RISK-BASED SAMPLING (RBS) MANUAL – PART I

Multi-authored manual on the what, why and how of RBS

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PREFACE

***Stephanie Bloem*[1]**

1. Executive Director for the North American Plant Protection Organization

The internationally accepted *Glossary of Phytosanitary Terms* (ISPM 5) defines a national plant protection organization (NPPO) as the "official service established by a government to discharge the actions specified by the International Plant Protection Convention (IPPC)". These functions encompass all actions needed to protect the plant resources of a country from the introduction and/or spread of plant pests. In addition to the roles stated in the text of the IPPC (FAO, 1997), NPPOs are encouraged to align their plant health or phytosanitary measures with adopted international standards for phytosanitary measures (ISPMs) developed by the IPPC. This alignment promotes harmonization of phytosanitary measures and is a central element of both the IPPC and the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (the WTO-SPS Agreement).

As stated in the IPPC, inspection of consignments of plants moving in international trade and, where appropriate, inspection of other regulated articles to prevent the introduction and/or spread of pests is an NPPO function. Inspection is the most widely used phytosanitary measure around the world, is supported by two specific ISPMs (see below) and is mentioned in many other adopted ISPMs.

ISPM 23 (*Guidelines for Inspection,* adopted in 2005) describes procedures for inspection of consignments at import and export. It focuses on the determination of a consignment's compliance with phytosanitary regulations, based on visual examination, as well as on verification of documentation, identity, and integrity of the consignment.

ISPM 31 (*Methodologies for Sampling of Consignments,* adopted in 2008) provides guidance to NPPOs in selecting sampling methodologies for inspection (or testing) of consignments to verify compliance with phytosanitary requirements. The methodologies are based on several common (statistically based) sampling concepts and include parameters such as acceptance level, level of detection, confidence level, efficacy of detection and sample size, and result in data with an associated statistical level of confidence.

ISPMs 23 and 31 tell us that inspection:

- is a (phytosanitary) risk management procedure;
- should be technically justified and fairly applied in the same way as other phytosanitary measures;
- is sampling and, as such, should consider sampling concepts;
- can have a deliberate design – statistical or non-statistical;

- data derived from well-designed schemes is a key source of information for risk analysis and resource management (including inspection personnel and budgets to fund this activity).

Sampling methodologies that are not statistically based (such as convenience, haphazard, percentage-based or selective sampling) may provide valid data on the presence or absence of a regulated pest, but limited statistical inferences can be made from the data. It is also important to remember that even though inspection using statistically based sampling methodologies provide results with a certain level of confidence, they cannot categorically prove the absence of a pest from a consignment – therefore NPPOs must accept some degree of risk that non-conforming consignments may not be detected during inspection.

Laboratory selection of fruit samples for inspection and testing.
Source - https://twitter.com/ICACOLOMBIA/status/1247576792145301506/photo/1

ISPM 20 (*Guidelines for a phytosanitary import regulatory system*, adopted in 2017) indicates that inspections may be conducted at the point of entry (import), at points of trans-shipment, at the point of destination or at other places, such as major markets, provided consignment integrity is maintained and appropriate phytosanitary procedures can be carried out. Bilaterally agreed inspections may also be done in the country of origin (export) as a part of a pre-clearance program in cooperation with the NPPO of the exporting country. Phytosanitary inspections may be applied to all consignments as a condition of entry or as a part of an import monitoring program where the level of monitoring (i.e., the number of consignments inspected) is established based on predicted risk.

ISPMs 23 and 31 were adopted more than 10 years ago but their implementation has fallen short of expectations even though the fate of thousands of consignments around the world is decided every day based on inspection for both the certification of exports and the clearance of imports. Proper implementation of these ISPMs requires a common understanding of the conceptual, operational, and policy consequences of different inspection designs and their relationship to the principles of safe trade (Griffin, 2017).

Many NPPOs currently use inspection designs that result in data that is not as useful for risk management decisions as it could be. In many cases this is because the conceptual background for inspection is not well-understood by NPPOs. Historical thoughts on inspection were that its purpose was to find pests, establish or confirm their identification, determine their regulatory status, and then take the appropriate (risk management) action. This way of thinking resulted in countries focusing their inspection data gathering efforts on lists of pest interceptions and action records on those pests and not on the results of inspection that produced negative finds (where the data point for inspection = zero pests found).

The WTO-SPS Agreement tells us that inspection is a phytosanitary measure and must be fair, technically justified and applied consistently for similar situations and risk levels. As such, inspection designs should follow relevant international standards (ISPMs 23 and 31) and pest-actions resulting from inspections should be based on Pest Risk Analysis (PRA), appropriate adopted ISPMs, or emergency (urgent) measures.

The RBS Manual Part I is one of the deliverables resulting from the first International Symposium for Risk-Based Sampling co-organized by the North American Plant Protection Organization (NAPPO) and the United States Department of Agriculture, Animal and Plant Health Inspection Service, Plant Protection and Quarantine (USDA-APHIS PPQ). The Symposium was held in mid-2017 in Baltimore, Maryland, USA. The primary objective of the Symposium was to promote harmonization though a common understanding and shared experiences in the implementation of ISPMs 23 and 31. The Symposium Agenda was designed by an RBS Steering Committee composed of subject matter experts from the three NAPPO member countries. The Symposium was attended by 122 participants from 27 countries. Symposium speakers and participants included professionals representing 31 government agencies, 4 academic institutions, 15 industries and 3 international organizations. A Symposium Proceedings was published in 2018 in English and Spanish and is available electronically at: https://www.nappo.org/application/files/4215/8746/3813/RBS_Symposium_Proceedings_-10062018-e.pdf and https://nappo.org/application/files/8915/9350/0775/RBS_Symposium_Proceedings_-_10062018-s.pdf

Since publishing the Symposium Event Report available at – https://www.nappo.org/english/workshops/2017-International-Symposium-for-RBS and https://www.nappo.org/espanol/Talleres/2017-Taller-sobre-Muestreo-Fundamentado-en-el-Riesgo-MFR - NAPPO has continued to raise awareness and promote the implementation of Risk-Based Sampling though developing, collecting and making available relevant resources on RBS. Among these is the Proceedings, a repository of publications relevant to the topic, a narrated Training Module, and more recently a Sample Size Calculator and a Practical Exercise comparing the results of percentage-based and Risk-Based Sampling. The RBS Manual Part I will be added as another resource to assist with the implementation of phytosanitary Risk-Based Sampling.

The RBS Manual Part I can assist/guide NPPOs in reframing their inspection designs in order to generate statistically valid data that supports a risk-based approach to inspection. Risk-based inspection designs provide a consistent and reliable measure of action rates for high-risk commodities, approach rates for pests, and infestation rates for imported consignments. This process takes time and is iterative, but ultimately results in inspection programs that are better equipped to identify and rank non-compliant imports. Ranking based on pest interceptions and their associated action rates will help inspectors and policy makers identify riskier imports and then be able to adjust policies and resources (both human and monetary) to maximize the effectiveness of their inspection programs. This will result in technically justified inspection procedures.

The RBS Manual Part I addresses the fundamentals of RBS, including what, why, and how questions. The emphasis of Part I is on developing familiarity with RBS, its benefits, and the practical aspects of its implementation. Part I is designed to provide enough information for early steps of implementing the shift to RBS. Part II of the Manual – to be published in the future - follows with greater technical detail and additional reference material for more in-depth guidance on implementation of RBS.

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1. GLOSSARY AND DEFINITIONS

Acceptance sampling plan: A type of RBS plan where the cumulative results of inspections of lots dynamically determine inspection status (e.g., reduced, or standard) (NAPPO, 2017).

Acceptable level of risk: Concept through which an acceptable probability level for pest introduction is established (Sgrillo, 2004).

Action rate (or non-compliance rate): The number of phytosanitary actions for a particular volume in a specified pathway. The pathway could be a commodity, location, or type of movement (e.g., onions, port X, or maritime respectively). When pest detections are used as a proxy for pest risk, only actionable pest detections are counted to be risk-based (NAPPO, 2017).

Approach rate: The number of times a specific pest (or pest group/type) is found associated with a particular volume in a specified pathway (NAPPO, 2017).

Consignment: A quantity of plants, plant products or other articles being moved from one country to another and covered, when required, by a single phytosanitary certificate. A consignment may be composed of one or more commodities or lots (See definition of "lot" below. [FAO, 1990; revised ICPM, 2001] (FAO, 2019).

Efficacy (of a phytosanitary measure): Reduction in the probability of pest establishment that is achieved by the application of a phytosanitary measure. For hypergeometric sampling, efficacy may be thought of as the proportion of consignments with prevalence above the fixed threshold that are detected at a specified confidence level (Sgrillo, 2002).

Effectiveness of inspection: The degree to which the inspection is successful in finding a pest.

Establishment (of a pest): Perpetuation, for the foreseeable future, of a pest within an area after entry [FAO, 1990; revised ISPM 2, 1995; IPPC, 1997; formerly "established"] (FAO, 2019).

Euphresco: Network of organisations funding research projects and coordinating national research in the phytosanitary area, Euphresco is hosted by the European and Mediterranean Plant Protection Organization - EPPO.

Infestation level: The infestation level is defined as the percentage or proportion of infested units in the consignment or lot. The infestation level of the consignment is not likely to be known. The level of infestation to be detected should be fixed by the NPPO so that a sampling regime can be established (OEPP/EPPO, 2006). "Infested" in this context refers to infestation with quarantine pests or actionable pests.

Infestation rate: The total number of units estimated to have actionable pests in a specific volume (usually a consignment) based on sampling results.

Inspection: Official visual examination of plants, plant products or other regulated articles to determine if pests are present or to determine compliance with phytosanitary regulations [FAO, 1990; revised FAO, 1995; formerly "inspect"] (FAO, 2019).

Inspection unit (also known as the sample unit): The unit of a consignment designated for sampling and inspection purposes (e.g., a plant, a box, a tray) (NAPPO, 2017).

Inspection efficiency (or pest detection rate): The likelihood of finding a pest or pests that are present on a commodity (NAPPO, 2017). Inspection efficiency is important because it affects our estimates of how many pests or infested shipments inspectors will find and should inform sampling design and management decisions.

Also known statistically as "sensitivity." This variable depends mostly on how proficient an inspector is at pest detection. We know that inspector efficiency is never 100%, even though many sampling designs assume 100% and ignore this factor in calculations. The best available data shows it is somewhere between 20% and 80% (although 80% is probably rare and would be a generous assumption). Assumptions regarding inspection efficiency should be carefully considered in sample calculations, given that they can affect/bias outcomes. It is important to be consistent in efficiency assumptions, so even if the inspection results are biased, they can be analyzed and compared for risk-based adjustments.

Laboratory testing: Examination, other than visual, to determine if pests are present using official diagnostic protocols. Diagnostic protocols describe the minimum requirements for reliable diagnosis of regulated pests. Laboratory testing is often combined with inspection in a tiered approach to detection and identification (EFSA Panel on Plant Health (PLH), 2018)

Leakage rate (also known as slippage): Estimated number of undetected actionable pests in a specific volume. Alternatively, the estimated number of consignments in a specific volume that are infested with actionable pests but are released without action (NAPPO, 2017)**.**

Level of confidence: The level of confidence corresponds to the percentage of success in discovering a defect (OEPP/EPPO, 2006). In this context defect is understood as pest.

Lot: A number of units of a single commodity, identifiable by its homogeneity of composition, origin etc., forming part of a consignment [FAO, 1990] (FAO, 2019).

National Plant Protection Organization (NPPO): Official service established by a government to discharge the functions specified by the IPPC [FAO, 1990; formerly "plant protection organization (national)"] (FAO, 2019)

Outbreak: A recently detected pest population, including an incursion, or a sudden significant increase of an established pest population in an area [FAO, 1995; revised ICPM, 2003] (FAO, 2019).

Pathway: Any means that allows the entry or spread of a pest [FAO, 1990; revised FAO, 1995] (FAO, 2019).

Percentage-based sampling: Establishing the sample size for inspection based on a percentage of the lot size.

Pest: Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products. Note: In the IPPC, “plant pest” is sometimes used for the term “pest” [FAO, 1990; revised ISPM 2, 1995; IPPC, 1997; CPM, 2012] (FAO, 2019).

Pest action rate: Number of quarantine actions performed on a commodity divided by the total number of inspections performed on that commodity (NAPPO, 2017).

Pest risk management: Evaluation and selection of options to reduce the risk of introduction and spread of a pest (Devorshak, 2012)

Phytosanitary import requirements: Specific phytosanitary measures established by an importing country concerning consignments moving into that country [ICPM, 2005] (FAO, 2019).

Phytosanitary measures: Any legislation, regulation or official procedure having the purpose to prevent the introduction or spread of quarantine pests, or to limit the economic impact of regulated non-quarantine pests [ISPM 4, 1995; revised IPPC, 1997; ICPM, 2002] The agreed interpretation of the term phytosanitary measure accounts for the relationship of phytosanitary measures to regulated non-quarantine pests. This relationship is not adequately reflected in the definition found in Article II of the IPPC (1997). (FAO, 2019).

Probability: Defined depending on philosophical perspective: (1) the frequency with which samples arise within a specified range or for a specified category; (2) quantification of uncertainty as degree of belief regarding the likelihood of a particular range or category (EFSA Scientific Committee, 2018a). Probabilities are often expressed as proportions or as percentages (EFSA Panel on Plant Health (PLH), 2018).

Quarantine pest: A pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled [FAO, 1990; revised FAO, 1995; IPPC 1997] (FAO, 2019).

Regulated non-quarantine pest: A non-quarantine pest whose presence in plants for planting affects the intended use of those plants with an economically unacceptable impact and which is therefore regulated within the territory of the importing contracting party [IPPC, 1997] (FAO, 2019).

Risk: The likelihood of the occurrence and the likely magnitude of the consequences of an adverse event to animal or human health in the importing country during a specified time period, as a result of a hazard (CBD, 2018)

Risk-Based Inspection (RBI): An inspection design that concentrates effort on sources of imports with problematic inspection histories (NAPPO, 2017).

Risk-Based Sampling Approach (RBSA): An approach to inspections that prescribes sampling frequencies based on compliance history, origin, and intended use of the commodity (NAPPO, 2017).

Risk-Based Sampling (RBS): Sampling that takes account of the probability of detection to determine the sample size for an inspection. The number of items to be inspected will vary depending on the level of infestation to be detected, the size of the consignment, and the pest risk. In RBS sampling frequencies are based on the relationship between actionable pest detections and specific inspection variables (e.g., type of commodity, origin, consignee, etc.) (NAPPO, 2017).

Safe trade: The objective that is achieved by implementing phytosanitary measures that are justified by the risk, recognizing that neither unrestricted trade nor fully restricted trade is a feasible objective.

Sample size: The sample size is the number of units selected from the lot or consignment that will be inspected or tested (FAO, 2016a).

Sampling inspection: Sampling for phytosanitary inspection of consignments or lots is a form of 'discovery sampling'. Samples are taken from a finite population (the consignment or lot) without replacement of the units selected. The consignment or lot is rejected if one or more defects are detected in the sample (OEPP/EPPO, 2006). Pests or regulated articles targeted in phytosanitary inspections are considered "defects".

Single window: A facility that allows parties involved in trade and transport to lodge standardized information and documents with a single-entry point to fulfill all import, export, and transit-related regulatory requirements.

Skip-lot sampling: Inspection designs that allow for consignments to be released without inspection.

Strength of phytosanitary measures: the level of restrictiveness achieved from the application of prescribed phytosanitary measures. The term comes from Article II of the IPPC (Use of Terms) in the definition of pest risk analysis:

*"…the process of evaluating biological or other scientific and economic evidence to determine whether a pest should be regulated and **the strength of any phytosanitary measures** to be taken against it;" (emphasis added)*

Note. The strength of measures is not the same as the efficacy of measures. Measures may be effective at reducing risk without being restrictive and likewise, measures may be restrictive without being effective at reducing risk. For instance, many measures that are normal industry practices, (e.g., washing fruit), are effective for risk mitigation without being restrictive. On the other hand, prohibition is highly restrictive to trade but often increases the risk because it encourages smuggling. As implied by the definition, the strength of measures is strongly related to pest risk analysis where the factors of restrictiveness and effectiveness are weighed with other factors in the risk management process.

Target detection level: The level of detection for presence of a pest or contaminant that is based on the risk and practical considerations, and accounting for relevant statistical parameters affecting the probability.

Example: A target detection level of 5% means that the detection process e.g., inspection, surveillance, or laboratory testing, is designed to detect a pest or contaminant when its presence exceeds 5% with 95% confidence.

Technically justified: Justified on the basis of conclusions reached by using an appropriate pest risk analysis or, where applicable, another comparable examination and evaluation of available scientific information (FAO, 2011).

Test: Official examination of plants, plant products or other regulated articles, other than visual, to determine if pests are present, identify pests or determine compliance with specific phytosanitary requirements [FAO, 1990; revised CPM, 2018] (FAO, 2019)

Tolerance level: Tolerance level refers to the percentage of infestation in a consignment or lot that is the threshold for phytosanitary action (FAO, 2016a).

Visual examination: Examination using the unaided eye, lens, stereoscope or other optical microscope [ISPM 23, 2005; revised CPM, 2018] (FAO, 2019).

WTO-SPS Agreement: World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (WTO, 2019)

Note: other pertinent definitions are included in the text of this manual when the term is introduced or can be found in ISPM 5 Glossary of phytosanitary terms and RSPM 5 Guidelines for the establishment and application of emergency actions and emergency measures.

2. ACRONYMS AND ABBREVIATIONS

ALOP: Appropriate Level of Protection

APHIS-PPQ: Animal and Plant Health Inspection Service - Plant Protection and Quarantine

ASEAN: Association of Southeast Asian Nations

CBD: Convention on Biological Diversity

CPHST: Center for Plant Health Science and Technology

EFSA: European Food Safety Authority

EPPO: European and Mediterranean Plant Protection Organization **(OEPP:** Organisation Européenne et Méditerranéenne pour la Protection des Plantes)

FAO: Food and Agriculture Organization of the United Nations

IPPC: International Plant Protection Convention, as deposited in 1951 with FAO in Rome and as subsequently amended [FAO, 1990; revised ICPM, 2001] (FAO, 2019).

ISPM: International Standards for Phytosanitary Measures

NAPPO: North American Plant Protection Organization

NARP: National Agriculture Release Program (US)

NPPO: National Plant Protection Organization

OSCE: Organization for Security and Co-operation in Europe

RBS: Risk-Based Sampling

UNECE: United Nations Economic Commission for Europe

USDA: United States Department of Agriculture

WTO-SPS: World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (1994)

WTO-TF: World Trade Organization Trade Facilitation Agreement (2017)

3. RBS: FREQUENTLY ASKED QUESTIONS

Robert Griffin[1], Stephanie Bloem[2] and Maribel Hurtado[3]

1. National Coordinator for Agriculture Quarantine Inspection USDA, APHIS, PPQ - Retired
2. Executive Director for the North American Plant Protection Organization
3. Project Manager for RBS

3.1. What is Risk-Based Sampling?

Risk-Based Sampling (RBS) is an inspection design that takes account of the probability of detection to determine the sample size for an inspection. It consistently achieves a specific level of detection and confidence and is adjusted to correspond to different levels of risk. This means that the number of items to be inspected will vary depending on the level of infestation to be detected, the size of the consignment, and the pest risk. For additional information see Chapters 4 and 6.

3.2. Does RBS require more resources?

The objective of RBS is not to increase or decrease the resources devoted to inspection, but rather to maximize the effectiveness of existing inspection efforts. In many cases, the NPPO will realize resource savings as unnecessary inspection effort on large consignments is reduced. In other cases, the inspection effort will be increased as more effort is devoted to small consignments that had been under-inspected in the past. RBS provides the basis for objectively measuring and comparing the pest risk for different consignments based on actionable interceptions. For additional information see Chapter 7.

3.3. Is it necessary to have a statistician to implement RBS?

RBS is based on conventional statistical concepts that are well-known and widely practiced in research and other disciplines where sampling is done (e.g., quality control in manufacturing). The simplest implementation of RBS requires only a calculator or table to determine the sample size for a specific level of detection in a specific size consignment and to randomize samples. However, the results of RBS inspections provide data which is useful for many other analyses which can take advantage of statistical expertise. Consistent inspection results make it possible for phytosanitary actions to be correlated to numerous different variables such as pests, pathways, ports, or any other trade variable. Infestation rates can be calculated for individual consignments, true approach rates can be calculated and tracked for pests, and the same can be done for action rates on commodities/pathways. For additional information see Chapters 7 and 10.

3.4. Are special locations or equipment required for RBS?

Randomization of the sample universe provides statistical confidence and promotes the detection of pests and trends that might be otherwise unnoticed. Enough secure space and equipment for unloading and manipulating cargo is needed to ensure access to every sample unit in a consignment for a full random inspection. Conditions and resources may limit the possibilities for full and frequent randomization, but the more randomization that can be done, the higher the confidence in results. For additional information see Chapter 5.

3.5. Is the implementation of ISPMs mandatory?

Article 3 of the WTO-SPS Agreement states: … *Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations* (emphasis added). Because the IPPC is the standard setting organization specifically identified in the WTO-SPS Agreement to provide international standards for phytosanitary measures, the ISPMs are obligations under the WTO-SPS Agreement even if they are not legally binding for Contracting Parties to the IPPC.

3.6. Can interceptions represent pest risk?

The number, type and frequency of interceptions that require phytosanitary actions are indicators of risk and can be useful as a proxy for risk in inspection designs. The actual risk for specific pests will vary. A Pest Risk Analysis (PRA) is needed for a full characterization of individual pests or pathways. For additional information see Chapter 4.

3.7. Is inspection an effective phytosanitary measure?

Inspection is rarely 100% and is never 100% effective. There is always some probability that pests will be missed because pests have different levels of detectability and inspectors have different levels of efficiency. For additional information see Chapter 4.

3.8. What confidence level is required for RBS?

The statistical convention for confidence is 95%, i.e., if confidence is not expressed, it is assumed to be 95%. This means that 95 times out of 100, the results will be correct, or 5% of results can be incorrect. Higher levels of confidence require higher rates of sampling and vice versa. For additional information see Chapters 5 and 10.

3.9. Does RBS require more time than traditional inspections?

RBS does not require more time or economic resources than traditional inspection designs. For example, when compared to percentage-based inspection of large consignments, RBS sample sizes are smaller and have specific levels of detection and confidence. RBS optimizes the work of inspectors, allowing them extra time to focus on inspection of higher risk consignments.

3.10. What are the advantages of RBS for countries that mostly trade in small consignments?

Risk-Based Sampling schemes allow inspectors to calculate a specific level of detection therefore allowing them to justify the level of inspection resources needed to reach the appropriate (or desired) level of detection.

3.11. What data do I need to implement RBS in my country?

A Risk-Based Sampling Excel workbook was developed (Chapter 10, Appendix 1) to assist countries in collecting and organizing inspection data and to assist in determining sample sizes and randomizing samples for inspection. The workbook should be very useful for countries that do not have data collection systems in place. The workbook has the following sections:

- **a.** Sample size calculator
- **b.** Database to collect inspection data (Spreadsheet)
- **c.** How to randomize samples for inspection
- **d.** Directory of Importers
- **e.** Directory of Exporters
- **f.** Directory of Producers.

The database fields include basic parameters that countries should collect when performing inspections at ports, airports, and border crossings. The database will provide historical data that will allow countries to analyze trends for future implementation of RBS. The Excel workbook is freely available and downloadable from the NAPPO website at this link – https://nappo.org/english/learning-tools/sample-size-calculator

3.12. How can countries deal with issues of staff continuity, lack of training and reluctance to change?

Member countries of the World Trade Organization – WTO - have the obligation to apply RBS, as stated in Article 5, item 2 of the WTO-SPS Agreement - "In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest — or disease — free areas; relevant ecological and environmental conditions; and quarantine or other treatment" and the WTO Trade Facilitation Agreement, Article 7, item 4: "Each Member *shall* *concentrate* customs control and, to the extent possible other relevant border controls, on *high-risk consignments and expedite the release of low-risk consignments* …" (emphasis supplied).

Therefore, we recommend that competent regulatory authorities around the world include RBS concepts in technical documents that support/inform inspection/sampling activities such as manuals, guidelines, and procedures, to ensure that those responsible for inspection understand and apply the concepts. In addition, inspectors should receive training on RBS to insure they grasp the concepts, understand the advantages, and recognize how important the application of RBS is for inspection activities.

The lack of well-established and accepted parameters for sampling records becomes an opportunity to countries to include the required parameters for RBS analysis and implementation in the country's single window for foreign trade. This avoids information duplication and saves time and resources through inter-institutional coordination between the NPPO and customs, and the processes automatization, simplification and standardization.

3.13. What options do I have if it is not possible to completely randomize the samples?

If randomization is not possible, RBS can nonetheless help determine the appropriate sample size to make the inspection results meaningful. For additional information see Chapters 4 and 6.

4. INTRODUCTION

Robert Griffin[1] and Maribel Hurtado[2]

1. National Coordinator for Agriculture Quarantine Inspection USDA, APHIS, PPQ - Retired
2. Project Manager for RBS

For over a century, inspection has been the most widely used and commonly applied of all phytosanitary measures. Inspection is the primary means for phytosanitary officials to verify compliance with import requirements and a key factor in motivating producers and shippers to recognize and address phytosanitary concerns. The fact that the international movement of people and goods is subject to inspection is often sufficient motivation for compliance, whether or not anything is inspected.

Inspection has been the most widely used and commonly applied of all phytosanitary measures and it is the responsibility of the national plant protection organizations (NPPO).

The threat of inspection, or rather the fear of negative repercussions from the results of inspection, can be a powerful motivation against smuggling or other non-authorized movement of goods. Knowing and accepting that inspection is a deterrent, but not a fool-proof safeguard against pest introduction, raises questions regarding the desired effectiveness of inspection and its role in risk management. According to Article IV of the International Plant Protection Convention (IPPC), one of the primary responsibilities of a national plant protection organization (NPPO) is "*the inspection of consignments of plants and plant products moving in international traffic and, where appropriate, the inspection of other regulated articles, particularly with the object of preventing the introduction and/or spread of pests*". This mandate covers a multitude of different objectives for which inspection is used, including verifying the integrity of a consignment, checking documentation, and collecting trade information.

These aspects of inspection complement the focus on determining whether a consignment meets phytosanitary requirements. In most cases, sampling consignments to visually detect the presence of quarantine pests or regulated non-quarantine pests is the key to determining the phytosanitary status of consignments. This procedure typically results in decisions regarding actions that will be taken to mitigate the risk of pest introduction. It also provides useful information for evaluating the potential risk associated with similar and future shipments (of, for example, the same commodity, or of commodities from the same country).

The IPPC developed and adopted International Standard for Phytosanitary Measures (ISPM) 23 (*Guidelines for inspection*) in 2005. This was followed by the adoption of ISPM 31 (*Methodologies for sampling of consignments*) in 2008. These complementary standards identify inspection as a risk management procedure and point to the need for inspection to be technically justified and fairly applied in the same way as other phytosanitary measures.

The IPPC developed and adopted International Standard for Phytosanitary Measures (ISPM) 23 (Guidelines for inspection) in 2005, followed by the adoption of ISPM 31 (Methodologies for sampling of consignments) in 2008.

The standards recognize that different inspection designs and methods will produce different outcomes which can substantially affect trade and trade policy. Proper implementation of these ISPMs requires a common understanding of the conceptual, operational, and policy consequences of different inspection designs and their relationship to the principles of safe trade reflected in the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (the WTO-SPS Agreement) (WTO, 2020a) and complemented by the IPPC (FAO, 1997).

The disciplines created by the WTO-SPS Agreement are designed to ensure that barriers to trade which have the objective of providing protection are not overly restrictive or politically motivated. It creates a regulatory focus on safe trade as a singular objective, recognizing that neither extremes of exaggerated protection nor completely open trade are desirable. From a practical standpoint, this translates to a much stronger role for analysis and gathering data -- especially inspection data -- needed to understand where, when, how, and how strongly risk management measures should be applied. This is where the role of inspection as a phytosanitary measure becomes critical for justified risk management. That is not to question the value of inspection as a deterrent, but rather to ask whether inspection is being applied consistently and in a defendable way based on risk, as envisioned by the WTO-SPS Agreement, and is technically justified according to the IPPC.

Assuming that all NPPOs and their inspection agencies/branches are also striving for more efficient and effective pest exclusion, there are additional questions about whether sampling is the best strategy. Other important questions are whether the information derived from inspections is helpful for informing inspectors about specific areas of risk (= targeting), helping NPPOs to better allocate inspection resources for risk management (= prioritization), identifying changes in risk (= trend analysis) and other processes that support the best use of each NPPO's limited pest exclusion resources as part of risk management.

The primary assumption behind the use of inspection is that the pests of concern are detectable. The organism or its signs/symptoms must be visually discernible and distinct enough that there is little potential for confusion with non-pest organisms or other conditions. However, some pests are not detectable without specialized procedures or laboratory testing. Others have very different levels of detectability. These differences contribute variability to the interpretation of inspection results and the design of inspection programs.

The primary assumption behind the use of inspection is that the pests of concern are detectable.

Inspection itself does nothing to change pest status. It is the actions taken because of inspection that ultimately determine how pest risk is changed. At an operational level, these decisions will usually be consignment acceptance (= no action), consignment rejection, or the application of other phytosanitary measures (e.g., treatment). It is important to remember that each pest interception and the collective history of interceptions also have the potential to contribute valuable data for a better understanding of the risk associated with the pest(s), origin(s), and pathway(s).

Each pest interception and the collective history of interceptions have the potential to contribute valuable data for a better understanding of the risk associated with the pest(s), origin(s), and pathway(s).

Since inspection is rarely 100% and always involves a degree of error and variability, the acceptance of a tolerance is inherent in the use of inspection as a risk management tool. Inspection is essentially equivalent to sampling against the probability of detection. This means that there is always some probability that pests will not be detected. Inspection is therefore not an appropriate stand-alone strategy if the ultimate objective is ensuring pest freedom.

By acknowledging the role of probability, NPPOs can understand the important role of basic statistical concepts such as the acceptance of a tolerance and the limits of confidence. Following this is the need to identify target detection levels to form the technical requirements for inspection that make it a useful tool for risk management. Acceptance of a tolerance and variability is inherent in the adoption of inspection as a phytosanitary procedure. For this reason, inspection cannot be aligned with risk management without an understanding of the level of tolerance and variability that is associated with the procedure.

The discipline that is most critical to understanding the correct application of risk-based inspection is acceptance sampling. The application of this statistical concept in risk management allows us to determine whether inspection is the most appropriate phytosanitary measure to use for managing pest risk and the characteristics of a proper inspection design, recognizing the concepts of tolerance associated with the probability of detection and considering the limitations of confidence in acceptance sampling.

For example, inspecting two boxes of fruit from a total consignment of ten boxes and finding them free of pests does not provide absolute assurance that all ten boxes are free of pests. There is some probability that pests occur in the remaining boxes and there is a degree of uncertainty (both variability and error) associated with the two boxes that were inspected. The issues that must be considered are the level of tolerance and confidence that are considered acceptable, and the level of consistency (or the range of variability) in inspection.

Visual inspection of bananas. Commercially produced bananas are typically grown under covers that discourage pest infestation. Pests are also easily detected on their smooth yellow surface.
Source - https://www.usda.gov/media/blog/2013/01/09/new-vision-means-better-inspection-services-fruits-and-vegetables

Note here that the concept of tolerance applies to the entire population (the entire consignment), not only to the sample. The level of pest presence in a sample is properly known as the acceptance level. The concept of tolerance is often misapplied, as when a "zero tolerance" refers to rejection based on a single pest detection in a sample. The correct designation is a zero-acceptance level which translates to some tolerance in the population based on the size of the population, the size of the sample, and the confidence level.

A risk-based inspection is one that has as its objective to detect a defined level of pest prevalence with a specific level of confidence and then adjust inspection frequency and/or inspection intensity to the risk. Pest interceptions are used to represent risk in an operational sense. It is important to recall that all interceptions are not equally risky, but the number of interceptions can be a useful indicator of relative risk. A pest risk assessment (part of the PRA process) is needed for the true risk of interceptions to be fully understood.

A risk-based inspection is one that has as its objective to detect a defined level of pest prevalence with a specific level of confidence and then adjusts inspection frequency and/or intensity to the risk.

A risk-based inspection differs from an inspection that is based on arbitrary or intuitive criteria, or one that is designed only for operational convenience. By establishing reference points (inspection objectives) and a means to measure the results, it becomes possible to identify, in an analytically defendable and transparent manner, the areas where inspection resources are most needed, and the level of resources required for proper inspection. These determinations then correspond with the acceptable level of risk and the strength of phytosanitary measures to be applied.

Managing for a fixed (pest) prevalence (= a defined detection level) results in larger or smaller sample sizes depending on the consignment size. This is a fundamental point to understand for risk-based inspection. A risk-based inspection design will aim to balance the resources available for inspection with the need to detect specific levels of pest prevalence.

This means that the maximum allowable prevalence would be a fixed value associated with a fixed confidence. The result is a sampling design where the sample size varies according to the consignment size and the intensity of inspection is adjusted to the risk and to available resources. This approach maximizes the risk management value of inspection by focusing more inspection effort on higher risk imports and less on lower risk imports.

Managing for a fixed (pest) prevalence (a defined detection level) results in larger or smaller sample sizes depending on the consignment size.

A sample size calculator or hypergeometric table greatly simplifies the process of determining the appropriate sample size to consistently detect the same level of infestation from different consignment sizes (see Chapter 10 Appendices 1 and 2). Once we are able to consistently detect the same level of infestation in each consignment, we can legitimately compare consignments and calculate true approach rates for pests (=the number of different quarantine pests found associated with a specific number of consignments) and desired action rates for pathways (= the number of phytosanitary actions required for a specific number of consignments of the same commodity), entities, and countries of origin (Griffin, 2017).

Traditional operational inspections also frequently stop when a pest is found, even if the entire sample has not been inspected. The rationale for this is that pest presence represents non-compliance, which usually changes the phytosanitary status of the consignment. As noted above, inspection is not absolute. The detection of one pest does not mean that it is the only pest present, and failure to detect a pest does not mean that a shipment is pest-free. The entire sample must be inspected, and the full results recorded to understand how many different pests may be present and the degree of infestation in a way that can be compared and analyzed (Griffin, 2017).

RBS requires adjusting the sample size to correspond with the consignment size for a consistent level of detection… and inspecting the full sample.

Full inspection of a statistically derived sample size not only provides a more complete picture of non-compliance, but the results support much more robust analyses of approach rates for pests, action rates for the pathway, entity, or country, and infestation rates for the consignment. A data stream based on a history of consistent sampling allows for the analysis of trends and supports ranking and prioritization for risk management as well as resource allocation for inspection (Griffin, 2017).

In addition to adjusting the sample size to correspond with the consignment size, and inspecting the full sample, it is also crucial that the sampling be truly random. This is very important from the standpoint of statistical validity. It is also one of the most difficult aspects of Risk-Based Sampling for inspectors to embrace because their tendency is to bias the selection of samples for the detection of pests based on their experience and expertise. Asking an inspector to inspect a sample that he/she does not believe will have a pest, while also ignoring part of the consignment where he/she might feel more confident about detecting a pest, is counterintuitive and may be demoralizing to inspectors accustomed to demonstrating competence by their selection of samples (Griffin, 2017).

it is also crucial that the sampling be truly random… from the standpoint of statistical validity.

There are two main problems with the intuitive or haphazard sampling that has dominated traditional inspection around the world. The first is that it lacks statistical validity. This makes inspection results inconsistent and much less valuable in the long run. The second problem is that it strongly favors the detection of pests that have been previously detected, making it more difficult to become aware of new pests or see changes in approach rates, infestation patterns, and new outbreaks.

While a random sample may miss a pest that the inspector believes is present based on experience, it has a higher likelihood of finding pests that are unanticipated by the inspector. As noted above, all inspections have some probability of missing pests, sometimes known as slippage or leakage, but ensuring that inspection results have statistical validity is key to using the results for better identifying differences in risk. Discovering new pests and unanticipated infestation patterns is likewise important (Griffin, 2017).

Based on the discussions above, the best inspection designs have the following sampling characteristics:

- The sample size corresponds to a fixed detection level for a specific consignment size;
- The samples are randomly selected;
- The full sample is inspected, and all results are recorded.

Inspections with these design elements provide more and better data to support risk and resource management decisions. When fairly and consistently applied, such inspection designs are also technically defendable and greatly expand opportunities for an NPPO to conduct a range of useful analyses (including adjustments in inspection intensity and/or frequency to focus more effort on higher risk commodities and away from lower risk commodities) thereby creating incentives for producers to reduce risk. This is consistent with the obligations of NPPOs under the IPPC, the WTO-SPS Agreement, and the Risk Management provisions of the recently completed and ratified World Trade Organization Trade Facilitation Agreement (WTO, 2014).

4.1. Scope and objectives of the RBS manual

The RBS Manual is a resource to support global harmonization in the design and analysis of inspection procedures by NPPOs. It connects with the objectives of the IPPC and the IPPC Strategic Framework 2020-2030, particularly to assist with the implementation of ISPMs 23 and 31, and the ISPM 31 explanatory document available here https://www.ippc.int/static/media/files/publications/en/2013/06/04/1252507962732_ispm31_ed_in_format_201304232112en.pdf

The RBS Manual can also be used to develop procedural guidelines and policy frameworks and to inform training programs at the national level. The manual provides options, examples and case-studies for competent authorities to use to design, re-design, evaluate and manage inspection policies and procedures that will provide more useful and better data to support risk and resource management decisions in their NPPO.

4.2. Target audience

The RBS Manual is intended for use by policy makers and analysts within the competent authorities responsible for import and export inspections. In addition, the manual is a technical reference for officials designing, evaluating, and managing those measures. The manual may also provide the documentary basis for developing training tailored to the specific needs of a country. The manual can also be useful to inspectors as a technical reference for operational decision-making, (e.g., calculating sample sizes). Producers, importers, exporters, brokers, and other stakeholders may also find the manual useful to help understand the proper role and application of inspection as a phytosanitary measure.

4.3. Use of the RBS Manual

National phytosanitary policies and phytosanitary inspection designs are the sovereign domain of each NPPO. Recognizing that every country has unique conditions and challenges, this manual provides guidance to assist competent authorities with understanding and adapting their individual policies and procedures to be consistent with their SPS and IPPC obligations without prescribing specific changes. Likewise, the manual supports implementation of WTO Member obligations for risk management under the Trade Facilitation Agreement. The manual provides a range of technical detail for NPPOs interested in different levels of sophistication in their RBS designs.

The RBS Manual is divided into two parts. The first provides background and basic guidance for beginning to understand and implement RBS. It includes FAQs and case studies to help relate the guidance to operational realities. The second section provides additional detailed technical explanations, including tools, formulas, and other reference material for advance applications of RBS by NPPOs.

Careful inspection, selection and culling in the packing operation help ensure pest-free products.
Source - https://www.gob.mx/cms/uploads/image/file/578855/punto_inspeccion.jpeg

5. HOW TO - GUIDE FOR IMPLEMENTING RISK-BASED SAMPLING (RBS)

Robert Griffin[1] and Maribel Hurtado[2]

1. National Coordinator for Agriculture Quarantine Inspection USDA, APHIS, PPQ - Retired
2. Project Manager for RBS

The implementation of RBS will be a different experience for every country, but taking some time to examine the characteristics of RBS that are likely to be similar for all countries is a useful way to begin building new national inspection designs that are internationally harmonized. In many cases, the shift from traditional inspection designs to RBS will most likely require significant changes in regulatory policy and inspection practice. These changes do not necessarily translate into needing additional (monetary or human) resources, but they do require effort and commitment from the phytosanitary regulatory and inspection authorities. Above all, a thoughtful, phased process is important to provide the best opportunity for success.

The discussion below covers the main areas that countries need to address and the procedures they need to begin implementing RBS. It is organized into three sections representing generic steps that every country can adapt for their own RBS implementation process. It begins with prerequisites to establish the foundation. This is followed with simple sampling designs to become more aware of sampling issues and familiar with statistically designed sampling. The last step leads to ranking, which uses the data from sampling to identify higher and lower risk consignments based on interceptions. Flowcharts have been added to illustrate the discussion.

5.1. Prerequisites

The first and most critical aspect of RBS implementation is ensuring that relevant personnel, including inspectors, policy makers, and regulatory leaders understand and embrace the underlying concepts of RBS. The commitment to RBS should be motivated by recommendations of international standards (ISPMs 23 and 31), and by an organization's commitment to RBS as a more efficient, effective, technically justified and transparent way to conduct inspection. This may seem like a simple and obvious prerequisite, but the difficulty in shifting to RBS from traditional inspection procedures that have been used for over a century should not be underestimated.

> *The first prerequisite to RBS implementation is the combination of training and commitment to ensure that the concepts are understood and supported.*

Special attention is needed to train inspectors who are accustomed to using their experience and judgment to determine where, what, how, and how much to sample during inspection. Without proper training to provide inspectors with a working knowledge of RBS, they may be confused and resistant to change. One point that is important to emphasize here is that inspectors must still strive to be good inspectors (that is, effective at finding pests) but by following /embracing RBS, they greatly enhance the ability for their country/NPPO to appreciate, defend, and benefit from their work.

Statistics is another important prerequisite. There is clearly a statistical background to RBS. The statistics used for RBS are not new, complex, or sophisticated. Nearly all personnel with scientific training in their background will have been exposed to the statistical concepts underlying RBS, and science-based organizations like NPPOs usually have statisticians or statistically trained personnel within their ranks. Nevertheless, some NPPOs may not feel comfortable or confident that they have the statistical knowledge/credibility necessary for training and decision-making related to designing and implementing RBS.

The second prerequisite to implementing RBS is establishing adequate statistical expertise. This does not mean hiring a team of statisticians but rather developing basic statistical competency within the NPPO and establishing links to experts for more sophisticated inputs as needed.

Over the long term, NPPOs should consider either building internal statistical expertise or establishing a relationship with an outside organization such as another government agency or university to provide ongoing statistical support to their agency. In the short term, and to begin the process of shifting to RBS, simply consulting a statistician may provide sufficient reassurance.

RBS implementation requires a balance between the pure application of statistical concepts and the practical realities of inspection.

It is important to highlight that RBS implementation requires a balance between the pure application of statistical concepts and the practical realities of inspection. For example, statistical convention holds that true random samples are needed for maximum confidence. The reality is that it may not be practical to completely unload a consignment and randomize all its contents. In fact, unloading may increase the risk of pest escape! This means that an approach needs to be adopted which randomizes sampling to the extent safely and practically possible, recognizing that the results will suffer from lower confidence. Whenever possible, a full random sample may be taken for comparison to explore/understand the degree of lost confidence. These types of comparisons require statistical expertise beyond what is needed for routine analyses.

A simple data collection mechanism is essential to capturing inspection results for later analysis. NPPOs should consider developing such systems in conjunction with Customs to avoid duplication, increase efficiency and enhance collaboration for Single Window implementation under the WTO Trade Facilitation Agreement.

The final prerequisite for implementing RBS is a structure for data collection. Again, this may seem obvious and it is highly likely that most countries have some data collection mechanism in place. The focus here should be on anticipating the needs for RBS and capturing the essential data for analysis.

5.2. Sampling

The first step to implementation of RBS is understanding the nature of current inspection procedures. This is done by selecting a typical in-use inspection scenario; a port (land border, airport, seaport), a commodity (fruits, vegetables, plants for planting), a pathway (commodity x from country y), a specific period of time (summer) – some discreet universe that can be used to represent the current state of inspection in a country. Start by collecting data from normal inspections for analysis. Alternatively, historic data from past inspections may be used where it exists. Data from many inspection variables can be included, but the most important thing at this stage is having the size of the consignment and the size of the sample. By using hypergeometric tables (Chapter 10 - Appendix 2) the level of detection for each inspection can be determined with 95% confidence and then recorded. Records should be collected and reviewed to ensure that the data represents the full range of variability in the observations, especially for consignments of different sizes.

Specialized facilities, equipment and personnel are used for inspecting live plants. The risk of pest introduction is often higher with live plants because the pest enters the environment with its host.
Source - https://www.aphis.usda.gov/aphis/ourfocus/planthealth/ppq-program-overview/plant-protection-today/articles/rbs

The second step is reviewing the results of the first step to discover the extent of variability in the detection level in the dataset. Then, try to identify the lowest and the highest levels and the range where most inspections fall. After this initial review two questions need to be answered:

1. Is the range of variability acceptable to the NPPO or the country?
2. What level of detection is desired by the NPPO or the country?

By referring back to the hypergeometric tables (Chapter 10 - Appendix 2) or sample size calculator (Chapter 10 - Appendix 1), it is easy to determine the sample size that would provide the desired level of detection for each consignment and eliminate/reduce variability. It is also possible to see how changing the detection level will result in needing more or less sampling depending on the size of the consignment. This allows for adjusting the detection level to correspond with the resources available for sampling.

For instance, if an average of 100 inspections/day are normally completed, then the detection threshold that corresponds with this level of sampling for the number and size of consignments can be found. This exercise should be repeated using different commodities, origins, and other inspection variables for which data is available. The results will help demonstrate the magnitude of variability in current inspection processes.

Warning: In most cases, NPPOs will be surprised (even disappointed?) at the high variability in their detection levels and in the low level of detection they are achieving using current inspection designs. This is useful for demonstrating the lack of awareness that exists around the poor efficacy and arbitrariness of historical inspection designs and the importance of shifting to RBS. If 'time for inspection' is another variable for which data is collected, NPPOs will also notice that very large blocks of time are devoted to inspecting large consignments that result in detecting an extremely low level of infestation. This contrasts with relatively short inspection times needed for inspecting small consignments where very high levels of infestation are not detected. These contrasts can often be found on the same commodities where the only difference is the size of the consignment.

Ultimately, a decision needs to be taken by the NPPO on whether the results of this analysis suggest the need for a change in inspection design. If the results are judged to be acceptable, it may be necessary to expand the data analysis to include other inspections for a broader view. The findings may confirm that the existing inspection design is operating within what the NPPO considers to be acceptable limits. However, it is more likely that additional analysis will uncover additional variability and further highlight the need to switch to RBS.

Assuming that a decision is taken to begin using RBS, the next step is to identify a subset of inspections to begin sampling with RBS. This is most often done with a particular commodity or group of commodities at a single location. For example, in the United States, the pilot for shifting to RBS focused on imported plants for planting that came into the 12 Plant Inspection Stations managed by the U.S. NPPO.

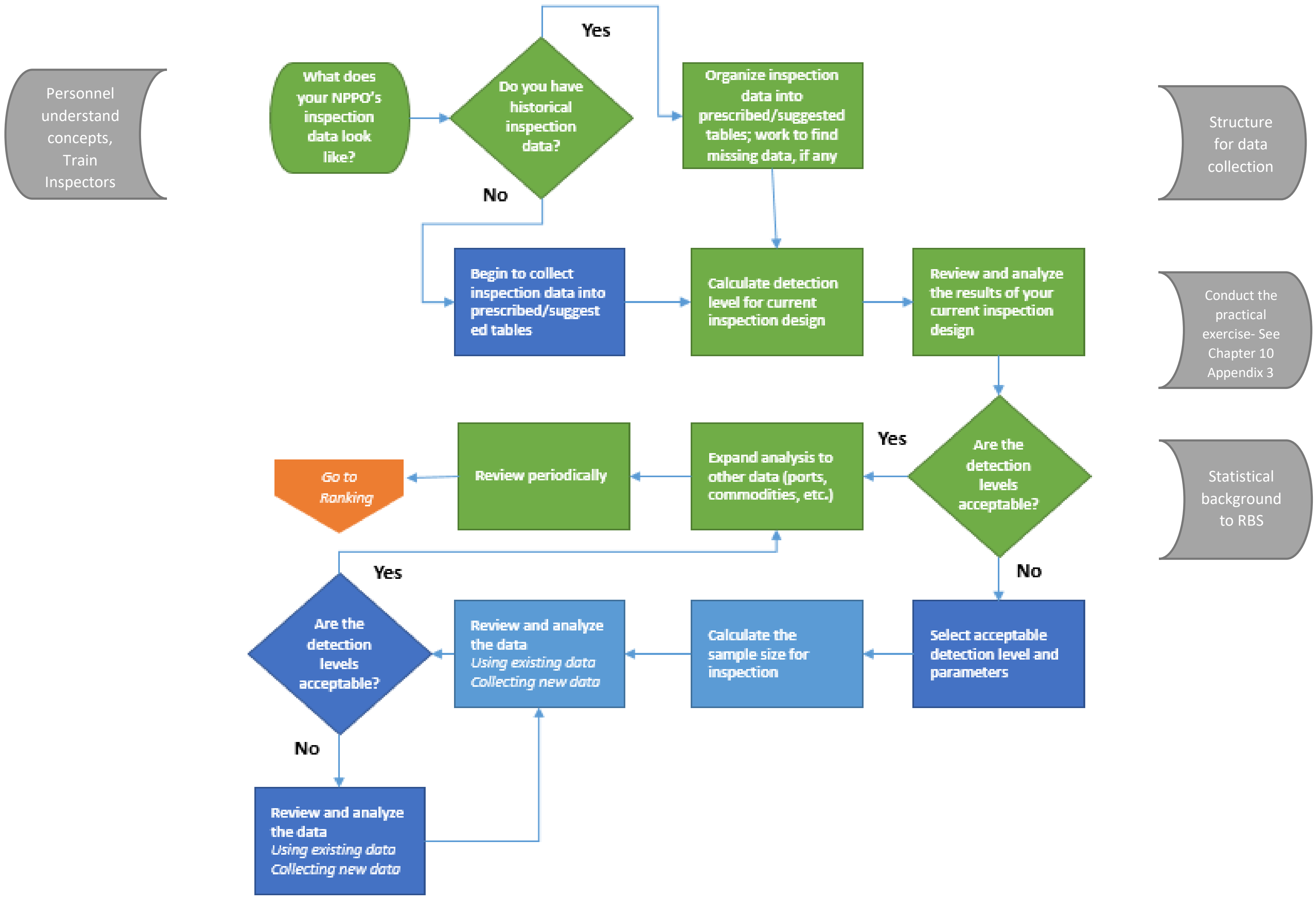
The next step would be selection of a detection level and the establishment of sampling guidelines or calculators for inspectors to use for determining sample sizes. Careful consideration needs to be given to the expected number and size of consignments in order to select a detection level that will result in sampling that is feasible given available resources. It is important to avoid trying to demonstrate high levels of protection by attempting to detect very low levels of infestation from the very start. This results in high sample sizes which can become a strain on inspection resources. After a period of sampling and adjusting the detection level as necessary, sampling can be expanded stepwise by adding additional commodities and locations while paying close attention to the impact on inspection resources. In many cases, the NPPO will realize a savings as unnecessary inspection effort on large consignments is reduced. In other cases, the inspection

A note on Confidence:

Statistical convention is to assume 95% confidence unless otherwise stated. When adjusting sampling for RBS it can be tempting to use different confidence levels for sample size calculations to avoid adjustments in the sample size or detection level that may be uncomfortable. For instance, reducing the confidence from 95% to 80% when calculating the sample size for a consignment of 1000 articles will reduce the sample size from 29 to 16 for detecting a 10% infestation rate. Alternatively, the 29 samples used to detect a 10% infestation with 95% confidence could also detect a 5% infestation rate with 80% confidence. If confidence is used as a variable in RBS, it is important to either be consistent about using 95% or be transparent about any other level of confidence.

effort will be increased as more effort is devoted to small consignments that had been under-inspected in the past. It is important to follow these changes and adjust the detection level accordingly to avoid either too much or too little work for the available resources.

The flow chart below provides a summary of the process to begin to implement RBS.


Personnel understand concepts, Train Inspectors
What does your NPPO's inspection data look like?
Do you have historical inspection data?
Yes
No
Organize inspection data into prescribed/suggested tables; work to find missing data, if any
Structure for data collection
Begin to collect inspection data into prescribed/suggested tables
Calculate detection level for current inspection design
Review and analyze the results of your current inspection design
Conduct the practical exercise- See Chapter 10 Appendix 3
Go to Ranking
Review periodically
Expand analysis to other data (ports, commodities, etc.)
Yes
Are the detection levels acceptable?
No
Statistical background to RBS
Yes
Are the detection levels acceptable?
Review and analyze the data Using existing data Collecting new data
Calculate the sample size for inspection
Select acceptable detection level and parameters
No
Review and analyze the data Using existing data Collecting new data

5.3. Ranking

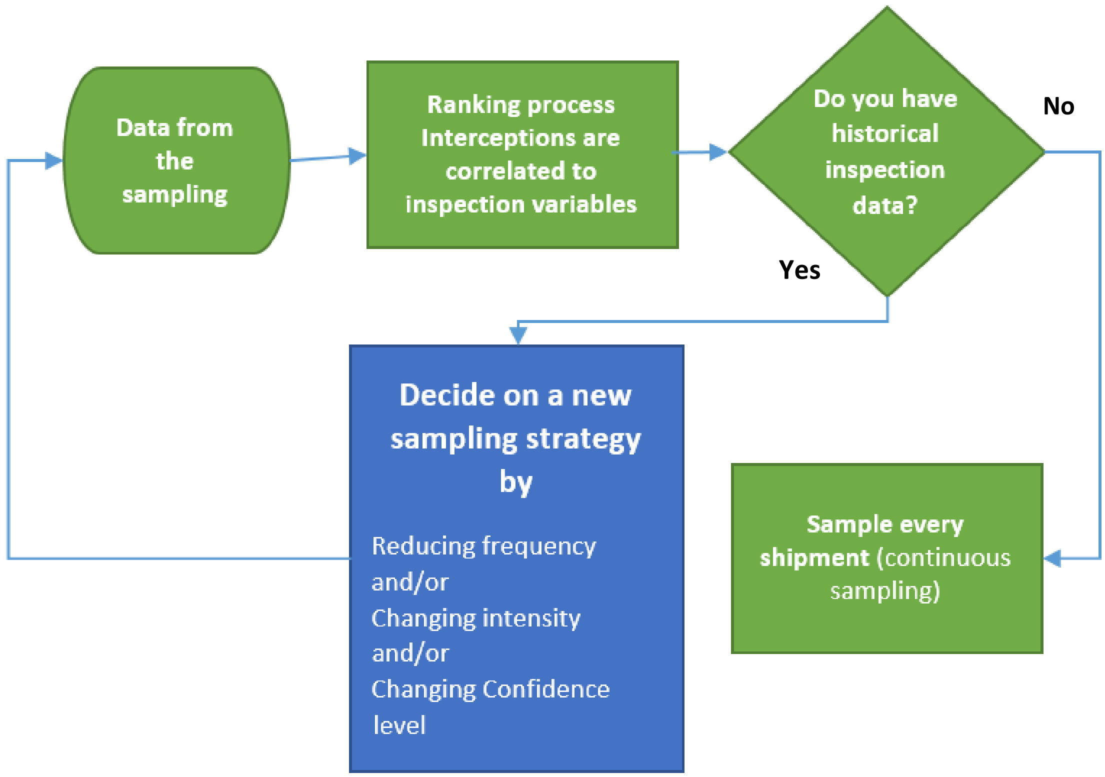
Once a history of RBS data has been established (e.g., more than 10 consignments for a particular commodity/origin) the NPPO will be able to make several important observations:

1. The true rate of regulatory actions based on pest interceptions;
2. Trends and variability in the action rate;
3. How action rates compare across commodities;
4. How action rates compare across origins, suppliers, ports, inspectors, - any inspection variable for which there is sufficient data for analysis.

These rates can then be ranked (= ordered from high to low) and decisions made on where inspection can be reduced or increased. Certain types of consignments are likely to have obviously low or high rates of regulatory actions. Those with consistently low rates of regulatory actions (high compliance; low risk) can be considered for less frequent or less rigorous inspection (or both). Rather than inspect every consignment, the NPPO may move to only inspect every other consignment or every third, fifth, or tenth consignment depending on the policy framework they have established. Likewise, the NPPO can reduce the rigor of the inspection by changing the detection level to reduce sampling intensity.

Those types of consignments with a higher number of regulatory actions will require closer scrutiny to understand the nature of the non-compliances (e.g., types of pests) and risk. These may require more frequent or more rigorous inspection. In cases where the risk is considered unacceptably high or highly variable, the NPPO may choose to adopt other measures (e.g., mandatory treatment or prohibition). A great advantage of RBS is that it facilitates these types of analyses and justifies such adjustments.

The flow chart below provides a summary of the process to begin using RBS results for ranking.


Data from the sampling
Ranking process Interceptions are correlated to inspection variables
Do you have historical inspection data?
No
Yes
Decide on a new sampling strategy by
Reducing frequency and/or Changing intensity and/or Changing Confidence level
Sample every shipment (continuous sampling)

6. WHAT IS RISK-BASED SAMPLING?

Michael Ormsby[1], Andrew Robinson[2] and Robert Griffin[3]

1. Manager Ministry for Primary Industries, Biosecurity Science and Risk Assessment, Wellington, New Zealand
2. Director, CEBRA, School of Biosciences - Reader & Associate Professor in Applied Statistics Australia
3. National Coordinator for Agriculture Quarantine Inspection USDA, APHIS, PPQ – Retired

There are numerous international and regional instruments which have developed to deal with the challenges of plant pests moving in trade. Ormsby, et al., 2017, noted that efforts to expand and improve the mitigation of pest introduction and spread via trade should include updating existing tools and resources to be more effective and align all measures with contemporary principles of safe trade to meet the expectations of international agreements. Inspection is a critical aspect of this alignment because it is the most widely used phytosanitary measure in trade. Risk-Based Sampling (RBS) is an inspection design that makes inspection more efficient and effective within a framework based on risk.

Risk-Based Sampling (RBS) is an inspection design that makes inspection more efficient and effective within a framework based on risk

6.1. Inspection

The IPPC *Glossary of Phytosanitary Terms* (ISPM 5) defines inspection as the "*Official visual examination of plants, plant products or other regulated articles to determine if pests are present or to determine compliance with phytosanitary regulations*" (FAO, 2019). Inspection is therefore used to either find pests (as a measure) or verify that other measures applied against pests have been used (verification). ISPM 23 (*Guidelines for inspection*) further notes that inspections can be used to confirm compliance with either import or export requirements relating to plant pests. An export inspection is used to ensure that the consignment meets the phytosanitary requirements of the importing country at the time of inspection (FAO, 2019 a)

As inspection of an entire consignment is usually not feasible, phytosanitary inspection is based on sampling. A common definition of *sampling* is "*a small amount of something that shows you what the rest is or should be like*". In a statistical sense, a *sample* could be defined as "*a set of observations drawn from a portion of a population*".

Boxes of fruit loaded in a container. True random sampling for inspection under these conditions may be impractical for every shipment because of the time and effort required for unloading and reloading.
Source - ICA

Samples can be taken from a consignment by any number of methods. However, for the sample to be as representative as possible of the entire consignment, the method used should ensure the sampled items are chosen randomly. While it is very unlikely that the distribution of pests within any consignment would be uniform (e.g., a homogeneous infestation), to enhance the representativeness of selected samples, a consignment should represent only a single lot. A *lot* in this instance is defined in ISPM 5 as "*A number of units of a single commodity, identifiable by its homogeneity of composition, origin etc., forming part of a consignment*".

As indicated previously, due to practical limitations associated with the consignment or the location where samples are to be taken, sampling designs are sometimes used to enable near-random samples to be collected under restrictive conditions. For example, when taking samples from large shipments of grain, samples are usually collected as a series of small subsamples taken as the grain is unloaded. Sampling from items packed into packages within a container may necessitate taking subsamples from a few selected packages rather than opening all or most of the packages for sampling. Where the complete devanning (= unloading cargo from a container) is not feasible or practical, samples may be taken from the portion of the consignment that is available, recognizing that confidence in the results is reduced because the sample is less representative.

The application of statistically based methods provides results with a statistical confidence level that is easily determined from a table or calculation. Sampling methods that are not statistically based, such as convenience sampling, haphazard sampling, or selective sampling, may result in the detection of a pest, but no statistical inference can be made on this basis (ISPM 31) (FAO, 2016a).

6.1.1. Level of Pest Infestation

The key to any inspection and sampling design is to first determine the acceptable level of pest infestation within the consignment. ISPM 5 defines the *tolerance level (of a pest)* as the "*Incidence of a pest specified as a threshold for action to control that pest or to prevent its spread or introduction*". The central point to understand from this concept is that because inspection usually does not extend to all the articles in a consignment and is not 100% effective in any case, there is always some probability that some pests will be undetected and infested consignments will escape. Most consignments undergo some degree of dispersion within the importing country, and the pests themselves may undergo some degree of mortality and dispersion through shipping and handling. This has the effect of reducing the likelihood of pest introduction, but there is always some background level of infestation that passes unmitigated. The important question to answer is what level of infestation can be tolerated. This tolerance is a key factor in determining the appropriate level of sampling.

The tolerance represents a potential level of pest infestation in a consignment that may exceed the country's appropriate level of protection (ALOP). The concept of an ALOP is introduced under the (WTO-SPS Agreement) (WTO, 2020a) and defined by that agreement as "*The level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory*". While the concept of an ALOP has been widely debated internationally, the important consideration in the context of pest tolerances is that countries that are members of the WTO "*shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade*" (WTO, 2020a). This means that the tolerance assigned to a pest for a consignment should not vary arbitrarily or unjustifiably in different situations. This aspect of pest tolerance is extremely important when comparing different inspection designs, especially fixed proportion sampling against Risk-Based Sampling.

6.1.2. Level of Confidence

According to ISPM 31 "*The confidence level indicates the probability that a consignment with a degree of infestation exceeding the level of detection will be detected*". For example, if we set the detection level of pest at 0.5% (1 infested unit in 200), then a sample size that provided a 95% level of confidence would indicate that 95% of all samples of that size would detect a 0.5% level of pest infestation. Since a confidence level of 100% is not feasible under the normal operational conditions of inspection, the required level of confidence is conventionally set at 95%.

6.1.3. Efficiency of detection (sensitivity)

The efficiency of inspection refers to the detectability of a pest if it is present. Certain pests are more easily detected and certain inspectors may be better at finding some pests than others. The conditions for inspection (e.g., indoors versus outdoors) can also be an important factor affecting sensitivity. The process of inspection is highly variable and has notoriously low sensitivity, but inspectors tend to wrongly assume sensitivity is 100% or they ignore it altogether.

6.1.4. Level of Pest Risk

In the same way that all pests are not equally detectable, all pests do not have the same risk. Risk is defined as the likelihood of the pest causing an impact and the magnitude of that impact (= consequences). As most consignments undergo some degree of dispersion within the importing country, and the pests themselves may undergo some degree of mortality and dispersion in the consignment, the likelihood of a single pest in a consignment causing a significant impact is quite low. If the pest needs to successfully complete its development, find a mate, breed, establish a new population and then spread into areas where impacts can occur, it is likely that many individuals will need to infest the consignment or infest many consignments that have the same destination for risk to be substantial. Thus, understanding the level of tolerance and the level of infestation is critical to linking inspection results to pest risk.

6.1.5. When is inspection not appropriate?

ISPM 23 notes that the use of inspection to detect the presence or incidence of pests in a consignment is based on the following assumptions:

- The pests of concern, or the signs or symptoms they cause, are visually detectable;
- Inspection is operationally practical; and
- Some probability of pests being undetected is recognized and accepted.

The reliance on inspection as a phytosanitary measure is therefore not appropriate when the pest is too difficult to detect because the ability to detect the pest using inspection is below the required tolerance level. In other words, the level of protection required by the importing country cannot be achieved by using inspection.

Other measures must be considered in circumstances where inspection is not effective or feasible. An example of this can be seen with the importation of large consignments of grain for processing. Visual inspection of a consignment for some types of pests can require very large samples to be taken requiring many hours of inspection. In this case, safeguarding (= protecting) the integrity of the grain consignment until the grain is processed and the pest risk eliminated is a more practical measure to implement.

Inspection of fresh fruit using a hand lens. Although the fruit is smooth and light colored, the calyx end can harbor small pests and protect them from washing and detection.
Source - *https://www.eppo.int/MEETINGS/2003_meetings/wk_inspectors_2003*

6.2. Fixed proportion sampling

When sampling first became widespread as part of inspection protocols for phytosanitary protection, most of the sampling methods relied on percentage-based sampling. To undertake percentage- based sampling, a target sample size is selected as a percentage of the total consignment size, e.g., 10%. The size of the sample is then calculated as a percentage of the total consignment size. For example, if the chosen percentage is 10% and the consignment contains 8,400 items, the sample size would be 10% of 8,400 or 840 items. This form of sampling provides a linear relationship between sample size and consignment size (see **Figure 1**).

There are several advantages to using percentage- based sampling. First, the sample size is easy to calculate. If you know in advance what the percentage sample size will be, all those involved in the trade (producers, exporters, importers, inspectors, etc.) can determine how large the sample size will be. Second, if destructive sampling is required (the sample units are destroyed during inspection, e.g., dissected), then only a small proportion of small consignments will be destroyed. A major disadvantage to percentage-based sampling is that large samples are required for large consignments (see **Figure 1**). This can make percentage sampling impractical for many forms of trade.

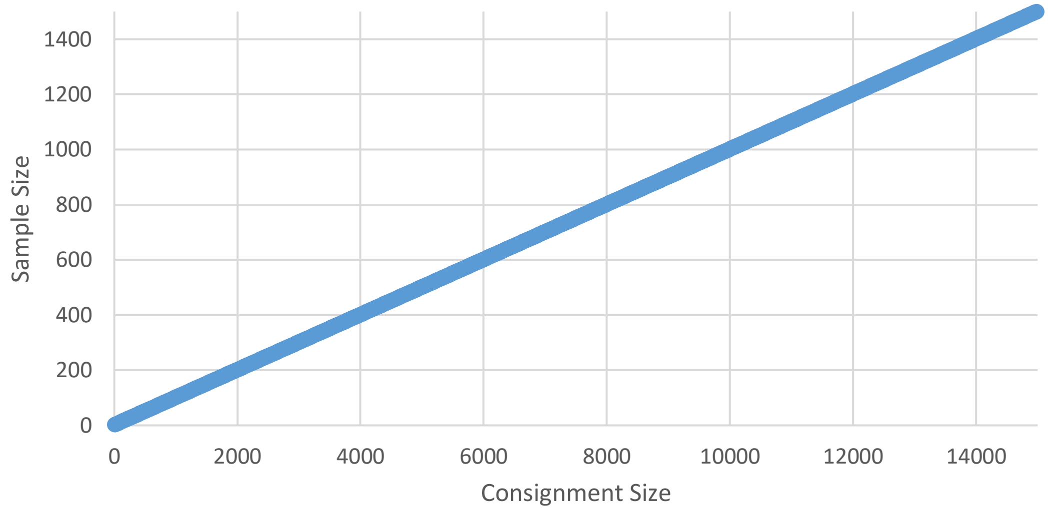


Figure 1. *The relationship between sample size and consignment size using a percentage-based sampling that equals 10%.*

The most significant problem with percentage-based sampling that makes it inappropriate and not technically justified for use in international trade relates to the relationship between sample size and the Appropriate Level of Protection (ALOP).
Figure 2 demonstrates the relationship between the consignment size in
Figure 1 and the level of protection (= the level of pest infestation detected at the 95% level of confidence) under a 2% percentage sampling regime.

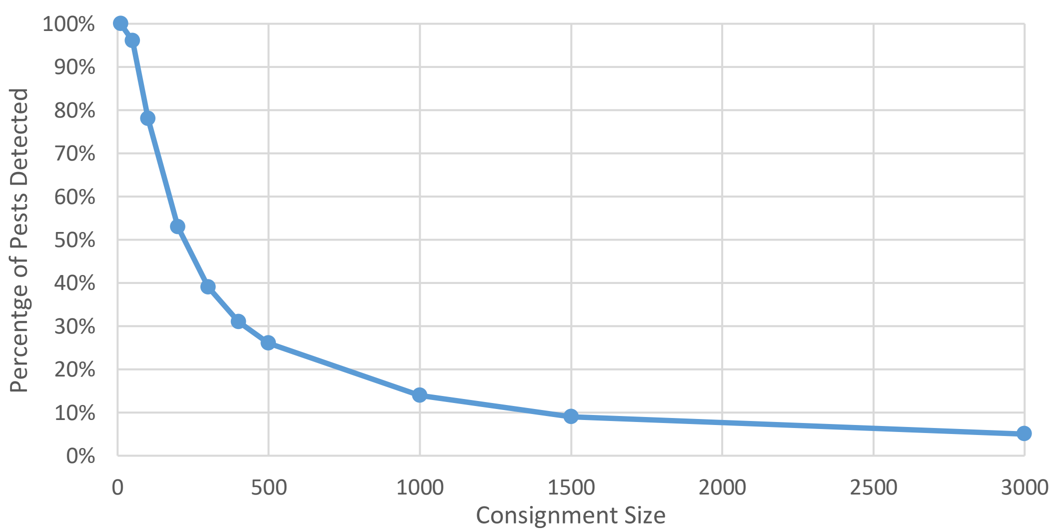


Figure 2. *The pest infestation rate detected at the 95% level of confidence provided by a 2% sampling regime for increasing consignment sizes.*

It is apparent from **Figure 2**, that as the consignment size increases, so too does the level of protection provided by the sample. In effect, the level of protection (pest tolerance) varies depending on consignment size. This is inconsistent with the requirements of the WTO-SPS agreement that states member countries "*shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade* (WTO, 2020a)".

6.3. Risk-Based Sampling

Risk-Based Sampling methods, in their simplest form, ensure the level of sampling for inspection maintains a consistent level of protection across all consignment sizes. Risk-Based Sampling designs also ensure that the limited resources available to phytosanitary authorities are fairly applied to consistently mitigate risk.

Risk-Based Sampling (RBS) applies a statistically based sampling method involving the determination of several interrelated parameters and the selection of the most appropriate statistically based sampling method (ISPM 31). Using RBS for inspection promotes technically justified approaches consistent with International Standards for Phytosanitary Measures (ISPMs) and with obligations according to the WTO-SPS Agreement and the WTO-Trade Facilitation Agreement (WTO-TF).

ISPM 31 lists parameters that should be considered when determining the appropriate sample size under RBS. These include the acceptance number, level of detection, confidence level, efficacy of detection, acceptable level of pest infestation, and the statistical distribution used to determine the sample size estimation. These terms are defined below.

6.3.1. Acceptance number

The acceptance number is the number of infested units or the number of individual pests that are permissible in a sample of a given size before phytosanitary action is taken (ISPM 31). As it is usual for phytosanitary authorities to want to apply the smallest sample size possible to minimize restrictions to trade, the most common acceptance number in a sample is zero. However, there may be several pests of concern potentially associated with the consignment. If one of these pests has a higher infestation tolerance than the other pests, it may be acceptable to allow one or more pests to be detected before rejecting a consignment. This is consistent with the principle of managed risk, recognizing that different pests have different risks.

6.3.2. Level of detection

The level of detection is the minimum percentage or proportion of infestation that the sampling methodology will detect at the specified efficacy of detection and level of confidence and which the NPPO intends to detect in a consignment (ISPM 31).

6.3.3. Confidence level

The confidence level is discussed in the numeral 6.1.2. A confidence level of 95% is conventionally used and should be assumed unless otherwise specified.

6.3.4. Efficacy of detection (sensitivity)

The efficacy of detection is the probability that an inspection or test of an infested unit(s) will detect a pest. In general, the efficiency should not be assumed to be 100% (ISPM 31).

6.3.5. Acceptable level of pest infestation

The concept of an acceptable level of pest infestation is represented by the acceptance number discussed above. Any value below this number is an acceptable level of infestation and represents the tolerance.

6.3.6. Statistical distribution

According to the ISPM 31, the hypergeometric distribution is appropriate to describe the probability of finding a pest in a relatively small lot when sampling without replacement which is typical of phytosanitary inspections. When sampling large lots that are sufficiently mixed (homogeneous), the likelihood of finding an infested unit may be approximated by either the hypergeometric distribution or simple binomial statistics.

In the case of aggregated spatial distribution of pests, sampling can be adjusted to compensate for aggregation. For this adjustment to apply, it should be assumed that the commodity is sampled in clusters (for example, boxes) and that each unit in a chosen cluster is examined (cluster sampling). In such cases, the proportion of infested units is no longer constant across all clusters but will follow a beta density function (ISPM 31). Other statistical distributions may also be appropriate.

6.3.7. Advantages and disadvantages of Risk-Based Sampling

The main disadvantage of Risk-Based Sampling (RBS) is the need to calculate the sample size for different size consignments. While this disadvantage can be easily overcome by using published tables or a web-based sample size calculator, determining the values required as parameters for the calculations can initially seem complex. Risk-Based Sampling also creates difficulties in destructive sampling of small consignments (see **Figure 3**). If most of the consignment must be sampled, much of the consignment may be destroyed.

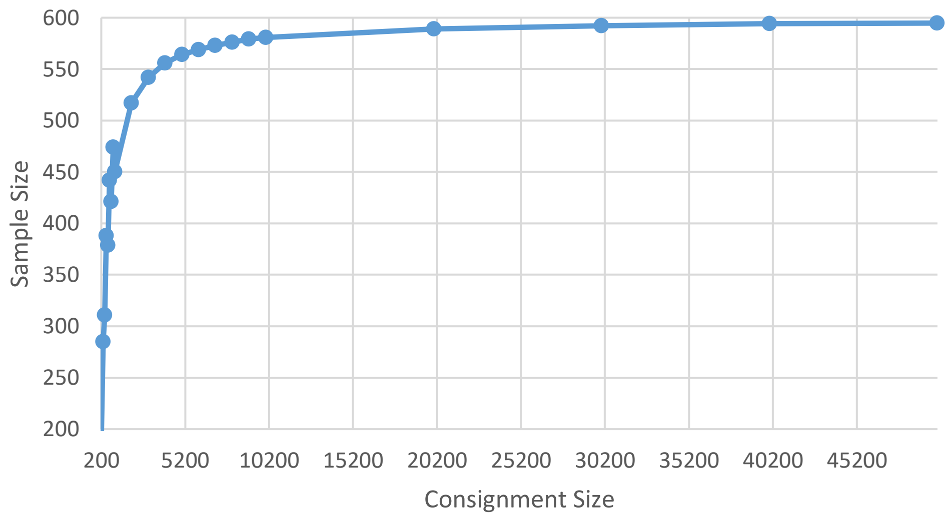


Figure 3. *Risk-based sample sizes assuming a 100% level of detectability, 95% level of confidence, a 0.5% acceptable level of infestation, and using a hypergeometric distribution.*

The main advantage of Risk-Based Sampling is that the level of detection is consistent across all sizes of consignments. This ensures phytosanitary authorities are applying inspection as a phytosanitary measure consistent with their WTO-SPS Agreement obligations. The other advantage is that the sample size plateaus as the consignment size increases. We see in **Figure 3** that the sample size for small consignments is relatively large but becomes a smaller proportion of the consignment as consignment size increases until it becomes almost constant. This extends the versatility of inspection across even the largest consignments.

6.4. Risk-Based Sampling systems and policies

Risk-Based Sampling is focused on single consignments. Risk-Based Sampling system designs (RBS systems) look at inspections broadly to include samples taken from many consignments over a period of time, in a defined area, or across a particular inspection variable such as origin or commodity class. Risk-Based Sampling system designs (reduced herein to simply RBS systems) reflect the practical reality that phytosanitary authorities world-wide have only limited resources to apply to the management of phytosanitary pests moving in trade and thus need to prioritize their efforts to focus on risk and apply inspection policies consistently across their imports.

RBS systems combine evidence and statistics from RBS inspections to inform inspection priorities and help phytosanitary authorities to systematically adjust inspection designs to optimize the effectiveness and efficiency of inspection activities as a risk management procedure. The implementation of RBS methodologies is the key to providing consistent inspection results that can be used to promote technically justified approaches for phytosanitary inspections. Risk-Based Sampling forms the foundation for RBS systems that allow for expedited t*rade in low-risk commodities (Euphresco, see Objective 2017-R-4.1).*

RBS systems were first applied to air pollution control problems by Resources for the Future's Winston Harrington in 1988 (Epanchin-Niell , et al., 2016). In Harrington's model, firms make the decision to "comply" or "violate" an emissions standard, and the regulator sets a policy to achieve a target compliance rate with the lowest number of inspections. Firms are divided into high- and low-compliance groups, each with an assigned inspection frequency and penalty for non-compliance. Firms with the worse compliance records are subject to some combination of more intense inspection, greater penalties for violations, or tougher standards. However, firms can move between groups based on outcomes of recent inspections and an assumed set of transition rules (Epanchin-Niell , et al., 2016).

Harrington found that a direct benefit of this type of targeted inspection policy is that incentives for cleaner activity are steered toward the dirtiest entities. An additional indirect incentive—known as "enforcement leverage"—is generated from the threat of moving into the high-inspection/high-penalty group or the prospect of escaping into the low-inspection/low-penalty group (Epanchin-Niell , et al., 2016).

By designing whole-system inspection processes around basic statistical concepts, inspection programs are better able to identify and rank non-compliant imports. Ranking based on action rates associated with pest interceptions helps inspectors and policy makers identify riskier imports and then adjust resources and policies to maximize the effectiveness of inspection. By doing so, RBS systems enable phytosanitary authorities to allocate resources to higher risk pathways and consignments.

In Risk-Based Sampling, the design of the sampling plan is based upon sound principles and the experience of experts. Organizations using this method will have a baseline number for sample size based upon risk and performance, and that number can change based on prior inspection results – it may be reduced due to good results or tightened due to poor results. Implementing a risk-based method can help authorities and industry spend less time and money, but it requires a data collection and analysis mechanism to detect trends and track changes in the sampling system.

The shift from flat percentage sampling to RBS systems requires appropriate data and analysis to identify the concern, the magnitude of the concern, and changes in its status over time. This requires metrics that come from the analysis of data not previously available or not previously used in the same way.

One starting point for this shift is to analyze existing inspection processes in order to calculate the level of detection that is currently achieved and identify weaknesses. This approach can provide insight into the degree of variability in inspection results and issues that limit the use of inspection results for analysis and targeting. Another starting point is to select a desired level of detection (e.g., a 5% infestation rate) and design a pilot inspection process that achieves the specified objective with statistically valid results. This approach is especially useful to understand the resource commitment (human and monetary) required to achieve different levels of detection.

In either scenario, the objective is to be able to distinguish (rank) commodities, entities, countries, or whatever is being targeted using pest detections as a proxy (= a figure that can be used to represent the value of something in a calculation) for risk and then adjusting the design to redistribute the inspection effort for better management of the higher risk goods.

Once a design is in place to consistently detect a specific level of infestation and valid data is available to rank results, the risk-basis for actions may be added to the calculus by evaluating the pests and pathways of concern for the probability and impact of pest introduction. Combining statistically designed inspection results with data from pest or pathway risk analysis provides a complete and dynamic view of inspection as a phytosanitary measure and opens multiple doors for additional analysis. Phytosanitary actions can be correlated to numerous different trade variables and targeting systems developed for pests, pathways, ports, or any other trade variable that we want to correlate with the risk.

Perhaps the most important points to make in support of the shift to RBS systems is that it is fair and predictable to trade, defendable to stakeholders and trading partners, and provides all involved with a meaningful basis for using inspection as a phytosanitary measure

RBS is the incorporation of basic statistical concepts into the policies and operations associated with inspection. RBS uses the statistical background for inspection to better identify risks and balance risk and resources. Perhaps the most important points to make in support of the shift to RBS systems is that it is fair and predictable to trade, defendable to stakeholders and trading partners, and provides all involved with a meaningful basis for using inspection as a phytosanitary measure.

7. WHY USE RISK-BASED SAMPLING

Robert Griffin[1], Maribel Hurtado[2], Tamara Gálvez[3] and María Elena Gatti[4]

1. National Coordinator for Agriculture Quarantine Inspection USDA, APHIS, PPQ - Retired
2. Project Manager for RBS
3. Jefa Subdepartamento Regulaciones Fitosanitarias de Importación, División Protección Agrícola y Forestal – SAG Chile
4. Coordinadora General de Regulaciones Fitosanitarias. Dirección de Comercio Exterior Vegetal – SENASA Argentina

International trade fosters economic development. Many countries depend on exports and imports of agricultural products to sustain their economy and feed their citizens. Globalization has greatly accelerated and expanded worldwide commerce, increasing the opportunities for more and faster trade, but also increasing the risk for the introduction and spread of pests associated with agricultural products. Regulatory programs cannot focus on only protection or only trade facilitation but must balance trade with protection in a way that minimizes phytosanitary risks and maximizes/optimizes the use of limited inspection resources. In other words, safe trade is the objective.

The WTO-SPS Agreement and the recently completed WTO Trade Facilitation Agreement (WTO-TF) identify relevant principles and obligations for trade. The International Plant Protection Convention (IPPC) and its International Standards for Phytosanitary Measures (ISPMs) provide specific guidance to governments on key aspects of managing plant health risks. The combination of these international agreements and associated standards create an international framework for harmonizing national systems and facilitating safe trade.

The international regulatory framework has been established through agreement by the governments that are members of the WTO (https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm) and contracting parties to the IPPC (https://www.ippc.int/en/publications/269/). Although legally enforceable through the binding Dispute Settlement process of the WTO, an essential reason for adherence is that harmonization[1] of best practices creates a common design that benefits all countries. Harmonization is especially important for inspection because visual inspection of consignments is the phytosanitary measure used most frequently in international trade.

The question addressed in this chapter is why RBS is the preferred design for inspection. The answer has two simple parts. First, the application of RBS is consistent with international obligations under the IPPC, the WTO-SPS Agreement, and the Trade Facilitation Agreement. Second, RBS is an approach that helps risk managers to dynamically balance risk and resources in

[1] The establishment, recognition and application by different countries of phytosanitary measures based on common standards [FAO, 1995; revised CEPM, 1999; based on the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (WTO, 1994)] (FAO, 2019)

a predictable, technically sound, and scientifically defendable way when using inspection as a phytosanitary measure. These points are elaborated further in the sections that follow.

7.1. Perspectives on inspection

The answer to "why RBS?" begins with understanding the many different perspectives that impact decisions on inspection designs for a National Plant Protection Organization (NPPO). The range of themes that emerge from these perspectives demonstrate the importance and complexity of thoughtful inspection designs.

- **NPPO Inspectors** – The inspector wants to find pests and demonstrate effective job performance. Inspectors perform best when provided with optimal conditions and clear guidance on priorities, risks, and best practices.

- **Producers, importers, and exporters** – This group of stakeholders represent the commercial interests in trade. They are primarily interested in moving their products with minimum cost and delay. They appreciate predictability and inspection designs that are consistently applied. Importers and exporters are motivated by inspection designs that reward compliance.

- **The NPPO** – Importing countries are also exporting countries. NPPOs expect inspection designs to be transparent, technically justified, consistent (predictable) for both exports and imports. Phytosanitary officials are also concerned with maximizing the effectiveness of risk management designs given their limited resources. They recognize that data derived from well-designed inspection schemes is a key source of information to enhance risk analysis and resource management.

- **Customs** – The WTO-Trade Facilitation Agreement (WTO-TF) identifies Customs as having overall responsibility for clearing goods and expediting the release of regulated articles moving in international trade. The NPPO plays an important role in assisting Customs with border clearance procedures. A strong collaborative relationship between Customs and the NPPO is needed to facilitate implementation of the WTO-TF.

- **IPPC** – The IPPC helps the NPPOs of its contracting parties to implement inspection procedures and sampling designs that are technically defendable by developing international plant health standards, including ISPM 23 (*Guidelines for Inspection*) and ISPM 31 (*Methodologies for Sampling Consignments*).

- **WTO-SPS and WTO-TF Agreements** – These international agreements are designed to reduce trade tensions by promoting free, fair, safe, and fast trade through a framework of obligations, principles, and concepts agreed by member governments. Inspection is a central area for the application of these provisions because it strongly affects trade.

- **Paying stakeholders** – Stakeholders required to pay fees for phytosanitary services want to pay the minimum necessary for good service, well-designed programs, and consistent, defendable results. This includes inspection designs.

- **The general public** – The public want to have confidence that all products that have been inspected and released into commerce are "safe" and that plant health authorities have maximized the effectiveness of their resources for risk management.

Based on this diversity of viewpoints/perspectives, the ideal inspection design would:

- be fully consistent with international obligations and standards;
- provide maximum risk management value for the NPPO;
- be scientifically sound;
- technically defendable;
- predictable for trade, and limit costs and delays; and
- flexible enough to adjust for changes in risk and resources.

The ideal inspection design rewards high compliance with expedited clearance while shifting more of the inspection effort to high risk consignments.

The starting point for RBS by every NPPO is an assessment of how their current inspection operations can be revised to better meet criteria listed above. The discussions that follow are designed to highlight the advantages of adopting RBS.

Inspection of pineapples with tops. The rough surface of pineapples and rigid upward habit of the crown make them excellent pathways for contaminating pests, including weed seeds that fall into the crown and pests that may be at large in the box.

Source - *https://www.flickr.com/photos/sag-chile/50123017177/in/album-72157711380187833/*

7.2. The International Regulatory Framework

Any discussion of the international regulatory framework should begin with the understanding that its constituent agreements and standards have been created by member countries who have agreed on principles, concepts, terminology, procedures and processes that they believe are in the best interest of all parties. The objective of this framework is not to create burdens or barriers, but rather to encourage harmonization and facilitate safe trade for all who participate.

The legal significance of the international regulatory framework cannot be overstated. The further countries stray from agreed guidance, the greater the risk of program failures and the threat of a challenge from trading partners, potentially leading to a formal dispute. The history of dispute settlement in the WTO offers many valuable lessons on the importance of understanding and correctly implementing the provisions of the WTO-SPS agreement and the international plant health standards developed by the IPPC (WTO, 2020b). Because inspection is a central element of all phytosanitary systems and has a major impact on trade, the application of inspection as a phytosanitary measure is a key area for alignment with the international regulatory framework. Fortunately, there is substantial guidance available to support the creation and adoption of harmonized inspection designs.

7.2.1. The International Plant Protection Convention – IPPC (the Convention)

Article IV.2c of the International Plant Protection Convention (the Convention) states that inspection is a central responsibility of the NPPO. Article V.2a refers to the inspection of consignments for phytosanitary certification. Article VII.1.a explicitly identifies inspection as a phytosanitary measure. Article VII.2e talks about inspection requirements that take into account the perishability of consignments. These provisions highlight the importance of inspection.

In addition, the Convention identifies and provides substantial guidance and disciplines relating to all phytosanitary measures, including inspection. Article VI.2 clearly limits the application of phytosanitary measures to regulated pests. The entirety of Article VII.2 contains provisions directly associated with minimizing interference with international trade. These provisions require that all phytosanitary measures, including inspection, are technically justified and represent the least restrictive measures available.

The Convention highlights the importance of inspection as a phytosanitary measure and identifies key points that are obligations for contracting parties to understand and implement. Complementary guidance is provided by ISPMs 23 and 31 that are devoted specifically to inspection and sampling methodologies.

"Regulated pest"- a quarantine pest or a regulated non-quarantine pest; (IPPC Art II)

7.2.2. International Standards

ISPM 23: *Guidelines for inspection*, was adopted in 2005 (FAO, 2019 a). This standard describes the concept of inspection and procedures consistent with the current IPPC definition:

> *"Official visual examination of plants, plant products or other regulated articles to determine if pests are present or to determine compliance with phytosanitary regulations [FAO, 1990; revised FAO, 1995; formerly "inspect"]"*

It broadly identifies inspection as a procedure for verification of compliance with phytosanitary requirements and risk management. The standard establishes that inspection usually requires sampling and implies a tolerance for pests that escape detection. The importance of relating inspection to pest risk analysis (PRA) is also discussed in terms of using PRA to establish risk priorities and conversely, to use inspection to inform PRA. A distinction is made between general inspection for unspecified pests and a targeted inspection for specific pests. The standard also relates inspection to laboratory testing which has the same conceptual background and requires similar designs for sampling.

ISPM 31: *Methodologies for sampling of consignments*, was adopted in 2008 (FAO, 2016a). This standard complements ISPM 23 with specific guidance on sampling consignments for inspection or testing. It provides technical discussions on relevant statistical concepts, their importance to sampling for inspection, and their application. The standard distinguishes between statistical and non-statistical sampling and provides basic guidance on selecting a sampling method. Tables and formulas are provided as references and to assist with calculations.

7.2.3. The WTO-SPS Agreement

A central tenet of the WTO-SPS Agreement is that governments should use the least restrictive measures to achieve their appropriate level of protection (ALOP). Another fundamental concept in the WTO-SPS Agreement is that phytosanitary measures should be technically justified and based on either international standards or risk assessment.

ISPM 1: *Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade*) (FAO, 2016b) includes other key concepts related to inspection as a phytosanitary measure. These include *necessity, managed risk, transparency, non-discrimination, equivalence,* and *modification*. Annex C of the WTO-SPS Agreement (Control, inspection, and approval procedures) discusses provisions that specifically address inspection: fees, confidentiality of information, and reasonable sampling. All other provisions in foundation documents that apply to phytosanitary measures in general would also apply to inspection.

7.2.4 The WTO-Trade Facilitation Agreement

The WTO-Trade Facilitation Agreement (2017) (WTO-TF) is the first multilateral trade agreement to be concluded since the World Trade Organization (WTO) was established in 1994. The Agreement is expected to reduce total trade costs by more than 14% for low-income countries and more than 13% for upper-middle income countries by streamlining the flow of trade across borders (WTO, 2020c).

The WTO-TF has no explicit provisions for agriculture or plant protection but is focused instead on expediting the movement, release, and clearance of all goods, including goods in transit. A central feature of the Agreement is the establishment of the Single Window for streamlining documentation requirements. This is complemented by provisions for moving towards entirely digital processes. The TF also sets out measures for effective cooperation between Customs and other border authorities on trade facilitation and customs compliance issues.

Although the WTO-TF Agreement has no specific provisions for phytosanitary clearances, some aspects of the Agreement are strongly relevant. The following discussions cover key points for NPPOs to note in the context of inspection.

Single window:
"A facility that allows parties involved in trade and transport to lodge standardized information and documents with a single-entry point to fulfill all import, export, and transit-related regulatory requirements."

- Article 7: Release and clearance of goods

According to the WTO-TF, each member shall adopt or maintain procedures allowing for the submission of import documentation and other required information, including manifests, in order to begin processing prior to the arrival of goods with a view to expediting the release of goods upon arrival, providing, as appropriate, for advance lodging of documents in electronic format for pre-arrival processing of such documents.

The WTO-TF states that *"…each Member shall, to the extent possible, adopt or maintain a risk management system for customs control, as well as design and apply risk management in a manner as to avoid arbitrary or unjustifiable discrimination, or a disguised restriction on international trade*." The WTO-TF does not prescribe a specific inspection design, but Article 7.4 identifies characteristics of the clearance process that would strongly support the use of RBS.

Art 7.1.1: "Each Member shall adopt or maintain procedures allowing for the submission of import documentation and other required information, including manifests, in order to begin processing prior to the arrival of goods with a view to expediting the release of goods upon arrival."

Art 7.4.3: "Each Member shall concentrate customs control and, to the extent possible other relevant border controls, on high-risk consignments and expedite the release of low-risk consignments. A Member also may select, on a random basis, consignments for such controls as part of its risk management."

Art 7.5.2: “Each Member shall select a person or a consignment for post-clearance audit in a risk-based manner, which may include appropriate selectivity criteria. Each Member shall conduct post-clearance audits in a transparent manner. Where the person is involved in the audit process and conclusive results have been achieved the Member shall, without delay, notify the person whose record is audited of the results, the person's rights and obligations, and the reasons for the results.”

Article 8: Border agency cooperation - Each Member shall ensure that its authorities and agencies responsible for border controls and procedures dealing with the importation, exportation, and transit of goods cooperate with one another and coordinate their activities in order to facilitate trade. Such cooperation and coordination may include alignment of working days and hours, procedures and formalities, development and sharing of common facilities, joint controls, establishment of one stop border post control.

Article 10: Formalities connected with importation, exportation and transit - In this article related to the Single Window, the WTO-TF mentions that members shall endeavor to establish or maintain a single window, enabling traders to submit documentation and/or data requirements for importation, exportation, or transit of goods through a single entry point to the participating authorities or agencies. After the examination by the participating authorities or agencies of the documentation and/or data, the results shall be notified to the applicants through the single window in a timely manner.

In cases where documentation and/or data requirements have already been received through the single window, the same documentation and/or data requirements shall not be requested by participating authorities or agencies except in urgent circumstances and other limited exceptions which are made public. Finally, members shall notify the Committee of the details of operation of the single window. Members shall, to the extent possible and practicable, use information technology to support the single window.

Article 12: Customs cooperation - Customs is responsible for:

- Transparency
- Confidentiality
- Reducing costs and administrative burden
- System security

Full implementation of the WTO-TF will have significant and far-reaching impacts on the phytosanitary community, especially the policies, procedures, and processes associated with border controls because:

- Customs is wholly responsible for border clearance operations;
- Border clearance agencies must collaborate with Customs;
- Customs operates the Single Window System;
- The Single Window System aims for fully digital clearance processes.

This raises both challenges and opportunities for NPPOs. One challenge is that it will no longer be possible for the NPPO to unilaterally establish or change inspection requirements. Customs collaboration is required for all border operations. An opportunity is that the WTO-TF provides an excellent opening for cooperation in the creation of a data collection system.

7.3. Operational advantages of RBS

Conformity with relevant international agreements and standards is a compelling reason for implementing Risk-Based Sampling (RBS), but inspection design is a practical and technical matter for front-line officials who are operationalizing inspection to balance resources and risk within their national policy framework.

As mentioned previously, a full inspection cannot guarantee zero risk. Pests have different levels of detectability, and inspectors have different levels of effectiveness. This means there is always some probability that pests will be missed. This leakage or slippage results in an inherent tolerance associated with inspection. Measuring and managing this tolerance is the key to understanding the efficacy of inspection and opens possibilities for linking inspection to risk and adjusting it for maximum risk management given the available resources.

In normal practice, inspection requires a portion of each consignment to represent the whole consignment. We can think of inspecting a consignment as equivalent to sampling for the detection of pests. The concept of sampling includes statistical parameters such as the acceptance level, the detection level, the confidence level, inspection efficiency and sample size. If we understand these basic concepts and their relationship in sampling, we can begin to imagine sampling designs that maximize the effectiveness of inspection as a phytosanitary measure. This could mean that we increase or decrease the sample size to achieve specific risk management objectives. We can also change the frequency of consignments we sample.

Once we accept that it is not possible to eliminate risk using inspection, we begin thinking of inspection as a phytosanitary measure with statistical foundations. This leads us to think about the desired level of effectiveness and the statistical methods that can help us to create inspection designs that achieve our risk management objectives. Risk-Based Sampling helps us take advantage of the statistical parameters associated with sampling. To demonstrate these concepts, it is useful to study an example:

Assume that we know the probability of detection for a pest in consignments of apples from Country A and Country B to be 14% and 86%, respectively. We then need to ask:

- Is a 14% infestation rate acceptable?
- Is an 86% infestation rate acceptable?
- Is a range of 72% (from 14% to 86%) acceptable?
- How well are we managing risk?

Imagine now that we have had 10 similar consignments of apples from these countries over the last month and we are sampling 2% of each. Let us also say that one of the ten consignments from

Country A is rejected for a pest, but none of the shipments from Country B are rejected. Are apples from Country A, a higher risk for the importing country? Based on the number of actions per consignment it would appear so, but we really do not know because we cannot compare consignments that were inspected for vastly different detection levels.

If 22 boxes is the maximum number that our inspectors are able to inspect, then we also need to ask ourselves how we can adjust all the inspections to achieve similar detection levels. Again, we can use a hypergeometric table or calculate the sample size for the same detection level in different size consignments (Chapter 10, Appendices 2 and 1). If we do this, we see that to detect a 14% infestation rate in a shipment of 1,000 boxes, we need to sample 20 boxes.

Now consider what would happen if Country B also started shipping consignments of 5,000 boxes. A 2% sample now jumps to 100 boxes. This inspection will require five times more effort than the 1,000 box shipments from Country A! If we again calculate our detection level, we find that this level of sampling will detect an infestation level of approximately 3%. If we assume the infestation level of the apples is the same in consignments of 1,000 boxes as it is in 5,000 boxes, we can expect substantially more rejections for the large consignments because the inspection is much more rigorous. That should lead us to question the justification for this inconsistency.

Finally, imagine that we have decided to adopt a Risk-Based Sampling approach and adjust inspection procedures to consistently detect a 20% infestation rate in all shipments regardless of size. The sample size for consignments from Country A will be 14 boxes and the sample size for small consignments from Country B will be 13 boxes. The sample size for large consignments from Country B will be 14 boxes.

If all three consignments were to arrive at the same time, the total number of boxes arriving and needing inspection would be 6,100 (5,000 + 1,000 + 100). Using 2% sampling a total of 122 boxes would be sampled (100 + 20 + 2) with detection levels ranging from 3% to 14% to 86%.

However, using Risk-Based Sampling the total number of samples required to consistently detect a 20% infestation rate for all boxes arriving would be 41 (14 + 14 + 13).

Based on this simple but realistic example, percentage-based sampling results in much more work and poorer results. Not only is it less effective risk management, but it also requires more resources and holds larger consignments to a higher standard. How can a more rigorous inspection be justified for the same commodity from the same source when the only difference is the size of the consignment?

7.3.1. Risk and resource management

For over a century, NPPOs have placed great importance on inspection as a primary strategy for preventing the introduction of harmful pests. Whether or not anything is inspected, the fact that the international movement of people and goods is subject to inspection is a motivation for compliance. The threat of inspection, or rather the fear of negative repercussions from the results of inspection, are a deterrent to smuggling or other non-authorized movements. Risk managers rely on this “deterrent effect”, but the positive effect of inspection as a deterrent can be lost because of either ignorance of requirements or a strong desire to circumvent requirements.

Knowing and accepting the reality that inspection is a deterrent, but not a fool-proof safeguard against pest entry, opens the discussion to questions regarding the desired effectiveness of inspection, the tolerance for slippage, targeting for higher risk, maximizing the detection value of available resources, and the consistent, and justified use of inspection as a phytosanitary measure under the obligations of the WTO-SPS Agreement. These are the questions that challenge NPPOs who continuously strive for maximum risk management value from the resources provided to them, recognizing that the situation in trade is constantly changing.

The work of inspectors generates data that can be integrated and analyzed to provide useful insight for risk management. Because of this, it is important to identify critical data and have the means to capture and store the data that support analyses for risk-based decision-making. One possible objective for such analyses is the classification of trade based on risk related to pest interceptions. Such analyses help risk managers to identify high risk imports and subsequently adjust policies, resources, and operations to take maximum advantage of inspection effectiveness.

In the exercise above, we imagine that ten consignments arrive from each source in one month and one is rejected. We intuitively react to the perceived increase in risk and may consider taking measures to modify future inspections or entry requirements as a result. However, if we analyze the variation in detection levels, we realize that the data we have collected for a month cannot help us because it cannot be compared. It cannot be compared because it is not consistent. The results of RBS inspections provide consistent results that we can use to compare consignments and risk, notice changes and trends, and adjust inspection accordingly.

7.3.2. Trade

Perhaps the most important points to make in support of the shift to RBS is that it is fair and predictable to trade, defendable to stakeholders and trading partners, and provides all involved with a meaningful basis for using inspection as a phytosanitary measure. These points and others described above are demonstrated in the example in numeral 7.3. RBS also helps international trade by providing a transparent and predictable process designed to consistently detect the same level of infestation independent of consignment size. This means that importers, exporters, and NPPOs will all have a similar understanding of inspection and confidence in the results.

Because RBS is based on consistent detection levels, the results of RBS inspections can be used to rank or categorize consignments according to their pest interception risk and track changes to that condition over time. This allows NPPOs to identify consistently high or low risk consignments and respond with adjustments in their requirements. Exporters with consistently low risk consignments can be rewarded with less frequent and less rigorous inspections while those with consistently higher risk consignments can be subjected to more stringent inspection or other measures. The result is transparent and defendable processes that motivate shippers to meet or exceed compliance requirements.

7.3.3. Using inspection to improve inspection

The work of inspectors generates data that when integrated and analyzed can provide useful information and insight. Because of this it is important to identify critical data and have the means to capture and store the data that support analyses that aid in risk-based decision-making. The simple example above demonstrates how basic information on the number of consignments and rejections can be used to categorize trade based on risk related to pest interceptions. Such analyses help risk managers to adjust policies, resources, and operations to take maximum advantage of inspection effectiveness.

7.4. Conclusion: Why implement RBS?

NPPOs face complex challenges in facilitating safe trade while preventing the entry and spread of pests. As all NPPOs strive for more efficient and effective pest exclusion, there are many questions about whether inspection is the best strategy, how effective inspection is for pest exclusion, and how the information it provides can support the role of pest exclusion as a key strategy for risk management.

We know that the historical role of inspection as a deterrent to noncompliance based on case-by-case sampling for detection has limited value as a risk management strategy and questionable status as a phytosanitary measure. RBS inspection designs acknowledge the relevant principles of probability and confidence without compromising the deterrence effect of inspection. These designs begin with designating the desired level of detection and statistical parameters such as the confidence level to calculate the sample size based on the shipment size. RBS inspection designs provide a substantially more consistent and effective inspection effort.

The results of RBS inspections can substantially increase the possibilities for analysis and the ability to better measure, adjust, and defend the inspection effort. They provide a demonstrable level of efficacy and can be used to calculate true action rates for consignments, approach rates for pests, and infestation rates for commodities. These calculations can be used to support ranking, targeting, and defendable policy frameworks for strengthening the role of exclusion in managing pest risk. In addition, the data offer potent possibilities for trend and pathway analysis as well as a fair, consistent, transparent, and predictable approach to the application of inspection as a phytosanitary measure.

The arguments are clear. Shifting to RBS helps NPPOs make the most of limited resources (inspectors, facilities, and budgets) while meeting international obligations and providing better risk management. RBS is the right approach for safe trade.

Inspection of orchid plants with flowers. Wild collected plants require more careful inspection than cultivated orchids. Plants with flowers require careful handling and timely inspection to preserve the value of the consignment.

Source - *https://www.usda.gov/media/blog/2012/02/14/usda-does-its-part-bring-valentines-day-cheer*

8. CASE STUDIES

8.1. Building a risk-based compliance framework for Plant Protection and Inspection Services of the Ministry of Agriculture of Israel

Ziva Patir[1], and Valentin Nikonov[2]

1. CEO of Patir Consultants, for many years Ziva Patir was Director General of the Standards Institute of Israel and Vice President and Head of Technical Management Board of ISO - Ziva.Patir@gmail.com
2. Project Manager at Patir Consultants, Valentin is also Coordinator of the Group of Experts on Risk Management in Regulatory Systems of the United Nations Economic Commission for Europe – Valentin.Nikonov@gmail.com

8.1.1. Introduction

This case study describes a project aimed at building a risk-based import compliance framework for plants and plant products within the Israeli Ministry of Agriculture, implemented by the company Patir Consultants in 2018-2020. At the time of the writing this contribution, the risk management framework was already in its pilot implementation phases, so we believe that approaches, methodologies and data management processes that were developed (as well as lessons learned from the project realization itself), might be helpful for regulatory authorities already running or planning to build a risk-based import compliance framework.

8.1.2. Background

In October 2017, the Ministry of Agriculture of Israel initiated a project aimed at building a risk-based compliance framework for the Israeli Plant Protection and Inspection Services (PPIS). The scope of the project included the development of a risk-based approach for running import inspections of plants and plant products at the country's ports of entry. Importantly, the project was initiated within a broader context of the government's policy aimed at decreasing the regulatory burden on business. As such, the rationale for the project was the need to establish the right balance between:

- various import related costs for business companies and,
- the essential need of protecting Israeli agriculture from the introduction of pests and other import-related threats.

Together, the direct and indirect costs of compliance account for a large part of the regulatory burden on business, especially for companies involved in international trade of food products, animals and products of animal origin, and plants and plant products. At the same time, import-related hazards - not only pests, but also counterfeit products, contaminated goods, etc. might present substantial risks to the importing country. Building a risk-based compliance framework that would ideally limit inspections to situations where an inspection is indeed necessary - i.e., when only what is identified as non-compliant is inspected - is an essential and smart way to reduce the regulatory burden without increasing the risks to agriculture and to consumers.

Building a risk-based compliance framework is also important from the trade facilitation perspective. Indeed, the World Trade Organization Trade Facilitation Agreement (WTO, 2014), Agreement on Technical Barriers to Trade (WTO, 2020d) and Agreement on the Application of Sanitary and Phytosanitary Measures (WTO, 2020e) set out basic principles of sound risk management that should be applied by regulatory authorities dealing with non-compliance risks (at the border and in general). These principles include:

- **Proportionality of regulatory requirements** - Technical regulations and standards, as well as other requirements (i.e., import requirements) should be proportionate (commensurate) to the risks that a product might pose to consumers, society, environment, and to other areas of the security of that country (WTO-TBT and WTO-SPS).

- **Proportionality of compliance procedures** - Compliance procedures used by regulatory authorities to identify products that do not meet their codified regulatory requirements, should be proportionate to the risks that a non-compliant product might pose (WTO-TBT and WTO-SPS).

- **Systematic risk management** - Regulatory authorities should develop and maintain a risk management system to deal with all non-compliance risks (WTO-TF).

- **Tolerable levels of risks** - Regulators should focus border controls on high-risk consignments so that release of low-risk consignments can be expedited (WTO-TF).

- **Prioritizing inspections based on risk -** Regulatory authorities should develop appropriate selectivity criteria to identify high-risk and low-risk consignments, so that consignments identified for checks are selected in a risk-based manner. According to the WTO-TF, the selectivity criteria could be based on the Harmonized Systems (HS) code, nature and description of the goods, country of origin, country from which the goods were shipped, value of the goods, compliance records of traders, and other parameters (WTO-TF).

- **Principle of "uniform flexibility**"- Even though the WTO-TF states that "each Member shall apply common customs procedures and uniform documentation requirements for release and clearance of goods", it also recognizes that this "shall not prevent Members from differentiating its procedures and documentation requirements for goods based on risk management".

Our project focused on the risk of product non-compliance – i.e., on risks associated with non-conformity to existing regulatory requirements. As such, the first principle listed above – Proportionality of regulatory requirements - was not applicable within the context of our project as our objective didn't include changing existing legislation or import requirements to products.

However, the other risk management principles of the WTO agreements, such as Proportionality of compliance procedures, will be relevant to the systems we develop.

8.1.3. Project Objectives

The project officially started in March 2018. The project scope was limited to fresh products subjected to uniform inspection policies. For most products, sampling plans were designed according to the IPPC International Standard for Phytosanitary Measures (ISPM) 31 (FAO, 2016a) using a 95% confidence level and a 0.5% level of detection, which results in an average inspection of 600 units per consignment.

The objective of the project was defined as developing a risk management framework that would allow the PPIS (the National Plant Protection Organization [NPPO] of Israel) to:

- Plan import inspections based on a formal risk management methodology using the best available data. It was agreed, as well, that the system would provide additional information to inspectors (enriching their intuition) and would not be a substitute for their expertise and judgment.
- Replace uniform inspections with a Risk-Based Sampling scheme, setting priorities in import compliance inspections and devising sampling plans based on the evaluation of the non-compliance risk of every incoming consignment. This would allow PPIS inspectors to shift inspections from lower risk consignments to those having a higher level of risk.
- Reallocate resources for inspection based on the evaluation of non-compliance risks, explicitly considering the risk tolerance of the PPIS.

A project team was assembled to include all necessary areas of expertise to build such a system. The team consisted of representatives from:

- The Israeli NPPO (PPIS), who provided the foundational and most significant professional knowledge on agricultural risks and on imported products, as well as expertise on import related processes;
- The regulatory policy department, responsible for project coordination and overall guidance;
- Patir consultants, who provided the necessary expertise in various aspects of risk management in regulatory systems.

8.1.4. Guiding principles for building the framework - learning from existing systems and methodologies

Building a risk-based import compliance framework requires bringing together knowledge and expertise from a range of independent fields. These fields, among others, include:

- **Trade facilitation**. Import compliance is the frontline of any trade facilitation framework (risk management principles found in the WTO agreements were mentioned earlier). Import inspections do not facilitate trade (every instance when a consignment is at the border awaiting inspection can be thought of as trade disruption) but are essential, and best practices in trade facilitation are highly relevant to risk-based import compliance.

- **Risk Management**. The very notion of risk is at the core of any risk-based system and risk management methodologies are essential. Risk is defined in the ISO 31000 (ISO, 2018) standard as "effect of uncertainty on objectives". In an import compliance system, the uncertainty comes from our lack of knowledge about something that exists in the present. Indeed, non-compliance risks come from our lack of knowledge about what is inside an uninspected consignment; risk management approaches can help by using what we know to make predictions about something we don't know, so that we can make optimal decisions.

- **Regulation and regulatory systems**. Import compliance procedures for given products along with post-market controls, form part of the larger market surveillance framework for these products, which, in turn, are one of the building blocks of a regulatory system (alongside regulatory requirements and conformity assessment processes)[2]. Developing efficient import compliance procedures requires deep understanding and consideration of the entire regulatory framework.

- **Import compliance and border management**. Inspections that aim at ensuring that no quarantine pests are present in the consignment are only one type of inspection conducted at the border (OSCE UNECE, 2018). Understanding the broader context of inspections from the border management perspective, along with organizational issues and limitations related to conducting inspections (such as equipment requirements, etc.) is essential.

- **Sampling techniques**. Because every inspection is sampling, knowledge of sampling techniques is critical to any risk-based import compliance system.

- **Data management.** Building a risk-based import compliance framework requires the best available historical data of what happened in the past as sources of evidence for assessing the future or the unknown present. Hence best practices and tools for data management are another critical part of the project methodology.

When we initiated the project there was no commonly accepted standard or guidance that covered all the knowledge and expertise highlighted above, so investigating and learning from international best practices in the field – including existing systems in agriculture as well as other fields – was one of the most important tasks of our project. We admit that our system can best be described as a compilation of features from other existing frameworks.

Below we describe each of the sources of inspiration for our project methodology (it is also a wonderful opportunity for us to make all the necessary acknowledgments!). Analysis of each of

[2] For a comprehensive description of risk management in regulatory systems please see UNECE (2012). Risk Management in Regulatory Frameworks: Towards a Better Management of Risks.

the existing frameworks helped us in the formulation of the guiding principles and building blocks we incorporated into our system.

8.1.5. The New Zealand Risk Engine - risk of non-compliance as a graph

The New Zealand Risk Engine (Morfee, 2018), a methodology for evaluating the risk of product non-compliance for electrical appliances, is a predictive risk management tool which was developed and is currently used by New Zealand regulators (and regulators from other countries as well) to choose appropriate regulatory interventions. The following graph in the **Figure 4** represents the NZ Risk Engine in action and shows the main elements of the tool:

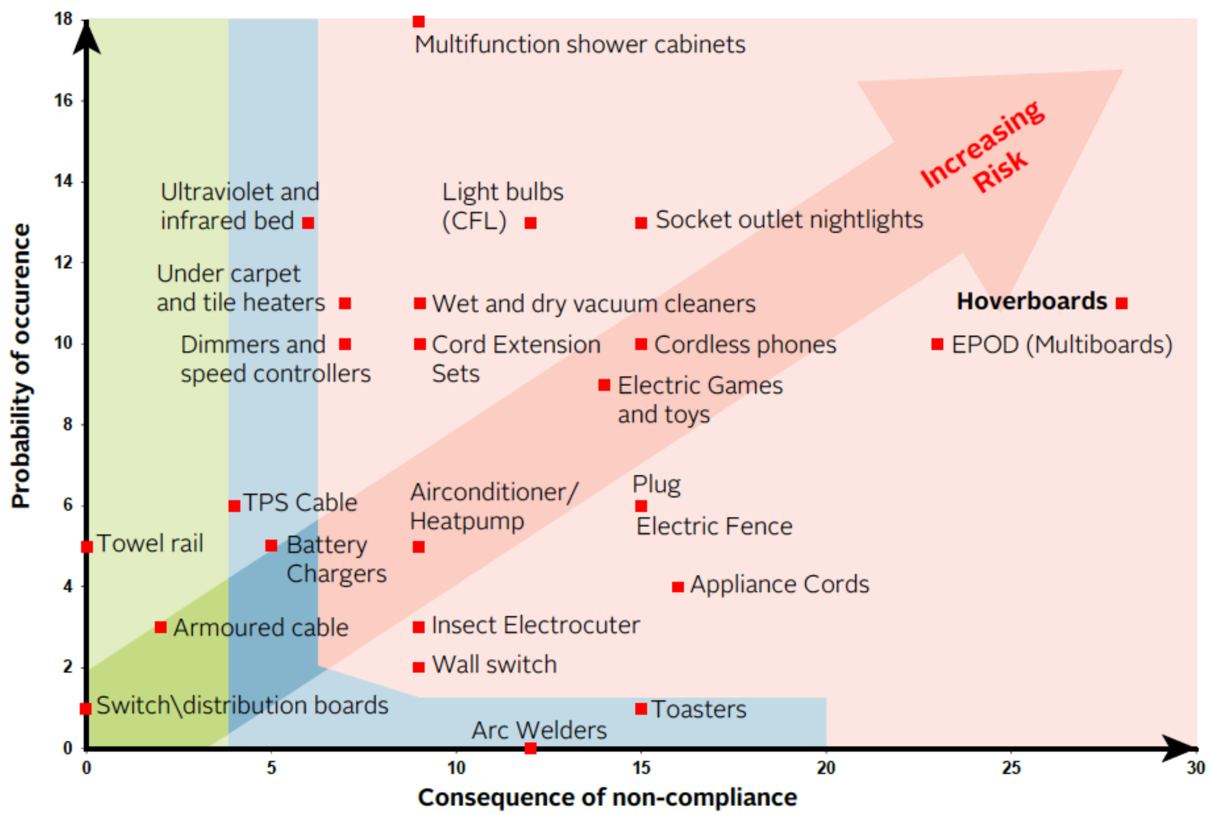


***Figure 4**. New Zealand Risk Engine: non-compliance risk of electrical appliances*

- **The X-axis** is a measure of the consequences of non-compliance associated with an assortment of electrical products within the responsibility of the regulatory authority. The X-axis scale has the total of 30 units – the higher the units, the more dangerous a product is when it is non-compliant. The scale is based on a list of 30 technical factors. Each factor is a feature of the product itself or of the environment that it is being used in that makes the product more dangerous when it is non-compliant. For example, a technical factor for electrical appliances might be that a product can be hand-held, or a product can be used by unsupervised children. Each electrical product is evaluated against each factor. If a factor is relevant to the product, it receives a score of 1. If the factor is not relevant to the product, it gets a score of 0. In this way, the number of technical factors relevant to a product represent an index that measures how dangerous a non-compliant product can be.

- **The Y-axis** is a measure of the probability of finding a non-compliant electrical product on the market. The approach is like that of measuring the consequences of non-compliances, however, a set of different factors is used (for example – there has been a recent change in the product standard, or the product has high compliance costs). The Y-axis scale contains 18 probability factors and each product is evaluated against each factor as indicated above. The sum of relevant/applicable factors represents the probability of non-compliance.

- **Each data point** in the graph represents a product within the scope of responsibility of the regulatory authority, with measures of the consequences of non-compliance and the probability of finding a given product on the market in a non-compliant state.

This visual representation is very useful for devising regulatory interventions. A product can be very dangerous when non-compliant, but the probability of non-compliance can be extremely low. Or, conversely, the product can have a very high probability of non-compliance, but the consequences of non-compliance can be very low. Both cases are less important than a situation in which a product is both dangerous when non-complaint and also has a high probability of being found to be non-compliant in the market.

The New Zealand Risk Engine, which is now used by Australia and the ASEAN (Association of Southeast Asian Nations) countries and which was modified to be used for gas appliances and other families of products, helped us building the following principles of the risk-based import compliance system for Israel.

- **Principle 1.** A risk-based import compliance framework should be based on the evaluation of the non-compliance risk of a product, which is different from the inherent (or essential) risk of the product (risk associated with the product that meets the requirements of the existing regulations).

- **Principle 2.** The non-compliance risk of a product can be relative (not absolute) and can be evaluated in comparison to a certain benchmark, e.g., the non-compliance risk of other products.

- **Principle 3.** The best way to represent the risk of non-compliance of a product is in a graph on which all products belonging to a certain family of products are represented (like the graph above) showing:
    a. How dangerous (or harmful) each product can be when non-compliant
    b. How probable it is that each product on the market (or in a consignment) is non-compliant.

Such a graph allows the regulator to rank products according to their non-compliance risk by using the Pareto optimality principle[3] in terms of the probability and the consequences of non-compliance. The latter means that one can say that one product has a higher level of non-compliance risk only if for a given probability of non-compliance, the consequences of non-compliance are higher; or, if two products that have the same consequences of non-compliance, but the probability of non-compliance associated with one product is higher. In other words, priority in import compliance should be given to a certain product only if the following conditions are met: 1) there is no other product that having the same level of consequences of non-compliance has a higher probability of non-compliance; and 2) there is no other product that having the same probability of non-compliance has higher consequences of non-compliance.

8.1.6. Technical and Probability factors approach and respective indices

Another important lesson learned from the New Zealand Risk Engine was that of using the technical and probability factors for evaluating the probability as well as the consequences of non-compliance. Although the factor approach itself is not new for the evaluation of risk (any hypothesis testing technique is based on known factors), the conceptual factors developed by New Zealand were extremely helpful. They include features that can be applied to all products and that can help us to characterize non-compliance risk. For example, probability factors like "the product uses new technology", "there are cost disincentives for compliance" and technical factors like "the product is likely to be installed by unskilled persons", "the product is likely to be moved during uses" can be easily adapted for and applied to agricultural products. As such, another principle that we formulated based on our analysis of the New Zealand Risk Engine was:

- **Principle 4.** Evaluations of non-compliance risk should not be a "black box" but instead be based on a set of understandable factors; each quantitative evaluation of both probability and consequences of non-compliance should be traced-back to applicable factors and be explained in simple language. For example, electrical product A has a higher level of non-compliance risk than product B, because when compared to product B it is hand-held during its use and it also has high compliance disincentives.

a. The United States Food and Drug Administration (FDA) Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) - evaluating each incoming shipment instead of groups of products

In 2011 the FDA implemented PREDICT (FDA , 2018), a computerized tool designed to improve the screening of FDA-regulated imports and the targeting of entry lines for examination. PREDICT was designed to estimate the risk of imports using information such as the history of the production facility, inspection records, and country of origin. FDA's motivation for introducing a

[3] **Pareto efficiency** or **Pareto optimality** is a situation that cannot be modified so as to make any preference criterion better off without making at least one criterion worse off. (Wikipedia).

risk-based import inspection approach was mainly driven by the increasing volume of imported food that made it impractical to inspect every consignment.

According to the FDA, it would "face a Sisyphean task if its employees were asked to inspect everything that enters our ports"[4], and according to the estimates for 2011, there were "20 million shipments of FDA–regulated imports handled by fewer than 500 inspectors". The available descriptions of the PREDICT[5] system allowed us to infer some of the data sources and probability factors used to calculate the scores that characterize the non-compliance risk of every incoming consignment of food products. The simplified logic of the PREDICT system is presented in the **Figure 5.**

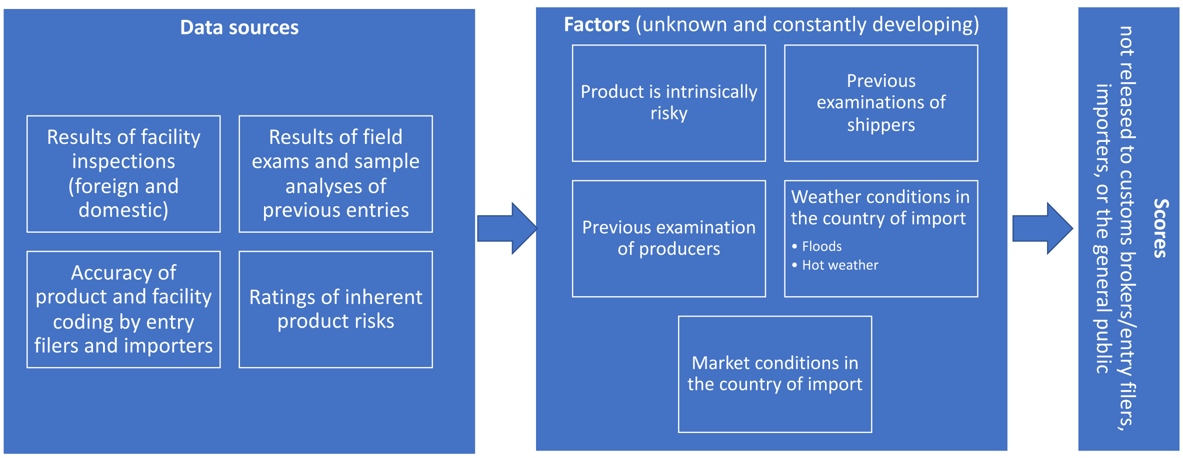


Figure 5. *Presumed logic of the PREDICT framework*

The most important principle that we learned from the PREDICT system was not related to the nature of the data sources or to the probability factors that can be applied. It was the following:

- **Principle 5.** The risk of non-compliance changes from consignment to consignment. Even if the consequences of non-compliance change only when there is a change in the product itself, the probability of non-compliance is different for every consignment. As such, the evaluation of the non-compliance risk associated with every consignment, and planning the inspections accordingly, is required to make the import compliance framework efficient.

This principle could improve many of the existing risk-based compliance frameworks currently in use. In many countries, risk-based inspections are designed by setting an inspection rate for a group of products that is determined on, say, a country of import – product level. In this design, all products of a certain type coming from a given country are subjected to the same inspection scheme. This approach does not consider different aspects associated with changes in the supply chain for a given consignment and thus may lead to biased evaluations of the non-compliance risk.

[4] The Sisyphean myth is a metaphor about man's incessant and futile effort.
[5] See, for example, https://www.gao.gov/assets/680/677538.pdf

b. Australia's Compliance-Based Inspection Scheme (CBIS) - consecutive successful inspections as the main parameter representing the past

Even at the early stages of our project, it was clear that the history of non-compliance by importers, suppliers and other stakeholders involved in a specific product supply chain would be one of the major factors when evaluating the probability of non-compliance of a consignment of that product. One can use many parameters to understand the compliance history of, say, an importer. For example, the average compliance rate per month, that total number of non-compliance cases, the percent of non-compliance cases, etc.

We found an excellent application of the history of non-compliance when we examined the CBIS (Compliance Based Inspection [now – Intervention] Scheme) used by the Australian Department of Agriculture[6]. One of the central ideas of CBIS is to use the number of consecutive consignments of a given product associated with a given importer and found compliant as a measure of the probability that the next similar consignment (of the same product from the same importer) might be non-compliant. For example, this approach might imply that if five consecutive consignments of the same product from a certain importer were compliant, a different, less stringent compliance regime could be used on the next consignment of the same product/importer in the future. For a given combination importer-product, the necessary number of consecutive consignments for applying a less stringent compliance regime could be determined by performing statistical analysis on the historic data.

Within the CBIS, the parameter that characterizes the practical application of this framework and which has the highest visibility to importers is the inspection rate. The inspection rate is applied as a probability of inspection for each importer-product consignment and can range from 10 to 50 percent frequency. Even though the idea of probability of inspection is equally important, the main lesson that we learned from analyzing the CBIS was that:

- **Principle 6.** Consecutive number of successful/unsuccessful inspections provides for an adequate representation of compliance history.

c. The International Symposium for Risk-Based Sampling (RBS) - adjusting a sampling plan to the level of the non-compliance risk

The North American Plant Protection Organization (NAPPO) RBS symposium materials constitute the world's largest repository of best practices in import compliance for plants and plant products (NAPPO, 2017). Our project team wishes to acknowledge and thank Mr. Robert Griffin for his invaluable advice on RBS as well as for exposing our team to the most relevant information on the recent developments in RBS for plant health. These materials gave us some important insights on sampling and inspection of plant products. The following aspects were of outmost importance for us.

[6] https://www.agriculture.gov.au/import/goods/plant-products/risk-return

First, it is clear that 100% inspection does not guarantee absolute product compliance. This is due to the following factors:

- Experience level and inspector efficiency/effectiveness - a seasoned inspector might detect a pest in a consignment where a less experienced inspector may not; even a seasoned inspector might make an error due to distraction or tiredness; inspectors might interpret the protocols differently, etc.
- Appropriateness of inspection - inspection is only appropriate when the pests of concern or the signs or symptoms they cause are visually detectable and when it is recognized that there exists some probability that some pests will go undetected.
- Bad luck - as it was explained, "from time to time we'll fail to detect a pest even though it was present in a consignment simply because it was not in the units that were sampled. A pest might also be missed if it is present in the consignment but in a life stage that is not easily detectable through inspection (for example, the egg stage for Tephritid fruit flies)".

Also, a formal linking of sampling plan parameters to the level of non-compliance risk associated with a consignment was very important. Since inspection is equivalent to sampling, the level of scrutiny of an inspection and its associated regulatory regime is determined by the following parameters:

- Tolerance level, which is the measurable level of the pest prevalence that regulators are willing to accept for a given a commodity.
- Confidence level, which is our level of certainty that we will be able to detect a level of pest prevalence that exceeds our accepted tolerance.

We formulated the following principles based on our analysis of the RBS symposium materials:

- **Principle 7.** Zero risk or absolute safety cannot be a valid regulatory objective, even with 100% inspection of every consignment. This conclusion can also be found in the UNECE Recommendations on Risk Management in Regulatory Frameworks (UNECE, 2011) (UNECE, 2016).
- **Principle 8.** An RBS plan should reflect the non-compliance risk of an incoming consignment in the following way:
  - The confidence level should reflect the probability of non-compliance associated with an incoming consignment.
  - The level of detection should reflect the consequences of non-compliance associated with the incoming consignment.

d. The new European Union (EU) Regulation 625 - an integrated approach

The EU Regulation 2017/625 (European Commission, 2020) on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, requires Member States to perform official controls on consignments upon their arrival at border control posts, including identity checks and physical checks at an appropriate frequency dependent on the risk posed by each consignment.

The Regulation also requires the frequency of physical checks to be determined and modified based on risks (to human, animal or plant health and to the environment) so that inspection resources are allocated where the risk is highest. When managing risks, Competent Authorities should make use of available data sets and information and of computerized data collection and management systems.

The approach of EU Regulation 625 helped us formulate the following two integration principles:

- **Principle 9.** The import compliance framework for plants and plant products should be built in such a way as to allow the possible integration with other areas, such as animal health, food safety and animal welfare.
- **Principle 10.** The import compliance framework should be built in such a way as to allow a possible integrated framework with Customs.

8.1.7. How did we do the project?

After the main principles for building the risk-based import compliance framework for plants and plant products were identified, planning and implementing the project was straightforward. The building blocks and the implementation logic are shown in the **Figure 6**:

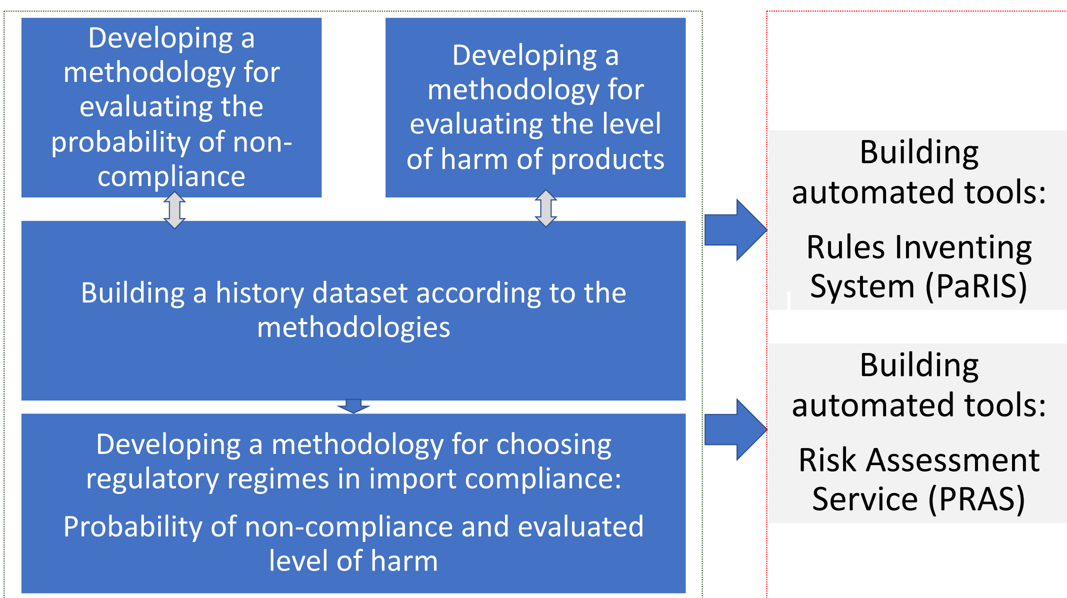


Figure 6. *The logic of the project implementation*

We worked simultaneously on developing methodologies to evaluate the probability and consequences of non-compliance of incoming consignments. When the first iterations of the methodologies were developed, we embarked on evaluating and expanding existing data and developing new datasets (e.g. with product evolutions). This was necessary not only for matching the data with the methodologies, but also for enriching the methodologies by the insights from the data.

After the datasets for both methodologies – for evaluating the probability and consequences of non-compliance - were developed, we began working on approaches to formally select risk-based regulatory regimes (compliance rules) and matching them with various sampling plans. We used data simulations to evaluate what would have occurred if certain risk-based compliance rules had been applied.

These three methodologies – evaluating the probability and the consequences of non-compliance and choosing the regulatory regimes according the risk tolerance of the regulator, formed the methodological core of our risk-based import compliance framework for plants and plant products. From an operational perspective, no matter what compliance rules are chosen by the regulator, the system functions as shown in the **Figure 7**:

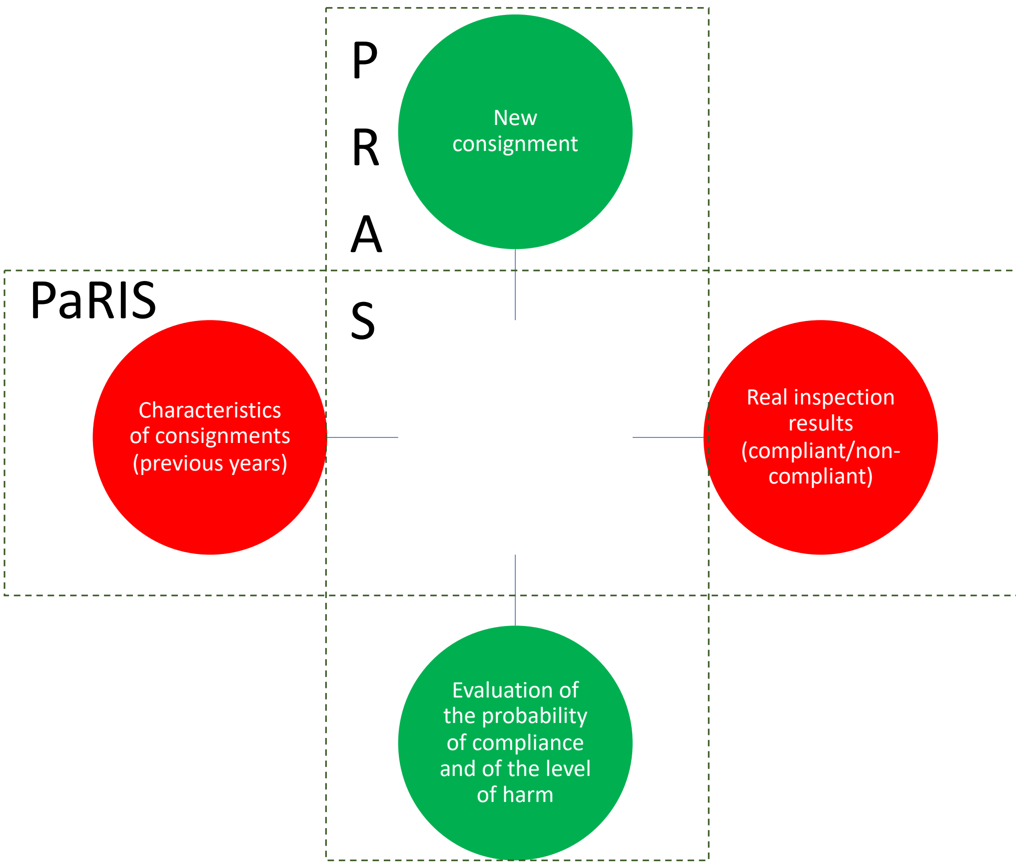


Figure 7. *Risk management in import compliance: the main processes and tools*

The first process – we called it and the respective IT tool that implements it PaRIS (an acronym for Plant Rules Inventing Service) - aims at designing compliance rules based on the analysis of historic data and expert judgment. Rules can be developed to allow a regulator to take into account various characteristics of the supply chain of each consignment (and of the imported products) that are known before the consignment is inspected.

The second process and the IT tool to implement it is necessary for applying the compliance rules to the actual incoming consignments. The process compares the known characteristics of the incoming consignments with the established compliance rules and outputs a sampling plan which is proportionate to the level of the non-compliance risk. We called this second process and the respective IT tool PRAS – it stands for Plant Risk Assessment Service (it was chosen as an acronym because it also means Prize in Hebrew!). We began building these tools as soon as the three methodologies were developed. Below we describe the three methodologies and the operational processes in more detail.

8.1.8. Developing a ranking methodology for products according to product evaluation and consequences of non-compliance

This group of tasks focused on developing a list of factors to rank products according to the consequences of non-compliance and for evaluating the products within our project scope. This required in-depth knowledge of plant risk assessment, and our team relied on the professional knowledge of PPIS analysts. A series of brainstorming sessions were conducted during which a set of factors that could be used for product characterization and evaluation were identified. Examples of these factors included, among others:

- 100% inspection of the product is required;
- A product might be infested with pests/diseases that could be missed during visual inspection.

During product evaluation, PPIS suggested a different approach based on the New Zealand Risk Engine, in which a binary evaluation was used (a factor is relevant or not). A 1-3 scale and grades representing the weight of each factor was developed and later combined into a total score and a weighted score, according to certain formulae (see

Figure 9). Using this approach, each evaluated product was given a score indicating how dangerous it is and a weighted score. Both parameters represent the consequences of non-compliance of an imported product, which is an essential input into the import compliance framework.

8.1.9. Factors for evaluating the probability of non-compliance

Developing a methodology for evaluating the probability that an incoming consignment contains a non-compliant product was the central task of our project. If the consequences of non-compliance associated with a product are not supposed to change unless the product itself or its production conditions change, the probability of non-compliance is consignment specific. As such, a methodology that would allow evaluation of every incoming consignment was needed. The inspectors should know how probable it is that each incoming consignment contains an infested/non-compliant product. Clearly, if two products/consignments have the same level of consequences of non-compliance, priority should be given to a product/consignment that has a higher probability of non-compliance.

To develop the methodology for evaluating the probability of non-compliance, our team worked in two main directions:

- Determining the factors/sources of evidence that can be used to evaluate the probability of non-compliance. In other words, we identified parameters of consignments that have an impact on the probability of non-compliance (i.e., something that we know now (evidence) that can be used to make judgments about the future (probability)). We should be able to derive these parameters from the existing data.
- Reviewing and improving existing datasets on history of compliance checks to get a complete dataset and understand which data is available to use for building probability factors.

Principles for building the framework that were described previously, as well as interviews with local and international stakeholders involved in import compliance and with expertise in risk management helped us formulate three main sets of questions and identify sources of information that are (explicitly or implicitly) considered when making a judgment on the probability that an incoming consignment contains a non-compliant product. The questions include:

1. Is there anything new within the supply chain associated with the consignment -- something we didn't see before, e.g., a new product, a new supplier, a new importer? Since past experience reduces the level of uncertainty, every new element within the supply chain makes the level of uncertainty associated with a consignment higher.

2. To what extent do stakeholders focus on a limited number of products involved in the import process associated with the product? The hypothesis behind this question is that when an importer/supplier works with a limited number of products, he or she has more experience and knowledge about these products, and hence the level of uncertainty associated with an imported consignment is lower.

3. What is the compliance history of the stakeholders associated with the incoming consignment? Compliance history is important evidence to evaluate the probability of non-compliance. Clearly, the probability that an importer with a history of non-compliance would import another non-compliant product is higher.

After the questions were formulated, our team designed a set of parameters to cover all sources of information identified in the questions above.

For the first question - something new in the supply chain – a set of parameters easily derived from existing historical datasets were identified and include the following:

- New country/Old country: Old country means that at least one product from this country has already been imported into Israel (by any of the suppliers and importers).
- New Product from Country: A consignment/inspection is identified (flagged) as New product from x Importing Country when it is the first time the product is imported from that country.

The product could have been imported from other countries or other products could have been imported from that country in the past.

- New Product from Importer: A consignment/inspection is characterized (flagged) as New Product for Importer when it is the first time the importer imports this product. He could have imported other products in the past.
- New Product from Supplier: A consignment/inspection is characterized (flagged) as New Product for Supplier when it is the first time the product has been imported into Israel by this supplier. The supplier could have imported the product to other countries.

We also introduced the following parameters to assess importers and suppliers:

- Importer diversity: If the importer has experience working with more than five different products, the importer is considered *very high divers*ity. If with two to five products the importer is considered *medium diversity* and if with only one product, the importer is considered a *single product importer.*
- Supplier diversity: same classification as indicated for importer diversity above.

Finally, to address the compliance history of the entire supply chain, we introduced an innovative approach focusing on interrelationships among the various chains in the network, as shown in the **Figure 8**.

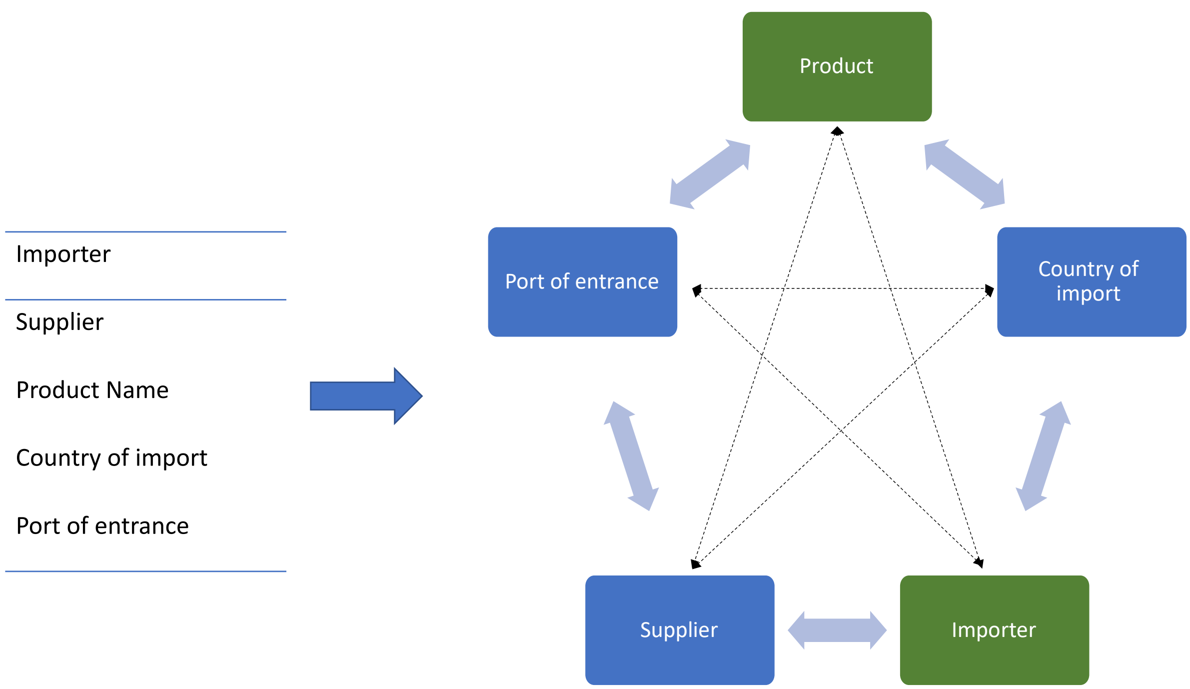


Figure 8. *Developing probability factors for the import compliance framework*

The development of this prediction model was inspired by the Australian CBIS and the FDA PREDICT (see descriptions in sections ***8.1.6. a*** and ***8.1.6. b***). We broadened the set of parameters for the incoming consignment as much as we could. In addition to the number of successful inspections for a given importer-product combination, other supply chain combinations were considered. For example, how many successful checks has the product supplier had. We were looking at the number of consecutive successful inspections for different combinations:

- importer – supplier,
- supplier-product,
- product – country of import,
- importer – country of import, etc.

These parameters provide regulators with an opportunity to design very flexible and understandable compliance rules that reflect their vision of the world. This approach reflects the real world, in that, the number of non-compliance checks an importer has had in the past is less important than how stable the importer's compliance is at present. The number of consecutive successful checks perfectly reflects the current compliance status. As such, this approach was applied to the various combinations of supply-chain stakeholders.

Examples of some of the parameters that were derived include:

- the number of consecutive successful checks for an importer until the present inspection (with all products),
- the number of consecutive successful checks for the supplier until the present inspection (with all products),
- the number of consecutive successful checks for an importer with the given product,
- the number of consecutive successful checks for a supplier with the given product.

Based on the above, we derived ~ 60 parameters that are known before the consignment is inspected and that can be used as evidence for the probability of non-compliance, as shown in the **Figure 9** below.

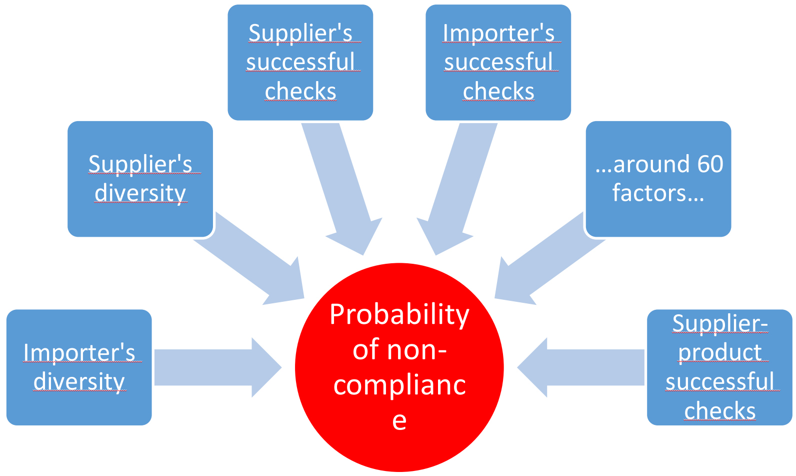


Figure 9. *Probability factors*

An automated system was developed by our team that processes the data (Product, Importer, Supplier, Country) and returns a table with the parameters described above. Enriched with data, these probability factors (sources of evidence) were used to build models based on the history of inspections and to run simulations to choose the optimal risk-based regulatory approach.

8.1.10. Developing compliance rules and choosing sampling plans

Building a framework and an IT tool (PaRIS) to allow the PPIS to choose regulatory approaches, i.e., to develop compliance rules and choose sampling plans, was another key task of our project. All parts of the system described earlier (evaluating the probability of non-compliance and evaluating the level of risk of imported products) were put together and a number of simulations of risk-based import compliance approaches were performed.

The logic behind this task is shown in the following **Figure 10**.

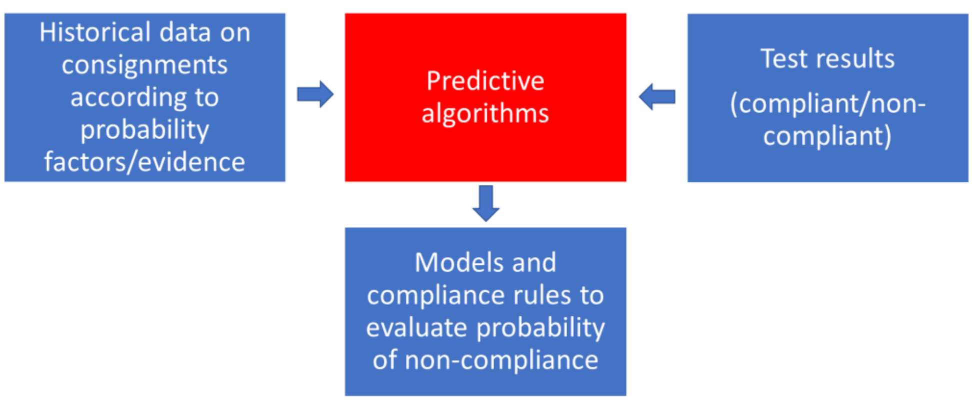


Figure 10. *Developing compliance rules*

As a result of the simulations, together with the application of various predictive algorithms and consultation with various stakeholders, the following regulatory approach was approved for the pilot project. See **Figure 11** below.

High "probability" • Rule 1 or • Rule 2 or • Rule 3 • …	CL 90% DL 5% (45 units)	CL 95% DL 2% (149 units)	CL 90% DL 0.5% (459 units)	CL 99% DL 0.5% (915 units)
Medium/Normal "probability" • Everything not in the "high" and "low"	CL80% DL 5% (32 units)	CL 90% DL 2% (114 units)	CL 90% DL 1% (229 units)	CL 95% DL 0.5% (596 units)
Low "probability" • Rule 1 and • Rule 2 and • Rule 3 • Rule 4 • …	CL80% DL 5% (32 units)	CL 90% DL 5% (45 units)	CL 90% DL 1% (229 units)	CL 90 DL 0.5% (459 units)

X units out of a consignment of 100 000 units

Consequences of non-compliance

LOW	**MEDIUM**	**HIGH**	**VERY HIGH**	**EXTREMELY HIGH**

Figure 11. *Risk-based regulatory regime: compliance rules and sampling plans. CL = Confidence Level; DL = Detection Level.*

As you can see, the graph is similar to the one used in the New Zealand Risk Engine, only the names of products are missing. Since our methodology is consignment specific, any product can only move up and down within a given risk group.

The horizontal axis reflects the evaluation of products according to their level of potential risk, based on parameters described earlier (a product can belong to one of the five risk designations), and the probability of non-compliance is evaluated based on the set of defined compliance rules. For example, the probability of non-compliance of product A coming from country B from supplier C is low**,** if at the moment of consignment arrival:

- Product A from country B meets certain compliance history conditions (represented by the number of successful consecutive checks), and
- Product A from supplier C meets certain compliance history conditions, and
- The compliance history of Supplier C meets the defined requirements, and
- There were no interceptions with any product coming from country B (the latest inspection was successful), etc.

Conditions that an incoming consignment should meet to get into the high probability group are defined using similar logic, whereas the probability is considered to be medium in case the consignment doesn't belong to either group.

The distribution of sampling plans for each combination of risk level and probability of non-compliance is shown in the graph above (the distribution is based on ISPM 31 and the numbers come from the sampling tables in ISPM 31). As the level of detection (LOD) increases the level of risk associated with the product decreases.

8.1.11. How does the system work now?

The system is currently in the pilot implementation phase at PPIS. The risk of non-compliance for incoming consignments is being evaluated and sampling plans are being designed accordingly, but the actual inspections are being performed with routine sampling plans (95% confidence level, 0.5% level of detection) for all consignments. In case a non-compliance is identified, the inspectors are requested to note during which stage of the inspection it happened in order to assess whether the non-compliance would have been missed if the Risk-Based Sampling plan had been used.

The process for applying compliance rules at the border (the PRAS process) – which lies at the center of any risk-based import compliance framework - has the following structure:

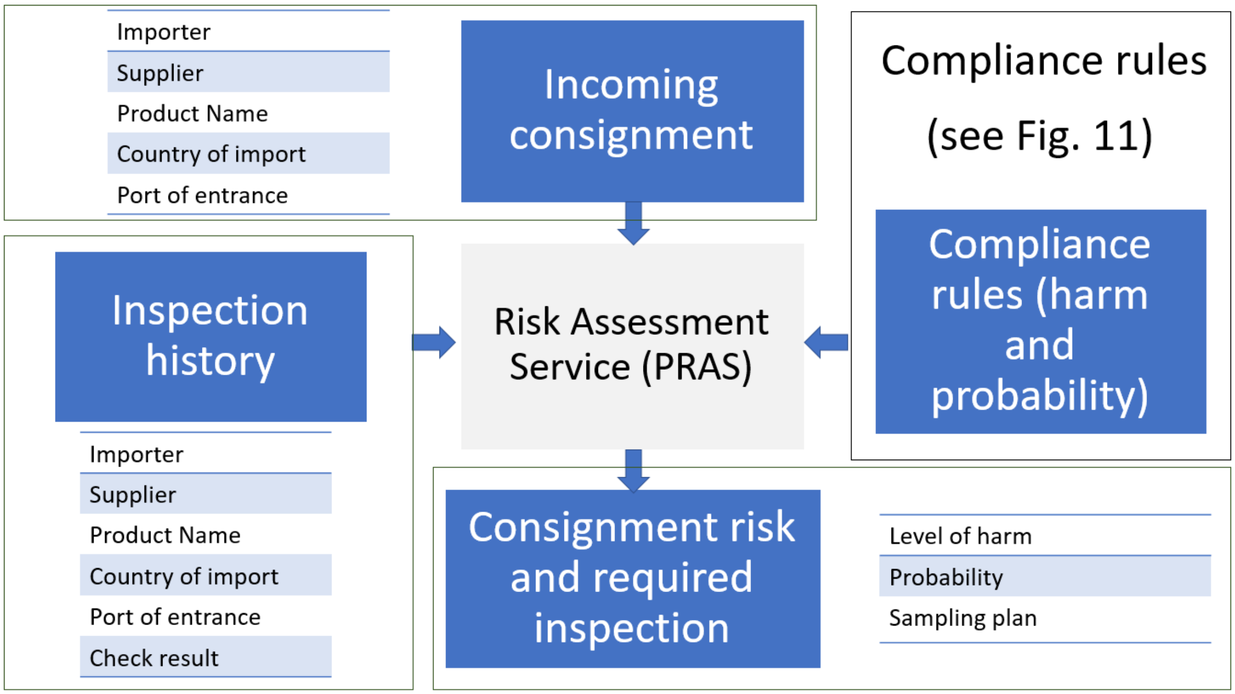


***Figure 12**. The risk assessment service*

The process has two major phases:

- setting the system, and
- evaluation of each incoming consignment.

To set the system it is necessary to:

- upload the historical inspection data, information on importers, products, suppliers, importing countries, etc. (for a period that PPIS considers relevant),
- update and upload the product evaluation,
- enter the chosen compliance rules (as described above).

When the system is set, it calculates all necessary parameters to evaluate the incoming consignment according to the compliance rules.

We then need to:

- enter identifying data on the incoming consignment - importer, supplier, importing country, etc.,
- receive the output with all the consignment characteristics and the type of inspection as set in the compliance rules.

During the pilot, the system is being operated semi-manually, with comments explaining the logic behind the proposed sampling plan. For example, for one of the shipments it was noted that although supplier C has recently passed more than X successful checks with product A (but not in the last inspection), there was an interception in product A from country B (from another supplier). That is why the probability is medium, if there were no interceptions from other suppliers, the probability would be low.

8.1.12. Conclusions

Although the system is still in its pilot implementation phase, and statistically representative results are not yet available (we still need to wait until we have a sufficient number of interceptions to confirm that the non-compliance risk was properly evaluated), we can evaluate the initial results of the project.

Approximately 40 consignments were evaluated during the pilot and the effectiveness of the proposed sampling plans was checked. Preliminary results indicate that the number of samples could have been reduced without creating unnecessary risks to agriculture. In the future, we will be able to prove that the risk evaluation is correct and respective sampling plans are efficient in cases of non-compliance only when we have such cases (and we haven't experienced them during the pilot project). In any case, final decisions on the application of compliance rules will be made by the PPIS.

Independent of the compliance rules that will be applied (compliance rules will be subject to change since they are systematically updated) results of the pilot project already have shown that a regulator can plan inspections based on a formal risk management methodology using the best available data; the inspectors receive information on the incoming consignment that they wouldn't be able to get intuitively. At the same time, the system is not supposed to take the place of inspectors' judgment but rather to enrich it – it provides a 'suggested sampling plan' and the final decision remains in the hands of the inspector.

Finally, the system allows for implementation of very risk averse strategies while sufficient evidence is gathered to support risk management strategies that achieve the level of risk considered acceptable by regulators.

The most important result is, of course, that the system allows regulatory authorities to evaluate every incoming consignment and to use Risk-Based Sampling instead of uniform inspections. This means that inspectors do not have to inspect *different* (from the non-compliance risk perspective) shipments in the *same* way; but rather make justified and evidence-based decisions for each shipment resulting in compliance procedures that are proportionate to the level of the non-compliance risk. This is, in turn, is a prerequisite for balancing compliance costs for businesses with the need to protect consumers, agriculture and the environment from import related risks. If this balance is achieved, import inspections will most likely not be considered a regulatory burden -- even by importers.

8.2. Risk-Based Sampling: Experiences from the United States

***Barney Caton*[1]**

1. Pest Exclusion Analysis Coordinator, Phytosanitary Advanced Analytics Team (PAAT). Center for Plant Health Science and Technology. Plant Protection and Quarantine, USDA

The experiences of the United States Department of Agriculture, Animal and Plant Health Inspection Service, Plant Protection and Quarantine (USDA-APHIS-PPQ) with risk-based inspection designs go back more than thirty years. The first efforts took place at selected ports-of-entry along the southern border with Mexico, where the intensity of inspection was adjusted based on the pattern of interceptions of regulated pests in consignments of plant products entering the United States from Mexico. The land border ports of Nogales, Arizona, in 1987, and Hidalgo, Texas, in 1991, were the first to institute these practices. By 1993, the USDA-APHIS-PPQ expanded this approach to all southern border ports and named this effort the "Border Cargo Release Program". Subsequently, a "National Cargo Release Program (NCRP)" was established with the following objectives:

1. increase inspection efficiency and allow redirection of inspection resources to high-risk consignments;
2. use systematic sampling designs to more accurately measure pest risk; and
3. maintain effective safeguards against the entry and establishment (= introduction) of regulated pests.

The NCRP lowered the frequency of inspection for high-volume low-risk consignments. The NARP evolved over time (see section 8.2.1.) and generated a risk-based program specifically for consignments of cut flowers which is discussed below (see section 8.2.2.).

More recently, the USDA-APHIS-PPQ piloted and successfully deployed Risk-Based Sampling (RBS) for the importation of plants for planting. The RBS pilot program began in late 2013 and fourteen of the sixteen USDA-APHIS-PPQ Plant Inspection Stations were using the program by September 2014. The goal of the RBS pilot was to develop an operationally feasible inspection system that was both statistically sound and scientifically (technically) defendable. During the RBS pilot, sampling parameters were set to detect a 5% infestation rate with a 95% confidence level, assuming 80% inspection efficiency. The RBS pilot program is described in detail by Katsar, et al., 2017 and is available here https://nappo.org/application/files/5415/8676/4129/RBS_Symposium_Proceedings_-10062018-e.pdf

For successful implementation of RBS for plants for planting, it was important to understand the data history, the availability of baseline statistical information, and the variety of ways in which consignments arrived and were inspected at Plant Inspection Stations. This information was useful to adjust inspection intensity in cases where consignments contained mingled or commingled plant taxa and where risk was linked to the plant taxon and its country of origin. Cazier-Mosley, 2017, describes this in an article published in the Proceedings of the International

Symposium for Risk-Based Sampling available here https://nappo.org/application/files/5415/8676/4129/RBS_Symposium_Proceedings_-10062018-e.pdf

8.2.1. USDA-APHIS-PPQ National Agriculture Release Program (NARP)

The National Cargo Release Program (NCRP) ended in 1999 (PPQ, 1999). The program was subsequently revaluated and expanded as a collaborative effort between USDA-APHIS-PPQ and the Department of Homeland Security Customs and Border Protection (DHS-CBP), after responsibility for inspection of most regulated plant products (except for plants for planting) was transferred to DHS-CBP. The National Agricultural Release Program (NARP) began in January 2007 (CBP, 2016). It operated nationwide, ensuring that eligible consignments arriving at any United States port-of-entry would be processed according to NARP program guidelines.

To qualify for NARP, consignments had to meet three requirements:

1. Consistent high-volume consignments,
2. Low (pest) action rate (defined as the number of phytosanitary actions for the consignment volume in the last 12 months and over the previous 6 years),
3. No high-risk pests intercepted in the consignment, based on a (living) list of more than twenty insect, mollusk, and pathogen species.

Eligible consignments were identified as country-commodity combinations, such as 'Mexico strawberry' or 'Guatemala cantaloupe.' This design meant that all stakeholders in the country's supply chain were responsible for and affected by the program's results. Inspection frequencies were lowered for consignments (fresh and frozen fruits and vegetables) meeting the abovenamed requirements. Eligibility and inspection frequency were checked and adjusted quarterly, bi-annually, or annually (by USDA-APHIS-PPQ). Inspection frequency could increase if high-risk pests were found during the relevant time frame, or eligibility could be rescinded if the consignment failed any other requirement. The DHS-CBP data management system automatically determined NARP consignment eligibility and randomly determined if the consignment was inspected or cleared without inspection. The NARP used hypergeometric sampling instead of percentage-based sampling. Sample sizes were determined based on 95 percent confidence in detecting a 10 percent pest infestation rate. Consignments of eligible frozen and processed commodities received only cursory examination to verify that items were accurately described in the shipping documents and met entry requirements. By 2012, the number of eligible country-commodity combinations was above forty. Thirty-nine of these came from three countries—China, Guatemala, and Mexico.

Figure 13 shows the difference between NARP eligible commodities inspected before release with those released without inspection over several years (2009-2018). Overall, the consignments were cleared by inspecting about 4.8 percent, on average, resulting in approximately a 95 percent reduction in inspection resources. The mean volume cleared without inspection increased from an average of 4.1 billion kg in 2009-2011 to 6.1 billion kg in 2016-2018, while the mean pest detection rate over that time period was only 0.02 percent. Given that some consignments were inspected at higher intensities dictated by hypergeometric sampling, the results support the associated NARP program-defined low pest action rates.

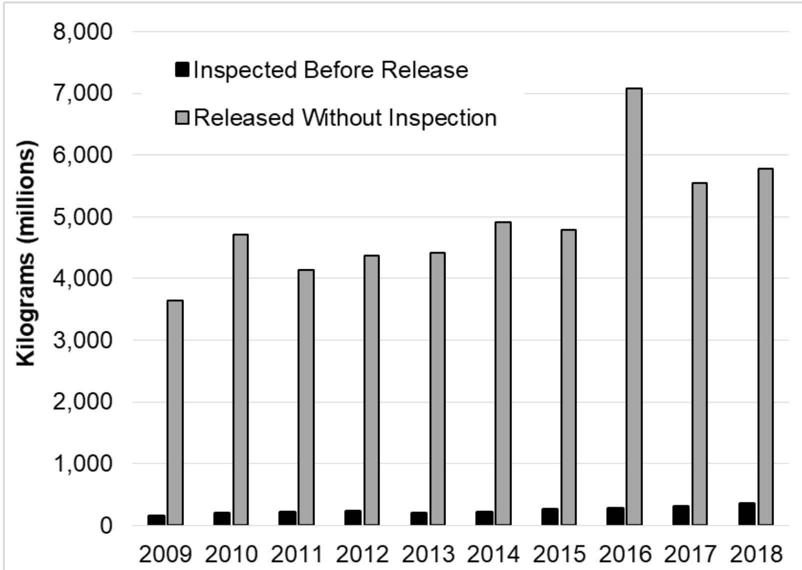


Figure 13. *Agricultural imports of National Agriculture Release Program (NARP) commodities from fiscal years 2009 to 2018, showing goods cleared with (black bars) and without (gray bars) hypergeometric sampling inspection.*

8.2.2. Cut flower release program

A separate but similar RBS program was developed for cut flowers and tested at the port of Miami. The cut flower program also had a high-volume requirement (250,000+ stems annually) and a consignment action rate threshold of 1 percent. Categorization of pest risk was done differently than for the NARP; mean interceptions were calculated over time and weighted by the risk rating (1 to 3) associated with each intercepted pest. This metric allowed uncertainty (confidence intervals) to be determined and facilitated placing the country-commodity combinations into three risk categories: low, moderate, and high. Country-commodity combinations that were low risk and had action rates of less than 1 percent were eligible for cargo release. In the cut flower program, eligible consignments were named as origin by genus (e.g., 'Colombia *Rosa*,' 'Guatemala *Dianthus*' or 'Ecuador *Limonium*'). Out of the initial 40 origin by genus combinations evaluated, two were found to be high risk while 33 were determined to be low risk (CPHST, 2003).

The sampling plan for the cut flower program was different than that for regular cargo, because consignments typically consisted of mixed lots that could include many plant genera and different producers. For origin by genus combinations determined to be moderate risk, one box per genus per farm was sampled. Inspectors sampled two boxes per genus per farm for high risk combinations. High-volume low risk combinations were sampled similarly to moderate risk combinations (e.g., (PPQ, 2006)).

The sampling scheme for program-eligible origin by genus combinations operated differently from that of the NARP. Rather than use a fixed chance of inspection by country-commodity combination, intensive inspections rotated throughout the month to a different origin by genus combination termed "flower of the day". This design allowed inspection of most origin by genus combinations two to three times per month. Combinations that were not designated as "flower of the day" were cleared without inspection.

Monitoring activities were designed to identify atypical program trends in pest interceptions. The process for updating the risk ratings for origin by genus combinations operated in a more ad hoc fashion than for NARP and other cargo. Risk-ratings could be re-assessed and increased if interception trends suggested a change in action rates, but the eligibility standards were stringently followed. Industry stakeholders would often request reassessment of the risk-rating for a specific origin by genus combination on behalf of exporters.

The cut flower program has been very successful. The most recent manual (PPQ, 2018) identifies low risk genera from thirteen countries, including Israel, the Netherlands, and South Africa. Thirty-seven different flower genera and types (e.g., orchids) have qualified as low risk origin by genus combinations. In the months before Valentine's Day (February 14), over one billion cut flower stems enter the United States (CBP, 2018). Quickly clearing these consignments through the cut flower release program results in significant savings in terms of time and inspection resources.

8.2.3. Recent work on RBS for cargo

While NARP and the cut flower release program are still in operation today, the USDA-APHIS-PPQ continues its collaboration with DHS-CBP to design and expand RBS programs to other cargo environments. The goal is to eventually manage most cargo inspections using RBS sampling designs. Both agencies are interested in moving away from ratings-based programs, like NARP, and favor shifting to more dynamic inspection schemes in which the frequency of inspection depends on (recent) outcomes (e.g., (ISO, 2005); (Stephens, 1995)). As such, in 2018, both agencies launched a six-month trial using a skip-lot sampling program at two ports located on the southern border with Mexico. Further trials in different pathways and at different ports are planned for 2019, hopefully leading towards wider implementation of RBS in the future.

It's interesting to note that RBS activities have seemingly come full circle for USDA-APHIS-PPQ. RBS efforts began at two southern border ports in the 1990's. Three decades later, USDA-APHIS-PPQ in partnership with DHS-CBP are moving toward the next generation of RBS programs by testing new approaches at two southern border ports.

8.2.4. Risk-Based Sampling program benefits

Risk-based inspection programs in the United States have benefitted everyone involved. From the trade perspective, the private sector benefits through cost savings, shorter time delays to market, and lower costs associated with loss in product quality. Inspectors (DHS-CBP) benefit by employing more efficient inspection designs to process low risk consignments, which allows more time for them to focus on higher risk consignments. Finally, the USDA-APHIS-PPQ benefits by maintaining a demonstrably effective, science-based and technically defendable inspection program.

8.3. Mexican experience with Risk-Based Sampling

***Marta Elva Ramírez Guzmán*[1]**

1. Professor of Statistics Colegio de Postgraduados Mexico.

8.3.1. Introduction

The development of risk-based inspection programs and guidelines in Mexico has been supported through close collaboration between institutions of higher learning and the Mexican regulatory and inspection authorities. Subject matter experts from academia have designed statistically based sampling programs and written inspector-focused manuals used at Mexican ports of entry and other inspection facilities.

The framework and procedures for sampling fresh fruits and vegetables, dehydrated plant products, plants for planting, grain, cut flowers and fresh foliage in Mexico are presented below. Statistical concepts as well as logistics constraints and cost issues were considered when designing this framework. Specific examples are part of this case study.

8.3.2. Introduction to acceptance sampling

For agricultural commodities entering Mexico it is important to ensure that inspections conducted at ports of entry reliably detect pests. As such, developing and implementing sampling schemes that meet the sanitary and phytosanitary import requirements while maximizing the probability of consignment acceptance ensures that Mexican stakeholders have ready access to safe and high-quality agricultural commodities. Acceptance sampling forms the basis for sampling programs used to inspect imported plant commodities in Mexico.

8.3.3. Background

The IPPC ISPMs 23, 31 and 32 (*Categorization of commodities according to their pest risk*), provided foundational guidance when redesigning sampling plans for use by the Mexican regulatory and inspection authorities. The driving force behind the redesign of sampling plans based on statistical and risk-based principles has been to build the capacity of Mexican inspectors and certify their competence to Mexican standard EC 0819 – *Inspection of products and agri-food materials traded in commerce* (CONOCER, 2016).

The redesign of sampling plans in Mexico occurred gradually. It began in 2006, when the Director General of the Mexican Plant Protection Service requested the assistance of academics from the Colegio de Postgraduados - COLPOS (https://www.colpos.mx/wb/index.php/campus-montecillo) - in the development of a statistically-based sampling manual for inspection of imported seed. Once completed, the manual served as the basis for development of additional manuals for the inspection of grains, plants for planting, fruits and vegetables, cut flowers and foliage and dehydrated agricultural products - all completed during 2007. In 2013, the Director of the Mexican Association of Seed Growers (AMSAC) requested that a new seed sampling plan be developed to foster compliance adherence by seed importers. Academics at COLPOS suggested the application of skip-lot sampling (CSP-3), which offers the opportunity of avoiding 100% inspection of consignments, but only for those industries/importers who have demonstrated an excellent record of clean consignments, free of quarantine pests. The skip-lot sampling strategy ultimately improves the quality of imports because when a consignment is found infested and is rejected, the importer will be forced to take appropriate measures to ensure that their future shipments are free of pests (and therefore not rejected). In addition, this methodology allows the importing country to make better decisions based on seed import quality (p1 – proportion of product that does not meet the pest absence criteria from the total product that was sampled) and the desired level of protection (Pr). In other words, skip-lot sampling allows the selection of a sampling plan with a stated level of confidence to reject lots that do not comply with the agreed-upon phytosanitary specifications. A skip-lot sampling system (CSP-3) is recommended when control of process quality for seed lot production (p1), the Average of Outgoing Quality (AOQ) and the established level of confidence (Pr) is codified in an agreement between the competent regulatory authority (SENASICA) and the seed companies.

Recently SENASICA has requested that COLPOS provide a series of new inspection/sampling workshops for inspectors. The workshops will focus on the latest sampling plans using hypergeometric distributions (**Figure 14**) and ISPMs 23 and 31. The primary workshop topics will be: 1) determination of the most appropriate sampling methodologies and sample sizes; 2) tables to assign sample size and criteria for acceptance; 3) determination of sample size for toxicology analysis; management and shipments of animal product and waste samples; 4) sample size for certification and diagnostics of causal agents for viral infections in crustaceans; and 5) sampling schemes for nuts, vegetable products and sub products, and for processed and dehydrated products. Countries other than Mexico that are members of OIRSA (Organismo Internacional Regional de Sanidad Agropecuaria), one of three Regional Plant Protection Organizations in Latin America, have requested and have already been trained on the Mexican sampling schemes.

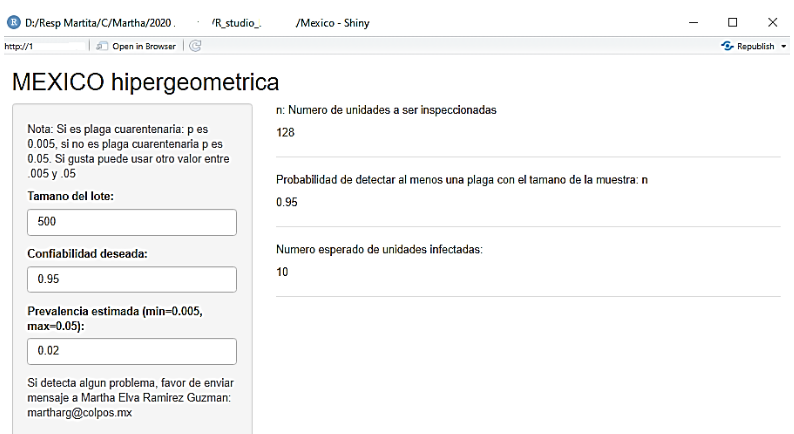


Figure 14 Hypergrometric sample size calculator developed with Rsudio[7] (29015).

[7] RStudio Team (2015). RStudio: Integrated Development for R. RStudio, Inc., Boston, MA URL http://www.rstudio.com/.

8.3.4. Conclusions

The leadership and vision of the regulatory services in Mexico (SENASICA) and of industry associations aware of and on board with international phytosanitary guidance has allowed Mexico to effectively compete in international trade of agricultural products and be a model to other Latin American counties such as those that from part of OIRSA. The use of statistically designed and Risk-Based Sampling schemes, as well as the close collaboration and teamwork between inspection services and academics and the constant capacity building for inspectors has facilitated increased protection for native agricultural products and optimization of financial and human resources.

In general, acceptance sampling uses statistical designs to determine whether to accept or reject a specified lot of material. For many years, acceptance sampling has been a quality control technique used in industry. In this context, it is usually performed as products leave the factory or, in some cases even within the factory itself. Most often, a producer supplies a consumer with a number of items and the decision to accept or reject the items is made by determining the number of defective items in a sample from the lot. The lot is accepted if the number of defects falls below the minimum acceptance number; otherwise the lot is rejected. In general, acceptance sampling is employed when one or several of the following are true:

- Testing is destructive,
- The cost of 100% inspection is very high and,
- 100% inspection takes too long.

Using acceptance sampling results in cost savings, as less labor is required for/dedicated to inspection activities. Furthermore, less commodity handling when using acceptance sampling preserves/maintains the quality of the inspected commodity. Inspection efficiency is also improved as decisions based on inspection outcomes are made based on lots, not on individual commodity samples.

A disadvantage of using acceptance sampling is the risk of rejecting lots that meet inspection parameters or accepting lots that do not meet these parameters. Acceptance sampling also provides less information about commodity production processes.

8.4. New Zealand experience with Risk-Based Sampling - International developments in determining levels of intervention in Risk Pathways

Michael Ormsby[1]

1 Manager Ministry for Primary Industries, Biosecurity Science and Risk Assessment, Wellington, New Zealand

8.4.1. Abstract

In recent years considerable research and analysis has been undertaken at the international, regional, and country levels to develop methods to more accurately determine appropriate levels of risk mitigation on risk pathways. These methods have been used to determine levels of pathway interventions, including inspection and sampling systems, for international standards (ISPMs) and in response to local threats from important pests such as fruit flies (Tephritidae) and Brown Marmorated Stink Bug (*Halyomorpha halys*). Tools used include Bayesian statistics (Bayes Network) and risk models that take into account biological attributes such as Allele effects, propagule pressures, and pest epidemiology. This case study describes how New Zealand has used these methods to determine the performance requirements for Risk-Based Sampling and inspection.

8.4.2. Background

Inspection of plant products before sale has been occurring for as long as humans have bartered goods. Historically, such inspections occurred at the point of sale (at the end of a simple supply chain) or relatively close to the place of production. In New Zealand, it wasn't until the late 1980's that integrated phytosanitary systems were developed which moved interventions, such as inspections and treatments, away from the point of sale in the country of destination toward the place of production in the country of origin.

In the early 1990's (Baker, et al., 1990) and (Cowley , et al., 1993) developed a model to estimate the level of protection required for fruit fly host materials entering New Zealand from Australia. This model formed the basis for New Zealand's trading system with Australia and other countries. The maximum pest limit model by (Baker, et al., 1990) identified the maximum number of immature stages of a pest needed to enable enough adults to develop and successfully establish a new pest population in an area. The model described by (Baker, et al., 1990)and (Cowley , et al., 1993) also determined the sampling size required for assessment of the commodity infestation level to ensure that a chosen phytosanitary measure would appropriately mitigate the risk. The model by (Baker, et al., 1990) relied on seven assumptions:

1. The mean number of fruit flies within an infested fruit is known;
2. The lot (inspected produce) is homogeneous (or near homogeneous);
3. The detection rate per inspection is 100%;
4. The efficacy of the phytosanitary measure (e.g., a treatment) is known, and it is not necessary to assume that the efficacy of the treatment is probit 9 (Cowley , et al., 1993)
5. The phytosanitary measure acts independently on different fruit fly individuals;
6. Pest infestation rates are only reduced by the phytosanitary measure; and

7. The maximum lot size assembled per day at one location (in the country of destination) is known.

Using an estimation of the maximum pest limit (*MPL*), the mean number of pests per infested fruit (μ), the maximum assembled lot size (*V*), and the efficacy of the required phytosanitary measure (*TE*), Baker *et al*. (1990) developed the following equation to determine the required pre-treatment sample detection sensitivity (*DS*):

$$\boldsymbol{DS = \frac{MPL}{\mu \times V \times TE}}$$

This equation was used by New Zealand regulators to determine the sample size required before any treatment of known efficacy was applied (Cowley , et al., 1993). The pre-treatment sample ensured that the infestation rate did not overwhelm treatment efficacy (e.g. the number of survivors did not exceed the MPL). In unpublished calculations, the MPL was estimated as 5, the mean number of pests per infested fruit ($\boldsymbol{\mu}$) as 15, the maximum assembled lot size (***V***) as 1,000,000 units, and the treatment efficacy (***TE***) as 99.9933% (= 1 survivor in 15,000). The estimates provided a target sample detection sensitivity of 0.5%, or no more than 1 in 200 fruit infested with pests. A sample size of 600 was than calculated using a hypergeometric probability distribution with an acceptance number of zero.

These calculations, based on the worst-case scenario (1,000,000 accumulated units), allowed New Zealand to establish relatively straight forward import requirements. A sample of 600 was required to be taken prior to the application of a treatment that achieved or exceeded an efficacy of 99.9933% pest mortality, and if any pests were found in the sample at inspection, the lot would be rejected for import into New Zealand. The results of each sample are independent of all other samples.

8.4.3. Developments in systems management

In recent years, considerable research and analysis has been undertaken at the international, regional, and country levels to develop methods to more accurately determine appropriate levels of risk mitigation required for risk pathways, particularly since the adoption of the international phytosanitary standard for *methodologies for sampling of consignments* (ISPM 31, 2016). The focus has been to remove some of the assumptions that have underpinned calculations of sample size and required efficacy of measures and improve the versatility of phytosanitary measures throughout the plant product supply chain. Two assumptions that have generated additional analysis are 'inspection detection rates' and 'natural pest mortality', and these are discussed below.

a. Assumption 1: The detection rate per inspection is 100%

It has been customary to assume that inspection efficiency is always 100% likely to detect pests when they are present in a commodity. This assumption is apparent in the almost universal application of a standard sampling rate (e.g., 60 or 600) across many commodities and pathways, irrespective of the type or nature of the pest or its association with the commodity. However, this assumption is not supported by data on pest detection efficacy by trained and experienced inspectors. Gould (1995) determined that inspectors using destructive sampling (fruit cutting/dissection) detected fruit fly infestations 18% to 84% of the time (depending on both fruit type and specific inspector), with an average of around 44%. (Perrone, et al., 2013) designed trials in which fresh commodities were artificially infested at various prevalence levels (with several surface-dwelling arthropods of variable size and mobility) to test if these pests were reliably detected on inspection. They found that pests (or signs of pest presence) that were large enough to be seen with the naked eye or magnifying glass were found without difficulty. The trials ran into difficulties with smaller and mobile pests, highlighting the difficulty in carrying out meaningful research in this area (Perrone, et al., 2013). Little or no further work has been published on research to measure the ability of inspections to detect pests infesting plant commodities.

b. Assumption 2: Pest infestations are only reduced by phytosanitary measures

The number of pests infesting a commodity at origin (before packaging and transport) is unlikely to be the same once the commodity reaches its destination, even if no phytosanitary measures are applied. It is well known that pest mortality occurs during a pest's lifecycle, during commodity transport, and once the pest is exposed to a new environment (e.g., due to climate, predation etc.) (Ormsby , 2012). As such, for a male and a female of a species to have a reasonable chance of surviving, emerging and breeding once the infested commodity arrives at its destination (e.g., in New Zealand), more than the maximum pest limit is required in the commodity at the time of infestation (e.g., before harvest). **Figure 15** shows a commodity pathway where natural mortality reduces pest infestation by at least 40% before the commodity reaches its destination.

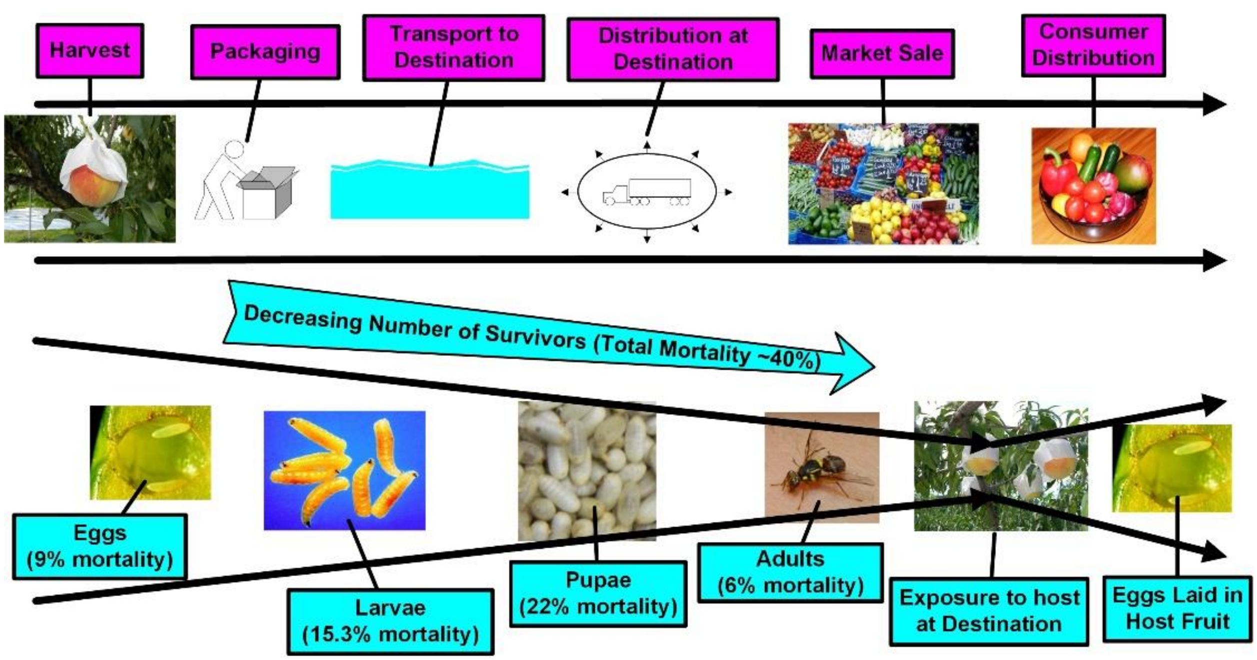


Figure 15. *The example of reduction in the level of pest infestation due to natural mortality*

Taking into account the effects of natural or trade-induced pest mortality has significantly lowered the levels of intervention required for risk mitigation (Ormsby , 2012). Research in New Zealand is evaluating the use of Bayesian Networks to develop decision support models to evaluate biosecurity risks (Jamieson *et al*. 2016). Similarly, the European Food Safety Authority Plant Health Panel is developing a method for pest risk assessment and the identification and evaluation of risk-reducing options that focuses on changes in pest abundance during the invasion process (Gilioli et al., 2017).

8.4.4. Improving the versatility of phytosanitary measures throughout the supply chain

Connecting storage and transport with commodity production offers opportunities to identify additional mitigation steps, including the use of statistical sampling methods. (Quinlan, et al., 2016) from the Beyond Compliance research program, demonstrated the use of a Control Point–Bayesian Network (CP-BN) to collate and present phytosanitary risk-based knowledge about a system. Each CP-BN identifies the stages along the pathway (e.g., planting, growing, harvest, packing and export). Arrows link each stage to specific measures (e.g., field cover sprays, pest surveillance, fruit bagging and inspection). Objectives of each measure and verification measures are also identified and linked (Quinlan, et al., 2016). An example of a CP-BN for fruit fly management on dragon fruit (*Hylocereus undatus*) is provided in **Figure 16**.

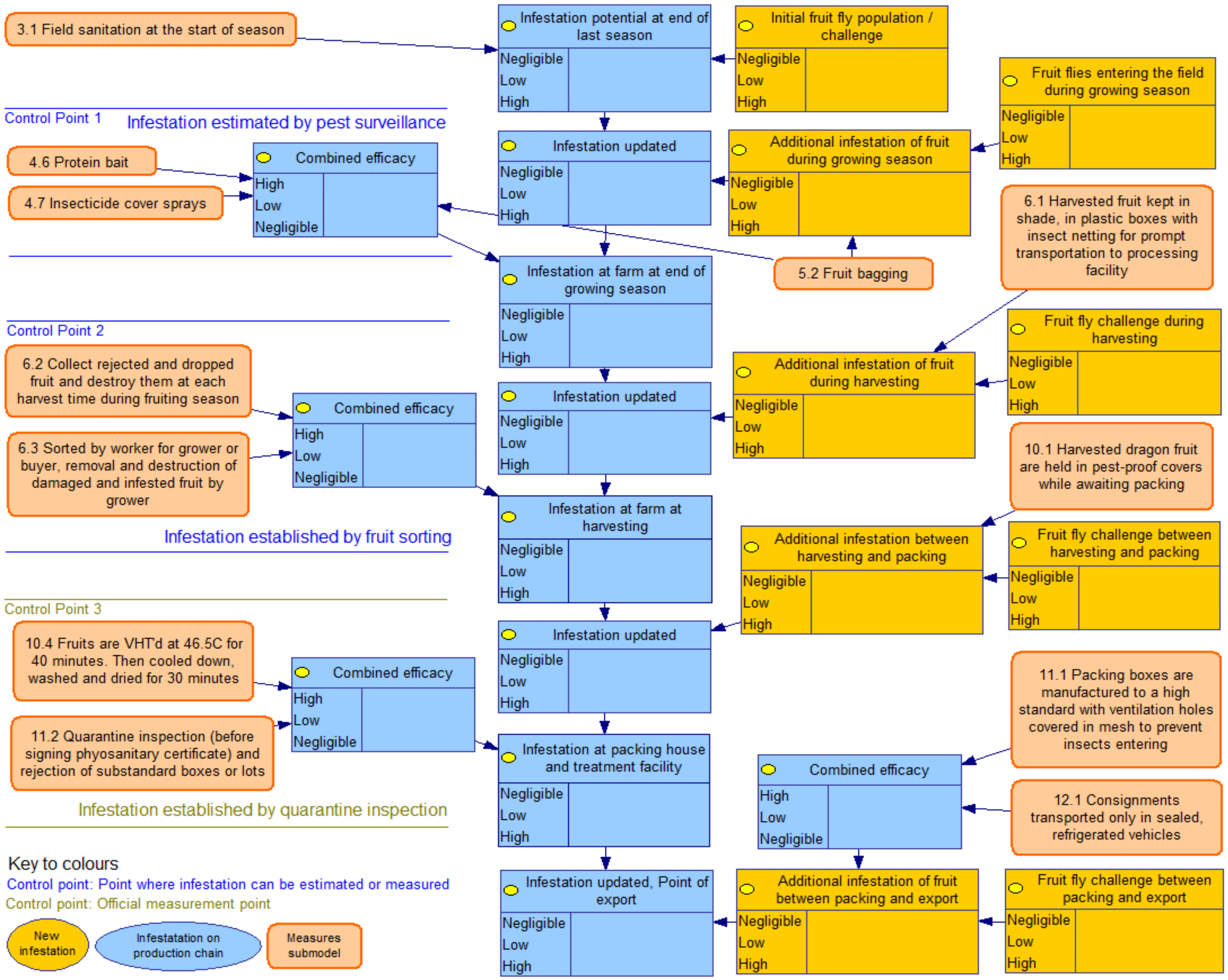


Figure 16. *Beyond Compliance Bayesian Network showing measures used, resulting in an acceptable result at the point of export (last box in the Production Chain, blue box in the center at the bottom) (from Quinlan et al. 2016) (VHT = vapor heat treatment).Figure generated using the software"GeNIe Modeler", "SMILE Engine" or "QGeNIe Modeler") together with the Licensors name "BayesFusion, LLC" available free of charge for academic teaching and research use at http://www.bayesfusion.com/*

8.4.5. Using statistical sampling methods

Statistical sampling can useful at several intervention points in the plant production and supply chain. However, where inspection relies on eyesight and mental dexterity, there are practical limitations on the number of sample sizes that can be taken/examined if overall performance is to be maintained, even when inspection tools such as a magnifying glass is employed. Repetitive activities that deliver rare successes are likely to reduce performance over extended periods even when relatively small samples are taken.

Use of small samples to detect pest populations exceeding the MPL threshold (after the application of phytosanitary measures) should be considered less than optimal. In the example above, the MPL of 5 in a lot of 1,000,000 units (or an infestation rate of 0.0005%) is considered acceptable. An infestation of 10 in 1,000,000 units (or an infestation rate of 0.001%) would be considered a failure. However, a sample of 600 (assuming 100% detectability) would only have a 0.6% probability of detecting the infestation (e.g., provide a 0.6% level of confidence that the MPL has not been exceeded).

While failure of a sample before the application of phytosanitary measures has clear and simple decision criteria (e.g., rejection), failure of a sample after the application of phytosanitary measures could, in theory, occur under two circumstances:

1. The phytosanitary measure (treatment) has failed or has been failing over multiple lots and the failure has finally been detected; or
2. The infestation rate is at or below the MPL, however because so many samples have been taken over time, a pest has been detected even though the lot is compliant.

In the latter case, using the example of an MPL of 5 pests in 1,000,000 units, a pest will be detected once in every 1,000 independent samples even at this low level of infestation.

8.4.6. Conclusions

The use of risk-based statistical sampling methods has allowed New Zealand to establish relatively straight forward import requirements. As risk-based statistical sampling provides the same level of detection sensitivity across all samples, the decision criteria for lot rejection or acceptance is straightforward. Statistical sampling, like any sampling systems, has its limitations. Where detection thresholds are far below the sensitivity of the sample, decision criteria become more complicated. In these circumstances the results from multiple samples can be accumulated to provide an indication of production chain compliance over an extended period such as one production season.

The use of production chain (pathway) analyses allows for the use of statistical sampling at numerous points of intervention, both to provide simple decision criteria, and to measure overall system performance over time. Risk-Based Sampling provides a consistent measure of pest infestation thresholds. When implementing Risk-Based Sampling in quarantine inspection systems, care should be taken to ensure that any limitations in detection sensitivity are understood, and fully acknowledge and consider the implications for any resulting failure in phytosanitary decision criteria.

8.5. EPPO Approaches to Risk-Based Sampling Risk-Based Inspection and Risk-Based Sampling in Europe and the Mediterranean region

Dominic Eyre[1], Anastasia Korycinska[2] and Rob Tanner[3]

1. Plant Health Entomologist | Risk and Horizon Scanning | Animal and Plant Health | Department for Environment, Food and Rural Affairs (Defra, UK)
2. Pest Risk Analyst | Risk and Horizon Scanning | Animal and Plant Health | Department for Environment, Food and Rural Affairs (Defra, UK)
3. Scientific Officer, EPPO

8.5.1. Introduction

This case-study describes activities and initiatives that have been implemented in Europe and the region that focus inspection efforts on higher risk consignments and Risk-Based Sampling. The case-study is presented three sections with the first detailing initiatives led by the Regional Plant Protection Organization for Europe – EPPO. The second section examines how legislation in the European Union has been used to focus phytosanitary inspections and sampling. Lastly, examples from the United Kingdom of how risks have been evaluated at a national level are provided.

8.5.2. EPPO

The European and Mediterranean Plant Protection Organization (EPPO) is an international organization responsible for cooperation and harmonization in plant protection within the European and Mediterranean region. Under the IPPC article IX (FAO, 1997), EPPO is the Regional Plant Protection Organization (RPPO) for the Euro-Mediterranean region. One of EPPO's main aims is to provide assistance and guidance to member governments on the administrative, legislative and operational measures necessary to prevent the introduction and spread of non-native plant pests (Smith, 1979); (Roy, 2011).

EPPO has a long history of developing regional standards for phytosanitary inspection. The first standards on inspection were approved in the 1990s. Before 2003, EPPO standards on different phytosanitary procedures were developed under the work program of the EPPO Panels on Phytosanitary Measures and on Phytosanitary Measures for Potato. In 2003, a specific panel was formed. The EPPO Panel on Phytosanitary Inspections and EPPO established a detailed work program for developing standards for inspection of consignments, inspection of places of production and area-wide surveillance. EPPO's regional inspection standards are part of a series called PM 3 *Phytosanitary Procedures*. Standards in this series describe methods for performing inspections of commodities moving in trade, or surveys for quarantine pests. They include guidance on risk-based inspection and sampling for the detection of pests of concern for the EPPO region. These standards are developed by experts from across the region and reviewed by EPPO Panels. The target audience for EPPO standards are National Plant Protection Organizations (NPPOs) in Europe, who are encouraged to use the standards to develop national guidelines for inspectors on how to perform inspection, including how, when and what should be sampled.

One of the first standards developed after the formation of the Panel was PM 3/72: *Elements common to inspection of places of production, area-wide surveillance, inspection of consignments and lot identification* (EPPO , 2008). The standard presents information on the principles and limitations of inspection. It is a reference standard and references to PM 3/72 are made in standards addressing specific consignments, crops or pests for the EPPO region. All EPPO inspection standards provide information on defining a lot (a number of units of a single commodity, identifiable by its homogeneity of composition, origin etc., forming part of a consignment (FAO, 2019). PM 3/72 makes it clear that if consignments consist of one or more commodities or lots it is important that inspection consist of several visual examinations. To maximize pest detection, PM 3/72 indicates that inspection methodology needs to be transparent and documented and that the two international standards on inspection (ISPM 23 *Guidelines for inspection* [FAO, 2019] and ISPM 31 *Methodologies for sampling of consignments* (FAO, 2016a) should be followed. ISPMs 23 and 31 provide guidance for inspection procedures and statistical methods to determine detection levels and confidence, respectively. EPPO standards provide examples of how many units to sample within a lot, based on ISPM 31. For example, based on guidance in PM 3/81 (*Inspection of Consignments for Xylella fastidiosa* [EPPO, 2016a]), 448 plants from a lot of 10,000 plants would be sampled to provide 99% confidence of detecting evident symptoms in 1% of plants. Importantly, and as detailed in PM 3/81, the confidence level should increase for consignments arriving from countries where the pest is known to occur (the objective would be to detect an infection level of 0.1 % or more with a confidence level of at least 99%). EPPO inspection standards also highlight specific factors to consider when targeting inspections (e.g., most susceptible cultivars, origin, producers). The current standards in series PM 3 can be downloaded from https://gd.eppo.int/standards/PM3/.

Other regional standards on inspection, focused on specific commodities, either at import or at places of production, include, PM3/078 - *Consignment inspection of seed and grain of cereals* (EPPO, 2016b). PM3/078 indicates that sampling for visual inspection and laboratory testing of these commodities should be performed following the guidelines from the International Seed Testing Association (ISTA). PM3/078 provides examples of the minimum number of primary samples to be taken from containers, bags, or seed lots defined by weight. PM 3/80 - *Consignment inspection of seed of Solanum lycopersicum* (EPPO, 2016c) follows the same sampling methodology and notes that when considering pests recommended for regulation it is important to target consignments most likely to carry these pests. High-risk consignments may include non-compliant consignments from certain origins or from certain producers, consignments of commodities susceptible to specific pests, and consignments from origins where certain pests are present.

The development of the two regional inspection standards for *Xylella fastidiosa* (PM 3/81 *Inspection of consignments for Xylella fastidiosa* (EPPO, 2016a) and PM 3/82 I*nspection of places of production for Xylella fastidiosa* (EPPO, 2016d), a bacterium that has caused significant economic damage to plants in the EPPO region, were developed concurrently with an update of the diagnostic protocol PM 7/24 for *Xylella fastidiosa* (EPPO, 2018a). Concurrent development of the standards and diagnostics was important as laboratory results and detection levels inform inspectors on risk-based inspection methods, and on sample sizes for both symptomatic and asymptomatic plants. The recently completed PM 3/84 - *Inspection of places of production for 'Candidatus* Phytoplasma pyri'

(EPPO, 2018b) – also underscores the importance of sampling symptomatic and asymptomatic plants to maximize pest detection for asymptomatic pests.

Other elements are important for risk-based inspection and sampling including the results of pest risk analysis (PRA), horizon scanning, up-to-date information on pest biology and interception reports along specific pathways. EPPO conducts PRAs and pathway analyses and develops pest lists to inform member countries. These activities assist NPPOs in the region to determine where to deploy plant health resources and what legislative changes to implement in order to effectively deal with current and emerging plant health threats. One of the basic questions for countries is which pests to be concerned with. To address this concern, EPPO maintains lists of pests recommended for regulation. The EPPO A1 list includes pests which are absent from the EPPO region and considered to have an unacceptably high risk to the region. The A2 list includes species that are present in some but not all EPPO countries and that have been shown to have an unacceptably high risk. The EPPO PM 3 Standards include a detailed appendix highlighting the A2 pests relevant to crops. For example, PM 3/85 - *Inspection of places of production – Vitis plants for planting* (EPPO, 2018c) details pests of *Vitis* within the EPPO region, along with information on symptoms, identification and sampling. In addition to the A1 and A2 Pest Lists, EPPO has established an Alert List to draw the attention to certain pests likely to present a risk to the EPPO region. This Alert List is a tool for early warning and used by EPPO region inspectors when performing inspections.

Another valuable tool for risk-based inspection and Risk-Based Sampling in the EPPO region is the EPPO Global Database (EPPO, 2019). The database provides pest-specific information produced or collected by EPPO. Information of specific relevance to inspectors includes geographic distribution useful in targeting inspection on high risk origins, host plants, host commodities or in targeting inspection of relevant commodities. Detailed information is available on 1,650 pest species. Finally, summary notifications of non-compliance are available as pest detections from EPPO member countries are published in the EPPO Reporting Service. This helps inspectors to target import inspections.

In addition to the PM 3 *Phytosanitary Procedures* Standards Series, EPPO publishes the PM9 series - *National Regulatory Control Systems*. The PM9 series can be used to develop contingency plans and, in the absence of such plans, to guide containment and eradication measures. PM9 standards can provide guidance on surveys to detect pests and detail communication and collaboration between stakeholders that can facilitate both pest surveys and pest management. For example, PM9/15 (1) - *Anoplophora glabripennis: Procedures for official control,* recommends that surveys should be pathway-based to allow resources to be targeted to the locations/materials most likely to harbor this pest (EPPO, 2013). The standard recommends that inspection should be prioritized on wood packaging material associated with imports of stone for countries where *A. glabripennis* is known to occur. In addition, PM 9/1 (6) - *Bursaphelenchus xylophilus and its vectors: procedures for official control* (EPPO, 2018d) recognizes that surveys should be, in part, pathway-based concentrated on potential points of pest introduction.

8.5.3. European Union

a. The reduced checks system

The current European Union Plant Health Legislation (the Plant Health Directive 2000/29/EC, Annex VB, EU 2000) lists the plants and plant products requiring inspection when moved into the EU from non-EU countries. All consignments listed in Annex VB should be inspected upon arrival in the EU, however, there is an option to reduce inspection frequency for high volume combinations (product by country of origin combinations) that have a history of low pest interceptions. The legislation that formed the basis for this option was approved in 2004 (UE, 2004). and came into effect on January 1, 2015. Criteria for eligibility for a reduced inspection frequency include:

- an average of ≥200 consignments/year for the specific product/country of origin combination for the past three years;
- ≥600 samples inspected in that period;
- pest interception rates for this period should have been <1%; and
- pest interceptions are rated on based on pest mobility - for example, an adult moth (Lepidoptera) is rated as more mobile than an egg.

Consignments of plants for planting are not eligible for the reduced inspection scheme because they are considered to have an inherently higher risk. The same applies to consignments that are imported under a derogation (i.e., an exemption from or relaxation of a rule or law) and consignments subject to emergency measures.

In 2017, there were 52 “product by country of origin” combinations included in the reduced frequency of inspection scheme. This number increased to 54 in 2018 and 65 in 2019. In some cases, the combinations were subjected to 100% inspection (i.e., all consignments should be inspected by member states) because interception rates were high in the previous year or the average number of consignments inspected per year may have dropped below the minimum acceptable threshold. These combinations might remain within the scheme, despite not reaching the above-named criteria in a given year, in order to allow data gathering to reduce inspection rate in future years. **Figure 17** shows the country of origin and product type for combinations recommended for reduced frequency of inspection in 2018. Thirty-two of the eligible combinations were for fruit, 12 for cut flowers, seven were for vegetables and three were for wood commodities. The EU publishes the combinations for which a reduced frequency of inspections are allowed and the lists are updated annually.
(https://ec.europa.eu/food/plant/plant_health_biosecurity/non_eu_trade/less_frequent_checks_en)

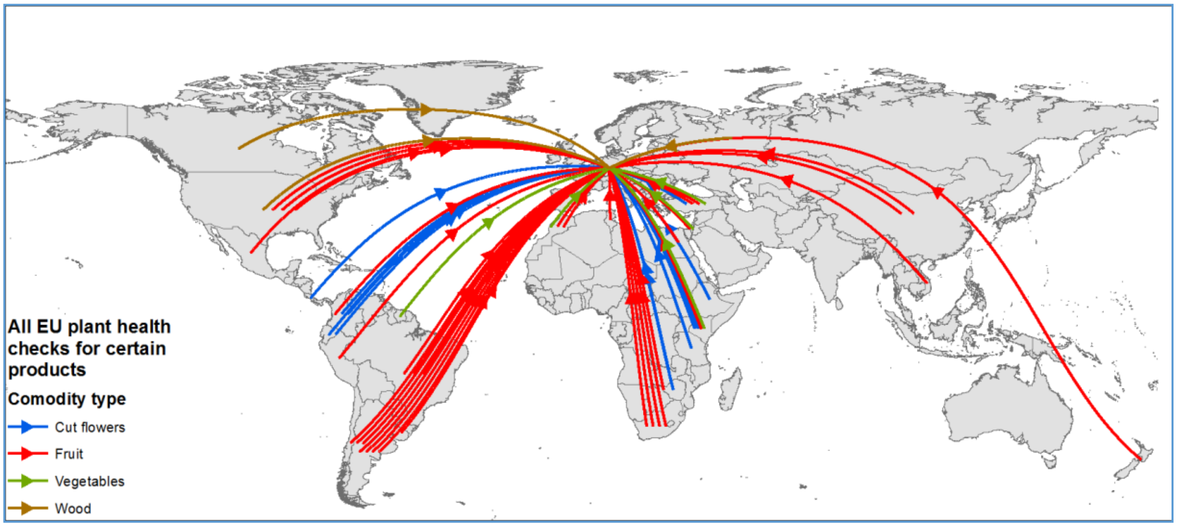


Figure 17. *Product by country of origin combinations included in the European Union reduced inspection scheme in 2018*

b. Destructive sampling of host trees of *Anoplophora chinensis* (Coleoptera: Cerambycidae)

For most regulated plants in the EU, the Plant Health Legislation is not prescriptive about the number of plants that should be inspected and how inspections should be carried out. However, there are specific requirements covering hosts of *Anoplophora chinensis* from China. In the 2000's, outbreaks of *Anoplophora chinensis* were detected in Italy (Parabiago, Montichiari, Gussago and Rome), France (Soyons), the Netherlands (Westland and Boskoop) and Croatia (Turanj-Sveti Filip I Jakov) (Eyre, et al., 2017). Numerous interceptions of *A. chinensis* on plants for planting, particularly from China (Haack, et al., 2010); (Giltrap, *et al*., 2009). were also recorded. These interceptions and outbreaks prompted EU member states and the European Commission to implement emergency measures to reduce and manage the risk from this pest. The emergency measures currently in place (EU, 2012) require that EU member states importing *A. chinensis* hosts from China carry out destructive sampling of consignments. For consignment sizes of between 1 and 4,499 plants, 10% of plants must be destructively sampled; for consignments of plants of 4,500 or more, 450 plants must be destructively sampled. The 10% rate selected for consignments of less than 4,500 plants represents a balance between detection efficacy and economic viability of continuing trade in smaller consignments. It is justified by statistics. However, the crossover point (4,500 plants or higher) is taken from an approximation from ISPM 31 and represents the number of samples required to detect a 1% infestation with 99% confidence. The efficacy of detection is assumed to be 100%. Destructive sampling was considered appropriate for these high-risk consignments as the larvae of *A. chinensis* reside in and feed within their host plants and, as such, it can be difficult to detect their presence by external visual examination. This sampling requirement is prescriptive in the number of samples and how sampling should be carried out. Destructive sampling results in significant costs to the exporter and importer, but in this example, it was thought to be justified given the identified pest risk. Statistically, the approach does not comply with ISPM 31, but it provides an opportunity to detect infested consignments. It also provides a mechanism to audit whether other legislative requirements have been followed in the exporting country, e.g., that plants have been grown in protected situations or grown at a site with a 2km buffer zone.

c. Post-entry inspection at destination

In addition to general inspections conducted at points of entry such as airports, there are also inspections at other inland sites. For plants that have been imported from countries outside of the European Union, this provides an additional opportunity to detect quarantine pests. Some of the advantages of post-entry inspection are:

i) the plants are likely to have been unpacked and plants will be visible from all sides without being moved around;
ii) plants imported in a dormant state may have foliage at the time of post-entry inspection which may facilitate the detection of some quarantine pests;
iii) quarantine pests that were present in low numbers or were difficult to detect at the time of import, may now have become more apparent and easier to detect.

There are also disadvantages to post-entry inspection including:

i) the longer infested plants go without inspection, the higher the opportunities for pests to disperse to other plants;
ii) plants in an infested or infected consignment may have been sold by the time a post-entry inspection takes place.

Managers working for the UK's Plant Heath and Seeds Inspectorate, developed guidance for field inspectors as to how many inspections should be conducted at businesses growing or trading plants in England and Wales. The guidance is based upon three characteristics of each business: the size of the business, the type of business and the origin of the plant material traded by that business. The size of the business is relative to other similar businesses in the area covered by the inspector and is independent of geographic or financial parameters. The type of business is considered a good indicator of the potential to spread a pest and considers the number and geographic locations of the business. For example, a distribution center may send plants to garden centers across the UK or to a region in the UK, whereas a garden center is more likely to sell plants to members of the local public. The source of the plant material is the third parameter considered, with those businesses trading only in plants from the UK considered to represent a lower risk than those trading plants from the EU or from non-EU countries. Further details can be seen in **Table 1.**

Table 1. Scheme for determining an appropriate number of visits to carry out general quarantine inspections (per site per year) for businesses trading in plants in England and Wales (UK).

RISK	1 points	2 points	3 points
Volume of trade	Small	Medium	large
Business Activity	Garden Centre Produce trader Processing business Landscapers Aquatic plant retailers	Production nursery Wholesaler	Propagator Distribution Centre
Origin of plant material	UK	EC	Third Country

Inspectors would use the table above to determine the risk category for a specific business. The total number of risk points are calculated by adding up the points for each measure. The risk point total determines the recommended number of visits per site per year as follows:

- Low risk (3 or 4 points) – one visit every two years,
- Medium risk (5 or 6 points) – two visits per year,
- High risk (7 or 8 points) – 5-6 visits per year,
- Very high risk (9 points) – 10-12 visits per year.

A similar system has been developed in the Netherlands, however the number of visits is based on the plant species or genus and ability to properly inspect the plants for certain quarantine pests at the time of import.

8.5.4. United Kingdom

a. Analysis of trade pathways

Trade pathways around the world are numerous and complex. **Figure 18** shows an example of pepper *(Capsicum* spp.) imports into the UK from non-EU countries over a 27-month period starting in January 2014. The map was produced using Eurostat data by searching for two commodities: 07096010 – sweet peppers and 07096099 – "Peppers (other than sweet) (*Capsicum* spp.)".

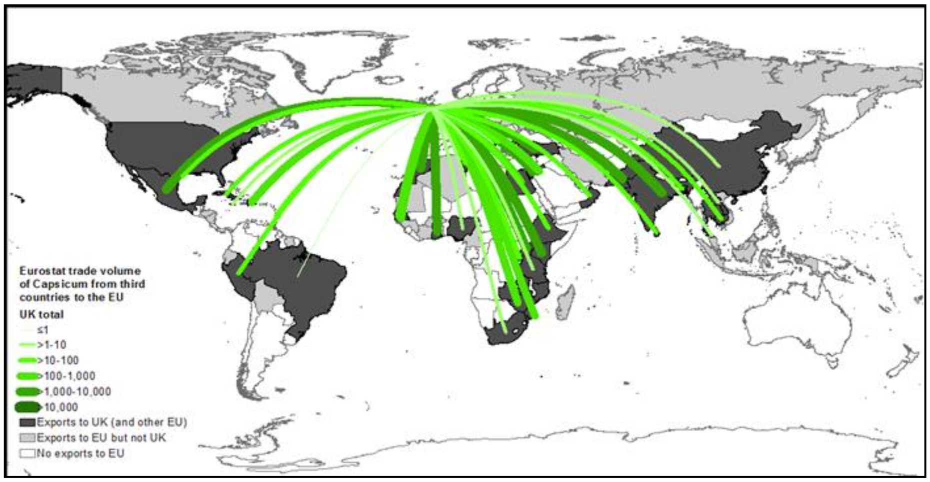


Figure 18. *Origin of peppers (Capsicum spp.) imports into the UK between January 2014 and March 2016*

If pest interception data is combined with trade data, metrics for the relative risk of different trade pathways can be calculated. For example,

Figure 19 shows that during the period between January 2014 and March 2016, there were less than 0.25 interceptions of quarantine pests per ton of peppers imported into the UK from Mexico, whereas there were over five interceptions per ton of peppers imported into the UK from Brazil. This map combines the Eurostat data from **Figure 18** with data from the Procedure for Electronic Application for Certificates (PEACH) and General Quarantine Inspection (GQI) data from the UK. PEACH is an online tool for processing import requirements for plants or fruits and vegetables commodities that are subject to Specific Marketing Standards when imported into the UK from outside the European Community. GQI relates to inspections of commodities other than regulated products. These checks are carried out to ensure that significant problems with unregulated products are detected. Metrics such as the number of interceptions per ton of imported fruit or vegetable commodities or number of interceptions per consignment can be used to match inspection efforts to risk.

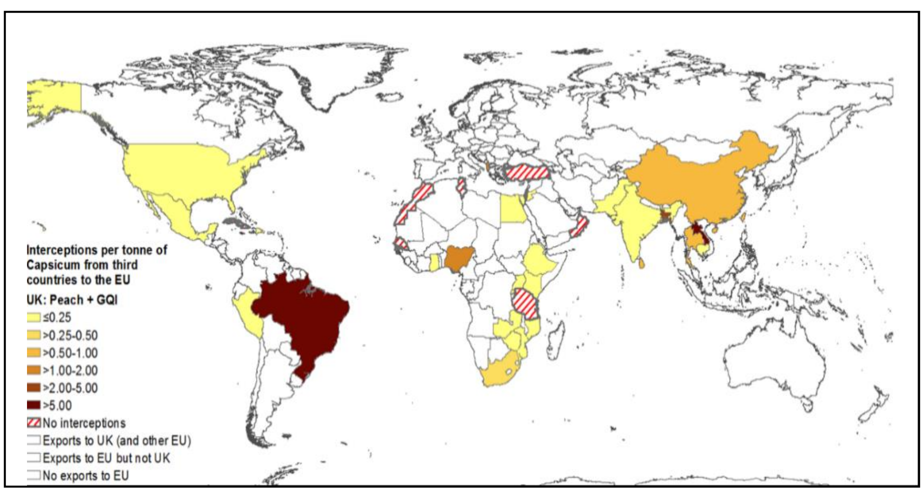


Figure 19. The number of interceptions of quarantine pests per ton of peppers (Capsicum sp.) imported into the UK from several countries. Data for the period between Jan 2014 and March 2016

b. The UK plant health risk register

When the UK confirms the presence of quarantine pests on imported consignments of fruits and vegetables, the action is nearly always destruction or re-export of the consignment. The action is the same independent of the species of quarantine pest. However, not all quarantine pests are equal in terms of the level of threat they pose to the UK. Following the confirmation of ash dieback (*Hymenoscyphus pseudoalbidus*) in the UK in 2012, the Tree Health and Plant Biosecurity Task Force was established. One of the recommendations of the task force was that the UK should set up a Risk Register (RR) in order to prioritize actions to prevent the establishment of pests in the UK. This led to the development of the UK Plant Health Risk Register (a database of evaluations and ratings for pest species) and its release on a public website in January 2014 (Defra 2014)[8]. Originally, species added to the RR were dominated by EU quarantine pests, all pests on the EPPO A1, A2 and alert lists, and organisms for which a UK pest risk assessment had been carried out. Since its publication, hundreds of additional species have been added, mostly those that have been identified as potential threats. There are over 1,000 species on the RR (January 2019).

(Baker, et al., 2014) described the methods used to calculate the ratings in the RR. Some of the factors used to calculate the likelihood of arrival of a particular pest are: geographic range of the pest, host range of the pest, the likelihood of association with the commodity at origin, the volume of commodity imported and the likelihood of pest survival along the pathway. In order to simplify the calculations, each pathway has been awarded a risk rating out of five, with five given to plants for planting and one given to fruits and vegetables. In addition to overall scores indicating the risk of species to the UK, the RR lists whether the species should be a priority for further actions which include surveillance, contingency planning and legislation. As such, the RR can be used as tool to determine the sampling effort that should be assigned to different commodities based on their association with key quarantine pests.

8.5.5. Summary points

- A risk-based inspection system needs to be dynamic in order to respond to changes in trade patterns within and between years. This means occasional inspection of commodity by country combinations that have been traditionally considered low risk should be conducted as it is necessary to periodically monitor for changes in risk.
- Quarantine pests are not equal in the risk they pose. The risk will partly be determined by the species but also by the life stage present.
- Some types of traded commodities are inherently more risky (e.g., plants for planting) than others (e.g., fruits or vegetables), because they provide more opportunities for the continued development and spread of the pest.

[8] https://secure.fera.defra.gov.uk/phiw/riskRegister/index.cfm

- A truly Risk-Based Sampling scheme would need to incorporate infestation level, the risk related to pests that are known and anticipated to be associated with consignments, and an assessment of the risk relating to specific pathways.

8.5.6. Acknowledgements

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9. BIBLIOGRAPHY

Baker, R. et al., 2014. The UK Plant Health Risk Register: a tool for prioritizing actions. EPPO Bulletin 44:, pp. 187-194.

Baker, R. T., Cowley, J. M., Harte, D. S. & Frampton, E. R., 1990. Development of a maximum pest limit for fruit flies (Diptera: Tephritidae) in produce imported into New Zealand.. Journal of Economic Entomology , pp. 83: 13-17..

Cazier-Mosley, M., 2017. Comprobación del estatus – Estaciones de inspección de plantas en los Estados Unidos. Baltimore, Maryland, s.n.

CBD, 2018. Glossary of terms. Convention on Biological Diversity., s.l.: s.n.

CBP, 2016. National Agriculture Release Program (NARP). Customs and Border Protection (CBP), Department of Homeland Security, Washington, D.C. [On line] Available at: https://www.cbp.gov/border-security/protecting-agriculture/narp

CBP, 2018. CBP Inspects Hundreds of Millions of Cut Flower Imports at Miami International Airport Ahead of Valentine's Day. Customs and Border Protection (CBP), Department of Homeland Security, Wasjington D.C. [On line] Available at: https://www.cbp.gov/newsroom/local-media-release/cbp-inspects-hundreds-millions-cut-flower-imports-miami-international.

CONOCER, 2016. EC0819 Inspección sanitaria de productos/materiales agroalimentarios movilizados. [On line] Available at: https://conocer.gob.mx/contenido/publicaciones_dof/EC0819.pdf

Cowley, J. M., Baker, R. T. & Harte, D. S., 1993. Measurement of parameters and application of the maximum pest limit concept for importation of fruit fly (Diptera: Tephritidae) hosts. EPPO Bulletin , pp. 23: 713-728..

CPHST, 2003. Risk-Based Management of the Cut Flower Pathway: Assessment of Pest Risks Posed by Additional Cut Flowers at Miami. Raleigh (N.C.): Center for Plant Health Science andTechnology (CPHST), Plant Protection and Quarantine, Animal and Plant Health Inspection Service. U.S. Department of Agriculture.

Devorshak, C., 2012. Risk Analysis. Concepts and Applications. USA: CAB International.

EFSA Panel on Plant Health (PLH), 2018. Guidance on quantitative pest risk assessment. EFSA Journal, pp. 1-86.

Epanchin-Niell , R., Springborn , M. & Lindsay, A., 2016. Protecting against Invasive Species: A Risk-Based Approach to Live Plant Inspection. [On line] Available at: https://www.resourcesmag.org/archives/protecting-against-invasive-species-a-risk-based-approach-to-live-plant-inspection/

EPPO, 2008. PM 3/72: Elements common to inspection of places of production, area-wide surveillance, inspection of consignments and lot identification. EPPO Bulletin, pp. 38:394-395.

EPPO, 2013. PM 9/15 Anoplophora glabripennis: procedures for official control. EPPO Bulletin 43:, pp. 510-517.

EPPO, 2016a. PM 3/81 (1) Inspection of consignments for Xylella fastidiosa. EPPO Bulletin 46:, pp. 395-406..

EPPO, 2016c. PM 3/80 Consignment inspection of seed of Solanum lycopersicum. EPPO Bulletin 46:, pp. 68-72..

EPPO, 2016d. PM 3/82 Inspection of places of production for Xylella fastidiosa. EPPO Bulletin 46, pp. 407-418.

EPPO, 2018a. PM 7/24 Xylella fastidiosa. Bulletin 48, pp. 175-218.

EPPO, 2018b. PM 3/84 Inspection of places of production for 'Candidatus Phytoplasma pyri'. EPPO Bulletin, 48:, pp. 323-329.

EPPO, 2018c. PM 3/85 Inspection of places of production – Vitis plants for planting.. EPPO Bulletin, 48, pp. 330-349.

EPPO, 2018d. PM 9/1 Bursaphelenchus xylophilus and its vectors: procedures for official control. EPPO Bulletin, 48:, pp. 503-515.

EPPO, 2019. EPPO Global Database. [On line] Available at: https://gd.eppo.int/

EU, 2012. Commission implementing decision of 1 March 2012 as regards emergency measures to prevent the introduction into and the spread within the Union of Anoplophora chinensis (Forster) 2012. [On line].

EU, 2012. Commission implementing decision of 1 March 2012 as regards emergency measures to prevent the introduction into and the spread within the Union of Anoplophora chinensis (Forster) 2012. [On line] Available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32012D0138

European Commission, 2020. Legislation on official controls. [On line] Available at: https://ec.europa.eu/food/safety/official_controls/legislation_en

Eyre, D. & and Haack, R., 2017. Invasive cerambycid pests and biosecurity measures. In Cerambycidae of the world: Biology and management.. s.l.:edited by Q. Wang. Boca Raton: CRC Press.

FAO, 1997. New Revised text of the International Plant Protection Convention. Food and Agriculture Organization of the United Nations, Roma: s.n.

FAO, 2011. IPPC- International Plant Protection Convention 1997 ARTICLE II. Use of terms. [On line]

Available at: https://www.ippc.int/static/media/files/publications/en/2013/06/06/1329129099_ippc_2011-12-01_reformatted.pdf

FAO, 2016a. Methodologies for sampling of consignments. International Standard for Phytosanitary Measures No. 31. Rome. Published by FAO on behalf of the Secretariat of the International Plant Protection Convention (IPPC). [On line]Available at: https://www.ippc.int/static/media/files/publication/en/2016/01/ISPM_31_2008_En_2015-12-22_PostCPM10_InkAmReformatted.pdf

FAO, 2016b. Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade. ISPM No. 1. [On line]

Available at: https://www.ippc.int/static/media/files/publication/en/2016/01/ISPM_01_2006_En_2015-12-22_PostCPM10_InkAmReformatted.pdf

FAO, 2019a. Guidelines for inspection. International Standard for Phytosanitary Measures No. 23. [On line] Available at: https://www.ippc.int/static/media/files/publication/en/2019/05/ISPM_23_2005_En_Inspection_2019-04-30_PostCPM14_InkAm.pdf [Último acceso: 2020].

FAO, 2019. Glossary of phytosanitary terms. International Standard for Phytosanitary Measures No. 5. Rome. [On line] Available at: https://www.ippc.int/static/media/files/publication/en/2019/06/ISPM_05_2019_En_Glossary_2019-06-26_PostCPM-14-Fixed.pdf

FDA, 2018. U.S. Food and Drug. PREDICT For Imports. [On line]

Available at: https://www.fda.gov/industry/import-program-food-and-drug-administration-fda/predict-imports

Giltrap, N., D. Eyre, and P. Reed. 2009. Internet sales of plants for planting – an increasing trend and threat? EPPO Bulletin 39:168-170.

Gilioli G., Schrader G., Gregoire J.-C., MacLeod A., Mosbach-Schulz O., Rafoss T., Rossi V., Urek G., van der Werf W. (2017) The EFSA quantitative approach to pest risk assessment –methodological aspects and case studies. Bulletin OEPP/EPPO Bulletin 0 (0), 1–7.

Gould W.P. (1995) Probability of detecting Caribbean fruit fly (Diptera: Tephritidae) infestations by fruit dissection. Florida Entomologist 78(3): 502-507.

Griffin, R. L., 2017. Introduction to the International Symposium for Risk-Based Sampling. Proceedings International Symposium for Risk- Based Sampling, pp. 6-11.

Haack, R., Hérard, F., Sun, J. & and Turgeon, J., 2010. Managing invasive populations of Asian longhorned beetle and citrus longhorned beetle: a worldwide perspective.. Annual Review of Entomology 55:, pp. 521-546.

ISO, 2005. International Standard 2859-3 Sampling procedures for inspection by attributes — Part 3: Skip-lot sampling procedures (Second Edition). International Organization for Standardization (ISO). Geneva, Switzerland: s.n.

ISO, 2018. Popular Standards. ISO 31000. Risk management – Guidelines. [On line]

Available at: https://www.iso.org/iso-31000-risk-management.html

Jamieson L.E., Woodberry O., McDonald C.M., Ormsby M. (2016) Developing a generic biosecurity risk assessment model for imports. New Zealand Plant Protection 69: 186-199.

Katsar, C., Hong, S., Kim, B. & Griffin, R., 2017. Muestreo fundamentado en el riesgo: La perspectiva de la ONPF (USDA-APHIS-PPQ) de los Estados Unidos. Baltimore, Maryland, s.n.

Morfee, P., 2018. "Review of the Risk Engine". Presentation made at the Webinar of the UNECE Group of Experts on Risk Management in Regulatory Systems. Graph provided by P. Morfee.. [On line].

NAPPO, 2017. Proceedings International Symposium for Risk-Based Sampling. [On line]

Available at: https://www.nappo.org/files/4415/3919/4230/RBS_Symposium_Proceedings_-10062018-e.pdf

OEPP/EPPO, 2006. Sampling of consignments for visual phytosanitary inspection. Bulletin OEPP/EMPPO Bulletin, pp. 195-200.

Ormsby, M. D., 2012. Potential level of protection required for fruit fly host material imported from Australia. s.l.:Technical Paper (draft). New Zealand Ministry of Primary Industries.

Ormsby, M. & Brenton-Rule, E., 2017. A review of global instruments to combat invasive alien species in forestry.. Biol Invasions, p. 19:3355–3364.

OSCE UNECE, 2018. Handbook of Best Practice at Border Crossings – A Trade and Transport Facilitation Perspective.. [On line] Available at: https://www.osce.org/eea/88238?download=true

Perrone, S. et al., 2013. Plant biosecurity: Detectability of arthropods in fresh produce consignments.. s.l.:ACERA 1006C:.

PPQ, 1999. National Cargo Release Program Guidelines. [On line].

PPQ, 2006. Cut Flowers and Greenery Import Manual. Plant Protection and Quarantine (PPQ). Washington, DC.: Animal and Plant Health Inspection Service, U.S. Department of Agriculture.

PPQ, 2018. Cut Flowers and Greenery Import Manual. Plant Protection and Quarantine (PPQ). Washington, DC.: Animal and Plant Health Inspection Service, U.S. Department of Agriculture,.

Quinlan, M. M. et al., 2016. Beyond Compliance. A Production Chain Framework for Plant Health Risk Management in Trade.. Chartridge: Books Oxford.

Roy, A., 2011. EPPO activities on emerging pests and diseases.. s.l.:Edited by J. Macek and S. Trdan, Zbornik Predavanj in Referatov, 10. Slovenskega Posvetovanja o Varstvu Rastlin, Podcetrtek, Slovenia, 1.-2. Marec 2011.

Sgrillo, R., 2002. Efficacy and equivalence of phytosanitary measures: A discussion and reference paper prepared for the IPPC Expert Working Group on the Efficacy of Phytosanitary Measures. Cocoa Research Center (CEPLAC/CEPEC) - University of Santa Cruz (UESC).

Sgrillo, R. B., 2004. Quantitative Analysis Tools for Phytosanitary Measures: a Perspective from South. Cocoa Research Center (CEPLAC/CEPEC).

Smith, I., 1979. EPPO: the work of a regional plant protection organization, with particular reference to phytosanitary regulations. In Plant health: the scientific basis for administrative control of plant diseases and pests.. s.l.:edited by D. L. Ebbels and J. E. King. Oxford: Blackwell Scientific Publications..

Stephens, K. S., 1995. Volume 4: How to Perform Skip-Lot and Chain Sampling (Second Edition). s.l.:ASQC Quality Press, Milwaukee, WI..

UNECE, 2011. Recommendations on regulatory cooperation and standarization policies. United Nations Economic Commission for Europe. [On line] Available at: https://www.unece.org/fileadmin/DAM/trade/wp6/Recommendations/Rec_R_Eng.pdf

UNECE, 2016. Applying Predictive Risk Management Tools. United Nations Economic Commission For Europe. [On line] Available at: https://www.unece.org/fileadmin/DAM/trade/wp6/Recommendations/WP6_Recommendations_E_2018.pdf

Whyte, C. F., 2009. Explanatory document on international standard for phytosanitary measures No. 31 (methodologies for sampling of consignments). Auckland, New Zealand: s.n.

WTO, 2014. The Trade Facilitation Agreement: An overview. [On line] Available at: https://www.wto.org/english/tratop_e/tradfa_e/tradfatheagreement_e.htm

[Último acceso: 2020].

WTO, 2019. World Trade Organization, Sanitary and Phitosanitary Measures: Text of the Agreement. [On line] Available at: https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm#fnt7

WTO, 2020a. The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). [On line] Available at: https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm#fnt2

[Último acceso: 2020].

WTO, 2020b. WTO Analytical Index, Interpretation and application of WTO agreements. [On line]

Available at: https://www.wto.org/english/res_e/publications_e/ai17_e/ai17_e.htm

WTO, 2020c. Trade facilitation. [On line] Available at: https://www.wto.org/english/tratop_e/tradfa_e/tradfa_e.htm

WTO, 2020d. Agreement on Technical Barriers to Trade. [On line]Available at: https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm

[Último acceso: 2020].

WTO, 2020e. The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). [On line] Available at: https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm

WTO, 2020. The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). [On line] Available at: https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm

10. APPENDICES

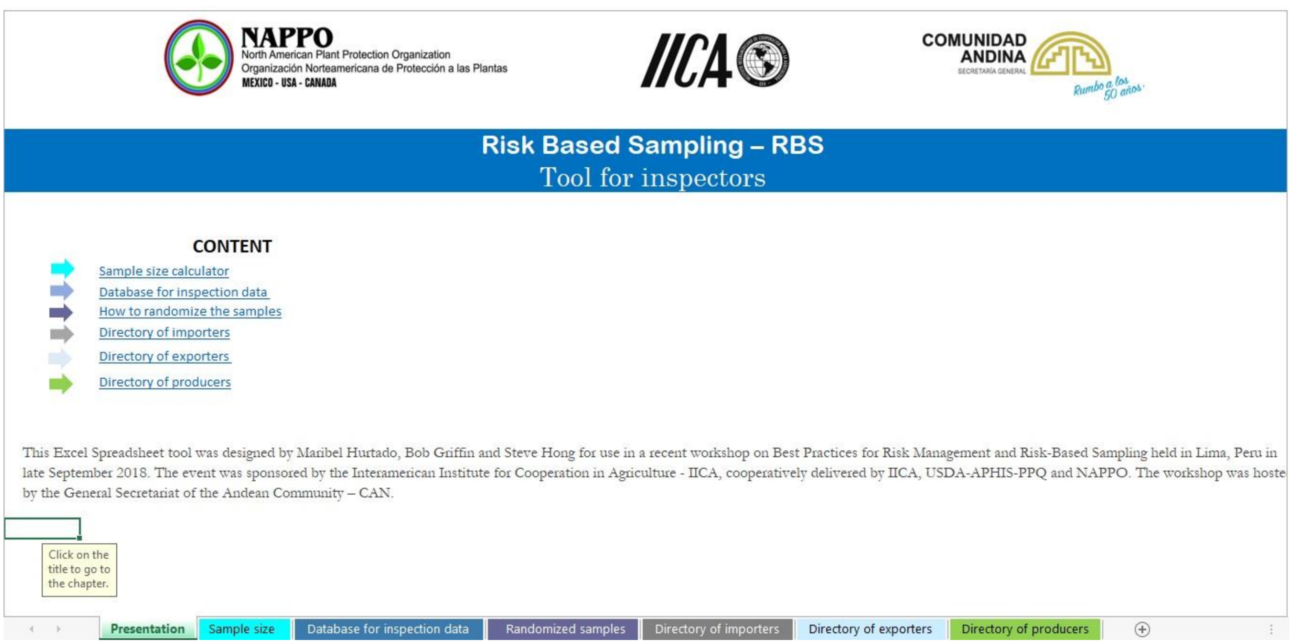
10.1. Appendix 1. Sample size calculator

The sample size calculator is an Excel Spreadsheet TOOL designed by Maribel Hurtado, Bob Griffin and Steve Hong for use in a recent workshop on Best Practices for Risk Management and Risk-Based Sampling held in Lima, Peru in late September 2018. The event was sponsored by the Interamerican Institute for Cooperation in Agriculture - IICA, the cooperatively delivered by IICA, USDA-APHIS-PPQ and NAPPO. The workshop was hosted by the General Secretariat of the Andean Community – CAN.

The tool can be used to organize data derived from inspections conducted at ports, airports, and border points. The formulae can be used to estimate sample sizes based on Risk-Based Sampling concepts.

Sample size calculator Excel spreadsheet content

- Sample size calculator
- Database for inspection data (Spreadsheets)
- How to randomize the samples
- Directory of importers
- Directory of exporters
- Directory of producers



To go to the Sample size calculator, click on the follow link:

https://www.nappo.org/english/learning-tools/Resources-and-Learning-Tools-for-Risk-Based-Sampling/Sample-Size-Calculator

10.2. Appendix 2. Hypergeometric Tables

10.2.1. How to use a hypergeometric table

To determine Sample Size

Begin by locating the table with the **Lot Size** closest to the size of the actual lot. Lot size is noted in the top center of each table. In this example, use **Lot Size = 1,000.**

1. Determine the maximum acceptable infestation level (titled **Percentage of Infestation Detected** in the chart below), or hereinafter in the text (= in risk level). In this example, maximum acceptable infestation level or percentage of infestation detected = **10%.**
2. Read across from **Percentage of Infestation detected** of 10% to the column representing the desired **Confidence level**. In this case, **95%.**
3. The corresponding cell value indicates the number of samples required. The results for this example would be 29. This means that 29 samples would be required to have 95% confidence that the infestation rate was not above 10%.

(Assuming 100% Efficiency) Step 1

Lot Size			1,000			
Percentage of Infestation Detected	Confidence Level					
	80%	85%	90%	95%	99%	99.9%
1%	148	173	205	258	368	497
2%	77	90	108	138	204	290
3%	52	61	73	94	141	203
4%	39	46	55	71	107	156
5%	31	37	44	57	86	126
6%	26	31	37	48	72	106
7%	22	26	32	41	62	91
8%	20	23	28	36	54	80
9%	17	20	25	[illegible]	48	71
10%	16	18	22	29	43	64
11%	14	17	20	26	39	58
12%	13	15	18	24	36	53
13%	12	14	17	22	33	49
14%	11	13	16	20	31	45
15%	10	12	15	19	28	42
16%	10	11	14	18	27	39
17%	9	11	13	16	25	37
18%	9	10	12	16	23	35
19%	8	9	11	15	22	33
20%	8	9	11	14	21	31

To determine Risk Levels (= Percentage of Infestation Detected)

Using the same chart, we can determine the percentage of infestation that would be detected at various confidence levels with various sample sizes.

1. Begin by locating the table with the **lot size** closest to the size of the actual lot. In this example **Lot size = 1,000.**
2. In the column titled **Confidence level** locate desired confidence level. In this case, **Confidence level = 95%.**
3. Reading down the **Confidence Level** column, we can select a sample size and then determine the **Percentage of Infestation Detected** (= risk level) associated with it. For example, we would have 95% confidence that a sample of 20 would detect an infestation rate of 14%. For a confidence level of 95%, larger sample sizes would be required to detect smaller infestation rates.

(Asuming 100% Efficiency) Step 1

Lot Size	1,000					
Percentage of Infestation Detected	Confidence Level					
	80%	85%	90%	95%	99%	99.9%
1%	148	173	205	258	368	497
2%	77	90	108	138	204	290
3%	52	61	73 Step 2	94	141	203
4%	39	46	55	71	107	156
5%	31	37	44	57	86	126
6%	26	31	37	48	72	106
7%	22	26	32	41	62	91
8%	20	23	28	36	54	80
9%	17	20	25	32	48	71
10%	16	18	22	29	43	64
11%	14	17	20	26	39	58
12%	13	15	18	24	36	53
13%	12	14	17	[illegible]	33	49
14%	11	13	16	20	31	45
15%	10 Step 3	12	15	19	28	42
16%	10	11	14	18	27	39
17%	9	11	13	16	25	37
18%	9	10	12	16	23	35
19%	8	9	11	15	22	33
20%	8	9	11	14	21	31

10.2.2. Abbreviated hypergeometric tables for Risk-Based Sampling in commodity inspection

Optimum Sample Sizes
(Assuming 100% Efficiency)

Lot Size	100					
Percentage of Infestation Detected	Confidence Level					
	80%	85%	90%	95%	99%	99.9%
1%	80	85	90	95	99	100
2%	56	61	69	78	90	97
3%	42	47	54	63	78	90
4%	33	38	44	52	68	81
5%	27	31	37	45	59	74
6%	23	27	32	39	53	67
7%	20	24	28	34	47	61
8%	18	21	25	31	43	56
9%	16	19	22	28	39	52
10%	15	17	20	25	36	48
11%	13	16	18	23	33	45
12%	12	14	17	21	31	42
13%	11	13	16	20	29	39
14%	11	12	15	19	27	37
15%	10	12	14	17	25	35
16%	9	11	13	16	24	33
17%	9	10	12	15	22	31
18%	8	10	11	15	21	30
19%	8	9	11	14	20	28
20%	7	9	10	13	19	27
21%	7	8	10	12	18	26
22%	7	8	9	12	17	25
23%	7	8	9	11	17	24
24%	6	7	9	11	16	23
25%	6	7	8	10	15	22
26%	6	7	8	10	15	21
27%	6	6	8	10	14	20
28%	5	6	7	9	14	19
29%	5	6	7	9	13	19
30%	5	6	7	9	13	18
31%	5	6	7	8	12	17
32%	5	5	6	8	12	17
33%	4	5	6	8	11	16
34%	4	5	6	8	11	16
35%	4	5	6	7	11	15
36%	4	5	6	7	10	15
37%	4	5	5	7	10	14
38%	4	4	5	7	10	14
39%	4	4	5	6	10	14
40%	4	4	5	6	9	13

Optimum Sample Sizes

(Assuming 100% Efficiency)

Lot Size	200					
Percentage of Infestation Detected	Confidence Level					
	80%	85%	90%	95%	99%	99.9%
1%	111	123	137	155	180	194
2%	66	75	87	105	136	164
3%	47	54	63	78	106	136
4%	36	42	50	62	86	114
5%	30	34	41	51	73	98
6%	25	29	34	43	62	86
7%	22	25	30	38	55	76
8%	19	22	26	33	49	68
9%	17	20	23	30	44	62
10%	15	18	21	27	40	56
11%	14	16	19	25	36	52
12%	13	15	18	23	33	48
13%	12	14	16	21	31	44
14%	11	13	15	19	29	41
15%	10	12	14	18	27	39
16%	10	11	13	17	25	36
17%	9	10	13	16	24	34
18%	8	10	12	15	22	32
19%	8	9	11	14	21	31
20%	8	9	11	14	20	29
21%	7	8	10	13	19	28
22%	7	8	10	12	18	26
23%	7	8	9	12	17	25
24%	6	7	9	11	17	24
25%	6	7	8	11	16	23
26%	6	7	8	10	15	22
27%	6	6	8	10	15	21
28%	5	6	7	9	14	21
29%	5	6	7	9	14	20
30%	5	6	7	9	13	19
31%	5	6	7	8	13	18
32%	5	5	6	8	12	18
33%	5	5	6	8	12	17
34%	4	5	6	8	11	17
35%	4	5	6	7	11	16
36%	4	5	6	7	11	16
37%	4	5	6	7	10	15
38%	4	5	5	7	10	15
39%	4	4	5	7	10	14
40%	4	4	5	6	9	14

Optimum Sample Sizes

(Assuming 100% Efficiency)

Lot Size	300					
Percentage of Infestation Detected	Confidence Level					
	80%	85%	90%	95%	99%	99.9%
1%	125	141	161	189	235	270
2%	70	81	95	117	160	204
3%	49	57	67	84	119	159
4%	37	44	52	66	94	129
5%	30	35	42	54	78	109
6%	25	30	36	45	66	93
7%	22	26	31	39	58	82
8%	19	22	27	34	51	73
9%	17	20	24	31	46	65
10%	15	18	22	28	41	59
11%	14	16	20	25	37	54
12%	13	15	18	23	34	50
13%	12	14	17	21	32	46
14%	11	13	15	20	30	43
15%	10	12	14	18	28	40
16%	10	11	13	17	26	38
17%	9	11	13	16	24	35
18%	9	10	12	15	23	33
19%	8	9	11	14	22	32
20%	8	9	11	14	20	30
21%	7	8	10	13	19	28
22%	7	8	10	12	19	27
23%	7	8	9	12	18	26
24%	6	7	9	11	17	25
25%	6	7	8	11	16	24
26%	6	7	8	10	15	23
27%	6	7	8	10	15	22
28%	5	6	7	10	14	21
29%	5	6	7	9	14	20
30%	5	6	7	9	13	19
31%	5	6	7	9	13	19
32%	5	5	6	8	12	18
33%	5	5	6	8	12	17
34%	4	5	6	8	12	17
35%	4	5	6	7	11	16
36%	4	5	6	7	11	16
37%	4	5	6	7	10	15
38%	4	5	5	7	10	15
39%	4	4	5	7	10	14
40%	4	4	5	6	10	14

Optimum Sample Sizes

(Assuming 100% Efficiency)

Lot Size	400					
Percentage of Infestation Detected	Confidence Level					
	80%	85%	90%	95%	99%	99.9%
1%	133	151	175	211	273	328
2%	73	84	100	124	174	230
3%	50	58	69	88	126	173
4%	38	44	53	68	99	138
5%	31	36	43	55	81	115
6%	26	30	36	46	68	98
7%	22	26	31	40	59	85
8%	19	23	27	35	52	75
9%	17	20	24	31	46	67
10%	16	18	22	28	42	61
11%	14	16	20	25	38	55
12%	13	15	18	23	35	51
13%	12	14	17	21	32	47
14%	11	13	16	20	30	44
15%	10	12	14	19	28	41
16%	10	11	14	17	26	38
17%	9	11	13	16	24	36
18%	9	10	12	15	23	34
19%	8	9	11	15	22	32
20%	8	9	11	14	21	30
21%	7	9	10	13	20	29
22%	7	8	10	12	19	27
23%	7	8	9	12	18	26
24%	6	7	9	11	17	25
25%	6	7	8	11	16	24
26%	6	7	8	10	16	23
27%	6	7	8	10	15	22
28%	5	6	8	10	14	21
29%	5	6	7	9	14	20
30%	5	6	7	9	13	20
31%	5	6	7	9	13	19
32%	5	5	6	8	12	18
33%	5	5	6	8	12	18
34%	4	5	6	8	12	17
35%	4	5	6	7	11	16
36%	4	5	6	7	11	16
37%	4	5	6	7	11	15
38%	4	5	5	7	10	15
39%	4	4	5	7	10	14
40%	4	4	5	6	10	14

Optimum Sample Sizes

(Assuming 100% Efficiency)

Lot Size	500					
Percentage of Infestation Detected	Confidence Level					
	80%	85%	90%	95%	99%	99.9%
1%	138	158	184	225	300	373
2%	74	86	102	129	183	248
3%	51	59	71	90	131	182
4%	38	45	54	69	101	144
5%	31	36	43	56	83	118
6%	26	30	36	47	70	100
7%	22	26	31	40	60	87
8%	19	23	27	35	53	77
9%	17	20	24	31	47	69
10%	16	18	22	28	42	62
11%	14	17	20	26	38	56
12%	13	15	18	23	35	52
13%	12	14	17	22	33	48
14%	11	13	16	20	30	44
15%	10	12	14	19	28	41
16%	10	11	14	17	26	39
17%	9	11	13	16	25	36
18%	9	10	12	15	23	34
19%	8	9	11	15	22	32
20%	8	9	11	14	21	31
21%	7	9	10	13	20	29
22%	7	8	10	12	19	28
23%	7	8	9	12	18	26
24%	6	7	9	11	17	25
25%	6	7	8	11	16	24
26%	6	7	8	10	16	23
27%	6	7	8	10	15	22
28%	5	6	8	10	14	21
29%	5	6	7	9	14	20
30%	5	6	7	9	13	20
31%	5	6	7	9	13	19
32%	5	5	7	8	12	18
33%	5	5	6	8	12	18
34%	4	5	6	8	12	17
35%	4	5	6	8	11	16
36%	4	5	6	7	11	16
37%	4	5	6	7	11	15
38%	4	5	5	7	10	15
39%	4	4	5	7	10	15
40%	4	4	5	6	10	14

Optimum Sample Sizes

(Assuming 100% Efficiency)

Lot Size	600					
Percentage of Infestation Detected	Confidence Level					
	80%	85%	90%	95%	99%	99.9%
1%	141	162	191	235	321	409
2%	75	87	104	132	190	261
3%	51	60	72	91	134	189
4%	39	45	54	70	103	148
5%	31	36	44	56	84	121
6%	26	30	37	47	70	102
7%	22	26	31	40	61	88
8%	20	23	28	35	53	78
9%	17	20	24	31	47	69
10%	16	18	22	28	43	63
11%	14	17	20	26	39	57
12%	13	15	18	24	35	52
13%	12	14	17	22	33	48
14%	11	13	16	20	30	45
15%	10	12	15	19	28	42
16%	10	11	14	17	26	39
17%	9	11	13	16	25	36
18%	9	10	12	15	23	34
19%	8	9	11	15	22	32
20%	8	9	11	14	21	31
21%	7	9	10	13	20	29
22%	7	8	10	12	19	28
23%	7	8	9	12	18	26
24%	6	7	9	11	17	25
25%	6	7	9	11	16	24
26%	6	7	8	10	16	23
27%	6	7	8	10	15	22
28%	5	6	8	10	14	21
29%	5	6	7	9	14	20
30%	5	6	7	9	13	20
31%	5	6	7	9	13	19
32%	5	5	7	8	12	18
33%	5	5	6	8	12	18
34%	4	5	6	8	12	17
35%	4	5	6	8	11	17
36%	4	5	6	7	11	16
37%	4	5	6	7	11	15
38%	4	5	5	7	10	15
39%	4	4	5	7	10	15
40%	4	4	5	6	10	14

Optimum Sample Sizes

(Assuming 100% Efficiency)

Lot Size	700					
Percentage of Infestation Detected	Confidence Level					
	80%	85%	90%	95%	99%	99.9%
1%	144	166	196	243	336	438
2%	76	88	106	134	195	271
3%	51	60	72	92	136	194
4%	39	45	55	70	105	151
5%	31	37	44	57	85	123
6%	26	31	37	47	71	104
7%	22	26	32	41	61	89
8%	20	23	28	36	54	79
9%	17	20	25	32	48	70
10%	16	18	22	28	43	63
11%	14	17	20	26	39	57
12%	13	15	18	24	36	52
13%	12	14	17	22	33	48
14%	11	13	16	20	30	45
15%	10	12	15	19	28	42
16%	10	11	14	18	26	39
17%	9	11	13	16	25	37
18%	9	10	12	15	23	35
19%	8	9	11	15	22	33
20%	8	9	11	14	21	31
21%	7	9	10	13	20	29
22%	7	8	10	13	19	28
23%	7	8	9	12	18	27
24%	6	7	9	11	17	25
25%	6	7	9	11	16	24
26%	6	7	8	10	16	23
27%	6	7	8	10	15	22
28%	5	6	8	10	14	21
29%	5	6	7	9	14	21
30%	5	6	7	9	13	20
31%	5	6	7	9	13	19
32%	5	5	7	8	12	18
33%	5	5	6	8	12	18
34%	4	5	6	8	12	17
35%	4	5	6	8	11	17
36%	4	5	6	7	11	16
37%	4	5	6	7	11	16
38%	4	5	5	7	10	15
39%	4	4	5	7	10	15
40%	4	4	5	6	10	14

Optimum Sample Sizes

(Assuming 100% Efficiency)

Lot Size	800					
Percentage of Infestation Detected	Confidence Level					
	80%	85%	90%	95%	99%	99.9%
1%	146	169	200	249	349	461
2%	76	89	107	136	199	278
3%	52	60	73	93	138	198
4%	39	46	55	71	106	153
5%	31	37	44	57	85	124
6%	26	31	37	47	72	105
7%	22	26	32	41	61	90
8%	20	23	28	36	54	79
9%	17	20	25	32	48	70
10%	16	18	22	28	43	63
11%	14	17	20	26	39	58
12%	13	15	18	24	36	53
13%	12	14	17	22	33	49
14%	11	13	16	20	30	45
15%	10	12	15	19	28	42
16%	10	11	14	18	27	39
17%	9	11	13	16	25	37
18%	9	10	12	15	23	35
19%	8	9	11	15	22	33
20%	8	9	11	14	21	31
21%	7	9	10	13	20	29
22%	7	8	10	13	19	28
23%	7	8	9	12	18	27
24%	6	7	9	11	17	25
25%	6	7	9	11	16	24
26%	6	7	8	10	16	23
27%	6	7	8	10	15	22
28%	5	6	8	10	15	21
29%	5	6	7	9	14	21
30%	5	6	7	9	13	20
31%	5	6	7	9	13	19
32%	5	5	7	8	12	18
33%	5	5	6	8	12	18
34%	4	5	6	8	12	17
35%	4	5	6	8	11	17
36%	4	5	6	7	11	16
37%	4	5	6	7	11	16
38%	4	5	5	7	10	15
39%	4	4	5	7	10	15
40%	4	4	5	6	10	14

Optimum Sample Sizes

(Assuming 100% Efficiency)

Lot Size	900					
Percentage of Infestation Detected	Confidence Level					
	80%	85%	90%	95%	99%	99.9%
1%	147	171	203	254	359	481
2%	77	90	108	137	202	285
3%	52	61	73	94	140	201
4%	39	46	55	71	106	155
5%	31	37	44	57	86	125
6%	26	31	37	48	72	105
7%	22	26	32	41	62	91
8%	20	23	28	36	54	80
9%	17	20	25	32	48	71
10%	16	18	22	29	43	64
11%	14	17	20	26	39	58
12%	13	15	18	24	36	53
13%	12	14	17	22	33	49
14%	11	13	16	20	31	45
15%	10	12	15	19	28	42
16%	10	11	14	18	27	39
17%	9	11	13	16	25	37
18%	9	10	12	16	23	35
19%	8	9	11	15	22	33
20%	8	9	11	14	21	31
21%	7	9	10	13	20	29
22%	7	8	10	13	19	28
23%	7	8	9	12	18	27
24%	6	7	9	11	17	25
25%	6	7	9	11	16	24
26%	6	7	8	10	16	23
27%	6	7	8	10	15	22
28%	5	6	8	10	15	21
29%	5	6	7	9	14	21
30%	5	6	7	9	13	20
31%	5	6	7	9	13	19
32%	5	5	7	8	13	18
33%	5	5	6	8	12	18
34%	4	5	6	8	12	17
35%	4	5	6	8	11	17
36%	4	5	6	7	11	16
37%	4	5	6	7	11	16
38%	4	5	5	7	10	15
39%	4	4	5	7	10	15
40%	4	4	5	6	10	14

Optimum Sample Sizes

(Assuming 100% Efficiency)

Lot Size	1,000					
Percentage of Infestation Detected	Confidence Level					
	80%	85%	90%	95%	99%	99.9%
1%	148	173	205	258	368	497
2%	77	90	108	138	204	290
3%	52	61	73	94	141	203
4%	39	46	55	71	107	156
5%	31	37	44	57	86	126
6%	26	31	37	48	72	106
7%	22	26	32	41	62	91
8%	20	23	28	36	54	80
9%	17	20	25	32	48	71
10%	16	18	22	29	43	64
11%	14	17	20	26	39	58
12%	13	15	18	24	36	53
13%	12	14	17	22	33	49
14%	11	13	16	20	31	45
15%	10	12	15	19	28	42
16%	10	11	14	18	27	39
17%	9	11	13	16	25	37
18%	9	10	12	16	23	35
19%	8	9	11	15	22	33
20%	8	9	11	14	21	31
21%	7	9	10	13	20	29
22%	7	8	10	13	19	28
23%	7	8	9	12	18	27
24%	6	7	9	11	17	25
25%	6	7	9	11	16	24
26%	6	7	8	10	16	23
27%	6	7	8	10	15	22
28%	5	6	8	10	15	21
29%	5	6	7	9	14	21
30%	5	6	7	9	13	20
31%	5	6	7	9	13	19
32%	5	5	7	8	13	18
33%	5	5	6	8	12	18
34%	4	5	6	8	12	17
35%	4	5	6	8	11	17
36%	4	5	6	7	11	16
37%	4	5	6	7	11	16
38%	4	5	5	7	10	15
39%	4	4	5	7	10	15
40%	4	4	5	6	10	14

Optimum Sample Sizes

(Assuming 100% Efficiency)

Lot Size	2,000					
Percentage of Infestation Detected	Confidence Level					
	80%	85%	90%	95%	99%	99.9%
1%	154	181	217	277	410	582
2%	79	92	111	143	216	315
3%	53	62	75	96	146	215
4%	40	46	56	73	110	163
5%	32	37	45	58	88	131
6%	26	31	37	48	74	109
7%	23	26	32	41	63	93
8%	20	23	28	36	55	82
9%	18	21	25	32	49	72
10%	16	18	22	29	44	65
11%	14	17	20	26	40	59
12%	13	15	18	24	36	54
13%	12	14	17	22	33	50
14%	11	13	16	20	31	46
15%	10	12	15	19	29	43
16%	10	11	14	18	27	40
17%	9	11	13	17	25	37
18%	9	10	12	16	24	35
19%	8	10	11	15	22	33
20%	8	9	11	14	21	31
21%	7	9	10	13	20	30
22%	7	8	10	13	19	28
23%	7	8	9	12	18	27
24%	6	7	9	11	17	26
25%	6	7	9	11	17	25
26%	6	7	8	10	16	23
27%	6	7	8	10	15	22
28%	5	6	8	10	15	22
29%	5	6	7	9	14	21
30%	5	6	7	9	14	20
31%	5	6	7	9	13	19
32%	5	5	7	8	13	19
33%	5	5	6	8	12	18
34%	4	5	6	8	12	17
35%	4	5	6	8	11	17
36%	4	5	6	7	11	16
37%	4	5	6	7	11	16
38%	4	5	5	7	10	15
39%	4	4	5	7	10	15
40%	4	4	5	6	10	14

Optimum Sample Sizes

(Assuming 100% Efficiency)

Lot Size	3,000					
Percentage of Infestation Detected	Confidence Level					
	80%	85%	90%	95%	99%	99.9%
1%	156	183	221	284	425	615
2%	79	93	112	145	220	324
3%	53	62	75	97	148	219
4%	40	47	56	73	111	165
5%	32	37	45	58	89	132
6%	26	31	37	49	74	110
7%	23	27	32	42	63	94
8%	20	23	28	36	55	82
9%	18	21	25	32	49	73
10%	16	18	22	29	44	65
11%	14	17	20	26	40	59
12%	13	15	18	24	36	54
13%	12	14	17	22	33	50
14%	11	13	16	20	31	46
15%	10	12	15	19	29	43
16%	10	11	14	18	27	40
17%	9	11	13	17	25	37
18%	9	10	12	16	24	35
19%	8	10	11	15	22	33
20%	8	9	11	14	21	31
21%	7	9	10	13	20	30
22%	7	8	10	13	19	28
23%	7	8	9	12	18	27
24%	6	7	9	11	17	26
25%	6	7	9	11	17	25
26%	6	7	8	11	16	24
27%	6	7	8	10	15	23
28%	5	6	8	10	15	22
29%	5	6	7	9	14	21
30%	5	6	7	9	14	20
31%	5	6	7	9	13	19
32%	5	5	7	8	13	19
33%	5	5	6	8	12	18
34%	4	5	6	8	12	17
35%	4	5	6	8	11	17
36%	4	5	6	7	11	16
37%	4	5	6	7	11	16
38%	4	5	5	7	10	15
39%	4	4	5	7	10	15
40%	4	4	5	6	10	14

Optimum Sample Sizes

(Assuming 100% Efficiency)

Lot Size	4,000					
Percentage of Infestation Detected	Confidence Level					
	80%	85%	90%	95%	99%	99.9%
1%	157	185	223	288	433	632
2%	79	93	113	146	222	328
3%	53	62	75	98	149	221
4%	40	47	57	73	112	166
5%	32	37	45	58	89	133
6%	26	31	38	49	74	111
7%	23	27	32	42	63	95
8%	20	23	28	36	55	83
9%	18	21	25	32	49	73
10%	16	18	22	29	44	66
11%	14	17	20	26	40	59
12%	13	15	18	24	36	54
13%	12	14	17	22	33	50
14%	11	13	16	20	31	46
15%	10	12	15	19	29	43
16%	10	11	14	18	27	40
17%	9	11	13	17	25	37
18%	9	10	12	16	24	35
19%	8	10	11	15	22	33
20%	8	9	11	14	21	31
21%	7	9	10	13	20	30
22%	7	8	10	13	19	28
23%	7	8	9	12	18	27
24%	6	7	9	11	17	26
25%	6	7	9	11	17	25
26%	6	7	8	11	16	24
27%	6	7	8	10	15	23
28%	5	6	8	10	15	22
29%	5	6	7	9	14	21
30%	5	6	7	9	14	20
31%	5	6	7	9	13	19
32%	5	5	7	8	13	19
33%	5	5	6	8	12	18
34%	4	5	6	8	12	17
35%	4	5	6	8	11	17
36%	4	5	6	7	11	16
37%	4	5	6	7	11	16
38%	4	5	5	7	10	15
39%	4	4	5	7	10	15
40%	4	4	5	6	10	14

Optimum Sample Sizes

(Assuming 100% Efficiency)

Lot Size	5,000					
Percentage of Infestation Detected	Confidence Level					
	80%	85%	90%	95%	99%	99.9%
1%	158	186	224	290	438	643
2%	80	94	113	147	223	331
3%	53	62	76	98	149	222
4%	40	47	57	73	112	167
5%	32	37	45	59	89	133
6%	26	31	38	49	74	111
7%	23	27	32	42	64	95
8%	20	23	28	36	55	83
9%	18	21	25	32	49	73
10%	16	18	22	29	44	66
11%	14	17	20	26	40	59
12%	13	15	19	24	36	54
13%	12	14	17	22	34	50
14%	11	13	16	20	31	46
15%	10	12	15	19	29	43
16%	10	11	14	18	27	40
17%	9	11	13	17	25	38
18%	9	10	12	16	24	35
19%	8	10	11	15	22	33
20%	8	9	11	14	21	31
21%	7	9	10	13	20	30
22%	7	8	10	13	19	28
23%	7	8	9	12	18	27
24%	6	7	9	11	17	26
25%	6	7	9	11	17	25
26%	6	7	8	11	16	24
27%	6	7	8	10	15	23
28%	5	6	8	10	15	22
29%	5	6	7	9	14	21
30%	5	6	7	9	14	20
31%	5	6	7	9	13	19
32%	5	5	7	8	13	19
33%	5	5	6	8	12	18
34%	4	5	6	8	12	17
35%	4	5	6	8	11	17
36%	4	5	6	7	11	16
37%	4	5	6	7	11	16
38%	4	5	5	7	10	15
39%	4	4	5	7	10	15
40%	4	4	5	6	10	14

Optimum Sample Sizes

(Assuming 100% Efficiency)

Lot Size	6,000					
Percentage of Infestation Detected	Confidence Level					
	80%	85%	90%	95%	99%	99.9%
1%	159	186	225	291	442	650
2%	80	94	113	147	224	333
3%	53	62	76	98	150	223
4%	40	47	57	73	112	167
5%	32	37	45	59	90	134
6%	26	31	38	49	74	111
7%	23	27	32	42	64	95
8%	20	23	28	36	56	83
9%	18	21	25	32	49	73
10%	16	18	22	29	44	66
11%	14	17	20	26	40	60
12%	13	15	19	24	36	54
13%	12	14	17	22	34	50
14%	11	13	16	20	31	46
15%	10	12	15	19	29	43
16%	10	11	14	18	27	40
17%	9	11	13	17	25	38
18%	9	10	12	16	24	35
19%	8	10	11	15	22	33
20%	8	9	11	14	21	31
21%	7	9	10	13	20	30
22%	7	8	10	13	19	28
23%	7	8	9	12	18	27
24%	6	7	9	11	17	26
25%	6	7	9	11	17	25
26%	6	7	8	11	16	24
27%	6	7	8	10	15	23
28%	5	6	8	10	15	22
29%	5	6	7	9	14	21
30%	5	6	7	9	14	20
31%	5	6	7	9	13	19
32%	5	5	7	8	13	19
33%	5	5	6	8	12	18
34%	4	5	6	8	12	17
35%	4	5	6	8	11	17
36%	4	5	6	7	11	16
37%	4	5	6	7	11	16
38%	4	5	5	7	10	15
39%	4	4	5	7	10	15
40%	4	4	5	6	10	14

Optimum Sample Sizes

(Assuming 100% Efficiency)

Lot Size	7,000					
Percentage of Infestation Detected	Confidence Level					
	80%	85%	90%	95%	99%	99.9%
1%	159	187	226	292	444	655
2%	80	94	114	147	225	334
3%	53	63	76	98	150	224
4%	40	47	57	74	112	168
5%	32	37	45	59	90	134
6%	26	31	38	49	75	111
7%	23	27	32	42	64	95
8%	20	23	28	36	56	83
9%	18	21	25	32	49	73
10%	16	18	22	29	44	66
11%	14	17	20	26	40	60
12%	13	15	19	24	36	54
13%	12	14	17	22	34	50
14%	11	13	16	20	31	46
15%	10	12	15	19	29	43
16%	10	11	14	18	27	40
17%	9	11	13	17	25	38
18%	9	10	12	16	24	35
19%	8	10	11	15	22	33
20%	8	9	11	14	21	32
21%	7	9	10	13	20	30
22%	7	8	10	13	19	28
23%	7	8	9	12	18	27
24%	6	7	9	11	17	26
25%	6	7	9	11	17	25
26%	6	7	8	11	16	24
27%	6	7	8	10	15	23
28%	5	6	8	10	15	22
29%	5	6	7	9	14	21
30%	5	6	7	9	14	20
31%	5	6	7	9	13	19
32%	5	5	7	8	13	19
33%	5	5	6	8	12	18
34%	4	5	6	8	12	17
35%	4	5	6	8	11	17
36%	4	5	6	7	11	16
37%	4	5	6	7	11	16
38%	4	5	5	7	10	15
39%	4	4	5	7	10	15
40%	4	4	5	6	10	14

Optimum Sample Sizes

(Assuming 100% Efficiency)

Lot Size	8,000					
Percentage of Infestation Detected	Confidence Level					
	80%	85%	90%	95%	99%	99.9%
1%	159	187	226	293	446	659
2%	80	94	114	147	225	335
3%	53	63	76	98	150	224
4%	40	47	57	74	113	168
5%	32	37	45	59	90	134
6%	26	31	38	49	75	111
7%	23	27	32	42	64	95
8%	20	23	28	36	56	83
9%	18	21	25	32	49	73
10%	16	19	22	29	44	66
11%	14	17	20	26	40	60
12%	13	15	19	24	36	54
13%	12	14	17	22	34	50
14%	11	13	16	20	31	46
15%	10	12	15	19	29	43
16%	10	11	14	18	27	40
17%	9	11	13	17	25	38
18%	9	10	12	16	24	35
19%	8	10	11	15	22	33
20%	8	9	11	14	21	32
21%	7	9	10	13	20	30
22%	7	8	10	13	19	28
23%	7	8	9	12	18	27
24%	6	7	9	11	17	26
25%	6	7	9	11	17	25
26%	6	7	8	11	16	24
27%	6	7	8	10	15	23
28%	5	6	8	10	15	22
29%	5	6	7	9	14	21
30%	5	6	7	9	14	20
31%	5	6	7	9	13	19
32%	5	5	7	8	13	19
33%	5	5	6	8	12	18
34%	4	5	6	8	12	17
35%	4	5	6	8	11	17
36%	4	5	6	7	11	16
37%	4	5	6	7	11	16
38%	4	5	5	7	10	15
39%	4	4	5	7	10	15
40%	4	4	5	6	10	14

Optimum Sample Sizes

(Assuming 100% Efficiency)

Lot Size	9,000					
Percentage of Infestation Detected	Confidence Level					
	80%	85%	90%	95%	99%	99.9%
1%	159	187	227	294	447	662
2%	80	94	114	148	226	336
3%	53	63	76	98	150	224
4%	40	47	57	74	113	168
5%	32	37	45	59	90	134
6%	26	31	38	49	75	111
7%	23	27	32	42	64	95
8%	20	23	28	36	56	83
9%	18	21	25	32	49	73
10%	16	19	22	29	44	66
11%	14	17	20	26	40	60
12%	13	15	19	24	36	54
13%	12	14	17	22	34	50
14%	11	13	16	20	31	46
15%	10	12	15	19	29	43
16%	10	11	14	18	27	40
17%	9	11	13	17	25	38
18%	9	10	12	16	24	35
19%	8	10	11	15	22	33
20%	8	9	11	14	21	32
21%	7	9	10	13	20	30
22%	7	8	10	13	19	28
23%	7	8	9	12	18	27
24%	6	7	9	11	17	26
25%	6	7	9	11	17	25
26%	6	7	8	11	16	24
27%	6	7	8	10	15	23
28%	5	6	8	10	15	22
29%	5	6	7	9	14	21
30%	5	6	7	9	14	20
31%	5	6	7	9	13	19
32%	5	5	7	8	13	19
33%	5	5	6	8	12	18
34%	4	5	6	8	12	17
35%	4	5	6	8	11	17
36%	4	5	6	7	11	16
37%	4	5	6	7	11	16
38%	4	5	5	7	10	15
39%	4	4	5	7	10	15
40%	4	4	5	6	10	14

Optimum Sample Sizes

(Assuming 100% Efficiency)

Lot Size	10,000					
Percentage of Infestation Detected	Confidence Level					
	80%	85%	90%	95%	99%	99.9%
1%	159	187	227	294	448	665
2%	80	94	114	148	226	337
3%	53	63	76	98	151	225
4%	40	47	57	74	113	168
5%	32	37	45	59	90	134
6%	26	31	38	49	75	112
7%	23	27	32	42	64	95
8%	20	23	28	36	56	83
9%	18	21	25	32	49	74
10%	16	19	22	29	44	66
11%	14	17	20	26	40	60
12%	13	15	19	24	37	54
13%	12	14	17	22	34	50
14%	11	13	16	20	31	46
15%	10	12	15	19	29	43
16%	10	11	14	18	27	40
17%	9	11	13	17	25	38
18%	9	10	12	16	24	35
19%	8	10	11	15	22	33
20%	8	9	11	14	21	32
21%	7	9	10	13	20	30
22%	7	8	10	13	19	28
23%	7	8	9	12	18	27
24%	6	7	9	11	17	26
25%	6	7	9	11	17	25
26%	6	7	8	11	16	24
27%	6	7	8	10	15	23
28%	5	6	8	10	15	22
29%	5	6	7	9	14	21
30%	5	6	7	9	14	20
31%	5	6	7	9	13	19
32%	5	5	7	8	13	19
33%	5	5	6	8	12	18
34%	4	5	6	8	12	17
35%	4	5	6	8	11	17
36%	4	5	6	7	11	16
37%	4	5	6	7	11	16
38%	4	5	5	7	10	15
39%	4	4	5	7	10	15
40%	4	4	5	6	10	14

Optimum Sample Sizes

(Assuming 100% Efficiency)

Lot Size	20,000					
Percentage of Infestation Detected	Confidence Level					
	80%	85%	90%	95%	99%	99.9%
1%	160	188	228	296	453	676
2%	80	94	114	148	227	340
3%	53	63	76	99	151	226
4%	40	47	57	74	113	169
5%	32	37	45	59	90	135
6%	27	31	38	49	75	112
7%	23	27	32	42	64	95
8%	20	23	28	36	56	83
9%	18	21	25	32	49	74
10%	16	19	22	29	44	66
11%	14	17	20	26	40	60
12%	13	15	19	24	37	55
13%	12	14	17	22	34	50
14%	11	13	16	20	31	46
15%	10	12	15	19	29	43
16%	10	11	14	18	27	40
17%	9	11	13	17	25	38
18%	9	10	12	16	24	35
19%	8	10	11	15	22	33
20%	8	9	11	14	21	32
21%	7	9	10	13	20	30
22%	7	8	10	13	19	28
23%	7	8	9	12	18	27
24%	6	7	9	11	17	26
25%	6	7	9	11	17	25
26%	6	7	8	11	16	24
27%	6	7	8	10	15	23
28%	5	6	8	10	15	22
29%	5	6	7	9	14	21
30%	5	6	7	9	14	20
31%	5	6	7	9	13	19
32%	5	5	7	8	13	19
33%	5	5	6	8	12	18
34%	4	5	6	8	12	17
35%	4	5	6	8	11	17
36%	4	5	6	7	11	16
37%	4	5	6	7	11	16
38%	4	5	5	7	10	15
39%	4	4	5	7	10	15
40%	4	4	5	6	10	14

Optimum Sample Sizes

(Assuming 100% Efficiency)

Lot Size	30,000					
Percentage of Infestation Detected	Confidence Level					
	80%	85%	90%	95%	99%	99.9%
1%	160	189	229	297	455	680
2%	80	94	114	148	228	340
3%	53	63	76	99	151	226
4%	40	47	57	74	113	169
5%	32	37	45	59	90	135
6%	27	31	38	49	75	112
7%	23	27	32	42	64	96
8%	20	23	28	36	56	83
9%	18	21	25	32	49	74
10%	16	19	22	29	44	66
11%	14	17	20	26	40	60
12%	13	15	19	24	37	55
13%	12	14	17	22	34	50
14%	11	13	16	20	31	46
15%	10	12	15	19	29	43
16%	10	11	14	18	27	40
17%	9	11	13	17	25	38
18%	9	10	12	16	24	35
19%	8	10	11	15	22	33
20%	8	9	11	14	21	32
21%	7	9	10	13	20	30
22%	7	8	10	13	19	28
23%	7	8	9	12	18	27
24%	6	7	9	11	17	26
25%	6	7	9	11	17	25
26%	6	7	8	11	16	24
27%	6	7	8	10	15	23
28%	5	6	8	10	15	22
29%	5	6	7	9	14	21
30%	5	6	7	9	14	20
31%	5	6	7	9	13	19
32%	5	5	7	8	13	19
33%	5	5	6	8	12	18
34%	4	5	6	8	12	17
35%	4	5	6	8	11	17
36%	4	5	6	7	11	16
37%	4	5	6	7	11	16
38%	4	5	5	7	10	15
39%	4	4	5	7	10	15
40%	4	4	5	6	10	14

Optimum Sample Sizes

(Assuming 100% Efficiency)

Lot Size	33,000					
Percentage of Infestation Detected	Confidence Level					
	80%	85%	90%	95%	99%	99.9%
1%	160	189	229	297	456	681
2%	80	94	114	148	228	341
3%	53	63	76	99	151	227
4%	40	47	57	74	113	169
5%	32	37	45	59	90	135
6%	27	31	38	49	75	112
7%	23	27	32	42	64	96
8%	20	23	28	36	56	83
9%	18	21	25	32	49	74
10%	16	19	22	29	44	66
11%	14	17	20	26	40	60
12%	13	15	19	24	37	55
13%	12	14	17	22	34	50
14%	11	13	16	20	31	46
15%	10	12	15	19	29	43
16%	10	11	14	18	27	40
17%	9	11	13	17	25	38
18%	9	10	12	16	24	35
19%	8	10	11	15	22	33
20%	8	9	11	14	21	32
21%	7	9	10	13	20	30
22%	7	8	10	13	19	28
23%	7	8	9	12	18	27
24%	6	7	9	11	17	26
25%	6	7	9	11	17	25
26%	6	7	8	11	16	24
27%	6	7	8	10	15	23
28%	5	6	8	10	15	22
29%	5	6	7	9	14	21
30%	5	6	7	9	14	20
31%	5	6	7	9	13	19
32%	5	5	7	8	13	19
33%	5	5	6	8	12	18
34%	4	5	6	8	12	17
35%	4	5	6	8	11	17
36%	4	5	6	7	11	16
37%	4	5	6	7	11	16
38%	4	5	5	7	10	15
39%	4	4	5	7	10	15
40%	4	4	5	6	10	14

Optimum Sample Sizes

(Assuming 100% Efficiency)

Lot Size	40,000					
Percentage of Infestation Detected	Confidence Level					
	80%	85%	90%	95%	99%	99.9%
1%	160	189	229	297	456	682
2%	80	94	114	149	228	341
3%	53	63	76	99	151	227
4%	40	47	57	74	113	169
5%	32	37	45	59	90	135
6%	27	31	38	49	75	112
7%	23	27	32	42	64	96
8%	20	23	28	36	56	83
9%	18	21	25	32	49	74
10%	16	19	22	29	44	66
11%	14	17	20	26	40	60
12%	13	15	19	24	37	55
13%	12	14	17	22	34	50
14%	11	13	16	20	31	46
15%	10	12	15	19	29	43
16%	10	11	14	18	27	40
17%	9	11	13	17	25	38
18%	9	10	12	16	24	35
19%	8	10	11	15	22	33
20%	8	9	11	14	21	32
21%	7	9	10	13	20	30
22%	7	8	10	13	19	28
23%	7	8	9	12	18	27
24%	6	7	9	11	17	26
25%	6	7	9	11	17	25
26%	6	7	8	11	16	24
27%	6	7	8	10	15	23
28%	5	6	8	10	15	22
29%	5	6	7	9	14	21
30%	5	6	7	9	14	20
31%	5	6	7	9	13	19
32%	5	5	7	8	13	19
33%	5	5	6	8	12	18
34%	4	5	6	8	12	17
35%	4	5	6	8	11	17
36%	4	5	6	7	11	16
37%	4	5	6	7	11	16
38%	4	5	5	7	10	15
39%	4	4	5	7	10	15
40%	4	4	5	6	10	14

Optimum Sample Sizes

(Assuming 100% Efficiency)

Lot Size	50,000					
Percentage of Infestation Detected	Confidence Level					
	80%	85%	90%	95%	99%	99.9%
1%	160	189	229	298	457	683
2%	80	94	114	149	228	341
3%	53	63	76	99	151	227
4%	40	47	57	74	113	169
5%	32	37	45	59	90	135
6%	27	31	38	49	75	112
7%	23	27	32	42	64	96
8%	20	23	28	36	56	83
9%	18	21	25	32	49	74
10%	16	19	22	29	44	66
11%	14	17	20	26	40	60
12%	13	15	19	24	37	55
13%	12	14	17	22	34	50
14%	11	13	16	20	31	46
15%	10	12	15	19	29	43
16%	10	11	14	18	27	40
17%	9	11	13	17	25	38
18%	9	10	12	16	24	35
19%	8	10	11	15	22	33
20%	8	9	11	14	21	32
21%	7	9	10	13	20	30
22%	7	8	10	13	19	28
23%	7	8	9	12	18	27
24%	6	7	9	11	17	26
25%	6	7	9	11	17	25
26%	6	7	8	11	16	24
27%	6	7	8	10	15	23
28%	5	6	8	10	15	22
29%	5	6	7	9	14	21
30%	5	6	7	9	14	20
31%	5	6	7	9	13	19
32%	5	5	7	8	13	19
33%	5	5	6	8	12	18
34%	4	5	6	8	12	17
35%	4	5	6	8	11	17
36%	4	5	6	7	11	16
37%	4	5	6	7	11	16
38%	4	5	5	7	10	15
39%	4	4	5	7	10	15
40%	4	4	5	6	10	14

Optimum Sample Sizes

(Assuming 100% Efficiency)

Lot Size	60,000					
Percentage of Infestation Detected	Confidence Level					
	80%	85%	90%	95%	99%	99.9%
1%	160	189	229	298	457	684
2%	80	94	114	149	228	341
3%	53	63	76	99	152	227
4%	40	47	57	74	113	169
5%	32	37	45	59	90	135
6%	27	31	38	49	75	112
7%	23	27	32	42	64	96
8%	20	23	28	36	56	83
9%	18	21	25	32	49	74
10%	16	19	22	29	44	66
11%	14	17	20	26	40	60
12%	13	15	19	24	37	55
13%	12	14	17	22	34	50
14%	11	13	16	20	31	46
15%	10	12	15	19	29	43
16%	10	11	14	18	27	40
17%	9	11	13	17	25	38
18%	9	10	12	16	24	35
19%	8	10	11	15	22	33
20%	8	9	11	14	21	32
21%	7	9	10	13	20	30
22%	7	8	10	13	19	28
23%	7	8	9	12	18	27
24%	6	7	9	11	17	26
25%	6	7	9	11	17	25
26%	6	7	8	11	16	24
27%	6	7	8	10	15	23
28%	5	6	8	10	15	22
29%	5	6	7	9	14	21
30%	5	6	7	9	14	20
31%	5	6	7	9	13	19
32%	5	5	7	8	13	19
33%	5	5	6	8	12	18
34%	4	5	6	8	12	17
35%	4	5	6	8	11	17
36%	4	5	6	7	11	16
37%	4	5	6	7	11	16
38%	4	5	5	7	10	15
39%	4	4	5	7	10	15
40%	4	4	5	6	10	14

Optimum Sample Sizes

(Assuming 100% Efficiency)

Lot Size	70,000					
Percentage of Infestation Detected	Confidence Level					
	80%	85%	90%	95%	99%	99.9%
1%	160	189	229	298	457	684
2%	80	94	114	149	228	342
3%	53	63	76	99	152	227
4%	40	47	57	74	113	170
5%	32	37	45	59	90	135
6%	27	31	38	49	75	112
7%	23	27	32	42	64	96
8%	20	23	28	36	56	83
9%	18	21	25	32	49	74
10%	16	19	22	29	44	66
11%	14	17	20	26	40	60
12%	13	15	19	24	37	55
13%	12	14	17	22	34	50
14%	11	13	16	20	31	46
15%	10	12	15	19	29	43
16%	10	11	14	18	27	40
17%	9	11	13	17	25	38
18%	9	10	12	16	24	35
19%	8	10	11	15	22	33
20%	8	9	11	14	21	32
21%	7	9	10	13	20	30
22%	7	8	10	13	19	28
23%	7	8	9	12	18	27
24%	6	7	9	11	17	26
25%	6	7	9	11	17	25
26%	6	7	8	11	16	24
27%	6	7	8	10	15	23
28%	5	6	8	10	15	22
29%	5	6	7	9	14	21
30%	5	6	7	9	14	20
31%	5	6	7	9	13	19
32%	5	5	7	8	13	19
33%	5	5	6	8	12	18
34%	4	5	6	8	12	17
35%	4	5	6	8	11	17
36%	4	5	6	7	11	16
37%	4	5	6	7	11	16
38%	4	5	5	7	10	15
39%	4	4	5	7	10	15
40%	4	4	5	6	10	14

Optimum Sample Sizes

(Assuming 100% Efficiency)

Lot Size	80,000					
Percentage of Infestation Detected	Confidence Level					
	80%	85%	90%	95%	99%	99.9%
1%	160	189	229	298	457	685
2%	80	94	114	149	228	342
3%	53	63	76	99	152	227
4%	40	47	57	74	113	170
5%	32	37	45	59	90	135
6%	27	31	38	49	75	112
7%	23	27	32	42	64	96
8%	20	23	28	36	56	83
9%	18	21	25	32	49	74
10%	16	19	22	29	44	66
11%	14	17	20	26	40	60
12%	13	15	19	24	37	55
13%	12	14	17	22	34	50
14%	11	13	16	20	31	46
15%	10	12	15	19	29	43
16%	10	11	14	18	27	40
17%	9	11	13	17	25	38
18%	9	10	12	16	24	35
19%	8	10	11	15	22	33
20%	8	9	11	14	21	32
21%	7	9	10	13	20	30
22%	7	8	10	13	19	28
23%	7	8	9	12	18	27
24%	6	7	9	11	17	26
25%	6	7	9	11	17	25
26%	6	7	8	11	16	24
27%	6	7	8	10	15	23
28%	5	6	8	10	15	22
29%	5	6	7	9	14	21
30%	5	6	7	9	14	20
31%	5	6	7	9	13	19
32%	5	5	7	8	13	19
33%	5	5	6	8	12	18
34%	4	5	6	8	12	17
35%	4	5	6	8	11	17
36%	4	5	6	7	11	16
37%	4	5	6	7	11	16
38%	4	5	5	7	10	15
39%	4	4	5	7	10	15
40%	4	4	5	6	10	14

Optimum Sample Sizes

(Assuming 100% Efficiency)

Lot Size	90,000					
Percentage of Infestation Detected	Confidence Level					
	80%	85%	90%	95%	99%	99.9%
1%	160	189	229	298	458	685
2%	80	94	114	149	228	342
3%	53	63	76	99	152	227
4%	40	47	57	74	113	170
5%	32	37	45	59	90	135
6%	27	31	38	49	75	112
7%	23	27	32	42	64	96
8%	20	23	28	36	56	83
9%	18	21	25	32	49	74
10%	16	19	22	29	44	66
11%	14	17	20	26	40	60
12%	13	15	19	24	37	55
13%	12	14	17	22	34	50
14%	11	13	16	20	31	46
15%	10	12	15	19	29	43
16%	10	11	14	18	27	40
17%	9	11	13	17	25	38
18%	9	10	12	16	24	35
19%	8	10	11	15	22	33
20%	8	9	11	14	21	32
21%	7	9	10	13	20	30
22%	7	8	10	13	19	28
23%	7	8	9	12	18	27
24%	6	7	9	11	17	26
25%	6	7	9	11	17	25
26%	6	7	8	11	16	24
27%	6	7	8	10	15	23
28%	5	6	8	10	15	22
29%	5	6	7	9	14	21
30%	5	6	7	9	14	20
31%	5	6	7	9	13	19
32%	5	5	7	8	13	19
33%	5	5	6	8	12	18
34%	4	5	6	8	12	17
35%	4	5	6	8	11	17
36%	4	5	6	7	11	16
37%	4	5	6	7	11	16
38%	4	5	5	7	10	15
39%	4	4	5	7	10	15
40%	4	4	5	6	10	14

Optimum Sample Sizes

(Assuming 100% Efficiency)

Lot Size	100,000					
Percentage of Infestation Detected	Confidence Level					
	80%	85%	90%	95%	99%	99.9%
1%	161	189	229	298	458	685
2%	80	94	114	149	228	342
3%	53	63	76	99	152	227
4%	40	47	57	74	113	170
5%	32	37	45	59	90	135
6%	27	31	38	49	75	112
7%	23	27	32	42	64	96
8%	20	23	28	36	56	83
9%	18	21	25	32	49	74
10%	16	19	22	29	44	66
11%	14	17	20	26	40	60
12%	13	15	19	24	37	55
13%	12	14	17	22	34	50
14%	11	13	16	20	31	46
15%	10	12	15	19	29	43
16%	10	11	14	18	27	40
17%	9	11	13	17	25	38
18%	9	10	12	16	24	35
19%	8	10	11	15	22	33
20%	8	9	11	14	21	32
21%	7	9	10	13	20	30
22%	7	8	10	13	19	28
23%	7	8	9	12	18	27
24%	6	7	9	11	17	26
25%	6	7	9	11	17	25
26%	6	7	8	11	16	24
27%	6	7	8	10	15	23
28%	5	6	8	10	15	22
29%	5	6	7	9	14	21
30%	5	6	7	9	14	20
31%	5	6	7	9	13	19
32%	5	5	7	8	13	19
33%	5	5	6	8	12	18
34%	4	5	6	8	12	17
35%	4	5	6	8	11	17
36%	4	5	6	7	11	16
37%	4	5	6	7	11	16
38%	4	5	5	7	10	15
39%	4	4	5	7	10	15
40%	4	4	5	6	10	14

Optimum Sample Sizes

(Assuming 100% Efficiency)

Lot Size	200,000					
Percentage of Infestation Detected	Confidence Level					
	80%	85%	90%	95%	99%	99.9%
1%	161	189	229	298	458	687
2%	80	94	114	149	228	342
3%	53	63	76	99	152	227
4%	40	47	57	74	113	170
5%	32	37	45	59	90	135
6%	27	31	38	49	75	112
7%	23	27	32	42	64	96
8%	20	23	28	36	56	83
9%	18	21	25	32	49	74
10%	16	19	22	29	44	66
11%	14	17	20	26	40	60
12%	13	15	19	24	37	55
13%	12	14	17	22	34	50
14%	11	13	16	20	31	46
15%	10	12	15	19	29	43
16%	10	11	14	18	27	40
17%	9	11	13	17	25	38
18%	9	10	12	16	24	35
19%	8	10	11	15	22	33
20%	8	9	11	14	21	32
21%	7	9	10	13	20	30
22%	7	8	10	13	19	28
23%	7	8	9	12	18	27
24%	6	7	9	11	17	26
25%	6	7	9	11	17	25
26%	6	7	8	11	16	24
27%	6	7	8	10	15	23
28%	5	6	8	10	15	22
29%	5	6	7	9	14	21
30%	5	6	7	9	14	20
31%	5	6	7	9	13	19
32%	5	5	7	8	13	19
33%	5	5	6	8	12	18
34%	4	5	6	8	12	17
35%	4	5	6	8	11	17
36%	4	5	6	7	11	16
37%	4	5	6	7	11	16
38%	4	5	5	7	10	15
39%	4	4	5	7	10	15
40%	4	4	5	6	10	14

10.3. Appendix 3. Practical exercise

Practical exercise: comparison of results when conducting inspection using percentage-based versus Risk-Based Sampling

Inspections traditionally conducted at ports of entry are based on sampling a percentage of the consignment (usually 2%). Traditional inspections usually stop when the inspector finds a pest, independent of whether the entire sample was inspected or not.

For Risk-Based Sampling (RBS) it is necessary to calculate the sample size based on the consignment size taking into consideration a maximum acceptable infestation level or percent infestation to be detected in a consignment (for example, 10 %). In this type of sampling, the level of confidence and the probability that a consignment with a degree of infestation higher than the detection level will be detected are also defined. A 95% confidence level indicates that sampling will detect a non-compliant consignment an average of 95 out of 100 times.

The objective of this exercise is to demonstrate how percentage-based sampling and Risk-Based Sampling (RBS) differ with respect to efficacy and consistency of results. Below we list the required materials and instructions on how to conduct the exercise.

10.3.1. Materials and their organization

a) Five fabric or plastic bags with string or zip-lock closure that will represent consignments or lots of different sizes. Label the bags as shown below.

b) Beans. Dark and light-colored beans of similar size and shape are needed. Light-colored beans will represent non-infested samples in the consignment or lot. Dark-colored beans will represent infested samples in the consignment or lot.

Each bag should contain the following number of beans according to the consignment size, **representing a 10% infestation in each bag**:

Bag labeled	light-colored beans	dark-colored beans	Total # of beans in each bag
Consignment size = 100	90	10	100
Consignment size = 500	450	50	500
Consignment size = 1,000	900	100	1,000
Consignment size = 2,000	1,800	200	2,000
Consignment size = 5,000	4,500	500	5,000
Total beans needed	**7,740**	**860**	**8,600**

10.3.2. Conducting the exercise

a) Percentage-based sampling (2%)

i. Sample size calculation: Calculate a sample size of 2% for each consignment:

Consignment or lot size	2% sample = # of beans to sample from each bag
100	2
500	10
1,000	20
2,000	40
5,000	100

ii. Sampling procedure

- Work with one consignment size at a time.
- To take a sample, remove a single bean out of the bag.
- Do not return the beans to the bag until you finish your sample.

- If you find a dark-colored bean (= an infestation) before completing your 2% sample (see table above), record the number of beans you removed before finding the infestation in the results table below. Return all the beans to the bag and shake the bag before resampling.
- If you complete your 2% sample without finding an infestation, record your result as "no detection." Return all the beans to the bag and shake the bag before resampling.
- Repeat the process 3 different times for each consignment size.

iii. Calculating the results

- For each consignment size, calculate the mean number of beans you sampled before detecting the infestation. See example below for a consignment size of 5,000:

  Assay 1 = 23 samples (beans) taken before finding a dark bean
  Assay 2 = 28 samples (beans) taken "…"
  Assay 3 = 27 samples (beans) taken "…"

  Calculate the mean: 23+28+27 = 78/3 = 26

- Now, calculate the mean percentage sampled:

$$\frac{26}{5{,}000} = 0.0052$$

$$(0.0052 * 100) = \mathbf{0.52}\%$$

- In this example, 0.52% was the true percentage sampled to find the infestation in the consignment.

- If the result of one or more of your assays was "no detection" for a determined consignment size, then record "no detection" for that sample size.

iv. Recording and presenting the data

Use the table below to record your sampling data, including the mean and the true percentage sampled. See example below for a consignment size of 5,000.

Consignment size	2% sample rate	Number of samples taken before finding the infestation			Results	
		Assay 1	Assay 2	Assay 3	Mean	True percentage sampled
100	2					
500	10					
1,000	20					
2,000	40					
5,000	100	23	28	27	26	0.52%

b) Risk-Based Sampling - RBS

Calculate the sample size: use the hypergeometric tables (see Chapter 10, Appendix 2) or the sample size calculator found here https://nappo.org/english/learning-tools/Resources-and-Learning-Tools-for-Risk-Based-Sampling/Sample-Size-Calculator to calculate the sample size. Use a 10% detection level and a 95% confidence level. These parameters result in the following sample sizes per consignment:

Consignment or lot size	Sample size
100	25
500	28
1,000	29
2,000	29
5,000	29

i. Sampling procedure

- As before, for each consignment and without looking inside the bag, remove one bean at a time until you find an infestation or until completing the sample size indicated in the table.
- When you find a dark bean, count the number of beans sampled before finding the infestation and record the data in the table and continue sampling until you reach the calculated sample size.
- Return all beans to their bag and mix them up before repeating the assay.
- Repeat the sampling process for each consignment three times.

ii. Calculating the results

- As above, calculate the mean samples taken from each consignment.
- Then, divide the mean by the total number of beans in the consignment.

- Multiply that number by 100 to determine the percentage of beans sampled before finding the infestation.
- If the result is "no detection" in any of the assays for a specific consignment size, then record "no detection" for that consignment size.

iii. Recording and presenting the data

As above, record your results in the table below.

Consignment	Sample size	Number of samples before finding the infestation			Results	
		Assay 1	Assay 2	Assay 3	Average	Percentage
100	25					
500	28	23	28	27	26	5.2%
1,000	29					
2,000	29					
5,000	29					

c) Consolidation and comparison of results

Place tables side by side to allow easy comparison of the data. Review and compare the results obtained, and record the most relevant observations with regard to each of the sampling methods:

Percentage-based sampling:

- ____
  ____
- ____
  ____
- ____
  ____

Risk-Based Sampling:

- ____
  ____
- ____
  ____
- ____
  ____

d) Document the exercise by taking some photographs

To share the results with other groups we suggest that you consider taking photographs of the following parts of the exercise:

- ✓ Preparation of consignments
- ✓ Conduct of both exercises
- ✓ Fully completed table of percentage-based sampling (2%) results
- ✓ Fully completed table of RBS results.

10.3.3. Points to consider

When we compare the results from the 2% sampling with those from Risk-Based Sampling we see that with RBS we detect the infestation in most of consignments, which is not the case with percentage-based sampling. The latter is less effective at detecting infestation, especially for smaller consignments.

Percentage-based sampling results in less likelihood of detecting low infestation rates in small consignments, and for large consignments percentage-based sampling results in oversampling (= more time and resources). Furthermore, detection levels per consignment are not consistent for different lot sizes. Inconsistent detection levels mean that percentage-based sampling is not a technically justified measure as a risk management tool.

With Risk-Based Sampling we can detect infestations at a defined detection level regardless of the consignment size, which is technically justified. Risk-Based Sampling uses smaller sample sizes for larger lots allowing resources to be used in a more efficient manner.

In RBS, even after finding an infested sample, the process continues until the entire sample is examined. This provides information on how many different pests may be present and their level of infestation.