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منظمة الأغذية والزراعة للأمم المتحدة | 联合国粮食及农业组织 | Food and Agriculture Organization of the United Nations | Organisation des Nations Unies pour l'alimentation et l'agriculture | Organización de las Naciones Unidas para la Agricultura y la Alimentación

COMMISSION ON PHYTOSANITARY MEASURES

Third Session

Rome, 7 – 11 April 2008

Adoption of International Standards – Under the Regular Process

Agenda Item 9.2 of the Provisional Agenda

I. Introduction

1. This document presents four annexes which contain amendments to an existing ISPM as well as three new ISPMs. The Standards Committee (SC) recommends these annexes for adoption by the Commission on Phytosanitary Measures (CPM).

2. The annexes are as follows:

- Annex 1 contains amendments to ISPM No. 5 (*Glossary of phytosanitary terms*), including the terms originally included with the draft supplement to ISPM No. 5 on debarked and bark-free wood.
- Annexes 2 to 4 are new ISPMs:
  - *Establishment of areas of low pest prevalence for fruit flies (Tephritidae)* (Annex 2)
  - *Methodologies for sampling of consignments* (Annex 3)
  - *Replacement or reduction of methyl bromide as a phytosanitary measure* (Annex 4).

3. In May 2007, the SC approved six draft ISPMs for member consultation through the regular standard setting process. The drafts were sent in June 2007 for a 100 day consultation period.

4. In July and August 2007, seven IPPC regional workshops on draft ISPMs supported the preparation of member comments in the Asia, French and English-speaking Africa, Caribbean, Latin America, Near East and Pacific regions.

5. Technical, editorial and translation comments were received from 42 individual countries and the European Commission and its Members States. Comments were received from an

additional three countries during the Standards Committee meeting in November, at which point it was impossible to compile them with others into the tables of comments.

6. The Secretariat also received comments from four Regional Plant Protection Organizations (RPPOs): Comité Regional De Sanidad Vegetal Del Cono Sur (COSAVE), European and Mediterranean Plant Protection Organization (EPPO), Organismo Internacional Regional De Sanidad Agropecuaria (OIRSA) and Pacific Plant Protection Organisation (PPPO).

7. In total, the Secretariat received approximately 2000 comments on the draft standards during the consultation period, and the SC revised the drafts and incorporated comments as appropriate. Members are invited to refer to the report of the SC (November 2007) which contains, for each draft, an overview of the main points of discussion and a summary of SC reactions to some comments. This should help indicate to members the result of their input into the redrafting of the standards, especially for substantive comments which have not been incorporated.

8. The SC recommended four of the six drafts (as presented in Annexes 1 to 4) that went for member consultation for adoption by the CPM. Of the remaining two drafts, most of the draft *Supplement to ISPM No. 5 on debarked and bark- free wood* was referred back to the TPFQ for its consideration in relation to the new topic on the *International movement of wood* (the specification for which was sent for member consultation in December 2007). The three definitions for *bark*, *bark-free wood* and *debarked wood* were incorporated into the amendments to ISPM No. 5 (*Glossary of phytosanitary terms*) (in Annex 1). The draft ISPM on *Classification of commodities into phytosanitary risk categories* was not recommended by the SC for adoption by the CPM and will be redrafted.

II. Guidelines for submitting comments on ISPMs presented for adoption

9. Members are invited to take the following points into account in preparation for the CPM and in accordance with the decision at the 6th Session of the Interim Commission on Phytosanitary Measures (ICPM-6) in 2004 in relation to the improvements of standard-setting procedures:

a) Members should endeavour to provide only substantive comments at meetings of the CPM.
b) Members should endeavour to provide comments in writing to the Secretariat at least 14 days before the CPM. The Secretariat will provide a copy of all comments received (in original form or as compiled comments) at the start of the CPM.
c) Members should indicate which comments are strictly editorial (i.e. they do not change the substance of the text) and could be incorporated by the Secretariat as considered appropriate and necessary.
d) The electronic format/template for country comments should preferably be used for submitting comments and can be found on the IPP (https://www.ippc.int/id/190736) or requested from the IPPC Secretariat.

10. In accordance with the decision of ICPM-6, comments that were received during the June-September 2007 consultation are available on the IPP (https://www.ippc.int/id/189217).

III. Amendments to ISPM No. 5: Glossary of phytosanitary terms (Annex 1)

11. In 2006, CPM-1 established the Technical Panel for the Glossary (TPG). The TPG met in Rome (Italy) in October 2006 to review proposals for definitions of new terms, and revision and deletion of existing terms. Proposed amendments to the *Glossary of phytosanitary terms*

suggested by the TPG were subsequently reviewed by the SC in May 2007 and sent for member consultation in June 2007.

12. Over 50 comments were compiled and submitted for review by the TPG at its meeting held in Rome (Italy) in October 2007 and by the SC working group (SC-7) in November 2007. Draft amendments to the glossary were submitted to the SC in November 2007. The SC adjusted the draft and incorporated the three definitions from the draft *Supplement to ISPM No. 5 on debarked and bark-free wood* (see paragraph 8). It recommended that proposed new/revised definitions and deletions be presented to the CPM-3 for adoption, with explanations in support of the proposals.

13. The CPM is invited to:

1. *Adopt* the amendments to ISPM No. 5 (*Glossary of phytosanitary term*s), contained in Annex 1.
2. *Note* that the proposed definition for "debarked wood" will replace the existing definition for "debarking" in ISPM No. 5 (*Glossary of phytosanitary terms*).

IV. Establishment of areas of low pest prevalence for fruit flies (Tephritidae) (Annex 2)

14. The topic of areas of low pest prevalence for fruit flies was added to the IPPC standard setting work programme in 2004. A draft ISPM was developed by the Technical Panel on Pest Free Areas and Systems Approaches for Fruit Flies (TPFF) at its meeting in San Jose (Costa Rica) in September 2005, reviewed by the SC in May 2006 and sent for member consultation in June 2006. At its November 2006 meeting, the SC adjusted the draft, which was presented for adoption to CPM-2 in 2007.

15. CPM-2 agreed to a process for revision of the standard by the steward, in consultation with a small group of experts, and its resubmission to the SC in May 2007. The SC in May 2007 recommended that the draft ISPM be sent for a second round of member consultation. Over 530 comments were compiled and submitted for review by the steward and SC-7, and a revised draft was submitted to the SC in November 2007. The SC adjusted the draft as appropriate and recommended it for adoption by the CPM.

16. The CPM is invited to:

1. *Adopt* as an ISPM: *Establishment of areas of low pest prevalence for fruit flies (Tephritidae)*, contained in Annex 2.

V. Methodologies for sampling of consignments (Annex 3)

17. In 2004, ICPM-6 added the topic of sampling to the standard setting work programme. An expert working group (EWG) meeting was held in July 2005 in Ottawa (Canada). The SC, due to the volume of work, was unable to review the draft ISPM in 2005. The SC in May 2006 reviewed the draft and requested that the steward and EWG members redraft the text. The modified text was reviewed by the SC in May 2007 and sent for member consultation, accompanied by a support document.

18. Over 350 comments were compiled and submitted for review by the steward and SC-7, and a revised draft was submitted to the SC in November 2007. The SC adjusted the draft as appropriate and recommended it for adoption by the CPM.

19. The CPM is invited to:

1. *Adopt* as an ISPM: *Methodologies for sampling of consignments*, contained in Annex 3.

VI. Replacement or reduction of methyl bromide as a phytosanitary measure (Annex 4)

20. In 2004, ICPM-6 added the topic of alternative strategies to methyl bromide to the standard setting work programme. An EWG was originally planned in conjunction with the first meeting of the Technical Panel on Phytosanitary Treatments (TPPT) in Raleigh (USA) in December 2004, but the EWG meeting was cancelled due to logistical problems. The TPPT met in 2004 and completed some tasks outlined in its specification which also addressed many of the tasks in the specification for the standard on alternatives to methyl bromide. At its second meeting in Stellenbosch (South Africa) in August 2005, the TPPT developed a draft ISPM on the subject. The SC in November 2005 felt that the expertise outlined in the specification was needed and it requested the Secretariat to organize an EWG, which was held in November 2006 in Orlando (USA). This EWG considered the draft prepared by the TPPT and a revised draft was reviewed by the SC in May 2007, and sent for member consultation.

21. Over 480 comments were compiled and submitted for review by the steward and SC-7, and a revised draft was submitted to the SC in November 2007. Some comments related to the content of the document and some others to the format of the document, i.e. whether it should be an ISPM or an other type of document.

22. The SC adjusted the draft and agreed to its content. It also agreed that the information in this draft was extremely important and should be given a high profile, to help reflect the work that the IPPC is doing in regard to alternative strategies to methyl bromide and to reflect the importance that Contracting Parties should give to this topic. However, the SC could not reach an agreement on the format of this document. It was noted that currently, in addition to ISPMs, the CPM adopts decisions which are captured in CPM reports either in the body of the report or as appendices to CPM reports. The SC also noted that a proposal would be made at CPM-3 to capture CPM recommendations/policies which are not ISPMs in a different format than what is currently done (see agenda item 13.5).

23. The SC suggested that this text be presented for adoption as an ISPM at CPM-3, with the additional suggestion that, if the CPM decides to adopt CPM recommendations/policies, then the adopted ISPM could be transformed into such a CPM recommendation/policy.

24. The CPM is invited to:

1. *Adopt* as an ISPM: *Replacement or reduction of methyl bromide as a phytosanitary measure*, contained in Annex 4.
2. *Consider* whether the adopted ISPM should be transformed by the Secretariat and published as a CPM recommendation.

AMENDMENTS TO ISPM No. 5 (*GLOSSARY OF PHYTOSANITARY TERMS*)

1. NEW TERMS AND DEFINITIONS

1.1 Prevalence (of a pest)

Background: a definition of *prevalence (of a pest)* was sent for consultation. However, after discussion of comments received, this term and definition have been withdrawn. A definition of an alternative term, *incidence*, will be presented to the SC in May 2008, prior to member consultation.

1.2 Tolerance level

Background: a definition of *tolerance level* was sent for member consultation. However, after discussion of comments received, this term and definition have been withdrawn. A redrafted definition will be presented to the SC in May 2008, prior to member consultation.

2. REVISED TERM AND DEFINITION

2.1 Beneficial organism

Background

Discussions of the revision of the definition of *biological control* (after CPM-1) led to the proposal that this term should be deleted from the Glossary (adopted at CPM-2) and that the definition of *beneficial organism* should be revised to cover sterile insects. Some comments suggested deleting reference to "biological control agents", to "sterile insects" or to both. If the reference to "biological control agents" is deleted, the definition is not needed. If reference to "sterile insects" is deleted, there will be no change to the existing definition, and this fails to take account of the intent for ISPM No. 3 to cover sterile insects.

Definition proposed for CPM adoption

beneficial organism	Any **organism** directly or indirectly advantageous to **plants** or **plant products**, including **biological control agents** and **sterile insects**

3. TERMS ARISING FROM THE DRAFT SUPPLEMENT ON DEBARKED AND BARK-FREE WOOD

Background

Three definitions were part of the draft Supplement on debarked and bark-free wood sent for member consultation in 2007. After consideration of comments received, the SC felt that it was appropriate to proceed only with the definitions at this time. The rest of the supplement was referred back to the Technical Panel on Forest Quarantine (TPFQ) to have specific provisions related to bark presented within the appropriate standards (revised ISPM No. 15 and a future ISPM on international movement of wood).

New definition proposed for CPM adoption

bark	The layer of a woody trunk, branch or root outside the cambium

Revised definitions proposed for CPM adoption

bark-free wood	**Wood** from which all **bark**, except ingrown bark around knots and bark pockets between rings of annual growth, has been removed
debarked wood*	**Wood** that has been subjected to any process designed to remove **bark**. (Debarked wood is not necessarily **bark-free wood**.)

* Note: this will replace the current term *debarking*.

4. PROPOSED DELETIONS

ICPM-7 adopted the revised ISPM No. 3 (2005). A number of terms in the Glossary were defined when ISPM No. 3 (1996) was originally developed. It is proposed that the following terms and their definitions should be deleted. Reasons for the deletion are given for each term.

Term	Reason for deletion
authority	ISPM No. 3 (2005) uses the words "NPPO or responsible authority". The existing definition of authority does not apply to that use, and also mentions the "Code", which was in ISPM No. 3 (1996). The term does not have a meaning that is specific to the work of the IPPC and a definition is not needed.
biological pesticide (biopesticide)	The current definition is out of date. The term is used in ISPM No. 3 (2005) and in ISPM No. 9 but does not have a meaning that is specific to the work of the IPPC, and a definition is not needed. There is no IPPC usage of *biopesticide*, which is a requirement for a term to be defined in ISPM No. 5.
- classical biological control, **- introduction (of a biological control agent),** **- establishment (of a biological control agent)**	The three definitions were linked to ISPM No. 3 (1996). These are not used in a meaning specific to the IPPC. There is no need for specific definitions in relation to any ISPM.
exotic	The term and definition were linked to ISPM No. 3 (1996) and the term is not used in the 2005 revision. It is proposed to: - delete the term and definition because: • the term is used only in ISPM No. 9; • the term causes confusion in Spanish and French because "alien" and "exotic" are translated by the same word ("exotico" in Spanish and "exotique" in French); • the definition uses the term "ecoarea", which has been deleted from the Glossary. - use the term *non-indigenous*. Suitable wording has been proposed in the draft supplement to ISPM No. 5 on CBD terminology (for SC in May 2008) to specify that "exotic" and "non-indigenous" could be considered as synonyms.
Import Permit (of a biological control agent)	*Import Permit* (without a parenthetical addition) is defined in the Glossary and its definition covers the case of import permits for biological control agents.
micro-organism	This is a common term that does not have a meaning specific to the work of the IPPC.
specificity	The definition was linked to ISPM No. 3 (1996). This term is self-explanatory and the current definition might cause confusion.

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

ISPM No. --

ESTABLISHMENT OF AREAS OF LOW PEST PREVALENCE FOR FRUIT FLIES (TEPHRITIDAE)

(200-)

CONTENTS

INTRODUCTION

SCOPE

This standard provides guidelines for the establishment and maintenance of areas of low pest prevalence for fruit flies (FF-ALPPs) by a National Plant Protection Organization (NPPO). Such areas may be utilised as official pest risk management measures alone, or as part of a systems approach, to facilitate trade of fruit fly host products, or to minimize the spread of regulated fruit flies within an area. This standard applies to fruit flies (Tephritidae) of economic importance.

REFERENCES

Agreement on the Application of Sanitary and Phytosanitary Measures, 1994. World Trade Organization, Geneva.
Determination of pest status in an area, 1998. ISPM No. 8, FAO, Rome.
Establishment of pest free areas for fruit flies (Tephritidae), 2006. ISPM No. 26, FAO, Rome.
Glossary of phytosanitary terms, 2007. ISPM No. 5, FAO, Rome.
Guidelines for surveillance, 1997. ISPM No. 6, FAO, Rome.
International Plant Protection Convention, 1997. FAO, Rome.
Pest reporting, 2002. ISPM No. 17, FAO, Rome.
Requirements for the establishment of areas of low pest prevalence, 2005. ISPM No. 22, FAO, Rome.
The use of integrated measures in a systems approach for pest risk management, 2002. ISPM No. 14, FAO, Rome.

DEFINITIONS

Definitions of phytosanitary terms used in the present standard can be found in ISPM No. 5 (*Glossary of phytosanitary terms*).

OUTLINE OF REQUIREMENTS

The general requirements for establishment and maintenance of an area of low pest prevalence for fruit flies (FF-ALPP) include:

- confirming the operational and economic feasibility of the FF-ALPP
- describing the purpose of the area
- listing the target fruit fly species(s) for the FF-ALPP
- operational plans
- determination of the FF-ALPP
- documentation and record keeping
- supervision activities.

For the establishment of the FF-ALPP, parameters used to estimate the level of fruit fly prevalence and the efficacy of trapping devices for surveillance should be determined as stated in Annex 1. Surveillance, control measures and corrective action planning are required for both establishment and maintenance. Corrective action planning is described in Annex 2.

Other specific requirements include phytosanitary procedures, as well as suspension, loss and reinstatement of the status of the FF-ALPP.

BACKGROUND

The International Plant Protection Convention (IPPC, 1997) contains provisions for areas of low pest prevalence (ALPPs), as does the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (Article VI of the WTO-SPS Agreement). ISPM No. 22 (*Requirements for the establishment of areas of low pest prevalence*) describes different types of ALPPs and provides general guidance on the establishment of ALPPs. ALPPs may also be used as part of a systems approach (ISPM No. 14: *The use of integrated measures in a systems approach for pest risk management*).

Fruit flies are a very important group of pests for many countries because of their potential to cause damage to fruits and restrict national and international trade for plant products that are hosts of fruit flies. The high probability of introduction of fruit flies associated with a wide range of hosts results in restrictions imposed by many importing countries and the need for phytosanitary measures to be applied in exporting countries related to movement of host material or regulated articles to ensure that the risk of introduction is appropriately mitigated.

This standard provides guidance for the establishment and maintenance by the NPPO of FF-ALPPs with the aim to facilitate trade by minimizing the risk of introduction or spread of regulated fruit flies.

FF-ALPPs are generally used as a buffer zone for fruit fly-pest free areas (FF-PFAs), fruit fly free places of production or fruit fly free production sites (either as a permanent buffer zone or as part of an eradication process), or for export purposes, usually in conjunction with other risk mitigation measures as a component of a systems approach (this may include all or part of an FF-ALPP that acts as a buffer zone).

They may occur naturally (and subsequently be verified, declared and monitored or otherwise managed); they may occur as a result of pest management practices during crop production that suppress the population of fruit flies in an area to limit their impact on the crop; or they may be established as a result of management practices that reduce the number of fruit flies in the area to a specified low level.

The decision to establish an FF-ALPP may be closely linked to market access as well as to economic and operational feasibility.

If an FF-ALPP is established for export of fruit fly host commodities, the parameters for establishment and maintenance of the FF-ALPP should be determined and agreed in conjunction with the importing country and in consideration of the guidelines presented in this standard.

The requirements for the establishment of FF-ALPPs laid down in this standard can also be applied in domestic trade for movement of fruit in ALPPs within a country.

REQUIREMENTS

1. General Requirements

The concepts and provisions of ISPM No. 22 (*Requirements for the establishment of areas of low pest prevalence*) apply to the establishment and maintenance of ALPPs for a specified pest, or a group of pests including fruit flies, and therefore ISPM No. 22 should be referred to in conjunction with this standard.

An FF-ALPP may be established in accordance with this standard under a variety of situations. Some of them may require the application of the full range of elements provided by this standard, whereas others may require the application of only some of those elements.

Phytosanitary measures and specific procedures as further described in this standard may be required for the establishment and maintenance of an FF-ALPP by the NPPO. The decision to establish an official FF-ALPP may be based on all or some of the technical factors provided in this standard, as appropriate. They include necessary components such as pest biology and control methods, which will vary according to the species of fruit fly for which the FF-ALPP is being established.

The establishment of an official FF-ALPP should be considered against the overall operational and economic feasibility of establishing a programme to meet and maintain the low pest level and the objectives of the FF-ALPP.

An FF-ALPP may be applied to facilitate the movement of fruit fly hosts from one FF-ALPP to another of the same fruit fly pest status to protect areas endangered by a regulated fruit fly pest.

The essential prerequisite for establishment of an FF-ALPP is an area that exists naturally, or that can be established, and that can be delimited, monitored and verified by the NPPO to be of a specified fruit fly prevalence level. The area may be in place to protect an FF-PFA or support sustainable crop production, or may have developed in response to suppression or eradication actions. It may occur naturally as a result of climatic, biological or geographical factors that reduce or limit the fruit fly population through all or part of the year.

An area can be defined as an FF-ALPP for one or more target fruit fly species. However, for an FF-ALPP covering multiple target fruit fly species, trapping devices and their deployment densities and locations should be specified, and low pest prevalence levels determined for each target fruit fly species.

FF-ALPPs should include public awareness programmes of a similar nature as outlined in section 1.1 of ISPM No. 26 (*Establishment of pest free areas for fruit flies (Tephritidae)*).

1.1 Operational plans

An official operational plan is needed to specify the required phytosanitary procedures to establish and maintain an FF-ALPP.

The operational plan should describe the main procedures to be carried out such as surveillance activities, procedures to maintain the specified level of low pest prevalence, the corrective action plan and any other procedures that are required to achieve the objective of the FF-ALPP.

1.2 Determination of an FF-ALPP

Elements to be considered in the determination of an FF-ALPP are as follows:

- delimitation of the area (size of location, detailed maps including an accurate description of the boundaries or Global Positioning System (GPS) coordinates showing the boundaries, natural barriers, entry points, location of commercial and, as appropriate, non-commercial hosts of the target fruit fly and urban areas)
- target fruit fly species and its/their seasonal and spatial distribution within the area
- location, abundance and seasonality of hosts, including wherever possible specifying primary (biologically preferred) hosts
- climatic characteristics, including rainfall, relative humidity, temperature, and prevailing wind speed and direction.

In areas where prevalence of fruit flies is naturally at a low level because of climatic, geographical or other reasons (e.g. natural enemies, availability of suitable hosts, host seasonality), the target fruit fly population may already be below the specified level of low pest prevalence without applying any control measures. In such cases, surveillance should be undertaken to validate the low prevalence status and this status may be recognized in accordance with the examples listed in section 3.1.1 of ISPM No. 8 (*Determination of pest status in an area*). If, however, the fruit flies are detected above the specified level of low pest prevalence (for example, because of extraordinary climatic conditions or other reasons) corrective actions should be applied. Guidelines for corrective action plans are provided in Annex 2.

1.3 Documentation and record keeping

The phytosanitary procedures used for the determination, establishment, verification and maintenance of an FF-ALPP should be adequately documented. These procedures should be reviewed and updated regularly, including the corrective actions if required (as described in ISPM No. 22: *Requirements for the establishment of areas of low pest prevalence)*. It is recommended that a manual of procedures relating to the operational plan be prepared for the FF-ALPP.

Documentation for determination and establishment may include:

- list of fruit fly hosts known to occur in the area, including seasonality and commercial fruit production in the area

- delimitation records: detailed maps showing the boundaries, natural barriers and points where fruits may enter the area; description of agro-ecological features such as soil type, the location of main host areas of target fruit fly, and marginal and urban host areas; and meteorological conditions, for example rainfall, relative humidity, temperature, and prevailing wind speed and direction
- surveillance records:
  - trapping: types of surveys, number and type of traps and lures, frequency of trap inspection, trap density, trap array, number of target fruit flies captured by species for each trap
  - fruit sampling: type, quantity, date, frequency and result
- record of control measures used for fruit flies and other pests that may have an effect on fruit fly populations: type(s) and locations.

For verification and maintenance, documentation should include the data recorded to demonstrate the population levels of the target fruit fly species are below the specified level of low pest prevalence. The records of surveys and results of other operational procedures should be retained for at least 24 months. If the FF-ALPP is being used for export purposes, records should be made available to the NPPO of the relevant importing country on request.

Corrective action plans should also be developed and maintained (see section 2.4).

1.4 Supervision activities

The FF-ALPP programme, including applicable domestic regulations, surveillance procedures (e.g. trapping, fruit sampling) and corrective action plans, should comply with officially approved procedures. These procedures may include official delegation of responsibility assigned to key personnel, for example:

- a person with defined authority and responsibility to ensure that the systems/procedures are implemented and maintained appropriately
- entomologist(s) with responsibility for the identification of fruit flies to species level.

The NPPO should evaluate and/or audit the operation of the procedures for establishment and maintenance of the FF-ALPP to ensure that effective management is maintained even where the responsibility to carry out specific activities has been delegated to outside the NPPO. Supervision of operational procedures include:

- operation of surveillance procedures
- surveillance capability
- trapping materials (traps, attractants) and procedures
- identification capability
- application of control measures
- documentation and record keeping
- implementation of corrective actions.

2. Specific Requirements

2.1 Establishment of the FF-ALPP

Elements for consideration when establishing an FF-PFA are described in sections 2.1 and 2.2 of ISPM No. 26 (*Establishment of pest free areas for fruit flies (Tephritidae)*) and may also be applied to an FF-ALPP as defined in following subsections.

2.1.1 Determination of the specified level of low pest prevalence

Specified levels of low pest prevalence will depend on the level of risk associated with the target fruit fly species–host–area interaction. These levels should be established by the NPPO of the country where the FF-ALPP is located and with sufficient precision to allow assessment of whether surveillance data and protocols are adequate to determine that pest prevalence is below these levels.

Individual NPPOs may draw on a variety of different factors when determining exactly what an appropriate level of pest prevalence should be for a given FF-ALPP. Some commonly considered factors include the following:

- levels stipulated by trading partners in order for trade to proceed
- levels in use by other NPPOs for the same or similar fruit fly species, hosts and agro-ecological conditions (including experience and/or historical data gained from the operation of other FF-ALPPs as to what levels are required to be maintained to achieve pest free fruits).

Establishment of the parameters used to estimate the level of fruit fly prevalence is described in Annex 1.

2.1.2 Geographical description

The NPPO defines the limits of a proposed FF-ALPP. Isolation of the area (physical or geographical) is not necessarily required for establishment of FF-ALPP.

Boundaries used to describe the delimitation of the FF-ALPP should be established and closely related to the relative presence of primary hosts of the target fruit fly species or adjusted to readily recognizable boundaries.

2.1.3 Surveillance activities prior to establishment

Prior to the establishment of an FF-ALPP, surveillance to assess the presence and level of prevalence of the target fruit fly species should be undertaken for a period determined by its biology, behaviour, climatic characteristics of the area, host availability and appropriate technical considerations for at least 12 consecutive months.

2.2 Phytosanitary procedures

2.2.1 Surveillance activities

Surveillance systems based on trapping are similar in any type of ALPP. The surveillance used in an FF-ALPP may include those processes described in ISPM No. 6 (*Guidelines for surveillance*), section 2.2.2.1 on trapping procedures of ISPM No. 26 (*Establishment of pest free areas for fruit flies (Tephritidae)*) and any other relevant scientific information.

Fruit sampling as a routine surveillance method is not widely used for monitoring fruit flies in low prevalence areas except in areas where sterile insect technique (SIT) is applied, where it may be a major tool.

The NPPO may complement trapping with fruit sampling for fruit fly surveillance and/or monitoring. However, fruit sampling alone will not provide sufficient accuracy for describing the size of the population and should not be solely relied on to validate or verify the FF-ALPP status. Surveillance procedures may include those described in section 2.2.2.2 on fruit sampling procedures of ISPM No. 26 (*Establishment of pest free areas for fruit flies (Tephritidae)*).

The presence and distribution of fruit fly hosts should be recorded separately identifying commercial and primary non-commercial hosts. This information will help in planning the trapping and host sampling activities and may help in anticipating the potential ease or difficulty of establishing and maintaining the phytosanitary status of the area.

The NPPO should have, or have access to, appropriate identification capabilities for identification of the target fruit fly species detected during the surveys (whether adult or larvae). This capability should also exist for the ongoing verification of FF-ALPP status for the target fruit fly species.

2.2.2 Reduction and maintenance 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 may involve the use of more than one control option; some of these are described in section 3.1.4.2 of ISPM No. 22 (*Requirements for the establishment of areas of low pest prevalence*).

Since the target fruit fly species are endemic or established in the area, preventive and/or sustainable control measures to maintain fruit fly populations at or below the specified level of low pest prevalence are nearly always necessary (some FF-ALPPs may occur naturally). Efforts should be made by NPPOs to select those measures with least environmental impact.

Available methods may include:

- chemical control (e.g. selective insecticide bait, aerial and ground spraying, bait stations and male annihilation technique)
- physical control (e.g. fruit bagging)

- use of beneficial organisms (e.g. natural enemies, SIT)
- cultural control (e.g. stripping and destruction of mature and fallen fruit, elimination or replacement of other host plants by non-host plants where appropriate, early harvesting, discouraging intercropping with fruit fly host plants, pruning before the fruiting period, use of perimeter trap hosts).

2.2.3 Phytosanitary measures related to movement of host material or regulated articles

Phytosanitary measures may be required to reduce the risk of entry of the specified pests into the FF-ALPP. These are outlined in section 3.1.4.3 of ISPM No. 22 (*Requirements for the establishment of areas of low pest prevalence*).

2.2.4 Domestic declaration of an FF-ALPP

The NPPO should verify the status of the FF-ALPP (in accordance with ISPM No. 8: *Determination of pest status in an area*) specifically by confirming compliance with the procedures established in accordance with this standard (surveillance and controls). The NPPO should declare and notify the establishment of the FF-ALPP, as appropriate.

To verify the status of the FF-ALPP and for purposes of internal management, the continuing FF-ALPP status should be verified after it has been established and any phytosanitary measures for the maintenance of the FF-ALPP have been put in place.

2.3 Maintenance of the FF-ALPP

Once the FF-ALPP is established, the NPPO should maintain the relevant documentation and verification procedures (auditable), and continue the application of phytosanitary procedures.

2.3.1 Surveillance

In order to maintain the FF-ALPP status, the NPPO should continue surveillance, as described in section 2.2.1 of this standard.

2.3.2 Measures to maintain low prevalence levels of target fruit fly species

In most cases the control measures as identified in section 2.2.2 may be applied to maintain the FF-ALPP, since the target fruit flies are still present in the established area.

If the monitored fruit fly prevalence level is observed to be increasing (but remains below the specified level for the area), a threshold established by the NPPO for the application of measures may be reached. At this point the NPPO may require implementation of additional control measures (e.g. as described in section 3.1.4.2 of ISPM No. 22: *Requirements for the establishment of areas of low pest prevalence*). This threshold should be set to provide adequate warning of potentially exceeding the specified level of low pest prevalence and avert suspension.

2.4 Corrective action plans

A corrective action plan for the FF-ALPP should be applied by the NPPO when the population level of the target fruit fly exceeds the specified level of low pest prevalence. Annex 2 provides guidelines on corrective action plans for FF-ALPPs.

2.5 Suspension, reinstatement and loss of FF-ALPP status

2.5.1 Suspension of FF-ALPP status

If the specified level of low pest prevalence of the target fruit fly species is exceeded either throughout the whole FF-ALPP area or within a part of the FF-ALPP, the entire FF-ALPP is normally suspended. However, where the affected area within the FF-ALPP can be identified and clearly delimited, then the FF-ALPP may be redefined to suspend only that area.

Relevant importing NPPOs should be notified without undue delay of these actions (further information on pest reporting requirements is provided in ISPM No. 17: *Pest reporting*).

Suspension may also apply if faults in the procedures or their application are found (for example, inadequate trapping or pest control measures or inadequate documentation).

If an FF-ALPP is suspended, an investigation by the NPPO should be initiated to determine the cause of the failure and introduce measures to prevent such failures from reoccurring.

When an FF-ALPP is suspended, the criteria for reinstatement should be made clear.

2.5.2 Reinstatement of FF-ALPP status

Reinstatement of FF-ALPP status applies only to suspended areas and may take place when:

- The population level no longer exceeds the specified level of low pest prevalence and this is maintained for a period determined by the biology of the target fruit fly species and the prevailing environmental conditions.
- Faulty procedures have been corrected and verified.

Once the specified level of low prevalence has been achieved and maintained as required above or procedural faults have been rectified through the application of corrective actions contained in the plan, the FF-ALPP status can be reinstated. If the FF-ALPP is established for export of host fruits, the reinstatement may be subject to recognition by the relevant importing country(ies). This recognition of reinstatement should be carried out without undue delay by the NPPO of the importing country.

2.5.3 Loss of FF-ALPP status

Loss of FF-ALPP status should occur after suspension if reinstatement has failed to take place within an acceptable time frame. Relevant importing NPPOs should be notified without undue delay of the change in status of the FF-ALPP (further information on pest reporting requirements is provided in ISPM No. 17: *Pest reporting*).

In the event that FF-ALPP status is lost, the procedures for establishment and maintenance outlined in this standard should be followed to achieve the FF-ALPP status again, and should take into account all background information related to the area.

ANNEX 1

PARAMETERS USED TO ESTIMATE THE LEVEL OF FRUIT FLY PREVALENCE[1]

Parameters used to determine the level of fruit fly prevalence in the FF-ALPP are defined by the NPPO. The most widely used parameter is flies per trap per day (FTD). More precise spatial data may be presented on the basis of trap density (i.e. FTD per unit area) or temporally for each trap present in an area over time.

The FTD is an index used to estimate the population by averaging the number of flies captured by one trap in one day. This parameter estimates the relative number of fruit fly adults in a given time and space. It provides baseline information to compare fruit fly populations among different places and/or time.

The FTD is the result of dividing the total number of captured flies by the product obtained from multiplying the total number of inspected traps by the average number of days the traps were exposed. The formula is as follows:

$$FTD = \frac{F}{T \times D}$$

Where
F = total number of flies captured
T = number of inspected traps
D = number of days traps were exposed in the field.

In cases where traps are regularly inspected on a weekly basis, or longer in the case of winter surveillance operations, the parameter may be "flies per trap per week" (FTW). It estimates the number of flies captured by one trap in one week. Thus, FTD can be obtained from FTW by dividing by 7.

Specified levels of low pest prevalence, as expressed in FTD values, should be established in relation to the risk of infestation of the fruits that are intended to be protected by the FF-ALPP, and in relation to any specific related objectives of the FF-ALPP (e.g. fruit-fly free commodities for export). In situations where a single FF-ALPP contains more than one host species (i.e. the ALPP is intended to protect more than one target fruit fly host), the specified level of low pest prevalence should be based on scientific information relating to the primary host of the fruit fly species, the risks of infestation and comparative preferences of the target fruit fly species for the different hosts. However, in situations where the FF-ALPP is established to protect only one type of host, consideration should be given as to whether that host is a primary host or a secondary host. In such situations, lower specified levels of low pest prevalence are usually established for the primary host(s) of the target fruit fly species and comparatively higher levels for secondary hosts.

The biology of the target fruit flies (including number of generations per year, host range, host species present in the area, temperature thresholds, behaviour, reproduction and dispersion capacity) plays a major role in establishing appropriate specified levels of low pest prevalence. For an FF-ALPP with several hosts present, the established specified levels of low pest prevalence should reflect host diversity and abundance, host preference and host sequence for each target fruit fly species present. Although an FF-ALPP may have different specified levels of low pest prevalence for each relevant fruit fly target species, those levels should remain fixed for the whole area and duration of the FF-ALPP operation.

Efficiency of the types of traps and attractants used to estimate the levels of the pest population and the procedures applied for servicing the traps should be taken into consideration. The rationale is that different trap efficiencies could lead to different FTD results at the same location for a given population, so they have a significant effect in measuring the prevalence level of the target fruit fly species. Thus, when specifying the level of low pest prevalence accepted in terms of an FTD value, the efficacy of the trapping system should be stated as well.

[1] This annex is an official part of the standard.

Once a specified level of low pest prevalence has been established for a given situation using a specific lure/attractant, the lure/attractant used in the FF-ALPP must not be changed or modified until an appropriate specified level of low pest prevalence is established for the new formulation. For FF-ALPPs with multiple target fruit fly species present that are attracted to different lures/attractants, trap placement should take into consideration possible interactive effects between lures/attractants.

Fruit sampling can be used as a complementary surveillance method to trapping to assess the profile of the fruit fly population levels. However, fruit sampling will not provide sufficient accuracy for describing the size of the population and should not be solely relied on to validate or verify the FF-ALPP status.

ANNEX 2

GUIDELINES ON CORRECTIVE ACTION PLANS FOR FRUIT FLIES IN AN FF-ALPP[2]

The detection of a population level exceeding the specified level of low pest prevalence for the target fruit fly species in the FF-ALPP should trigger the application of a corrective action plan. The objective of the corrective action plan is to ensure suppression of the fruit fly population to below the specified level for low pest prevalence as soon as possible. It is the responsibility of the NPPO to ensure that appropriate corrective action plans are developed. Corrective action plans should not be repeatedly implemented because this may lead to a loss of FF-ALPP status and the need to re-establish the area in accordance with the guidelines of this standard.

The corrective action plan should be prepared taking into account the biology of the target fruit fly species, the geography of the FF-ALPP, climatic conditions, phenology, and host abundance and distribution within the area.

The elements required for implementation of a corrective action plan include:
- declaration of suspension of FF-ALPP of status, where appropriate
- legal framework under which the corrective action plan can be applied
- time scales for the initial response and follow-up activities
- delimiting survey (trapping and fruit sampling) and application of the suppression actions
- identification capability
- availability of sufficient operational resources
- effective communication within the NPPO and with the NPPO(s) of the relevant importing country(ies), including provision of contact details of all parties involved
- a detailed map and definition of the suspension area.

Application of the corrective action plan

1. Notice to implement corrective actions

The NPPO notifies interested stakeholders and parties, including relevant importing countries, when initiating the application of a corrective action plan. The NPPO, or an NPPO-nominated agency, is responsible for supervising the implementation of corrective measures.

2. Determination of the phytosanitary status

Immediately after detecting a population level higher than the specified level of low pest prevalence, a delimiting survey (which may include the deployment of additional traps, fruit sampling of primary host fruits and increased trap inspection frequency) should be implemented to determine the size of the affected area and more precisely gauge the level of the fruit fly prevalence.

3. Suspension of FF-ALPP status

If the specified level of low pest prevalence of the target fruit fly species is exceeded, the FF-ALPP status should be suspended as stated in section 2.5.1.

4. Implementation of control measures in the affected area

Specific suppression actions should immediately be implemented in the affected area(s). Available methods include:
- selective insecticide-bait treatments (aerial and/or ground spraying and bait stations)
- sterile insect technique
- male annihilation technique
- collection and destruction of affected fruit
- stripping and destruction of primary host fruits, if possible
- insecticide treatments (ground, cover).

5. Notification of relevant agencies

[2] This annex is an official part of the standard.

Relevant NPPOs and other agencies should be kept informed of corrective actions. Information on pest reporting requirements under the IPPC is provided in ISPM No. 17 (*Pest reporting*).

APPENDIX 1

GUIDELINES ON TRAPPING PROCEDURES[3]

Information about trapping is available in the following publication of the International Atomic Energy Agency (IAEA): *Trapping Guidelines for area-wide fruit fly programmes*, IAEA/FAO-TG/FFP, 2003. IAEA, Vienna.

This publication is widely available, easily accessible and generally recognized as authoritative.

[3] This appendix is not an official part of the standard. It is provided for information only.

APPENDIX 2

TYPICAL APPLICATIONS OF FF-ALPPS[4]

1. An FF-ALPP as a buffer zone

In cases where the biology of the target fruit fly species is such that it is likely to disperse from an infested area into a protected area, it may be necessary to define a buffer zone with a low fruit fly prevalence (as described in ISPM No. 26: *Establishment of pest free areas for fruit flies (Tephritidae)*). These FF-ALPPs are usually established at the same time as establishing the FF-PFA and may subsequently be redefined to improve protection of the FF-PFA.

1.1 Determination of an FF-ALPP as a buffer zone

Determination procedures may include those listed in section 1.2 of this ISPM. In addition, in delimiting the buffer zone, detailed maps may be included showing the boundaries of the area to be protected, distribution of hosts, host location, urban areas, entry points and control checkpoints. It is also relevant to include data related to natural biogeographical features such as prevalence of other hosts, climate, and location of valleys, plains, deserts, rivers, lakes and sea, as well as those areas that function as natural barriers. The size of the buffer zone in relation to the size of the area being protected will depend on the biology of the target fruit fly species (including behaviour, reproduction and dispersal capacity), the intrinsic characteristics of the protected area, and the economic and operational feasibility of establishing the FF-ALPP.

1.2 Establishment of an FF-ALPP as a buffer zone

The establishment procedures are described in section 2.1. The movement of relevant fruit fly host commodities into the area may need to be regulated. Additional information can be found in section 2.2.3 of ISPM No. 26 (*Establishment of pest free areas for fruit flies (Tephritidae)*).

1.3 Maintenance of an FF-ALPP as a buffer zone

Procedures include those listed in section 2.3. Since the buffer zone has features similar to the area or place of production it protects, procedures for maintenance may include those listed for the FF-PFA as described in section 2.3 of ISPM No. 26 (*Establishment of pest free areas for fruit flies (Tephritidae)*) and sections 3.1.4.2, 3.1.4.3 and 3.1.4.4 of ISPM No. 22 (*Requirements for the establishment of areas of low pest prevalence*). The importance of information dissemination may also be considered in the maintenance of an FF-ALPP as a buffer zone.

2 FF-ALPPs for export purposes

FF-ALPPs may be used to facilitate fruit exports from the area. In most cases the FF-ALPP is the main component of a systems approach as a pest risk mitigation measure. Examples of measures and/or factors used in conjunction with FF-ALPPs include:

- pre- and post-harvest treatments
- production of secondary hosts or non-hosts in preference to primary hosts
- export of host material to areas not at risk during particular seasons
- physical barriers (e.g. pre-harvest bagging, insect-proof structures).

2.1 Determination of an FF-ALPP for export purposes

Determining procedures may include those listed in section 1.2. In addition, the following elements should be considered for the determination of an FF-ALPP:

- a list of products (hosts) of interest
- a list of other commercial and non-commercial hosts of the target fruit fly species present but not intended for export and their level of occurrence, as appropriate
- additional information such as any historical records in connection with biology, occurrence and control of the target fruit fly species or any other fruit fly species that may be present in the FF-ALPP.

2.2 Maintenance of an FF-ALPP for export purposes

[4] This appendix is not an official part of the standard. It is provided for information only.

Maintenance procedures may include those described in section 2.3.2 and should be applied if hosts are available. If appropriate, surveillance may continue at a lower frequency during the off-season period. This will depend on the biology of the target fruit fly species and its relationship with hosts present during the off-season period.

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INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

METHODOLOGIES FOR SAMPLING OF CONSIGNMENTS

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INTRODUCTION

SCOPE

This standard provides guidance to National Plant Protection Organizations (NPPOs) in selecting appropriate sampling methodologies for inspection or testing of consignments to verify compliance with phytosanitary requirements.

This standard does not give guidance on field sampling (for example, as required for surveys).

REFERENCES

Cochran, W.G. 1977. *Sampling techniques*. 3rd edn. New York, John Wiley & Sons. 428 pp.
Glossary of phytosanitary terms, 2007. ISPM No. 5, FAO, Rome.
Guidelines for inspection, 2005. ISPM No. 23, FAO, Rome.
Guidelines for phytosanitary import regulatory systems, 2004, ISPM No. 20, FAO Rome.
Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms, ISPM No. 11, 2004, FAO, Rome.
Pest risk analysis for regulated non-quarantine pests, 2004. ISPM No. 21, FAO, Rome.
Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade, 2006. ISPM No. 1, FAO, Rome.

DEFINITIONS

Definitions of phytosanitary terms used in the present standard can be found in ISPM No. 5 (*Glossary of phytosanitary terms*).

OUTLINE OF REQUIREMENTS

The sampling methodologies used by NPPOs in selecting samples for the inspection of consignments of commodities moving in international trade are based on a number of sampling concepts. These include parameters such as acceptance level, level of detection, confidence level, efficacy of detection, sample size and tolerance level.

The application of statistically based methods, such as simple random sampling, systematic sampling, stratified sampling, sequential sampling or clustered sampling, provides results with a statistical confidence level. Other sampling methods that are not statistically based, such as convenience sampling, haphazard sampling or selective sampling, may provide valid results in determining the presence or absence of a regulated pest(s) but no statistical inference can be made on their basis. Operational limitations will have an effect on the practicality of sampling under one or another method.

In using sampling methodologies, NPPOs accept some degree of risk that non-conforming lots may not be detected. Inspection using statistically based methods can provide results with a certain level of confidence only and cannot prove the absence of a pest from a consignment. Sampling may result in an NPPO undertaking phytosanitary action on the consignment.

BACKGROUND

This standard provides the statistical basis for, and complements, ISPMs No. 20 (*Guidelines for phytosanitary import regulatory systems*) and No. 23 (*Guidelines for inspection*). Inspection of consignments of regulated articles moving in trade is an essential tool for the management of pest risks and is the most frequently used phytosanitary procedure worldwide to determine if pests are present and/or the compliance with phytosanitary import requirements.

It is usually not feasible to inspect entire consignments, so phytosanitary inspection is performed mainly on samples obtained from a consignment. It is noted that the sampling concepts presented in this standard may also apply to phytosanitary procedures, notably selection of units for testing.

Sampling of plants, plant products and other regulated articles may occur prior to export, at the point of import, or other points as determined by NPPOs.

It is important that sampling procedures established and used by NPPOs are documented and transparent, and take into account the principle of minimum impact (ISPM No. 1: *Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade*), particularly because inspection based on sampling may lead to refusal to issue a phytosanitary certificate, refusal of entry, or treatment or destruction of a consignment or part of a consignment.

Sampling methodologies used by NPPOs will depend on the sampling objectives (for example, sampling for testing) and may be solely statistically based or developed noting particular operational constraints. Methodologies developed to achieve the sampling objectives, within operational constraints, may not yield the same statistical confidence levels in the results as fully statistically based methods, but such methods may still give valid results depending on the desired sampling objective. If the sole purpose of sampling is to increase the chance of finding a pest, selective or targeted sampling is also valid.

OBJECTIVES OF SAMPLING OF CONSIGNMENTS

Sampling of consignments is done for inspection and testing in order to:

- detect regulated pests
- provide assurance that the number of regulated pests or infested units in a consignment does not exceed the specified level for the pest
- provide assurance of the general phytosanitary condition of a consignment
- detect organisms for which a phytosanitary risk has not yet been determined
- optimize the probability of detecting specific regulated pests
- maximize the use of available sampling resources
- gather other information such as for monitoring of a pathway
- verify compliance with phytosanitary requirements
- determine the proportion of the consignment infested.

It should be noted that inspection and/or testing based on sampling always involves a degree of error. The acceptance of some probability that the pests are present is inherent in the use of sampling procedures for inspection and/or testing. Inspection and/or testing using statistically based sampling methods can provide confidence that the incidence of a pest is below a certain level, but it can never prove that a pest is truly absent from a consignment.

REQUIREMENTS

1. Lot Identification

A consignment may consist of one or more lots. Where a consignment comprises more than one lot, the inspection to determine compliance may have to consist of several separate visual examinations, and therefore the lots will have to be sampled separately. In such cases, the samples relating to each lot should be segregated and identified in order that the appropriate lot can be clearly identified if subsequent inspection or testing reveals non-compliance with phytosanitary requirements. Whether or not a lot will be inspected should be determined using factors stated in ISPM No. 23 (*Guidelines for inspection*, section 1.5).

A lot to be sampled should be a number of units of a single commodity identifiable by its homogeneity in factors such as:

- origin
- grower
- packing facility
- species, variety, or degree of maturity
- exporter
- area of production
- regulated pests and their characteristics
- treatment at origin
- type of processing.

The criteria used by the NPPO to distinguish lots should be consistently applied for similar consignments.

Treating multiple commodities as a single lot for convenience may mean that statistical inferences can not be drawn from the results of the sampling.

2. Sample Unit

Sampling first involves the identification of the appropriate unit for sampling (for example, a fruit, stem, bouquet, unit of weight, bag or carton). The determination of the sample unit is affected by issues related to homogeneity in the distribution of pests through the commodity, whether the pests are sedentary or mobile, how the consignment is packaged, intended use, and operational considerations. For example, if determined solely on pest biology, the appropriate sample unit might be an individual plant or plant product in the case of a low-mobility pest, whereas in the case of mobile pests, a carton or other commodity container may be the preferred sample unit. However, when inspection is to detect more than one type of pest, other considerations (for example, practicality of using different sample units) may apply.

3. Statistical and Non-Statistical Sampling

The sampling method is the process approved by the NPPO to select units for inspection and/or testing. Sampling for phytosanitary inspection of consignments or lots is done by taking units from the consignment or lot without replacement of the units selected[1]. NPPOs may choose either a statistically based or targeted sampling methodology.

Sampling based on statistical or targeted methods is designed to facilitate the detection of a regulated pest(s) in a consignment and/or lot.

3.1 Statistically based sampling

Statistically based sampling methods involve the determination of a number of interrelated parameters and the selection of the most appropriate statistically based sampling method.

3.1.1 Parameters

Statistically based sampling is designed to detect a certain percentage or proportion of infestation with a specific confidence level, and thus requires the NPPO to determine the following interrelated parameters: acceptance number, level of detection, confidence level, efficacy of detection and sample size. The NPPO may also establish a tolerance level for certain pests (e.g. regulated non-quarantine pests).

3.1.1.1 Acceptance number

The acceptance number is the number of infested units or the number of individual pests that are permissible in a sample of a given size before phytosanitary action is taken. Many NPPOs determine this number to be zero for quarantine pests. For example, if the acceptance number is zero and an infested unit is detected in the sample then phytosanitary action will be taken. It is important to appreciate that a zero acceptance number within a sample does not mean a zero tolerance level in the consignment as a whole. Even if no pests are detected in the sample there remains a probability that the pest may be present in the rest of the consignment, albeit at a very low level.

[1] Sampling without replacement is selecting a unit from the consignment or lot without replacing the unit before the next units are selected. Sampling without replacement does not mean that a selected item cannot be returned to a consignment (except for destructive sampling); it means only that the inspector should not return it before selecting the remainder of the sample.

The acceptance number is linked to the sample. The acceptance number is the number of infested units or the number of individual pests that are permissible in the sample whereas the tolerance level (see section 3.1.1.6) refers to the status of the entire consignment.

3.1.1.2 Level of detection

The level of detection is the minimum percentage or proportion of infestation that the sampling methodology will detect at the specified efficacy of detection and level of confidence, which the NPPO intends to detect in a consignment.

The level of detection may be specified for a pest, a group or category of pests, or for unspecified pests. The level of detection may be derived from:

- a decision based on pest risk analysis to detect a specified level of infestation (the infestation determined to present an unacceptable risk)
- an evaluation of the effectiveness of phytosanitary measures applied before inspection
- an operationally based decision that inspection above a certain level is not practical.

3.1.1.3 Confidence level

The confidence level indicates the probability that a consignment with a degree of infestation exceeding the level of detection will be detected. A confidence level of 95% is commonly used. The NPPO may choose to require different confidence levels depending on the intended use of the commodity. For example, a higher confidence level for detection may be required for commodities for planting than for commodities for consumption, and the confidence level may also vary with the strength of the phytosanitary measures applied and historical evidence of non-compliance. Very high confidence level values quickly become difficult to achieve, and lower values become less meaningful for decision-making. A 95% confidence level means that the conclusions drawn from the results of sampling will detect a non-compliant consignment, on average, 95 times out of 100, and therefore, it may be assumed that, on average, 5% of non-compliant consignments will not be detected.

3.1.1.4 Efficacy of detection

The efficacy of detection is the probability that an inspection or test of an infested unit(s) will detect a pest. In general the efficacy should not be assumed to be 100%. For example, pests may be difficult to detect visually; plants may not express symptoms of disease (latent infection); or efficacy may be reduced as a result of human error. It is possible to include lower efficacy values (for instance, an 80% chance of detecting the pest when an infested unit is inspected) in the determination of sample size.

3.1.1.5 Sample size

The sample size is the number of units selected from the lot or consignment that will be inspected or tested.

3.1.1.6 Tolerance level

Tolerance level refers to the percentage of infestation in the entire consignment or lot that is the threshold for phytosanitary action. The level of detection should be less than, or equal to, the tolerance level.

Tolerance levels may be established for regulated non-quarantine pests (as described in ISPM No. 21: *Pest risk analysis for regulated non-quarantine pests*, section 4.4) and may also be established for conditions related to other phytosanitary import requirements (for example, bark on wood or soil on plant roots).

Most NPPOs have a zero tolerance level for all quarantine pests, taking into account probabilities of pest presence in the non-sampled components as described in section 3.1.1.1. However, an NPPO may determine to establish a tolerance level for a quarantine pest based on pest risk analysis (as described in ISPM No. 11: *Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms*, section 3.4.1) and then determine sampling rates from this. For example, NPPOs may determine a tolerance level that is greater than zero because small numbers of the quarantine pest may be acceptable if the establishment potential of the pest is considered low or if the intended end use of the product (for example, fresh fruit and vegetables imported for processing) limits the potential of entry of the pest into endangered areas.

3.1.2 Links between the parameters

The six parameters (acceptance number, level of detection, confidence level, efficacy of detection, sample size and tolerance level) are statistically related. The NPPO should determine the efficacy of the detection method used and decide upon the acceptance number in the sample; any two of the remaining four parameters can also be chosen, and the remainder will be determined from the values chosen for the rest.

If a tolerance level based on risk analysis is used, the level of detection chosen should be equal to (or less than, if the acceptance number is greater than zero) the tolerance level to ensure that consignments having an infestation level greater than the tolerance level will be detected with the specified confidence level.

If no pests are detected in the sample unit, then the percentage of infestation in the consignment can not be stated beyond the fact that it falls below the level of detection at the stated confidence level. If the pest is not detected with the appropriate sample size, the confidence level gives a probability that the tolerance level is not exceeded.

3.1.3 Statistically based sampling methods

3.1.3.1 Simple random sampling

Simple random sampling involves drawing the sample units in accordance with a tool such as a random numbers table. The use of a predetermined randomization process is what distinguishes this method from haphazard sampling (described in section 3.2.2).

This method is often used when little is known about the pest distribution or rate of infestation. To use this method, each unit should have an equal probability of selection. In cases where a pest is not distributed randomly through the lot, this method may not be optimal. Random sampling may require greater resources depending on the type and/or configuration of the consignment.

3.1.3.2 Systematic sampling

Systematic sampling involves drawing a sample from units in the lot at fixed, predetermined intervals. However, the first selection must be made at random, and the assumption is made that the pest is randomly distributed through the lot. Biased results are possible if pests are not randomly distributed. Such biases may be reduced when consignments have been subjected to grading, sorting and mixing during the packing process.

Two advantages of this method are that the sampling process may be automated through machinery and that it requires the use of a random process only to select the first unit.

3.1.3.3 Stratified sampling

Stratified sampling involves separating the lot into separate subdivisions (that is, strata) and then drawing some of the samples from each subdivision. Within each subdivision, samples are taken using a particular method (systematic or random). Under some circumstances, different numbers of samples may be taken from each subdivision – for instance, the number of samples may be proportional to the size of the subdivision, or based on prior knowledge concerning the infestation of the subdivisions.

If at all feasible, stratified sampling will almost always improve detection accuracy. The smaller variation associated with stratified sampling yields more accurate results. This is especially true when infestation levels may vary across a lot depending on packing procedures or storage conditions. Stratified sampling is the preferred choice when knowledge about the pest distribution is presumed and operational considerations will allow it.

3.1.3.4 Sequential sampling

Sequential sampling involves drawing a series of samples using one of the above methods. After each sample (or group) is drawn, the data are accumulated and compared with predetermined ranges to decide whether to accept the consignment, reject the consignment or continue sampling.

This method can be used when a tolerance level greater than zero is determined and the first set of samples does not provide sufficient information to allow a decision to be made on whether or not the tolerance level is exceeded. This method would not be used if the acceptance number in a sample of any size is zero.

Sequential sampling may reduce the number of samples required for a decision to be made or reduce the possibility of rejecting a conforming consignment.

3.1.3.5 Clustered sampling

Clustered sampling involves selecting groups of units (for example, boxes of fruit, bunches of flowers) to make up the total number of sample units required from the lot. It is useful if resources available for sampling are limited and works well when the distribution of pests is expected to be random.

Clustered sampling can be stratified, and can use either systematic or random methods for selecting the groups. Of the statistically based methods, this method is often the most practical to implement.

3.2 Non-statistically based sampling

Other sampling methods that are not statistically based, such as convenience sampling, haphazard sampling or selective or targeted sampling, may provide valid results in determining the presence or absence of a regulated pest(s). The following methods may be used based on specific operational considerations or when the goal is purely detection of pests.

3.2.1 Convenience sampling

Convenience sampling involves selecting the most convenient (for example, accessible, cheapest, fastest) units from the lot, without selecting units in a random or systematic manner.

3.2.2 Haphazard sampling

Haphazard sampling involves selecting arbitrary units without using a true randomization process. This may often appear to be random because the inspector is not conscious of having any selection bias. However, unconscious bias may occur, so that the degree to which the sample is representative of the lot is unknown.

3.2.3 Selective or targeted sampling

Selective sampling involves deliberately selecting samples from parts of the lot most likely to be infested, or units that are obviously infested, in order to increase the chance of detecting a specific regulated pest. This method may rely on inspectors who are experienced with the commodity and familiar with the pest's biology. Use of this method may also be triggered through a pathway analysis identifying a specific section of the lot with a higher probability of being infested (for example, a wet section of timber may be more likely to harbour nematodes). Because the sample is targeted, and hence statistically biased, a probabilistic statement about the infestation level in the lot can not be made. However, if the sole purpose of sampling is to increase the chance of finding a regulated pest(s), this method is valid. Separate samples of the commodity may be required to meet general confidence in detection of other regulated pests.

4. Selecting a Sampling Method

In most cases the selection of an appropriate sampling method is necessarily dependent on information available about the pest’s incidence and distribution in the consignment or lot as well as the operational parameters associated with the inspection situation in question. In most phytosanitary applications, operational limitations will dictate the practicality of sampling under one or another method. Subsequently, determining the statistical validity of practical methods will narrow the field of alternatives.

The sampling method that is ultimately selected by the NPPO should be operationally feasible and be the most appropriate to achieve the objective and be well documented for transparency. Operational feasibility is clearly linked to judgements concerning situation-specific factors, but should be consistently applied.

If sampling is undertaken to increase the chance of detecting a specific pest, one of the targeted sampling methods (described in section 3.2) may be the preferred option, as long as the inspectors can identify the section(s) of the lot with a higher probability of being infested. Without this knowledge, one of the statistically based methods will be more appropriate. Targeted methods also do not result in each unit having an equal probability of being included in the sample, so the true confidence level and level of detection may not be equal to the values chosen by the NPPO.

If sampling is undertaken to provide knowledge about the general phytosanitary condition of a consignment, to detect multiple quarantine pests, to verify compliance with phytosanitary requirements, or for information gathering, one of the statistically based methods will be appropriate.

In selecting a statistically based method, consideration may be given to how the consignment has been treated in harvesting, sorting and packing, and the likely distribution of the pest(s) in the lot. Sampling methods may be combined: for instance, a stratified sample may have either random or systematic selection of sample units (or clusters) within strata.

If sampling is undertaken to determine whether a specific non-zero tolerance level has been exceeded, a sequential sampling method may be appropriate.

Once a sampling method has been selected and correctly applied, repeating the sampling with the aim of achieving a different result is unacceptable. Sampling should not be repeated unless considered necessary for specific technical reasons (for example, suspected incorrect application of sampling methodology or suspected infestation due to the inspection or test results).

5. Sample Size Determination

To determine the number of samples to be taken, the NPPO should select a confidence level (for example, 95%), a level of detection (for example, 5%) and an acceptance number (for example, zero), and determine the efficacy of inspection or testing (for example, 80%). From these values and the lot size, a sample size can be calculated. Appendices 1-5 set out the mathematical basis of sample size determination.

5.1 Pests distributed randomly in the lot

Because sampling is done without replacement and the population size is finite, the hypergeometric distribution should be used to determine the sample size. This distribution gives a probability of detecting a certain number of infested units in a sample of a given size drawn from a lot of a given size, when a specific number of infested units exist in the lot (see Appendix 1). The number of infested units in the lot is estimated as the level of detection multiplied by the total number of units in the lot.

As lot size increases, the sample size required for a specific level of detection and confidence level approaches an upper limit. When the sample size is less than 5% of the lot size, the sample size can be calculated using either the binomial or Poisson distribution (see Appendix 2). All three distributions (hypergeometric, binomial and Poisson) give almost identical sample sizes for specific confidence and detection levels at large lot sizes, but binomial and Poisson distributions are easier to calculate.

5.2 Pest distribution aggregated in the lot

Most pest populations are aggregated to some degree in the field. Because commodities may be harvested and packed in the field without being graded or sorted, the distribution of infested units in the lot may be clustered or aggregated. Aggregation of infested units of a commodity will always lower the likelihood of finding an infestation. However, phytosanitary inspections are aimed at detection of infested units and/or pest(s) at a low level. The effect of aggregation of the infested units on the detection efficacy of a sample and on the required sample size is small in most cases. When NPPOs identify that there is a high likelihood that there will be aggregation of infested units in the lot a stratified sampling method may help increase the chance of detecting an aggregated infestation.

When pests are aggregated, the calculation of sample size should ideally be performed using a beta-binomial distribution (see Appendix 3). However, this calculation requires knowledge of the degree of aggregation, which is generally not known and therefore this distribution is not practical for general use. One of the other distributions (hypergeometric, binomial or Poisson) can be used; however, the confidence level of the sampling will decline as the degree of aggregation increases.

5.3 Fixed proportion sampling

Sampling a fixed proportion of the units in the lot (for example, 2%) results in inconsistent levels of detection or confidence levels when lot size varies. As shown in Appendix 4, fixed proportion sampling results in changing confidence levels for a given level of detection, or in changing levels of detection for a given confidence level.

6. Varying Level of Detection

The choice of a constant level of detection may result in a varying number of infested units entering with imported consignments because lot size varies (for example, a 1% infestation level of 1000 units corresponds to 10 infested units, while a 1% infestation level of 10,000 units corresponds to 100 infested units). Ideally the selection of a level of detection will reflect in part the number of infested units entering on all consignments within a particular period of time. If NPPOs want to manage the number of infested units entering with each consignment as well, a varying detection level may be used. A tolerance level would be specified in terms of a number of infested items per consignment, and the sample size would be set in order to give the desired confidence and detection levels (further described in Appendix 4).

7. Outcome of Sampling

The outcome of activities and techniques related to sampling may result in phytosanitary action being taken (further details can be found in ISPM No. 23: *Guidelines for inspection*, section 2.5).

APPENDIX 1
CALCULATING SAMPLE SIZES FOR SMALL LOTS: HYPERGEOMETRIC-BASED SAMPLING (RANDOM SAMPLING)[2]

The hypergeometric distribution is appropriate to describe the probability of finding a pest in a relatively small lot. A lot is considered as small when the sample size is more than 5% of the lot size. In this case, sampling of one unit from the lot affects the probability of finding an infested unit in the next unit selected.

It is also assumed that the distribution of the pest in the lot is not aggregated and that random sampling is used. This methodology can be extended for other schemes such as stratified sampling (further details can be found in Cochran, 1977).

The probability of detecting *i* infested units in a sample is given by

$$P(X = i) = \frac{\binom{A}{i}\binom{N-A}{n-i}}{\binom{N}{n}} \qquad \text{Formula 1}$$

Where:

$$\binom{a}{b} = \frac{a!}{b!(a-b)!} \quad \text{where a!= a(a-1)(a-2)….. 1 and 0!=1}$$

P(X = i) is the probability of observing i infested units in the sample, where i = 0, …, *n*.

The confidence level corresponds to: 1- P(X = i)
A = number of infested units in the lot that could be detected if every unit in the lot was inspected or tested, given the efficacy of the inspection method or test (level of detection × N × efficacy, truncated to an integer)
i = number of infested units in the sample
N = number of units in the lot (size of the lot)
n = number of units in the sample (sample size)

In particular the approximation that can be used for the probability of finding no infested units is

$$P(X=0) = \left(\frac{N-A-u}{N-u}\right)^{n} \qquad \text{Formula 2}$$

where u = (n-1)/2 (from Cochran, 1977).

Solving the equation to determine *n* is difficult arithmetically but can be done with approximation or through maximum likelihood estimation.

Tables 1 and 2 show sample sizes calculated for different lot sizes, levels of detection and confidence levels, when the acceptance number is 0.

[2] This appendix is not an official part of the standard. It is provided for information only.

Table 1. Table of minimum sample sizes for 95% and 99% confidence levels at varying detection levels according to lot size, hypergeometric distribution

Number of units in lot	P = 95% (confidence level) % level of detection × efficacy of inspection or test					P = 99% (confidence level) % level of detection × efficacy of inspection or test				
	5	2	1	0.5	0.1	5	2	1	0.5	0.1
25	24*	-	-	-	-	25*	-	-	-	-
50	39*	48	-	-	-	45*	50	-	-	-
100	45	78	95	-	-	59	90	99	-	-
200	51	105	155	190	-	73	136	180	198	-
300	54	117	189	285*	-	78	160	235	297*	-
400	55	124	211	311	-	81	174	273	360	-
500	56	129	225	388*	-	83	183	300	450*	-
600	56	132	235	379	-	84	190	321	470	-
700	57	134	243	442*	-	85	195	336	549*	-
800	57	136	249	421	-	85	199	349	546	-
900	57	137	254	474*	-	86	202	359	615*	-
1 000	57	138	258	450	950	86	204	368	601	990
2 000	58	143	277	517	1553	88	216	410	737	1800
3 000	58	145	284	542	1895	89	220	425	792	2353
4 000	58	146	288	556	2108	89	222	433	821	2735
5 000	59	147	290	564	2253	89	223	438	840	3009
6 000	59	147	291	569	2358	90	224	442	852	3214
7 000	59	147	292	573	2437	90	225	444	861	3373
8 000	59	147	293	576	2498	90	225	446	868	3500
9 000	59	148	294	579	2548	90	226	447	874	3604
10 000	59	148	294	581	2588	90	226	448	878	3689
20 000	59	148	296	589	2781	90	227	453	898	4112
30 000	59	148	297	592	2850	90	228	455	905	4268
40 000	59	149	297	594	2885	90	228	456	909	4348
50 000	59	149	298	595	2907	90	228	457	911	4398
60 000	59	149	298	595	2921	90	228	457	912	4431
70 000	59	149	298	596	2932	90	228	457	913	4455
80 000	59	149	298	596	2939	90	228	457	914	4473
90 000	59	149	298	596	2945	90	228	458	915	4488
100 000	59	149	298	596	2950	90	228	458	915	4499
200 000+	59	149	298	597	2972	90	228	458	917	4551

Those values in the table marked with an asterisk (*) are because some scenarios presented in the tables result in a fraction of a unit being infested (for example, 300 units with 0.5% infestation corresponds to 1.5 infested units in the shipment). This is not possible for an individual shipment (whole numbers of units are infested). Therefore, values are given for the calculated number of infested units rounded down to a whole number. This means that the sampling intensity increases slightly, and may be greater for a shipment size where the number of infested units is rounded down than for a larger shipment where a larger number of infested units are calculated (for example, compare results for 700 and 800 units in the lot). It also means that a slightly lower proportion of infested units might be detected than the proportion indicated by the table, or that such infestation is more likely to be detected than the confidence level shown.

Those values in the table marked with a dash (-) are because some of the scenarios that are presented are not possible (less than one unit infested).

Table 2: Table of sample sizes for 80% and 90% confidence levels at varying detection levels according to lot size, hypergeometric distribution

Number of units in lot	P = 80% (confidence level) % level of detection × efficacy of inspection or test					P = 90% (confidence level) % level of detection × efficacy of inspection or test				
	5	2	1	0.5	0.1	5	2	1	0.5	0.1
100	27	56	80	-	-	37	69	90	-	-
200	30	66	111	160	-	41	87	137	180	-
300	30	70	125	240*	-	42	95	161	270*	-
400	31	73	133	221	-	43	100	175	274	-
500	31	74	138	277*	-	43	102	184	342*	-
600	31	75	141	249	-	44	104	191	321	-
700	31	76	144	291*	-	44	106	196	375*	-
800	31	76	146	265	-	44	107	200	350	-
900	31	77	147	298*	-	44	108	203	394*	-
1 000	31	77	148	275	800	44	108	205	369	900
2 000	32	79	154	297	1106	45	111	217	411	1368
3 000	32	79	156	305	1246	45	112	221	426	1607
4 000	32	79	157	309	1325	45	113	223	434	1750
5 000	32	80	158	311	1376	45	113	224	439	1845
6 000	32	80	159	313	1412	45	113	225	443	1912
7 000	32	80	159	314	1438	45	114	226	445	1962
8 000	32	80	159	315	1458	45	114	226	447	2000
9 000	32	80	159	316	1474	45	114	227	448	2031
10 000	32	80	159	316	1486	45	114	227	449	2056
20 000	32	80	160	319	1546	45	114	228	455	2114
30 000	32	80	160	320	1567	45	114	229	456	2216
40 000	32	80	160	320	1577	45	114	229	457	2237
50 000	32	80	160	321	1584	45	114	229	458	2250
60 000	32	80	160	321	1588	45	114	229	458	2258
70 000	32	80	160	321	1591	45	114	229	458	2265
80 000	32	80	160	321	1593	45	114	229	459	2269
90 000	32	80	160	321	1595	45	114	229	459	2273
100 000	32	80	160	321	1596	45	114	229	459	2276
200 000	32	80	160	321	1603	45	114	229	459	2289

APPENDIX 2

SAMPLING OF LARGE LOTS: BINOMIAL OR POISSON BASED SAMPLING[3]

For large lots sufficiently mixed, the likelihood of finding an infested unit is approximated by simple binomial statistics. The sample size is less than 5% of the lot size. The probability of observing i infested units in a sample of *n* units is given by:

$$P(X=i) = \binom{n}{i} p^{i} (1-\phi p)^{n-i} \qquad \text{Formula 3}$$

p is the average proportion of infested units (infestation level) in the lot and ϕ represents the percentage inspection efficacy divided by 100.
P(X = *i*) is the probability of observing i infested units in the sample. The confidence level corresponds to: 1-P(X = *i*), i = 0, 1, 2, …, n.

For phytosanitary purposes, the probability of not observing a pest specimen or symptom in the sample is determined. The probability of not observing an infested unit in a sample of *n* units is given by

$$P(X=0) = (1-\phi p)^{n} \qquad \text{Formula 4}$$

The probability of observing at least one infested unit is then:

$$P(X>0) = 1 - (1-\phi p)^{n} \qquad \text{Formula 5}$$

This equation can be rearranged to determine n

$$n = \frac{\ln[1 - P(X > 0)]}{\ln(1 - \phi p)} \qquad \text{Formula 6}$$

The sample size n can be determined with this equation when the infestation level (p), efficacy (ϕ) and the confidence level (1- P (X > 0)) are determined by the NPPO.

The binomial distribution can be approximated with the Poisson distribution. As *n* increases and p decreases, the binomial distribution equation given above tends to the Poisson distribution equation given below,

$$P(X=i) = \frac{(n\phi p)^{i} e^{-n\phi p}}{i!} \qquad \text{Formula 7}$$

where *e* is the base-value of the natural logarithm.

The probability of finding no infested units simplifies to

$$P(X=0) = e^{-n\phi p} \qquad \text{Formula 8}$$

The probability of finding at least one infested unit (the confidence level) is calculated as

$$P(X>0) = 1-e^{-n\phi p} \qquad \text{Formula 9}$$

Solving for n gives the following, which can be used to determine the sample size:

$$n = -\ln[1-P(X>0)]/\phi p \qquad \text{Formula 10}$$

Tables 3 and 4 show sample sizes when the acceptance number is 0, calculated for different levels of detection, efficacy and confidence levels with the binomial and Poisson distributions, respectively. A comparison of the case for 100% efficacy with the sample sizes in Table 1 (see Appendix 1) shows that the binomial and Poisson give very similar results to the hypergeometric distribution when n is large and p is small.

[3] This appendix is not an official part of the standard. It is provided for information only.

Table 3: Table of sample sizes for 95% and 99% confidence levels at varying detection levels, according to efficacy values where lot size is large and sufficiently mixed, binomial distribution

% efficacy	P = 95% (confidence level) % detection level					P = 99% (confidence level) % detection level				
	5	2	1	0.5	0.1	5	2	1	0.5	0.1
100	59	149	299	598	2995	90	228	459	919	4603
99	60	150	302	604	3025	91	231	463	929	4650
95	62	157	314	630	3152	95	241	483	968	4846
90	66	165	332	665	3328	101	254	510	1022	5115
85	69	175	351	704	3523	107	269	540	1082	5416
80	74	186	373	748	3744	113	286	574	1149	5755
75	79	199	398	798	3993	121	305	612	1226	6138
50	119	299	598	1197	5990	182	459	919	1840	9209
25	239	598	1197	2396	11982	367	919	1840	3682	18419
10	598	1497	2995	5990	29956	919	2301	4603	9209	46050

Table 4: Table of sample sizes for 95% and 99% confidence levels at varying detection levels, according to efficacy values where lot size is large and sufficiently mixed, Poisson distribution

% efficacy	P = 95% (confidence level) % detection level					P = 99% (confidence level) % detection level				
	5	2	1	0.5	0.1	5	2	1	0.5	0.1
100	60	150	300	600	2996	93	231	461	922	4606
99	61	152	303	606	3026	94	233	466	931	4652
95	64	158	316	631	3154	97	243	485	970	4848
90	67	167	333	666	3329	103	256	512	1024	5117
85	71	177	353	705	3525	109	271	542	1084	5418
80	75	188	375	749	3745	116	288	576	1152	5757
75	80	200	400	799	3995	123	308	615	1229	6141
50	120	300	600	1199	5992	185	461	922	1843	9211
25	240	600	1199	2397	11983	369	922	1843	3685	18421
10	600	1498	2996	5992	29958	922	2303	4606	9211	46052

APPENDIX 3

SAMPLING FOR PESTS WITH AN AGGREGATED DISTRIBUTION: BETA-BINOMIAL BASED SAMPLING[4]

In the case of aggregated spatial distribution, sampling can be adjusted to compensate for aggregation. For this adjustment to apply, it should be assumed that the commodity is sampled in clusters (for example, boxes) and that each unit in a chosen cluster is examined (cluster sampling). In such cases, the proportion of infested units, *f,* is no longer constant across all clusters but will follow a beta density function.

$$P(X=i) = \binom{n}{i} \frac{\prod_{j=0}^{i-1}(f+j\theta)\prod_{j=0}^{n-i-1}(1-f+j\theta)}{\prod_{j=0}^{n-1}(1+j\theta)} \qquad \text{Formula 11}$$

f is the average proportion of infested units (infestation level) in the lot.
P(X = i) is the probability of observing i infested units in a lot.
n = number of units in a lot.
$\prod$ is the product function
θ provides a measure of aggregation for the *j*th lot θ is $0<\theta<1$.

Phytosanitary sampling is often more concerned with the probability of not observing an infested unit after inspecting several batches. For a single batch, the probability that X=0 is

$$P(X=0) = 1- \prod_{j=0}^{n-1}(1-f+j\theta)/(1+j\theta) \qquad \text{Formula 12}$$

and the probability that each of several lots has no infested unit, Pr(X=0), equals $P(X=0)^m$, where *m* is the number of lots. When *f* is low, equation 1 can be estimated by

$$P(X=0) \approx (1-n\theta)^{-(f/\theta)}$$
$$Pr(X=0) \approx (1+n\theta)^{-(mf/\theta)}$$

The probability of observing one or more infested units is given by 1- Pr (X=0). Formula 13

This equation can be rearranged to determine *m*

$$m= \frac{-\theta}{f}\left[\frac{\ln(1-P(x>0)}{\ln(1+n\theta)}\right] \qquad \text{Formula 14}$$

Stratified sampling offers a way of reducing the impact of aggregation. Strata should be chosen so that the degree of aggregation within the strata is minimized.

When the degree of aggregation and the confidence level are fixed, the size of the sample can be determined. Without the degree of aggregation, the sample size can not be determined.

Efficacy (ϕ) values of less than 100% can be included by substituting ϕf for *f* in the equations.

[4] This appendix is not an official part of the standard. It is provided for information only.

APPENDIX 4

COMPARISON OF HYPERGEOMETRIC AND FIXED PROPORTION SAMPLING RESULTS[5]

Table 5: Confidence in the results of different sampling schemes for a 10% detection level

	Hypergeometric-based sampling (random sampling)		Fixed proportion sampling (2%)	
Lot size	sample size	confidence in detection	sample size	confidence in detection
10	10	1	1	0.100
50	22	0.954	1	0.100
100	25	0.952	2	0.191
200	27	0.953	4	0.346
300	28	0.955	6	0.472
400	28	0.953	8	0.573
500	28	0.952	10	0.655
1 000	28	0.950	20	0.881
1 500	29	0.954	30	0.959
3 000	29	0.954	60	0.998

Table 6: Minimum levels that can be detected with 95% confidence using different sampling schemes

	Hypergeometric-based sampling (random sampling)		Fixed proportion sampling (2%)	
Lot size	sample size	minimum detection level	sample size	minimum level of detection
10	10	0.10	1	1.00
50	22	0.10	1	0.96
100	25	0.10	2	0.78
200	27	0.10	4	0.53
300	28	0.10	6	0.39
400	28	0.10	8	0.31
500	28	0.10	10	0.26
1 000	28	0.10	20	0.14
1 500	29	0.10	30	0.09
3 000	29	0.10	60	0.05

[5] This appendix is not an official part of the standard. It is provided for information only.

APPENDIX 5

FORMULAE USED IN APPENDICES 1–4[6]

Formula No.	Purpose	Appendix No.
1	Probability of detecting *i* infested units in a sample.	1
2	Approximation for calculating the probability of finding no infested units.	1
3	Probability of detecting *i* infested units in a sample of n units (sample size is less than 5% of the lot size).	2
4	Binomial distribution probability of not observing an infested unit in a sample of n units.	2
5	Binomial distribution probability of observing at least one infested unit.	2
6	Binomial distribution formulae 5 and 6 rearranged to determine *n*.	2
7	Poisson distribution version of binomial formula 6	2
8	Poisson distribution probability of finding no infested units (simplified).	2
9	Poisson distribution probability of finding at least one infested unit (the confidence level).	2
10	Poisson distribution to determine the sample size for *n*.	2
11	Beta-binomial based sampling for aggregated spatial distribution	3
12	Beta-binomial – probability of not observing an infested unit after inspecting several lots (for a single lot)	3
13	Beta-binomial – probability of observing one or more infested units	3
14	Beta-binomial formulae 12 and 13 rearranged to determine m.	3

[6] This appendix is not an official part of the standard. It is provided for information only.

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

ISPM No. --

REPLACEMENT OR REDUCTION OF METHYL BROMIDE AS A PHYTOSANITARY MEASURE

(200-)

CONTENTS

INTRODUCTION

SCOPE

This standard[1] provides guidance to National Plant Protection Organizations (NPPOs) on the replacement of or reduction in the use of methyl bromide as a phytosanitary measure in order to reduce emissions of methyl bromide.

REFERENCES

Copenhagen Amendment to the Montreal Protocol on Substances that Deplete the Ozone Layer [from the Fourth Meeting of the Parties to the Montreal Protocol, Copenhagen, 1992].
Glossary of phytosanitary terms, 2007. ISPM No. 5, FAO, Rome.
Guidelines for a phytosanitary import regulatory system, 2004. ISPM No. 20, FAO, Rome.
Guidelines for inspection, 2005. ISPM No. 23, FAO, Rome.
Guidelines for regulating wood packaging material in international trade, 2002. ISPM No. 15, FAO, Rome.
Guidelines for the determination and recognition of equivalence of phytosanitary measures, 2005. ISPM No. 24, FAO, Rome.
International Plant Protection Convention, 1997. FAO, Rome.
Montreal Protocol on Substances that Deplete the Ozone Layer, 2000. UNEP Ozone Secretariat, United Nations Environment Programme. ISBN: 92-807-1888-6. http://www.unep.org/ozone/pdfs/Montreal-Protocol2000.pdf
Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms, 2004. ISPM No. 11, FAO, Rome.
Pest risk analysis for regulated non-quarantine pests, 2004. ISPM No. 21, FAO, Rome.
Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade, 2006. ISPM No. 1, FAO, Rome.
Phytosanitary treatments for regulated pests, 2007. ISPM No. 28, FAO, Rome.
Report of the Second Session of the Commission on Phytosanitary Measures, 2007. FAO, Rome.
Requirements for the establishment of areas of low pest prevalence, 2005. ISPM No. 22, FAO, Rome.
Requirements for the establishment of pest free areas, 1995. ISPM No. 4, FAO, Rome.
Requirements for the establishment of pest free places of production and pest free production sites, 1999. ISPM No. 10, FAO, Rome.
The use of integrated measures in a systems approach for pest risk management, 2002. ISPM No. 14, FAO, Rome.

DEFINITIONS

Definitions of phytosanitary terms used in the present standard can be found in ISPM No. 5 (*Glossary of phytosanitary terms*).

OUTLINE OF REQUIREMENTS

This standard outlines areas for action and guidelines to replace or reduce the use of methyl bromide as a phytosanitary measure. With the overall aim of reducing release of methyl bromide into the atmosphere, NPPOs may consider methods of reducing the quantities of methyl bromide used, reducing methyl bromide emissions by physical means, and promoting and implementing phytosanitary measures that are economically and technically feasible as viable alternatives to the use of methyl bromide. The standard also provides guidance on monitoring the use of methyl bromide.

[1] Nothing in this standard shall affect the rights or obligations of contracting parties under other international agreements. Provisions of other international agreements may be applicable, for example the Montreal Protocol.

BACKGROUND

The main purpose of the International Plant Protection Convention (IPPC) and the responsibility of its contracting parties is to prevent the spread and introduction of pests of plants and plant products and to promote appropriate measures for their control. In doing so, contracting parties also undertake the promotion of appropriate measures for the control of regulated pests. In its preamble, the IPPC states that contracting parties take into account internationally approved principles governing the protection of plant, human health and the environment. The second meeting of the Commission on Phytosanitary Measures (CPM) "Encouraged contracting parties to promote best fumigation practices, recapture technology and development and use of alternatives to methyl bromide in phytosanitary measures where this was technically and economically feasible". Thus, while pursuing the IPPC's purpose, contracting parties are also encouraged to take into account environmental concerns, among which is protection of the ozone layer by reducing methyl bromide emissions.

IPPC contracting parties may also be party to the Montreal Protocol on Substances that Deplete the Ozone Layer. This obliges them to protect the ozone layer by reducing, and ultimately eliminating, emissions of ozone-depleting substances through a phase-out of production and import of such substances.

In the 1992 Copenhagen Amendment to the Montreal Protocol, methyl bromide was listed as an ozone-depleting substance subject to phase-out provisions of the Montreal Protocol. However, the use of methyl bromide for quarantine and pre-shipment (QPS)[2] purposes is currently exempt from the protocol's phase-out provisions because of difficulties in identifying technically and economically feasible alternatives. There is currently no limit on the amount of methyl bromide that can be used for these QPS purposes. In 1999, in the Beijing Amendment to the Montreal Protocol, mandatory requirements for the provision of statistical data on amounts of methyl bromide used annually for QPS purposes were agreed to. This amendment entered into force in January 2001. Therefore, parties to the Montreal Protocol already have obligations to monitor and report their use of methyl bromide for QPS applications.

Methyl bromide has been widely used as a pest control treatment for many decades. It offers a broad spectrum of control for insects, nematodes, weeds, pathogens and rodents. Methyl bromide has been employed primarily as a soil fumigant before planting crops, and is also used for commodity treatment and structural fumigation. Most uses of methyl bromide as a phytosanitary measure are for the treatment of durable commodities, such as grains, cereals and dried foodstuffs, wood packaging materials, wood and logs, as well as perishable commodities, such as fruit.

It is recognized that alternatives to methyl bromide for use as phytosanitary measures are needed, particularly because there may be future restrictions on the use of methyl bromide. It is also recognized that there is a need for contracting parties to continue to use methyl bromide until equivalent and feasible alternative phytosanitary measures are available.

Some countries have already successfully reduced or eliminated the use of methyl bromide.

To be considered viable under the IPPC, phytosanitary measures that are alternatives to methyl bromide and that are equivalent to methyl bromide fumigation as per ISPM No. 24 (*Guidelines for the determination and recognition of equivalence of phytosanitary measures*) should also be economically and technically feasible. In comparison, the United Nations Environment Programme's Methyl Bromide Technical Options Committee defined alternatives as those non-chemical or chemical treatments and/or procedures that are technically feasible for controlling pests, thus avoiding or replacing the use of methyl bromide.

REQUIREMENTS

To reduce the risk of introduction of some quarantine pests, the need for methyl bromide as a phytosanitary measure remains until a range of equivalent alternatives has been developed. Contracting parties are encouraged to put in place a strategy that will help them to reduce the use of methyl bromide for

[2] This document refers to some terms used by the Montreal Protocol as follows: QPS (quarantine and pre-shipment) purposes, National Ozone Units. These are not IPPC terms and should not be interpreted as such.

phytosanitary measures and/or reduce emissions of methyl bromide. This may include the following areas for action:

- replacing methyl bromide use
- reducing methyl bromide use
- physically reducing methyl bromide emissions
- accurately recording methyl bromide use for phytosanitary measures.

In developing and implementing strategies to replace and/or reduce methyl bromide use and reduce emissions, contracting parties should also take into account any international obligations to which they may be subject and relevant IPPC principles. These principles are described in ISPM No. 1 (*Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade*).

1. Replacement of Methyl Bromide Use as a Phytosanitary Measure

In recognition of the desire to minimize the use of methyl bromide, contracting parties should, where possible, take actions to replace methyl bromide usage by increasing the application of alternative phytosanitary measures. Where methyl bromide fumigation is currently used as a phytosanitary treatment for regulated pests it may be replaced by an alternative phytosanitary measure in which no methyl bromide is used. This may involve the implementation of systems approaches, pest free areas (PFAs), areas of low pest prevalence (ALPPs), pest free places of production, pest free production sites and equivalence.

The following are examples of phytosanitary measures that may be implemented independently or in conjunction with other phytosanitary measures to replace methyl bromide as a phytosanitary treatment when equivalent:

- use of other chemicals such as treatments mentioned in Appendix 1 (e.g. sulfuryl fluoride)
- application of physical treatments (e.g. heating, cooling, irradiation)
- immediate commodity processing (e.g. grain being milled into flour on arrival)
- methods of production (e.g. soil-free growing media, tissue culture, sterile culture).

In situations where consignments are identified as non-compliant at the point of import, the use of methyl bromide should be avoided where possible (appropriate actions to be taken in the case of non-compliance are described in section 5.1.6.1 of ISPM No. 20: *Guidelines for a phytosanitary import regulatory system*).

The CPM, largely through the provisions of ISPM No. 28 (*Phytosanitary treatments for regulated pests*), is actively pursuing recognition of treatments that are viable alternatives to methyl bromide. As these alternatives become recognized, contracting parties are encouraged to use them in place of methyl bromide, where appropriate.

Where a standard contains options for various treatments for a commodity, and one of the options is methyl bromide (currently the only standard for which this is the case is ISPM No. 15: *Guidelines for regulating wood packaging material in international trade*) and others are considered to present less of an adverse environmental impact, parties are encouraged to use the lower-impact option(s).

Appendix 1 contains a list of articles that have historically been treated with methyl bromide and presents possible alternative phytosanitary measures that could be used to replace or reduce the use of methyl bromide.

2. Reducing Volumes of Methyl Bromide Use as a Phytosanitary Measure

The reduction of methyl bromide emissions can be achieved through the use of reduced dosages of methyl bromide as a phytosanitary measure or decreased treatment frequency. In addition, existing methyl bromide use should be analysed carefully to determine if the treatment is appropriate and necessary.

The following approaches may, where appropriate, be pursued to reduce the use of methyl bromide as a phytosanitary measure:

- inspection-based fumigation instead of mandatory fumigation, i.e. to detect and identify the quarantine pest of concern
- avoidance of unjustified refumigation with methyl bromide (i.e. refumigation should be used only when a quarantine pest situation is evident)

- improvement of treatment facilities as appropriate in order to increase exposure time with a reduction of dosage
- compliance with phytosanitary requirements for exporting commodities
- avoidance of application in situations where efficacy is doubtful or marginal
- reassessment of doses and exposure times in order to reduce them
- use of higher temperatures when fumigating
- use of appropriately sized treatment facilities.

3. Physically Reducing Methyl Bromide Emissions

Contracting parties should aim to minimize or eliminate the release of methyl bromide to the atmosphere by physical means. This may be achieved by upgrading facilities as appropriate to increase efficiency of methyl bromide application to improve:

- methyl bromide emissions control, e.g. by recapture, and/or reusage or destruction, through the use of leak-proof chambers and containment/capture bubbles, etc.
- fumigation performance, e.g. by use of bioassay controls in lieu of concentration × time (C×T) products, use of higher temperatures during fumigation through supplemental heat when necessary combined with air circulation, pressure testing etc., reduction of leakage
- gas circulation, e.g. by use of a carrier gas such as CO_2
- gas and temperature monitoring including proper calibration of equipment.

4. Recording Methyl Bromide Use as a Phytosanitary Measure

To measure progress in reduction of methyl bromide emissions arising from use of methyl bromide as a phytosanitary measure, NPPOs are encouraged to accurately record and collate data on current usage and share this data with their country's National Ozone Unit[3] (the national body responsible for the implementation of the Montreal Protocol).

The information on methyl bromide use for phytosanitary measures should contain:

- quantities of methyl bromide used in kilograms
- description of the articles[4] fumigated
- whether the use was on import or export commodities
- target pests.

5. Guidelines for Appropriate Use of Methyl Bromide as a Phytosanitary Measure

NPPOs could be involved in the coordination of the following actions:

1. Review and consider how to change phytosanitary policies (e.g. phytosanitary import requirements) to reduce and/or replace methyl bromide where it is required and where an equivalent, practically viable and economically feasible alternative exists. This may also require review and revision of bilateral agreements between countries.
2. Ensure that methyl bromide fumigation is used only for quarantine pests and that it is authorized or performed by the NPPO, including fumigation as emergency action for pests not previously assessed (as described in section 5.1.6.2 of ISPM No. 20: *Guidelines for a phytosanitary import regulatory system*).
3. Provide guidance to those responsible for methyl bromide fumigations for quarantine purposes on the importance of pursuing feasible alternative phytosanitary measures.
4. Develop and utilize phytosanitary measures that are equivalent, viable and feasible alternatives to methyl bromide.
5. Communicate to other NPPOs where there are viable alternatives to methyl bromide use.
6. Submit phytosanitary treatments that are effective, efficacious, documented, feasible and applicable alternatives to the use of methyl bromide to the IPPC Secretariat using the guidelines in ISPM No. 28 (*Phytosanitary treatments for regulated pests*).
7. Give highest priority to the development of alternative treatments for those commodities for which methyl bromide usage is high.
8. Liaise with research groups and funding bodies to develop alternative treatments as appropriate.

[3] Obligations for recording and reporting on methyl bromide usage exist under the Montreal Protocol.
[4] The first column of the table in Appendix 1 provides a list of articles commonly fumigated.

9. Facilitate the annual collection and reporting of methyl bromide usage data.
10. Post or link details of NPPO-approved alternatives for methyl bromide treatment on the International Phytosanitary Portal (https://www.ippc.int) for exchange of information.
11. Cooperate with the National Ozone Unit to implement a strategy to replace and reduce methyl bromide usage.
12. Exchange information on alternatives to methyl bromide usage between the NPPO and the National Ozone Unit.
13. Identify current treatments where methyl bromide is the only option, and provide sufficient information to the IPPC Secretariat for consideration in the development of potential viable alternatives (e.g. identify the commodity, pests associated with it for which methyl bromide is used, required efficacy).

APPENDIX 1

EXAMPLES OF POTENTIAL PHYTOSANITARY TREATMENTS TO REPLACE OR REDUCE METHYL BROMIDE

Listed in the table below are treatments that could be considered and validated as alternatives to methyl bromide and that are currently registered, where necessary, and used in at least one country. These treatments may be employed to replace or reduce methyl bromide use in certain circumstances. The use of the names of the articles presented in this appendix may be helpful for ensuring consistency in reporting QPS use.

The following considerations affect the choice of a measure:

- combination of crop type (flowers, fruits, foliage etc.) and/or species and pest species (insects, bacteria, fungi, virus etc.)
- lack of a national registration or existing equivalency agreement between countries, which may preclude use of particular treatments in particular countries
- economic factors that may preclude use of the treatment in particular countries
- processes in the supply chain that may reduce pests to an acceptable level (e.g. washing, freezing, dicing)
- occurrence of resistance of a pest towards the envisaged alternative, which may change the necessary dosage schedule or preclude the alternative
- irradiation (often used only on specific life stages for sterility, not for eradication)
- intended use of the commodity
- undesirable effects of chemical residues for operators
- provisions in relevant ISPMs
- other treatments that may be agreed to by countries based on bilateral agreements.

List of articles fumigated	**Examples of potential phytosanitary treatments to consider to replace or reduce methyl bromide**
Commodities	
Bulbs, corms, tubers and rhizomes (intended for planting)	Hot water, pre-plant quarantine soil sterilization (steam or chemical), pesticide dip, or a combination of these treatments
Cut flowers and branches (including foliage)	Controlled atmosphere + combination treatment, hot water, irradiation, phosphine, phosphine/carbon dioxide mixture**,** pyrethroids + CO_2, ethyl formate + CO_2
Fresh fruit and vegetables	Cold treatment, high-temperature forced air, hot water, irradiation, phytosanitary systems approach (PRA, PFA, ALPP etc.), quick freeze, vapour heat treatment, chemical dip, hydrogen cyanide, phosphine, combination of treatments
Grain, cereals and oil seeds for consumption including rice (not intended for planting)	Heat treatment, irradiation, ethyl formate, carbonyl sulphide, phosphine, phosphine + CO_2, controlled atmosphere (CO_2, N_2)
Dried foodstuffs (including herbs, dried fruit, coffee, cocoa)	Heat treatment, carbon dioxide under high pressure, irradiation, ethyl formate, ethylene oxide, phosphine, phosphine + carbon dioxide, controlled atmosphere, sulfuryl fluoride, propylene oxide
Nursery stock (plants intended for planting other than seed), and associated soil and other growing media	Hot water, phytosanitary systems approach (PRA, PFA, ALPP etc.), soil sterilization (steam or chemical e.g. methyl isothiocyanate (MITC) fumigants), pesticides dip, phosphine, combination of any of these treatments

List of articles fumigated	Examples of potential phytosanitary treatments to consider to replace or reduce methyl bromide
Seeds (intended for planting)	Hot water, phytosanitary systems approach (PRA, PFA, ALPP etc.), pesticide dip or dusting, phosphine, combination treatments
Wood packaging materials[5]	Heat treatment (contained in Annex 1 of ISPM No. 15). Further alternative treatments may be added in the future.
Wood (including round wood, sawn wood, wood chips)	Heat treatment, microwave, irradiation, MITC/sulfuryl fluoride mixture, methyl iodide, chemical impregnation or immersion, phosphine, sulfuryl fluoride
Whole logs (with or without bark)	Heat treatment, irradiation, removal of bark, phosphine, sulfuryl fluoride
Hay, straw, thatch grass, dried animal fodder (other than grains and cereals listed above)	Heat treatment, irradiation, high pressure + phosphine, phosphine, sulfuryl fluoride
Cotton and other fibre crops and products	Heat treatment, compression, irradiation, phytosanitary systems approach (PRA, PFA, ALPP etc.), phosphine, sulfuryl fluoride
Tree nuts (almonds, walnuts, hazelnuts etc.)	Carbon dioxide under high pressure, controlled atmosphere, heat treatment, irradiation, phytosanitary systems approach (PRA, PFA, ALPP etc.), ethylene oxide, ethyl formate, phosphine, phosphine + carbon dioxide, propylene oxide, sulfuryl fluoride
Structures and equipment	
Buildings with quarantine pests (including elevators, dwellings, factories, storage facilities)	Controlled atmosphere, heat treatment, pesticide spray or fogging, phosphine, sulfuryl fluoride
Equipment (including used agricultural machinery and vehicles), empty shipping containers and reused packaging	Controlled atmosphere, heat treatment, steam, hot water, pesticide spray or fogging, phosphine, sulfuryl fluoride
Other items	
Personal effects, furniture, crafts, artefacts, hides, fur and skins	Controlled atmosphere, heat treatment, irradiation, ethylene oxide, pesticide spray or fogging, phosphine, sulfuryl fluoride

[5] It is noted that ISPM No. 15 (*Guidelines for regulating wood packaging material in international trade*) is the only ISPM currently listing approved treatments for wood packaging material. Wood packaging material is the only commodity for which specific treatments are currently described in an ISPM.