Appendix 1
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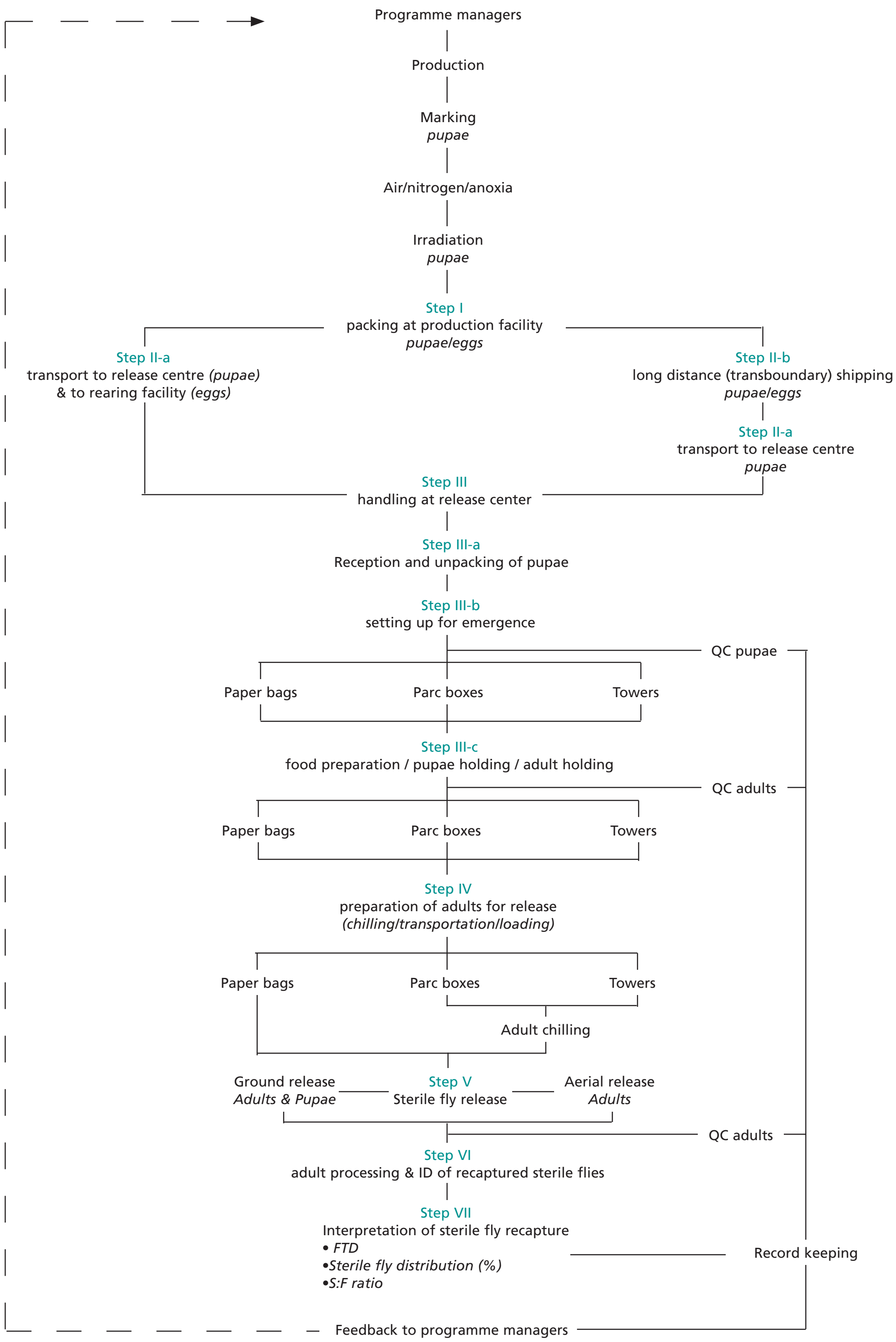
APPENDIX 2
Flow chart of sterile fly release process



Appendix 3
Data sheets for shipment of sterile pupae

A copy of this datasheet should be present within each box of the consignment.

Name and address of the facility (origin):	**Name and address of the recipient:**

Consignment General Information			
Irradiation date:	____________	Irradiation dose (Gy):	____________
Packing date:	____________	Shipping date:	____________
Total No of boxes:	____________	Total weight (kg):	____________

	Box Number within the Consignment											
Elements	1	2	3	4	5	6	7	8	9	10	**Total**	**Observations**
Number of pupae containers inside the box[1]											a	
Weight (kg)											b	
Number of pupae containers with radiation sensitive indicator											c	
Number of indicators that were exposed to the recommended dose[2]											d	
Number of indicators countersigned at the origin, after irradiation											e	

[1] Plastic bags, "sausages" or other
[2] "Visual determination"

Observations: ____
____

Authorization: ____

(a) Ideally a=c=d=e

(b) This value should be equal to the total weight reported under "General Information"

(d) Should it differ from value in (a), the consignment should be disposed safely and not used

Appendix 4
History of transboundary shipments of sterile tephritid fruit flies

Year	Tephritid species	Site of production	Amount shipped (million pupae)	Recipient	Observations
1963-1990	Mexican fruit fly, *Anastrepha ludens*	Monterrey, Mexico	Unknown	Texas, USA	
1970/71	Mediterranean fruit fly, *Ceratitis capitata*	Seibersdorf, Austria	Unknown	Procida, Italy, and Greece	Relatively small amount since sterile flies were used for field trials
1970	Mediterranean fruit fly	Costa Rica	Unknown	Nicaragua	Relatively small amount since sterile flies were used for field trials
1975-1977	Mediterranean fruit fly	Madrid, Spain	302	Canary Islands	
1978	Mediterranean fruit fly	Seibersdorf, Austria	Unknown	Guatemala	Sterile pupae shipped from the IAEA laboratories (Seibersdorf) to a packing and emergence facility in Guatemala for field trials and staff training in SIT techniques
1979-2000	Mediterranean fruit fly	Chiapas, Mexico	280,000	Guatemala	Biweekly transboundary shipments have been carried out for the past 21 years
1989-1994	Mediterranean fruit fly	Chiapas, Mexico	6,670	California, USA	To assist the CDFA in eradication of medfly outbreaks
1990	Mediterranean fruit fly	Chiapas, Mexico	552	Chile	Sterile flies donated by the Mexican government to Chile
1989-1990	Mediterranean fruit fly	Seibersdorf, Austria	Unknown	Israel	Pilot trials
1994	Mediterranean fruit fly	Seibersdorf, Austria	60	Tunisia	Pilot trials
1996-2000	Mexican fruit fly	Chiapas, Mexico	2,511	California, USA	To assist the CDFA in eradication of Mexican fruit fly outbreaks
1994-2001	Mediterranean fruit fly	El Pino, Guatemala	51,800	California, USA	To assist the CDFA in eradication of medfly outbreaks
1997/98	Mediterranean fruit fly	Madeira, Portugal	206	Israel	In support of pilot suppression programme
1997-2000	Mediterranean fruit fly	El Pino, Guatemala	1,000	Israel	In support of pilot suppression programme
1998-2001	Mediterranean fruit fly	El Pino, Guatemala	19,500	Florida, USA	To assist the State of Florida in eradication of medfly outbreaks
1999-2000	Mediterranean fruit fly	El Pino, Guatemala	600	South Africa	In support of pilot suppression programme
TOTAL			**363,201**		

Appendix 5
Transboundary shipment of sterile insects

Prepared by an FAO/IAEA Consultants Group
30 July to 3 August 2001, Vienna, Austria

PREAMBLE

A Consultants Group Meeting was held to discuss the potential risk[1] from transboundary[2] shipment of sterile insects for pest control programmes. This meeting took place in Vienna at the Joint FAO/IAEA Division of Nuclear Techniques in Food and Agriculture, from 30 July through 3 August 2001. The group of consultants (see Annex 1) was called together in response to requests for guidance from national plant protection organizations (NPPOs) in light of the growing demand for alternatives to pesticide use as an exclusive control measure and the increasing interest from the private sector to invest in the Sterile Insect Technique (SIT).

The aim of the meeting was to characterize the potential risk posed by transboundary shipment of sterile insects shipped for SIT programmes and to reach conclusions regarding the level of risk. In the process of this analysis, the group identified some routinely applied procedures, including best practices for shipment that reduce the risk to a negligible level. However, there currently are no internationally recognized guidelines for regulating shipment of sterile insects.

Harmonized guidance regarding regulation of the shipment of sterile insects will facilitate trade while addressing concerns about shipment of what could be quarantine pests. This document was developed as a discussion paper for consideration by the Interim Commission on Phytosanitary Measures (ICPM), the governing body for the International Plant Protection Convention (IPPC).

One possible result of this discussion paper will be the development of an international standard providing guidance on measures pertaining to the transboundary shipment of sterile insects. Alternatively, this topic could be added to the International Standard on Phytosanitary Measures (ISPM) regarding biological control agents (IPPC, 1996) at the time of its revision. However, certain provisions in the ISPM on biological control agents are inappropriate when considering sterile insects (e.g. holding in quarantine for the next generation). In addition, the IPPC Glossary of Terms (IPPC, 2001) definition of biological control excludes the SIT.

In the interest of harmonization, similar discussions may be needed at the Office International des Epizooties (OIE) and the World Health Organization (WHO)

[1] "Risk" in this context includes both the likelihood and the consequences of an adverse event occurring

[2] "Transboundary" in this context refers to entry (Customs and Agriculture clearance) of a shipment into the importing country as well as transit shipment through a third country. Transit may or may not involve transloading.

regarding the use of sterile insects for control of human or animal diseases.

EXECUTIVE SUMMARY

- The increased use of the Sterile Insect Technique (SIT) to suppress or eradicate insect pest populations is resulting in increased shipment of the sterile target insect pests from one country to another, often passing in transit through other countries. These transboundary shipments are not subjected to international standards for biological safety.

- As the SIT becomes more commercial, the need for guarantees that the sterile insects can be safely and legally shipped are essential to encourage financial investments in commercial sterile insect mass rearing facilities. Also, international regulations are required to reduce the need for independent development of national regulations that may hinder the insect control programmes.

- The objective of the Consultants Meeting was to prepare a discussion paper for consideration of the Interim Commission on Phytosanitary Measures (ICPM), the governing body for the International Plant Protection Convention (IPPC), as a first step towards developing an international standard or other guidance on the transboundary shipment of sterile insects. Additional discussions may be needed to address shipments of sterile insects for control of pests of veterinary and medical importance.

- The scope of the discussions was limited to radiation-sterilized insects for use in Sterile Insect Technique (SIT) control programmes against plant insect pests. Insect strains produced artificially by genetic engineering or other modern biotechnology methods were excluded.

- Four potential hazards were identified with regard to transboundary shipments of sterile insects:
  - Outbreak of the target pest in a new area, where it does not already occur.
  - Increase of fitness of the local pest population through the introduction of genetic material from the escaped insects into an area where the pest already exists.
  - Unnecessary regulatory actions being initiated following false identification of captured sterile insects and conclusion that it is a quarantine threat.
  - Introduction of exotic contaminant organisms in a shipment, other than the target species for the SIT programmes.

- Transboundary shipment of sterile insects has taken place on a continuous basis for nearly 50 years. The total number of sterile insects shipped was estimated at 962 billion in more than 12,000 shipments to 22 recipient countries from 50 sterile insect factories in 25 countries. During this long period and many precedents, no problems associated with the hazards listed above or any other have been identified, and thus the shipment of sterile insects have never been subjected to any regulatory action.

- The potential risks of the identified hazards were evaluated using a scenario analysis technique.

- The events considered for hazard 1, were: sterilization failure, shipment packages opened accidentally, escape, survival and reproduction of the sterile insects. For hazard 2, in addition to the above sequence of events, the escaped insects would have to reproduce with a local population and undesirable traits established in the population. For hazard 3, the critical points would be shipment packages opened accidentally, escape, survival and captured insects not recognized to be sterile. Hazard 4 is not unique to sterile insects and was thus not assigned a risk, as it is possible in shipments of goods of any type.

- For each hazard the calculated estimated risk was:
  1. 0.5×10^{-18}
  2. 0.5×10^{-23}
  3. 1×10^{-11}
  4. Many-fold less likely than the risk of moving biological control agents

- It was concluded by the consultants that the present systems of transboundary shipment of sterile insects for SIT programmes is very safe. However, international regulations should be developed for approval by the Interim Commission on Phytosanitary Measures (ICPM) to facilitate commercial development of the SIT.

I. INTRODUCTION

There is a growing demand for cost effective control of insect pests of plants, as well as insects of veterinary and medical importance. At the same time insecticides are under greater scrutiny for potential toxicological and environmental impacts. An alternative insect pest control method is the Sterile Insect Technique (SIT). This involves mass production of the target insect species, sterilization using ionising radiation and repeated release into the target population. The release of sterile insects that target a population of the same species is a form of "birth control". The sterile insects mate with the wild population but fertilization results in no viable offspring. Repeated releases of sterile insects lead to a reduction in the pest population.

The SIT differs from classical biological control, which involves the introduction of exotic biological control agents, in the following key areas:

- Sterile insects are not self-replicating and cannot become established in the environment.
- Autocidal control is by definition intraspecific.
- SIT used against an established pest never introduces an exotic species into the ecosystem where the SIT programme is being implemented.

The SIT has been used for nearly 50 years for eradication, suppression and control programmes of both plant and animal pests (e.g. Mediterranean fruit fly (medfly, *Ceratitis capitata*) and New World screwworm (NWS, *Cochliomyia hominivorax*). Because of the limited number of facilities for rearing and sterilization, sterile insects are often shipped for release in other locations. Transboundary shipments have gone from production facilities to release sites in countries throughout the world. Demand for SIT is rising and new commercial facilities may be constructed soon to meet this demand.

I–A. Background on transboundary shipments

Transboundary shipments of sterile insects have been made on a continuous basis for the past 46 years. The first shipment of sterile NWS was from its production site at the USDA/APHIS mass rearing facility in Florida, USA, to the Caribbean island of Curaçao in 1954. This effort resulted in the eradication of the NWS from the island that same year. This was the first eradication of an insect pest population using the SIT.

Most of the transboundary shipments of sterile insects have originated from production facilities in North and Central America for shipment to at least 22 countries in 4 continents including the Americas, Europe, Africa and Asia (see Annex 3). One example is the ongoing shipment of sterile medfly pupae from the production factory in Tapachula, Chiapas, Mexico, to the packing and emerging facility in the southwest of Guatemala. Since 1979, biweekly ground and air shipments have been carried out amounting to 280 billion sterile flies (ca. 4,830 tons) in 21 years. Another important case is the ground and air shipment, since 1992, of 104 billion sterile NWS (ca. 1,733 tons) from the screwworm factory in Tuxtla Gutierrez, Chiapas, Mexico, to all of Central America, Panama and the Caribbean.

In Europe, most transboundary shipments of sterile insects have been carried out in support of SIT pilot projects. The first case involved sterile Mediterranean fruit flies shipped from the FAO/IAEA Agriculture and Biotechnology Laboratory in Seibersdorf, Austria, to the island of Procida, Italy, in 1970. There are some other examples of transboundary shipments of sterile insects produced in Europe such as the case of the 206 million sterile Mediterranean fruit flies shipped from the mass rearing facility in Madeira, Portugal to Israel during 1997/98.

Other cases involving Europe include transit shipments of sterile pupae from Guatemala, Central America, through Amsterdam, Frankfurt or Madrid, to Israel and South Africa and from Mexico, through Frankfurt, to Libya, (see Table in Annex 3).

In the past 46 years, at least 962 billion sterile insects (equivalent to about 18,000 tonnes) have been shipped domestically and internationally. None of these shipments has ever been prohibited from transit or entry for phytosanitary reasons by the 22 recipient countries or numerous transiting countries. The sterile insects are shipped by air cargo (commercial airlines or charter planes) or by ground in refrigerated trucks. They are packed in labelled, sealed containers to prevent contamination or escape. These safeguards are in place to protect the integrity of the sterile insects and not that of the public, property or the environment in the event of a massive escape. The same measures serve as safeguards against the hazards identified in this document, however, thereby greatly reducing any risk.

I–B. EXISTING GUIDELINES

Internationally recognized guidelines on many steps in the mass rearing and sterilization of insects and quality control (materials used in production, the product and process) already exist (see References Section IX) but there are no internationally recognized guidelines for regulating shipment of sterile insects. Some countries do not regulate shipment of sterile insects, others only require labelling and documentation, and still others are regulating sterile insects under their biological control measures. In order to encourage a harmonized approach to national treatment of this method of plant pest control, some guidance on the risks involved will be very useful.

II. SCOPE

This discussion paper characterizes the risks involved with the transboundary shipment and importation (either in-transit through third countries or directly to the importing country) of sterile insects for use as autocidal control agents in control programmes of plant insect pests. Mass production site hazards and risks related to the release of sterile insects did not fall within the terms of reference of this Consultants Group.

Shipment of sterile, mass reared insects was considered including those developed through traditional selection and mutation breeding, for example sexing strains. Sterile insects resulting from strains which may be created artificially by genetic engineering or other modern biotechnology methods were excluded.

This discussion paper is also limited to the shipment of sterile insects resulting from radiation-induced sterility and does not deal with sterile insects resulting from the application of other sterilization techniques (e.g. chemosterilants or transgenically-induced sterilization).

III. HAZARD IDENTIFICATION

A key objective of the Consultants Group was to identify and characterize potential phytosanitary hazards associated with the transboundary shipment of sterile plant insect pests. The Consultants identified hazards and distinguished independent events leading to the occurrence of each hazard. This provided a format for estimating the likelihood and characterizing the consequences of each hazard in a scenario analysis[3]. Figure 1 shows the scenarios for each of the hazards.

Four potential hazards were identified as follows:

Hazard	Primary event that could result in this hazard
1. Outbreak of target insect pest in a new area	Faulty sterilization
2. Increase of fitness of local pest population	Faulty sterilization
3. Unnecessary regulatory action initiated	Faulty ID of sterile insect
4. Introduction of exotic (new) contaminant organisms	Presence of hitch-hikers in shipments

The first two scenarios require failure of the sterilization treatment as the first event. This could mean absolute failure (i.e. the shipment was not treated) or that the treatment was less than necessary to meet the required specifications for sterility.

The second event that must occur in the first two scenarios is a breach of the package to allow for spillage or escape. It is assumed that in most situations this will be under adverse conditions (e.g. airport cargo handling environment). As a result, the pest must not only be liberated (event c), but it must also survive to escape into a favourable environment (event d). Finally, it must mate and reproduce for either hazard 1 or 2 to occur. However, in the case of hazard 2, the scenario recognizes that the introduction of new genetic material in itself does not present a risk unless an undesirable genetic trait is expressed and also has a selective advantage to become established in the population (event e).

The situation in hazard 3 is not related to biological consequences but rather based on regulatory actions (e.g. delimiting survey) that may be unnecessarily taken by the country where the pest is detected but not recognized as sterile. Adverse phytosanitary measures may be put in place by trading partners based on reporting the detection without distinguishing the pest as sterile.

Hazard 4, the introduction of exotic contaminating organisms, was not characterized in the same way as the other three hazards because it is a complex

[3] Reference for scenario analysis technique (L. Miller *et. al.*, 1993).

set of sub-scenarios depending on the nature of the contaminant organisms (e.g. parasitoids, virus, etc). This hazard is also different because it is not unique to sterile insects. Similar hazards exist with shipment of biological control agents and to some extent with any shipment. In fact, the sterile insect mass rearing process virtually eliminates any parasitoids.

In each of the three scenarios (hazards 1, 2 and 3) for which independent events were identified, the likelihood of each event occurring is represented by rough estimates of the probability (a point estimate). The product of the estimates for independent events in each scenario gives an overall estimate for the probability of the hazard occurring. It is noted that the mathematical relationship of these events means that where any event in a scenario is zero, the probability for the entire scenario is also zero.

The estimates are based on data, past programme records, and experience and expert opinion, primarily as regards fruit fly and some Lepidoptera species. They involve extremely rare events for which the primary source of evidence is the substantial history of experience with SIT shipments since 1954 and detailed knowledge of the technical/scientific aspects of the technology.

This approach was used to allow the comparison of risk levels between events and hazards associated with the transboundary shipment of sterile insects. It was not intended to be quantitatively precise, but more importantly to clarify the relative differences in magnitude. It is also useful to facilitate the comparison of phytosanitary risks associated with the transboundary shipment of sterile insects with those associated with other transboundary shipments (e.g. biological control agents).

The scenario analysis process is limited to characterizing direct phytosanitary hazards associated with the range of insect plant pests historically and currently controlled by SIT for phytosanitary applications. It should be noted that the scenarios are useful for pest risk management to the extent that they help to distinguish control points where risk-reducing measures may be applied.

The process does not consider indirect hazards or evaluate the risks against the benefits (e.g., increased pesticide use without SIT). In particular, it should be recognized that although the level of risk for any particular hazard may be the same for an importing and transit country, the transit country does not benefit to the same degree as the importing country from accepting this risk. In any case measures decided by either importing or transit countries should be technically justified (based on risk analysis or an international standard).

IV. LIKELIHOOD OF THE EVENT

IV–A. Hazard 1: Outbreak of the target insect pest in a new area

Event a: Sterilization failure

An estimated 12,000 ground and air shipments of sterile insects have occurred since 1954 and two instances of partial failure to sterilize (1 confirmed and 1 unconfirmed) have been reported. The confirmed incident occurred in 1982 in a shipment of medflies from Costa Rica to Guatemala (S. Sanchez, personal communication, 1982) and the unconfirmed incident with a shipment of medflies from Peru to California, USA, in 1980 (Rohwer, 1987). Since then, international quality control standards were put in place and there have been no sterilization failures despite the significant increase in the use of SIT.

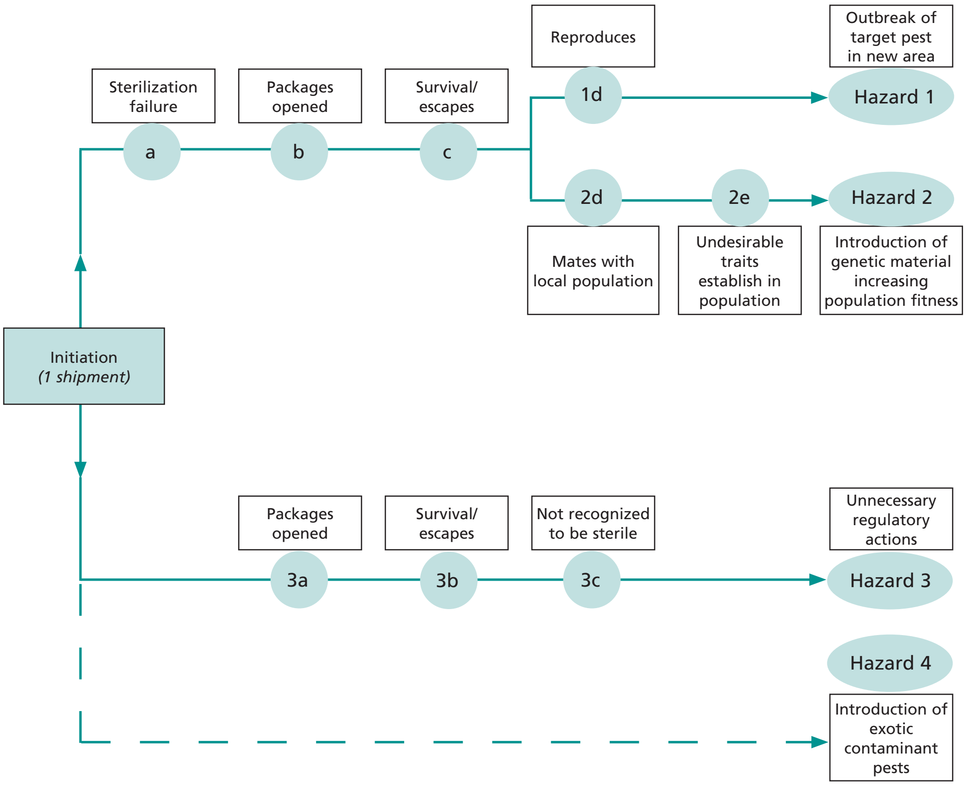


FIGURE 1
Hazard Scenarios for Transboundary Shipment of Sterile Insects

Current safeguards to prevent sterilization failure:

- Modern production facilities employ failsafe irradiation systems (i.e. physical and/or procedural) to prevent this.
- Each treated container has a dosimetry device that assures the container was irradiated.
- Minimum dosage received by all the insects far exceeds the dosage required to sterilize the females.
- Irradiators are equipped with automatic exposure settings that are tamper-proof.
- Procedures are observed for routine calibration of the equipment.
- Packages are clearly labelled as containing irradiated insects.
- A sample of insects from each shipment is bio assayed for sterility at factory and release site for quality control.

The likelihood was estimated by the consultants group to be an ***extremely rare event*** *with an estimated probability of* 0.5×10^{-6}

Event b: Packages open

In addition to the above event, it would be unlikely for the packages carrying the fertile insects to open because:

- From tens of thousands of containers shipped since 1954 there has been no documented case of breakage of shipping package.

- Using one of the longest routes (i.e. Guatemala City-Miami-Frankfurt-Tel Aviv) from 1998 to 2001, 1 out of over 400 shipments was never recovered. In this event, due to the length of time involved, highly perishable material (i.e. sterile insects) would not survive.

- Current safeguards to prevent mishandling leading to breakage of package include:
  - All consignments are double packaged, some triple packed, and then sealed.
  - Consignments are closely tracked with commercial motivation for rapid transit of highly perishable material.
  - Rapid feedback from receiver when the package is delayed.
  - Size and weight of package designed to minimize breakage.
  - All packages are appropriately labelled (e.g. fragile, biological material) and numbered.

- Content of package does not attract theft.

The likelihood was estimated by the consultant group to be an ***extremely rare event*** *with an estimated probability of 1* **× *10***$^{-5}$

Event c: Survives/escapes

In addition to the above events, the fertile insects would be unlikely to survive and disperse to a favourable habitat because:

- Immediate in-transit area is inhospitable (i.e. lack of water, food, wrong temperature, no host, concrete/asphalt substrate). Presence of insecticide/ toxicants at airports.
- Airport security prevents unauthorized removal of packages from the airport.
- Limited survival from pupal to adult stage, and even lower chance to survive to sexual maturity and disperse because of high predation, desiccation, starvation, drowning, temperature stress, etc.

The likelihood was estimated by the consultant group to be a ***fairly unlikely event*** *with an estimated probability of 1* **× *10***$^{-3}$

Event d: Reproduces

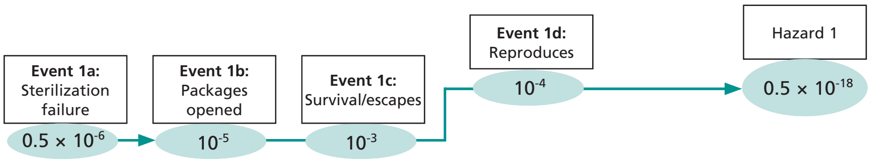
In addition to the above events, reproduction by the escaped insects would be unlikely because:

- Event may occur during seasonally inhospitable period.
- Climatic factors not suitable for establishment.
- Factory strain has lower fitness for survival in nature.
- Too few survivors to disperse and find suitable environment, mating partners and hosts.

The likelihood was estimated by the consultant group to be a ***rare event*** *with an estimated probability of* ***1 × 10***$^{-4}$

For the scenario for hazard 1 the likelihood of all four events occurring was estimated as a negligible risk with a probability of 0.5×10^{-18}

Summary of hazard 1: Outbreak of the target insect pest in a new area



IV–B. Hazard 2: Increase of fitness of the local pest population through introduction of genetic material from the escaped insects

For this scenario to take place, events 2a, 2b and 2c must occur. These have the same values as 1a, 1b and 1c. In addition, events d and e must occur:

Event d: Escaped insects reach sexual maturity and mate with local population

In addition to the above events, the escaped insects would be unlikely to reach maturity and mate. This event is very similar to *1d* but assumes that an established pest population exists in the area and that wild mates are receptive to mating.

The likelihood was estimated by the consultants group to be a ***fairly unlikely event*** *with an estimated probability of* $\mathbf{1 \times 10^{-3}}$.

Event e: Undesirable traits established in the population

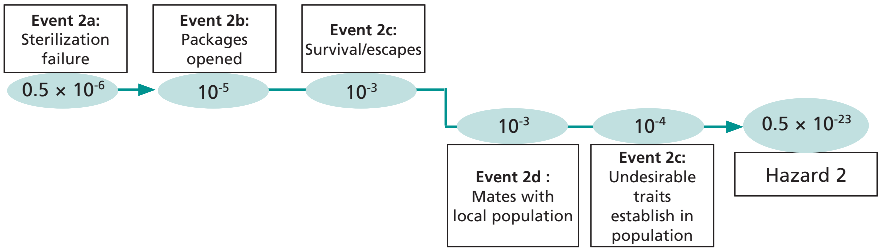
In addition to the above events, the escaped insects would have to possess traits that convey a selective advantage leading to increased fitness. Furthermore, these traits would have to become established in the population. However, this is extremely unlikely because:

- Most introductions of genetic material have neutral or even a detrimental effect on the population. Furthermore, because of the small numbers of escaped insects, it is unlikely that these traits would become established in the wild population.
- Under mass rearing conditions over many generations, all laboratory strains are known to loose their fitness to survive under natural conditions, therefore they are highly unlikely to carry genetic traits that would increase the fitness of the wild population.
- In addition, the only known traits that have been introduced into mass reared strains through traditional selection and mutation breeding (i.e. markers and sexing features) are detrimental (e.g. temperature sensitive lethal).

The likelihood was estimated by the consultants group to be an ***extremely rare event*** *with an estimated probability of* $\mathbf{1 \times 10^{-6}}$.

For scenario 2 the likelihood of all five events occurring was estimated as a negligible risk of 0.5×10^{-23}

Summary of hazard 2: Increase of fitness of the local pest population through introduction of genetic material from the escaped insects.



IV–C. Hazard 3: Unnecessary regulatory actions initiated due to failure to recognize the detected insect as sterile

Event 3a (i.e. packages opened) is identical to event 1b. Event 3b (i.e. survives and escapes) is the same as event 1c.

Event c: Not recognized to be sterile

In addition to the above events, the escaped insects would have to be detected and not recognized as sterile.

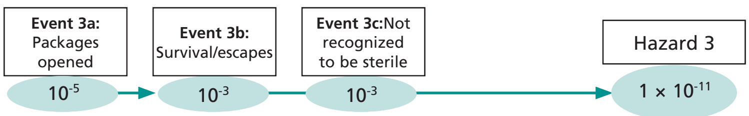
For this to occur the insect must be of regulatory significance:

- The plant protection authorities would have to be conducting detection surveys.
- The plant protection authorities would have to fail to recognize that this could be a sterile insect, which is an unlikely event. Those countries that are most likely to take a regulatory action have standard operation procedures that recognize the possibility of capturing sterile insects.
- The sterile insect marking process and cytological identification for sterility would have to fail.

The likelihood was estimated by the consultant group to be a ***fairly unlikely event*** *with an estimated probability of* ***1 × 10***$^{-3}$.

For scenario 3 the likelihood of all three events occurring was estimated as a negligible risk of 1 × 10^{-11}**.**

Summary of hazard 3: Unnecessary regulatory actions initiated due to failure to recognize the detected insect as sterile



IV–D. Hazard 4: Introduction of exotic (new) contaminant organisms

The introduction of exotic contaminant organisms was characterized in a different way because of the complexity of the sub-scenarios involved depending on the nature of the contaminant organisms (e.g. parasitoids versus micro-organisms). This hazard is also different because it is not unique to sterile insects. Similar hazards exist with shipment of biological control agents and to some extent with any shipment. Therefore it was compared to the risks from the shipment of biological control agents, which is widely practiced.

The risk of sterile insect shipments introducing exotic organisms were estimated to be considerably smaller based on the following considerations:

- There is no documented evidence that such an event has occurred during the past 46 years of sterile insect shipping.
- The items being shipped undergo sterilization. This would effectively reduce the risk of introducing unwanted parasitoids.
- Wild-collected organisms are never shipped for SIT purposes. The product is mass reared over many generations under quality control procedures aimed at eliminating unwanted organisms.
- The standard operating procedures for insect mass rearing specifically provide mechanisms to prevent unwanted organisms.
- Biological control agents are sometimes shipped with live hosts or prey. Sterile insects are not.

For scenario 4, the consultants estimated that this risk would be many-fold less likely than the risk of introducing exotic organisms involved when moving biological control agents.

V. CONSEQUENCES IN CASE THE IDENTIFIED HAZARDS OCCURRED

Assuming that the identified hazards have occurred, the expert group described the following potential consequences:

Hazard 1: Outbreak of the target insect pest in a new area

The consequence of this hazard is the incursion or establishment of a serious insect plant pest. Negative impact of the new pest could include:

- Decrease in production of crops.
- Reduction in quality.
- Increase in production costs.
- Impact on trade.
- Impact on the environment.

These consequences apply to both incursions and establishment. In the case of incursions, the negative impact would be limited in scope and duration. This is because for an incursion, the conditions would not be suitable for permanent pest establishment (e.g. pest not able to survive winter or summer temperatures). However, in the event of pest establishment, eradication would be an option since SIT and other eradication tools are available for the species that are currently shipped as sterile insects.

Hazard 2: Increase of fitness of the local pest population through introduction of genetic material from the escaped insects.

The consequences of the existing local pest population could increase as a result of the introduction of new genetic material. This negative impact could be:

- Decreased production on already affected crops.
- Increased cost on already affected crops.
- Losses on other crop species.
- Environmental impact.
- Impact on trade.

With the existence of a local population, however, control practices may already be in place that will effectively manage the fitter pest. This may reduce the consequences.

Hazard 3: Unnecessary regulatory actions initiated due to failure to recognize the detected insect as sterile

This would apply only to pests subjected to an active surveillance programme. The detection and failure to recognize the insect as sterile could trigger several different actions:

- An increase in trapping (i.e. delimiting trapping) to assess the status of the detection.
- The initiation of an emergency programme for eradication.
- Disruption of internal movement and marketing by domestic regulatory actions.
- Prohibition of host product by a trading partner.

The implementation of these actions could have significant short-term financial implications.

Hazard 4: Introduction of exotic (new) contaminant organisms

The introduction of an exotic organism into a new ecosystem can have the following negative impacts:

- Direct damage on agricultural crops if the introduced organism is an exotic plant pest.
- Indirect damage on agricultural crops if introduced organism has a negative impact on beneficial organisms (pollinators, predators and parasites).
- Change in biodiversity and natural ecosystem.

This hazard is not unique to the shipment of sterile insects, and therefore should be considered in comparison to or in the context of the same hazard associated with shipments of other commodities, including non-biological shipments.

VI. ASSESSED RISK

Risk is the product of the likelihood of the hazard times the consequences. The potential consequences from the identified hazards could be significant. However, the extremely low likelihood of the hazards occurring indicates an overall negligible risk.

VII. CONCLUSIONS

The Consultants held detailed discussions and reviewed reference documents taking into consideration the scientific, technical and operational aspects of the Sterile Insect Technique

(SIT) as applied to plant protection. Potential biological hazards and associated risks were identified for transboundary shipment of sterile insects for use in SIT programmes.

The consultants concluded the following:

- Evidence indicates that SIT is likely to become more widely used. There is also a shift from government to private responsibility for certain aspects of the technology. This will require a more formal approach to activities involving more than one country. This is particularly relevant to production that results in transboundary shipments of the sterile insects.

- The SIT has been used for nearly 50 years against insect pests of plants and animals. During this time, standard operating procedures have been developed by most individual programmes. In some cases, international standards have been developed and are in use worldwide. For fruit fly species, the most important of these are the quality control and dosimetry manuals[4] (FAO/IAEA/USDA, 1998 and FAO/IAEA, 2000). The proper application of these manuals precludes the hazards identified by the Consultants Group from occurring.

- There is a need for an internationally accepted code of conduct (or similar document) relating to transboundary shipments of sterile insects for use in SIT programmes. The International Plant Protection Convention (IPPC) is the international standard setting body for phytosanitary measures. Since the SIT is also used against insect pests of veterinary and medical importance, livestock insect pests and insect vectors of medical importance should be considered by the appropriate bodies in the near future.

- The Consultants Group identified the hazards and assessed the risks associated with the transboundary shipment of sterile insects for SIT programmes. Both the likelihood and the consequences were considered for each of the hazards identified. A series of sequential events would be required for any of these potential hazards to occur. None of the events alone would constitute a hazard (refer to Figure 1).

- The hazards identified, potential consequences and likelihood of the hazards occurring were:
  - Failure of sterilization, either total or partial, resulting in the target insect becoming an established pest in a new area, with the likelihood of 0.5×10^{-18}.
  - Introduction of new (intra-specific) genetic material into an established pest population by the "sterile insects", resulting in a more damaging insect pest, with the likelihood of 0.5×10^{-23}.
  - Failure to recognize a detected insect as sterile, resulting in an unnecessary and perhaps costly regulatory action, with the likelihood of 1×10^{-11}.
  - Introduction of an exotic contaminant organism, resulting in a new pest becoming established, was estimated to involve many folds less risk than from the movement of biological control agents, a risk already widely accepted.

- Because of the sequence of events required for any of the above hazards to occur, the Consultants Group concluded that transboundary shipment would result

[4] Comprehensive FAO/IAEA standard operating procedures exist for fruit fly species. For other plant pest species controlled by SIT, best practices are in place and standard procedures will be harmonized internationally over time. The Consultants Group believes that the risk will be negligible from transboundary shipment of these other species as well, when best practices are applied.

in negligible risk with the use of FAO/IAEA operating procedures[5] regarding sterilization, handling/packaging and shipment of sterile insects.

VIII. RECOMMENDATIONS

The Consultants Group recommends that this discussion paper be sent to the IPPC Secretariat for consideration by the ICPM as the basis for a standard. The Group also recommend that this standard be separate from the International Standard for Phytosanitary Measures number 3 on biological control agents.

Furthermore, the consultants recommend that the appropriate international bodies should assess the risks from transboundary shipment of insect pests of livestock and insects of medical importance controlled through SIT, and develop harmonized guidance.

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ANNEX 1
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Appendix 6

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LIMITED DISTRIBUTION

WORKING MATERIAL

Guidelines for export and import of sterile insects for the implementation of sit programmes against endemic/invasive crop pests

REPORT OF THE CONSULTANTS MEETING

SARASOTA, FLORIDA, USA.
11–15 MAY 2004

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TABLE OF CONTENTS

PREAMBLE 108

1. INTRODUCTION 109

2. SCOPE 109

3. REFERENCES 109

4. DEFINITIONS 110

5. OBJECTIVE 113

6. OUTLINE OF REQUIREMENTS 113

  6.1 International agreements, principles and standards 113

  6.2 Producer/End User 113

  6.3 Phytosanitary Measures 116

  6.4 Documentation 119

  6.5 Communication 119

ANNEX 1. Agenda 120

ANNEX 2. LIST OF PARTICIPANTS 122

ANNEX 3. EXAMPLE OF CERTIFICATE 123

PREAMBLE

A Consultants Group Meeting was held to develop guidelines, in support of the SIT aspects of a revised International Standard on Phytosanitary Measures ISPM No. 3 and the discussion paper on *Transboundary Shipment of Sterile Insects*, that can be used to harmonize and standardize processes to promote and facilitate the use of sterile insects for current and new SIT programmes against crop pests. This meeting took place in Sarasota, Florida, USA at the USDA–APHIS–PPQ Sterile Insect Facility, from 11–15 May 2004 (Annex 1). Consultant's names are listed in Annex 2.

Harmonized guidance regarding regulation of consignments of sterile insects will facilitate transboundary trade while addressing concerns with regards to consignments in relation to possible phytosanitary risks. This document was developed as a set of technical support guidelines for consideration by the Interim Commission on Phytosanitary Measures (ICPM), the governing body for the International Plant Protection Convention (IPPC).

One possible result of consideration of these guidelines will be the development of an international standard providing guidance on measures pertaining to consignments of sterile insects. In the interest of harmonization, similar discussions may be needed at the Office International des Epizooties (OIE) and the World Health Organization (WHO) regarding the use of sterile insects for control of human or animal diseases.

1. INTRODUCTION

The integrated use of the sterile insects technique (SIT) provides an effective and environmentally sound alternative to conventional control practices (insecticides, etc.) for an increasing number of key insect pests. Two major reasons for using SIT are that the released sterile insects are not self-replicating, intra-specific in their effect, and incapable of introducing an exotic species into the environment (see chapter on *Transboundary shipment of sterile insects for pest control programmes In: Product Quality Control and Shipping Procedures for Sterile Mass-Reared Tephritid Fruit Flies*, Version 5.0, May 2003).

The release of sterile insects targets a population of the same species and serves as a form of "birth control". The sterile insects mate with the wild population but fertilization results in no viable offspring. It is only through repeated releases of sterile insects on an area-wide basis that a reduction occurs in a pest population. Technological changes are occurring resulting in increased efficiency in mass rearing, sterilization and release, making SIT more affordable than in the past. More production facilities exist today than any time previous and consignments to destinations around the world have increased significantly.

For these reasons, officials, producers and end users need guidance for dealing with packing and transport of these organisms from the production facilities to their final destination. This document also serves to support SIT aspects of a revised International Standard on Phytosanitary Measures ISPM–3.

2. SCOPE

This document provides guidance on information for export and import including: first importation, production procedures, sterilization, packaging, transportation, receipt procedures, and release of sterile insects used for prevention, containment, suppression/ eradication. The document aims to address key issues related to export/import processes. Insect strains produced artificially by genetic engineering or other modern biotechnology methods are not covered under this document.

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Guidelines for regulating wood packaging material in international trade, 2004. ISPM No. 15, FAO, Rome.
Guidelines for the use of irradiation as a phytosanitary measure, 2003. ISPM No. 18, FAO, Rome.
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Standard Guide for Irradiation of Insects for Sterile Release Programs. Document Number ASTM E1940–98, 11 pages, 1998 ASTM International.

4. DEFINITIONS

Area-wide control	Control measures applied against a given plant pest over a geographically defined area that includes all known or potential hosts with the objective of preventing pest build-up while minimizing damage to commercial host. Control actions are conducted whenever and wherever the target pest exists regardless of host seasonality.
Absorbed dose	Quantity of radiation energy (in gray) absorbed per unit of mass of a specified target. [ISPM 18].
ASTM	American Society for Testing and Materials
Commodity	A type of plant, plant product, or other article being moved for trade or other purpose. [FAO, 1990; revised ICPM, 2001].
Compliance procedure (for a consignment)	Official procedure used to verify that a consignment complies with stated phytosanitary requirements. [CEPM, 1999].
Contaminants	For purpose of this document, any impurities in a consignment.
Consignment in transit	A consignment that is not imported into a country but passes through it to another country, subject to official procedures which ensure that it remains enclosed, and is not split up, not combined with other consignments nor has its packaging changed. [FAO, 1990; revised CEPM, 1996; CEPM 1999; ICPM, 2002 formerly country of transit]
Data sheet	Document that shows production facility and contact information, species (and where available strain identification), estimated insect count and weight, consignment number, bill-of-lading, etc.
Detention	Keeping a consignment in official custody or confinement for phytosanitary reasons. (See quarantine) [FAO, 1990; revised FAO, 1995; CEPM, 1999]
Emergency action	A prompt phytosanitary action undertaken in a new or unexpected phytosanitary situation. [ICPM, 2001]
Environmental data logger	A device used to monitor and record environmental conditions within a consignment.

Entry (of a consignment)	Movement through a point of entry into an area. [FAO, 1995].
Feral	Existing in a wild or untamed state. [The American Heritage Dictionary, 2nd College Ed. 1982 Houghton Mifflin Company]
Gray (Gy)	Unit of absorbed dose where one Gy is equivalent to the absorption of one joule per Kg. 1 Gy = 1 $J.kg^{-1}$
Infestation (of a commodity)	Presence in a commodity of a living pest of the plant or plant product concerned. Infestation includes infection. [CEPM, 1997; revised CEPM, 1999].
Inspection	Official visual examination of plants, plant products or other regulated articles to determine if pests are present and/or to determine compliance with phytosanitary regulations. [FAO, 1990; revised FAO, 1995; formerly *inspect*]
Inspector	Person authorized by a National Plant Protection Organization to discharge its functions. [FAO, 1990]
Intended use	Declared purpose for which plants, plant products, or other regulated articles are imported, produced, or used. [ISPM No. 16, 2002]
Interception (of a consignment)	The refusal or controlled entry of an imported consignment due to failure to comply with phytosanitary regulations. [FAO, 1990; revised FAO, 1995]
ICPM	International Commission on Phytosanitary Measures
Ionizing radiation	Charged particles and electromagnetic waves that as a result of physical interaction create ions by either primary or secondary processes. [ISPM No. 18, 2003]
IPPC	International Plant Protection Convention, as deposited in 1951 with FAO in Rome and as subsequently amended. [FAO, 1990; revised ICPM, 2001]
Irradiation	Treatment with any type of ionizing radiation. [ISPM No. 18, 2003]
Irradiation certificate	Document that verifies that the sterile insects in the consignment were irradiated in accordance with approved procedures. It includes the name of the production facility and contact information, date of treatment, number of packages treated, consignment number, and signatures of two authorized officials.
Irradiation indicators (radiation-sensitive indicator)	An indicator that verifies that sterile insects were exposed to ionizing radiation.
ISPM	International Standard for Phytosanitary Measures [CEPM, 1996; revised ICPM, 2001]

Labelling	A small piece of paper or cloth attached to an article to designate its origin, owner, contents, use, or destination.
Minimum absorbed dose (Dmin)	The localized minimum absorbed dose within the processLoad. [ISPM No. 18, 2003]
NPPO	National Plant Protection Organization. [FAO, 1990; ICPM, 2001]
Official	Established, authorized or performed by a National Plant Protection Organization. [FAO, 1990]
Quality control procedures	For purposes of this document, standardized testing procedures for assessing product, process and production controls in mass-rearing of insects.
Packaging	Material used in supporting, protecting or carrying a commodity. [ISPM No. 20, 2004]
Pest	Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products. [FAO, 1990; revised FAO, 1995; IPPC, 1997]
Point of entry	Airport, seaport or land border point officially designated for the importation of consignments, and /or entrance of passengers. [FAO, 1995]
Point of transhipment	The place where consignment is transferred from one conveyance to another before proceeding on to final point of entry.
Primary packaging	A sealed escape-proof container or bag for holding insects for irradiation and shipping. Irradiation indicator should be affixed on inside of the sealed container clearly visible from the exterior without need to open it.
Producer	For purposes of this document, the one who produces, sterilizes and ships sterile insects for use in control/eradication.
Production facility	A building designed specifically for mass-production/rearing and sterilization of insect species (single or multiple) for use in control/eradication.
Pre-clearance	Phytosanitary certification and/or clearance in the country of origin, performed by or under the regular supervision of the National Plant Protection Organization of the country of destination. [FAO, 1990; revised FAO, 1995]
Regulated non-quarantine pest	A non-quarantine pest whose presence in plants for planting affects the intended use of those plants with an economically unacceptable impact and which is therefore regulated within the territory of the importing contracting party. [IPPC, 1997]

RNQP	Regulated non-quarantine pest. [ISPM No. 16, 2002]
Secondary packaging	A container sufficiently sturdy and tamper-proof to withstand stacking, crushing and other perceived shipping processes. It holds primary packaging with sterile insects to protect product integrity during consignment from mechanical damage and environmental extremes. Wood packaging material/ dunnage is not recommended because of issues related to ISPM–15.
SPS	Sanitary and phytosanitary Standards
Test	Official examination, other than visual, to determine if pests are present or to identify pests. [FAO, 1990]
Treatment	Officially authorized procedure for the killing, inactivation or removal of pests, or for rendering pests infertile or for devitalization. [FAO, 1990, revised FAO, 1995; ISPM No. 15, 2002; ISPM No. 18, 2003]

5. OBJECTIVE

The objective of this document is to provide guidelines in support of the SIT aspects of a revised ISPM No. 3 that can be used to harmonize and standardize packing, shipment and release activities to facilitate internationally the use of sterile insects for current and new SIT programmes against crop pests.

6. OUTLINE OF REQUIREMENTS

6.1 International agreements, principles and standards

National governments have the sovereign right to regulate imports to achieve their appropriate level of protection, taking into account their international obligations. Rights, obligations and responsibilities associated with international agreements as well as the principles and standards resulting from international agreements, in particular the IPPC (1997) and the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (WTO–SPS Agreement), affect the structure and implementation of import regulatory systems. These include effects on the drafting and adoption of import regulations, the application of regulations, and the operational activities arising from regulations.

In particular, the phytosanitary procedures and regulations should take into consideration the concept of minimal impact and issues of economic and operational feasibility in order to avoid unnecessary trade disruption.

6.2 Producer/End User

6.2.1 Prior to first importation, the importer should prepare dossiers with information on the proposed sterile insect

- Accurate identification or, where necessary, sufficient characterization of the agent to allow its unambiguous recognition.

- A summary of all available information on its origin, distribution, biology, natural enemies and impact in its area of distribution.
- Full documentation of novel importations and their release programme as to identities, origins, numbers/quantity released, localities, dates, and any other data relevant to assessing the outcome, and maintenance of records of appropriate information with regard to other repeated releases of the same species.

6.2.2 Measures for consignments to be imported

The importer should indicate to the exporter/producer measures with which exported consignments should comply. These measures may be general, applying to all types of commodities, or the measures may be specific, applying to specified commodities from a particular origin. Systems approaches may also be used when appropriate.

Measures required from the producer (production facility) include:

- Inspection prior to export — ensure that the correct species is being shipped; minimize possible contaminants.
- Treatment prior to export — with ionizing radiation.
- Testing prior to export — routine quality control procedures in place to ensure that the product has received the required minimum absorbed dose and that the insects are marked to differentiate them from the wild insects (see FAO/IAEA/USDA *Product quality control and shipping procedures for sterile mass-reared tephritid fruit flies*, Version 5.0, May 2003).
- Maintenance of consignment integrity — placement of commodity in sealed primary and secondary packaging, use of radiation detectors inside primary packaging.
- Appropriate certification/documentation in place. (For an example see Annex 2 – Radiation Certificate).
- Additional requirements specified by end user.
- Accreditation procedures – personnel appropriately trained in irradiation procedures.

Measures required during consignment include:

- Use of the most direct route/method of transportation available.
- Avoid exposure to temperature extremes and direct sunlight.
- Maintain consignment integrity:
  - Primary packaging should be escape proof, tamper proof, transparent so that radiation indicator inside packaging can be clearly viewed without opening or compromising the integrity of the primary packaging.
  - Secondary packaging should be sufficiently sturdy to withstand stacking, crushing and sufficiently tamper proof to withstand the perceived shipping processes.
    i) Wood packaging material is not recommended because of issues related to ISPM–15.
- Consideration should be given to the use of environmental data loggers for monitoring temperature and humidity conditions during transport (see FAO/IAEA/USDA *Product quality control and shipping procedures for sterile mass-reared tephritid fruit flies*, Version 5.0, May 2003).
- All secondary packaging to be properly labelled with the words: “Fragile” and “Perishable”. In some cases, the mention “Live Insects” and some indication of the storage conditions (“This Side Up”, “Handle with Care”) are also present

on the secondary packaging. To facilitate tracking of consignments, these should have complete information on the location of the addressee, a consignment number and in addition, secondary packaging for each consignment should be numbered consecutively in large, clear writing on the outside of the container; e.g., "Consignment #, Box 3 of 24". Affix permits to secondary packaging as required.

Conveyances and Transport:

- For local transportation, air-conditioned or refrigerated vehicle should be used if ambient conditions are likely to result in overheating of material.
- For long-distance consignment, material is typically transported by commercial aircraft in a portion of the cargo hold where temperature and air pressure are held at cabin levels. Airline routing should be selected to minimize transshipment points and overall transit time.
- For misdirected/lost consignments, producer and end user should work with carrier to locate and forward the consignment to its intended destination. End user is responsible for final disposition (use or destruction).

Measures required at the point of entry include:

- Upon arrival at point of entry ensure appropriate procedures to clear consignment by required authorities.
- Consignment details should be verified with corresponding documentation.
- Documents should also include clear instructions to officials at transshipment or entry points on how a misdirected/lost consignments that are found are to be handled.
- If integrity of packaging is breached, containment actions must be taken (e.g., organisms immediately immobilized, collected and/or destroyed as appropriate for the commodity).

Measures required for transportation to processing/release facility:

- Where possible, transport vehicle should be secure and climate controlled.
- Procedural instructions should be in place to address transportation problems to the processing facility (e.g., break downs, traffic accidents).

Measures required after entry include:

- Inspection and verification of receipt of correct species, treatment certificate and radiation indicator labels. Receiver must carefully check the documentation that accompanies the consignment and verify that:
  - Documentation has been signed by the shipper.
  - Consignment contents match the information reported on the documentation. Any discrepancy in consignment contents should immediately be reported to the producer and a decision on final disposition of the consignment should be made. If there is no certificate in the consignment that verifies that the material was correctly irradiated, contact producer to ascertain if proper documentation can be obtained. If certificate cannot be obtained then affected insects should be destroyed.
  - Verification of the condition of the radiation sensitive indicators attached to each primary package. The indicators must clearly show that they have been exposed to the minimum absorbed dose (Dmin).

Inspection of packaging integrity.

- Examination of each primary package: The insects contained in the package must be destroyed if the radiation-sensitive indicator is missing, underexposed or partially exposed or if the packaging is ruptured or broken.

Other measures that may be required:

- Licences or permits.
- Limitations on points of entry for specified commodities (sterile insects).
- Advance notification of arrival of specified consignments.
- An audit of procedures in the exporting country.

6.2.3 Consignments in transit

Consignments in transit are not imported (see ISPM No. 5). However, the import regulatory system may be extended to cover consignments in transit and to establish technically justified measures to prevent the introduction and/or spread of pests (Article VII.4 of the IPPC, 1997).

Measures may be required to track consignments, to verify their integrity and/or to confirm that they leave the country of transit.

Producer and end user must take into consideration that in transit countries may:

- Establish points of arrival in transit country.
- Determine routes within the in transit country.
- Determine conditions for transportation and time spans permitted within their territories.

6.3 Phytosanitary Measures

6.3.1 Procedures in the production facility

Import regulations often include specific requirements that should be done in the country of export, such as production procedures (usually during the growing period of the commodity concerned) or specialized treatment procedures. In certain circumstances, such as in the development of a new trade, the requirements may include, in cooperation with the NPPO of the exporting country, an audit in the exporting country by the NPPO of the importing country such as:

- Production Systems (e.g., Standard Operation Procedures Manual and Quality Control Manual).
- Treatments (e.g., ionizing radiation).
- Inspection Procedures (e.g. product integrity, radiation sensitive indicators).
- Testing Procedures (e.g., process and quality control routine tests).
- Packaging.
  - Primary packaging holds the product that is escape proof, tamper proof and transparent (so that irradiation indicator inside packaging can be clearly viewed without opening or compromising the integrity of the primary packaging).
  - Secondary packaging that is sufficiently sturdy and tamper proof to withstand the perceived shipping processes. Wood packaging material is not recommended because of issues related to ISPM–15. Consideration must be given to official

inspection processes when secondary packaging is being designed so that primary packaging can remain intact whilst allowing organisms to be viewed.

6.3.2 Shipping concerns

- Labelling:
  - All secondary packaging to be properly labelled with the words: "Fragile" and "Perishable". In some cases, the mention "Live Insects" and some indication of the storage conditions ("This Side Up", "Handle with Care") are also present on the secondary packaging. To facilitate tracking of consignments, these should have complete information on the location of the addressee, a consignment number and in addition, secondary packaging for each consignment should be numbered consecutively in large, clear writing on the outside of the container; e.g., "Consignment #, Box 3 of 24". Affix permits to secondary packaging as required.

- Documentation should:
  - Conform to relevant regulations of exporting and importing countries especially concerning import permit, national transit permit, phytosanitary certificate, irradiation certificate, labelling and notification.
  - Include clear instructions to handlers and officials at point of embarkation, transhipment or entry on how consignment should be treated to avoid damage to contents and on action to be taken if consignment is breached (e.g., containment actions such as organisms immediately immobilized, collected and/or destroyed, as appropriate for the commodity).
  - Indicate that consignment is perishable and, therefore, rapid transit of material should be allowed.
  - Provide rapid feedback to end-user when consignment is delayed.
  - Provide relevant data to end user on quality of sterile insects in consignment.
  - Include clear instructions to officials at transhipment or entry points on final disposition if a lost consignment is found.

6.3.3 Compliance checking at point of entry

Some of the basic elements to compliance checking are:

- Advance notification and documentation of consignment specifying arrival information.
- Verification that required clearances for consignment have been obtained.
- Documentary checks (e.g., product contents correspond with documentation).
- Consignment integrity checks.

Compliance checking at point of entry of consignments may be required to:

- Determine compliance with phytosanitary regulations.
- Check that phytosanitary measures are effective in preventing the introduction of quarantine pests and limiting the entry of RNQPs.
- Detect potential quarantine pests or quarantine pests whose entry with that commodity was not predicted.

Phytosanitary inspections should be carried out by or under the authority of the NPPO.

6.3.4 Inspection

Inspections may be done at point of entry, transhipment, destination or other locations provided that phytosanitary integrity is maintained and appropriate phytosanitary procedures can be carried out. By agreement or other arrangement, they may also be done in the country of origin as a part of a pre-clearance programme in cooperation with the NPPO of the exporting country.

Phytosanitary inspections may be applied:

- To all consignments as a condition of entry.
- Where the level of monitoring (i.e. the number of consignments inspected) is established on the basis of predicted risk.

Inspection and sampling procedures may be based on general or specific procedures to achieve pre-determined objectives.

6.3.5 Transport to processing/release facility

- Where possible, transport vehicle should be secure and climate controlled.
- Procedural instructions should be in place to address transportation problems to the processing facility (e.g., break downs, traffic accidents).

6.3.6 Testing

Testing may be required for:

- Verification of the declared product — e.g., correct identification of species.
- Verification of product integrity.
- Audit or monitoring.

Testing should be performed by persons experienced in the appropriate procedures and, if possible, following internationally agreed protocols. Cooperation with appropriate academic and international experts or institutes is recommended when validation of test results is needed.

6.3.7 Action in case of non-compliance

Examples where phytosanitary action may be justified regarding non-compliance with import regulations include:

- Detection of a listed quarantine pest associated with consignments for which it is regulated.
- Evidence of failure to meet prescribed requirements (including bilateral agreements or arrangements, or import permit conditions) such as treatment and laboratory tests.
- Interception of a consignment which does not otherwise comply with import regulations, such as detected presence of undeclared commodities, soil or some other prohibited article or evidence of failure of specified treatments.
- Required documentation e.g., invalid or missing.
- Prohibited consignments or articles.
- Failure to meet ‘in-transit’ measures.

Type of action will vary with circumstances and should be minimum necessary to counter identified risk. Administrative errors such as incomplete required documentation may be resolved through liaison with production facility. Other infringements may require action such as:

Detention — This may be used if further information is required, taking into account need to avoid consignment damage as far as possible.

Destruction — Consignment may be destroyed in cases where NPPO considers consignment cannot be otherwise handled. If destruction is required it must be done at least under supervision of end user.

6.3.8 Emergency action

Emergency action may be required in a new or unexpected phytosanitary situation, such as detection of quarantine pests or potential quarantine pests:

- In consignments for which phytosanitary measures are not specified.
- In regulated consignments or other regulated articles in which their presence is not anticipated and for which no measures have been specified.
- As contaminants of conveyances, storage places or other places involved with imported commodities.

Emergency actions should result in destruction of consignment in cases where the NPPO considers consignment cannot be otherwise handled. If destruction is required it must be done at least under supervision of end user.

6.4 Documentation

6.4.1 Procedures

Procedures to be documented include:

- Inspection, sampling and testing methodology (including methods for maintaining sample integrity).
- Action on non-compliance, including treatment.
- Notification of non-compliance.
- Notification of emergency action.

6.4.2 Records

Records should be kept of all actions, results and decisions including:

- Records of inspection, sampling and testing.
- Non-compliance and emergency action (in accordance with ISPM No. 13: *Guidelines for the notification of non-compliance and emergency action*).

6.5 Communication

Producers and end users should ensure that there are communication procedures to contact:

- Producer/end user and appropriate industry representatives.
- NPPOs of exporting/importing countries.

ANNEX 1
AGENDA

Tuesday 11 May

08:30	09:00	Welcome / Administration	J. Stewart / C. Cáceres
09:00	09:30	Objectives of the meeting	C. Cáceres
09:30	10:30	Current technology for fruit fly SIT release programmes in Guatemala/Mexico	P. Gomes
10:30	10:45	Coffee break	
10:45	11:15	Anastrepha SIT release programmes in the USA	J. Worley
11:15	12:15	Available and required technology for Codling moth SIT and other moth release programmes	S. Bloem
12:15	14:00	Lunch	
14:00	15:30	Current technology for fruit fly SIT release programmes in California, USA	Eileen Smith
15:30	16:00	Visit to the USDA–APHIS Sarasota sterile fly emergence and release centre	J. Steward
16:00	16:30	Review of risk assessment document on transboundary shipment of sterile insects	G. Mynard/C. Cáceres
16:30	17:30	Regulatory issues to be considered in relation to sterile insect reception, emergence and release	G. Mynard

Wednesday 12 May

08:30	10:30	Structure of the document, general discussion	P. Gomes
		Divide into groups for drafting	
10:30	10:45	Coffee break	
10:45	12:00	Drafting of document	
12:00	13:30	Lunch	
13:30	15:30	Drafting of document	
15:30	15:45	Coffee break	
15:45	17:30	Drafting of document	

Thursday 13 May

08:30	10:30	Drafting of document	G. Mynard
10:30	10:45	Coffee break	
10:45	12:30	Drafting of document	
12:30	14:00	Lunch	
14:00	15:30	Drafting of document	
15:30	15:45	Coffee break	
15:45	17:30	Drafting of document	

Friday 14 May

08:30	10:30	General discussion of document components	G. Mynard
10:30	10:45	Coffee break	
10:45	12:30	Drafting of document	
12:30	14:00	Lunch	
14:00	15:30	Drafting of document	
15:30	15:45	Coffee break	
15:45	17:30	Drafting of document	

Saturday 15 May

08:30	10:30	Drafting of document	S. Bloem
10:30	10:45	Coffee break	
10:45	12:30	Presentation of the final draft	
12:30	14:00	Lunch	
14:00	15:30	Presentation of the final draft	
15:30	15:45	Coffee break	
15:45	17:30	Presentation of the final draft	

ANNEX 2
LIST OF PARTICIPANTS

Australia

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Guatemala

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United States of America

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FAO/ IAEA

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ANNEX 3
EXAMPLE OF CERTIFICATE

CERTIFICATE IRRADIATION

PROGRAMA MOSCAMED
EL PINO

FLORIDA
TSL STRAIN

PBX: 8870098
FAX: 8870114

THIS IS TO CERTIFY THAT 133 BAGS OF MEDITERRANEAN FRUIT FLY, *Ceratitis capitata* (Weideman), WERE IRRADIATED ON 05-12-2OO4 IN ACCORDANCE WITH THE APPROVED PROCEDURE.

DATE OF IRRADIATION: 05-12-04

BAGS IRRADIATED: 133

SHIPMENT NUMBER: **1408**

ING. OSCAR ZALDAÑO SUPERVISOR
NAME SUPERVISOR SIGNATURE

NOTE: THE BOXES NUMBER 01 TO 04 CONTAIN 09 BAGS OF 3.6 LTS. THE BOXES NUMBER 05 TO 10 CONTAIN 16 BAGS OF 1.8 LTS.

NOTE: THE BOX NUMBER 10 CONTAIN BAG FOR QUALITY CONTROL SAMPLE.

ING. OSCAR ZALDAÑO SUPERVISOR
NAME SUPERVISOR SIGNATURE

Appendix 7
List of suppliers for aerial release machines (list not comprehensive)

Name of Company	Contact Address
Shickel Corporation	115 Dry River Road Bridgewater Virginia 22812; phone: 540-828-2536 Tel: (540) 828-2536 Fax: (540) 828-4781 E-mail: shickel@shickel.com www.Shikel.com
USDA Aircraft and Equipment Operations	Plant Protection and Quarantine (PPQ) Mission, Texas USA E-mail: APHIS.Web@aphis.usda.gov www.aphis.usda.gov/ppq/ispm/aeo/
K&K Aircraft, Inc.	Post Office Box 7 1402 Airport Road Bridgewater Airport/VBW Bridgewater, Virginia 22812 USA Tel: (540) 828-6070 Fax: (540) 828-4031
Servicios Aereos Biologicos Y Forestales Mubarqui	Blvd. Enrique Cardenaz Gonzalez 1359 Fracc. Los arcos 87040 Cd.Victoria Tamaulipas Mexico Tel/Fax. 52-834-3164921 E-mail: rlmubarqui@yahoo.com.mx
Air Sal Leasing (Global ASL)	14005 SW 127th St Miami, FL 33186 United States of America Tel: (305) 251-1982 Fax: (305 251 1966 E-mail: airsal@bellsouth.net

Appendix 8
Glossary of terms

Area	An officially defined country, part of a country or all or parts of several countries [ISPM 5, FAO 2005]
Area-wide integrated pest management (AW–IPM)*	IPM against an entire pest population within a delimited geographic area, with a minimum size large enough or protected by a buffer zone so that natural dispersal of the population occurs only within this area.
Absorbed dose	Quantity of radiation energy (in gray) absorbed per unit of mass of a specified target. [ISPM 18, FAO 2005]
Classical biological control	The intentional introduction and permanent establishment of an exotic biological agent for long-term pest control [ISPM 3 1996, FAO 2005]
Commodity	A type of plant, plant product, or other article being moved for trade or other purpose. [FAO 1990; revised ICPM 2001]
Compliance procedure (for a consignment)	Official procedure used to verify that a consignment complies with stated phytosanitary requirements. [CEPM 1999]
Contaminants	For purpose of this document, any impurities in a consignment.
Contaminating pest	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. [ISPM 5 2005; FAO 2005]
Control (of a pest)	Suppression, containment or eradication of a pest population. [ISPM 5 2005; FAO 2005]
Consignment	A quantity of plants, plant products and/or other articles being moved from one country to another and covered, when required, by a single phytosanitary certificate. (A consignment may be composed of one or more commodities or lots.) [FAO 1990; revised ICPM 2001]
Consignment in transit	A consignment that is not imported into a country but passes through it to another country, subject to official procedures which ensure that it remains enclosed, and is not split up, not combined with other consignments nor has its packaging changed. [FAO, 1990; revised CEPM 1996, CEPM 1999, ICPM 2002 formerly *country of transit*]

Data sheet*	Document that shows production facility and contact information, species (and where available strain identification), estimated insect count and weight, consignment number, bill-of-lading, etc.
Detection survey	Survey conducted in an area to determine if pests are present. [FAO 1990, revised FAO, 1995]
Detention	Keeping a consignment in official custody or confinement for phytosanitary reasons. (See quarantine) [FAO 1990, revised FAO 1995, CEPM 1999]
Dispersion*	The act or an instance of dispersing; the process of being dispersed. . [Oxford Dictionary 1990]
Eclosion*	The emergence of an insect from a pupa-case or of a larvae from an egg. [Oxford Dictionary 1990]
Emerge*	Come up or out into view, especially when formerly concealed. [Oxford Dictionary 1990]
Emergence (adult emergence)*	The escape of the adult insect from the cuticle of the pupa.
Emergency action	A prompt phytosanitary action undertaken in a new or unexpected phytosanitary situation. [ICPM 2001]
Environmental data logger*	A device used to monitor and record environmental conditions within a consignment.
Entry (of a consignment)	Movement through a point of entry into an area. [FAO 1995]
Eradication	Application of phytosanitary measures to eliminate a pest from an area. [FAO 1990, revised FAO 1995]
Establishment*	Perpetuation, for the foreseeable future, of a pest within an area after entry.
Exotic	Not native to a particular country, ecosystem or ecoarea (applied to organisms intentionally or accidentally introduced as a result of human activity). As this Code is directed at the introduction of biological control agents from one country to another, the term "exotic" is used for organisms not native to a country. [ISPM 3 1996]
Feral	Existing in a wild or untamed state. [The American Heritage Dictionary, 2nd College Ed. 1982 Houghton Mifflin Company]
Gray (Gy)*	Unit of absorbed dose where one Gy is equivalent to the absorption of one joule per Kg. $1\ Gy = 1\ J \cdot kg^{-1}$.
Incubate*	Sit on or artificially heat (eggs) in order to bring forth young birds etc. [Oxford Dictionary 1990]

Incubation*	The act of incubating. [Oxford Dictionary 1990]
Incursions	An isolated population of a pest recently detected in an area, not known to be established, but expected to survive for the immediate future (FAO 2005).
Infestation (of a commodity)	Presence in a commodity of a living pest of the plant or plant product concerned. Infestation includes infection. [CEPM 1997, revised CEPM 1999]
Inspection	Official visual examination of plants, plant products or other regulated articles to determine if pests are present and/or to determine compliance with phytosanitary regulations. [FAO 1990; revised FAO 1995; formerly *inspect*]
Inspector	Person authorized by a National Plant Protection Organization to discharge its functions. [FAO 1990]
Intended use	Declared purpose for which plants, plant products, or other regulated articles are imported, produced, or used. [ISPM 16 2002]
Interception (of a consignment)	The refusal or controlled entry of an imported consignment due to failure to comply with phytosanitary regulations. [FAO 1990, revised FAO 1995]
Introduction	The entry of a pest resulting in its establishment. [FAO 1990, revised FAO 1995, IPPC 1997]
Ionizing radiation	Charged particles and electromagnetic waves that as a result of physical interaction create ions by either primary or secondary processes. [ISPM 18 2003]
Irradiation	Treatment with any type of ionizing radiation. [ISPM 18 2003]
Irradiation certificate*	Document that verifies that the sterile insects in the consignment were irradiated in accordance with approved procedures. It includes the name of the production facility and contact information, date of treatment, number of packages treated, consignment number, and signatures of two authorized officials.
Irradiation indicators (radiation-sensitive indicator)*	An indicator that verifies that sterile insects were exposed to ionizing radiation.
Labelling*	A small piece of paper or cloth attached to an article to designate its origin, owner, contents, use, or destination.
MACX	The MACX system is a conjunction of virtual and physic elements which make a fit up package for supervision and quality control requirements that ensures a fine development and performance at all levels of the packing, holding and release of sterile flies.

Medfly*	Mediterranean fruit fly.
Mexfly*	Mexican fruit fly.
Minimum absorbed dose (Dmin)	The localized minimum absorbed dose within the processLoad. [ISPM 18 2003]
Official	Established, authorized or performed by a National Plant Protection Organization. [FAO 1990]
Packaging	Material used in supporting, protecting or carrying a commodity. [ISPM 20 2004, FAO 2005]
Parasite	An organism which lives on or in a larger organism, feeding upon it. [FAO 2005]
Parasitoid	An insect parasitic only in its immature stages, killing its host in the process of its development, and free living as an adult. [FAO 2005]
Pathogen	Micro-organism causing disease. [FAO 2005]
Pest	Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products. [FAO 1990, revised FAO 1995, IPPC 1997]
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. [FAO 2005]
Phytosanitary measure	Any legislation, regulation or official procedure having the purpose to prevent the introduction and/or spread of pests. [FAO 2005]
Phytosanitary procedure	Any officially prescribed method for implementing phytosanitary regulations including the performance of inspections, tests, surveillance or treatments in connection with regulated pests. [FAO 2005]
Point of entry	Airport, seaport or land border point officially designated for the importation of consignments, and /or entrance of passengers. [FAO 1995]
Point of transhipment*	The place where consignment is transferred from one conveyance to another before proceeding on to final point of entry.
Preventative release*	Continued release of low density sterile insects over a delimited area to prevent introduction of fruit fly populations.
Prevention*	Application of phytosanitary measures in and/or around a pest free area to avoid the introduction of a pest.

Progeny*	The offspring of a particular mate, or of a particular individual in the case of asexual reproduction.
Primary packaging*	A sealed escape-proof container or bag for holding insects for irradiation and shipping. Irradiation indicator should be affixed on inside of the sealed container clearly visible from the exterior without need to open it.
Producer*	For purposes of this document, the one who produces, sterilizes and ships sterile insects for use in control/eradication.
Production facility*	A building designed specifically for mass-production/rearing and sterilization of insect species (single or multiple) for use in control/eradication.
Pre-clearance	Phytosanitary certification and/or clearance in the country of origin, performed by or under the regular supervision of the National Plant Protection Organization of the country of destination. [FAO 1990, revised FAO 1995]
Quality control procedures*	For purposes of this document, standardized testing procedures for assessing product, process and production controls in mass-rearing of insects.
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 2005]
Regulated non-quarantine pest	A non-quarantine pest whose presence in plants for planting affects the intended use of those plants with an economically unacceptable impact and which is therefore regulated within the territory of the importing contracting party. [FAO 2005]
Release (into the environment)*	Intentional liberation of an organism into the environment (see also introduction and establishment).
Release centre*	Packing, emergence and holding centre.
Secondary packaging*	A container sufficiently sturdy and tamper-proof to withstand stacking, crushing and other perceived shipping processes. It holds primary packaging with sterile insects to protect product integrity during consignment from mechanical damage and environmental extremes. Wood packaging material/dunnage is not recommended because of issues related to ISPM–15.
Sterility* (radiation induced)	A condition in which sperm or eggs from irradiated reproducing individuals do not result in fertile offspring following fertilization.

Suppression	The application of phytosanitary measures in an infested area to reduce pest populations. [FAO 2005]
Survey	An official procedure conducted over a defined period of time to determine the characteristics of a pest population or to determine which species occur in an area. [FAO 2005]
Test	Official examination, other than visual, to determine if pests are present or to identify pests. [FAO 1990]
Treatment	Officially authorized procedure for the killing, inactivation or removal of pests, or for rendering pests infertile or for devitalization. [FAO 1990, revised FAO 1995, ISPM 15 2002, ISPM 18 2003]
Wild*	Not domesticated or cultivated. [Oxford Dictionary 1990]

Terms marked with * do not appear in the International Plant Protection Convention's Glossary (ISPM No. 5) and may require review by an international panel.

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Appendix 9
Glossary of acronyms

ASTM	American Society for Testing and Materials.
FAO	Food and Agriculture Organization of the United Nations.
IAEA	International Atomic Energy Agency.
CPM	Committee on Phytosanitary Measures.
IPPC	The International Plant Protection Convention, as deposited in 1951 with FAO in Rome and as subsequently amended.
NPPO	National Plant Protection Organization.
RNQP	Regulated non-quarantine pest. [ISPM No. 16, 2002]
RPPO	Regional Plant Protection Organization with the functions laid down by Article IX of the IPPC.
SIT	Sterile Insect Technique.
SPS	Sanitary and Phytosanitary Standards.

Appendix 10
Other relevant literature

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