

WORKING MATERIAL

FAO/IAEA Guidelines for Implementing Systems Approaches for Pest Risk Management of Fruit Flies

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Summary

International trade in commodities provides food, consumer goods, and a livelihood to millions of people, but can also spread pests that cause serious damage to commercial crops and to the environment. Many Tephritidae fruit fly species are important plant pests, due to tendencies towards high fecundity, wide host range and potential to cause serious damage. These fruit fly species often are categorized as quarantine pests in the first phase of a Pest Risk Analysis, which is a harmonised framework for decisions regarding trade in plant products, developed under the International Plant Protection Convention. The National Plant Protection Organisation of each country is responsible for addressing the possible risks from trade to domestic plant resources. After assessing the risk, the need for pest risk management is determined. These guidelines focus on the final phase of the PRA, when a management plan is developed.

Some of the stand-alone options for managing fruit fly risk are non-host status, Pest Free Areas, and commodity treatments. Pest risk management measures may be combined in a Systems Approach, however, as described in the International Standard on Phytosanitary Measures No. 14 (*The use of integrated measures in a system approach for pest risk management*). This concept, described in depth in section IV, has been applied successfully to various combinations of different species of pest/host/area for many years. Yet, NPPOs still encounter challenges to the application of Systems Approach. The examples and descriptions in these guidelines seek to support its use against fruit fly pests.

Measures may be applied sequentially in the exporting country at the time of preharvest, harvest, post-harvest, export and transport, or at entry and distribution to the importing country. Area-wide integrated pest management programmes against fruit flies can play a significant role in suppressing pest populations to the low level required to reduce initial infestation in the field, thereby supporting the efficacy of all subsequent measures.

Measures may reduce the risk directly, as major independent components of the system, or may support implementation of those major components or verify their proper application. Sometimes several dependent measures combine to form a single major component. Additionally, safeguarding measures prevent re-infestation during the process of packing and shipping. In some instances, importing NPPOs agree to apply measures upon entry, such as limiting the season for shipping. Examples of these different types of measures appear in Appendix 1.

All of these measures should be contributing to the cumulative efficacy of the system, although there are instances where redundancy is built into a system until further data can support removal or reduction of measures. The efficacy of the whole system can be estimated using either qualitative or quantitative methods and then audited to confirm performance. This is done either through monitoring of the activities or the outcomes (end points) of the system. With the at least two independent measures required to be a Systems Approach, even failure of one major component does not cause the entire system to fail

only to suffer reduced efficacy. Thus Systems Approach provides a perhaps more complicated but flexible option for achieving the quarantine security level requested by an importing country or region, referred to as the Appropriate Level of Protection.

A Work Plan or Protocol for Export documents all of the components of a Systems Approach for each target pest/host/area combination. The exporting and importing NPPOs, and the involved stakeholders, use the process of preparing such a plan to reach agreement on the ways to verify the system and correct it as needed, as well as on the components and roles of each party. Appendices illustrate the contents of a Work Plan and give examples of existing Systems Approach-based trade.

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I. Background

International trade in plant products provides food, consumer goods, and a livelihood to millions of people around the world. However, trade also can spread pests into new areas, where serious damage to commercial crops and to the environment may result. Economically important fruit fly species¹ are frequently categorized as quarantine or regulated pests, requiring prevention or control. Their importance as a class of pests is due to tendencies towards high fecundity, wide host range, and, for preferred hosts, potential to cause serious damage. The threat of introduction of fruit fly species of the genera *Anastrepha*, *Bactrocera*, *Ceratitis*, *Dacus*, *Rhagoletis*, *Toxotrypana* and others often results in the establishment of phytosanitary barriers to trade.

Under the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) of the World Trade Organisation (WTO), essentially all trading countries have agreed to allow free trade to continue as far as possible, whilst maintaining individual country sovereignty in efforts to prevent the entry and spread of pests new to that area, such as fruit flies. The national plant protection authority is responsible for considering the possible risk to its domestic plant resources that may arise with trade and deciding on appropriate pest risk management measures.

A harmonised framework for decisions regarding international trade in plant products or commodities² has been developed by the approximately 173 contracting parties (as of March 2010) to the International Plant Protection Convention (IPPC), which is deposited in the Food and Agriculture Organization of the United Nations (FAO). Under this Convention, each National Plant Protection Organisation (NPPO), or other authorized entity, may evaluate the pest risk from proposed imports using a Pest Risk Analysis (PRA) methodology. In the PRA, the potential pest(s) of concern are categorized in terms of the likelihood of entry and establishment and the magnitude of the consequences if introduction does occur. This provides the basis for determining pest risk management measures, to reduce the risk to a level set by the importing country NPPO, at which trade will be allowed.

The International Standard on Phytosanitary Measures (ISPM) No. 14, *The use of integrated measures in a system approach for pest risk management* (FAO, 2002), describes an important approach to pest risk management that has been applied successfully for years to various cases of pest/host/area combinations. The Systems Approach (SA) facilitates the design of risk management that is proportional to the estimated pest risk. It provides a flexible method for achieving an importing country's or region's appropriate level of protection (ALOP) against the pest risk, as estimated in the PRA.

To complement ISPM no. 14 these guidelines provide additional details and examples. Guidance is provided on the fundamental building blocks of SA in

¹ In the rest of the document we use the words "fruit fly" to mean Tephritidae species.

² In the rest of the document we use the word "commodity" to mean fruit fly host materials, which could include fruit and vegetables (botanical fruit), destined for trade.

the context of fruit fly control, as well as the more complex concepts and challenging aspects of SA. Development and application of any SA requires a judicious selection of the available phytosanitary measures for risk management in the most effective combination. These guidelines draw on substantial global experience in evaluation, selection and design of pest risk management options aimed at one or more fruit fly species.

Although we present SA as based on a PRA, the reality is that the process may begin in the horticultural industry with exporters wishing to access a new market by overcoming trade restrictions. In this case, their NPPO would work with them to evaluate the options, including SA. Other scenarios for the development of a SA can be when the importing country for existing trade proposes new regulations, for example when previously used measures are no longer available (e.g. loss of registration of a pesticide). If the exporting industry and/or NPPO would prefer alternative measures, namely a SA, to those already required (whether stand-alone or SA), this process is described in the ISPM No. 24 (*Guidelines for the Determination and Recognition of Equivalence*, FAO, 2005).

It should be noted that we talk about fruit fly pests as a group, but often there is more than one species of economically important fruit fly species – or other pests – associated with the commodity. All or several of these species may be of quarantine concern for the importing NPPO. All of the phytosanitary risks identified will need to be addressed. Control for these pest species may, or may not, overlap with the planned SA. Thus, a commodity may end up being treated for one pest and passing through a SA, or may be subjected to two or more SAs. In this case the combination of measures selected for the target fruit fly species may be influenced by the impact on the other pests, in order to reduce the overall requirements of pest risk management measures. This point is not developed further in these guidelines.

II Pest Risk Analysis

2.1 The Pest Risk Analysis Process

The PRA process is described in ISPM No. 2 (*Guidelines for pest risk analysis*, FAO, 2007). ISPM No. 11 (*Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms*, FAO, 2004), provides more details for PRA of quarantine pests and ISPM No. 21 (*Pest risk analysis for regulated non-quarantine pests*, FAO, 2004) for regulated non-quarantine pests (RNQP) that may occur in an area but be restricted on imported planting material. In these guidelines, we focus on fruit flies designated as quarantine pests, although most of the information relates to either type of regulated pest, quarantine or RNQP. The Pest Risk Analysis (PRA) consists of an Initiation phase, Pest Risk Assessment phase and Pest Risk Management phase.

These guidelines relate most to the Pest Risk Management phase of PRA, when the level of risk and acceptability of this risk is reviewed by the importing NPPO. If the risk is considered unacceptable, Pest Risk Management

measures are recommended for reducing the risk by an appropriate level to meet the importing country's ALOP. Management options are described in the sections below.

When concluding a PRA, this process of evaluation and selection of risk management measures will occur for each quarantine pest species or pest group, fruit fly species or other types of pests; and also for each species or variety of host. (See flowchart in Figure 1.)

In each component of risk, there may be uncertainty due to lack of knowledge and data, or to natural variability. The PRA may rely on extrapolation from existing experience to a new, hypothetical situation. ISPM No. 11 notes the importance of documenting the source and degree of uncertainty. This is particularly important when SA will be applied.

2.2 The Appropriate Level of Protection

The Appropriate Level of Protection (ALOP) is the level of protection to be achieved through use of management measures in order to reach the estimated risk deemed appropriate by the country in regard to a quarantine risk (SPS Agreement Article 5 and Annex A, 3.5). This concept is the key factor in selecting pest management options, but it is not an easy term to define. For practical purposes, it is equivalent to the quarantine security level requested by the importing countries and it is based on the risk of introduction and potential economic impact of a pest.

Achieving the ALOP will depend on the assessed risk of the overall phytosanitary condition (pest/host/area). If the estimated initial risk from proposed trade falls within the ALOP, no measures are required. Some areas of the same country could have different requirements for management measures than other areas for the same pest and commodity, based on the risk of pest introduction (e.g. due to presence or absence of hosts, variation in seasonal limits to pest survival, etc) although the ALOP is the same.

Setting the management measures to meet the ALOP requires communication and cooperation between the exporting and importing countries.

III. Stand-alone Options for Fruit Fly Risk Management

There are a range of options for fruit fly risk management, including SA. These are briefly outlined below and on the following chart (Figure 1).

3.1 Non-host Status

Consideration of the status of fruits as potential hosts of the pest fruit fly species in question is a fundamental element in PRA. If the fruit is a non-host, this should be adequate as a stand-alone condition to allow the commodity to be traded, without the imposition of additional risk management options (unless for other pests). If deemed to be a host, then pest risk management

should be considered. The RSPM No. 30 (*Guidelines for the determination and designation of host status of a fruit or vegetable for fruit flies*, NAPPO, 2008) and RSPM No.4 (*Guidelines for the confirmation of non-host status of fruit and vegetables to Tephritid fruit flies*, APPC, 2005) provide guidance on application of this measure. It also is discussed further in 4.3.3 of this paper.

3.2 Pest Free Areas

A Pest Free Area is “an area in which a specific pest does not occur as demonstrated by scientific evidence and in which, where appropriate, this condition is being officially maintained” (ISPM No. 5, FAO 2010). Areas demonstrated to be initially free of fruit fly pests may remain so due to the presence of natural barriers or climatic conditions and/or through the implementation of host movement restrictions and related measures. An area also may be made “pest free” through area-wide eradication programmes.

The establishment and maintenance of Fruit Fly Pest Free Areas (FF-PFA) implies that no other phytosanitary measures specific to the target species are required for host commodities produced within a PFA (although safeguarding may be in place for transport). A FF-PFA very often operates under a Work Plan endorsed by trading partners, which includes an emergency action plan designed to maintain the FF-PFA status (ISPM No. 26, FAO 2006).

3.3 Single Postharvest Phytosanitary Treatment

The application of phytosanitary treatments to regulated articles is a phytosanitary measure used to kill, remove, deactivate or make unviable the pest and therefore to prevent its introduction and spread. Historically, a probit-9³ efficacy level is required for phytosanitary treatments used as a stand-alone measure. This level of efficacy provides high quarantine security; therefore, there is no need for a SA to mitigate risk.

However, a treatment with a lower efficacy level (for example less than probit-9) may be a component of an overall SA to reduce risk to the desired level. One benefit of a less stringent treatment is that a smaller sample size can be used to demonstrate the lower efficacy, for example at a 95% confidence level, and less physical damage to the commodity (see section 4.4.1 for further details).

3.4 Systems Approaches

For the establishment of a SA, the relationship between the target fruit fly species, host commodity and specific geographic site, place or area of production of the host commodity should be defined.

³ Probit-9 is a statistical standard demonstrating the efficacy level of a treatment as resulting in a mortality or sterility of the target pest at the confidence level of 99.9968%.

Systems Approaches may include a number of independent (at least two) and dependent measures for reducing risk, applied at the stage of: i) preharvest and harvest, ii) postharvest and shipping, and iii) entry and distribution within the importing country. An important requirement for the establishment of an SA is a low pest population level in the area of production of the host commodity preharvest. This enables proper functioning of other measures that are available for integration into the SA to reduce risk to an appropriate level.

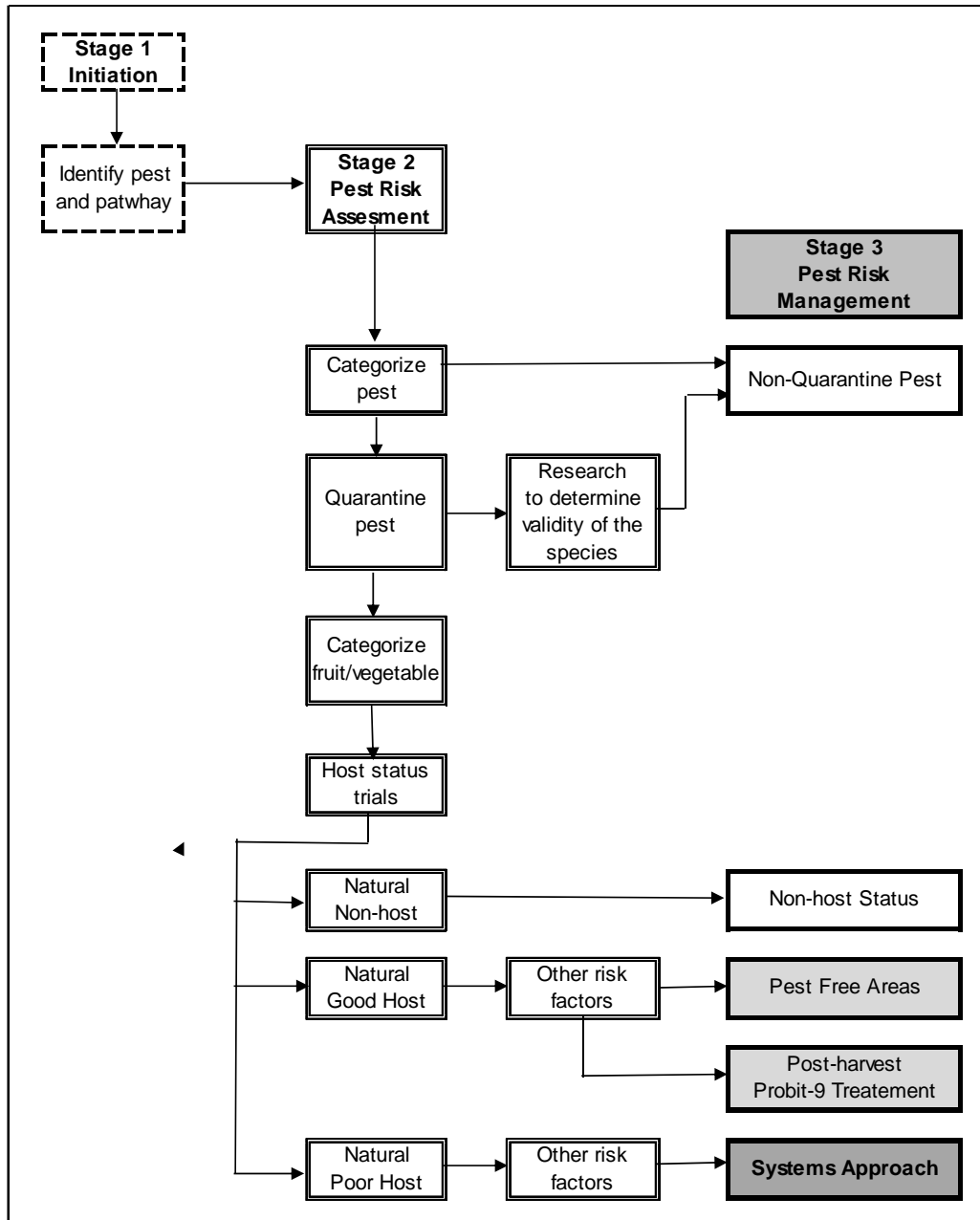


Figure 1. Relationship between the fruit fly risk and available risk management options. (Modified from RSPM No. 30 "Guidelines for the determination and designation of host status of a fruit or vegetable for fruit flies", NAPPO, 2008)

IV Systems Approaches

4.1 Concept

The basic concept of the SA to management of phytosanitary risk came from the realization amongst researchers and regulators that infestation of commodities by pests could be mitigated not only by using stand-alone measures such as single quarantine treatments aimed at near complete mortality, but by applying a series of sequential mitigation measures (systems components) each having some role in reducing the overall pest risk in an export consignment.

The actual presence and numbers of pests in exported commodities vary significantly. The level of infestation depends on a number of conditions that affect the pest and the hosts in particular growing areas. There may be advantages to designing postharvest treatments in line with an estimate of the pest population in consignments from specific areas. An additional value is that less severe treatments would likely reduce the myriad of postharvest quality issues that were frequently noted as a result of single quarantine postharvest treatments aimed at achieving near complete (probit-9) mortality. In such situations, integrated biological information about the pest and knowledge of the host-pest relationship could be used to sequentially reduce risk in pre-harvest, postharvest entry and distribution paths, while maintaining the quality of the commodity. In plant health, this integration of various phytosanitary measures is referred to a SA.

In their conceptual framework chapter on SA, Jang and Moffitt (1994) defined a SA as *“the integration of those pre and postharvest practices used in production, harvest, packing and distribution of a commodity which cumulatively meet requirements for quarantine security”*. The current definition of SA as accepted by the IPPC in ISPM No.14 (FAO, 2002), is *“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”*. This later definition added the concept of independent and dependent measures. Systems Approaches integrate risk management measures that can affect the incidence, viability, and reproductive potential of a pest into a series of practices and procedures that together achieve the ALOP required by the importing country.

The approach has been used for many years for pest risk management. However, it was not until the development of ISPM No. 14 (FAO 2002) that the approach was formalised and officially accepted by the international plant protection community. The ISPM No. 14 provides general guidance on developing and evaluating phytosanitary measures for integration into a SA framework to achieve the desired ALOP identified within a pest risk analysis for all regulated pests.

While a SA may include any number of measures, a minimum of two of these must act independently of each other. Accordingly, a failure of any independent measure will not affect the operation of other independent measures, and may not necessarily constitute a complete system failure, although the total level of protection may decrease.

Systems Approaches will vary in their level of complexity according to the efficacy of the individual components used, the availability of components to integrate into a system, the intended phytosanitary outcome of the system, and the level of inherent variability and uncertainty in a system.

As with any biological-based system, levels of uncertainty and variability will typically be identified in the biology and ecology of the target pest and its association and interaction with the host plant. While some levels of uncertainty are generally difficult to quantify, a SA makes provision for this uncertainty through the careful integration of multiple measures of demonstrated efficacy to provide a sequential mortality risk management framework.

The use of multiple measures, which in some cases may achieve a combined efficacy in excess of phytosanitary requirements, provides flexibility for subsequent modification of the SA design to continue to meet the desired ALOP if, for example, additional data reduces the level of uncertainty.

Systems Approaches could be implemented for any number of fruit fly species, host situations and size of areas. The following guidelines suggest, however, that SA work best with well-defined areas where hosts and fruit fly species can be clearly identified and populations/infestation for the target pest(s) identified in the PRA can be measured. These conditions of the pest/host/area provide a starting metric against which further reduction in pest risk might be implemented, modified and measured.

Specific factors to be taken into account include: the conditional host status (host susceptibility with ripeness or development), characteristics of the production areas (including geographical considerations), production times/seasonal windows and characteristics of the target fruit fly species. These can all be taken into account in either the pre-harvest, postharvest, or distribution stages and determines the basis for major independent components and its elements that might make up the parts of a SA.

Area-wide integrated pest management (AW-IPM) programmes against fruit flies can significantly reduce the population levels of the target pest in a defined area. A lower initial infestation makes it more likely that other pre or postharvest sequential (independent component) measures will successfully mitigate the remaining risk. Successful AW-IPM programmes have included the use of the sterile insect technique (SIT), male-annihilation technique (MAT), and/or biological control among the elements.

4.2 Parts of a Systems Approach

By defining types of phytosanitary measures associated with SA with useful terms, we can better understand, develop, and modify SA. This will also allow us to better understand the requirements regarding independent and dependent measures within the SA.

4.2.1 Independent Measures

We can define the large comprehensive phytosanitary measures as major components. These can be *poor host status*, *areas of low pest prevalence*, *pest exclusion structure*, and *less than probit-9 post-harvest commodity treatment among others*. These measures, by themselves, lower the risk of the pest and are thus independent measures for risk management. To be classed as a SA there must be two or more independent measures/major components working together in the pest risk management plan.

4.2.2 Dependent Measures

Several measures, that by themselves would not significantly lower the risk, may be used in a combination to create an independent measure/major component. For instance, the *pest exclusion structure* (which is an independent measure) is made up of several dependent measures/elements, like *self-closing doors*, *screening*, *double doors*, etc. Individually, these can be classed as dependent measures or elements.

Other dependent measures may be: *producer registration*, *training*, *trapping*, *field controls*, etc. and many other similar elements that help support the independent measure/major component for risk management.

Other dependent measures/elements associated with SA are being employed as safeguards (safeguard measures). They can be actions required either in the exporting country such as *containment of the shipment* to protect from re-infestation and to maintain the integrity of the shipment or in the importing country to protect the importing country from an introduction of the pest when further mitigation is taking place. Safeguard measures may also be required in a shipment transiting third countries.

At least one of the dependent measures/elements is an action that verifies the effectiveness and or compliance of the independent measure/major component for risk management. These related elements include *trapping by the NPPO* (dependent) in an *area of low pest prevalence* (independent), *regular inspections by the NPPO* (dependent) of a *pest exclusion structures* (independent), and *monitoring of performance by the NPPO* (dependent) of a *less than probit-9 post-harvest treatment* (independent).

Certain specific dependent measures/elements used by the grower to support the independent measure/major component for risk management may not be required by the importing NPPO, but are actions commonly used to ensure compliance with a required component. An example of this is when a low level

of pest population is required in a SA; the specific *field controls* used by the grower may be optional. This would be an outcome based requirement, as opposed to a prescriptive based requirement.

The dependent and independent measures that are integrated into a specific SA are agreed by the importing and exporting countries, or regions. These measures should be not only efficacious, but also technically and economically feasible.

For further information, appendices 1 and 2 list actual and potential dependent and independent measures used as part of SA.

4.3 Preharvest and Harvest Measures

This section provides an outline of the main pre-harvest independent measures/major components of a SA, and describes some of the pre-harvest dependent measures/elements that may collectively form major components.

4.3.1 Fruit Fly Areas of Low Pest Prevalence

The concept of an area of low pest or disease prevalence is referenced in the Article 6 of the WTO SPS Agreement, in the context of risk management options for exporting agricultural commodities. An Area of Low Pest Prevalence (ALPP) is defined as “an area, whether all of a country, part of a country, or all or parts of several countries, as identified by the competent authorities, in which a specific pest occurs at low levels and which is subject to effective surveillance control or eradication measures” (ISPM No. 5: FAO, 2010). The IPPC has further detailed the ALPP in ISPMs Nos. 22 (*Requirements for the establishment of areas of low pest prevalence*, FAO, 2005), 29 (*Recognition of pest free areas and areas of low pest prevalence*, FAO, 2007), and 30 (*Establishment of areas of low pest prevalence for fruit flies* FAO, 2008).

In ISPMs No. 29 and 30, it is indicated that an ALPP needs to be officially recognised by the importing country. It is not stated but is implied an ALPP should be recognised as a stand-alone option for pest risk management to achieve the ALOP agreed between the exporting and importing country. However, for quarantine pests ALPPs are not used as a stand-alone measure for export; in practice, they are employed as a major component of SA. Therefore, if a fruit fly area of low pest prevalence (FF-ALPP) is part of a SA, official recognition for the FF-ALPP is not necessary because the recognition would be for the SA as a whole. On this basis, hereinafter, when mentioning FF-ALPP, we refer to the area where the pest population is in low prevalence regardless of whether it has been officially recognised or not.

An ALPP can be established intentionally, can be confirmed to occur naturally or as a side product of a programme, such as the buffer zone of an established fruit fly free area or an on-going pest eradication programme.

Preharvest surveillance activities

Surveillance systems based on trapping as a component of SA are similar to any those in any type of FF-ALPP. The surveillance used in an FF-ALPP may include those processes described in ISPM No. 6 (*Guidelines for surveillance*, FAO, 1997), ISPM No. 26 (*Establishment of pest free areas for fruit flies*, FAO, 2006), the “*FAO/IAEA Guidelines for fruit fly trapping*” (FAO/IAEA, 2003) and any other relevant scientific information.

Fruit sampling as a routine surveillance method is not widely used for monitoring fruit flies except in areas under fruit fly control by SIT, where it may be an important tool.

Reduction of target fruit fly species population level

Specific control measures may be applied to reduce fruit fly populations to, or below, the specified level of “low pest prevalence”. Suppression of fruit fly populations usually involves the use of more than one control option. Thus, the integrated pest management of the total pest population within a delimited area – AW-IPM programmes – are the best option to suppress the target fruit fly pest. This would entail preventative control of an insect pest species, in this case the target fruit fly population, throughout its geographic range, rather than reactively as field-by-field control.

Suppression techniques commonly used in an AW-IPM approach against fruit fly populations include: the use of selective insecticide-bait for ground or aerial spraying, bait stations, sterile insect technique, male annihilation technique, and biological control. Additional measures are described in ISPM No. 22 (*Requirements for the establishment of areas of low pest prevalence*, FAO, 2005).

Measures related to movement of host material or regulated articles

Sometimes quarantine measures, other than official quarantine stations, may be required to reduce the risk of entry of the specified pests into the FF-ALPP. These are outlined in ISPM No. 22 (*Requirements for the establishment of areas of low pest prevalence*, FAO, 2005).

Public awareness

Public information and active stakeholder engagement is an essential element for successful AW-IPM of fruit flies. This is important for preventing reintroduction as well. Public awareness can be supported by media campaigns, field days, workshops, signage and active enforcement.

4.3.2 Preharvest Pest-Exclusion Structures

Exclusion structures to prevent fruit fly introduction to a production site may consist of a glasshouse or greenhouse. In this way, these structures act as enclosed, fruit fly free production sites.

Examples of dependent measures of pest exclusion structures include screening with an appropriate mesh size, self-closing doors and double doors to exclude fruit fly entry. Additional dependent measures for pest exclusion structures, which are shared by the FF-ALPP, may be surveillance, quarantine measures, and public awareness.

4.3.3 Host Status

Determination of host status is a fundamental aspect of pest risk assessment of fruit flies. There is evidence to indicate that some fruits, although listed in scientific literature as hosts of particular fruit fly species, are actually non hosts or non-natural hosts. In other cases, if true hosts, they can be very poor hosts. If non-natural host status is confirmed, risk management measures for that fruit fly species may not be required.

When in doubt about the relative susceptibility of a commodity targeted for export, an internationally accepted protocol to determine its host status and the factors that affect such status may be used. There are currently two regional standards for determination of host status: RSPM No. 30 prepared by the North American Plant Protection Organization (NAPPO) and the RSPM NO. 4 prepared by the Asia and Pacific Plant Protection Commission (APPPC).

Examples of dependent measures/elements of host status include: resistant or tolerant cultivars characterized as poor hosts, harvest at a specific maturity stage when the fruit is not susceptible, rigorous cultural and sanitation practices, and natural or artificially induced absence of preferred hosts.

4.4. Post-harvest Measures

This section provides an outline of the main post-harvest independent measures/major components of a SA, and describes some of the post-harvest dependent measures/elements that may collectively be part of them.

4.4.1 Less than Probit-9 Postharvest Treatments

A post-harvest treatment (heat, cold or fumigant) that achieves less than probit-9 efficacy for fruit fly control may be used as an independent measure in combination with (an) other independent measure(s) to achieve the desired level of risk management, or ALOP.

Acceptance of any treatment as a risk management measure is more likely if data is available showing the level of efficacy of the disinfestations (e.g. mortality, or impact on viability). In this instance, the treatment's efficacy may be estimated to be at least up to a specific level, i.e. less than probit 9, but perhaps not documented as being above that point. Therefore, to be accepted, it becomes a major component of SA with requirements for additional measures, rather than a stand-alone treatment.

Examples of post-harvest treatments include: heat treatments (vapour, forced air and hot water), cold treatment, fumigation (MB, ethyl formate, HCN etc.),

chemical dips, controlled atmosphere, and irradiation. Whilst there may be accepted protocols with demonstrated probit-9 outcomes, these same treatments may be applied in a way in which they become less than probit-9 post-harvest treatments (e.g. lower dosage, shorter time period, less temperature change, etc). The impact of any other treatments or procedures that are part of standard commercial practice that may not be directed at the target fruit fly species, but have a proven detrimental effect on the target species, may also be considered.

4.4.2 Segregation and Safeguarding of Commodities

Once SA procedures have been applied, it is crucial to ensure that post-harvest infestation with the target fruit fly species does not occur. The SA-managed commodities must be segregated from other products and safeguarded from other sources of (re)infestation during the processing and packaging phase.

Examples of dependent measures to ensure that fruit flies cannot infest a product at this stage are: screened processing facilities to exclude fruit fly entry, segregated containment facilities for products produced under a SA protocol, and appropriate packaging material (screened boxes, shrink wrapping, etc.) to exclude fruit fly infestation during transport.

4.5. Measures at Entry and Distribution

In some cases, in cooperation with the exporting country, the NPPO of the importing country may agree to implement one or more phytosanitary measures on arrival of the consignment as part of the SA.

4.5.1 Inspection

Inspection of a commodity for the specific fruit fly species of concern may be conducted post-harvest and prior to export and/or at the point of entry. This independent measure or major component can be a risk reduction measure and or a verification tool. Sampling rates may be increased or decreased dependent upon the level of security required by this component.

Inspection for larvae will generally require fruit cutting but external host damage or other external visual signs may also be used. Sample rates and methodology should be determined by the level of assurance required.

Examples of dependent measures/elements of inspection include: sampling during or immediately following harvest, in line fruit sampling prior to packaging (this may occur at various stages during the processing phase), sampling following processing and packaging of a commodity but prior to export and pre-clearance inspection by the importing country authorities prior to export.

4.5.2 Limited Distribution

Another possible independent measure/major component of a SA is limiting the points of entry or product distribution on a geographical basis to areas where it is considered that the likelihood of establishment and spread of the target fruit fly species is extremely low, should a consignment enter the area infested.

4.5.3 Seasonal Periods of Entry

Limited periods of entry may be used as an independent measure or major component to restrict entry on a seasonal basis to when it is considered that the likelihood of establishment and spread of the target fruit fly species is extremely low, should a consignment enter infested. This may be during periods with predictable harsh weather in the importing area, so that any entering pest could not survive, or when host plants in the importing area are not at a susceptible phase to be infested.

4.5.4 Reconciliation

If a commodity consignment is found to be infested, reconciliation steps may be taken to address the risk. Reconciliation is used as an independent measure or major component and may take the form of destruction, dumping or deep burial of the infested product, physical treatment (heat, cold, fumigation, irradiation, etc.) of the infested product using an approved disinfestation protocol, or redirection of the consignment to a non-fruit fly sensitive market. It should be noted that the specific steps taken are likely to be agreed in advance as part of a work plan, by bilateral discussions with the importing country.

4.6. Work Plan

Once an SA is designed and agreed between the exporting and importing country, there is a bilateral process for developing a protocol for the implementation and agreement on verification of efficacy and corrective actions if the system fails. This is normally documented in one file as a Work Plan (WP) or Protocol for Export.

This WP or Protocol for Export is based on the bilateral agreement between NPPOs and on agreements with other stakeholders. This discussion and agreement provides a high degree of phytosanitary security by providing clear understanding of the SA and its objectives, identifying the risk management capacity of each component/participant, and by defining the expectations of the importing NPPO. Components of the SA would be reviewed and evaluated regularly (see below) and the results should feedback into the WP. Appendix 3 provides more comprehensive information about the content of a WP.

It should be noted that currently for imports to the European Union member states, bilateral WPs are not widely used, but rather intervention occurs only

when it appears that the end point requirements are not being met. And, sometimes trade is agreed on a regional basis.

4.7. Verification and Corrective Actions

The system developed using SA will be verified over time using predetermined control points (points in the system that may be measured and monitored with indicators such as trapping, fumigation readings, fruit cutting, thermal treatment readings, inspection of exclusion structures) and end point performance in terms of absence of pests in the trade (or more accurately lack of detections).

Both individual components and the overall system may be audited against original objectives and expected effectiveness of measurements. Audits may be conducted by the importing or exporting countries at planned periods or in response to an event, such as an increase in trapped pests in the field or a pest detection in trade.

If there is a failure of the system, then one can increase the phytosanitary protection either by improving the individual components (either their design or their application) or by enhancing the overall system, for instance by adding additional components. Depending on the source of failure, additional components might be non-technical measures, such as improved record keeping, personnel training, or public information campaigns.

4.8. Assessment of Efficacy of a Systems Approach

An SA may be developed or evaluated in either a qualitative or quantitative manner, or a combination of both. A qualitative approach is more appropriate where efficacy is estimated by expert judgement (ISPM No. 14, FAO 2002), although judgement may be quantified using scores and ranking selected by the experts. A quantitative approach is more appropriate where suitable data is available, such as that usually associated with measuring the efficacy of treatments, expressed as mortality, infestation rate, etc. Efficacy can be estimated selectively, for parts of the system (individual measures), or for whole systems.

The overall efficacy of a SA is comprised primarily on the cumulative efficacy of required independent measures, since the role of dependent measures/elements is to support the function of the major component. Estimates of the efficacy of dependent measures may increase confidence of the whole system.

Clear estimates of efficacy are needed in the design phase of any SA, to compare it against the established or agreed ALOP. In certain cases (e.g. when there is high uncertainty about the pest or the impacts) the independent measures/major components of a SA are designed to intentionally provide redundancy to the system, which assures a significant level of protection even if one of the components fails.

Real performance is then measured against the efficacy as designed. When additional data is available, its potential impact on the efficacy of the system can be determined. An advantage to SA is the flexibility for adding components or removing components according to the ongoing performance in comparison to predicted efficacy, or an increase in confidence level after a certain volume of trade.

Wherever possible this should be expressed in quantitative terms with a confidence interval. For example, efficacy for a particular situation may be determined to be no more than five infested fruit from a total population of one million fruit with 95% confidence. Where such calculations are not possible or are not done, the efficacy may be expressed in qualitative terms such as high, medium and low (ISPM No. 14, FAO 2002).

4.8.1 Qualitative Methodologies

Use of expert judgment is a qualitative method often used in estimating efficacy of the independent measures/major components of a SA. Expert judgment may also be used in quantitative analysis. Expertise can be found in action agencies, industry and regulatory bodies with substantial experience in implementation of WPs, and other relevant sources.

Historical data and extrapolated data from similar situations also can be sources of important qualitative information.

4.8.2 Quantitative Methodologies

Quantifying the efficacy of single treatments (e.g. heat treatments) has been a standard practice when they are used as a stand-alone measure. Similarly treatment efficacy also can be applied when a lesser mortality level might be required, as an independent measure/major component of a SA. The procedures used to calculate efficacy in this case follow standard methodologies that result in a calculated level of mortality (or survivorship) subject to larger scale confirmatory tests.

The verification of a low pest prevalence area can employ efficacy measurements through statistical calculations based on trapping of target pests to establish a general qualitative population assessment (e.g. high to low populations). This can be followed by fruit cutting or holding of host commodities to allow surviving insects to emerge from infested fruit.

Other important sources of quantitative information can be derived from data on specific experimental components reported in scientific literature or historical data often available from end-users or regulatory bodies that collect information on target pests.

4.8.3 Methods of Quantifying

There is no internationally agreed or harmonized methodology to quantify or qualify efficacy of a SA at this time. Some of the commonly used methods

measure the efficacy of the whole system, while others measure major components.

Postharvest treatment (PHT) confirmatory tests for less than probit-9 mortality (i.e. 95%), follows similar, well-established methods to those used for probit-9 (99.9968%).

Sampling might provide efficacy calculations of the total system or a single major component. For example, fruit cutting of fruit on the tree can estimate infestation levels before the product is subjected to a PHT. If the fruit sampling is at the orchard level, the efficacy of the ALPP component may be determined.

Mathematical models (calculating probability e.g. of a mating pair of the pest surviving) can be useful in quantifying efficacy, but one must apply caution to assuming that outputs from mathematical models are completely accurate. Such models frequently require large data sets that not often available. Other examples of mathematical modeling act more as frameworks for considering available data, or preferred outcomes. This includes modeling to set maximum pest limits, using available data to estimate sequential mortality, and systems modeling.

Recent advances in the application of Bayesian modeling for plant health have shown how to use what data is available to provide estimates of efficacy. Whilst limited by lack of data, this approach can indicate which points in a system are most critical through sensitivity analysis, so that additional efforts to collect data or increase confidence may be focused on the most significant questions. Modeling of this nature also may help to clarify which measures are independent and dependent, and their relative relationships.

Point estimates, range estimates or probabilistic estimates can be used. At Risk™ and Oracle™ are 2 software packages that can be used for probabilistic estimates.

APPENDIX 1. Generic Examples of Systems Approaches

Case	Regulated Pest	Independent Measure (major component)/Stage	Dependent Measure (elements)/Stage
Tomatoes from Guatemala to USA	Mediterranean fruit fly (<i>Ceratitidis capitata</i>)	<ul style="list-style-type: none"> • Poor host status/Preharvest • Fruit fly free growing structure/Preharvest • Low prevalence area as buffer/Preharvest 	<ul style="list-style-type: none"> • Double doors/Preharvest • Traps/Preharvest • Documents that credit greenhouse and buffer area/Postharvest • Product packed in boxes and protected (covered) while being transported to facility/Postharvest • Sampling of 0.5% fruits (visual and dissection)/Postharvest • Insect proof packing facility/Postharvest • Traceability of the product (labeled boxes ID codes)/Postharvest • Phytosanitary certificate/ • Postharvest

Case	Regulated Pest	Independent Measure (major component)/Stage	Dependent Measure (elements)/Stage
Citrus from Florida to Japan	Caribbean fruit fly (<i>Anastrepha suspensa</i>)	<ul style="list-style-type: none"> • Poor host status/Preharvest • Low pest prevalence as buffer/Preharvest • Fruit cutting/Postharvest 	<ul style="list-style-type: none"> • Removal preferred host/Preharvest • Trapping/Trapping • Field control treatment/Preharvest • Restricted harvest period/Preharvest
Sweet melons and watermelons from Ecuador to the USA	South American melon fly (<i>Anastrepha grandis</i>)	<ul style="list-style-type: none"> • Pest free production site • Limited distribution in the USA 	<ul style="list-style-type: none"> • Boxing requirements • Trapping • Fruit cutting
Papayas from Guatemala to the USA	Mediterranean fruit fly (<i>Ceratitidis capitata</i>)	<ul style="list-style-type: none"> • Low prevalence area • Host status • Less than Probit-9 treatment 	<ul style="list-style-type: none"> • Trapping • Field sanitation

APPENDIX 2. Existing and Potential Measures for Systems Approaches

Measure	Description	Stage	Verification
Hygiene (cultural practices, etc.)	Systematic removal and destruction of culled fruit, and raking of soil and debris under host plants to destroy pupating larvae. Raking of soil and debris is resource-intensive and generally only applicable to perennial orchards.	Preharvest, harvest, grading and packing	Verification of orchard and pack house procedures (including visual observation of orchards and pack house procedures)
Management of alternative hosts	Treatment and/or destruction of alternative host plants (commercial, domestic and wild) to minimise potential fruit fly reservoirs.	Preharvest	Verification of orchard records (including visual observation of orchards)
Rotation of crops	Applicable only to annual crops where available production sites are extensive. May serve to slow the build-up of fruit fly pressure in production areas. Difficult to integrate in a SA.	Preharvest	Verification of orchard records
Trap cropping with preferred hosts	Minimal existing use. Difficulties in controlling timing of trap crop development to coincide with that of the crop being protected. May be useful as a measure for part of the duration of a production period. Chemical treatments will generally need to be applied to the trap crop. May also be useful as an indicator of pest prevalence.	Preharvest	Verification of orchard records
Minimise free-standing water	The use of trickle irrigation and mulching systems to minimise available water can assist fruit flies to die-off, particularly in hot temperatures	Preharvest	Verification of orchard records (including visible observation of orchards)
Production timing	Production may fully or partially coincide with periods of low pest prevalence (e.g. during winter or where host availability has been limited).	Preharvest, harvest, postharvest	Verification through agreed production and export periods based on fruit fly biology/ecology. Ongoing verification through monitoring pest populations.

Measure	Description	Application point	Verification
Use of marginal geographic areas	Geographical and climatic characteristics of some production areas or sites may limit pest populations.	Preharvest, harvest, postharvest	Verification through agreement and ongoing monitoring of pest populations.
Bagging of fruit	Physical pest exclusion and a means for maintaining fruit quality. Resource-intensive.	Preharvest, harvest	Verification of orchard records (including visual observation of fruit and harvest procedures).
Glasshouse/netting production systems	Pest exclusion through physical protection of production sites.	Preharvest, harvest	Verification through certification and visual observation of integrity of production sites. Ongoing pest monitoring within the protected area.
Maintenance of buffer zone	Buffer zones in the form of an area of low pest prevalence provide a barrier (either through natural characteristics or control activities) to the movement of pest species into the area being protected (e.g. pest free sites of production)	Preharvest, harvest, grading, packing	Verification through pest monitoring activities and audit of control programs.
Regulation of the movement of restricted articles	Not as strict as for pest free areas, it can be a key tool in protecting areas of low pest prevalence and pest free production sites, Regulation provides the foundation to enforce exclusion of human-assisted movement of pests into protected areas.	Preharvest, harvest, grading, packing	Verification through compliance audits and ongoing investigation of incidents.

Measure	Description	Application point	Verification
Sterile insect technique	The release of large numbers of sterile male fruit flies into a defined area-wide in order to suppress fruit fly populations. The technique achieves greatest success when the movement of wild fruit flies into the target area can be managed concurrently.	Preharvest, harvest, grading, packing	Verification through compliance audits of sterilisation activities and release programs.
Biological control – parasitoids, pathogens and predators	The release of large numbers of parasitoids, pathogens and predators may suppress fruit fly populations, Currently use of predators and pathogens is minimal, requires further investigation.	Preharvest, harvest, grading, packing	Verification through pest monitoring activities and examination of recovered larvae.
Host status	Independent (e.g. cultivar) or dependent (e.g. maturity + skin integrity) measures depending on host-fruit fly interactions.	Preharvest, harvest, post-harvest	Verification through audit of parent stock records (where applicable) and inspection of fruit during harvest, grading and packing operations.
Male annihilation	Use of pheromone attractant and insecticide to lure and kill male fruit flies. May interfere with trapping programs. Compatible with IPM as pest-specific.	Preharvest	Verification of orchard records and ongoing monitoring of fruit fly populations.
Bait sprays	The use of a protein bait and insecticide to attract and kill fruit flies. Requires a rigorous application regime and efficacy is dependent on climatic conditions. Compatible with IPM programs.	Preharvest	Verification of orchard records and monitoring fruit fly populations.

Measure	Description	Application point	Verification
Mass trapping	Same principle as male annihilation but a potentially more expensive option. Trapping is predominantly used for monitoring purposes but can be used intensively for the mass capture of insects. Compatible with IPM.	Preharvest	Verification through monitoring orchard records and trap catches.
In-field chemical sprays	Application of bait sprays to hosts (targets and alternatives) to manage pest fruit flies. Dependent on availability of chemicals for this application and is well suited to managing high pest pressures. Disruptive to IPM programs but useful for managing alternative hosts that cannot be removed.	Preharvest	Verification through canopy penetration tests, ongoing monitoring and orchard records.
Segregation and safeguarding of product	Certified product clearly segregated from non-certified product, and safeguarded to prevent infestation.	Harvest, postharvest	Verification through monitoring and auditing procedures and records.
Cold disinfestation	Physical treatment to meet agreed levels of phytosanitary protection. The rigor of the treatment will depend on the level of pest risk reduction achieved by other measures of the system. Can be conducted following pre-export, during export or on-arrival.	Pre-export, during export, on-arrival	Verification through treatment chamber certification processes and monitoring treatment records.
Heat disinfestation	Physical treatment to meet agreed levels of phytosanitary protection. The rigor of the treatment will depend on the level of pest risk reduction achieved by other measures of the system. Typically conducted prior to packing.	Pre-export, on-arrival	Verification through treatment chamber certification processes and monitoring treatment records.

Measure	Description	Application point	Verification
Irradiation	Physical treatment that can be used on a broad spectrum or targeted basis. Can be conducted pre-export or on-arrival.	Pre-export, on-arrival	Verification through treatment chamber certification processes and monitoring treatment records.
Inspection and reconciliation	Can be conducted at a number of points following harvest, including on arrival in the importing jurisdiction. Can be used as a risk reduction measure as well as a verification activity.	Postharvest, pre-export, on-arrival	Verification through auditing inspection and reconciliation procedures.
Processing	Processing of fruit removes/reduces pest risk. Not generally relevant to the fresh produce trade, but may be useful for the pre-packaged food trade and as a measure for treating non-conforming consignments.	Pre-export, on-arrival	Verification through auditing security arrangements and processing procedures.
Chemical disinfestation (fumigation)	Post-harvest dips, sprays and fumigation treatments. The rigor of the treatment will depend on the level of pest risk reduction achieved by other measures of the system. In the case of dips and sprays the treatment is generally conducted prior to packing. Fumigation may be conducted before or following packing.	Pre-export, on-arrival	Verification through treatment chamber/dip tank/spray equipment certification processes and monitoring treatment records.
Washing and waxing	Activities generally used to improve fruit quality and appearance may have minimal effects on fruit flies.	Pre-packing	Verification through audit of process procedures.

APPENDIX 3. Work Plan

This document, also called a Protocol for Export, is a guide for the implementation of a SA for export of a named commodity, from a specific area where a particular fruit fly species of phytosanitary concern occurs. It should always indicate this commodity (host)/area/pest combination, or say if it applied to more than one commodity or pest in that area.

Most often it includes:

- Products being exported
- Pest and organisms of concern
- Area of production
- Participating organizations and their responsibilities
- Operational procedures, including verification
- Contingency or corrective actions plans

Commodities for Export

A specific commodity, or group of related commodities, is named in the PRA. The commodity should be referred to by species, variety and type, if relevant. Based on the outcome of the PRA, the proposed trade of the commodity is accepted between the importing and exporting countries.

Pest and Organisms of Concern

The species of possible pests associated with the commodity for export/import, including fruit fly species, are identified in the PRA. The fruit fly species, and possibly other pests, covered by the SA should be referred to in the WP by specie, and if necessary by subspecies or race. Because there may be risk from more than one pest, there may be more than one pest risk management system.

Export Area

This is the production area from which the products are being exported, as proposed and accepted between the trading parties. Sometimes it is called the protocol area. As an example, the export area can comprise a single or several greenhouses/screen-houses, with an ALPP as a buffer zone surrounding them. It can also comprise single or several production sites with an ALPP as a buffer zone surrounding all of them.

Participating Organizations and their Responsibilities

There are two types of entities involved in the implementation of the WP, the NPPOs of the exporting and the importing countries, and the industry of each country. Industry, in this instance, includes the persons involved in producing and exporting the host commodities, and sometimes those involved in

importing them. These persons may be an individual, partnership, corporation, company, legal society, association, or other organized group.

The main responsibilities of the NPPO of the importing country are related to supervision, inspection and verification of activities outlined and described in the WP, which are carried out by the NPPO and industry of the exporting country. The main responsibilities of the NPPO of the exporting country are related to the administration of the WP, these activities may include:

- Approval and certification of the places of production
- Approval and certification of the packing houses
- Approval and certification of the treatment facilities
- Informing to their NPPO counterpart of any major problem that might jeopardize SA implementation
- Supervision of the activities carried out by the industry
- issuing of export phytosanitary documentation

Reviews

The WP should be reviewed and updated every year by the participants to keep an SA operating efficiently. This review takes place either at the beginning or at the end of the harvest season, or when serious failures are detected in the system. Any revisions, including the modifications agreed upon to prevent future failures, usually are made before the beginning of the following harvest season. If it is a continual-production commodity, modifications to the SA may be performed at any time agreed by the trading parties.

Compliance Agreement

To make sure that the industry of the exporting country understands the provisions of the WP and is willing to implement it, a “Compliance Agreement” between the NPPO of an exporting country and its industry is useful.

Major provisions included in the Compliance Agreement may be, but are not limited to:

- register with the NPPO for production, treatment and/or packing of the products for export
- cooperate with NPPO to carry out fruit fly surveillance and control procedures
- comply with the requirements relative to the origin of the product, its transportation to the treatment or packing facility, selection, packing, inspection, certification, security and transportation to the point of entry (e. g. use of stamps, specific labeled boxes, avoid reuse of packing material, etc)
- keep records of fruit fly surveillance and control procedures

- make records available at all times to NPPO's of the exporting and importing country
- Inform the NPPO's of the exporting country of any major problem that might jeopardize the implementation of SA.

The WP may include specific provisions related to the necessary funding to carry out the supervision, verification, inspection and administration activities.

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Glossary of Acronyms and Terms

ALOP	Appropriate level of protection
ALPP	Area of low pest prevalence. For the purpose of this guidelines the ALLP means an area in which the target pest occurs at low levels (adapted from the FAO ISPM no. 5, Glossary of Terms)
APPPC	Asia and Pacific Plant Protection Commission
AW	Area wide. This concept refers primarily to a total population in a delimited area, the influence of migration/dispersal on its dynamics, and its ecological relationships within its ecosystem (Hendrichs <i>et al.</i> 2007)
Compliance Agreement	A written agreement between the NPPO and the industry of the exporting country engaged in the production, treatment, packing and transport of host commodities to the importing country.
Element	A dependent measure when added with other dependent measures that will collectively constitute an independent measure (major component), as defined in this paper.
Host (Natural Host)	A plant species that has been unequivocally found infested under totally natural field conditions (i.e., nothing is manipulated) (Adapted from Aluja and Mangan, 2008)
IPPC	International Plant Protection Convention
IPM	Integrated pest management
ISPM	International Standard for Phytosanitary Measures
Major component	An independent measure consisting of numerous dependent measures (elements)
Non-host	A plant species that will not support the complete development of the target species regardless of the stage of maturity and physical characteristics (Adapted from APPC RSPM No.4)
NAPPO	North American Plant Protection Organisation
NPPO	National Plant Protection Organisation NPPO
PFA	Pest free area
PFPS	Pest free production site A defined unit(s) of production in which the target pest does not occur.
Phytosanitary Condition	Phytosanitary relationship between host commodity, target fruit fly species and specified area or site of production of the host commodity
PRA	Pest Risk Analysis
Protocol Area	An area where a SA is applied under agreement between the NPPO of the exporting and importing countries,
Probit-9	A statistical level reaching 99.9968%, for example used to refer to a treatment designed to achieve that level of mortality
Redundancy	The duplication of an effect created by two different measures in order to produce an impact higher than the required.
RNQP	Regulated non-quarantine pest
RSPM	Regional Standard for Phytosanitary Measures
SIT	Sterile Insect Technique
SPS	Agreement on the Application of Sanitary and Phytosanitary Measures, WTO
TFFF	Technical Panel on Fruit Flies on Pest Free Areas and Systems Approach of the IPPC
WP	Work Plan. Also known as Export Protocol.
WTO	World Trade Organisation