SCIENTIFIC OPINION

Draft guidance of the Scientific Panel on Plant Health on methodology for evaluation of the effectiveness of options to reduce the risk of introduction and spread of organisms harmful to plant health in the EU territory[1]

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ABSTRACT

The European Food Safety Authority (EFSA) requested the Panel on Plant Health to provide guidance for the evaluation of the effectiveness of options for plants and plant products to reduce the risk of introduction and spread of harmful organisms in the EU territory. This guidance has been developed to be used together with the two previous guidance documents of the PLH Panel and does not substitute them. Two operational tools are presented: a checklist for evaluating a proposed risk reduction option (RRO) and a database of references corresponding to published guidance documents or experimental assessments of RROs. The checklist can be used by the Panel or the dossier submitting parties to verify whether all required information is provided in support of a RRO, to quickly describe information supplied to EFSA, and to identify major data gaps. Four types of RRO assessments are distinguished in the proposed checklist according to their purposes and characteristics: experimental assessment of the option effectiveness to reduce pest infestation in plant material/product under laboratory/controlled conditions; experimental assessment of the option effectiveness to reduce pest infestation in plant material/product under operational conditions; analysis of the applicability of the RRO; assessment of option effectiveness to reduce risk of pest entry from an infested area to a pest free area. The database of references, not exhaustive, is intended to assist the Panel in (i) identifying potential RROs for a given pest and plant material, and (2) quickly retrieving relevant experimental data and guidance documents for assessing a proposed RRO. In addition, the current document provides recommendations for assessing RROs, specifically: on experimental design; on the use of statistical methods including approaches for studying uncertainty; on the use of quantitative pathway analysis and spread models describing their advantages and limitations; and recommendations for general surveillance and specific surveys.

KEY WORDS

checklist, effectiveness, experimental design, quantitative pathway analysis, risk reduction options, spread models, statistical methods

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SUMMARY

The European Food Safety Authority (EFSA) asked the Panel on Plant Health to deliver guidance on methodology for evaluation of the effectiveness of options to reduce the risk of introduction and spread of organisms harmful to plant health in the EU territory.

This guidance document has been prepared by the Panel to address mainly the quantitative evaluation of the effectiveness of risk reduction options. When data and/or information are available the quantitative methods described in this document could be applied. When only limited or no data and/or information are available, the Panel performs qualitative evaluations that are briefly described in this guidance document. The Panel developed this guidance document to be used for the assessment of risk reduction options together with the guidance on a harmonised framework for risk assessment (EFSA Panel on Plant Health (PLH), 2010a) and the guidance on the evaluation of pest risk assessments and risk management options prepared to justify requests for phytosanitary measures under Council Directive 2000/29/EC (EFSA Panel on Plant Health (PLH), 2009). The guidance provided in this document complements and does not replace the two above mentioned documents when responding to requests for scientific advice on issues related to the evaluation of the effectiveness of options to reduce the phytosanitary risks within the European Community in order to support the decision-making process under Council Directive 2000/29/EC.

Two operational tools are presented in this guidance document:

- a checklist for evaluating a proposed risk reduction option (RRO),
- a database of references of scientific documents presenting recommendations on how to assess RROs, and experimental assessments of RROs.

The two tools have different purposes. The checklist includes a series of items that can be used by the Panel to check whether all required information is provided to support a RRO. Four types of RRO assessments are distinguished in the proposed checklist according to their purposes and characteristics:

i. Experimental assessment of the option effectiveness to reduce pest infestation in plant material/product under laboratory/controlled conditions

ii. Experimental assessment of the option effectiveness to reduce pest infestation in plant material/product under operational conditions

iii. Analysis of the applicability of the RRO

iv. Assessment of option effectiveness to reduce risk of pest entry from infested area to pest free area

The checklist can be used by experts to make a preliminary assessment of documents and data submitted to EFSA to support a RRO (e.g. a temperature treatment of plant material) and, more specifically:

- to quickly describe the information provided to EFSA (i.e., report and experimental results) to support a proposed RRO
- to identify major gaps in data submitted to EFSA
- to organise the work of the Panel when evaluating a dossier.

This checklist could also be used by the author of the submitted dossier or by the author of a pest risk analysis to verify whether all the requested data are provided.

The second tool is a database of references corresponding to published guidance documents or experimental assessments of RROs.

The content of these documents have been summarised in a table presented in Appendix B. This database of references can be used by the Panel to find some specific experimental results on the effectiveness of a given RRO, or to find guidance documents for designing RROs. Although this database does not intend to include all existing references on RRO assessment, it may help the Panel

experts to quickly retrieve relevant experimental data and guidance documents for assessing a proposed RRO, or for assessing a range of options in a pest risk analysis. It can also be used to identify potential RROs for a given pest and/or plant material.

Finally, based on the literature review described in this guidance document and on its own experience, the Panel is able to formulate several recommendations on the use of quantitative methods for assessing RROs.

Recommendations on surveillance:

- General surveillance should evaluate the possible occurrence of a pest in an area, using all relevant (quantitative and qualitative) information on the current pest distribution in and near the area, ecological conditions of the area, presence of host plants and other potential pest niches, and import and trade rates of host plant products in the area. The conclusion of general surveillance and a discussion of the level of uncertainty should be presented along with all information used to reach the conclusion.
- Specific surveys should be conducted to test an explicitly formulated hypothesis on the occurrence of a pest in an area. They should be performed on a statistical basis, using relevant quantitative and qualitative information on the area, the pest, the host plants and other potential pest niches. They should provide a conclusion on pest occurrence and the uncertainty of the conclusion, expressed as the confidence level to detect the pest above the threshold prevalence of the survey.
- Methodology to integrate results from general surveillance and specific surveys should be implemented in cases where a conclusion on pest occurrence is difficult to reach.

Recommendations on the design of experiments:

- The checklist provided herewith should be used prior to, and during the experimentation.
- The information requested in the checklist and pertaining to the plant and to the pest should be first as complete and precise as possible.
- The objectives (e.g. mortality rates, maximal pest density acceptable) and confidence levels of the tests should be clearly stated and, when relevant, compared to the current standards.
- A complete description of the experimental design should be provided, including: variables used to measure effectiveness, factors influencing effectiveness which were or were not taken into account in the experiments, description of facilities and equipment; description of treatments; methodology followed for monitoring critical parameters, description of experimental design, presentation of the data, description of the statistical analysis.

The complete datasets produced by the experiment and used in the analyses should be kept available with a full definition of all the variables.

Recommendations on the use of statistical methods for assessing option effectiveness to reduce pest infestation:

- Uncertainty about effectiveness of RROs should be studied by computing confidence intervals with classical statistical methods or credibility intervals with Bayesian methods.
- The probit 9 threshold of mortality rate should not be systematically used as reference threshold for assessing RRO effectiveness. Instead of using a specific threshold for mortality rate, it is recommended to analyse the risks of pest entry and establishment associated with the RRO under consideration.
- Although not frequently used in plant pathology, equivalence tests and, more specifically, non-inferiority tests are useful tools for comparing two RROs and testing whether a proposed RRO is at least as good as a currently implemented RRO.

- Depending on the nature of the available experimental results, different types of generalised linear models can be fitted to data to study the relationship between the dose of a treatment and its effectiveness. Such models are commonly used in chemical risk assessment, but are also applicable in treatment effect assessment.

Recommendations on the use of quantitative pathway analysis and spread models

Quantitative pathway analysis and spread models have several advantages:

- They allow risk assessors to compare the effectiveness of several RROs and, also, to assess the effectiveness of combination of RROs.
- They allow risk assessors to quantify the effects of RROs on several variables like probabilities of entry, establishment, and spread, or magnitude of impact. They do not restrict the assessment of RRO on their capabilities to reduce pest infestation.
- Quantitative pathway analysis and spread models can address uncertainties and can be used to study the effect of different sources of uncertainty on the risk of entry, establishment, spread, and impact.
- They enable to perform a sensitivity analysis to identify the most influential parameters in a model that are defining the most effective RRO.

These advantages make these quantitative tools attractive for assessing the effectiveness of different RROs. However, their applications can be difficult in practice due to the amount of data required to develop such models. In case of missing data, the uncertainty associated with the model outputs could be high and decreasing the ability of the model to discriminate between different RROs thus diminishing the models usefulness and value.

TABLE OF CONTENTS

BACKGROUND AS PROVIDED BY EFSA

The EFSA Scientific Panel on Plant Health provides independent scientific advice on the risks posed by organisms which can cause harm to plants, plant products or plant biodiversity in the European Community. The Panel reviews and assesses those risks to assist risk managers in taking effective and timely decisions on protective measures under the Council Directive 2000/29/EC[4] to prevent the introduction and further spread of organisms considered harmful to plants or plants products in the European Community.

To assist the Panel in its work, the Panel has developed Guidance on the evaluation of pest risk assessments and risk management options[5] and Guidance on harmonised framework for pest risk assessment and the identification and evaluation of pest risk management options by EFSA[6]. These documents are constructed upon the international framework for pest risk analysis for quarantine pests, laid down in the International Standards for Phytosanitary Measures[7] (ISPM), and implement the EFSA principles of separation of risk assessment from risk management, and transparency.

In methodological terms the Guidance highlighted the need to develop quantitative approaches, in particular for the purpose of evaluation of the effectiveness of pest risk management options in reducing pest risks.

The Panel receives an increasing number of requests for evaluation of technical dossiers relating to options proposed to reduce pest risk and is also asked to identify and/or compare options that reduce the risk of introduction and spread of harmful organisms in the EU territory. Some of the requests require an urgent response from the Panel.

It is therefore opportune for the Panel to develop methodology for evaluation of the effectiveness of options to reduce pest risk. To enhance consistency and efficiency of the Panel response further guidance is needed on the information and data to be included in technical dossiers submitted for the Panel's evaluation.

[4] Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community. Official Journal of the European Communities L 169/1, 10.7.2000, p. 1–112.

[5] Guidance of the Panel on Plant Health on the evaluation of pest risk assessments and risk management options prepared to justify requests for phytosanitary measures under Council Directive 2000/29/EC, EFSA Journal (2009) 2654, 7-18.

[6] Guidance on a harmonized framework for pest risk assessment and the identification and evaluation of pest risk management options by EFSA, EFSA Journal (2010) 8(2):1495, 66pp.

[7] FAO IPPC International standards for phytosanitary measures 1 to 29 (2007 edition).

TERMS OF REFERENCE AS PROVIDED BY EFSA

The Panel on Plant Health is requested to produce a scientific opinion in the format of guidance on methodology for the evaluation of the effectiveness of options for plants and plant products to reduce the risk of introduction and spread of harmful organisms in the EU territory.

The Panel will include in its opinion guidance on:

a) quantitative methods to be applied by the Panel for evaluation of the effectiveness of options to reduce the pest risk;

b) information and data to be provided to demonstrate the effectiveness of options to reduce the pest risk;

c) experimental designs and statistical methods for assessing the effectiveness of options to reduce the level of risk of introduction and spread of harmful organisms in the EU territory.

In the development of this opinion, the Panel will consider other guidance documents of EFSA's scientific Panels and outcomes of relevant research projects including the EFSA Art.36 project *Prima phacie.*

The Panel's draft guidance document will be available for public consultation on its proposals in 12 months and delivery of the guidance document will follow 6 months after.

ASSESSMENT

1. INTRODUCTION

The European Food Safety Authority (hereinafter referred at as EFSA) is the keystone of the European Union risk assessment regarding food and feed safety. EFSA's remit covers food and feed safety, nutrition, animal health and welfare, plant protection and plant health. In all these fields, EFSA's most critical commitment is to provide objective and independent science-based advice grounded in the most up-to-date scientific information and knowledge.

The Scientific Panel on Plant Health of the European Food Safety Authority (hereinafter referred at as the Panel) was established in 2006 by Regulation (EC) No 575/2006 amending Regulation (EC) No 178/2002[8]. The mandate of the Panel as adopted by the EFSA Management Board is to address the increasing need expressed from the European Commission, the European Parliament, the Member States, or on its own initiative (as for the present opinion), for assessing, in independent and scientific manner, the risks posed by organisms harmful to plants, plant products and/or biodiversity.

Since the Panel initiated its activity contributing to the overall activity of EFSA as the European Union's (herinafter referred at as the EU) independent risk assessor, it produced different types of scientific opinions on requests of the European Commission as expressed in the examples below:

- Pest risk assessments for the EU territory including identification and evaluation of risk reduction options (e.g. *Dryocosmus kuriphilus*; *Gibberella circinata*; *Monilinia fructicola; Pospiviroids; Citrus canker*);
- Extension of the scope of national pest risk assessments to the entire EU (e.g. *Thaumetopoea processionea*, *Bactrocera zonata*) and evaluation of relevant EPPO pest risk analyses (e.g. *Lysichiton americanus*, *Hydrocotyle ranunculoides*);
- Re-evaluation of existing EU level pest risk assessments due to new evidence (e.g. *Phytophthora ramorum*);
- Evaluation of risk assessments prepared by individual Member States (e.g. French overseas departments (DOM) Pest Risk Analyses);
- Evaluation of technical files proposed by third countries requesting derogations of the phytosanitary requirements included in the Council Directive 2000/29/EC (e.g. *Agrilus planipennis*, *Bursaphelenchus xylophilus*, *Anoplophora chinensis, Bemisia tabaci*).

The Panel has developed two guidance documents (EFSA Panel on Plant Health (PLH), 2009; EFSA Panel on Plant Health (PLH), 2010a) defining the criteria for evaluating evidence used in support of the conclusion that an organism may pose a risk to plant health. In the above mentioned guidance document (EFSA Panel on Plant Health (PLH), 2010a), it is explicitly stated that the EFSA's procedures for pest risk assessment and the identification and evaluation of risk reduction options should be kept under review to take into account the experiences of the Panel and development work funded by EFSA under Article 36 of its founding regulation (EC) 178/2002 and by other organisations worldwide. Furthermore, in the same guidance document, a description of the full scheme for "Identification of management options and evaluation of their effect on the level of risk and of their technical feasibility" is given (p. 54). In this context, it is indicated which aspects should be considered (e.g. effectiveness of measures combination, stringency, safety, applicability... etc) and which excluded, as outside the EFSA remit, namely:

• the decision on acceptability of the risk,
• the selection of risk reduction options, and
• the evaluation of risk reduction options in terms of their cost-effectiveness and economic feasibility, minimal impact and non-discrimination.

[8] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

Therefore, in the context of its past mandates and considering the methodological advancements in the field of pest risk assessment, the Panel expressed the need to further develop guidance describing the methodology it considers to use when addressing the evaluation of risk reduction options.

This guidance document has been prepared by the Panel to address mainly the quantitative evaluation of the effectiveness of risk reduction options. When data and/or information are available the quantitative methods described in this document could be applied. When only limited or no data and/or information are available, the Panel performs qualitative evaluations that are briefly described in this guidance document. The Panel developed this guidance document to be used for the assessment of risk reduction options together with the guidance on a harmonised framework for risk assessment (EFSA Panel on Plant Health (PLH), 2010a) and the guidance on the evaluation of pest risk assessments and risk management options prepared to justify requests for phytosanitary measures under Council Directive 2000/29/EC (EFSA Panel on Plant Health (PLH), 2009). The guidance provided in this document complements and does not replace the two above mentioned documents when responding to requests for scientific advice on issues related to the evaluation of the effectiveness of options to reduce the phytosanitary risks within the European Community in order to support the decision-making process under Council Directive 2000/29/EC.

1.1. Purpose of the document

The purpose of this document is to provide guidance for the Panel in order to support the decision-making process under Council Directive 2000/29/EC, when performing:

- the assessments of documents and technical files prepared by EU Member States or third parties to justify requests for phytosanitary measures to be considered by the European Commission under Council Directive 2000/29/EC, and
- the identification and evaluation of options to reduce the phytosanitary risks within the EU.

The present guidance document clarifies the types of information and the methods that can be considered by the Panel when evaluating the evidence provided to justify requests for phytosanitary measures for consideration by the European Commission under Council Directive 2000/29/EC. The focus is given to quantitative approaches, however, qualitative methods to evaluate the effectiveness of the risk reduction options are also briefly addressed.

More specifically, the guidance document aims at:

- Listing the different types of information that need to be provided in order to assess risk reduction options;
- Presenting a database including references of some key documents (guidance documents, and documents presenting results of experimental assessment of options) that may be useful for the Panel when assessing risk reduction options;
- Presenting possible statistical methods and quantitative tools for assessing risk reduction options.

The Panel has adopted the following definitions used in the present guidance document:

Risk Reduction Options (hereinafter referred at as RRO): options to reduce the risk of introduction and spread of a pest and/or the risk that a pest causes a biological impact. In consideration of EFSA principles of separation of risk assessment from risk and transparency defined in EFSA's founding regulation EC N°178/2002, the Panel uses the term "risk reduction options" to replace "risk management options".

Effectiveness of a risk reduction option: Capability of an option to reduce the risk caused by a harmful organism. In its assessment the Panel should also consider the reliability and reproducibility of the option as well as the limitations of application in practice should be noted as recommended in EFSA Panel on Plant Health (PLH), 2010a.

1.2. Methods

1.2.1. Checklist: required information and data for assessing risk reduction options.

The information and data required for assessing the effectiveness of RROs were categorised, and a checklist was developed by the Panel. The checklist was then tested using seven RRO assessments submitted to the Panel (Table 1) and the criteria were adjusted and finalised.
The final checklist could be used both by the authors of the documents supporting a particular request and by experts commissioned to analyse this request. It includes five parts:

- Description of the proposed RRO;
- Experimental assessment of the effectiveness of the presented option in reduction of pest infestation in plant material/or product under laboratory/or controlled conditions;
- Experimental assessment of the effectiveness of the presented option in reduction of pest infestation in plant material/product under operational conditions;
- Analysis of the applicability and feasibility of the proposed RRO;
- Assessment of the effectiveness of proposed option in reducing the risk of pest entry from the infested area to a pest free area.

1.2.2. Review of existing approaches

The literature review performed by the Panel concerned:

i) existing guidance documents on the assessment of RROs and published experimental assessments of RROs,
ii) experimental designs, statistical methods, and quantitative tools for assessing RROs.

1.2.2.1. Review of existing guidance documents and of experimental assessments of risk reduction options

During the literature search, the principles of the extensive literature search (EFSA, 2011), corresponding to the first steps of a systematic review process (EFSA, 2010), were followed. After the literature search, a study selection was performed by the Panel to identify as many relevant studies as possible.
The fundamental aspects of the extensive literature search are the tailored search strategy/ies (i.e. combination of search terms and Boolean operators) and the extensive list of information sources used (i.e. bibliographic databases and other sources such as e.g. Journal tables of content etc). The process of extensive literature search is clearly reported to allow transparency and reproducibility and is an essential step of the systematic review process. Its output is an extensive collection of evidence (to be screened for relevance).

The extensive literature search was performed according to the following steps:

- Background legislation (Council Directive 2000/29/EC, emergency measures in the plant health field[9] and legislation concerning plant reproductive material) was screened and the cited RROs and requirements were extracted and categorised;

- The resulting classification was compared with the categories proposed in the relative International Standard for Phytosanitary Measures (hereinafter referred at as ISPM) (i.e. ISPM No 4,11, 14, and others in FAO (2011)) and in the "EFSA PLH Guidance on a harmonised framework for pest risk assessment and the identification and evaluation of pest risk management options" (EFSA Panel on Plant Health (PLH), 2010a);

- Seventeen categories of RROs were defined after the first two steps (see 3.1.1);

[9] http://ec.europa.eu/food/plant/organisms/emergency/index_en.htm

- The literature search was conducted in the ISI web of Knowledge by defining specific key words for each identified group and combining them in one or more strings (the full list of search strategies is presented in Appendix A);

- For each category, the Panel listed the documents considered as guidance (describing and prescribing the RROs), the documents where the evaluation of specific RROs was described (e.g. field experiments, study designs, statistical and probabilistic models) and other documents of more general interest or not fitting in one of the predefined groups.

- The lists of references resulting from the specific literature searches were distributed among experts for screening for relevance, and if needed were reallocated to a more adequate category. The screening process was unmasked (the reviewer screened the abstracts with the availability of coordinates of the articles: authors names, year, editor, journal name...). The full texts of the selected references were considered. The resulting lists of publications comprised peer-reviewed articles, PhD theses, technical reports from various organisations, international, regional, and national guidance documents. In addition, miscellaneous literature was included as a result of specific searches in other more specific portals (Agricola, European Commission, European and Mediterranean Plant Protection Organisation (EPPO), International Plant Protection Convention (IPPC), United States Department of Agriculture (USDA), Biosecurity New Zealand, Biosecurity Australia, etc...) and from the screening of the lists of references found within those previously selected documents described above.
- All documents were screened and selected for their relevancy and included in a database of references (Appendix B).

1.2.2.2. Review of experimental designs, statistical methods, and quantitative tools for assessing risk reduction options

Literature reviews were performed on the following topics:

- Experimental designs for RRO assessment
- Experimental designs for pest survey
- Statistical methods for assessing option efficiency to reduce pest infestation
- Quantitative pathway analysis (principles, advantages, limitations, examples)
- Spread models (principles, advantages, limitations, examples)
- Quantitative tools used by other EFSA panels

In each case, representative examples and key guidance documents were identified. Recommendations were formulated on the basis of the reviewed documents and on the Panel's past experience.

2. Information and data required to assess the effectiveness of risk reduction options

This section describes the information and data required by the Panel to assess the effectiveness of RROs. The items listed below can be used by the Panel to check whether all required information is provided to support a RRO, and can be used by the author of the submitted dossier to verify whether all the requested data are included.

2.1. Types of assessment

Four types of RRO assessments can be distinguished according to their purposes and characteristics:

i. Experimental assessment of the option effectiveness to reduce pest infestation in plant material/product under laboratory/controlled conditions

ii. Experimental assessment of the option effectiveness to reduce pest infestation in plant material/product under operational conditions

iii. Analysis of the applicability of the RRO

iv. Assessment of option effectiveness to reduce risk of pest entry from infested area to pest free area

The first two assessments aim at evaluating the capability of a given RRO to reduce pest infestation in plant material (e.g., wood packaging) or product (e.g., grains) either under laboratory/controlled conditions (type i) or under operational conditions (type ii). As a RRO found to perform well under laboratory/controlled conditions may not be as effective under operational condition, these two types of assessment need to be distinguished (FAO, 2009a).

The third type of assessment aims at analysing the applicability of the RRO, more specifically how the option will be implemented (plan of implementation) and how its implementation will be monitored (e.g., how the temperature of a plant material will be monitored during a temperature treatment).

The fourth type of assessment aims at estimating the probability of pest entry in the EU territory (or part of this territory) when the considered RRO is implemented. This type of assessment differs from type i-ii assessments because it needs to take into account factors other than the effectiveness of the considered RRO to reduce pest infestation such as the quantity of exported plant product/material, survival during transport, detection at the border etc. (e.g., Stansbury et al., 2002; EFSA Panel on Plant Health (PLH), 2010b).

Due to their different purposes and characteristics, the four types of assessment defined above require different information and data as explained in the next section.

2.2. A checklist for evaluating a proposed risk reduction option

The checklist presented below was derived from FAO (2009a), Bartell and Nair (2003), EFSA Panel on Plant Health (PLH) (2009), and from the information and data considered by the Panel in previous opinions. It can be used by experts to make a preliminary assessment of documents and data submitted to EFSA in support of RRO (e.g., a temperature treatment of plant material) and, more specifically:

- to quickly describe the information provided to EFSA to support a proposed risk reduction option;
- to identify major gaps in the documents and data submitted to EFSA;
- to organise the work of the working group in charge of the dossier.

This checklist could also be used by the author of the submitted dossier to verify whether all the requested data are provided.

Section 2.2.1 aims at describing the proposed RRO. When the option is based on a combination of several treatments, all treatments should be listed. Pest and plant material should be described based on the information available in the submitted documents, and any discrepancies with the terms of reference should be mentioned in the 'Comments' column.

Section 2.2.2 can be used by the experts to analyse the quality of any experiment carried out to assess the effectiveness of the proposed option (or combination of options) in reducing pest infestation under laboratory/controlled conditions.

When an experiment has been carried out to assess the effectiveness of a new option to reducing the pest infestation under operational conditions i.e., under the conditions of actual implementation (same equipment, environment), the quality of this experiment should be evaluated in a separate section (2.2.3).

Elements related to the applicability of the RRO and to its monitoring should be reported in section 2.2.4.

Finally, when a specific study has been performed to assess the effectiveness of the option in reducing the risk of pest entry from infested areas to pest free areas (e.g., quantitative pathway analysis), the quality of this study can be analysed in section 2.2.5.

2.2.1. Description of the proposed risk reduction option

Item	Description based on the submitted document(s)	Comments
Name		
Target pest	(e.g. species, strain)	
Target plant material/product	(e.g. species, cultivar)	
Origin of plant material/product		
Type of RRO	(e.g. heat treatment, fumigation, combination of several treatments)	
Place of implementation		
Other relevant information		

2.2.2. Experimental assessment of the option effectiveness to reduce pest infestation in plant material/product under laboratory/controlled conditions

Source (indicate the reference of the supporting documents and data and their confidentiality status if applicable):

Item	Description based on the submitted document(s) / data	Comments
Plant material information		
Type of plant material/product used in the experiment		
Plant identity (e.g. botanical name, variety)		
Conditions under which plant materials/products are managed		
Conditions of the plant commodity (e.g. degree of ripeness, presence of bark, etc.)		
Pest information		
Identity (species- strains biotypes if applicable-)		
Conditions under which the pests are cultured, reared or grown		
Method of infestation		
Level of infestation		
Stage of the pest that is most resistant to the treatment		(refer to research data if relevant)
Was the most resistant stage used in the experiment?		
Potential development of resistance to the option		
Experiment(s) description and analysis		
Variables used to measure effectiveness and target values	(e.g. mortality rate, count)	
Factors influencing effectiveness	(e.g. wood humidity)	

which were taken into account in the experiment		
Factors influencing effectiveness which were **not** taken into account in the experiment	(e.g. wood humidity)	
Description of facilities and equipment		
Description of treatment	(e.g. temperature/duration, chemicals, concentration)	
Methodology followed for monitoring critical parameters	(e.g. number and placement of temperature sensors)	
Description of experimental design	(e.g. randomisation, blocks, number of replicates)	
Presentation of the data		
Description of the statistical analysis	(e.g. anova, regression, test)	
Conclusions of the experiment		
Other relevant information		

2.2.3. Experimental assessment of the option effectiveness to reduce pest infestation in plant material/product under operational conditions

Source (indicate the reference of the supporting documents and data and their confidentiality status if applicable):

Item	Description based on the submitted document(s) / data	Comments
Plant material information		
Type of plant material/product used in the experiment		
Plant identity (e.g. botanical name, variety)		
Conditions under which plant materials/products are managed		
Conditions of the plant commodity (e.g. degree of ripeness, presence of bark, etc.)		
Pest information		
Identity (species- strains biotypes if applicable-)		
Conditions under which the pests are cultured, reared or grown		
Method of infestation		
Level of infestation		
Stage of the pest that is most resistant to the treatment		(refer to research data if relevant)
Was the most resistant stage used in the experiment?		
Potential development of resistance to the option		

Experiment(s) description and analysis		
Variables used to measure effectiveness and target values	(e.g. mortality rate, count)	
Factors influencing effectiveness which were taken into account in the experiment	(e.g. wood humidity)	
Factors influencing effectiveness which were **not** taken into account in the experiment	(e.g. wood humidity)	
Description of facilities and equipment		
Description of treatment	(e.g. temperature/duration, chemicals, concentration)	
Methodology followed for monitoring critical parameters	(e.g. number and placement of temperature sensors)	
Description of experimental design	(e.g. randomisation, blocks, number of replicates)	
Presentation of the data		
Description of the statistical analysis	(e.g. anova, regression, test)	
Conclusions of the experiment		
Other relevant information		

2.2.4. Analysis of the applicability of the risk reduction option

Source (indicate the reference of the supporting documents and data and their confidentiality status if applicable):

Item	Description based on the submitted document(s) / data	Comments
Plan of implementation		
Place of implementation		
Characteristics of the treated material	(e.g. maximum size of the lot)	
Description of the required facilities and equipments		
The degree to which the proposed option complements other phytosanitary measures	(e.g. potential for the treatment to be used as part of a systems approach for one pest or to complement treatments for other pests)	
Consideration of potential indirect effects	(e.g. impacts on the environment, impacts on non-target organisms, human and animal health)	
Monitoring of the plan		
Parameters that will be monitored	(e.g. wood temperature, presence of pest)	
Critical thresholds considered for	(e.g. minimum temperature	

these parameters	value)	
Equipments used for the monitoring	(e.g. temperature probes, detection techniques)	
Other relevant information		

2.2.5. Assessment of option effectiveness to reduce risk of pest entry from infested area to pest free area

Source (indicate the reference of the supporting documents and data and their confidentiality status if applicable):

Item	Description based on the submitted document(s) / data	Comments
Consignments		
Origin		
Type of commodities		
Surveillance	(e.g. survey, commodity inspection, monitoring etc...)	
Level of infestation of plant material/product		
Quantity of commodities		
Means of transportation	(e.g. boats, planes, trains, tourisms)	
Detection method of the pest in the plant material/product		
Place(s) of implementation	(e.g. truck, harbour)	
Sampling technique	(e.g. size, unit, number of samples)	
Type of detection method	(e.g. visual inspection, laboratory test)	
Accuracy	(e.g. sensitivity, specificity)	
Point(s) of entry	(e.g. city)	
Variable used to describe probability of pest entry	(e.g. entry rate, probability, score)	
Conclusion of the assessment		
Other relevant information		

2.3. Analysis of data from the documents submitted to the Panel

The checklist presented in 2.2 was applied to seven assessments related to RROs that were submitted to the Panel. These assessments were discussed in detail by the Panel in its published opinions (Table 1). Three of these assessments concerned the pinewood nematode (*Bursaphelenchus xylophilus*), one concerned a fungus (*Tilletia indica*), and three concerned insects (*Agrilus planipennis, Bemisia tabaci, Anoplophora chinensis*). Four of the seven proposed RROs were temperature treatments (Table 1).

Three of the proposed options were based on experimental assessments under laboratory conditions (Table 1). A statistical analysis was reported by the authors in only one of these experimental assessments. In the other two, conclusions were derived without any statistical analysis of the data.

None of the proposed options was assessed under operational conditions. Although effectiveness of the option in reducing the risk of pest entry was addressed in three cases, such risk was assessed quantitatively in only one of the submitted documents (*T. indica*) using a quantitative pathway analysis. Finally, only one type of assessment was reported in each submitted document (with one exception for *T. indica*). As a result, it was not possible to fully assess RRO based on the information in the submitted documents.

Table 1: Risk reduction option assessments submitted to the Panel

Pest	RRO	Experimental assessment under laboratory/controlled conditions	Experimental assessment under operational conditions	Analysis of the applicability of the RRO	Assessment of the option effectiveness to reduce risk of pest entry
Bursaphelenchus xylophilus	Treatment of wood shavings at a high temperature (398 °C), for a short period of time (3 minutes)	Yes (no statistical analysis of the data by the authors)	No	No	No
Bursaphelenchus xylophilus and insects (species not specified)	Not specified. Authorities are looking for alternative to the existing requirements	No	No	No	No, but a protocol was proposed to carry out the assessment
Bemisia tabaci	A cold treatment for strawberry transplants at 28 degrees Fahrenheit (-2.2 degrees Celsius) for 2 weeks	Yes (no statistical analysis of the data by the authors)	No	No	No
Tilletia indica	Detection of bunted wheat kernels.	No	No	Yes (partly)	Yes (quantitative assessment)
Anoplophora chinensis	Reduction in number of inspections. Two alternative proposals were submitted : Alternative 1:To allow grafting of scions from outside the cage; Alternative 2:to remove the net from the field cage during the winter months	No	No	No	Yes (partly, no quantitative assessment)
Bursaphelenchus xylophilus	Heat treatment (56°C/30 min)	No	No	Yes	No
Agrilus planipennis	Heat treatment of wood (60°C/60min)	Yes	No	No	No

3. Review of existing approaches, experimental design, statistical methods, and quantitative methods for assessing the effectiveness of risk reduction options

3.1. Literature review

3.1.1. General description of the selected documents

Selection of the categories for different RROs was based on EU legislation (Council Directive 2000/29/EC, emergency measures in the plant health field and legislation concerning plant reproductive material), on relevant ISPMs (FAO, 2011) of the IPPC as mentioned in the section 1.2.2.1 (Review of existing guidance documents and of experimental assessments of RROs), and on the 'EFSA PLH Guidance on a harmonised framework for pest risk assessment' (EFSA Panel on Plant Health (PLH), 2010a). According to ISPM No 11 (FAO, 2004a) appropriate measures should be chosen based on their effectiveness in reducing the probability of the pest introduction and can be classified into broad categories related to the pest presence in the pathway.

Based on the above, the following RRO categories were identified for the literature review:

Options for consignments

1. Prohibition.
2. Pest freedom: inspection or testing.
3. Prohibition of parts of the host or of specific genotypes of the host.
4. Pre-entry or post-entry quarantine system.
5. Phytosanitary certificates and other compliance measures.
6. Preparation of the consignment.
7. Specified treatment of the consignment/ reducing pest prevalence in the consignment.
8. Restriction on end use, distribution and periods of entry.

Options preventing or reducing infestation in the crop

9. Treatment of the crop, field, or place of production in order to reduce pest prevalence.
10. Resistant or less susceptible varieties.
11. Growing plants under exclusion conditions (glasshouse, screen, isolation).
12. Harvesting of plants at a certain stage of maturity or during a specified time of year.
13. Certification scheme.

Options ensuring that the area, place or site of production, remains free from the pest

14. Maintaining Pest Free Area (PFA).
15. Pest free production site.
16. Inspections, surveillance.

Options for other types of pathways

17. Natural spread, spread by human activities (people movement, transports, machineries, trade), vectors, phoresy.

18. Other relevant information

After extensive search for each category using methodology described in 1.2.2.1, the search yielded 358 publications including 347 full papers and 11 abstracts. These were not subjected to a systematic evaluation but certain key papers were identified from their titles and abstracts as relevant. After further reviewing the full text of these potentially relevant publications , 192 documents on assessing the effectiveness of RROs were chosen for application in this guidance document (see Appendix B), most of which comprise peer-reviewed articles and guidance documents issued by different authorities. In addition, a large number of publications emerged from specific searches carried out by the experts who have developed this opinion.

The table presented in the Appendix B includes some examples of existing guidance documents and articles on experimental assessments illustrating relevant RROs in a comprehensive manner. Therefore, to find the relevant RROs for a country/ commodity/ pest associations, it is necessary to recognise the categories of options that could be considered, starting from the time of production in the field, through harvest and post-harvest practices, up to the import process.

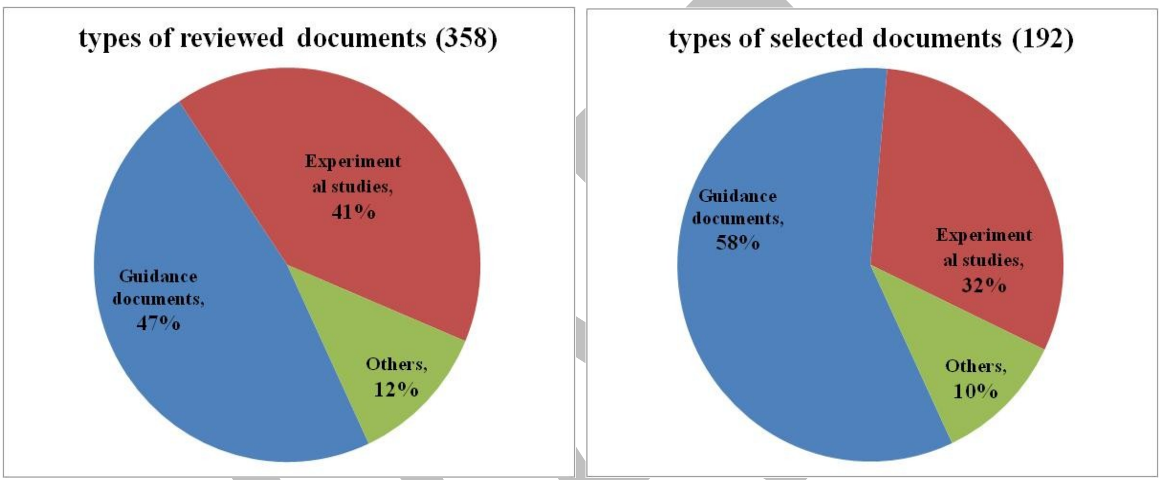
Examples of regulations from some countries were used as guidance for analysts in designing RRO recommendations that are in compliance with the existing import requirements. However the existing requirements stipulated in such regulations can be challenged according to the Article 4 (Para 1) ‘Equivalence’ of the Sanitary and Phytosanitary Agreement (SPS) of the World Trade Organization (WTO). In such cases, new options for reducing risk can be suggested if they are deemed to be equivalent in meeting countries’ Appropriate Level of Protection (ALOP). The new options for such proposals can often be found in publications of experimental nature, i.e., those testing survival of pests in commodities. Selecting guidance from publications based on experimental results found in research articles is not as straightforward as using adopted regulations. When assessing such publications it is important to examine the methodology for possible flaws, such as incomplete description of experimental design or inappropriate statistical methods used for data analysis (see sections 2.2 "A checklist for evaluating a proposed RRO" and 3.2 "Experimental designs and statistical methods used for assessing RRO" for specific guidance).

3.1.2. Results of the literature review

3.1.2.1. Summary of the results from the literature review

Among the 358 documents retrieved from the literature, 47% were guidance documents, 41% were documents presenting results of experimental assessment of RROs, and 12% were miscellaneous types of documents (mainly reviews) (Figure 1A).

Out of the 358 documents, only 192 relevant documents (55%) were selected for further analysis (Figure 1). Among them, 58% were guidance documents, while 32% were experimental studies (Figure 1B).



A. B.

Figure 1: Typologies of reviewed and selected documents.

Figure 2 shows the proportion of selected documents in each RRO category. The distribution is rather uneven with the categories 7 and 18 being the largest and including 39% and 19% of the selected documents, respectively. Category 14, on the other hand, includes 7% of the selected documents and categories 4 and 13 only 6% each. Each of the remaining categories includes less than 5% of the documents. Categories 5 and 12 do not include any document.

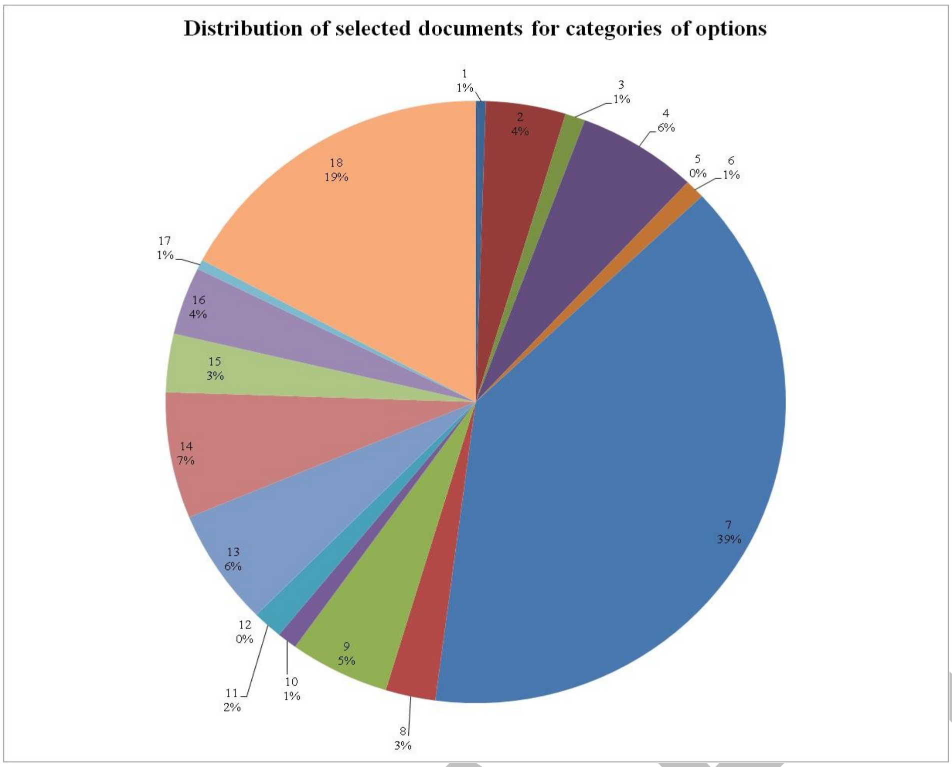
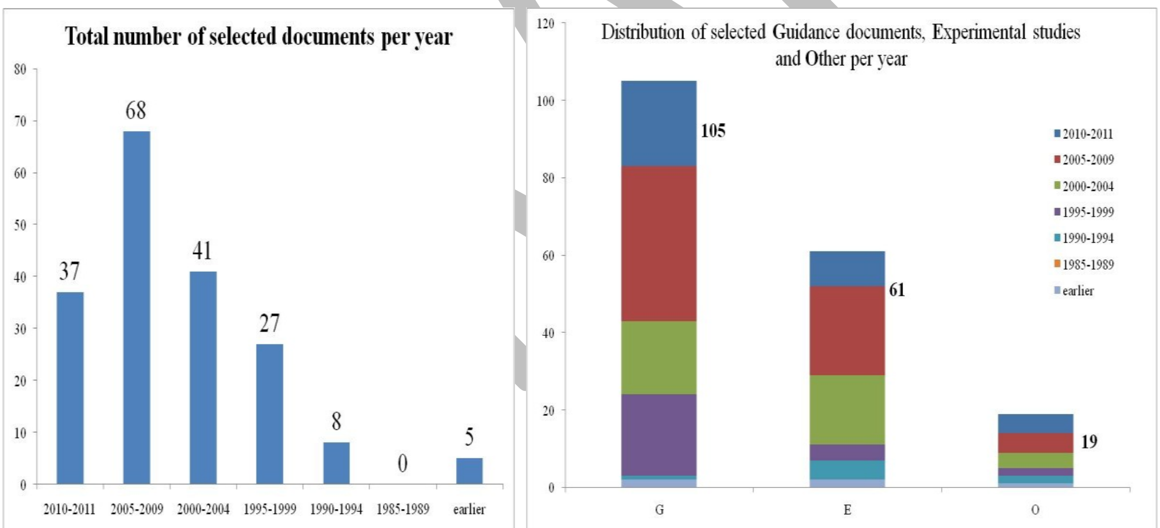


Figure 2: Proportions of papers allocated to the 18 RRO categories



A. B.

Figure 3: Distribution of the selected documents over time

Figure 3 shows the distribution of the selected documents according to their year of publication. More than half of the selected documents (56%) have been published in the last years, between 2005 and 2011 (Figure. 3.A). When classified in the three categories (guidance documents, experimental studies and others), the majority (57%) of the selected documents has been identified as guidance document (Figure 3.B). Among the guidance documents, the proportion of articles published since 2005 is higher than the general figure (59%).

3.1.2.2. Detailed analysis for each category

- **Options for consignments:**

<u>Category 1 :</u> Prohibition

The most relevant guidance document within this category outlines the requirements for preventing introduction into and spread within Canada of the Emerald Ash Borer, *Agrilus planipennis* Fairmaire (CFIA, 2010). The document lists in details all types of regulated articles that could harbour or sustain this pest throughout its life cycle as well as the requirements for their domestic movement and importation from the continental U.S. No experimental articles demonstrating effectiveness of the prohibition options were found within this group.

<u>Category 2:</u> Pest freedom, inspection or testing.

Only ten of the 25 reviewed documents were considered adequately representing options for consignments that refer to pest freedom via inspection or testing. Six of the ten selected documents are guidances and four are scientific articles presenting experimental results on inspection or testing. Among relevant examples is guidance on detection and surveillance for tomato leafminer, *Tuta absoluta* using trapping (USDA APHIS, 2011b). Of interest are also measures (including inspection) for a group of pests in sweet oranges from Italy imported to Australia (Biosecurity Australia, 2005). Other relevant documents include sampling for detection of pine wood nematode (PWN) in trees, wood and insects (Schroeder et al., 2009) and analysis of probit 9 as a standard for quarantine security (Chew, 1996). Among the experimental articles demonstrating effectiveness of the inspection or testing four documents were found relevant. Examples include Elmouttie et al. (2010) discussing importance of choosing the most appropriate biological model when developing sampling methodologies for insect pests in stored grain and Vail et al. (1993) on biological approach to decision making for selected hosts of Codling moth.

<u>Category 3</u>: Prohibition of parts of the host or of specific genotypes of the host

This category includes only two examples: one guidance document from a regulatory agency (CFIA, 2008) and one concept document under category of "other" (Armstrong, 1994). The concept document is based on using infestation-resistant or non-host commodities, cultivars, stages of maturity and appropriate growing periods for obtaining a pest free production. The regulatory document forms a basis for Canadian barbery certification program prohibiting importation and movement of certain varieties of barbery nursery stock susceptible to rust.

<u>Category 4</u>: Pre-entry or post-entry quarantine systems

This group includes ten relevant guidance documents and five experimental papers. Several USDA APHIS manuals provide guidance on specific methodologies for inspecting different types of quarantine commodities. Two protocols from Australia for quarantine detection of *Tilletia indica* in wheat were also considered relevant. Among statistical guidance documents of interest is a publication emphasising binomial-, beta-binomial-, and hypergeometric-based sampling strategies relevant to quarantine inspections for exotic pests (Venette et al., 2002). Experimental articles on visual inspection include sampling for injury in quarantine protection of fruit (Yamamura and Katsumata, 1999) and detection of the nematode *Bursaphelenchus xylophilus* in wood packaging material based on morphology and intergenic transcribed spacer restriction fragment length polymorphism (Gu et al., 2006). Also included is an article on PCR detection tools for phytoplasmas in fruit trees (Heinrich et al., 2001).

<u>Category 5</u>: Phytosanitary certificates and other compliance measures

A phytosanitary certificate is an attestation by the exporting country that the requirements of the importing country have been fulfilled. While the use of phytosanitary certificates is implemented by IPPC members, no scientific publications were found in their support as a RRO.

<u>Category 6 and 7</u>: Preparation of the consignment and specified treatment of the consignment/ reducing pest prevalence in the consignment

Results from the systematic literature search for these two groups were numerous but overlapping and were thus combined for the purpose of this discussion. Many guidance documents from plant protection organizations (e.g., EPPO, USDA APHIS, others) represent treatments of consignments applied either as a single RRO or in combination with other measures in a systems approach. Examples include heat treatment, irradiation, and chemical treatment and fumigation alternatives to methyl-bromide (USDA APHIS, 2011a). Many experimental studies were of dose-response relations for treatments of wood and wood packaging material (Mushrow et al., 2004; Myers et al., 2009). Some publications demonstrate possible failure of ISPM No 15 requirements to eradicate pests (Encinas and Briceno, 2010; Goebel et al., 2010). Several papers describe experiments intended to develop methods for effective replacement of methyl-bromide fumigations (e.g., Gupta, 2001). A number of papers discuss the feasibility and limitations of the probit-9 mortality standard (originally developed for eradication of fruit flies in fruit consignments) for other types of pests and commodities (e.g., Haack et al., 2011; Follett and Neven, 2006). Review of statistical methodology to assess the effectiveness of treatments in consignments is discussed in Mangan and Sharp (1994).

<u>Category 8:</u> Restriction on end use, distribution and periods of entry.

We found no experimental articles demonstrating effectiveness of either of these options. Examples for restrictions on end use of the commodity are imports of various processed fruits and vegetables instead of the fresh ones, e.g. cured figs and dates, raisins, nuts, and dried beans. The processed commodities are allowed to enter without permit or phytosanitary certificate thus meeting the appropriate level of protection (ALOP) for the United States. Limitations on distribution of fresh commodities potentially infested with internal pests are requirements to enter exclusively through the ports located north of 39° latitude and east of 104° longitude. This assumes that pest survival will be limited by environmental factors (suitable temperature and available hosts). Limitation can also relate to certain periods of the year, e.g., in some situations, entry is allowed from December 1 through April 30 only with additional safeguarding practices (i.e., using insect proof material to cover harvested commodity).

- **Options preventing or reducing infestation in the crop**

<u>Category 9:</u> Treatment of the crop, field, or place of production in order to reduce pest prevalence and possibly achieve areas of low pest prevalence (ALPPs)

Differing from the establishment of pest free areas (PFAs, see category 14 below), this option, which is described in ISPM No 22 (FAO, 2005), aims at establishing areas of low pest prevalence (ALPPs) for regulated pests in an area and, to facilitate export, for pests regulated by an importing country only. These measures can be combined with other options such as categories 6-8 above. The relevant literature comprises reviews, guidance documents and experimental articles on control of quarantine pests in various crops (i.e. ornamentals, fruit trees, grapes and vegetables), including pest and disease management in the crop and post harvest treatment (e.g., Jackson et al., 2010; Jamieson et al., 2009). Some examples of relevant publications include but are not limited to testing treatment effectiveness of fumigation (Zettler et al., 2002) and biological control of pests with parasitoids (El Wakeil et al., 2008).

<u>Category 10:</u> Resistant or less susceptible species (varieties)

RROs using resistant or less susceptible species or varieties as a sole measure do not often provide effective enough to prevent introduction of a quarantine pest. This might explain why only a few papers were found in support of this option. Relevant example by Badiger et al. (2011) describes an experiment where cotton hybrids containing Bt gene were successfully used against pink bollworm and tobacco caterpillar. Promising results were obtained by Zehnder et al. (1997) in a cucumber crop experiment studying effect of resistance induced by growth promoting rhizobacteria on the cucumber beetle. Research by Aluja et al. (2004) demonstrated that commercially cultivated and marketed avocado cultivar "Hass" should not be considered a natural host for *Anastrepha* ludens, *A. striata, A. sermentina*, and *A. obliqua* fruit flies in Mexico. This study became a basis for the importation requirements of "Hass" avocado variety to the United States under systems approach, without specific treatments against the above mentioned *Anastrepha* spp. (USDA APHIS, 2011a; CFR. 2011a,b).

Category 11: Growing plants under exclusion conditions (glasshouse, screen, isolation)

Only three guidance type documents were found relevant to this group all of which devoted to biological control. Albajes et al. (1999) authored a book that provides the basic strategies and tactics of integrated pest management, with special reference to greenhouse crops and with a pre-eminence of biological control. The second publication (Mahr et. al., 2001) is also a book reviewing biological control of pests in greenhouses. The third publication (Yano, 2006) reviews ecological bases for the biological control of aphids in a protected environment, evaluation of biological control agents, natural enemy release strategies, and the effects of intraguild predation on biological control.

Category 12: Harvesting of plants at a certain age or a specified time of year.

Only few relevant documents were found for this group. Examples include regulations for importation into the United States of green tomatoes from several regions (e.g., Central America, Mediterranean) that are admissible without treatments, while tomatoes with pink or red fruit are subject to certain risk mitigation requirements, depending on the country of origin (USDA APHIS, 2011a; CFR. 2011a).

Category 13: Certification scheme

Options for preventing or reducing infestation by certification system are very common in quarantine practice everywhere in the world. Many papers were found from different countries, including EPPO region, with certification schemes for various crops – seed potatoes, *Rubus*, rose, freesia, hyacinth, narcissus, petunia, kalanchoe, apple, pear, quince, cherries, almond, apricot, peach, plum. Usually this method is used against organisms that can be introduced or spread by planting material (e.g.,viruses), where other methods, i.e., chemical control, are not available. These options require systematic sampling and pathogen testing so that the certification system can guarantee healthy, pest free planting material.

- **Options ensuring that the area, place or site of production or crop is free from the pest**

Category 14: Maintaining pest free area.

The majority of selected documents are guidelines from different parts of the world. The relevant ISPMs (FAO, 2011) include No 4, 6, 8, 9, 10 and 26, of which No 4 on establishment of pest free areas, is the most important. Among National Plant Protection Organisation (NPPO) guidances, we note the guidelines for fruit fly systems approach by USDA APHIS (2003) developed to prevent the risk of introduction of fruit flies from Mexico to the USA via traded host commodities. A guidance document from India for Tephritid fruit flies (PQOI, 2005), was also selected and describes the requirements for establishment, maintenance and verification of fruit fly free areas in the country. From the regional guidelines, we selected the EPPO standard PM 9/10(1) for containment and eradication of plant pests which describes the generic elements for contingency plans (EPPO, 2009). Also of interest is Schröder et al. (2009**)** describing sampling for detection of the pine wood nematode in trees and wood which is very important for establishing areas free from this pest. The experimental paper of Melifronidou-Pantelidou (2009) concerns survey, delimitation of infested areas, and establishment of pest free areas for the red palm weevil *Rhynchophorus ferrugineus* in palm tree cropping. Sosnowski et al. (2009) present a review article on eradication of various plant pathogens using burning, burying, pruning, composting, soil- and biofumigation, solarization, steam sterilization and biological vector control.

Category 15: Pest free production site.

The most relevant documents retained for this option are in FAO (2011), the ISPMs No 4, 6, 8, 9 and 10, of which the most important is ISPM No 10 on requirements for establishment of pest free places of production and pest free production sites. As with the RRO Group 14, the publication of Schröder et al. (2009) is also relevant to the establishment of pest free production sites.

Category 16: Inspections, Surveillance.

One of the most relevant documents for the assessment of surveillance and inspection as a RRO is guidance from Australia for survey of plant pests in pacific area (McMaugh, 2005). This manual assists plant health scientists in devising surveillance programs and transmitting specimens to the laboratory for identification and preservation. Of equal importance is the USDA (2011) post entry manual for state inspectors for surveillance. Other publications of importance include Wardlaw et al. (2008) who compare different surveillance techniques for assessment of disease and pest impact in forest and their limitations. Also of interest are Sigvald and Hulle (2004) report on two models that assist in monitoring and forecasting the spread of a virus in potato crop and Dallot et al. (2004) models for assessing the impact of a cultural technique on the spread and the persistence of a plum pox virus.

- **Options for other types of pathways**

Category 17: Natural spread and spread by human activities (people's movement, transports, machineries), vectors, and phoresy.

Options preventing introduction of pests by natural spread practically do not exist, consequently no papers illustrating these options were found. Spread by human activities is a very important common pathway. Trade can be regulated by legal methods (prohibition, specific requirements, etc.), this is already discussed in other groups for RROs. Some treatment and disinfection methods can be used to reduce spread of pests by human activities. Some of the relevant examples are Heather et al. (1991) on desinfestation of fruit flies in mango with gamma irradiation and Evans et al. (2007) on prevention of the spread of *Bursaphelenchus xylophilus* from Portugal using intensive monitoring system.

Category 18: Other relevant information.

This group includes a significant number of relevant documents that cannot however be associated with a specific type of RRO identified above. Some of these documents present general principles ensuring the safety of commodities. Others deal with a wide range of options (e.g., pre-harvest treatment, post-harvest treatment, pest detection) and provide useful information about system approaches. Five of the selected documents allocated to this group describe quantitative risk models estimating the probability of introduction of pests depending on the type of RROs implemented in the pathway. Although these models were developed for specific pests, they can be adapted by the Panel to deal with pests other than those considered in the selected papers. Eight documents allocated to this group describe the phytosanitary requirements for importation of different commodities into New-Zealand and the USA. This group also includes several manuals for inspection, monitoring and treatment of plant commodities and provide information about the practical implementation of several RROs.

3.1.2.3. Database including the references of the selected documents

After the literature review, a database of references of documents useful for Panel members when writing opinions on RRO was developed. The database is divided into nineteen groups.

- The first group contains seven opinions on RRO (Table 1) and two guidance documents produced by the Panel before 2012.
- The next eighteen categories include the documents ranged according to the type of risk reduction options. These folders were divided into two sub-groups each: one with guidance documents and the other with reports of experimental nature.

The references of the selected documents are included in the summary table available in Appendix B. .

3.2. Experimental designs and statistical methods used for assessing risk reduction options

The assessment of RRO depends on the nature of these options. Among the eighteen categories deriving from ISPM No 11 (FAO, 2004a) which we considered above, all have to be operationally assessed by surveillance (surveys and sampling) in real time. In addition, six of these options must also be developed and assessed experimentally before and after practical implementation.

3.2.1. Experimental designs for assessment of risk reduction options

ISPM No 28 (FAO, 2007a) provides a series of annexes that define criteria for treating specific commodities.

The six categories of RROs described in ISPM No 11 (FAO, 2004a) that need to be experimentally developed and tested, and assessed after implementation, are described in Table 2:

Table 2: Risk reduction option that need experimental development prior to implementation and experimental assessment after implementation

Category	Treatment	Experimental assessment
Category 6 - Options for consignments - Preparation of the consignment	e.g. handling to prevent infestation or reinfestation	Experimental comparison of the prepared shipment with an unprepared control lot, or with a control lot containing a known quantity of naturally or artificially contaminated material
Category 7 - Options for consignments - Specified treatment of the consignment/ Reducing pest prevalence in the consignment.	Such treatments are applied post-harvest and could include mechanical, chemical, irradiation, physical and controlled atmosphere treatments	Specific treatments to be tested on samples with material naturally or artificially contaminated with a known quantity of the pest.
Category 9 - Options preventing or reducing infestation in the crop - Treatment of the crop, field, or place of production in order to reduce pest prevalence and possibly achieve areas of low pest prevalence (ALPPs)	Chemical control, cultural control, biological control	Experimental comparison of treated and untreated plots
Category 10 - Options preventing or reducing infestation in the crop - Resistant or less susceptible varieties	Resistant varieties, cultivars, species	Experimental comparison of pest prevalence on different varieties, cultivars or species
Category 11 - Options preventing or reducing infestation in the crop - Growing plants under exclusion conditions (glasshouse, screen, isolation).	glasshouses, greenhouses, in-vitro culture, plastic foil.	Comparison of the levels of pest prevalence with or without exclusion conditions
Category 12 - Options preventing or reducing infestation in the crop - Harvesting of plants at a certain stage of maturity or during a specified time of year	Early- or late planting or sowing, early or late harvesting	Comparison of the levels of pest prevalence under different conditions of planting/sowing or harvesting

A comprehensive analysis of the many experimental methods for testing RRO exceeds the scope of this mandate, and therefore the Panel restricted itself to specific treatments of consignments in view of reducing pest prevalence as addressed in category 7 above.

ISPM No 28 (FAO, 2007a) presents in its annexes phytosanitary treatments evaluated and adopted by the Commission on Phytosanitary Measures (CPM). It also describes the requirements for submission and evaluation of the effectiveness data and other relevant information on a phytosanitary treatment that can be used as a phytosanitary measure after adoption. National and Regional Plant Protection

Organizations may "*submit data and other information for the evaluation of effectiveness, feasibility and applicability of treatments. The information should include a detailed description of the treatment, including effectiveness data, the name of a contact person and the reason for the submission. Treatments that are eligible for evaluation include mechanical, chemical, irradiation, physical and controlled atmosphere treatments. The effectiveness data should be clear and should preferably include data on the treatment under laboratory or controlled conditions as well as under operational conditions*."

The checklists presented in sections 2.2.2. (Experimental assessment of the option efficacy to reduce pest infestation in plant material/product under laboratory/controlled conditions) and 2.2.3. (Experimental assessment of the option efficacy to reduce pest infestation in plant material/product under operational conditions) include these criteria. These checklists however have a larger coverage, including plant material information and pest information; the Panel checklist includes additional items such as factors influencing effectiveness not taken into account in the experiments, the methodology for monitoring critical parameters, the presentation of the data, the description of the statistical analysis and the conclusions of the experiment. A comparison between the criteria presented in ISPM No 28 (FAO, 2007a) and the checklists prepared by the Panel is presented in Appendix C.

ISPM No 28 presently provides 14 annexes (FAO, 2007a) which all define criteria for post harvest treatments of fruit crops by irradiation for the following species: *Anastrepha ludens, A. obliqua, A. serpentina, Bactrocera jarvisi, B. tryoni, Cydia pomonella, Tephritidae (generic), Rhagoletis pomonella, Conotrachelus nenuphar, Grapholita molesta, Grapholita molesta* under hypoxia*, Cylas formicarius elegantulus, Euscepes postfasciatus, Ceratitis capitata*. Minimal irradiation doses range from 60 to 232 Gy (1 Gy = 1 gray = 1 J/kg), with values for the Effective Dose (ED) ranging from 99.9921 to 99.9980 at the 95% confidence level. These annexes explicitely accept a certain level of extrapolation, which extends to all fruits and vegetables because dosimetry systems measure actual radiation dose absorbed by the target pest independent of host commodity. ISPM No 18 (FAO, 2003), *Guidelines for the use of irradiation as a phytosanitary measure,* describes the procedures to be followed and criteria to respect for irradiation treatments. The NPPO of the importing country has the liberty to define the treatment effectiveness by providing a precise description of the required response and its expected statistical level.

Another commodity, wood packaging material, is regulated by ISPM No 15 (FAO, 2009b). As emphasised by Haack et al. (2011), the 2009 revision reduced the initial scope ("*practically eliminate the risk for most quarantine pests and significantly reduce the risk from a number of other pests that may be associated with wood packaging material*") to a less ambitious objective: "*reduce significantly the risk of introduction and spread of most quarantine pests*". According to ISPM No 15, wood packaging material must be treated at the core to 56 °C during 30 min. This norm is based on two reports (Eolas, 1991; Smith 1991), and one conference proceeding (Smith, 1992). It was originally established against the pine wood nematode, *Bursaphelenchus xylophilus.* Alternative treatments that are more environmentally friendly are being pursued (FAO, 2010). For the establishment of these alternative treatments, precise criteria have been defined, based on two requirements:

i) identification of most treatment-resistant test organism and life stage and establishment of its susceptibility to the proposed treatment;

ii) detailed effectiveness testing of this most resistant species to provide confidence that treatment is effective against all pests.

Requirements for treating firewood against the emerald ash borer *Agrilus planipennis* have been developed in the USA. In 2008, the US Authorities (USDA APHIS, 2008a) adopted a heat treatment schedule against the emerald ash borer in firewood of 71.1°C during 75 min. This treatment however has been initially developed to control Basidiomycete fungi on Douglas-fir poles (Newbill and Morrell, 1991). Based on a study by Myers et al. (2009), the modified temperature/time norm for the

US was reduced to 60°C/60 min (USDA APHIS, 2011). The Panel questioned the effectiveness of this proposed treatment (EFSA Panel on Plant Health (PLH), 2011a) based on the data provided.

Based on the available literature, there is a considerable level of uncertainty regarding the effectiveness of these different treatments because they were established against particular species that were not necessarily the most treatment-resistant test organisms and life stage and couldn't be automatically extrapolated. Whilst the 56°C/30 min norm is considered acceptable against the pine wood nematode, *Bursaphelenchus xylophilus* (ISPM No 15: FAO, 2009b), a higher norm (60°C/60 min) was established by Myers et al. (2009) to treat firewood against the emerald ash borer *Agrilus planipennis* and was adopted by the US authorities. To add to this uncertainty, this latter norm has been questioned since by one experimental study (Goebel et al., 2010) and one statistical re-analysis of the results of Myers et al. (2009) (EFSA Panel on Plant Health, 2011a). Another element of high uncertainty is the unpublished nature of the sources for the norm used in ISPM No 15 (Eolas, 1991; Smith, 1991; Smith, 1992).

From the examples above, and referring again to its checklist, the Panel concludes that it is of uttermost importance for any experimental assessment that the objectives of a proposed RRO (e.g. expected infestation levels, pest incidence) are clearly established.

3.2.2. Systematic surveillance

3.2.2.1. Surveillance and risk reduction options

Surveillance is an obligatory element of plant health risk reduction. Under the IPPC,

- NPPO's are obliged to perform:
  - the surveillance of growing plants, including both areas under cultivation (inter alia fields, plantations, nurseries, gardens, greenhouses and laboratories) and wild flora, and plants and plant products in storage or in transportation, particularly with the object of reporting the occurrence, outbreak and spread of pests, and of controlling those pests, (Art IV-2-b)
  - the protection of endangered areas and the designation, maintenance and surveillance of pest free areas and areas of low pest prevalence (Art IV-2-e).

and

- contracting parties shall, to the best of their ability,
  - conduct surveillance for pests
  - develop and maintain adequate information on pest status in order to support categorisation of pests, and for the development of appropriate phytosanitary measures. This information shall be made available to contracting parties, on request. (Art VII-2-j).

According to ISPM No 6 *"Guidelines for surveillance*" (1997) (FAO, 1997), surveillance may consist of any combination of 'general surveillance' and 'specific surveys'. 'General surveillance' for plant health risk is the systematic collection, verification and compilation of qualitative and quantitative information from a wide range of sources on particular pests which are of concern for an area, to be available for use by the NPPO. 'Specific surveys' for plant health risk are procedures by which NPPOs obtain information on pests of concern through structured, representative sampling on specific sites in an area over a defined period of time. ISPM No 6 serves as a reference for other ISPMs:

- Determination of pest status in an area (ISPM No 8: FAO, 1998)
- Requirements for the establishment of pest free areas (ISPM No 4: FAO, 1995)
- Requirements for the establishment of pest free places of production and pest free production sites (ISPM No 10: FAO, 1999)
- Requirements for the establishment of areas of low pest prevalence (ISPM No 22: FAO, 2005)
- Establishment of pest free areas for fruit flies (Tephritidae) (ISPM No 26: FAO, 2006)
- Recognition of pest free areas and areas of low pest prevalence (ISPM No 29: FAO, 2007b)
- Establishment of areas of low pest prevalence for fruit flies (Tephritidae) (ISPM No 30: FAO, 2008a)

Several RROs require information from surveillance. Depending on the perceived risk of the pest, the current state of information on pest occurrence and the specific RRO, the emphasis may be on general surveillance or on specific surveys, as illustrated in table 3 below.

Table 3: General surveillance and specific surveys

Risk component	Required surveillance
Maintenance of official pest list	In the importing country, general surveillance of cultivated and non-cultivated plants is required to maintain adequate information on pest status (ISPM No 6 in FAO(1997)), and may be required to support pest listing (ISPM No 20 in FAO (2004b))
Probability of entry	General surveillance in the exporting country, as required by the importing country, to demonstrate pest absence (ISPM No 4, 10 and 26 in FAO(1995, 1990, 2006) or low pest prevalence (ISPM No 22 and 30 in FAO(2005, 2008)) in the area of origin of the commodity. This area of origin can be referred to as the country, an area within the country, a place of production or a production site. Additional requirements for the area may be formulated, e.g. a buffer zone, or the 'immediate vicinity' of a place of production. Depending on the current distribution of the pest in or near the area of origin and the potential impacts of the pest in the importing country, the importing country may require a detailed plan for specific surveys (describing the power of the survey) and quantitative reports of specific surveys, including risk maps of the area.
Probability of establishment	The importing country may perform repeated, specific surveys at points of entry and at importing companies and their environments for early detection of pest presence and subsequent eradication
Probability of spread	The importing country may perform specific surveys to delimit the infested area in order to contain the pest within the boundaries of the infested area
Impact of pest occurrence	The importing country may perform general surveillance and specific surveys in order to monitor pest prevalence in the country as part of official control programs.

3.2.2.2. Quality criteria for general surveillance

In order to conclude on the absence or low prevalence of a pest, general surveillance reports must be based on systematic collection, verification and compilation of information on the pest in the area by plant health experts.

ISPM No 6 provides guidance on how to conduct systematic general surveillance, including the distribution of reports derived from surveillance, but does not provide details on the reports. In turn, ISPM No 8 provides guidance on good reporting practices that mostly concern accuracy, timeliness, and completeness of the reports, without indicating specific information that should be included to ensure such completeness. This is also not covered in ISPM No 17 (FAO, 2002), which provides guidance on reporting immediate or potential danger.

The Panel recommends that reports of general surveillance for the purpose of developing RROs by the NPPO or the NPPOs trading partners should include the following information:

- Identification of the pest of concern,
- Description and clear demarcation of the area for which general surveillance is performed,
- Hypothesis on the presence or absence of the pest of concern in this area,
- Description and listing of data sources used in the general surveillance (e.g. NPPO pest records, communications with extension officers, producers and trading companies, reports from research institutes, trade data, etc.),
- Evaluation of the potential presence of the pest in the area of concern based on:
    - the current and recent distribution of the pest within and near the area,
    - climatic and other ecological conditions of the area for development of pest populations,

  - the presence of host plants or other potential niches suitable for pest populations in the area,
  - the import and trade rates of distinguished host plant products in the area,
- Discussion of the actual presence of the pest in the area, based on all information obtained,
- If the pest is present at low prevalence in the area, additional information needs to be presented characterising the nature the pest distribution in the area. The IPPC defines area of low pest prevalence as "*an area, whether all of a country, part of a country, or all or parts of several countries, as identified by the competent authorities, in which a specific pest occurs at low levels and which is subject to effective surveillance, control or eradication measures*". This definition is ambiguous. It covers situations where many fields are infested but at a low incidence in each field as well as situations where only a few fields in the area are infested, but possibly at high incidence levels. In both cases, the pest would occur at low levels in the area. However, the different distributions may require different sources of information. Since ALPPs may be established for different purposes, the size and description of the ALPP will depend on the purpose. Specified levels for the relevant pests should be established by the NPPO of the country where the ALPP is located, with sufficient precision to allow assessment of whether surveillance data and protocols are adequate to determine that pest prevalence is below these levels (ISPM No 22 in FAO (2005).
- A clear conclusion on the pest status (ISPM No 8 in FAO (1998) in the area of concern.

3.2.2.3. Quality criteria for specific surveys

Just like the inspection of a sample from a consignment of plants cannot give certainty about the absence of pests in the consignment, no survey can demonstrate the absence of a pest in an area with 100% certainty. The level of uncertainty of the results of the survey or, inversely, the confidence level of the survey, needs to be specified in order to recognise the value of its results. For that purpose, the area under investigation can be considered as a population of potential niches for the pest under investigation, where each potential pest niche has the binary characteristic of either being infested or free from the pest. Depending on the target of the survey, a potential niche can be defined as a plant of a host species, a field planted with a host crop, a landscape element (a length of river shore or a natural stand with host plants), a storage facility for host plant products, etc. The survey can then be considered as a sample of inspected niches from the population of total potential niches in the area. The results of the survey are interpreted according to the principles for sampling of consignments (see ISPM No 31: FAO, 2008b).

In statistics, the power of a statistical test is the probability of rejecting the null hypothesis when the null hypothesis is false. For specific surveys with the purpose to demonstrate the absence or presence of a pest in an area, a null hypothesis may be formulated as "the pest is absent in the area". Under the assumptions that:

- the total number of potential pest niches is large relative to the number of infested pest niches,
- infested niches are randomly distributed in the area, and
- each observation is 100% effective in detecting a pest if it is present,

the survey may be designed based on the binomial probability distribution (Venette, 2010). The probability of a type II error (β) of the survey, that is concluding that the pest is absent when it is actually present (false absence), is calculated as $(1-p)^n$, where n is the number of potential pest niches in the survey and p is the minimum fraction of infested niches in the area under investigation above which detection is required.

The power of the survey, or its confidence level, that is the probability of concluding that the pest is present when it is actually present (probability of true presence), then equals $1-\beta$. The value of p is set arbitrarily in relation to the expected level of confidence.

Our capability to correctly conclude on a pest presence can be improved by increasing the number of surveyed potential pest niches, but it is reduced when the required level of detection is set to a lower value.

In reality the confidence level may be lower than the theoretical value, if:

- the distribution of the pest in the area is aggregated rather than random. The level of aggregation of the pest in the area is not known in advance of a survey, but it may be estimated from the biological characteristics of the pest. The survey may then be based on more complex statistical models, e.g. a beta-binomial distribution (Venette et al, 2002) or the negative binomial distribution (Schomaker and Been, 1999; Binns et al., 2000).
- the effectiveness of each single observation is less than perfect (e.g. when individuals of the pest are hidden, or when the survey is performed at a time when the pest has not developed symptoms or visible life stages).

The confidence level may be increased by:

- timing the survey according to environmental conditions that are optimal for host plant growth, pest population development (in particular visible life stages) and symptom expression,
- targeting the observations using knowledge of pest biology, area characteristics and the distribution of host plants and other potential pest niches in the area, and
- the use of traps and lures (extensively discussed in PRATIQUE (2011) final report)
- the training of inspectors
- laboratory testing of samples , where appropriate (ISPM No 6: FAO, 1997)

Several papers discuss methodologies for optimisation of survey design. Probability-based designs such as (stratified) random sampling and cluster sampling have the advantage in producing unbiased estimates of proportions and variances (Snedecor and Cochran, 1980). Barron (2006) concluded that results of random sampling, as opposed to those of cluster sampling, are not affected by aggregation of the pest at low incidence levels and, therefore, random sampling is preferred over cluster sampling when the level of aggregation is unknown. Huebner (2007) compared four sampling methods to detect and monitor invasive exotic plants and concluded that the timed-meander method performed best in detecting exotic invasive plant species, followed by stratified random sampling. Demon et al. (2011) also showed that random sampling may not yield the highest detection probabilities. They compared a modelling framework using simulated annealing with four other survey designs and found that simulated annealing, probability map sampling and distance-based sampling resulted in larger detection probabilities than (stratified) random sampling. However, the simulated annealing method requires epidemiological information, in particular the source of infestation, as well as detailed knowledge of the environment and the distribution of potential pest niches in the area, and hence may not be always applicable.

The Panel recommends that reports of specific surveys for use in plant health risk reduction meet the following qualifications:

- demarcation of the area for which the survey is performed and the year of the survey;
- identification of the pest under survey and a description of its ecology and biology in relation to the environmental characteristics of the area, relevant to survey objectives;
- quantitative information of host plants and other potential pest niches present in the area (number of fields/ locations, area covered with host plants, etc.) and maps of their distributions;
- formulation of survey hypothesis (pest X is absent in the identified area);
- explanation of applied mathematical background (e.g. binomial distribution, beta binomial distribution) and its justification;
- sampling method (e.g. random sampling, stratified sampling, planned number and timing of observations, timing of observations);

- confidence level (the survey has 95% confidence to detect the pest in the area, if it is present at or above the level of p);
- the methodology and instruments for performing an individual observation, including the use of traps, lures and laboratory testing;
- results of the survey, i.e. the list of observations including for each observation the date, the geographical reference of the potential pest niche, the observation method and details, and the result of the observation, and maps presenting the results of observed and total potential pest niches in the area);
- a clear conclusion of the survey and formulation of pest status according to the procedures described in ISPM No 8 (FAO, 1998).

3.2.2.4. Integrating general surveillance and specific surveys.

Martin et al. (2007) compared the strengths and weaknesses of general surveillance and specific surveys as tools to demonstrate absence or presence of a pest. They presented a method based on scenario trees to integrate the information from both approaches, in order to quantitatively estimate the probability that an area is free from a pest. Using all available data, Barrett et al. (2010) presented a remarkably similar approach to the design of surveillance systems using data from multiple sources and decision trees, although no reference to Martin et al. (2007) was made. In both papers the concept of 'survey system component' (SSC) is introduced, where each SSC refers to a separate data source, with its specific sensitivity to detect a pest. Such SSCs may include results from general surveillance (e.g. collection and aggregation of data from literature, collection of records from farmers on pest occurrence) and results from specific surveys by NPPO experts. With this methodology all available information is integrated quantitatively to evaluate the pest occurrence in an area.
The Panel recommends the implementation of the methodology proposed by Martin et al. (2007) and Barrett et al. (2010) for those cases where a clear conclusion on either the absence of the pest in the area, or the demarcation of the presence of the pest in an area is difficult to reach.

3.2.3. Statistical methods for assessing option effectiveness to reduce pest infestation

In this section, several statistical methods are presented for:

- Assessing uncertainty of RRO effectiveness
- Comparing RRO effectiveness to a threshold
- Testing the equivalence of two RROs
- Estimating dose – effectiveness relationship

3.2.3.1. Assessing uncertainty of risk reduction options effectiveness

Uncertainty in pest detection and treatment effectiveness can be assessed in different ways. Several approaches are presented below.

- <u>Assessing errors in detection</u>

The application of a detection method for pest presence in plant material can lead to four possible outcomes (Swets, 1988): true positive, true negative, false positive, false negative (Table 4). True positives (A) occur when a positive detection corresponds to the actual presence of a pest in the tested material. False positives (B) occur when detection is positive, but the pest is not present. True negatives (C) occur when the pest is both not detected and not present in the tested material. False negatives (D) occur when the pest is not detected but present. Outcomes A and C will lead to correct decisions, while outcomes B and D would lead to erroneous decisions about pest presence or absence.

Table 4: Outcomes of a detection method

		Actual condition	
		Present	Absent
Detection result	Positive	True positive (A)	False positive (B)
	Negative	False negative (D)	True negative (C)

When outcomes for the method (i.e., positive or negative) are available for *N* different samples of plant materials with known conditions (i.e., pest presence or absence), the results can be used to assess the accuracy of the considered detection method. This is achieved by computing relevant quantities such as sensitivity, specificity, likelihood ratio, and overall accuracy (e.g., Swets, 1988; Smith et al., 1999; Venette et al., 2002) defined by:

$$Sensitivity = \frac{\text{Number of true positive (A)}}{\text{Number of true positive (A) + Number of false negative (D)}},$$

$$Specificity = \frac{\text{Number of true negative (C)}}{\text{Number of true negative (C) + Number of false positive (B)}},$$

$$Likelihood\ ratio = \frac{\text{Sensitivity}}{1 - \text{Specificity}},$$

$$Overall\ accuracy = \frac{\text{Number of true positive and of true negative (A+C)}}{\text{Total number of tested samples } (A+B+C+D)}.$$

Sensitivity and specificity values range from zero to one. A good detection method is characterised by sensitivity and specificity values close to one. The likelihood ratio can be used to compare the probability of correctly detecting a pest’s presence with the probability of incorrectly detecting a pest’s presence. The ratio should thus be as high a possible. A ratio close to one indicates that the two probabilities are similar and that the detection method is not very useful. The overall accuracy ranges from zero to one: values approaching one indicate high level of accuracy. If the pest prevalence is known, the sensitivity and specificity can also be used to calculate the probability of pest presence (or absence) in function of the result of the detection method as follows:

$$\text{Prob. of pest presence in case of positive detection} = \frac{\text{Sensitivity} \times \text{Pest prevalence in plant materials}}{\text{Sensitivity} \times \text{Pest prevalence in plant materials} + (1\text{-Specificity}) \times (1\text{-Pest prevalence in plant materials})}$$

Table 5: Numerical example

Assume that *N*=150 plant samples have been tested for the presence of a given pest using a given detection method

Total number of plants N=150		Actual condition	
		Present A+D = 20	Absent B+C=130
Detection result	Positive A+B=72	True positive A=17	False positive B= 55
	Negative	False Negative	True negative

	D+C=78	D=3	C=75

The sensitivity shows that 85% (A/(A+D)=17/20=0.85) of the actual infested plant samples were correctly tested as “positive”. The specificity shows that 56% (C/(C+D)=55/130=0.56) of the not infested plant samples were correctly tested as “negative”.

In the numerical example above, the considered detection method has a low specificity. A consequence is that a risk assessor using this method will only have 1.92 higher probability of correctly detecting a pest’s presence than incorrectly.

$$\text{Likelihood Ratio} = \frac{\text{Sensitivity}}{1 - \text{Specificity}} = \frac{85\%}{100\% - 56\%} = 1.92$$

This result shows that the detection method is not very useful for confirming pest presence. This is confirmed by the low positive predictive value of the method defined by:

$$\frac{\text{Number of true positive (A)}}{\text{Number of true positive (A)} + \text{Number of false positive (B)}} = 17/72 = 24\%$$

On the contrary, the detection method is useful to confirm absence of the pest as shown by its high negative predictive value defined by:

$$\frac{\text{Number of true negative (C)}}{\text{Number of true negative (C)} + \text{Number of false negative (D)}} = 75/78 = 96\%$$

The simple techniques presented above can be applied to different types of detection methods, such as symptomatic inspections, serological and molecular tests, and others. When several detection methods have been applied to the same set of *N* samples of plant material, it is possible to compare their sensitivity, specificity, likelihood ratio, and overall accuracy using statistical tests in order to select the best one (Pepe, 2003).

- <u>Confidence and credible intervals of survival rate</u>

Effectiveness of many treatments (e.g., temperature treatment, fumigation, pesticide application) is often assessed by estimating survival rates (or mortality rates) from experimental data (e.g., Follett, 2004; Follett and Sanxter, 2001; Powell, 2002). For example, assume that n insects were treated and that x survivors were found after treatment. The survival rate after the treatment can then be estimated by $\hat{\pi} = \frac{x}{n}$. It is important to note that this is not the true survival rate; it is an estimated rate for a sample size of n.

Uncertainty about survival rate estimates can be studied by computing confidence intervals with classical statistical methods or by computing credible intervals with Bayesian methods (Carlin and Louis, 2008 ; Newcombe, 1998). The width of these intervals (and so the level of uncertainty) depends on both the number of survival x and the sample size n. Several confidence intervals have been proposed for proportions (e.g., Newcombe, 1998) and the most familiar interval is based on asymptotic Gaussian approximation:

$$\hat{\pi} \pm z_{1-\alpha/2}\sqrt{\hat{\pi}(1-\hat{\pi})/n}$$

For example, if x=25 and n=300, the survival rate is 25/300=0.0833 (i.e., 8.33% of survival after treatment) and the 95% confidence interval is defined by [0.0521, 0.1146].

This interval based on Gaussian approximation is not appropriate when dealing with small n, or with very low and very high π value (survival rate close to zero or one). Other confidence intervals should be used in such cases, but all would have advantages and disadvantages (Newcombe, 1998). For example, the Pearson-Clopper confidence intervals [p_1; p_2] for the probability π can be used even for small n, but are strictly conservative, which means sometimes too large. These intervals can be derived from F percentiles as follows:

$$p_1 = \frac{x \cdot F_{2x,2(n-x+1);\alpha/2}}{n-x+1+x \cdot F_{2x,2(n-x+1);\alpha/2}}$$

$$p_2 = \frac{(x+1) \cdot F_{2(x+1),2(n-x);1-\alpha/2}}{n-x+(x+1) \cdot F_{2(x+1),2(n-x);1-\alpha/2}}$$

and

$$p_1 = 0$$
$$p_2 = \frac{F_{2,2n;1-\alpha}}{n+F_{2,2n;1-\alpha}}, \text{ if } x=0$$

$$p_1 = \frac{x \cdot F_{2x,2;\alpha}}{1+x \cdot F_{2x,2;\alpha}}, \text{ if } x=n$$
$$p_2 =$$

An alternative is to compute a Bayesian credible interval using a Beta probability distribution given by $Beta(x+1, n-x+1)$ (e.g., Carlin and Louis, 2008). This distribution corresponds to the posterior distribution for the survival rate obtained with *x* survivals out of *n* (i.e, distribution of survival rates conditionally to *x*) and with a uniform prior probability distribution for the survival rate (distribution of survival rates before the measure of *x*). A 95% credible interval can be defined from the 2.5 and 97.5% percentiles of the posterior distribution. This approach can be implemented with any values of *n* and *x*, even when *x*=0 (a common case in experimental studies of pest treatments). For example, Figure 4 shows the posterior distributions obtained in two experiments with a sample size equal to 1000 and 5000 respectively and with *x*=0 in both cases (no survival after treatment). The corresponding credibility intervals are [2.53 10^{-5}, 3.68 10^{-3}] if *n*=1000 and [5.06 10^{-6}, 7.37 10^{-4}] if *n*=5000. The survival rate is thus likely to be much lower in the second experiment than in the first one although both experiments led to zero survival. This is due to the larger sample size used in the second experiment that led to a strong reduction of the uncertainty.

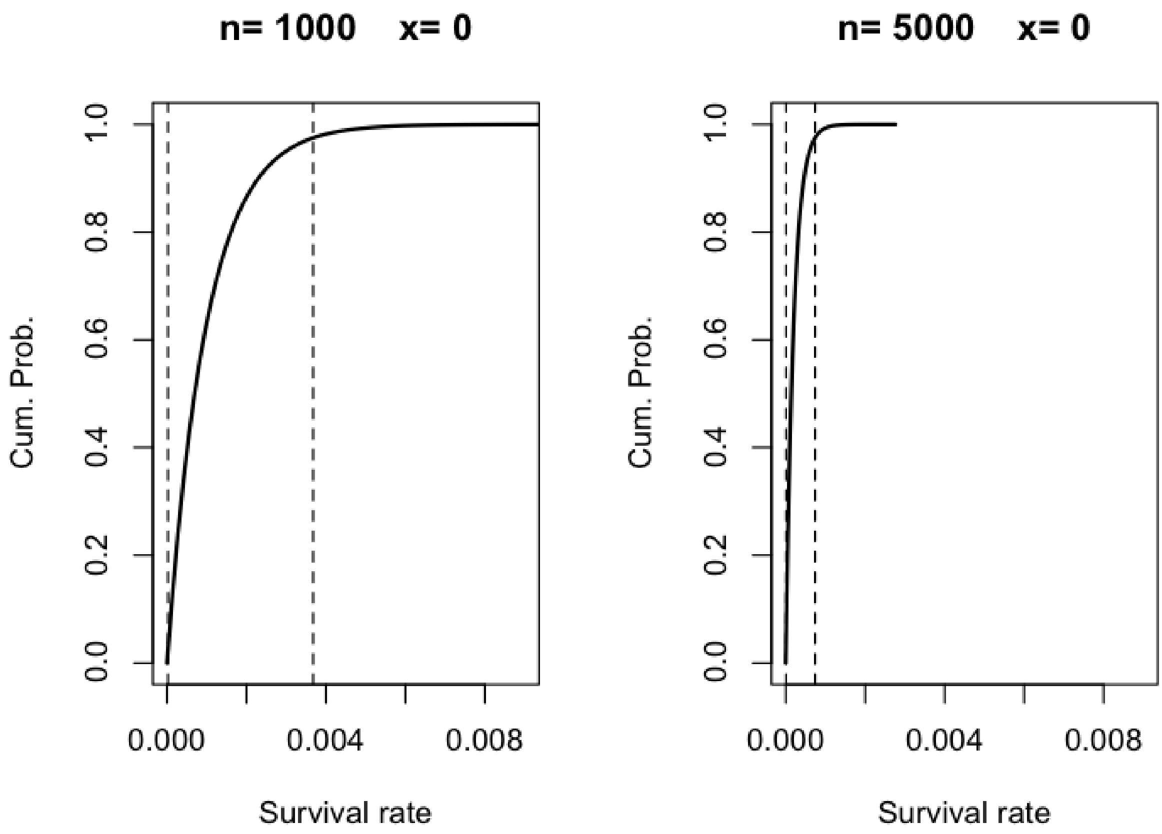


Figure 4: Cumulative probabilities for the survival rates estimated with x=0, and n=1000 or n=5000. Dashed lines show the 95% credible intervals.

While the estimation of a survival rate depends on the number of treated pests, the probability to have surviving pests in treated lots depends on the amount of plant materials and the infestation before treatment (pest prevalence). When data about pest prevalence and lot size are available, prognosis intervals could be computed to calculate the probability of pest survival in the lot under consideration after the treatment.

3.2.3.2. Comparing risk reduction options effectiveness to a threshold

Survival rates (or mortality rates) need sometimes to be compared to a threshold in order to assess the degree of quarantine security associated with a given RRO. This approach can be formally defined as a test of the hypothesis H_0: « $\pi > \pi_0$ » where π is the survival rate after the application of a RRO and π_0 is the threshold (i.e., a low value of survival rate). This hypothesis can be tested by counting the number of survivors x in a sample of n individuals (e.g., insects) treated with the considered RRO. The probability of zero survival among the n individuals is equal to $p(x=0)=(1-\pi)^n$. If H_0 is true, $\pi > \pi_0$, and $p(x=0)<(1-\pi_0)^n$. If x=0 and if the probability $p(x=0)$ is low enough (e .g., 0.05), the hypothesis H_0: « $\pi > \pi_0$ » can be rejected with a low risk of error (type 1 error) and the risk assessor can conclude that the RRO leads to a survival rate lower than π_0.

For example, assume that n=300 insects have been treated (e.g., heat treatment), that no survival was found, and that a risk assessor would like to test H_0: « $\pi > 0.01$ » versus H_1: « $\pi \leq 0.01$ » (i.e., to test if the survival rate after treatment is higher than 1% or not). In this case, $p(x=0)<(1-0.01)^{300}$ and $p(x=0)<0.049$. Based on this result, H_0 is rejected (with a risk of type 1 error of 5%) and the conclusion is that the survival rate is lower than 1%.

The test will confirm the efficiency of the treatment when no survivor is observed. Based on the test result, the maximal survival probability π can be computed by:

$$\pi_j = - \sqrt{\alpha}$$

This is an alternative approach to calculate the upper confidence limit for *π*, when the number of observed pest after treatment is zero. Finally, the same reasoning can be used to calculate how many pests are needed before the treatment to test its efficiency.

Table 6: Sample size needed to confirm different mortality rates by "no survivors" (with significance level α=5%)

Significance	α =0.05		
probit	Survival π	Mortality q=1-π	Sample size n
	10.0000000%	90.0000000%	29
	1.0000000%	99.0000000%	299
	0.1000000%	99.9000000%	2995
	0.0100000%	99.9900000%	29956
	0.0010000%	99.9990000%	299572
	0.0001000%	99.9999000%	2995731
1	15.8655254%	84.1344746%	18
2	2.2750132%	97.7249868%	131
3	0.1349898%	99.8650102%	2218
4	0.0031671%	99.9968329%	94587
5	0.0000287%	99.9999713%	10450778

The probability $p(x=0)$ depends both on the chosen threshold π_0 and on the sample size *n*. The so-called "probit 9" (which is in fact probit 4, see table 6) was a common mortality threshold in the past (Follett and Neven, 2006). It corresponds to 99.9968329% mortality (i.e., 0.0031671% survival) (Follett and Neven, 2006). However, the use of this threshold has been criticised (Follett and Neven, 2006; Schortemeyer et al., 2011; Haack et al., 2011). According to Schortemeyer et al. (2011), this threshold is arbitrary and may be too stringent for rarely infested commodities or poor host. Indeed, the probability of entry of pest depends on the mortality of the pest after treatment, but also on the number of imported commodities and on the prevalence of the pest in these commodities. It is thus possible to have a low probability of entry with a mortality rate lower than probit 9 in case of low prevalence and/or low quantities of imported commodities. Another issue is that a high number *n* of individuals need to be treated (*n*>94000) in order to conclude that the mortality rate is higher than probit 9 with a sufficient level of confidence (0.95) (Follett and Neven, 2006; Schortemeyer et al., 2011; Haack et al., 2011).

Development of new RROs aiming at mortality level of probit 9 is difficult to achieve under experimental conditions. Artificially infesting certain commodities (i.e., wood with wood boring insects) is a cumbersome task and can also lead to increased mortality (Schortemeyer et al., 2011; Haack et al., 2011). Additional controls therefore would be required to compensate for this artifact, and mortality in these controls would have to be taken into account (Follett and Neven, 2006). For these reasons, it is not recommended to use probit 9 as a systematic reference threshold for assessing effectiveness of most RROs.

3.2.3.3. Testing equivalence of risk reduction options

In the terms of reference provided by the European Commission, in some cases EFSA has been requested to determine whether an alternative RRO provides a comparable level of protection of the EU as those currently stipulated in the EC regulation. When a new RRO is proposed as an alternative to a standard RRO, it is useful to know whether the alternative RRO is at least as good as the standard RRO (Sgrillo, 2002). Non-inferiority can be tested using a specific equivalence test called *non-inferiority test* (Blackwelder, 1982; D'Agostino et al., 2003; EFSA Scientific Committee, 2011; Garrett, 1997). The null hypothesis of the non-inferiority test is that the standard RRO is more effective than the alternative RRO by at least some specified amount. This test puts the burden of proof on the experimenter to demonstrate that the alternative RRO is non-inferior compared to the standard RRO with a « reasonable » tolerance. Note that equivalence tests are considered as useful tools in other areas e.g., to test equivalence between genetically modified crops and conventional crops (EFSA Panel on Genetically Modified Organisms (GMO), 2009).

Assume that q_S and q_A are the mortality rates obtained with the standard and alternative RRO respectively. In a non-inferiority test, the tested hypotheses are

H_0 « $q_A \leq q_S - \delta$ » versus H_1 « $q_A > q_S - \delta$ »

where $\delta > 0$ is a tolerance margin (a minimum difference of practical interest). Assuming a sufficiently large sample to justify normal approximation, we reject H_0 if the one-sided α-level confidence bound on $\hat{q}_A - \hat{q}_S$ is greater than $-\delta$ (Blackwelder, 1982). That is, we reject H_0 if

$$\hat{q}_A - \hat{q}_S - z_{1-\alpha}\sqrt{\hat{q}_A\left(1-\hat{q}_A\right)/n_A + \hat{q}_S(1-\hat{q}_S)/n_S} > -\delta$$

where $\hat{q}_A$ and $\hat{q}_S$ are the measured mortality rates based on samples of sizes n_A and n_S respectively.

For example, assume that a standard heat treatment applied on n_S=110 insects led to a mortality rate of 0.82 and that an alternative heat treatment applied on n_A=150 insects led to a mortality rate of 0.83, then the 95% confidence bound is equal to

$$\hat{q}_A - \hat{q}_S - z_{1-\alpha}\sqrt{\hat{q}_A\left(1-\hat{q}_A\right)/n_A + \hat{q}_S(1-\hat{q}_S)/n_S} = -0.06$$

This result shows that, although the estimated mortality rate was slightly higher (by 1%) with the alternative RRO than with the standard RRO, we cannot exclude that the alternative RRO decreases the mortality rate by 6% due to uncertainty in the estimated values. If we set δ=0.05 (i.e., if we accept a mortality rate reduction of 5%), we do not reject the null hypothesis that the alternative RRO is less effective, and we cannot conclude that the alternative RRO is at least as good as the standard RRO. On the other hand, if we set δ=0.1 (i.e., if we accept a mortality rate reduction of 10%), we reject the null hypothesis that the alternative RRO is less effective and we conclude that the alternative RRO is at least as good as the standard RRO.

A limitation of this method is that it relies on a Gaussian approximation that is not valid for small samples or for very high or very low mortality rates. An interesting alternative is to compute a credibility interval for the difference between q_S and q_A using a Bayesian approach and to compare this credibility interval to δ. Assuming a uniform prior distribution for the mortality rates, the posterior distributions for q_S and q_A are the Beta probability distributions $Beta\left(x_A+1, n_A-x_A+1\right)$ and $Beta\left(x_S+1, n_S-x_S+1\right)$ where x_S and x_A are the observed number of deaths with the standard and alternative RRO respectively. Credibility intervals can be derived from these two distributions by Monte Carlo simulation.

For example, assume that x_A=n_A=10 insects, and x_S=n_S=50 insects. In this case, the measured mortality rate is 100% with both the standard and the alternative, but the number of tested insects is higher for the standard. The probability distribution of the difference between q_S and q_A is shown in Figure 5. The 5% percentile of this distribution is -0.22 (i.e. 5% chance to have more than 22% reduction in mortality rate with the alternative compared to the standard). This strong reduction is due to the large uncertainty induced by the small sample sizes, especially for the alternative RRO (n_A=10). Unless considering a very high tolerance threshold, it is not reasonable to conclude that the alternative is at least as good as the standard in this case.

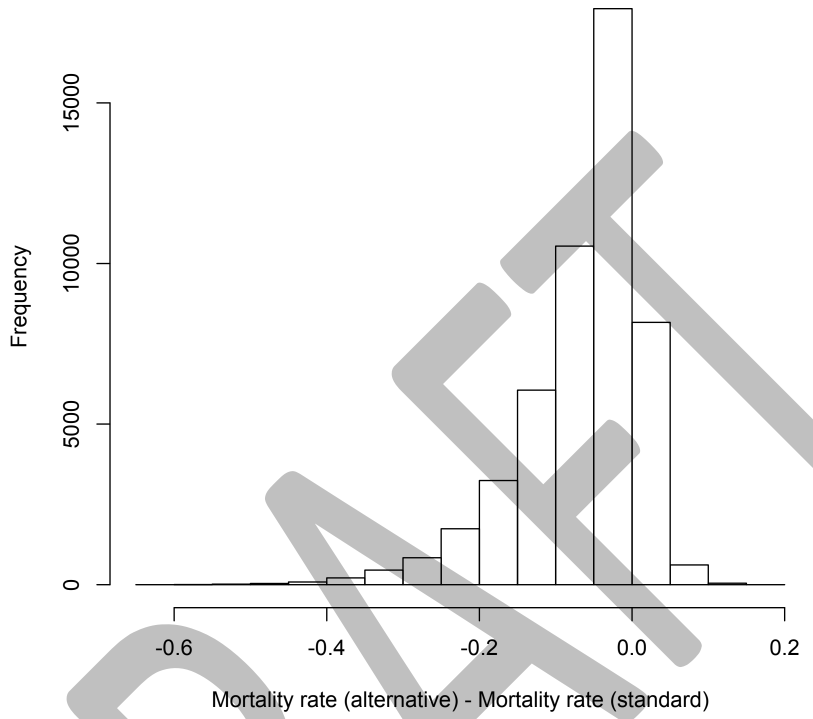


Figure 5: Probability distribution of the difference of mortality rates between a standard RRO and an alternative RRO when x_A=n_A=10 insects, and x_S=n_S=50 insects (50000 Monte Carlo simulations).

3.2.3.4. Estimating dose – effectiveness relationship

When the effectiveness of an option depends on the dose of the applied treatment, it is useful to estimate the relationship between dose (e.g. pesticide concentration, duration, temperature etc. and effectiveness to optimise the treatment dose. This is the case, for example, for pesticide treatment (its effectiveness depends on the quantity of applied pesticide), heat treatment (its effectiveness depends on temperature and duration), and for irradiation treatment (its effectiveness depends on the dose of irradiation).

Experimental data available for studying Dose – Effectiveness relationship generally consists in a series of doses (e.g., several temperatures for heat treatment) applied to plant materials for which pest survival after treatment has been measured. Pest survival is usually expressed either as survival (or mortality) rate (e.g., Follett and Sanxter, 2001, Tables 1-3) or as a number of individuals found alive after treatment (e.g., Follett, 2004, Table 2).

Dose – Effectiveness relationship can be studied by fitting generalised linear models to such data and the uncertainty can be assessed by computing confidence intervals for the fitted models (Agresti, 2003). The type of generalised linear model fitted to data must be chosen carefully depending on the nature of the available data. When survival or mortality rates have been measured, logit, probit or log-log regression models should be used. When count data are available (i.e., number of surviving individuals after treatment), it is advised to use Poisson regression models (Figure 6) as shown in the EFSA Panel on Plant Health (PLH) (2011) opinion on the effectiveness of the heat treatment of *Agrilus planipennis*. It is not recommended to transform count data into survival or mortality rates because such transformation requires the estimation of the initial level of infestation of plant material and may increase uncertainty (EFSA Panel on Plant Health (PLH), 2011a). Several software packages are available to fit these models.

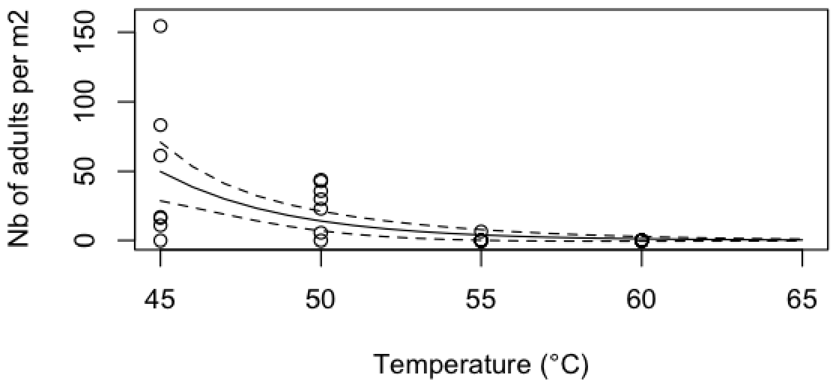


Figure 6: Number of surviving insects (Emerald ash borer) in function of the temperature of the heat treatment (heat treatment duration=60min). Points correspond to measurements obtained in an experiment (data from Myers et al., 2009), the continuous curve indicates the expected numbers of survivals derived from a Poisson regression model, and the dashed lines indicate 95% confidence intervals.

3.2.3.5. Recommendations

- Uncertainty about effectiveness of RROs should be studied by computing confidence intervals with classical statistical methods or credibility intervals with Bayesian methods. According to EFSA Scientific Committee (2011), more information can be presented in the estimate of the size of an effect and its uncertainty when described by a confidence interval than when expressed solely by the results of significance tests.
- The probit 9 threshold of mortality rate should not be systematically used as reference threshold for assessing RRO effectiveness. Instead of using a specific threshold for mortality rate, it is recommended to analyse the risks of pest entry and establishment associated with the RRO under consideration.
- Although not frequently used in plant pathology, equivalence tests and, more specifically, non-inferiority tests are useful tools for comparing two RROs and testing whether an alternative RRO is at least as good as a standard RRO.
- Depending on the nature of the available experimental results, different types of generalised linear models can be fitted to data to study the relationship between the dose of a treatment and its effectiveness. Such models are commonly used in chemical risk assessment, but are also applicable in treatment effect assessment.

3.3. Qualitative assessment of risk reduction options

Qualitative assessment methods have proved to be useful for the Panel to assess a large number of RROs in a short period of time (EFSA Panel on Plant Health, 2010a; 2011b). Moreover, due to the limited availability of data, the Panel is often performing qualitative assessments supported by documentary evidence to evaluate the RROs giving a special attention to listing and rating the level of uncertainty.

Various schemes have been proposed to assess RROs (e.g. EFSA Panel of Plant Health (PLH), 2010a; EPPO, 2011; PRATIQUE, 2011). They consist of a series of questions that need to be answered by risk assessors using qualitative ratings (e.g., very low, low, moderate, high, very high). A decision support system has been produced by the PRATIQUE EU-funded project for screening system approach measures (PRATIQUE, 2011). It can be used to quickly identify relevant combinations of RROs.

The Guidance document on the harmonised framework for risk assessment (EFSA Panel on Plant Health, 2010a) defined a principle of transparency under section 3.1: *"...Transparency requires that the scoring system to be used is described in advance. This includes the number of ratings, the description of each rating."*. Opinions of the Panel based on qualitative method should thus always include rating descriptors to provide clear justification when a rating is given. Examples of descriptors were provided in EFSA Panel on Plant Health (PLH) (2010c, 2010d).

A limitation of the qualitative approaches is that the individual scores cannot be easily combined in order to derive an overall risk level for a given RRO. It is thus difficult to compare the levels of effectiveness of different RROs using these approaches. Several techniques have been proposed for combining scores such as weighted sums, risk matrices, Bayesian belief network etc. (Holt, 2006; Cox, 2008; EFSA Plant Health Panel (PLH), 2010a; PRATIQUE, 2011; Prima Phacie, 2011). Several studies showed that, at least in some cases, the final result depends on the chosen technique used for combining the individual scores (Cox, 2008; Holt, 2006; Makowski and Mittinty, 2010; PrimaPhacie, 2011). The practical interests of the proposed score combination techniques still need to be evaluated.

3.4. Quantitative pathway analysis and other quantitative tools for assessing risk reduction options

Quantitative probabilistic models have been used in several instances in published literature and in risk assessment to estimate the probabilities of introduction and spread of plant pests (for examples see: Fowler et al., 2006; Harwood et al., 2009; Peterson et al., 2009; Roberts et al., 1998; Stansbury et al., 2002; Yemshanov et al., 2009). The Panel currently applies in its opinions quantitative methods for the assessment of climate suitability for establishment and of spread of plant pests. With regard to the quantitative assessment of the probability of introduction, in EFSA Panel on Plant Health (PLH), (2010b) the Panel has evaluated a quantitative pathway analysis of the likelihood of *Tilletia indica* M. introduction into EU with importation of US wheat (USDA APHIS, 2008b) (Figure 7). The Panel's review highlighted the key parameters of the quantitative pathway analysis model, identified though sensitivity analysis, and also showed that the proposed model did not consider the possibility of introduction of the pathogen through a single infected consignment.

Probabilistic pathway analyses can be used to evaluate quantitatively the probabilities of introduction of plant pests. This method is well known in exposure assessment of the human population to chemicals (Cullen and Frey, 1999), but needs to be adapted to the specific conditions and datasets for plant health risk assessment.

The main objective of a pathway model is to follow the "course of the pest from the source to the target" (compare IPCS, 2001). The start of the pathway is an infested area with known prevalence and number of host plants. The model should cover the pathway of the pest from the starting point of the pest to the end of the pathway (including isolation, re-exportation, elimination and reproduction of the pest) during a given period of time. The end of the pathway is a target area (e.g. an area cultivated with a given host plant in the EU).

Every pathway model has a spatial and a temporal component. The spatial resolution may correspond to a single potential niche, e.g. a plant, a field or a storage unit, or to a large area (e.g., regional, national). The temporal resolution may correspond to a hourly, daily, monthly, yearly time step or life cycle of plant products or pests.

Depending on the spatial and regional resolution, the quantification may have different interpretations from the probability of infestation of a single plant at a specific hour of one day to the total number of pests introduced into the EU within one year. The spatial and temporal resolutions should be chosen in accordance with the objective of the RRO.

To evaluate if a RRO achieves its objective the model can be run without and with the RRO and the model output difference can be used to quantify the risk reduction induced by the option. The model can thus be used to calculate a reduction rate as well as the remaining amount of the pest reaching the end of a pathway.

Where quantitative elements are included, transparency requires that every element of the calculation or mathematical modelling is communicated and justified, with a clear description of the model used, its accuracy and the parameter estimation. For quantitative models it is recommended to perform an uncertainty and sensitivity analysis. The result of such an analysis will correspond to a probabilistic pathway analysis and will allow risk assessors to assess the level of uncertainty associated with the estimated effect of the risk reduction option.

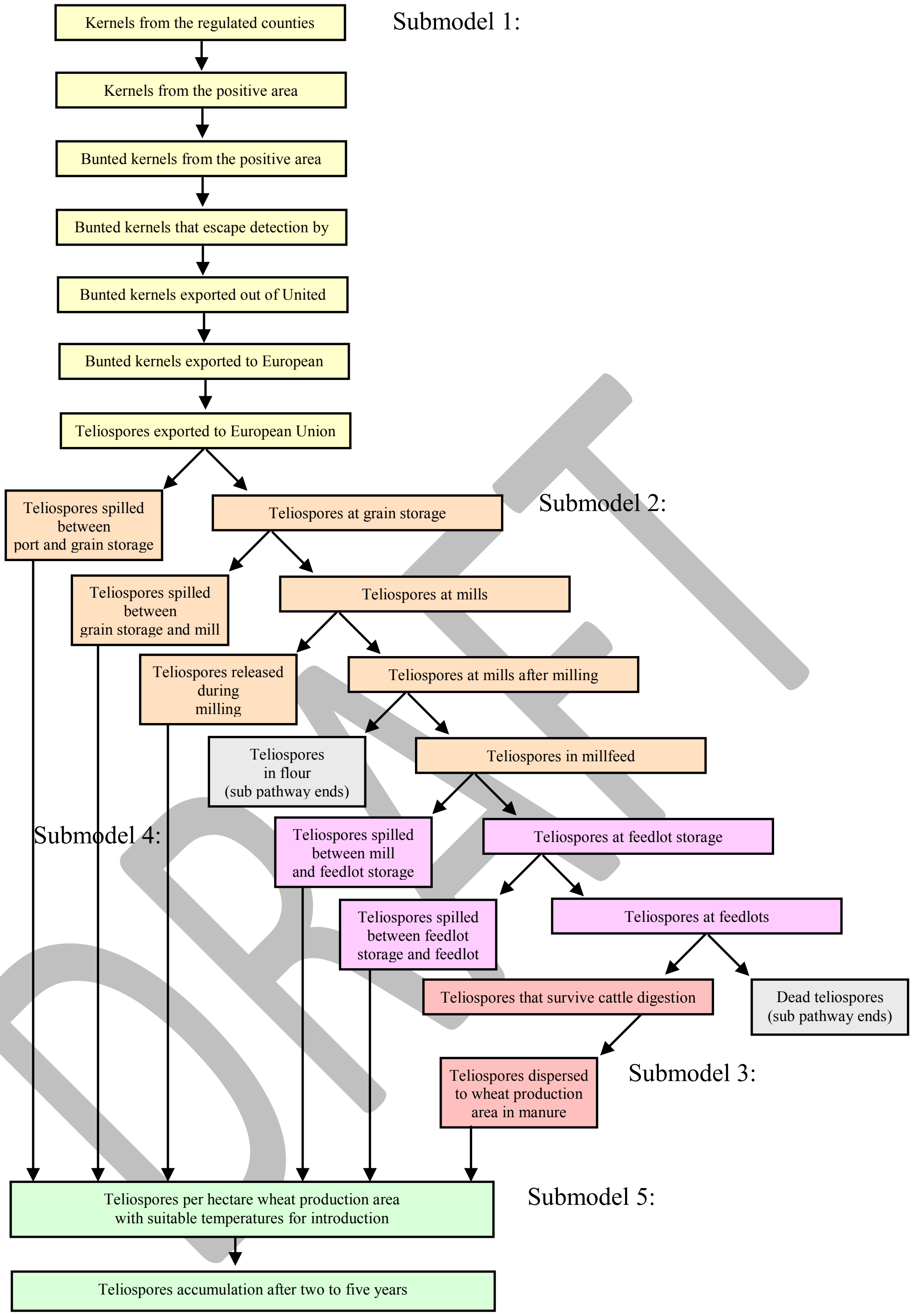


Figure 7: Example for a teliospore pathway model (from USDA APHIS, 2008b) discussed in EFSA opinion on *Tilletia indica* introduction into Europe (EFSA Panel on Plant Health (PLH), 2010b)

3.4.1. Quantitative pathway analysis

The main task of a pathway analysis is to model the total flow of infested material from the area of production to the endangered host plants in Europe. To achieve this task four key elements have to be defined:

- An estimation of the total amount of the pest to follow up through the pathway.
- A description of the total pathway under consideration.
- Estimations of the proportions of material following each branch of the pathway.
- Estimations of survival and growth of the pest (or probability of infection of host plants) on each branch of the pathway.

Given these key elements the simplest structure of a pathway model is:

$$Y = X \cdot \left[p \cdot s_1 + (1-p) \cdot s_2\right]$$

with:

X	total amount of the pest at the beginning of the pathway (production side)
p	proportion of material going into the 1st path of the pathway
s_1	survival rate of the pest on the 1st path
s_2	survival rate of the pest on the 2nd path
Y	resulting amount of the pat at the end points of the pathways

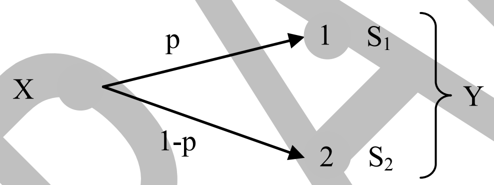


Figure 8: Graphical representation of a simple pathway model

With a global view such pathway model can been interpreted as weighted average of all survival rates of the pathogen on the different pathways, weighted with the proportion of the specific pathway on the total flow.

Typical extensions of this simple model are

- Incorporation of all possible paths
- Use of infection rate instead of survival of the pathogen as output variable
- Stratification by regions, e.g. EU countries etc.
- Stratification by time, e.g. month, year etc.

Such extensions can be used to incorporate further differences in the path i.e., in the behaviour of the pathogen, between EU countries and in the life cycle of the pest and the host plants. Additional data sources, like climatic data, might be used to get more precise estimations of survival and infection rates.

All parameters can be defined as random variables in order to incorporate further variations within the paths and to analyse uncertainties in the estimation. With this approach, distribution of values is generated for each model output instead of single value (point estimator). The final calculation is obtained via simulation, choosing a random set of parameters for each calculation and iterate this procedure several times to get again a sample of possible output values, expressing the final distribution of possible outputs.

Main advantage of pathway models is that all assumptions are collected and documented in a transparent way. In some cases, it is also possible to evaluate (or calibrate) the model using real observations of pathogen occurrence at the end points.

When the total flow of the pathogen is included in the model, it is possible to assess a wide range of RROs using the model. Figure 9 shows a systematic of RROs for entry, establishment, spread and impact. These options influence different parts of the pathway model (Table 7).

Table 7: Parameters influenced by risk reduction options

Risk reduction option	*Parameter in pathway model*
Entry	
Monitor the prevalence	Total amount of material / pest
Reduce the infestation at the import	
Reduce the infestation on production site	Total amount of material / pest
Reduce the infestation during transport before import	Survival rate during transport
Reduce infestation at the boarder	Survival rate at the boarder
Establishment	
Restrict import to unfavourable regional/ temporal conditions	
Restrict import to unfavourable climatic conditions	Infection rate in EU regions
Restrict import to regions without suitable host plants	Infection rate in EU regions
Restrict import to seasons without dangerous life stages	Infection rate in EU regions
Avoid any release of material or pest during transformation	
Avoid any release during transport	Proportion of transportation loss
Avoid any release during storage	Proportion of storage loss
Avoid any release during processing	Proportion of production loss
Avoid any release by waste	Proportion of waste
Avoid any release during consumption	Proportion of consumption loss
Avoid any release to the environment (e.g. by planting)	Proportion of direct release
Spread	
Monitor prevalence of the pest to avoid spread	Completeness of model
Clear buffer zones / isolate infested plants	Infection rate at outbreak sites
Apply eradication methods	Survival rate at outbreak sites
Reduce velocity of spread by delete means of transport	Infection rate in EU
Reduce velocity of spread by changing agricultural practice	Infection rate in EU
Reduce natural spread	Infection rate in EU
Reduce spread by human activities	Infection rate in EU
Impact / consequences	
Reduce impact by use of resistant hosts	Infection rate in EU
Reduce impact by changing agricultural practice	Infection rate in EU

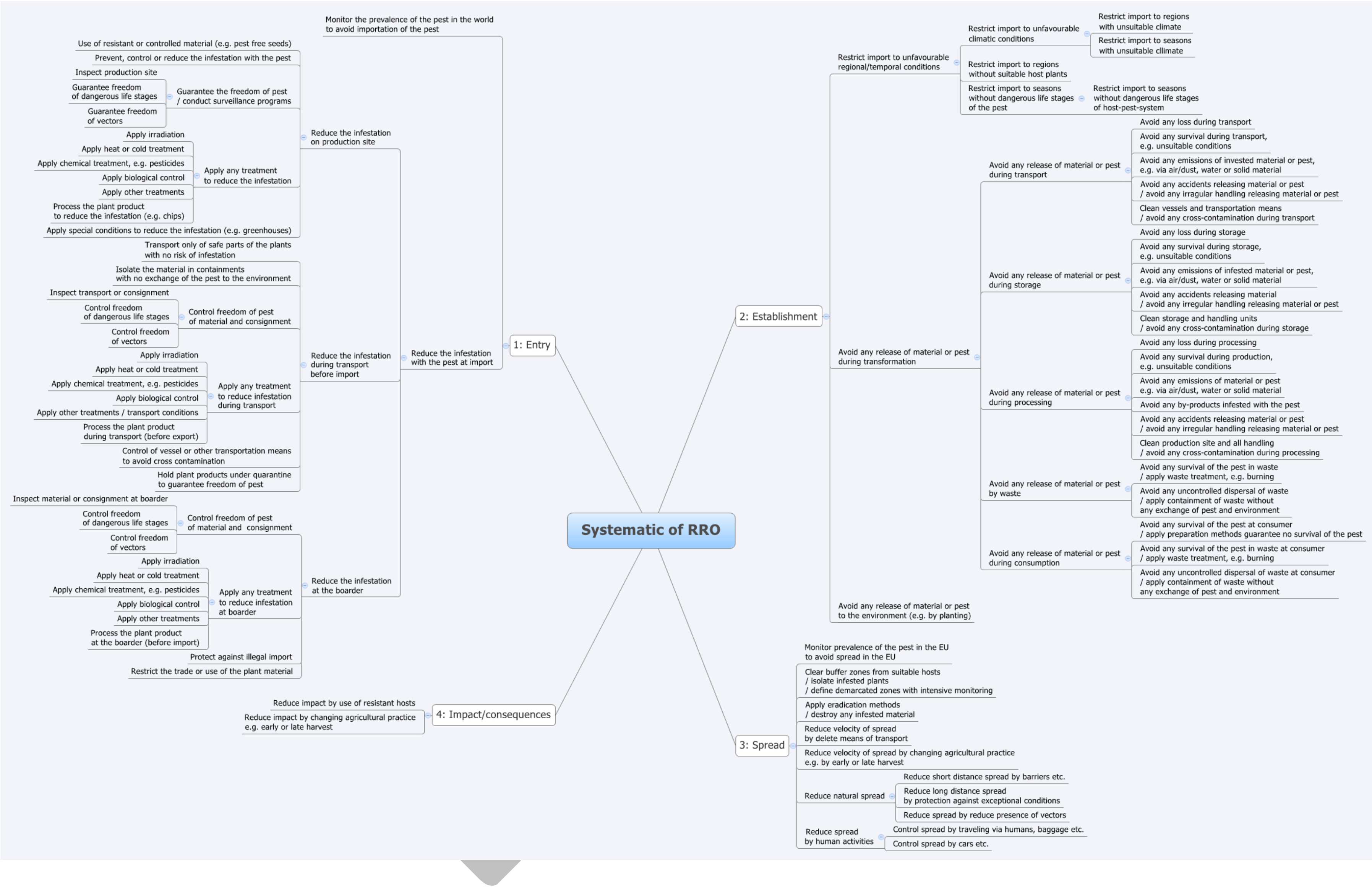


Figure 9: Systematic of risk reduction options on entry, establishment, spread and impact

The development of a comprehensive pathway model has several advantages:

- It allows risk assessors to assess RRO at relevant scales..
- The model can be used to identify influential parameters and to indentify the options that would strongly reduced the risk.
- Several RROs can be compared on a common scale using such model.
- Several RROs can be combined and evaluated together in the comprehensive pathway model. Quantitative pathway models can thus be used to assess system approaches.

As all models, quantitative pathway models have some limitations:

- Quantitative pathway models usually include many parameters, which might be uncertain.
- Calibration and evaluation against real measurements is generally missing, because this type of model is usually used to assess future risks.
- Quantitative models do not usually predict the complete absence of a pest. All results should therefore be compared to limits of acceptable infestation or risk of infection.

3.4.2. Spread models

Spread models can be seen as special cases of pathway models. They are used to model the flow of the pathogen from an infested plant, field or production site to the local environment. These models can take into account regional and temporal factors influencing pest spread, like wind directions or average wind speed, host distribution, geographic barriers or the local soil composition.

Simple models estimate the velocity of spread; this is the average distance of spread per time unit (e.g. year). Without any additional information the spread will be concentric around the source of the pest.

Short distance models (Spijkerboer et al., 2002; EFSA Panel on Plant Health (PLH), 2011b; Gilligan and van den Bosch, 2008) include information on the plant, the local conditions and the natural means of spread, e.g. by air, rain, vectors etc. Long distance models include extreme weather conditions (Aylor, 1990; 2003), unintended transportation of the pest or uncontrolled move of infested plant material (EFSA Panel on Plant Health (PLH), 2010d).

Spread models are typically calibrated against existing data, e.g. reports on infestations, detections etc. The model parameters are estimated to give best fit to the situation of the past.

A protocol has been recently developed in the PRATIQUE EU project for mapping endangered areas. This protocol summarises the information required to run the spread models, and formulate recommendations for their use (PRATIQUE, 2011; Baker et al., 2011).

3.4.3. Quantitative tools used by other EFSA panels

On April 2011 an internal mandate (M-2011-0173) was proposed by EFSA to the Plant Health Unit to provide a review of EFSA outputs on biological hazards relevant to methodologies for the evaluation of RROs (EFSA-Q-2011-00400).

The purpose of the review was to identify and evaluate the quantitative tools applied at EFSA in the published scientific opinions from 2004 to May 2011 by EFSA's Scientific Panels dealing with biological hazards (AHAW (Animal Health and Welfare), BIOHAZ (Biological Hazards), CONTAM (Contaminants), GMO (Genetically Modified Organisms) and PLH (Plant Health)) when identifying and evaluating RROs. During the review, 323 scientific opinions were examined and a report was delivered.

A general result that can be extracted from that report regards the low percentage of outputs, for each of the above mentioned Panels, where quantitative methodologies were applied. Nevertheless, when combining the data from all Panels, a temporal trend towards increased use of quantitative methods can be observed (from 5% of 2004 to 22% of 2010, which increases to 40% in 2011, considering only the scientific opinions published until May 2011).

CONCLUSIONS AND RECOMMENDATIONS

The European Food Safety Authority (EFSA) asked the Panel on Plant Health to deliver guidance on methodology for evaluation of the effectiveness of options to reduce the risk of introduction and spread of organisms harmful to plant health in the EU territory.

This guidance document has been prepared by the Panel to address mainly the quantitative evaluation of the effectiveness of risk reduction options. When data and/or information are available the quantitative methods described in this document could be applied. When only limited or no data and/or information are available, the Panel performs qualitative evaluations that are briefly described in this guidance document. The Panel developed this guidance document to be used for the assessment of risk reduction options together with the guidance on a harmonised framework for risk assessment (EFSA Panel on Plant Health (PLH), 2010a) and the guidance on the evaluation of pest risk assessments and risk management options prepared to justify requests for phytosanitary measures under Council Directive 2000/29/EC (EFSA Panel on Plant Health (PLH), 2009). The guidance provided in this document complements and does not replace the two above mentioned documents when responding to requests for scientific advice on issues related to the evaluation of the effectiveness of options to reduce the phytosanitary risks within the European Community in order to support the decision-making process under Council Directive 2000/29/EC.

Two operational tools are presented in this guidance document:

- a checklist for evaluating a proposed risk reduction option (RRO),
- a database of references of scientific documents presenting recommendations on how to assess RROs, and experimental assessments of RROs.

The two tools have different purposes. The checklist include a series of items that can be used by the Panel to check whether all required information is provided to support a RRO. Four types of RRO assessments are distinguished in the proposed checklist according to their purposes and characteristics:

v. Experimental assessment of the option effectiveness to reduce pest infestation in plant material/product under laboratory/controlled conditions

vi. Experimental assessment of the option effectiveness to reduce pest infestation in plant material/product under operational conditions

vii. Analysis of the applicability of the RRO

viii. Assessment of option effectiveness to reduce risk of pest entry from infested area to pest free area

The checklist can be used by experts to make a preliminary assessment of documents and data submitted to EFSA to support a RRO (e.g. a temperature treatment of plant material) and, more specifically:

- to quickly describe the information provided to EFSA (i.e., report and experimental results) to support a proposed RRO
- to identify major gaps in data submitted to EFSA
- to organise the work of the Panel when evaluating a dossier.

This checklist could also be used by the author of the submitted dossier or by the author of a pest risk analysis to verify whether all the requested data are provided.

The second tool is a database of references corresponding to published guidance documents or experimental assessments of RROs.

The content of these documents have been summarised in a table presented in Appendix B. This database of references can be used by the Panel to find some specific experimental results on the effectiveness of a given RRO, or to find guidance documents for designing RROs. Although this database does not intend to include all existing references on RRO assessment, it may help the Panel experts to quickly retrieve relevant experimental data and guidance documents for assessing a proposed RRO, or for assessing a range of options in a pest risk analysis. It can also be used to identify potential RROs for a given pest and/or plant material.

Finally, based on the literature review described in this guidance document and on its own experience, the Panel is able to formulate several recommendations on the use of quantitative methods for assessing RROs.

Recommendations on surveillance:

- General surveillance should evaluate the possible occurrence of a pest in an area, using all relevant (quantitative and qualitative) information on the current pest distribution in and near the area, ecological conditions of the area, presence of host plants and other potential pest niches, and import and trade rates of host plant products in the area. The conclusion of general surveillance and a discussion of the level of uncertainty should be presented along with all information used to reach the conclusion.
- Specific surveys should be conducted to test an explicitly formulated hypothesis on the occurrence of a pest in an area. They should be performed on a statistical basis, using relevant quantitative and qualitative information on the area, the pest, the host plants and other potential pest niches. They should provide a conclusion on pest occurrence and the uncertainty of the conclusion, expressed as the confidence level to detect the pest above the threshold prevalence of the survey.
- Methodology to integrate results from general surveillance and specific surveys should be implemented in cases where a conclusion on pest occurrence is difficult to reach.

Recommendations on the design of experiments:

- The checklist provided herewith should be used prior to, and during the experimentation.
- The information requested in the checklist and pertaining to the plant and to the pest should be first as complete and precise as possible.
- The objectives (e.g. mortality rates, maximal pest density acceptable) and confidence levels of the tests should be clearly stated and, when relevant, compared to the current standards.
- A complete description of the experimental design should be provided, including: variables used to measure effectiveness, factors influencing effectiveness which were or were not taken into account in the experiments, description of facilities and equipment; description of treatments; methodology followed for monitoring critical parameters, description of experimental design, presentation of the data, description of the statistical analysis.

The complete datasets produced by the experiment and used in the analyses should be kept available with a full definition of all the variables.

Recommendations on the use of statistical methods for assessing option effectiveness to reduce pest infestation:

- Uncertainty about effectiveness of RROs should be studied by computing confidence intervals with classical statistical methods or credibility intervals with Bayesian methods.
- The probit 9 threshold of mortality rate should not be systematically used as reference threshold for assessing RRO effectiveness. Instead of using a specific threshold for mortality

rate, it is recommended to analyse the risks of pest entry and establishment associated with the RRO under consideration.

- Although not frequently used in plant pathology, equivalence tests and, more specifically, non-inferiority tests are useful tools for comparing two RROs and testing whether a proposed RRO is at least as good as a currently implemented RRO.
- Depending on the nature of the available experimental results, different types of generalised linear models can be fitted to data to study the relationship between the dose of a treatment and its effectiveness. Such models are commonly used in chemical risk assessment, but are also applicable in treatment effect assessment.

Recommendations on the use of quantitative pathway analysis and spread models

Quantitative pathway analysis and spread models have several advantages:

- They allow risk assessors to compare the effectiveness of several RROs and, also, to assess the effectiveness of combination of RROs.
- They allow risk assessors to quantify the effects of RROs on several variables like probabilities of entry, establishment, and spread, or magnitude of impact. They do not restrict the assessment of RRO on their capabilities to reduce pest infestation.
- Quantitative pathway analysis and spread models can address uncertainties and can be used to study the effect of different sources of uncertainty on the risk of entry, establishment, spread, and impact.
- They enable to perform a sensitivity analysis to identify the most influential parameters in a model that are defining the most effective RRO.

These advantages make these quantitative tools attractive for assessing the effectiveness of different RROs. However, their applications can be difficult in practice due to the amount of data required to develop such models. In case of missing data, the uncertainty associated with the model outputs could be high and decreasing the ability of the model to discriminate between different RROs thus diminishing the models usefulness and value.

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Abbreviations

ALOP: Appropriate Level of Protection

ALPP: Areas of Low Pest Prevalence

CPM: Commission on Phytosanitary Measures

ED: Effective Dose

EFSA: European Food Safety Authority

EPPO: European and Mediterranean Plant Protection Organisation

EU: European Union

IPPC: International Plant Protection Convention

ISPM: International Standard for Phytosanitary Measures

NPPO: National Plant Protection Organisation

PFA: Pest free areas

PLH: Plant Health

RRO: Risk Reduction Option

SPS: Sanitary and Phytosanitary Agreement

SSC: Survey system component

WTO: World Trade Organization

APPENDICES

A. KEYWORDS AND STRINGS USED FOR THE LITERATURE SEARCH IN THE ISI WEB OF KNOWLEDGE

B. REFERENCES RESULTING FROM THE LITERATURE SEARCH

C. COMPARISON BETWEEN THE CRITERIA PRESENTED IN ISPM NO 28 AND THE CHECKLISTS IN SECTION 2.2. 2. AND 2.2.3. OF THIS DOCUMENT

A. Keywords and strings used for the literature search in the ISI web of Knowledge

1. Options for consignments – Prohibition.
    - Keywords:
      Prohibition of import, illegal import, Prohibitions of commodities (plants/crops)
    - String:
      Topic=(prohibition SAME import*) AND Topic=(plant* OR commodit* OR crop$)

2. Options for consignments - Pest freedom: inspection or testing.
    - Keywords:
      Sample (size/method/procedure &equipment), pest freedom, inspection, laboratory testing, pest free area, low pest prevalence
    - String:
      Topic=((sample$ (size OR method$ OR procedure$ OR equipment$)) AND (pest free area$)) AND Topic=(plant pest*)
      Topic=(sample$ method*) AND Topic=((pest free area$) AND (plant pest*)) AND Topic=(inspection*)
      Topic=(pest SAME ((free area*) OR prevalence)) AND Topic=(plant pest*) AND Topic=((inspection$ OR (laboratory test*)))

3. Options for consignments - Prohibition of parts of the host or of specific genotypes of the host.
    - Keywords:
      Resistant varieties, cultivars, plants, plant parts, species Prohibition of import, illegal import, Prohibitions of commodities (plants/crops)
    - String:
      Topic=(prohibition SAME (import* OR commodit* OR crop$)) AND Topic=(Resistant SAME (variet* OR cultivar$ OR plant*))

4. Options for consignments - Pre-entry or post-entry quarantine system.
    - Keywords:
      Inspection, testing, detectability, consignment, laboratory, detection, method, plants
    - String:
      Topic=(consignment$ AND (inspection$ OR test* OR detect*)) AND Topic=(pest$ AND (plant* OR crop*)) AND Topic=(laboratory OR (detection method*))

5. Options for consignments - Phytosanitary certificates and other compliance measures.
    - Keywords:
      plant passport, phytosanitary certificate, Europe
    - String:
      Topic=(phytosanitary certificate)

6. Options for consignments - Preparation of the consignment.
    - Keywords:
      Handling, debarking, wood processing, treatment, consignment, plant material
    - String:
      Topic=((handl* OR debark* OR process* OR treat*)) AND Topic=(plant* SAME pest$) AND Topic=(wood* SAME consignment$)
      Topic=((handl* OR debark* OR process* OR treat*) SAME wood*) AND Topic=(phytosanitary)
      Topic=((handl* OR debark* OR process* OR treat*) SAME wood*) AND Topic=(phytosanitary) AND Topic=(import* OR export*)

7. Options for consignments - Specified treatment of the consignment/ Reducing pest prevalence in the consignment.
    - Keywords:
      chemical treatment, fumigation, chemical pressure impregnation, suppression of germination thermal treatment, vapour heat treatment, heat treatment, cold treatment, hot water treatment, quick freeze treatment/drench, chemical pressure impregnation, suppression of germination, solarisation, compostation, sterilisation, Irradiation, suppression of germination, Waxing, seed coating, brushing, (protection against reinfestation)
    - String:
      Topic=((chemical treatment$) OR (pressure impregnation) OR fumigation OR (suppression of germination) OR (thermal treatment$) OR (vapour heat treatment$) OR (heat treatment$) OR (cold treatment$) OR (hot water treatment$) OR (quick freeze treatment$) OR drench* OR (chemical pressure impregnation) OR (suppression of germination) OR solarisation OR compostation OR sterilisation OR irradiation OR waxing OR (seed coating) OR brushing OR (protection against reinfestation)) AND Topic=((crop$ OR plant$) SAME pest$) AND Topic=(consignment$ OR inspection$ OR border$)

8. Options for consignments - Restriction on end use, distribution and periods of entry.
    - Keywords:
      Restriction/limitation of use, intended use, end use, period of consignment
    - String:
      Topic=(((restriction of use) OR (limitation of use) OR (intended use) OR (end use)) OR (period of consignment)) AND Topic=((crop$ OR plant$) SAME pest$) AND Topic=(consignment$ OR inspection$ OR border$)

9. Options preventing or reducing infestation in the crop - Treatment of the crop, field, or place of production in order to reduce pest prevalence .
    - Keywords:
      Spraying,control
    - String:
      A specific string was not defined, because, considering the amount of available publications on this field, the WG decided to include only some example.

10. Options preventing or reducing infestation in the crop - Resistant or less susceptible varieties.
    - Keywords:
      Resistant varieties, cultivars, plants, species
    - String:
      See point 3.
11. Options preventing or reducing infestation in the crop - Growing plants under exclusion conditions (glasshouse, screen, isolation).

    - Keywords:
      Protected conditions (glasshouse, isolation), greenhouse, in-vitro culture, plastic foil.
    - String:
      Topic=((protected condition$) AND (glasshouse$ OR greenhouse$ OR invitro OR in vitro OR (plastic foil$))) AND Topic=(plant$ SAME pest$) AND Topic=(restriction$)
      Topic=((protected condition$) AND (glasshouse$ OR greenhouse$ OR invitro OR in vitro OR (plastic foil$))) AND Topic=(plant$ SAME pest$) AND Topic=(guideline$ OR guidance$)

12. Options preventing or reducing infestation in the commodity - Harvesting of plants at a certain stage of maturity or during a specified time of year.

- Keywords:
  Early harvest, harvesting period, trap crops
- String:
  Topic=(((early harvest) OR (harvesting period)) AND (trap crops)) AND Topic=(plant$ SAME pest$) AND Topic=(infest*)

13. Options preventing or reducing infestation in the crop - Certification scheme.
    - Keywords:
      Certification system/scheme, virus, pathogens
    - String:
      Topic=(certification$ SAME (system$ OR scheme$)) AND Topic=(plant$ AND (virus* OR pathogen$ OR pest$)) AND Topic=(guidance OR guideline$)

14. Options ensuring that the area, place or site of production, remains free from the pest – Pest free area.
    - Keywords:
      Control, containment, eradication, surveillance, survey, demarcated zones, (method), protected zone, Europe
    - String:
      Topic=(eradication$ AND (pest$ SAME plant$)) AND Topic=(surveillance$ OR survey$) AND Topic=(demarcated OR protected)

15. Options ensuring that the area, place or site of production or crop is free from the pest - Pest free production site
    - Keywords:
      Pest free production site, pest free place of production
    - String:
      Topic=((pest free production site) OR (pest free place of production)) AND Topic=(crop$ OR plant$)

16. Options ensuring that the area, place or site of production or crop is free from the pest – Inspections, Surveillance
    - Keywords:
      Inspections, surveillance, testing, survey, latent infestation/infection
    - String:
      Topic=(latent SAME (infestation$ OR infection$)) AND Topic=(crop$ OR plant$) AND Topic=(inspection$ OR surveillance$ OR testing$ OR survey$)

17. Options for other types of pathways - Natural spread, spread by human activities (people movement, transports, machineries, trade), vectors, phoresy.
    - Keywords:
      Cleaning, disinfestations, fines, incentives, inspection, publicity, tourist, travellers, vector control, soil contamination,irrigation water
    - String
      Topic=((tourist$ OR traveller$ OR incentive$ OR vector$) AND pathway$) AND Topic=((crop$ OR plant$) SAME pest$) AND Topic=(control* OR inspection$)

18. Other relevant information.
    - This group includes a significant number of relevant documents that cannot however be associated with a specific type of RRO identified above. This groups results from the screening of the publications from the other 17 groups not retained in the specific groups but of general relevance.

B. Database of references selected from the literature search

Ref No	Type of Doc (G)uidance (E)xperiment (O)ther	Reference	Relevant part (Page, section, chapter paragraph etc.)	Risk reduction option	Plants and plant product	Pest(s)	Comments
Group 1: Options for consignments – prohibition (PRA step: Entry)							
1.	G	CFIA (*Canadian Food Inspection Agency*), 2010. Phytosanitary requirements to prevent the introduction into and spread within Canada of the Emerald Ash Borer, *Agrilus planipennis* Fairmaire. 2nd revision, 30 pp.	Whole document	Prohibition of movement from regulated to non regulated areas or from regulated areas to regulated areas transiting a non-regulated Area or between adjacent regulated areas;	logs, trees, wood, wood and bark chips, nursery stock, stand alone wood packaging materials, and other articles in the genus *Fraxinus* and firewood of all species	Emerald Ash Borer, *Agrilus planipennis*	The document contains phytosanitary requirements to prevent the entry and spread within Canada; conditions for authorization of movement of regulated articles within Canada are described requirements for imported regulated articles are also presented
Group 2: Options for consignments - Pest freedom: inspection or testing (PRA step: Entry)							
2.	G	USDA APHIS (Animal and Plant Health Inspection Ser vice), 2011. Federal Import Quarantine Order for Host Materials of Tomato Leafminer, *Tuta absoluta* (Meyrick). Federal order, 5 May 2011, 6 pp.	Relevant part - pages 4-6	detection and surveillance for tomato leafminer, *Tuta absoluta* is demonstrated (5 traps is sufficient to detect T. Absoluta - this is indicated by new research)	Tomato; plants for planting of *Solanum* spp., *Datura* spp. and *Nicotiana* spp , which are also hosts of *T. absoluta*, from all affected countries	*Tuta absoluta*	Beside prescribtion of 5 traps for detection and survelliance of T. Absoluta, additional import requirements are listed
3.	G	Biosecurity Australia (2005). Draft Extension of Existing Policy for Sweet Oranges from Italy. Canberra, Australia. March 2005, 176 pp.	Relevant part: Stage 3: Pest Risk Management - pages 58-64	Various risk management measures are recognized to manage the risks associated with sweet oranges: cold treatment or pest free area for Mediterranean fruit fly; inspection and remedial action for citrophilus mealybug, citrus pyralid and citrus flower moth;	Sweet oranges from Italy	Mediterranean fruit fly, citrophilus mealybug, citrus pyralid and citrus flower moth	

				and operational systems for the maintenance and verification of the phytosanitary status of sweet oranges			
4.	G	Chew V, 1996. Probit analysis and probit 9 as a standard for quarantine security. Plant Quarantine Statistics: A Review, ed. PW Bartlett, GR Chaplin and RJ van Velsen, 29-42	Whole document	Probit 9			Probit analyses and probit 9 as a standard for quarantine security is discussed.
5.	E	Elmouttie D, Kiermeier A and Hamilton G, 2010. Improving detection probabilities for pests in stored grain. Pest Manag Sci 2010; 66: 1280–1286	Whole document	Sampling programme - detection for pests in stored grain	Stored grain	Grain pests (e.g. *Rhyzopertha dominica*, *Cryptolestes* spp. *Sitophilus oryzae*	The study underlines the importance of considering an appropriate biological model when developing sampling methodologies for insect pests.
6.	G	MAF (Ministry of Agriculture and Forestry) Biosecurity Authority, 2003. Sea Container Review. MAF Discussion Paper No: 35, 116 pp.	Partly relevant – pages 11-13	Guidance on sampling	sea containers arriving to….	Miscellaneous	Methods for surveying ports (including number of containers to be surveyed and container selection procedure) are described. Facilities and procedures that exist for on-wharf external inspection and treatment, such as CCTV, x-ray machines, auto-washing and new treatments of Containers are listed and shortly described (not in detail).
7.	G	Schröder T, McNamara DG and Gaar V, 2009. Guidance on sampling to detect pine wood nematode *Bursaphelenchus xylophilus* in trees, wood and insects. OEPP/EPPO Bulletin 39, 179–188	Whole document	Guidance on sampling	trees, wood and insects	Bursaphelenchus xylophilus	Guidance on sampling to detect pine wood nematode (PWN) in trees, wood and insects are described: Detection of PWN in standing and cut trees; detection by the use of trap trees; sampling in sawmills and timber yards; extraction of nematodes from wood samples; detection of PWN in /on insects
8.	G	USDA (United States	Page 6	Sampling procedures	Nursery stock	Miscellaneous	The entry status of regulated plant

		Department of Agriculture) APHIS (Animal and Plant Health Inspection Service), 2007. Nursery Stock Restrictions. 432 pp.			(*Chaenomeles*, *Cydonia*, *Malus*, *Prunus*, and *Pyrus*)		materials capable of and intended for propagation (nursery stock) is presented
9.	E	Vail PV, Tebbets JS, Mackey BE and Curtis CE, 1993. Quarantine treatments: a biological approach to decision-making for selected hosts of codling moth (Lepidoptera: Tortricidae). Journal of Economic Entomology 86(1), 70-75.	Whole document	Systems approaches to quarantine	Cherry, nectarine, wallnut	Codling moth, Cydia pomonella	Biological approach to decision making for selected hosts of Codling moth is discussed. Systems approaches to quarantine include development development of more qualatitative biology data, modification of shipment volume, arrival times, and the distribution of the comodity upon arrival. It is suggested that quarantine treatment should be based on survival and that, in number of situations, treatment is not needed at all.
Group 3: Options for consignments - Prohibition of parts of the host or of specific genotypes of the host (PRA step: Entry)							
10.	O	Armstrong JW, 1994. Commodity resistance to infestation by quarantine pests. In Sharp L and Hallman GJ [eds.], Quarantine treatments for pests of food plants. 1994. Westview, Boulder, CO., 199-211.	Whole document	Commodity resistance	Fruits	Many	Review
11.	G	CFIA (Canadian Food Inspection Agency), 2008. D-01-04: Plant protection import and domestic movement requirements for barberry (*Berberis*, *Mahoberberis* and *Mahonia* spp.) under the Canadian Barberry Certification Program. 2nd revision, October 27, 2008, 16 pp.	All 16 pp	Many options	Plants for planting *Berberis, Mahoberberis, Mahonia* spp.	*Puccinia graminis*	Full guidance doc for Canada Relevant to most of the groups
Group 4: Options for consignments - Pre-entry or post-entry quarantine system (PRA step: Entry)							
12.	G	APHIS (Animal and Plant Health Inspection Service) AQIM (Agriculture Quarantine Inspection	Whole document	Inspection methodology for plant quarantine	NA	NA	USDA Agricultural Quarantine Inspection Monitoring handbook

		Monitoring), 2003. AQIM sampling process. AQIM handbook 06/2003-1 PPQ, 10 pp.					
13.	E	Asaad S and Abang MM, 2009. Seed-borne pathogens detected in consignments of cereal seeds received by the International Center for Agricultural Research in the Dry Areas (ICARDA), Syria. International Journal of Pest Management, 55:1, 69-77	Whole document	Detection of seed pathogens in seed consignments	Cereals	Tilletia caries; *T. foetida*; *T. controversa*; *Ustilago tritici*; *T. indica*; *Fusarium* spp.; *Helminthosporium* spp.; *Ustilago* spp.; *Urocystis agropyri*; *Anguina tritici*; *Ustilago hordei*	Survey made in 1995-2004, in Syria
14.	G	USDA (United States Department of Agriculture) APHIS (Animal and Plant Health Inspection Service), 2011. Cut flowers and greenery import manual, 158 pp.	Whole document	Inspection methodology for plant quarantine	NA	NA	USDA - A manual concerning the importation of cut flowers and greenery
15.	G	USDA (United States Department of Agriculture) APHIS (Animal and Plant Health Inspection Service), 2011. Fresh fruits and vegetables import manual, 610 pp	Whole document	Inspection methodology for plant quarantine	NA	NA	USDA-a listing of fruits and vegetables that have been approved for entry into the United States from foreign countries
16.	E	Gu J, Braasch H, Burgermeister W and Zhang J, 2006. Records of Bursaphelenchus spp. intercepted in imported packaging wood at Ningbo, China. For. Path. 36 (2006) 323–333	Whole document	Detection interception	wood packaging material	*Bursaphelenchus*	Morphology, ITS-RFLP

17.	E	Heinrich M, Botti S, Caprara L, Arthofer W, Strommer S, Hanzer V, Katinger H, Bertaccini A and da Câmara Machado ML, 2001. Improved Detection Methods for Fruit Tree Phytoplasmas. Plant Molecular Biology Reporter 19: 169-179.	Whole document	Detection method	Micropropagated fruit trees	Mycoplasma	
18.	G	Abbreviated hypergeometric tables for risk-based sampling in commodity inspection	Whole document	Inspection methodology for plant quarantine	NA	NA	Statistical tables for the hypergeometric distribution
19.	G	Griffin R, 1997. Inspection methodology for plant quarantine. Arab Journal of Plant Protection 15, 140–143.	Whole document	Inspection methodology for plant quarantine	NA	NA	FAO-Review
20.	G	Tan MK, Brennan JP, Wright D and Murray GM, 2010. An enhanced protocol for the quarantine detection of *Tilletia indica* and economic comparison with the current standard. Australasian Plant Pathology, 2010, 39, 334–342	Whole document	Protocol for quarantine detection of Tilletia indica	Wheat	Tilletia indica	A protocol developed in Australia and involving a highly sensitive one-tube molecular assay
21.	G	Tan MK and Wright D, 2009. Enhancing the detection of *Tilletia indica*, the cause of Karnal bunt. CRC20004 – Final Report. Cooperative Research Centre for National Plant Biosecurity, 30 June 2009, 64 pp.	Whole document	Protocol for quarantine detection of Tilletia indica	Wheat	Tilletia indica	Detection protocol, Australia
22.	E	Vilardi Tenente RC, Costa Manso ES and Figueira Filho ES, 1996. Inspeção e detecção de fitonematóides em introduções de germoplasma no Brasil no período de 1992-1994. Nematologia Brasileira 20(2), 68-73.	English summary p 65	Detection Thermal treatment Chemical treatment	Plant germplasm	Nematodes	
23.	G	Venette RC, Moon RD and Hutchison WD, 2002. Strategies and statistics of sampling for rare individuals.	Whole document	Sampling strategies for rare individuals	NA	NA	"Particular emphasis is placed on binomial-, beta-binomial-, and Fhypergeometric-based sampling

		Annu. Rev. Entomol. 2002. 47:143–74					strategies as they pertain to quarantine inspections for exotic pests, veterinary/medical entomology, and insecticide resistance monitoring."
Group 6: Options for consignments - Preparation of the consignment (PRA step: Entry)							
24.	O	Haack RA, Uzunovic A, Hoover K and Cook JA, 2011. Seeking alternatives to probit 9 when developing treatments for wood packaging materials under ISPM No. 15. OEPP/EPPO Bulletin 41, 39–45	Whole document	Treatment of consignment	WPM		Proposal for alternatives for probit-9
25.	G	Ibach RE, 1999. Wood preservation. Chapter 14 from Forest Products Laboratory. 1999. Wood handbook—Wood as an engineering material. Gen. Tech. Rep. FPL–GTR–113. Madison, WI: U.S. Department of Agriculture, Forest Service, Forest Products Laboratory. 463 p.	Whole document	Chemical preservation of wood	Wood		Broad and detailed coverage of methods
Group 7: Options for consignments - Specified treatment of the consignment/ Reducing pest prevalence in the consignment (PRA step: Entry)							
26.	G	USDA (United States Department of Agriculture) APHIS (Animal and Plant Health Inspection Service), 2011. Treatment manual, 90 pp	All pages	Various treatments (MBr, heat, radiation, etc)	Fruit, nuts and vegetables	Various	USA Treatment manual
27.	G	APHIS (Animal and Plant Health Inspection Service) AQIM (Agriculture Quarantine Inspection Monitoring), 2008. AQIS Heat Treatment Standard – Treatments and Fumigants – Version 1, 18 pp.	All pages	Dry heat treatment	Various	Various	Australia treatment manual
28.	E	Araya JE, Curkovic T and Zárate H, 2007. Mortality of *Frankliniella occidentalis* (Pergande) (Thysanoptera: Thripidae) by gamma irradiation. Agricultura Técnica (Chile) 67(2):196-	All	Irradiation	Not specified	Frankliniella occidentalis	Dose-response

		200 (Abril-Junio 2007)					
29.	E	Arcinas AC, 2002. Hot water drench treatments for the control of burrowing nematode, *Radophoplus similis*, in tropical ornamentals. Thesis (Master) in Botanical Sciences (Plant Pathology), University of Hawaii, 80 pp.	All	Hot water drenching	Palm species, Anthurium	Radopholis similis	Dose-response
30.	O	Armstrong JW and Mangan RL, 1998. Commercial quarantine heat treatments. Chapter 13 from CAB International 2007. Heat treatments for postharvest pest control. Eds J. Tang et al. 311-340	All pages	Heat treatment	Various	Various	Book chapter, review of methods
31.	O	Baker AC, 1939. The basis for treatment of products where fruitflies are involved as a condition for entry into the United States. Circular No 551, December 1939, United States Department of Agriculture, 8 pp.	All	Various	Fruit and vegetables	Fruit flies	Probit 9 approach
32.	E	Barak AV, Wang X, Yuan P, Jin X, Liu Y, Lou S and Hamilton B, 2006. Container Fumigation as a Quarantine Treatment for *Anoplophora glabripennis* (Coleoptera: Cerambycidae) in Regulated Wood Packing Material. J. Econ. Entomol. 99(3): 664-670.	All pages	Fumigation	WPM	Anoplophora glabripennis	
33.	E	Birla SL, Wang S, Tang J and Hallman G, 2004. Improving heating uniformity of fresh fruit in radio frequency treatments for pest control. Postharvest Biology and Technology, 33, 205–217	All	Radio frequency with temperature	Fruit (appel, orange)	Insects of fruit	Comparison of treatments
34.	G	Bond EJ, 2007. Manual of fumigation for insect control. FAO Plant Production and Protection Paper 54, 364 pp.	All especially Ch 13,	Fumigation	Various	Various	FAO Manual

35.	E	Brcka C, McSorley R and Frederick J, 2000. Effect of hot water treatments on root-knot nematodes and caladium tubers. Proc. Fla. State Hort. Soc. 113, 158-161.	All	Hot water treatment	Caladium	Meloidogyne incognita	Comparison of treatments
36.	G	FAO/WHO Food Standards, 1983. General standard for Irradiated Foods. CODEX STAN 106-1983, REV.1-2003, 3 pp.	All	Irradiation	Various fruit and vegetables	Various	
37.	E	Drake SR and Neven LG, 1997. Irradiation as an alternative to methyl bromide for quarantine treatment of stone fruits. Journal of Food Quality 22, 529-538.	All	Irradiation	Stone fruit	None	Dose- response of fruit quality
38.	O	EFSA Plant Health (PLH) Panel, 2009. Scientific Opinion of the Panel on PLH on a request from the European Commission on mortality verification of pinewood nematode from high temperature treatment of shavings. The EFSA Journal 1055, 1-19.	All	Heat treament	Wood shavings	Pinewood nematode	Exclusion of treatment in evaluation of experimental papers
39.	E	Encinas O and Briceño I, 2010. Effect of moisture content in Caribbean pine wood used for packing wood subject to heat treatment, ISPM 15. Revista Forestal Venezolana, 54(1), 21-27.	All	Heat treatment of wood packaging material	Wood packaging material	Wood fungi	Shortcomings of ISPM 15 requirements
40.	G	EPA (Environmental Protection Agency, United States), 2010. MeBr alternatives for applicators, commodity owners, shippers, and their agents. 68 pp.	All	Various	Various	Various	Alternatives to replace methyl-bromide fumigation
41.	G	EPPO (European and Mediterranean Plant Protection Organization), 2006. Disinfection procedures in potato production. PM 10/1 (1). OEPP/EPPO Bulletin 36, 463–466.	All	cleaning and disinfection procedures	Potato	*Clavibacter michiganensis* subsp. *Sepedonicus*, *Ralstonia solanacearum*	EPPO Standard

42.	G	EPPO (European and Mediterranean Plant Protection Organization), 2009. Disinfestation of wood with ionizing radiation. PM 10/8 (1). OEPP/EPPO Bulletin 39, 34–35.	All	Ionizing radiation	Round and sawn wood	Various	EPPO Standard
43.	G	EPPO (European and Mediterranean Plant Protection Organization), 2009. Disinfestation of production site against *Bemisia tabaci*. PM 10/13 OEPP/EPPO Bulletin 39, 478–479.	All	Insecticides	Ornamental and vegetable crops	*Bemisia tabaci*	EPPO Standard
44.	G	EPPO (European and Mediterranean Plant Protection Organization), 2009. Disinfestation of production site against *Liriomyza sativae*. PM 10/14 (1). OEPP/EPPO Bulletin 39, 480–481.	All	Insecticides	Ornamental and vegetable crops	*Liriomyza sativae*	EPPO Standard
45.	G	EPPO (European and Mediterranean Plant Protection Organization), 2009. Disinfestation of production site against *Thrips palmi*. PM 10/15. OEPP/EPPO Bulletin 39, 482–483.	All	Insecticides	Ornamental and vegetable crops	*Thrips palmi*	EPPO Standard
46.	G	EPPO (European and Mediterranean Plant Protection Organization), 2009. Fumigation of cut flowers to control insects and mites. PM 10/12 (1). OEPP/EPPO Bulletin 39, 39.	All	Fumigation	Cut Flowers	Insects and mites	EPPO Standard
47.	G	EPPO (European and Mediterranean Plant Protection Organization), 2009. Irradiation of stored products to control stored-product insects in general. PM 10/10 (1). OEPP/EPPO Bulletin 39, 37-38.	All	Irradiation	Stored products	Insects	EPPO Standard
48.	G	EPPO (European and	All	Low energy electron	Seed of	*Tilletia* caries,	EPPO Standard

		Mediterranean Plant Protection Organization), 2009. Low energy electron treatment of cereal seed against fungi. PM 10/9 (1). OEPP/EPPO Bulletin 39, 36.		treatment of seed surface	Triticum aestivum and Secale cereale	*Urocystis occulta*	
49.	G	EPPO (European and Mediterranean Plant Protection Organization), 2009. Methyl bromide fumigation of wood to control insects. PM 10/7 (1). OEPP/EPPO Bulletin 39, 32-33.	All	Methyl-Bromide fumigation	Wood	Wood related insect pests, e.g. Scolytidae, Buprestidae and Cerambycidae	EPPO Standard
50.	G	EPPO (European and Mediterranean Plant Protection Organization), 2009. Sulfuryl fluoride fumigation of dried fruits and nuts to control various stored product insects. PM 10/4 (1). OEPP/EPPO Bulletin 39, 29–30.	All	Sulfuryl fluoride fumigation	Dried fruits and nuts	Stored products insects	EPPO Standard
51.	G	EPPO (European and Mediterranean Plant Protection Organization), 2009. Heat treatment of wood to control insects and wood-borne nematodes. PM 10/6 (1). OEPP/EPPO Bulletin 39, 31.	All	Heat treatment	Wood	Wood related insects, Bursaphelenchus spp	EPPO Standard
52.	G	EPPO (European and Mediterranean Plant Protection Organization), 2009. Hot water treatment of *Dracaena* And *Yucca* cuttings against *Opogona sacchari*. PM 10/2 (1). OEPP/EPPO Bulletin 39, 28.	All	Hot water treatment	Cuttings of Yucca and Dracaena	*Opogona sacchari*	EPPO Standard
53.	E	Evans HF and Fielding NJ, 2002. Alternatives to Methyl Bromide for control of quarantine pests: can composting of bark provide consistent lethal heat accumulation? Proceedings: 2002 U.S. Department of	All	Composting	Bark, wood chips	Various	Heat inside compost heap is not sufficient

		Agriculture Interagency Research Forum GTR-NE-300, 20-22.					
54.	E	Ferriss RS, 1984. Effects of microwave oven treatment on microorganisms in soil. The American Phytopathological Society, 74(1), 121-126.	All	Microwave	Soil	Fungi, nematodes	Dose-response, MW is effective
55.	O	Fields PG and White NDG, 2002. Alternatives to Methyl Bromide treatments for stored-product and quarantine insects. Annu. Rev. Entomol. 47:331–59	All	Various	Various	Various	Review of alternatives to methyl-bromide
56.	E	Fleming MR, Janowiak JJ, Kimmel JD, Halbrendt JM, Bauer LS, Miller DL and Hoover K, 2005a. Efficacy of commercial microwave equipment for eradication of pine wood nematodes and cerambycid larvae infesting red pine. Forest Products Journal, 55(12), 226-232.	All	Microwaves	Wood	Pinewood nematode, beetles	MW can be effective
57.	E	Fleming MR, Janowiak JJ, Halbrendt JM, Bauer LS, Miller DL and Hoover K, 2005. Feasibility of eradicating cerambycid larvae and pinewood nematodes infesting lumber with commercial 2.45 GHz microwave equipment. Forest Products Journal 55(12):227-232.	Whole document	Heat treatment (microwaves)	Pine wood	Pine wood nematode	Effectiveness of commercial microwave equipement
58.	E	Follett PA, 2004. Irradiation to control insects in fruits and vegetables for export from Hawaii. Radiation Physics and Chemistry 71, 161–164.	All	Irradiation	Fruit	Fruit flies	Dose-response, confirmation of generic dose
59.	O	Follett PA and Neven LG, 2006. Current trends in quarantine entomology. Annu. Rev. Entomol. 51:359–85.	All	Generic	Generic	Generic	Probit 9 alternatives for phytosanitary measures
60.	O	Follett PA, 2009. Generic radiation quarantine	All	Irradiation	Fresh horticultural	Insects	Further research needs on irradiation

		treatments: the next steps. Journal of Economic Entomology, 102(4),1399-1406.			commodities		
61.	G	Forestry Commission, 2003. Verification of heat treatment facilities and authorisation of the use of the DB-HT mark to comply with the international standard for phytosanitary measures ISPM 15, 8pp.	All	Various treatments of wood packaging material	Wood packaging material	Wood related insects, *Bursaphelenchus* spp	Verification of facilities, authorization of the ISPM 15 Mark
62.	O	Follett PA and McQuate GT, 2001. Accelerated Development of Quarantine Treatments for Insects on Poor Hosts. J. Econ. Entomol. 94(5): 1005-1011.	All	Various	Fruit	Fruit flies	Probit 9 discussion
63.	E	Goebel PC, Bumgardner MS, Herms DA and Sabula A, 2010. Failure to phytosanitize ash firewood infested with emerald ash borer in a small dry kiln using ISPM-15 Standards. Journal of Economic Entomology 103(3), 597-602.	All	Kiln Drying	Ash firewood	Agrilus planipennis	Failure of ISPM 15 treatment
64.	O	Gupta, SC, 2001. Irradiation as an alternative treatment to methyl bromide for insect control, In Irradiation for Food Safety and Quality. Loaharanu, P. and Thomas, P., (eds.). International Atomic Energy Agency, Technomic Publishing Co., Inc. Pennsylvania, USA, 39-49.	All	Various alternatives for methyl-bromide	Various	Various	Review of alternatives to methyl-bromide
65.	E	Haack RA and Petrice TR, 2009. Bark- and Wood-Borer Colonization of Logs and Lumber After Heat Treatment to ISPM 15 Specifications: The Role of Residual Bark. Journal of Economic Entomology 102(3), 1075-1084.	All	Heat treatment	Wood packaging material	Wood insects	Failure of ISPM 15 treatment

66.	O	Haack RA, Uzunovic A, Hoover K and Cook JA, 2011. Seeking alternatives to probit 9 when developing treatments for wood packaging materials under ISPM No. 15. OEPP/EPPO Bulletin 41, 39–45.	All	Various treatments of wood packaging material	Wood packaging material	Wood related insects, Bursaphelenchus spp	Probit 9 alternatives for wood treatments
67.	O	Hallman GJ, 2011. Phytosanitary applications of irradiation. Comprehensive Reviews in Food Science and Food Safety, 10, 143-151.	All	Irradiation	Generic	Generic	Review of irradiation for phytosanitary purposes
68.	E	Hughs SE, Armijo CB and Staten RT, 2006. Boll weevil kill rates by gin processing and bale compression. American Society of Agricultural and Biological Engineers 22(1), 45-50.	All	Gin processing and bale compression	Cotton	Insect pests of cotton	Routine processing of cotton
69.	E	IAEA (International Atomic Energy Agency), 1999. Irradiation as a quarantine treatment of arthropod pests. Proceedings of the final meeting held in Honolulu, Hawaii, 3-7 November 1997, 170 pp.	All	Irradiation	Various	Various	Various experimental papers
70.	E	IAEA (International Atomic Energy Agency), 2002. Irradiation as a phytosanitary treatment of food and agricultural commodities. Proceedings of a final research coordination meeting, 189 pp.	All	Irradiation	Various	Various	Various experimental papers
71.	E	Jagdale GB and Grewal PS, 2004. Effectiveness of a hot water drench for the control of foliar nematodes *Aphelenchoides fragariae* in floriculture. Journal of Nematology 36(1):49–53.	All	Hot water drench	Hosta and Fern	Aphelenchoides fragariae	Dose-response
72.	E	Jang EB, Chan HT, Nishijima KA, Nagata JT, McKenney MP, Carvalho LA and Schneider EL, 2001. Effect of heat shock and	All	Cold treatment + transient warm spike	Avocado	Ceratitis capitata	Confirmation of effectiveness of method

		quarantine cold treatment with a warm temperature spike on survival of Mediterranean fruit fly eggs and fruit quality in Hawaii-grown 'Sharwil' avocado. Postharvest Biology and Technology 21 (2001) 311–320.					
73.	E	Report by Jones, 2009. Mortality verification of pinewood nematode from high temperature treatment of shavings. Annex 1 of the Request letter from DG SANCO to EFSA Executive Director sent on 17/02/2009, as documentation provided to EFSA for the preparation of the scientific opinion "Mortality verification of pinewood nematode from high temperature treatment of shavings" of the PLH Panel.	All	High temperature treatment	Wood shavings	Pinewood nematode	Negatively evaluated by the Panel
74.	O	Lurie S, 1998. Postharvest heat treatments. Postharvest Biology and Technology 14, 257–269.	All	Heat treatment	Harvested products	Various	Review of heat treatments
75.	O	Mangan RL and Hallman GJ, 1998. Temperature treatments for quarantine security: new approaches for fresh commodities. Chapter 8 from Hallman GL and Denlinger DL (eds.) Temperature sensitivity in insects and application in integrated pest management. Westview Press, Boulder, Colorado, 201-236.	All	Temperature treatment	Various	Various	Review of temperature treatments
76.	E	Mangan RL and Sharp JL, 1994. Combination and multiple treatments. Chapter 16 from Sharp JL and Hallman GL (eds.). Quarantine treatments for pests of food plants. Westview Press, Boulder,	All	Multiple treatments	Not specified	Not specified	Statistical evaluation of effectiveness of multiple treatments

		Colorado, USA, 239-247					
77.	E	MCCullough DG, Poland TM, Cappaert D, Clark EL, Fraser I, Mastro V, Smith S and Pell C, 2007. Effects of chipping, grinding, and heat on survival of emerald ash borer, *Agrilus planipennis* (Coleoptera: Buprestidae), in chips. Journal of Economic Entomology, 100(4), 1304-1315.	All	Chipping, grinding and heat treatment	Fraxinus wood	Agrilus planipennis	Failure of ISPM 15
78.	E	Mirić M and Willeitner H, 1984. Lethal temperature for some wood-destroying fungi with respect to eradication by heat treatment. The International Research Group on Wood Preservation. 8pp.	All	Heat treatment	Wood	Fungi	Dose-response, MSc thesis
79.	E	Moy JH and Wong L, 2002. The efficacy and progress in using radiation as a quarantine treatment of tropical fruits – a case study in Hawaii. Radiation Physics and Chemistry 63 (2002) 397–401.	All	Irradiation	Tropical fruits	Insects	Effective dose, routine application
80.	E	Mushrow L, Morrison A, Sweeney J and Quiring D, 2004. Heat as a phytosanitary treatment for the brown spruce longhorn beetle. The Forestry Chronicle, 80(2), 224-228.	All	Heat treatment	Spruce wood	Tetropium fuscum	Dose-response, Effective treatment
81.	E	Myers SW, Fraser I and Mastro VC, 2009. Evaluation of Heat Treatment Schedules for Emerald Ash Borer (Coleoptera: Buprestidae). J. Econ. Entomol. 102(6): 2048-2055.	All	Heat treatment	Fraxinus wood	Agrilus planipennis	Dose-response, Effective treatment
82.	G	NAPPO (North American Plant Protection Organization), 2009. TP No. 01 – Thermotherapy or Thermaltherapy, 5pp.	All	Heat treatment of greenhouse crops	Citrus	Citrus viruses and graft transmissible agents	NAPPO treatment protocol
83.	E	Newbill MA and Morrell JJ, 1991. Effect of elevated	All	Heat treatment	Douglas fir poles	Basidiomycete	Dose-response, Effective treatment

		temperatures on survival of Basidiomycetes that colonize untreated Douglas-fir poles. Forest Products Journal 41(6), 31-33.				s	
84.	E	Nzokou P, Tourtellot S and Kamdem DP, 2008. Kiln and microwave heat treatment of logs infested by the emerald ash borer (*Agrilus planipennis* Fairmaire) (Coleoptera: Buprestidae). Forest Products Journal 58(7/8), 68-72.	All	Kiln and microwave heat treatment	Fraxinus wood	Agrilus planipennis	Dose- response, Microwave less effective as Kiln
85.	E	Pawson SM and Watt MS, 2009. An experimental test of a visual-based push-pull strategy for control of wood boring phytosanitary pests. Agricultural and Forest Entomology, 11(3), 239–245.	All	Multiple light traps	Wood	Cerambycidae .	Potential alternative to fumigants
86.	O	Powell MR, 2002. A Model for Probabilistic Assessment of Phytosanitary Risk Reduction Measures. Plant Dis. 86:552-557.	All	Heat treatment as example	Wood as example	Fungi as example	Statistical model to assess effectiveness of phytosanitary measures
87.	G	USDA (United States Department of Agriculture) APHIS (Animal and Plant Health Inspection Service), 2008. Nonchemical treatments, 4 pp	All	Dry heat treatment	Niger seeds	Weed seeds	APHIS treatment manual
88.	E	Prasad JS and Varaprasad KS, 1992. Elimination of white-tip nematode, *Aphelenchoides besseyi*, from rice seed. Fundam. Appl. Nematol. 15(4), 305-308.	All	Chemical seed treatment (soaking)	Rice seeds	Aphelenchoid es besseyi	Effective method
89.	E	Ramsfield T D, Ball RD, Gardner JF and Dick MA, 2010. Temperature and time combinations required to cause mortality of a range of fungi colonizing wood. Canadian Journal of Plant Pathology, 32: 3, 368-375.	All	Heat treatment	Wood	Fungi	Failure of ISPM15
90.	O	Robertson JL, Preisler HK and Frampton ER, 1994.	All	Various	Various	Various	Review of tatistical methods to assess

		Statistical concept and minimum threshold. RE Paull JW Armstrong Insect pests and fresh horticultural products treatments and responses 1994. 47-65.					effectiveness of phytosanitary measures
91.	O	Schortemeyer M, Thomas K, Haack RA, Uzunovic A, Hoover K, Simpson JA and Grgurinovic CA, 2011. Appropriateness of Probit-9 in the Development of Quarantine Treatments for Timber and Timber Commodities. Journal of Economic Entomology, 104(3):717-731.	All	Various treatments of wood packaging material	Wood, wood packaging material	Wood related insects, *Bursaphelenchus* spp	Probit 9 discussion
92.	E	Sobek S, Rajamohan A, Dillon D, Cumming RC and Sinclair BJ, 2011. High temperature tolerance and thermal plasticity in emerald ash borer *Agrilus planipennis* Agricultural and Forest Entomology, 8 pp.	All	Heat treatment	Wood	*Agrilus planipennis*	Failure of ISPM15
93.	E	Tsang MMC, Hara AH and Sipes B, 2003. Hot-water treatments of potted palms to control the burrowing nematode, *Radopholus similis*. Crop Protection 22, 589–593.	All	Hot water drench and dipping	Palms	*Radopholus similis*	effective dos-response
94.	E	Tsang MMC, Hara AH and Sipes B, 2004. Efficacy of hot water drenches of *Anthurium andraeanum* plants against the burrowing nematode *Radopholus similis* and plant thermotolerance. Ann. appl. Biol., 145:309-316	All	Hot water drench and dipping	Anthurium	*Radopholus similis*	Effective dose-response
95.	O	UNEP (United Nations Environment Program), 2010. 2010 Report of the Methyl Bromide. Technical Options Committee. 2010 assessment. 396 pp.	Pp 195-326	Alternatives for methyl-bromide	Various	Various	Review of alternative methods to methyl-bromide fumigation
96.	O/G	USDA (United States	All	Methyl bromide alternative	Many	Many	Extensive review of methyl-bromide

		Department of Agriculture) APHIS (Animal and Plant Health Inspection Service), 2009. Methyl Bromide quarantine and preshipment interim national management strategy submission by the United States of America. October 30, 2009. 33pp.					and alternative treatments
97.	G	USDA (United States Department of Agriculture) APHIS (Animal and Plant Health Inspection Service), 2011. Treatment Manual. T300 - Schedules for Miscellaneous Plant Products. 01/2011-53 PPQ, 40 pp.	All	Many	Miscellaneous plant products	Many	
98.	E	Bi J, Ballmer G and Toscano NC, 2009. Evaluation of Strawberry Nursery Plant Cold Treatments on Survival of the Whitefly, *Bemisia tabaci*. 4 pp.	All	Cold treatment	Fragaria	*Bemisia tabaci*	Effective treatment
99.	E	Uzunovic A and Khadempour L, 2007. Heat Disinfestation of Mountain Pine Beetle-Affected Wood Adnan. Mountain Pine Beetle Initiative Working Paper 2007-14, 33 pp.	All	Heat treatment	Wood	Fungi associated with mountain pine beetle	Dose-response, effective treatment
100.	E	Wang X, Bergman R, Simpson WT, Verrill S and Mace T, 2009. Heat-treatment options and heating times for ash firewood. USDA, General Technical Report FPL–GTR–187, 31 pp.	All	Heat treatment	Fraxinus	*Agrilus planipennis*	Dose-response, extrapolation of lab-scale to practical scale, but no test with infested material
Group 8: Options for consignments - Restriction on end use, distribution and periods of entry (PRA step: Entry)							
101.	G	e-CFR (Electronic Code of Federal Regulations), webpage. Available from: http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=446e2e3a8627eeda6f4802db874c91dc&tpl=/ecfrbrowse/Title07/7cfr3	§ 319.56-31	Entry from December 1 through April 30	Peppers from greenhouses (Almeria or Alicante provinces of Spain)	Medfly	Safeguarding from harvest to export using insect proof material

		19_main_02.tpl Additional info on APHIS FAVIR (Fruits and Vegetables Import Requirements) Database, webpage. Available from: https://epermits.aphis.usda.gov/manual/index.cfm?action=pubHome					
	G	e-CFR (Electronic Code of Federal Regulations), webpage. Available from: http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=446e2e3a8627eeda6f4802db874c91dc&tpl=/ecfrbrowse/Title07/7cfr319_main_02.tpl Additional info on APHIS FAVIR (Fruits and Vegetables Import Requirements) Database, webpage. Available from: https://epermits.aphis.usda.gov/manual/index.cfm?action=pubHome	§ 319.56-34	Entry at ports located north of 39° latitude and east of 104° longitude or At ports that have approved cold treatment facilities	Clementines from Spain	Medfly	These restrictions are applied if the commodity treatment has not been completed or fails
	G	e-CFR (Electronic Code of Federal Regulations), webpage. Available from: http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=446e2e3a8627eeda6f4802db874c91dc&tpl=/ecfrbrowse/Title07/7cfr319_main_02.tpl Additional info on APHIS FAVIR (Fruits and Vegetables Import Requirements) Database, webpage. Available from: https://epermits.aphis.usda.gov/manual/index.cfm?action=pubHome	§ 319.56-3	Entry at ports located north of 39° latitude and east of 104° longitude or At ports that have approved cold treatment facilities	Grape (Fruit, or cluster of fruit) from Italy into North Atlantic (NA) ports	Medfly	These restrictions are applied if the commodity treatment has not been completed or fails
	G	e-CFR (Electronic Code of Federal Regulations), webpage. Available from: http://ecfr.gpoaccess.gov/cgi/t/text/text-	§ 319.56-3	Dry bulb only	Onion *Allium* spp. from France	All pests	Except garlic *A. sativum*

		idx?c=ecfr&sid=446e2e3a8627eeda6f4802db874c91dc&tpl=/ecfrbrowse/Title07/7cfr319_main_02.tpl Additional info on APHIS FAVIR (Fruits and Vegetables Import Requirements) Database, webpage. Available from: https://epermits.aphis.usda.gov/manual/index.cfm?action=pubHome					
	G	e-CFR (Electronic Code of Federal Regulations), webpage. Available from: http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=446e2e3a8627eeda6f4802db874c91dc&tpl=/ecfrbrowse/Title07/7cfr319_main_02.tpl Additional info on APHIS FAVIR (Fruits and Vegetables Import Requirements) Database, webpage. Available from: https://epermits.aphis.usda.gov/manual/index.cfm?action=pubHome	§ 319.56-11	Dried, cured, or processed fruits and vegetables including cured figs and dates, raisins, nuts, and dried beans and peas, may be imported without permit, phytosanitary certificate, or other compliance with this subpart, except as specifically provided otherwise in this section or elsewhere in this part.	All dried or processed from all countries	All	Except frozen fruits and vegetables and acorns and chestnuts from countries other than Canada and Mexico – treatment required
Group 9: Options preventing or reducing infestation in the crop - Treatment of the crop, field, or place of production in order to reduce pest prevalence (PRA step: Entry and Establishment/Spread/Impact)							
102.	G	Christie AW, 1959. Nursery tree certification insurance against root-rot. California Avocado Society 1959 Yearbook 43: 73-74.	Whole document	Fumigation; soil treatments	Avocado	*Phytophthora cinnamomi*	
103.	G	Daughtrey ML and Benson DM, 2005. Principles of plant health management of ornamental plants. Annu. Rev. Phytopathol., 43, 141–169.	Whole document	All treatments	Ornamental plants	Many	Review
104.	G	Evans HF, McNamara DG, Braasch H, Chadoeuf J and Magnusson C, 1996. Pest Risk Analysis (PRA) for the territories of the European	Whole document	In the forest During processing During transportation End use	Plants for planting Timber Sawn wood Packaging material	*Bursaphelenchus xylophilus*; *Monochamus* spp.	Review

		Union (as PRA area) on *Bursaphelenchus xylophilus* and its vectors in the genus *Monochamus*. OEPP/EPPO Bulletin 26, 199-249.		Inspection for holes Heat Chemical	Chips Sawdust		
105.	G	Hara AH, 2002. Preventing alien species invasion by pre-shipment disinfestations treatments. Micronesica Suppl. 6: 111–121.	Whole document	Pre-shipment treatments Controlled atmosphere heat treatment irradiation combinations of treatments	Cut flowers Plants for planting	Many species	Review
106.	E	Hata TY, Hara AH, Jang EB, Imaino LS, Hu BKS and Tenbrink VL, 1992. Pest management before harvest and insecticidal dip after harvest as a systems approach to quarantine security for red ginger. Journal of Economic Entomology 85(6), 2310-2316.	Whole document	Chemical treatments	fruits Red ginger, Alpinia purpurata,	Many species	Hawaï
107.	G	Jamieson LE, Meier X, Page B, Zulhendri F, Page-Weir N, Brash D, McDonald RM, Stanley J and Woolf AB, 2009. A review of postharvest disinfestation technologies for selected fruits and vegetables. The New Zealand Institute for Plant and Food Research Ltd, 36 pp.	Whole document	Physical/chemical treatments; segregation	Selected fruits and vegetables	Many	New Zealand: A review of postharvest disinfestation technologies for selected fruits and vegetables
108.	G	Quinlan MM, 2004. Trends in international phytosanitary standards: potential impact on fruit fly control. Proceedings of 6th International Fruit Fly Symposium 6–10 May 2002, Stellenbosch, South Africa, 195–200.	Whole document	Many options	fruits	Fruit flies	Review of existing options
109.	E	El-Wakeil NE, Awadallah KT, Farghaly HTh, Ibrahim AAM and Ragab ZA, 2008. Efficiency of the newly recorded pupal parasitoid *Pediobius furvus* (Gahan) for	Whole document	Biological control agents	maize and sorghum	Sesamia cretica	Efficiency of the pupal parasitoid *Pediobius furvus* to control *Sesamia cretica* was studied.

		controlling *Sesamia cretica* (Led.) pupae in Egypt. Archives Of Phytopathology And Plant Protection, 41:5, 340-348.					
110.	E	Jackson M, Bohac JR, Dalip KM, McComie L, Rhode L, Chung P, Seal D, Clarke-Harris D, Aseidu F and McDonald FD, 2010. Integrated pest management of major pests affecting sweetpotato, Ipomoea batatas, in the Caribbean. USAID Resources Management and Development Portal. 21pp. Available from: http://rmportal.net/library/content/nric/963.pdf/view?searchterm=health	Whole document	IPM	Miscellaneous (soil insect pests, including sweetpotato weevils, sweetpotato leaf beetles, flea beetles, and Wireworm-*Diabrotica-Systena*) complex.	Sweetpotato, *Ipomoea batatas*	The potential of resistant varieties, insect growth regulators and botanical insecticides for managing sweetpotato weevils and grubs of the sweetpotato leaf beetle was evaluated.
111.	E	Zettler JL, Follett PA and Gill RF, 2002. Susceptibility of *Maconellicoccus hirsutus* (Homoptera: Pseudococcidae) to Methyl Bromide. Journal of Economic Entomology, 95(6), 1169-1173.	Whole document	Fumigation	Plants for planting Table grape	*Maconellicoccus hirsutus* (Homoptera: Pseudococcidae)	Methyl Bromide
Group 10: Options preventing or reducing infestation in the crop - resistant or less susceptible species/varieties (PRA step: Entry and Establishment/Spread/Impact)							
112.	E	Badiger HK, Patil SB, Udikeri SS, Biradar DP, Chattannavar SN, Mallapur CP and Patil BR, 2011. Comparative efficacy of interspecific cotton hybrids containing single and stacked Bt genes against pink bollworm, Pectinophora gossypiella (Saund.) and tobacco caterpillar, Spodoptera litura (Fab.)*. Karnataka J. Agric. Sci.,24(3): 320 – 324.	the whole document	genetically modified crop	cotton	against pink bollworm and tobacco caterpillar	hybrids containing Bt genes
113.	E	Zehnder G, Kloepper J, Tuzun S, Yao C, Wei G,	the whole document	Induced resistance	Cucumbers	against a pest non-regulated	

		Chambliss O and Shelby R, 1997. Insect feeding on cucumber mediated by rhizobacteria-induced plant Resistance. Entomologia Experimentalis et Applicata 83: 81–85.	(Pages 81-85)			but not yet available in the EU	
Group 11: Options preventing or reducing infestation in the crop - growing plants under exclusion conditions (glasshouse, screen, isolation) (PRA step: Entry and Establishment/Spread/Impact)							
114.	G	Albajes R, Gullino ML and van Lenteren JC, 1999. Integrated Pest and Disease Management in Greenhouse Crops. Volume 14: Developments in plant pathology, 221 pp.	Parts 3, 4, 5	Biological control	Plants in greenhouses	Pests and diseases of greenhouse crops.	
115.	G	Mahr SER, Cloyd RA, Mahr DL and Sadof CS, 2001. Biological control of insects and other pests of greenhouses crops. University of Wisconsin-Extension, Cooperative Extension. 108 pp.	Whole document	Biological control	Plants in greenhouses	Pests of greenhouse crops	
116.	G	Yano E, 2006. Ecological considerations for biological control of aphids in protected culture. Popul Ecol, 48:333–339.	Whole document	Biological control	Plants in greenhouses	Aphids	
Group 13: Options preventing or reducing infestation in the crop - certification scheme (PRA step: Entry and Establishment/Spread/Impact)							
117.	G	AQIS (Australian Quarantine and Inspection Service), 2006. Phytosanitary Certificate Completion (Exports). Plant Program, 29 pp.	Whole document	Certification scheme	Different crops	Not specific	Instruction on phytosanitary certificate completion
118.	G	AUSVEG, 2007. Australian National Standard Certification of Seed Potato. 26 pp.	Whole document	Certification scheme	Seed potatoes	Fungal, bacterial viral and virus – like potato pathogens; potato cyst and root knot nematodes; insect pests	Australian national standard

119.	G	EPPO (European and Mediterranean Plant Protection Organization), 1998. EPPO Standards – Certification schemes. PM 4/22-26. OEPP/EPPO Bulletin 28, 221-225.	Whole document	Guidance for certification scheme	Different crops	Not specific	
120.	G	EPPO (European and Mediterranean Plant Protection Organization), 2009. Certification scheme for Rubus. PM 4/10 (2). OEPP/EPPO Bulletin 39, 271–277.	Whole document	Certification scheme	*Rubus*	Different pathogens	Scheme for the production of healthy plants for planting
121.	G	EPPO (European and Mediterranean Plant Protection Organization), 1997. Certification scheme – Pathogen-tested material of rose. PM 4/21 (1). OEPP/EPPO Bulletin 27, 621–640.	Whole document	Certification scheme	*Rosa* spp. and hybrids	Different pathogens	Standard on pathogen-tested material of rose
122.	G	EPPO (European and Mediterranean Plant Protection Organization), 1998. Certification scheme for freesia. PM 4/22 (1). OEPP/EPPO Bulletin 28, 227–234.	Whole document	Classification scheme	*Freesia*	Fungal and viral pathogens ,	Scheme for general sequence for the production of classified, vegetatively propagated plants
123.	G	EPPO (European and Mediterranean Plant Protection Organization), 1998. Certification scheme – classification scheme for hyacinth PM 4/23 (1). OEPP/EPPO Bulletin 28, 235–241.	the whole document	classification system for hyacinth	hyacinth	hyacinth mosaic potyvirus, tobacco rattle tobravirus, Xanthomonas hyacinthi, Ditylenchus spp., not true types	certification system
124.	G	EPPO (European and Mediterranean Plant Protection Organization), 1998. Certification scheme – classification scheme for narcissus. PM 4/24 (1). OEPP/EPPO Bulletin 28, 243–250.	the whole document	classification scheme for narcissus	narcissus	viruses affecting narcissus, Ditylenchus dipsaci, visible off-types, plants rogued	certification system
125.	G	EPPO (European and Mediterranean Plant	the whole document	certification scheme for kalanchoe	cultivars of Kalanchoe	virus pathogens affecting	pathogen tested material of kalanchoe

		Protection Organization), 1998. Certification scheme – Pathogen-tested material of kalanchoe. PM 4/25 (1). OEPP/EPPO Bulletin 28, 251–262.			blossfeldiana	kalanchoe	
126.	G	EPPO (European and Mediterranean Plant Protection Organization), 1998. Certification scheme – Pathogen-tested material of petunia. PM 4/26 (1). OEPP/EPPO Bulletin 28, 263–278.	the whole document	certification scheme for petunia	petunia	virus pathogens affecting petunia	pathogen tested material of petunia
127.	G	EPPO (European and Mediterranean Plant Protection Organization), 2001. Certification scheme for *Malus*, *Pyrus* and *Cydonia*. PM 4/27 (supplement). OEPP/EPPO Bulletin 31, 445–446.	the whole document	supplement to the certification system for Malus, Pyrus and Cydonia	apple, pear and quince	-	an added figure on the certification scheme
128.	G	EPPO (European and Mediterranean Plant Protection Organization), 2001. Certification scheme for cherry. PM 4/29. OEPP/EPPO Bulletin 31, 447–461.	the whole document	certification scheme for cherry	sweet cherry, sour cherry and their rootstocks	virus pathogens affecting cherries	scheme for production of healthy plants for planting
Group 14: Options ensuring that the area, place or site of production or crop is free from the pest - Pest free area (PRA step: Entry and Establishment/Spread/Impact)							
129.	G	EPPO (European and Mediterranean Plant Protection Organization), 2009. Generic elements for contingency plans. PM 9/10. OEPP/EPPO Bulletin 39, 471–474.	Whole document	Guidance for containment and eradication of plant pests	Not specific	Not specific	Generic elements for contingency plans
130.	G	USDA (United States Department of Agriculture) APHIS (Animal and Plant Health Inspection Service), 2003. Guidelines for Fruit Fly Systems Approach to Support the Movement of Regulated Articles between Mexico and the United	Whole document	Mitigation the risk for the introduction of fruit flies from Mexico to USA	Fruits; Fruit trees	Fruit flies, Tephritidae	Determination of places of production and buffer zones; pest detection and trapping program; control measures; sterile insect technique

		States. Draft Document: 05 June 03, 26 pp.					
131.	G	Glocke P and Hall B, 2010. Biosecure packaging for the transport of emergency plant pest samples. Cooperative Research Centre for National Plant Biosecurity, 26 pp.	Whole document	Development of protocols for packaging standards for transport of plants, soil and insect samples	Item for diagnostic laboratories- soil, seed, woody stems, herbaceous plants, soft and hard fruit or vegetables, fluid with seed and culture plates with agar	Emergency Plant Pests	Suitable packaging materials for different items are identified. Guidelines for transport of Emergency Plant Pests consistent with United Nation regulations are formulated
132.	G	FAO (Food and Agriculture Organization of the United Nations), 1999. ISPM (International Standards for Phytosanitary Measures) No 10. Establishment of pest free places of production and pest free production sites. 16 pp.	Whole document	Establishment of pest free places of production and pest free production sites	Not specific	Not specific	
133.	G	FAO (Food and Agriculture Organization of the United Nations), 1997. ISPM (International Standards for Phytosanitary Measures) No 6. Guidelines for surveillance. 15 pp.	Whole document	Guidelines for surveillance	Not specific	Not specific	
134.	G	FAO (Food and Agriculture Organization of the United Nations), 1998. ISPM (International Standards for Phytosanitary Measures) No 8. Determination of pest status in an area. 12 pp.	Whole document	Determination of pest status (presence, absence, low prevalence etc.)	Not specific	Not specific	
135.	G	FAO (Food and Agriculture Organization of the United Nations), 1998. ISPM (International Standards for Phytosanitary Measures) No 9. Guidelines for pest eradication programmes. 10 pp.	Whole document	Guidance for eradication	Not specific	Not specific	
136.	G	FAO (Food and Agriculture Organization of the United	Whole document	Establishment of pest free areas for fruit flies	Fruits Fruit trees	Fruit flies *Anastrepha,*	Surveillance - trapping and fruit sampling,

		Nations), 2006. ISPM (International Standards for Phytosanitary Measures) No 26. Establishment of pest free areas for fruit flies (Tephritidae). 15 pp.		(Tephritidae)		*Bactrocera, Ceratitis, Dacus, Rhagoletis* and *Toxotrypana*.	official control
137.	E	Melifronidou-Pantelidou A, 2009. Eradication campaign for *Rhynchophorus ferrugineus* in Cyprus. OEPP/EPPO Bulletin 39, 155–160.	Whole document	Eradication	Palm tree P. canariensis, P. dactylifera and Washingtonia spp.	Rhynchophorus ferrugineus (red palm weevil)	Surveys, delimitation of infested areas and establishment of pest free areas; Measures in the demarcated areas
138.	G	Narayanasamy P, 2007. Postharvest pathogens and disease management. AJ Whiley and Sons, Inc., Publication, 584 pp.	Part 3 of the book "Principles and practices of postharvest disease manageme nt" pages 253-537	Cultural practices - reduction in sources of infection, crop sanitation, crop sequences, application of organic manures and mulches, irrigation systems and using resistant cultivars ; Physical practices- ultraviolet- C (UV-C), different forms of heat, and modification of storage atmosphere; Chemical, and biological control methods.	Cereal grains, fruits, and vegetables	Fungal, bacterial and viral pathogens at pre- and postharvest stages of crop production	Detailed book (578 pp.) on postharvest pathogens - rapid detection and identification and disease management
139.	G	PQOI (Plant Quarantine Organization of India), 2005. Requirements for establishment of pest free areas for Tephritid fruit flies. NSPM-14, Directorate of Plant protection, Quarantine & Storage (Dte of PPQS), 29pp.	Whole document	Establishment of pest free areas for Tephritid fruit flies	Fruits; Fruit trees	*Bactrocera, Anastrepha, Ceratitis,*	Guidance and requirements for establishment, maintenance and verification of pest free areas
140.	G	Schröder T, McNamara DG and Gaar V, 2009. Guidance on sampling to detect pine wood nematode *Bursaphelenchus xylophilus* in trees, wood and insects. OEPP/EPPO Bulletin 39,	Whole document	Definition of pest free area	Trees, woods	Pine wood nematode	Guidance on sampling

		179–188.					
141.	E	Sosnowski MR, Fletcher JD,Daly AM, Rodoni BC and Viljanen-Rollinson SLH, 2009. Techniques for the treatment, removal and disposal of host material during programmes for plant pathogen eradication. Plant Pathology, 58, 621–635	Whole document Review article	Eradication of plant pathogen using burning, burying, pruning, composting, soil- and biofumigation, solarization, steam sterilization and biological vector control	Different host plants of the pathogens	Fungal, bacterial and viral pathogens:black Sigatoka of banana, apple scab, maize smut, fireblight, citrus canker and sharka disease of stone-fruit crops	Techniques for the treatment, removal and disposal of affected host plants are described
Group 15: Options ensuring that the area, place or site of production or crop is free from the pest - Pest free production site (PRA step: Entry and Establishment/Spread/Impact)							
142.	G	FAO (Food and Agriculture Organization of the United Nations), 1995. ISPM (International Standards for Phytosanitary Measures) No 4. Requirements for the establishment of pest free areas. 8 pp.	Whole document	Establishment of pest free area	Not specific	Not specific	
143.	G	FAO (Food and Agriculture Organization of the United Nations), 1997. ISPM (International Standards for Phytosanitary Measures) No 6. Guidelines for surveillance. 15 pp.	Whole document	Guidelines for surveillance	Not specific	Not specific	
144.	G	FAO (Food and Agriculture Organization of the United Nations), 1998. ISPM (International Standards for Phytosanitary Measures) No 8. Determination of pest status in an area. 12 pp.	Whole document	Determination of pest status (presence, absence, low prevalence etc.)	Not specific	Not specific	
145.	G	FAO (Food and Agriculture Organization of the United Nations), 1998. ISPM (International Standards for Phytosanitary Measures) No 9. Guidelines for pest eradication programmes. 10 pp.	Whole document	Guidance for eradication	Not specific	Not specific	
146.	G	FAO (Food and Agriculture	Whole	Establishment of pest free	Not specific	Not specific	

		Organization of the United Nations), 1999. ISPM (International Standards for Phytosanitary Measures) No 10. Requirements for the establishment of pest free places of production and pest free production sites. 16 pp.	document	places of production and pest free production sites			
147.	G	Schröder T, McNamara DG and Gaar V, 2009. Guidance on sampling to detect pine wood nematode *Bursaphelenchus xylophilus* in trees, wood and insects. OEPP/EPPO Bulletin 39, 179–188.	Whole document	Definition of pest free area	Trees, woods	Pine wood nematode	Guidance on sampling
Group 16: Options ensuring that the area, place or site of production or crop is free from the pest - Inspections, Surveillance (PRA step: Entry and Establishment/Spread/Impact)							
148.	E	Dallot S, Gottwald T, Labonne G and Quiot JB, 2004. Factors Affecting the Spread of Plum pox virus Strain M in Peach Orchards Subjected to Roguing in France. Phytopathology 94(12), 1390-1398.	Whole document	Rouging, Field control	Fruit	virus	Modelling of disease reduction option
149.	O	Gupta A, 2010. Emerald Ash Borer First Detector: a volunteer early detection programme. New Zealand Journal of Forestry Science 40 (2010) 123-132.	Whole document	Survey, surveillance	Forest tree	insect	Volonter inspector network
150.	G	Martin RR, 2000. Appendix I – Recommended procedures for detection of viruses of small fruit crops. USDA-ARS-HCRL, 14 pp.	Whole document	Inspection, detection	fruit	virus	Definition of standarts and procedur to validate reagents and protocols of detection
151.	G	McMaugh T, 2005. Guidelines for surveillance for plant pests in Asia and the Pacific. Australian Centre for International Agricultural Research, 55pp.	Whole document	survey	All crops	pest	Australian official Guidance for survey of plant pest in pacific area
152.	G	USDA (United States Department of Agriculture) APHIS (Animal and Plant Health Inspection Service),	Whole document	inspection	All crops	Pest and disease	US Post entry manual for State inspectors

		2011. Postentry quarantine manual for State inspectors. 1/2011-2 PPQ. 334pp.					
153.	E	Sigvald R and Hulle M, 2004. Aphid-vector management in seed potatoes: monitoring and forecasting. 12th EAPR Virology Section Meeting Rennes, France, 2004, 8-11.	Whole document	surveillance	Potato tuber	aphis	Model to monitoring and forcasting
154.	E	Wardlaw T, Bashford R, Wotherspoon K, Wylie R and Elliot H, 2008. Effectiveness of routine forest health surveillance in detecting pest and disease damage in eucalypt plantations. New Zealand Journal of Forestry Science, 38(2/3), 253-269.	Whole document	inspection	Forest tree	various	Comparison of surveillance technique to assess the impact of disease and pest in forest
Group 17: Options for other types of pathways - Natural spread, by human activities (people movement, transports, machineries...), vectors, phoresy (PRA step: Entry and Spread)							
155.	O	Evans HF, Schröder T, Mota MM, Robertson L, Tomiczek C, Burgermeister W, Castagnone-Sereno P and de Sousa EMR, 2007. QLK5-CT-2002-00672: Development of improved pest risk analysis techniques for quarantine pests, using pinewood nematode, *Bursaphelenchus xylophilus*, in Portugal as a model system. PHRAME – Plant Health Risk And Monitoring Evaluation. 246 pp.	Pages 128-135 Pages 180-217	Insecticides, nematicides, traps and lures modelling of ecoclimatic risk factors	*Bursaphelenchus xylophilus*	project for Portugal, Spain and the Iberian peninsula	
Group 18: Other relevant information							
156.	G	Addobediako A, Baharnu T, Jackai LEN and Bonsi CK, 2007. Assessment of Risk of Introduction of *Cylas formicarius elegantulus* (Coleoptera: Brentidae) into Weevil-Free Areas in the Southern United States J. Econ. Entomol. 100(2): 315-321.	Whole document	Reduction of introduction	Sweet potato, *Ipomoea batatas*	Sweet potato weevil (*Cylas formicarius elegantulus)*	Quantitative risk model to estimate the probability of introduction

157.	G	Webber J, 2010. Pest risk analysis and invasion pathways for plant pathogens. New Zealand Journal of Forestry Science 40 suppl., S45-S56.	Whole document	Management on pathways than the pest		Plant pathogens	Overview article Risk presented by the import of plants for planting; Genetic change and adaptationof the pathogens in new environments
158.	G	Follet PA and Vick KW, 2002. Desarrollo de estrategias de manejo integrado de plagas para eliminar las barreras sanitarias que restringen la exportación de productos agrícolas. Manejo Integrado de Plagas y Agroecolog.a (Costa Rica), 65, 43-49.	Whole document	System approach	Not specific	Not specific	In Spanish
159.	G	Bartell SM and Nair SK, 2003. Establishment Risks for Invasive Species. Risk Analysis, 24(4), 833-845.	Whole document	Reduction of entry	Not specific	Not specific	Quantitative approach based on a population model
160.	G	MAF (Ministry of Agriculture and Forestry) Biosecurity New Zealand, 2002a. MAF Biosecurity Authority (Plants) Standard 155.02.04: Import Health Standard for Cut Flowers and Foliage. 19 pp.	Whole document	Reduction of entry	Cut flowers and foliage	Not specific	Phytosanitary requirements for importation/clearance in NZ (e.g. sampling)
161.	G	MAF (Ministry of Agriculture and Forestry) Biosecurity New Zealand, 2002b. MAF Biosecurity Authority (Plants) Standard 155.09.05: Clearance of Fresh Cut Flowers and Foliage. 25 pp.	Whole document	Reduction of entry	Cut flowers and foliage	Not specific	Phytosanitary requirements for importation/clearance in NZ (e.g. sampling)
162.	G	MAF (Ministry of Agriculture and Forestry) Biosecurity New Zealand, 2003. Import Health Standard for Bark from All Countries, 14 pp.	Whole document	Reduction of entry	Bark	Not specific	Phytosanitary requirements for clearance in NZ (e.g. fumigation, heat treatment)
163.	G	MAF (Ministry of Agriculture and Forestry) Biosecurity New Zealand, 2009. Wood packaging material from all countries. 9pp.	Whole document	Reduction of entry	Wood packaging	Not specific	Phytosanitary requirements for clearance in NZ (e.g. fumigation, heat treatment)

164.	G	MAF (Ministry of Agriculture and Forestry) Biosecurity New Zealand, 2010. MAF Biosecurity New Zealand Import Health Standard 155.02.05: Importation of Seed for Sowing. 158 pp.	Whole document	Reduction of entry	Seed	Not specific	Phytosanitary requirements for importation in NZ (e.g., sampling)
165.	G	MAF (Ministry of Agriculture and Forestry) Biosecurity New Zealand, 2011a. MAF Biosecurity New Zealand Standard: 152.02: Importation and Clearance of Fresh Fruit and Vegetables into New Zealand. 414 pp.	Whole document	Reduction of entry	Fruit and vegetables	Not specific	Phytosanitary requirements for importation/clearance in NZ (e.g., sampling)
166.	G	MAF (Ministry of Agriculture and Forestry) Biosecurity New Zealand, 2011b. BNZ-NPP-HUMAN Standard. Importation of Stored Plant Products for Human Consumption into New Zealand. 39 pp.	Whole document	Reduction of entry	Stored plant products	Not specific	Phytosanitary requirements for importation in NZ (e.g., sampling)
167.	G	Merriman P and McKirdy S, 2005. Technical guidelines for development of pest specific response plans. Plant Health Australia, 42 pp.	Whole document	Reduction of entry, establishment and spread	Not specific	Not specific	
168.	G	FAO (Food and Agriculture Organization of the United Nations), 2011. Guide to implementation of phytosanitary standards in forestry. FAO Forestry Paper 164, 118 pp.	Chapters 3 and 4	Reduction of spread	Forest	Not specific	
169.	G	USDA (United States Department of Agriculture) APHIS (Animal and Plant Health Inspection Service), 2010a. Fresh fruits and vegetables import manual. 01/2010-93 PPQ, 608 pp.	Whole document	Reduction of entry	Fruit and vegetables	Not specific	Phytosanitary requirements for importation
170.	G	USDA (United States Department of Agriculture) APHIS (Animal and Plant Health Inspection Service),	Whole document	Reduction of entry	Not specific	Not specific	Inspection monitoring handbook

		2010b. Agricultural Quarantine Inspection Monitoring (AQIM) Handbook. 07/2010-11 PPQ, 209 pp.					
171.	G	USDA (United States Department of Agriculture) APHIS (Animal and Plant Health Inspection Service), 2010c. Seeds not for planting. 11/2010-33 PPQ, 134 pp.	Whole document	Reduction of entry	Seed not for planting	Not specific	Inspection monitoring handbook
172.	G	USDA (United States Department of Agriculture) APHIS (Animal and Plant Health Inspection Service), 2011a. Treatment manual. 10/2010-50 PPQ, 853 pp.	Whole document	Redusction of entry, establishment and spread	Not specific	Not specific	Treatment manual
173.	G	USDA (United States Department of Agriculture) APHIS (Animal and Plant Health Inspection Service), 2011b. Cut flowers and greenery import manual. 05/2011-39 PPQ, 198 pp.	Whole document	Reduction of entry	Cut flowers and greenery	Not specific	Import manual
174.	G	USDA (United States Department of Agriculture) APHIS (Animal and Plant Health Inspection Service), 2011c. Miscellaneous and processed products. 01/2011-07 PPQ, 324 pp.	Whole document	Reduction of entry	Miscellaneous and processed products	Not specific	Import manual
175.	G	USDA (United States Department of Agriculture) APHIS (Animal and Plant Health Inspection Service), 2011d. Plants for planting manual. Interim edition PPQ, 610 pp	Whole document	Reduction of entry	Plants for planting	Not specific	Import manual
176.	E	Bogich TL, Liebhold AM and Shea K, 2008. To sample or eradicate? A cost minimization model for monitoring and managing an invasive species. Journal of Applied Ecology, 45, 1134–1142.	Whole document	Detection and erradication		Gypsy moth	Simulation study
177.	G	EFSA Panel on Plant Health	Section 4	Not specific	Not specific	Not specific	Harmonized framework

		(PLH), 2010a. Guidance on a harmonised framework for pest risk assessment and the identification and evaluation of pest risk management options by EFSA. EFSA Journal 2010; 8(2):1495, 66 pp.					
178.	E	EFSA Panel on Plant Health (PLH), 2010b. Risk assessment of the oriental chestnut gall wasp, *Dryocosmus kuriphilus* for the EU territory on request from the European Commission. EFSA Journal 2010; 8(6):1619, 114 pp.	Section 3	Not specific	chestnut	Dryocosmus kuriphilus	
179.	E	Mastro V, Lance D, Reardon R and Parra G, 2007. Emerald ash borer – Research and development meeting. October 23-24, 2007 Pittsburgh, Pennsylvania, 136 pp.	P38-86	Not specific	Wood	Emerald ash borer	Proceedings
180.	E	Powell MR, 2002. A model for probabilistic assessment of phytosanitary risk reduction measures. Plant Dis. 86, 552-557.	Whole document	Heat treatment	Wood	Not specific	Optimization of temperature and duration
181.	G	Quinlan MM and Ikin R, 2009. A review of the application of Systems Approach to risk management in plant health. EU Framework 7 Research Project, PRATIQUE (Enhancements of Pest Risk Analysis Techniques). Deliverable number: 4.2 Date: 30/10/2009, 58 pp.	Whole document	System approach	Not specific	Not specific	Review of the application of systems approach and best practices
182.	E	Bogich T and Shea K, 2008. A state-dependent model for the optimal management of an invasive metapopulation. Ecological Applications, 18(3), 748–761.	Whole document	Not specific	Not cpecific	Not specific	Model for assessing RRO
183.	E	Stansbury CD, McKirdy SJ, Diggle Aj and Riley IT,	Whole document	Not specific	wheat	Tilletia indica	Model for assessing RRO

		2002. Modeling the risk of entry, establishment, spread, containment, and impact of *Tilletia indica*, the cause of karnal bunt of wheat, using an Australian context. Phytopathology, 92(3), 321-331.					
184.	G	IOBC (International Organization for Biological and Integrated Control of Noxious Animals and Plants), 2002. Guidelines for integrated production of pome fruits. IOBC wprs Bulletin 25(8), 11pp.	the whole document	technical guidelines for integrated production of pomefruits	pomefruits	general	healthy growing and integrated management methods
185.	G	IOBC/WPRS (International Organization for Biological and Integrated Control of Noxious Animals and Plants, West Palearctic Regional Section), 2002. Guidelines for integrated production of olives. IOBC wprs Bulletin, 25(4), 11pp.	the whole document	technical guidelines for integrated production of olives	olives	general	healthy growing and integrated management methods
186.	G	IOBC (International Organization for Biological and Integrated Control of Noxious Animals and Plants), 2003. Guidelines for integrated production of stone fruits. IOBC wprs Bulletin, 26(x), 10pp.	the whole document	technical guidelines for integrated production of stone fruits	stone fruits (peach, nectarine, apricot, plum and cherry)	general	healthy growing and integrated management methods
187.	G	IOBC/WPRS (International Organization for Biological and Integrated Control of Noxious Animals and Plants, West Palearctic Regional Section), 2005. Guidelines for integrated production of citrus. IOBC wprs Bulletin, 28( ), 10pp.	the whole document	technical guidelines for integrated citrus production	citrus fruits	general	healthy growing and integrated management methods
188.	G	Vickery J, webpage. Integrated Fruit Production (IFP): An Overview of Programmes. Available from http://www.pmac.net/intefrt.htm	the whole document	overview of guidelines for integrated fruit production	fruits, grapes	general	list of references with comment

C. Appendix A: Comparison between the criteria presented in ISPM No 28 and the checklists in section 2.2. 2. and 2.2.3. of this document

ISPM 28 Phytosanitary treatments for regulated pests (FAO, 2007)

PT 1: 2009 - IRRADIATION TREATMENT FOR *ANASTREPHA LUDENS*
PT 2: 2009 - IRRADIATION TREATMENT FOR *ANASTREPHA OBLIQUA*
PT 3: 2009 - IRRADIATION TREATMENT FOR *ANASTREPHA SERPENTINA*
PT 4: 2009 - IRRADIATION TREATMENT FOR *BACTROCERA JARVISI*
PT 5: 2009 - IRRADIATION TREATMENT FOR *BACTROCERA TRYONI*
PT 6: 2009 - IRRADIATION TREATMENT FOR *CYDIA POMONELLA*
PT 7: 2009 - IRRADIATION TREATMENT FOR FRUIT FLIES OF THE FAMILY *TEPHRITIDAE* (GENERIC)
PT 8: 2009 - IRRADIATION TREATMENT FOR *RHAGOLETIS POMONELLA*
PT 9: 2010 - IRRADIATION TREATMENT FOR *CONOTRACHELUS NENUPHAR*
PT 10: 2010 - IRRADIATION TREATMENT FOR *GRAPHOLITA MOLESTA*
PT 11: 2010 - IRRADIATION TREATMENT FOR *GRAPHOLITA MOLESTA* UNDER HYPOXIA
PT 12: 2011 - IRRADIATION TREATMENT FOR *CYLAS FORMICARIUS ELEGANTULUS*
PT 13: 2011 - IRRADIATION TREATMENT FOR *EUSCEPES POSTFASCIATUS*
PT 14: 2011 - IRRADIATION TREATMENT FOR *CERATITIS CAPITATA*

Checklists in sections 2.2.2. and 2.2.3.	**ISPM No 28**
Plant material information	
Type of plant material/product used in the experiment	
Plant identity (e.g. botanical name, variety)	
Conditions under which plant materials/products are managed	
Conditions of the plant commodity (e.g. degree of ripeness, presence of bark, etc.)	

Checklists in sections 2.2.2. and 2.2.3.	**ISPM No 28**
Pest information	
Identity (species- strains biotypes if applicable-)	
Conditions under which the pests are cultured, reared or grown	
Method of infestation	
Level of infestation	
Stage of the pest that is most resistant to the treatment (refer to research data if relevant)	
Was the most resistant stage used in the experiment?	
Potential development of resistance to the option	
Experiment(s) description and analysis	
Objectives (maximal pest density acceptable) For example, ISPM No 15 presently relies on the probit 9 norm (100% mortality of at least 93 613 test organisms, at a reliability of 0.99994) regarding the prevalence of pine wood nematodes (*Bursaphelenchus xylophilus*) in wood packaging material (IPPC, 2009). See also section 3.2.3.2 for a discussion on the use of probit 9.	
Level of confidence of laboratory or field test	Level of confidence of laboratory tests
Variables used to measure effectiveness (e.g., mortality rate, count)	Methodology to measure the effectiveness of the treatment (e.g. whether mortality is the proper parameter, whether the end-point mortality was assessed at the correct time, the mortality or sterility of the treated and control groups)

Checklists in sections 2.2.2. and 2.2.3.	**ISPM No 28**
Factors influencing effectiveness which were taken into account in the experiment (e.g., wood humidity)	Monitoring of critical parameters (e.g. exposure time, dose, temperature of regulated article and ambient air, relative humidity);
Factors influencing effectiveness which were **not** taken into account in the experiment (e.g., wood humidity)	
Description of facilities and equipment	Experimental facilities and equipment
Description of treatment (e.g., temperature/duration, chemicals, concentration)	Experimental conditions (e.g. temperature, relative humidity, diurnal cycle)
Methodology followed for monitoring critical parameters (e.g., number and placement of temperature sensors)	
	Determination of effectiveness over a range of critical parameters, where appropriate, such as exposure time, dose, temperature, relative humidity and water content, size and density
Description of experimental design (e.g., randomization, blocks, number of replicates)	Experimental design
Presentation of the data	
Description of the statistical analysis (e.g., anova, regression, test)	
Conclusions of the experiment	
Other relevant information	Methodology to measure phytotoxicity, when appropriate; dosimetry system, calibration and accuracy of measurements, if using irradiation