review of the implementation of the SPS Agreement (WTO, 2010), the need for examples of equivalence was highlighted by those countries wanting further guidance for its application. The report of this session further noted that, as of 2009, whereas the WTO had received 7,315 regular notifications and 1,163 emergency notifications on SPS matters, there had been only two regarding equivalence (WTO, 2007, 2008b), neither of them related to plant health. Members of the SPS Committee acknowledged that trade was occurring under equivalence agreements, some of which were developed with the SPS Committee guidance prepared earlier.

The general concern was that notification might benefit other exporters who had not expended the resources to achieve the agreement (WTO, 2010). This was a sentiment repeated in the survey of NPPOs of contracting parties (2011-2012). Zúñiga Schroder (2011) suggests that notification is required only when significant impact to trade is anticipated, and therefore is not relevant to many of these cases at any rate.

To date, official notification of equivalence agreements in plant health has been virtually nonexistent[19]. This lack of transparency holds back development of capacity for equivalence negotiations.

19/ If one uses the WTO online document search engine, with the document identifier of "*G/SPS/N/EQV/MEMBER/*" for notification of equivalence, not one response arises. However, this would be based on self-identification to some degree. A recent study of notifications (Lee M. Pearson, personal communication, 2012) also did not identify any notifications on plant health equivalence.

4 Common practice in plant health

4.1 The evolution of bilateral agreements on alternative measures

Before equivalence was a well-defined concept in plant health, it was clear that, "while not formalized under the title of *equivalence*, there is widespread application of equivalence in current phytosanitary practices" (ISPM 24 – FAO, 2005a).

In the 1980s and 1990s there was a significant expansion of pest risk management measures that were officially recognized for the purpose of trade. Prohibition of trade was becoming less acceptable (see discussion on the advent of the SPS Agreement, section II A) and the demand for more transparently justified pest risk management greatly heightened. In Australia, for example, a series of national reviews of quarantine services and government responses (DPIE, 1988; Nairn *et al.*, 1996; Nunn, 1997; summarized in Tanner, 1997) led to a culture shift towards more risk-based decision-making, greater transparency and accountability and, subsequently, the use of a continuum approach employing more pre- and post-border measures (ANAO, 2001), involving more pest risk management options. The greater awareness by the quarantine services of their own contracting party's export objectives, including through participation in the national market access committee, also affected the fortress mentality that had preceded risk-based decisions (Ikin, personal communication, 2011).

Over the same period, facilitation of exports from developing contracting parties became a stated objective for some important market contracting parties' foreign assistance programmes. This was in contrast to the earlier programmes for import substitution and food security from domestic production (~1960s) and the subsequent focus on debt relief, which was the principal objective for 70 percent of overseas development assistance by 2005 (Lal and Rajapatirana, 1987; IDA, 2008). The result was increasing assistance from the importing contracting party NPPO (although not generally under the financial auspices of the NPPOs) and related agencies in supporting market-access research. The atmosphere of collaboration and additional funding led to additional requests for entry of new products and some infrastructure support[20] (e.g. projects funded by the US Agency for International Development (USAID) Regional Office of Central America and Panama, called PROEXAG and EXITOS, 1986-1995 in Central America (see Chemonics, 2009)), additional PRAs (e.g. AusAID support of training in PRAs by the Secretariat of the Pacific Community (SPC) and the Pacific Plant Protection Organisation (PPPO)), and additional pest risk management research (e.g. US Department of Agriculture (USDA) collaboration with Latin America, in particular, for replacement of ethylene dibromide (EDB) fumigation, described in Wolfenbarger, 1995).

20/ One case in which the availability of equipment affected options was in the treatment of tropical fruits for export against fruit fly pest species. The operational methods and commercial equipment were developed and validated in both the USA (hot water treatment) and Japan (differential pressure-vapour heat treatment) for similar outcomes (Sugimoto *et al.*, 1983; USEPA, 1996; Armstrong and Mangan, 2007). Initially, the use of the alternative, equivalent treatments was divided by influence of commercial and development-assistance sectors, with the Americas and Caribbean using the US equipment and much of Southeast Asia and Australia employing Japanese equipment (Sharp and Heather, 2002). The availability of equipment for these two (in many ways competing) technologies initially limited the choice of market, until equivalence between methods was accepted by important market contracting parties.

In addition, there was a growing confidence in various options for pest risk management. Prior to this, the main measures employed were prohibition (embargo), inspection, fumigation and post-entry quarantine (Mathys and Baker, 1980). The viability of area-wide control programmes, including with sterile insect release, had been proven in several plant health scenarios (Frampton, 2000; Klassen, 2000). This was reflected, too, in the endorsement of an international standard for PFAs (ISPM 4 *Requirements for the establishment of pest free areas* – FAO, 1995b), the first standard specifically on pest risk management.

Another factor in the increase of options was the prohibition of post-harvest, broad-spectrum fumigants. These had been widely employed by plant quarantine services (Monro, 1961, 1969; Bond, 1984[21]; USEPA, 1996; UNEP, 2007; Shamilov, 2012) since their general availability in the 1940s (along with organophosphorus and chlorinated hydrocarbon insecticides – see chapter 17, National Research Council, 1969), and up until concerns about the health of applicators (Heather, 1985) and the impact on the ozone layer (UNEP, 1994) led to a ban on EDB and later restrictions on MB (EU, 2010).

This was a period when recognition of equivalence bilaterally was on the rise. Such agreements would generally be documented as operational agreements, letters and email discussions. While in some cases, the importing contracting party would publish the change (alternative measures) in regulation, these were not presented as equivalence agreements. Much of this activity occurred prior to the SPS Agreement and the notification system.

Phytosanitary treatments to be applied directly to commodities post-harvest (Sharp and Hallman, 1994), such as treatments using temperature manipulation, physical barriers, etc. (Armstrong, 1992; Hallman and Quinlan, 1996; Tang *et al.*, 2007), have effects on mortality that could be directly compared in laboratory settings. As new methods were developed, some of these options were not yet readily available to developing contracting parties. For example, the use of irradiation as a commodity treatment (Burditt, 1996) became well established for some trade, but lack of infrastructure was a serious limitation.

Another trend, perhaps related to the by-then widely understood integrated pest management approach, was more definition surrounding host status of commodities. There were a number of studies looking at the variability in the suitability of a host for particular pest species. Regulated fruit fly species were of particular interest. Plants previously considered hosts were shown to be non-hosts for some key pests (e.g. Liquido *et al.*, 1991). It was recognized, for example, that marginal host plants and their products could have less stringent treatments in comparison with preferred hosts, and quarantine security would still be achieved (Follett and McQuate, 2001; Aluja and Mangan, 2008). At that time, host status determination rested primarily on cage trials, in which the pest species was exposed to the potential host under highly artificial conditions. Bilateral trade agreements emerged based on factors affecting host status, such as the use of specified, less-susceptible varieties of crops and harvesting potential hosts while still immature (to prevent reaching the point when infestation could occur). Combinations of less-stringent treatments with marginal host status were promoted (Ouye and Gilmore, 1985).

Over the same years other approaches emerged that relied on knowledge of pest characteristics. These included trade being limited to part of the season prior to pest populations emerging or increasing in the export production zone. Another alternative was to limit entry to market countries to certain ports, so that zones with vulnerable domestic production would be avoided. Importing re-

21/ This was based on Monro (1961) and Monro (1969).

Box 4

US Framework Equivalency Work Plan agreement on irradiation as phytosanitary treatment

In this more recent development in bilateral agreements (USDA APHIS, 2002, 2006), the process for recognition encompasses:

- Facility approvals
- Approval of compliance agreements
- Acceptance of irradiation as a quarantine treatment
- The completion of administrative and regulatory requirements
- Development of program and inspection guidelines and recordkeeping
- Development of standards and procedures for certification and decertification
- Development and implementation of port-of-entry procedures.

For the USA to accept irradiation as a phytosanitary treatment, an Irradiation Framework Equivalency Agreement must be signed. Conditions required for specific trade (e.g. packaging and labelling) will be documented, as well as any additional measures required for pests not controlled by this treatment.

strictions included use of zones or times of the year when natural temperature extremes would prevent establishment of the pest in question. One could view many of these as early cases of recognition of equivalence, as they were offered as alternatives to the existing measures, albeit often by the NPPO of the importing contracting party proposing alternatives in collaboration with NPPOs of the exporting contracting parties.

Most commonly in plant health, as with the examples above, when equivalence has been agreed it was bilaterally through negotiations between the market country and country source of trade, for a particular pest risk, and associated with a specific commodity. With commodity treatments, it was usually determined based on a calculated level of mortality (or survivorship) subject to larger-scale confirmatory tests. Determination of efficacy, and therefore equivalence, requires other tools when more than one measure is employed, such as in a systems approach (FAO and IAEA, 2011) or when the measures were aimed at different objectives, such as a PFA in lieu of commodity treatment.

The US Framework Equivalency Work Plan agreement on irradiation as phytosanitary treatment (Box 4) is an interesting example of a review of an entire system rather than an individual measure. The review encompasses only irradiation treatments as defined in bilateral agreements, however. It is not an open-door policy for any irradiated products after certification. Furthermore, despite certification of the facilities and detailing of procedures, there also is a requirement for an Animal and Plant Health Inspection Service (APHIS) inspector to work with the exporting contracting party NPPO to carry out preclearance inspections, which implies a cost for covering the expense of this service. In this regard, it might be classed as a systems approach, particularly since, for example, many irradiation treatments will result in some live insects making it through the process, but will prevent viability in the next generation. Some trading partners do not consider this to be an equivalence agreement (personal communication with M. Quinlan, 2012), perhaps because it has a secondary objective of requiring market access for irradiated products from the USA, if the USA is opening its borders to irradiated products from the exporting contracting party.

The use of mutual recognition of overall systems, more frequently applied in food safety and animal health, is discussed further in the next section.

22/ The EU, USA and Australia are three of the places that have provided greater access to plant health documents than most countries and regions, and therefore are used as examples in many papers.

4.2 The European Union approach

Members of the EU followed a somewhat different path from that of the USA and Australia[22], for example. The European approach was greatly influenced by the regional interpretation of rights and responsibilities of the SPS Agreement.

The Plant Health Directive (Council Directive 77/93/EEC – EEC, 1977) harmonized trade between Member States of the then European Community and began a common set of rules for trade with third parties (Baker and Pemberton, 1993). There were numerous exceptions, however, with many national regulations being more stringent than the regional approach. In 1993, with the Maastricht Treaty, the entire European Community emerged as a single market, essentially eliminating internal borders. The aim of protecting the entire territory against regulated pests required a common definition of harmful organisms, against which import regulations would be imposed.

From the period of the creation of the European Common Market, the plant health legislation covering members of the EU (and some non-members that have chosen to match that legislation) has offered alternative measures against the same pest risk. The principal legislation is the Plant Health Directive (2000/29/EC – EEC, 2000). Based on the technically justified and transparent pest list provided in this legislation, unless further pest risk management is applied, trade of host materials is prohibited if the pest in question is present in the country or area of export. PFAs or pest free places of production are commonly offered as options to prohibition of trade. In some cases, additional options include commodity treatments, although these have been relied on much less than in the Americas and the South West Pacific. Technical advice on pest risk management options has come from the European and Mediterranean Plant Protection Organization (EPPO) Panel on Phytosanitary Measures, member state NPPOs and public, academic and private research bodies (Mathys and Smith, 1984; MacLeod *et al.*, 2010).

The legislation was developed in the spirit of the SPS Agreement with an underlying objective to avoid prohibition of trade when possible. Some derogations, which are based on the principles of a systems approach, have been adopted to change requirements over time (e.g. Decisions 2003/63, 2002/887, 2002/499, 2005/51, 2004/4, 2003/249, 93/423). This occurs generally when pest detections have been unacceptably high, frequent or ongoing from particular sources. The fact that the importing region collaborates with exporting contracting parties in these cases further demonstrates the commitment to avoiding prohibition (as a widely held, although perhaps unwritten, principle for the regional plant health system).

So again, although not explicitly developed under equivalence, these examples of single or combined measures listed in EU directives for the same pest risk situation, may be considered equivalent insofar as they are accepted as alternatives for entry into the entire EU. It is suggested that Annex 4 on emergency actions, from its beginnings, is based on the principle of equivalence (personal communication from survey respondent).

It may be argued, however, that the alternatives offered were not based on demonstrated equivalence with each other – nor with achieving the same ALOP, inasmuch as there is a single ALOP for the entire EU. They were, instead, based on a general acceptance of the residual risk from each alternative individually, which more closely reflects the attitude of the regulatory objective being met rather than uniformity in the measure or the effect (see Table 1). ISPM 24 (FAO, 2005a) did not address this approach in depth, but noted that inclusion of two or more options in import regulations allows for "different or changing phytosanitary situations in exporting countries." It further states that such alternative measures may achieve or exceed the ALOP of the EU, in this instance. The exporting contracting party is allowed the choice of which measures to employ without further negotiation.

Even within the EU, there are exceptions to cross-border recognition. Within the EU, there is not a binding, harmonized approach to diagnostics for plant health, for example, so that different NPPOs might arrive at different conclusions regarding the identity or presence of a pest. This and concern arising from the number of outbreaks (MacLeod *et al.*, 2010; Grousset *et al.*, 2012) led to a recent

evaluation of the Community's Plant Health Regime (FCEC, 2010). The European Commission (EC) is currently working to update plant health legislation.

The final risk-management decisions in the EU are taken by the Standing Committee on Plant Health, which is convened by the Directorate-General for Health and Consumers (DG SANCO) in the EC. Since the formation of EFSA (Regulation (EC) no. 178/2002) and the creation of the Panel on Plant Health (referred to as PLH) of EFSA in 2006, matters of equivalence have been referred to this body for technical review. This is because of the nature of EFSA as the primary source of scientific review and advice on risks, in this case risks posed by plant pests. Exporting contracting parties wishing to propose measures alternative to those in the legislation continue to present the request to DG SANCO, but it is assessed by the EFSA PLH. Further discussion of emerging approaches led by EFSA PLH appears below (in particular under *Information requirements*).

4.3 Other regional approaches

The evolution of the Mercado Común del Sur (MERCOSUR) mutual recognition of equivalency of systems has been a similar deliberate and transparent process towards recognition of equivalence. Originally a trade agreement, signed in 1991 among the countries of Brazil, Argentina, Paraguay and Uruguay, MERCOSUR led to extensive harmonization of sanitary and phytosanitary standards and procedures. In this way, while national authorities and systems still exist, the plant health systems have essentially been recognized as equivalent, even when the pest status may not be. However, these agreements are based on international standards whenever possible and on mutual understanding of international concepts. MERCOSUR links closely with the overlapping RPPO, Comité de Sanidad Vegetal del Cono Sur (COSAVE) (which also includes Bolivia, Peru and Chile) as the technical forum for discussions and development of regional standards, in a not dissimilar way to how the EC relates to EPPO for technical advice and support on most plant health issues (although EFSA is central for what could be termed advice on equivalence).

Some shared vision for pest risk and plant health has led to no-less-fundamental (but less comprehensive) agreements between Australia and New Zealand. Within the North American Plant Protection Organization (NAPPO), the governments of Canada, the USA and Mexico are required to implement the agreed Regional Standards for Phytosanitary Measures (RSPMs) and must provide a simple implementation plan on how this will be achieved – for example, if regulations must be changed to comply. The Asia and Pacific Plant Protection Commission (APPPC) also has uniform adherence to its RSPMs, which are developed through a consultation processes, although there is no mechanism for enforcement.

In some countries, the national (federal) authorities for plant health are devolved to the provincial or state level. The assumption is of equivalent delivery of services, but this conformity is not necessarily demonstrated or monitored (as proven by the disagreements between state and federal systems in these same countries). In situations where a third party (sub-national, other agency or private sector) is carrying out phytosanitary measures deemed as official control for the contracting party's NPPO, the NPPO is required to, at the minimum, audit and be aware of all activities. There is no process for determination of equivalence between what the NPPO programmes would achieve and what other players in official control may do, described under *official control* (ISPM 5 – FAO, 2012) adopted in 2001 (ICPM, 2001). These agreements, therefore, are more closely related to an acceptance of the outcome as meeting the regulatory objective, rather than exact uniformity (harmonization) or indeed equivalence (see Table 1).

These system-wide initiatives, particularly through RPPOs, are in the spirit of the IPPC and the SPS Agreement for promotion of harmonization in plant health. In CAC terms, these might be considered closer to MRAs. The outcomes are based on equivalency, but not everyone considers these to be equivalency agreements. Possibly with greater scientific foundation, analysis and auditing of equivalence, these initiatives could evolve to be officially recognized as equivalence agreements.

4.4 ISPMs and technical panels

Technical panels were established by recommendation of the Sixth ICPM (ICPM, 2004). Terms of reference for the panels were agreed at the Third CPM (CPM, 2008). Their role in standard setting is also explained in the IPPC procedure manual (IPPC, 2011).

There are now several ISPMs that include reference to pest risk management measures that would be considered to be equivalent (although not referred to as such in all texts). For example, ISPM 28 (FAO, 2007b) laid out an international mechanism for the TPPT to review proposed treatments. The purpose of the ISPM is for "mutual recognition of treatment efficacy" so that contracting parties might "accept equivalent treatments where possible", without using national or regional resources for each review. It is not obligatory for contracting parties to employ the approved treatments, however, presumably as each may require particular infrastructure and national acceptance of the treated products.

Under ISPM 28 (FAO, 2007b), in addition to specifically evaluating efficacy, the TPPT is to review "feasibility and applicability of treatments" and "costs, commercial relevance, level of expertise required to apply the treatment and versatility." The data requirements for review are listed in the ISPM, and also as annexes to the IPPC Procedural Manual (IPPC, 2011), as included as Annex B of this report.

To date, irradiation treatments against 14 species of pests have been approved, although others are nearing endorsement. Objections were raised against some proposed cold treatments, which the TPPT will address. Other treatments that may be considered under this mechanism are mechanical, chemical, physical and controlled atmosphere treatments. The irradiation treatments are supported by ISPM 18 (FAO, 2003), which lays out procedures for certification of facilities and other conditions to carry out the treatments properly.

Another listing of measures recognized to produce the same effect appears in ISPM 15 (FAO, 2009a; original version FAO 2002b). In this case, individual or groups of measures are considered to be effective against several species or classes of pests. The equivalent measures all require debarking of the timber before use and a registered mark as demonstration of the treatment. Even in this case, contracting party NPPOs have the right to make alternative bilateral arrangements with a trading partner rather than follow the ISPM. Yet, with the realities of movement of dunnage and packing material, most contracting parties are striving to comply with ISPM 15 (FAO, 2009a).

The benefits of harmonization are multifold and are particularly acute when resources are limited. One of the challenges of harmonizing recognition of equivalence for such treatments is to apply general principles against specific cases, which may vary. For the case of wood packaging, Schortemeyer *et al.* (2011) questioned the appropriateness of probit-9 for pests other than insects and for hosts other than fruits (for which it was first introduced). The criteria for treatments for wood packaging have been discussed and questioned and the ISPM 15 (FAO, 2009a) has been revised more than once. While this has been taxing for the CPM and NPPOs of individual contracting parties, any attempt to reach agreement on these issues bilaterally would be far more burdensome.

Calls have been made to harmonize components of plant health systems, such as approaches to surveillance or pest surveys (EFSA, 2011), beyond what is achieved with most ISPMs in order to increase the ease and accuracy of comparisons. Employment of such harmonized approaches could provide equivalence without individual bilateral negotiations. Currently, the standard setting process, including drafting through technical panels, is the only mechanism for harmonization at the global level. Several IPPC initiatives, however, have begun as RSPMs. Regions may agree on equivalence through development of RSPMs or similar protocols prior to international harmonization, as long as conclusions are not in conflict with ISPMs.

5 Remaining needs for clarification and support

5.1 More detail on determination of equivalence

The need for pest risk management is based on the level of risk (e.g. from trade in a particular commodity that could have associated pests), generally estimated in a PRA document, and its relationship with the target contracting party's or region's ALOP. If alternative measures are proposed, they must also close that gap between the estimated level of risk and the ALOP.

The impact of pest risk management measures on pest risk relates to: (a) the level of threat (e.g. pest population or infestation), (b) the efficacy of the measures as designed (i.e. as it performs under laboratory conditions), (c) the efficacy of the measures operationally and (d) the performance of the measures based on implementation or application (how the measures will be implemented, monitored and verified). Using the term effectiveness rather than efficacy, EFSA (2012) have added consideration of (e) how the implementation of the measures will be monitored and verified[23].

5.2 Representation of risk

Although a summary or cumulative risk estimate is suggested by the guidance on PRA, various studies have concluded that the probability of each step (entry, establishment and spread) need be recorded separately (or at least as two estimates: (1) entry, and (2) establishment and spread) in order to more accurately estimate the reduction of risk from the pest risk management measures (e.g. PRATIQUE, 2011; Griessinger *et al.*, 2012). This is due to the different objectives of various phytosanitary measures, even within the subset of pest risk management measures, e.g. reduction of prevalence of a pest, reduction of infestation of the host commodity, reduction of survival rate, reduction of release or exposure in the endangered area (importing contracting parties), etc. (as also discussed in EFSA, 2012). It is also important to facilitate documentation of uncertainty for each component of risk, although a sum total may be developed from these components of risk (MacLeod *et al.*, 2012).

The likelihood of introduction was broken down by subcomponents in one methodology (USDA, 2000), to comprise: quantity imported, survival of the pest after post-harvest treatment, survival during shipping, likelihood of detection at entry, likelihood of movement to suitable habitat and likelihood of contact with host. The NAPPO standard on pathway analysis considers: pathway magnitude, pathway factors affecting survivability of pests, detection of pests along the pathway, environmental compatibility and biological characteristics affecting pest establishment within its assessment (RSPM 31 – NAPPO, 2012).

By maintaining components of risk separately during the analysis, one can also start to address single pathways or multiple pathways (single pests or multiple pests) with more ease (NAPPO, 2012). There is interest in developing generic models that allow the combination of alternative pathways and alternative pests to be assessed (MacLeod *et al.*, 2012). Disaggregated estimates of risk would be more accurate, but could complicate determination of equivalence.

23/ This is a key point in the *Beyond Compliance* project mentioned below.

5.3 The threat

Examples from the 1980s and into the 1990s of experimentally based development of equivalent measures were overwhelmingly based on infestation under artificial conditions and the subsequent measurement of pest mortality after application of the treatment. These studies were subjected to statistical analysis based on probit-9, which was originally chosen to review treatment of preferred host fruits with high infestation of fruit fly pest species (Baker, 1939; Chew and Ouye, 1985). This approach has been recognized as over-estimating infestation (e.g. Landolt *et al.*, 1984; Jang and Moffitt, 1994), yet it was the cornerstone of determination of equivalence for commodity treatments for many years and resulted in significant trade. The challenges identified in those years for the evaluation of marginal hosts, sequential mortality (Jang, 1996), probability of introduction under natural mortality (Yamamura and Katsumata, 1999), areas of low prevalence and other common real-world conditions remain, to a large part, the same challenges faced today (EFSA, 2012).

In contrast to the worst-case-scenario estimates of infestation, at other times the surveillance system has not been designed to demonstrate pest populations in the field to the degree required. A recent review under the Implementation Review and Support System (IRSS) discovered uncoordinated and under-resourced surveillance programmes in many countries (IPPC Secretariat, 2012). Trapping may establish a general population level (high, medium, low) and this can be followed up by fruit cutting in an orchard situation, for example, if the objective is to reach an area of low pest prevalence (FAO and IAEA, 2011). Without proper surveillance, the initial threat remains unknown.

Ideally the potential (or, with monitoring) actual pest threat would be included as a component in equivalence determination. This may be achieved by requiring additional measures or stopping trade in response, for example, to reaching a threshold in the pest population as determined by surveillance. There are trade agreements and domestic programmes employing this component but they require more management and technical capacity.

5.4 Efficacy of measures

Determination of efficacy of measures remains one of the greatest challenges for establishing equivalence.

A common approach, albeit rarely intentional, has been to rely on failures of pest risk management measures to detect the target pest – or indeed outbreaks in the importing country – to indicate the limits of efficacy of the pest risk management. Reviewing a situation before and after changes of policy for pest risk management could be informative (Mathys and Baker, 1980). Yet, lack of outbreaks unfortunately does not indicate successful pest risk management since risk is based on the probability of an event, rather than the certainty. In other words, lack of failure may just be lucky.

Possible tools for estimating risk and pest risk management were presented in Liquido *et. al.* (1997). Griffin (2012c) shows how point estimates and linear event trees along the production chain of a potential pest host may provide quantitative estimates of the impact of each pest risk management measure, even when using expert judgement as the source. Simple fault trees may also clarify pest risk management options. Sgrillo (2002) demonstrated approaches to efficacy for pest risk management measures with different characteristics. For one it could be the portion of consignments for which the infestation is detected (good detection methodology available); another would be the prevalence of the pest; and the third presented was for reduction of the probability of establishment. Definition of the mode of action or objective of the measure is essential to choosing an approach for estimating efficacy.

A literature review of methods for evaluating risk reduction options resulted in five options that were tested on case studies (MacLeod *et al.*, 2012). Each

approach had some advantages, but new methods are required for optimal consideration of efficacy.

Drawing heavily on the concept of *control point*[24], and starting with prototypes from PRATIQUE (2011), the partners of the Standards and Trade Development Facility (STDF)-funded project, *Beyond Compliance* (Whittle *et al.*, 2010; Mengersen *et al.*, 2012), have designed a commodity-specific production chain exercise and the Excel based Decision Support System to organize information from a PRA or dossier, along with industry and expert opinion, into a Bayesian network. This system estimates the probability of consignments being shipped without significant infestation, based on hypothetical pest presence and population levels and the impact of pest risk management. While this returns, in some ways, to the worst-case scenario, the Bayesian network can be manipulated to represent various assumptions or conditions, and therefore serve as a communication tool to explore with stakeholders and target importing contracting party NPPOs some alternative scenarios and the necessity for further data.

5.5 Performance of measures

The performance of measures is the actual outcome in the field, at any given time and place. The TPPT refers to this as effectiveness. There are many reasons this could fall below the efficacy maintained in laboratory studies or operational trials. While the most reliable data is obtained by measuring some indicator of success of the measure at the end of its application, either directly or by proxy, periodic audits of the activities comprising pest risk management, or evaluation of the capacity of the implementing contracting party NPPO, are other ways to assess likely outcomes.

As mentioned before, capacity development of national phytosanitary systems will improve the performance of measures, as well as the confidence of the NPPO.

5.6 Sources of information

The best source of information for evaluation of equivalence is data from a well-designed experiment at as large a scale as possible. In an extensive literature review, the Prima Phacie project found that much of the published literature on efficacy or impact of risk reduction options failed to provide adequate information to be useful for a judgement on equivalence (MacLeod *et al.*, 2012).

The SPS Committee concluded (WTO, 2001) that historical trade and knowledge of and confidence in a trading partner's systems are good bases for judgments on equivalence.

The use of historical trade data for efficacy estimates was questioned by the TPPT, as the topic arose in review of phytosanitary treatments, with regard to a statistical basis for determining some level of efficacy. The members of the TPPT felt that it was unlikely that the infestation level prior to treatment would be known, nor would the accuracy or confidence level of subsequent inspections. The TPPT identified five difficulties with use of historical trade figures (TPPT, 2010):

- The condition of the target regulated article may vary [over] time;
- The life stage of the target pest may change over time;
- Environmental conditions critical to treatment efficacy may vary over time;
- The number of live target organisms infesting the regulated article was unknown at the time;
- The number of surviving target organisms post-treatment was not determined (with any degree of accuracy).

These concerns do not diminish the value of historical knowledge of a trading partner and its phytosanitary systems for developing trust, but rather highlight the difficulty in stating equivalence.

24/ Control point in the context of plant health was originally defined in ISPM 14 (FAO, 2002a), as below, but removed as an official definition of the IPPC Glossary in – in accordance to decision by the CPM 7, 2012 – because it was not considered to be a term unique to the IPPC. The author disagrees with this deletion, because the term is not understood or employed consistently. *Control point* a step in a system where specific procedures can be applied to achieve a defined effect and can be measured, monitored, controlled and corrected [ISPM 14 – FAO, 2002a] https://www.ippc.int/publications/glossary-phytosanitary-terms.

5.7 Information requirements

One challenge for exporting contracting parties that are requesting recognition of equivalence has been the lack of transparency at to what information will be requested. The guidance in ISPM 24 (FAO, 2005a) and that from ISPM 28 (FAO, 2007b) are the first efforts to define exact requirements. The EFSA PLH has carried out and commissioned several studies (EFSA, 2009, 2011, 2012; MacLeod *et al.*, 2012) to clarify policy and procedures for evaluation of what is referred to as "risk reduction options" and the nature of information required to make a proper decision about equivalence. The most recent paper now provides a checklist of data requirements (and a comparison of their requirements with those from the IPPC Procedural Manual (IPPC, 2011), which appear in Annex B of this report) and an explanation of the preferred approaches for analysis by EFSA, which should greatly facilitate application for recognition in the future (EFSA, 2012).

The TPPT and other technical panels may wish to review this work to report on any implications for their own data requirements, as it goes beyond the current proposal.

Both the EFSA study (2012) and the FAO and IAEA paper (2011) note the recent advances in use of Bayesian modelling for plant health and for efficacy of measures in particular. Decision-making is limited by lack of data, but such an approach could provide insight into which factors are most critical through sensitivity analysis. This then directs resources to the most significant areas of uncertainty or missing data. The Prima Phacie study, commissioned by EFSA, found that risk matrices were commonly used, but introduced limitations in terms of representing uncertainty, either by the assessor in terms of assigned values or as presented in summary risk estimates, which would fail to represent the weight of various rankings (e.g. high, medium, low) but instead would attempt an average (MacLeod *et al.*, 2012). In both cases, Bayesian networks can overcome these limitations.

Expert judgement is frequently used in plant health PRA and for evaluation and selection of risk management options. One suggestion is to employ methods designed for elicitation to provide more consistency in this source of data.

The burden of demonstrating equivalence is on the exporting contracting party (Zúñiga Schroder, 2011). Several sources of guidance recommend that the value and benefit of entering into equivalence negotiations are considered. The costs of obtaining all necessary data may prove prohibitive for the value of the outcome, particularly in the case in which industry does not take up the alternative measures after negotiations are complete.

5.8 Limitations of this study

For this study, a survey from student research was evaluated to learn more about attitudes and experiences of the NPPOs of contracting parties in relation to equivalence. Further results of that survey appear in the final section (VI). To take advantage of what was collected by the student, the survey was not altered to reflect other objectives. Experiences in the application of equivalence could be collected through the IPPC process, perhaps under the IRSS, more effectively than through use of the notification to the Sanitary and Phytosanitary Committee of the WTO. As there is no current system for collecting this information, this limits valuable learning from current experiences in the field.

Many of the examples in this review are based on pests in commodity trade or dunnage. No literature on equivalence of measures was discovered for situations in which the plant itself is the potential pest (weed). Similarly there is no attempt to discuss equivalence of measures for beneficial organisms, nor to address equivalence of measures for *living modified organisms* that are categorized as pests.

COSAVE experience has indicated (personal communication with M. Quinlan, 2012) that it is more difficult to consider alternative phytosanitary measures for planting material (Category 4 under ISPM 32 *Categorization of commodities according to their pest risk* – FAO, 2009b), which is considered one of the highest risk pathways for pests (e.g. Grousset *et al.*, 2012). The distinction of pest risk management measures for quarantine pests versus for regulated non-quarantine pests reveals some of the difficulty. While the former refers to options to reduce the risk for introduction and spread, the latter is defined as "evaluation and selection of options to reduce the risk that a pest in plants for planting causes an economically unacceptable impact on the intended use of those plants [FAO, 1995; revised ISPM 11, 2001]" (ISPM 5); for further discussion see Glossary Supplement 2 of ISPM 5. To define equivalence in terms of economic impact would appear beyond the scope of the current ISPM 24 (FAO, 2005a).

It is most likely that clarification of issues raised for pest risk management measures for quarantine pests will support later examination of these more specific topics of plants as pests, regulated non-quarantine and other categories of pests.

6 Comments from NPPOs

6.1 Feedback from NPPOs

Some of the issues requiring more clarification for the application of ISPM 24 (FAO, 2005a) were identified by respondents to the global survey or in individual interviews (Dudley, 2012; and personal communications with M. Quinlan, 2011-2012). These include:

1. generally more guidance on how to negotiate equivalence
2. less complicated, time-consuming and onerous methods for agreeing to equivalence (such as a common framework for evaluation)
3. increased capacity to carry out the systems approach
4. assistance with understanding the data required or how to determine efficacy
5. more transparency in the review of information submitted
6. guidance on how to remove measures when no longer justified (when fewer would meet the ALOP)
7. ways to avoid the long process of negotiation when, in the end, the industry will not comply or attempt to use the equivalent measures negotiated (i.e. how to make sure that the measures will be implemented before going through the negotiation)
8. improved coordination within countries, so that the NPPO has authority to complete equivalence negotiations and, once concluded, the inspectors, customs, etc., are informed
9. how to proceed when equivalence negotiations are held back by what appear to be political and protectionist delays
10. the continued use of the IPPC to reach agreement on equivalent measures through ISPMs (e.g. the variety of approved treatments for ISPM 15 (FAO, 2009a) treatment of dunnage).

There was also comment on the failure of the Doha Round of GATT negotiations. There is some question as to whether there is any hope for multilateral solutions through the WTO. While a valid observation, this concern is not explored in the current report.

From this and other sources, it appears that the main challenges for NPPOs seeking equivalence agreements are:

a. the time and resources required to negotiate the equivalence
b. the delays and lack of transparency in evaluation process of the importing contracting party's NPPO
c. lack of a common framework for considering the impact or efficacy of measures, and thus for comparing them
d. the issue of capacity for application of measures – varying views of the need for assistance in capacity or favoured treatment versus the need of an importing contracting party to ensure that the ALOP is achieved
e. overall capacity to carry out new measures, especially systems approach.

These issues and challenges may be clustered under the following topics, as enumerated above:

- market access negotiation skills (list items 1, 6, 9, b)
- overall capacity for national phytosanitary systems, including interactions with the private sector and other public agencies (list items 3, 4, 7, 8, a, d, e)
- a common framework for determination of equivalence and data requirements (list items1, 2, 4, 5, a, b, c).

6.2 Possible responses to these issues

Overall capacity in national phytosanitary systems has been considered in the IPPC National Phytosanitary Capacity Strategy, which is now guided by the IPPC Capacity Development Committee (CDC). The recent development of the IRSS will also contribute to enhanced capacity, including skills for implementing ISPM 24 (FAO, 2005a), such as surveillance.

Skills in negotiation are not frequently addressed, although IICA has conducted highly effective training for market access and participation in the SPS Committee and standard setting bodies for over a decade (e.g. IICA, 2010). Another project funded by the STDF, *Beyond Compliance*, is underway in the Southeast Asian sub-region to increase confidence and competence in the use of the systems approach (Whittle *et al.*, 2010; Mengersen *et al.*, 2012). These regional initiatives have been complemented by a new guide to market access (IPPC, 2013), which the IPPC Secretariat commissioned. The guide covers rights and obligations and a practical approach to achieving and maintaining trade. Such efforts should be built on and expanded to address the need for capacity and confidence in market access skills.

6.3 Conclusions

For more than a decade, the international plant health community has debated key concepts relating to equivalence, through the mechanisms of the IPPC and at the WTO SPS forum. The revision of ISPM 1 (FAO, 2006; original document endorsed by the FAO Conference in 1993), which lays out the general principles underlying plant health, as well as operational principles, advanced the concepts. Attempts to codify understanding of ALOP and efficacy of measures did not result in ISPMs, but contributed to discussions. Other key concepts, including on inspection (ISPM 23 *Guidelines for inspection* – FAO, 2005b) and sampling (ISPM 31 *Methodologies for sampling of consignments* – FAO, 2008), were clarified over this same period. The ISPM 24 (FAO, 2005a) on determination of equivalence was endorsed by the ICPM in 2005.

The period since the endorsement of ISPM 24 (FAO, 2005a) has seen a rise in the requests for recognition of equivalence, according to NPPOs of contracting parties surveyed. There is little anecdotal evidence, however, that this is due to the ISPM. Instead, drivers for seeking equivalence in recent years appear to be related to loss of pesticides, impact on market quality and situations in which the existing measures are not reaching compliance levels for some reason that can be addressed by switching approaches. Possibly increased confidence of NPPOs of lower-resource export contracting parties will also lead to the increase in equivalence proposals, supported by recent tools and capacity-enhancing projects.

Another impetus may be the clearer guidance on evaluation of treatments – with the ISPM on treatments (ISPM 28 – FAO, 2007b) and the TPPT deliberations. In addition there are now international agreements with aspects of equivalence, such as the options encapsulated in ISPM 15 (FAO, 2009a), which are available for all countries to employ and, in that sense, do not require bilateral negotiation and recognition. Additional international discussions and ISPMs demonstrating agreed equivalence on specific pest risk management measures should reduce the requests for bilateral agreement. Future ISPMs could introduce broader use of system-wide equivalence agreements to further encourage its application and provide savings in resources for individual contracting parties. Further consideration of the mechanisms described in Table 1 could clarify thinking in plant health vis-à-vis food safety and animal health.

For the present, the cases of officially recognized equivalence in plant health remain overwhelmingly unpublished and on the basis of a common-sense, case-by-case manner. Improvements in PRA methodologies and interest in quantifying the pest risk management measures could lead to significant changes in the use of this principle for plant health, over the next decade.

Bibliography and other resources

A note on ISPMs

The ISPMs are fundamental to this study. Also, because of the historical perspective, different versions of the ISPMs and the IPPC convention text are cited. In order to simplify the referencing, in each instance the ISPM is cited by number and the year of the version being cited. **For the full proper reference, see references under FAO as author**.

For those less familiar with ISPMs, numbers were assigned to ISPMs in order of their adoption by the governance body of the IPPC (first the Committee of Experts on Phytosanitary Measures (CEPM), then the ICPM and finally the CPM). A later date for an earlier ISPM number implies that the standard has gone through a revision.

A note on reports from technical panels

Although these may more properly be cited as "FAO", they have been cited in this report by panel names (TPG, TPPT) to make them easily distinguishable.

A note on the survey of NPPOs of contracting parties

Much of the information on application of equivalence is not documented. To address this, an Imperial College London student prepared and sent out a survey for her MSc study (Dudley, 2012). This MSc final report is not publically available, because the student did not comply with college requirements to make corrections requested by her supervisors. One of the supervisors, M. Quinlan, has carried on with the same survey, despite having different objectives, in order to make responses comparable. The questions appear, with the amendment of the contact information, as Annex C. Therefore, the responses to the surveys are referred to as Dudley, 2012; and personal communications with M. Quinlan, 2011-2012. The responses are confidential, as promised in the survey and cannot be attributed to individuals or particular NPPOs or contracting party governments. Most were unofficial responses, at any rate, based on the opinion of the individual completing the survey.

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Annexes

Annex A. Texts from the WTO

WTO Uruguay Round Agreement. Agreement on Technical Barriers to Trade

Article 6: Recognition of Conformity Assessment by Central Government Bodies

With respect to their central government bodies:

6.1 Without prejudice to the provisions of paragraphs 3 and 4, Members shall ensure, whenever possible, that results of conformity assessment procedures in other Members are accepted, even when those procedures differ from their own, provided they are satisfied that those procedures offer an assurance of conformity with applicable technical regulations or standards equivalent to their own procedures. It is recognized that prior consultations may be necessary in order to arrive at a mutually satisfactory understanding regarding, in particular:

6.1.1 adequate and enduring technical competence of the relevant conformity assessment bodies in the exporting Member, so that confidence in the continued reliability of their conformity assessment results can exist; in this regard, verified compliance, for instance through accreditation, with relevant guides or recommendations issued by international standardizing bodies shall be taken into account as an indication of adequate technical competence;

6.1.2 limitation of the acceptance of conformity assessment results to those produced by designated bodies in the exporting Member.

6.2 Members shall ensure that their conformity assessment procedures permit, as far as practicable, the implementation of the provisions in paragraph 1.

6.3 Members are encouraged, at the request of other Members, to be willing to enter into negotiations for the conclusion of agreements for the mutual recognition of results of each others conformity assessment procedures. Members may require that such agreements fulfil the criteria of paragraph 1 and give mutual satisfaction regarding their potential for facilitating trade in the products concerned.

6.4 Members are encouraged to permit participation of conformity assessment bodies located in the territories of other Members in their conformity assessment procedures under conditions no less favourable than those accorded to bodies located within their territory or the territory of any other country.

SPS Agreement and the Committee on Sanitary and Phytosanitary Measures

The following excerpted material is given in this section:

- Article 4 from the Agreement on the Application of Sanitary and Phytosanitary Measures (WTO SPS)
- WTO Recommended Procedures for the Completion of the Notification Format
- WTO CSPM form for notification of recognition of equivalence.

SPS Agreement Article 4: Equivalence

1. Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.

2. Members shall, upon request, enter into consultations with the aim of achieving bilateral and multilateral agreements on recognition of the equivalence of specified sanitary or phytosanitary measures.

Notification of recognition of equivalence

Recommended Procedures for the Completion of the Notification Format

In accordance with the Decision on Equivalence (G/SPS/19), a Member which has made a determination recognizing the equivalence of sanitary or phytosanitary measures of another Member or Members shall notify other Members through the Secretariat of the measure(s) recognized to be equivalent and of the products affected by this recognition.

For the purposes of this notification, equivalence is defined to be the state wherein sanitary or phytosanitary measures applied in an exporting Member, though different from the measures applied in an importing Member, achieve, as demonstrated by the exporting Member and recognized by the importing Member, the importing Member's appropriate level of sanitary or phytosanitary protection. A determination of the recognition of equivalence may be with respect to a specific measure or measures related to a certain product or categories of products, or on a systems-wide basis.

Notification should also be made of significant variations to existing equivalence arrangements, including their suspension or rescission.

Item	Description
1. Member notifying	Government, including the competent authorities of the European Communities, which is making the notification.
2. Title of the text stating determination of the recognition of equivalence	Title of any formal or informal agreement, Memorandum of Understanding or other document establishing the determination of recognition of equivalence.
3. Parties involved	Name of the exporting Member or Members whose measure has been determined to be equivalent.
4. Date of entry into force of the determination of the recognition of equivalence and any associated procedures or regulations	Date from which procedures, regulations or other measures based on the determination of recognition of equivalence took effect.
5. Products covered (HS or CCCN where applicable, otherwise national tariff heading)	Tariff item number(s) (normally HS, chapter or heading and number) as contained in national schedules deposited with the WTO of the product(s) which are imported on the basis of the determination of the recognition of equivalence.
6. Brief description of the measure(s) recognized to be equivalent	Clearly indicate the nature of the recognition of equivalence, including which measure(s) of the exporting Member have been determined to be equivalent and which elements of the importing Member's usual requirements are met by these equivalent measures.
7. Further information available from:	The agency or authority from which an interested Member may request further information regarding the specific determination of equivalence being notified. If this is the national enquiry point, check the box provided. If available from another body, give its address, fax number and (if available) E-mail address. Provide the world wide web address of the document, if available.

World Trade Organization
G/SPS/N/EQV/#

Date of circulation
(00-0000)

Committee on Sanitary and Phytosanitary Measures
Original:

Notification of Determination of the Recognition of Equivalence of Sanitary or Phytosanitary Measures

The following notification of determination of the recognition of equivalence has been received.

1. **Member notifying**
2. **Title of the text stating the determination of the recognition of equivalence**
3. **Parties involved**
4. **Date of entry into force of the determination of the recognition of equivalence and any associated procedures or regulations** (dd/mm/yy)
5. **Products covered** (HS or CCCN where applicable, otherwise national tariff heading)
6. **Description of measures recognized to be equivalent**
7. **Further information available from** [ ] **National Enquiry Point** [ ] **Other** (specify)

Annex B. Checklists of Data Needed for Evaluation of Equivalence (IPPC, 2011)

The numbered annexes below are excerpted from the *International Plant Protection Convention procedure manual* (IPPC, 2011).

Annex 13: Submission Form for Phytosanitary Treatments

Find the *IPPC Procedure Manual* on the IPP at www.ippc.int, where you can download this form

The following form must be completed in accordance with ISPM 28 (Phytosanitary treatments for regulated pests), available at https://www.ippc.int/id/13399?language=en. Copies of all relevant supporting information and publications should be supplied with the treatment submission, preferably in PDF format for ease of subsequent distribution.

The following refers to the relevant sections of ISPM 28 and are numbered accordingly. Submission number: (Secretariat use only)

Complete the following form, preferably in electronic format, and submit by e-mail to the IPPC Secretariat (ippc@fao.org) no later than 15 October 2009. Please use one form per phytosanitary treatment. An electronic version of this form is available at: https://www.ippc.int/id/137399?language=en. Incomplete submissions will be returned. Please save the completed submission form with the following file name: COUNTRY or RPPO NAME –Title of treatment.doc, prior to submitting to the IPPC Secretariat via e-mail.

(Text in brackets given for explanatory purposes)

Name of treatment (Provide enough detail to identify the treatment; for example, cold treatment of citrus for Mediterranean fruit fly) (If quoting the taxonomy of any citrus spp., it should be in accordance with the reference Cottin, R. 2002. *Citrus of the world: a citrus directory.* France, INRA- CIRAD.)
Submitted by (Name of national or regional plant protection organization)
Contact (Contact information of an individual able to clarify issues relating to this submission, including sources of efficacy data)
Nam
Position and organization
Mailing address
Phone
Fax
E-mail

Treatment description
Active ingredient (Brand names alone will not be accepted)
Treatment type (For example, chemical, irradiation, heat, cold)
Target pest (Scientific name)
Target regulated articles
Treatment schedule (Include a brief description such as active ingredient, dose, time and temperature and the efficacy of the treatment (effective dose and confidence limits))
Other relevant information (This should include any assumptions or extrapolations and the supporting evidence for these)

References
3.2 Efficacy data in support of the submission of a phytosanitary treatment The source of all efficacy data (published or unpublished) should be provided in the submission. Supporting data should be presented clearly and systematically.
3.2.1 Efficacy data under laboratory/controlled conditions (Treatments may be considered without efficacy data under laboratory/controlled conditions if sufficient efficacy data is available from the operational application of the treatment (section 3.2.2) and if no data under laboratory/controlled conditions exists this section may be left blank.)
Pest information
Identity of the pest to the appropriate level, life stage, and if a laboratory or field strain was used
Conditions under which the pests are cultured, reared or grown
Biological traits of the pest relevant to the treatment
Method of natural or artificial infestation
Determination of most resistant species/life stage (in the regulated article where appropriate)
Regulated article information
Type of regulated article and intended use
Botanical name for plant or plant product (where applicable)
Conditions of the plant or plant product
Experimental parameters
Level of confidence of laboratory tests provided by the method of statistical analysis and the data supporting that calculation

Experimental facilities and equipment
Experimental design
Experimental conditions
Monitoring of critical parameters
Methodology to measure the effectiveness of the treatment
Determination of efficacy over a range of critical parameters, where appropriate
Methodology to measure phytotoxicity, when appropriate
Dosimetry system, calibration and accuracy of measurements, if using irradiation
3.2.2 Efficacy data using operational conditions (historical data, may in some cases substitute for the requested information below)
Pest information
Identity of the pest to the appropriate level, life stage, and if a laboratory or field strain was used
Conditions under which the pests are cultured, reared or grown
Biological traits of the pest relevant to the treatment
Method of natural or artificial infestation
Determination of most resistant species/life stage (in the regulated article where appropriate)
Regulated article information
Type of regulated article and intended use
Botanical name for plant or plant product (where applicable)
Conditions of the plant or plant product
Experimental parameters
Level of confidence of laboratory tests provided by the method of statistical analysis and the data supporting that calculation
Experimental facilities and equipment
Experimental design
Experimental conditions
Monitoring of critical parameters
Methodology to measure the effectiveness of the treatment

Determination of efficacy over a range of critical parameters, where appropriate
Methodology to measure phytotoxicity, when appropriate
Dosimetry system, calibration and accuracy of measurements, if using irradiation
Factors that affect the efficacy of the treatment
Monitoring of critical parameters
Special procedures that affect the success of the treatment, if applicable
3.3 Feasibility and applicability (Information should be provided where appropriate on the following items)
Procedure for carrying out the phytosanitary treatment
Cost of typical treatment facility and operational running costs if appropriate
Commercial relevance, including affordability
Extent to which other NPPOs have approved the treatment as a phytosanitary measure
Availability of expertise needed to apply the phytosanitary treatment
Versatility of the phytosanitary treatment
The degree to which the phytosanitary treatment complements other phytosanitary measures
Summary of available information of potential undesirable side-effects
Applicability of treatment with respect to specific regulated article/pest combinations
Technical viability
Phytotoxicity and other effects on the quality of regulated articles, when appropriate
Consideration of the risk of the target organism having or developing resistance to the treatment

Send submissions to:
E-mail: ippc@fao.org (preferred)
Fax: (+39) 06 5705 6347
Mail: IPPC Secretariat (AGPP)
Food and Agriculture Organization of the United Nations
Viale delle Terme di Caracalla – 00153 Rome, Italy

Annex 14: Prioritization Criteria for Proposed Phytosanitary Treatments & Score Definitions[25]

Criteria	Considerations
Technical	Extent of evidence in support of the treatment (scientific, historical and/or practical information/experience)
	Credibility of evidence in support of the treatment (e.g. one or more NPPOs or RPPOs have adopted the treatment, evidence published in peer-reviewed international journals)
Practicality	Feasibility of approving the phytosanitary treatment within a reasonable time schedule
	Feasibility of carrying out the phytosanitary treatment at a global level (includes ease of use, risks to operators, technical complexity)
	Stage of development of the phytosanitary treatment (is it already widely used by NPPOs?)
	Availability of expertise needed to apply the proposed phytosanitary treatment globally
Benefit/cost	Estimated value of trade affected by proposed phytosanitary treatment
	Estimated value of new trade opportunities provided by the approval of the proposed phytosanitary treatment
	Relevance and value to an ISPM under review or development requiring phytosanitary treatment(s)
Alternative to methyl bromide	Utility as a replacement to existing methyl bromide treatments. Estimated reduction in methyl bromide use as a result of the application of the proposed phytosanitary treatment
Strategic	Frequency with which a phytosanitary treatment emerges as a repeated source of trade disruption (e.g. disputes or need for repeated bilateral discussions)
	Relevance and utility to developing countries
	Coverage (application to a wide range of countries/pests/commodities)
	Degree to which the treatment complements other treatments or procedures (for example potential for the treatment to be used as part of a systems approach for one pest or to complement treatments for other pests)
	Expected treatment longevity (i.e. chemicals likely to be banned or withdrawn would be low priority)

25/ TPPT (2005).

Annex C. Questionnaire

Your feedback to this questionnaire will inform research for a project- Beyond Compliance- which is exploring enhanced application of systems approach to phytosanitary risk. Systems approaches are often employed in requests for equivalence.

The research will consider the IPPC standards that relate to equivalence; how equivalence agreements have been taken up across IPPC members; and perceptions and experiences of various elements of equivalence agreements. This also covers agreements that are not formally referred to as equivalence agreements, but have facilitated a change in risk management measures from the existing measures for the traded commodity.

Your response will not be attributed to you, your organisation or country, unless you agree to that in writing. Full and frank answers would help to give a more thorough and more balanced view of this topic.

The answers that you provide will be treated with complete anonymity and will remain confidential, except as combined results.

If you have any further questions, please contact me at m.quinlan@imperial.ac.uk

Background on equivalence

One result of the Uruguay Round of Multilateral Trade Negotiations was the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). Article 4 of the SPS Agreement refers specifically to equivalence, and obliges all member states to accept, from any other member state, alternative measures different to their own, as long as they are scientifically proven to meet the set appropriate level of protection (ALOP). Such measures would be deemed equivalent.

Equivalence appears in ISPM 1: Phytosanitary Principles for the Protection of Plants and the Application of Phytosanitary Measures in International Trade, which outlines the general principles of the IPPC.

ISPM 24: Guidelines for the Determination and Recognition of Equivalence of Phytosanitary Measures, was endorsed in 2005. This ISPM outlines the key requirements for the determination of equivalence, as well as providing a proposed procedure for the process.

Despite these official statements on equivalence, there are still challenges to its application. This questionnaire is to review the current status of the use of equivalence agreements in plant health.

Further information/texts of these Agreements and specific ISPMs can be found on the World Trade Organization and IPPC websites.

Instructions for the questionnaire

All references to equivalence agreements in the questionnaire are in the context of these Agreements and Standards. However, I am also interested in **agreements that are not formally referred to as equivalence agreements**, but which allow alternative risk management measures – or additional options – to those prevailing at the time for that commodity trade. For example, circumstances where your country was already exporting a particular commodity to a market (importing) country using fumigation for some years, but then some other type of commodity treatment or a pest free area was added to the options for compliance to enter that market country. These other options would be considered to be equivalence agreements in the context of this questionnaire.

Questionnaire

General trends

1. Does your NPPO have any trading agreements based on Systems Approach?
   ☐ **Yes** ☐ **No**
   (If several, please use the table provided at the end of the questionnaire)

2. Can you note any drivers in your country that would/have encourage(d) the use of Systems Approach for trade? (e.g. loss of a pesticide or fumigant, quality problems with existing measures, continued interceptions even with measures used, etc.)

   .....
   .....
   .....

3. In these instances, did Systems Approach replace an existing risk management option (either a single measure or a different systems approach)?
   ☐ **Yes** ☐ **No**

4. Has the creation of ISPM 24 (on equivalence) made a difference to the undertaking of equivalence agreements within your NPPO?
   ☐ **Yes** ☐ **No**
   What?

   .....
   .....
   .....

5. Are you aware of any trends/changes in the number of countries equivalence agreements?

   .....
   .....
   .....

6. Are you aware of any trends/changes in the number of countries within each individual equivalence agreement (i.e. predominantly bilateral, multilateral)?

   .....
   .....
   .....

7. Please comment on any patterns/trends (including no change) that you have noted in regards to how equivalence agreements have been carried out since:
   a) 1997 (SPS/IPPC revision):

   .....
   .....
   b) 2005 (ISPM 24):

   .....
   .....

Your country's (NPPO) equivalence agreements

Have you been part of an equivalence agreement now or in the past?
(See instructions about what is meant by equivalence agreement.)
☐ **Yes** ☐ **No**
If Yes, note these on the table on the last page of this questionnaire, and then proceed to question 9.
If No, proceed to question 11.

8. Have these agreements evolved over time (renegotiations, countries joining/leaving)?

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9. What have you found to be the failings/difficulties of equivalence agreements?

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10. What have you found to be the successes/benefits of equivalence agreements?

.....

.....

.....

11. Are you planning to initiate negotiations for equivalence on a commodity in the near future?

☐ **Yes** ☐ **No**

13. Any other comments on your experiences with equivalence agreements (e.g. negotiation, implementation)?

.....

.....

.....

Your opinion on equivalence agreements

14. What would you consider to be the most significant deterrents to entering into an equivalence agreement?
[More than one answer may be given.]

☐ the costs outweigh any benefits (financially, politically, etc.);
☐ you are receptive to the idea, but have found other negotiating parties' not to be;
☐ there is no clear guidance on how to negotiate and implement an agreement;
☐ there is a lack of transparent information;
☐ it would require a systems approach, which you don't have the capacity for or find burdensome;
☐ importing countries take too long to come to a decision;
☐ it is too big/daunting an undertaking; or
☐ any other:

.....

.....

.....

15. Please rank (1-4) which scale of agreement you would consider preferable to enter into:

☐ bilateral
☐ regional (please describe region)
☐ regional: all members of your RPPO
☐ IPPC-wide: in the form of an ISPM

Why?

.....

.....

.....

16. Have you been part of a Pest Risk Assessment (PRA) which is: [More than one answer may be given.]
☐ bilateral, but based on a PRA already done for a different exporter
☐ regional (please describe region)
.....
☐ regional: all members of your RPPO
☐ other (please explain)
.....
.....
.....

17. Would you consider entering into (as an importer or exporter) an equivalence agreement with more than one/a group of exporters?
☐ **Yes** ☐ **No**
Why?
.....
.....
.....

18. Would you consider entering into (as an importer or exporter) an equivalence agreement in which the countries of origin of trade are geographically divided, but which have harmonised pest status, methods, etc. and can meet the same ALOP?
☐ **Yes** ☐ **No**

19. Within a regional agreement, responsibility for a failure of compliance/detection of the target pest can be assigned at various scales. Consequences could range from a request for improved application of measures (a warning), or requirement of additional measures, to stopping trade. The lower the scale the greater the management burden (and so, costs) on all members of the agreement. A balance must therefore be found between these upfront, increased costs, and the scale of trade that would be cut off, for example, if there were to be a breach.
Where do you think this balance is best met?
☐ Entire country
☐ Sub-regions of country
☐ Individual packing houses
☐ Individual producers
.....

20. Does your NPPO have any cost recovery system for the additional burden of carrying out systems approach or other additional measures that arose from entering into an equivalency agreement?
☐ **Yes** ☐ **No**
[If Yes, please summarise the level of recovery and method, e.g. 100% cost recovery on inspections, certifications of growing areas, etc. but a set fee for issuing a phytosanitary certificate...]
.....
.....
.....

Please list any agreements referenced in this survey that you have entered into to date	Was this as an importer or an exporter?	On what scale is this agreement on? (Number of other countries/ continental/ RPPO)	Is this agreement based on a Systems Approach?	Is there currently trade going on under this agreement? If not, please explain why	Has this been a formal equivalence agreement; a formal process to add options, but not referred to as an equivalence agreement; an adjustment to an existing operational/work plan; or other

IPPC

The International Plant Protection Convention (IPPC) is an international plant health agreement that aims to protect cultivated and wild plants by preventing the introduction and spread of pests. International travel and trade are greater than ever before. As people and commodities move around the world, organisms that present risks to plants travel with them.

Organization

- The number of contracting party signatories to the Convention exceeds 181.
- Each contracting party has a National Plant Protection Organization (NPPO) and an Official IPPC contact point.
- 10 Regional Plant Protection Organizations (RPPOs) have been established to coordinate NPPOs in various regions of the world.
- IPPC liaises with relevant international organizations to help build regional and national capacities.
- The Secretariat is provided by the Food and Agriculture Organization of the United Nations (FAO-UN).

International Plant Protection Convention (IPPC)

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