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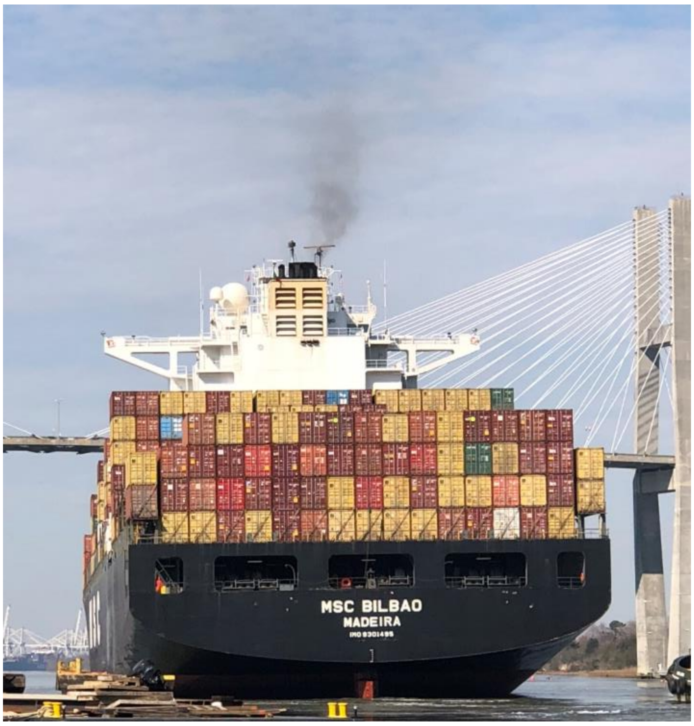

NAPPO
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Organización Norteamericana de Protección a las Plantas
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Griffin - Introduction to the International Symposium for Risk-Based Sampling

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Every day, the fate of hundreds of consignments in ports around the world is decided based on inspection. Whether for the clearance of imports or the certification of exports, inspection is the most commonly used phytosanitary measure in the world. It has been a central strategy for detecting pests and determining compliance with phytosanitary requirements for over a century. The use of inspection for border clearance is also a primary activity for checking compliance with non-phytosanitary import and export requirements. In a more contemporary context, inspection is also a phytosanitary measure, which requires a deeper understanding of its conceptual foundation and application in the context of the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement).

The International Plant Protection Convention (IPPC) is identified in the SPS Agreement as the global standard-setting organization for phytosanitary measures. The IPPC 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 standards (ISPMs 23 and 31) recognize that different inspection designs and methods will produce different outcomes which can substantially affect trade and trade policy. Proper implementation of the 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.

Australia, New Zealand, and the United States have started shifting their inspection procedures toward statistically-based designs that are consistent with the principles of the SPS Agreement and the guidance provided by ISPMs 23 and 31. Other countries have similar plans or are considering strategies that move in the same direction. Sharing views and experiences contributes to a better understanding of the conceptual foundation, the operational and regulatory challenges, and responses to inspector and stakeholder perceptions.

The International Symposium for Risk-Based Sampling (RBS) was conceived as a forum for sharing knowledge, expertise, needs, and experience. It was designed to encourage collaboration, advance harmonization, and facilitate implementation. The ultimate objective of the Symposium was to support the evolution of the phytosanitary community toward more efficient and effective inspection programs that are consistent with the international regulatory framework.

Historical perspective

A general awareness of the need for plant quarantine emerged in the late 1800s and early 1900s. Prior to this time, it was widely believed that the introduction of plants and animals into new environments was vital to promoting prosperity. The issue came to a head in the United States in 1910 when hundreds of large flowering cherry trees were given to the US government as a diplomatic gift from Japan. The trees were inspected by the United States Department of Agriculture (USDA) scientists and found to be badly infested with harmful pests. After being convinced by USDA scientists, then President Taft authorized the trees to be burned on the Capitol Mall in Washington DC. The incident proved to be a diplomatic embarrassment for both countries and a turning point for US policy. A subsequent shipment of trees from Japan was inspected by USDA and found clean enough for planting around the Tidal Basin in Washington DC. The cherry trees thrived and have been a national landmark for over a century, but the incident marked a tipping point that resulted in the US joining other major trading countries in developing legislation establishing national authority for border inspections to control the entry of plants, plant products and other articles that could result in the introduction of harmful pests.

Establishing legal authority was prerequisite to creating the institutions, developing the workforce, and crafting the procedures for plant quarantine enforcement. Chief among these was the establishment of inspection regimes at the border, recognized since Biblical times as the control point for quarantine. The border mantra of "subject to inspection" made it universally understood that authorities could exercise border procedures which had the potential to change the entry status of a consignment. The fact that this authority existed and could result in obstacles to trade became partial motivation for shippers to be aware of plant quarantine requirements and to be careful about pest contamination. This "deterrent effect" has always been one of the most significant effects of inspection – whether or not inspection is actually performed, or any pests are detected in the process.

Originally, the presence of any pest associated with the cross-border movement of consignments was probable cause for rejection, treatment, or destruction of the consignment. Over time, it was recognized that taking such actions for pests present in both the exporting and the importing countries was unfair and the focus then shifted to quarantine pests. A common understanding of the concept emerged when the IPPC came into force in 1952 and developed definitions for "quarantine pest" and the certification process. Thus, the first significant shift in the concept of inspection was to focus on the presence of quarantine pests as the justification for actions. This represented the earliest stages of international harmonization and the beginning of an enduring love affair with terminology in the IPPC.

In the period between when the IPPC came into force in 1952 and the SPS Agreement came into force in 1994, the primary driver for inspection was the detection of quarantine pests. Inspection procedures varied widely, but the detection of a quarantine pest under any inspection regime was generally considered to be sufficient justification for taking regulatory action irrespective of the inspection design used. The prevailing logic was to provide protection through pest exclusion using border inspection as the primary tool for ensuring compliance. This became the central strategy for phytosanitary border control by every National Plant Protection Organization (NPPO) in the world and continues today.

The SPS Agreement substantially shifted the regulatory landscape with an emphasis on managed risk and the technical justification for phytosanitary measures. As the most common and widely applied phytosanitary measure, inspection is easily identified as a key area for rethinking in the context of SPS principles and obligations. Specifically, the SPS Agreement anticipates that inspection will be consistently applied for similar situations, based on risk, and implemented according to relevant international standards. This background argues for harmonization around the criteria for using inspection, as well as harmonization of its design and application in practice. ISPMs 23 and 31 provide the starting point for this shift. This Symposium aims to facilitate the process.

Fundamental concepts

The significance of several basic characteristics of inspection must be recognized and understood at the outset[1]:

[1] Inspection may have many different objectives including the detection of regulated articles (e.g., prohibited fruit), non-compliance with requirements (e.g., fruit not treated), or the presence of regulated pests. The discussion here refers to pests, recognizing that many aspects also extend to other inspection objectives.

1. The more you look, the more you find. This seemingly obvious point reminds us that our ability to detect pests is partly a function of effort. It also tells us that actions we take in trade based on inspection will vary based on inspection frequency and intensity. Thus, the inspection design and especially the intensity of inspection is a key variable affecting the rate of detection and therefore the rate of regulatory actions against consignments.

2. All pests are not equally detectable. Larger, mobile pests are more easily detected than tiny sedentary pests, and some pests (such as pathogens) may not be detectable without laboratory testing. Inspection should not be the primary phytosanitary measure for pests that are high risk and/or are difficult to detect.

3. All pests are not equally risky. Risk is related to the ability of the pest to establish via the pathway in question and the impact of its establishment. Some pests and pathways are higher risk than others. The interception of a pest in a pathway is evidence of the pest-pathway association but not of the true pest risk. For instance, irradiated commodities may well have live pests but the inability of irradiated pests to reproduce eliminates any risk of establishment and therefore the need for any further risk mitigation based on detection.

4. Inspection is usually not 100%. A portion of a consignment is generally inspected, which means there is always some probability that pests are present but are undetected. The level of infestation or contamination therefore has a relationship with the probability of detection, which is represented by a detection threshold.

5. Inspection is not 100% effective. There is always some probability that the pests present in the portion of the consignment that was inspected were not detected. This concept is represented by the efficiency (or sensitivity) of inspection, which varies with every situation depending on the pests, commodities, inspector, location, and conditions. Inspection efficiency is therefore highly variable. Based on the few available studies, efficiency can range from around 20% up to 80% but is very unlikely to ever achieve 100%.

Leakage and statistics

The last two points above tell us that inspection leaks -- that is, it misses pests. It always leaks. This is a fundamental point from which to begin the discussion about RBS. The pests we are able to stop with inspection are not a problem. The pests that we do not find are the risk. In order to manage the risk and properly implement inspection as a phytosanitary measure we need to measure and manage the leakage.

Inspection as it is traditionally practiced is a form of discovery sampling, which means that there is a threshold for pest detection based on the probability of discovery in a particular sample. The more pests that are present in shipments and the more frequently they enter, the greater the probability of leakage. Thus, the level and frequency of infestation or contamination found associated with a consignment, a commodity, a supplier, or a country is also an indicator of the level of risk. Our ability to adjust inspection to detect different levels of pest infestation is the key to understanding its value as a risk management tool – measuring and controlling leakage.

Each inspection scenario has a consignment size and sample size which can be used to calculate the level of pest infestation that can be detected with some level of confidence and efficiency. Similar calculations can be used to determine how the sample size can be adjusted to detect a specified level of infestation or contamination in a certain size consignment. These simple statistical methods help us to better understand the effectiveness of inspection and how to best use it for risk management. They also offer us the opportunity to create inspection design which provide consistent data to demonstrate the effectiveness of inspection programs, perform trend analysis, and adjust inspection efforts to better target risks. Targeting is crucial for maximizing the effectiveness of resources. It can also serve as an incentive for safer trade because it reduces the inspection of low-risk trade, thereby rewarding suppliers of cleaner product.

Most traditional inspections are based on sampling a percentage of the consignment (e.g., 2%). Because of the statistical relationship of the probability of detection to sample size and consignment size, the level of detection will vary as the size of the consignment changes. Since we generally have no control over consignment size, we can expect to have different detection levels for different size consignments when the sampling is done at a flat rate. This results in inconsistent levels of risk management. To achieve a consistent level of detection, we must adjust the sampling rate based on consignment size. A sampling calculator or table simplifies the process of determining the appropriate sample size to consistently detect the same level of infestation from different consignment sizes. Once we are able to consistently detect the same level of infestation, we can legitimately compare shipments and calculate true approach rates for pests and action rates for pathways, entities, and countries of origin.

Traditional inspections also frequently stop when a pest is found, whether or not the entire sample has been inspected. The rationale for this is that pest presence represents non-compliance, which usually changes the status of the consignment. As noted above, inspection is not absolute. The detection of one pest does not mean it is the only pest present, and the 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.

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 analysis 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 analysis as well as for resource allocation.

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 RBS 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 shipment where they feel more confident about detecting a pest, is counterintuitive and may be demoralizing to inspectors accustomed to demonstrating competence by their selection of appropriate samples.

There are two main problems with the intuitive or haphazard sampling that has dominated traditional inspection. The first is that it lacks statistical validity. This makes the results much less valuable. 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, 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 (leakage) but ensuring that inspection results have statistical validity is key to using the results for better targeting. Discovering new pests and unanticipated infestation patterns is likewise important for targeting.

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 shipment size;
- The samples are randomly selected;
- The full sample is inspected, and all results recorded.

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

Inspection reset

In an era when both the volume and frequency of trade is greatly outpacing the resources devoted to inspection, there is a practical need to prioritize resources by redistributing the inspection effort devoted to low risk trade to focus on higher risk trade. The focus may be on business entities such as producers, exporters, shippers, brokers, or importers. It may also be on commodity groups such as cut flowers or specific types of commodities such as cut roses. It could be on countries of origin or on specific ports of entry. Regardless of the focus, the shift from one-size-fits-all inspection to targeted designs 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 that has not been available or used in the same way previously.

One starting point for the shift to RBS is to analyze existing inspection processes in order to calculate the level of detection that is currently achieved and to identify existing 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 latter approach is especially useful to understand the resource commitment 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 for risk and then adjusting the design to redistribute the inspection effort for better management of the higher risk pests and 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 (entry and establishment). This goes back to our early observation that all pests are not equally risky by introducing the biological and economic aspects of pest interceptions that inform risk beyond simply the presence or absence of a pest in the pathway.

Combining statistically-designed inspection results with 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. 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. Leakage can be estimated because the effectiveness of inspection can be measured and adjusted according to risk and balanced with the availability of resources.

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. The Symposium was designed as a forum to encourage sharing inspection expertise and experience; promoting collaboration with each other, stakeholders, trade and other agencies; working toward a better understanding of the foundational concepts; and harmonizing around shared objectives that advance the practice of inspection by the phytosanitary community.

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Ransom - Australia's Experience with Risk-Based Sampling

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Summary

Australia is continuing to evolve its biosecurity system - applying principles of evidence-led, risk-based intervention to efficiently manage sanitary and phytosanitary risks at or before the border. Integral to this is the concept of 'risk return'. In simple terms, it is "doing what matters most" to detect and manage biosecurity risks and reduce the risk of a pest incursion.

Australia adopted the 600-unit sample inspection rate on 1 January 1999 as a practical and consistent way of defining an acceptable level of risk in imported consignments. This rate provides a 95% confidence of a 0.5% infection or infestation level of pests being detected in consignments of more than 1,000 units. A sampling rate of 450 units is applied to consignments of less than 1,000 units. Inspectors are assisted by guidance in work instructions.

We are adopting new approaches to verification that provide confidence that Australia's import conditions and appropriate level of protection have been met, including working closely with importers and exporting National Plant Protection Organizations (NPPOs) to recognize activities in the production and trading system that contribute to managing phytosanitary risks. Novel systems, like the Compliance-Based Inspection system (CBIS) use inspection data to reward compliant import pathways, reduce regulatory burden and provide greater assurance that phytosanitary risks are managed to achieve Australia's appropriate level of protection.

Introduction

We live with risk. It is part of the human condition to identify, assess, accept or manage risk in our daily lives – should I cross the road? Is this action good for my well-being? Should I buy this or save for that? We are weighing the impacts of risks all the time in making everyday decisions.

In the phytosanitary world, we apply the concepts of risk management on specific pest risks to an acceptable level. Relevant phytosanitary principles and concepts are codified in international agreements, including the SPS Agreement and the IPPC. Risk management is also addressed in the ISPMs of the IPPC.

The reality for phytosanitary regulators everywhere is that resource constraints prevent NPPOs from doing everything. Like many NPPOs, the Australian Department of Agriculture and Water Resources (DAWR) or the department) doesn't have the inspectors to check 100% of all goods, passengers, mail, courier parcels and containers arriving on our shores for injurious plant pests, which is why we view phytosanitary risk management as a shared responsibility. The costs of such activity and their impact to delay clearance of goods, travellers and mail would be publicly unacceptable. We must get smarter about identifying and targeting the risks that are most important – by examining the likelihood of occurrence and the severity of their impact and resulting consequences. Our phytosanitary interventions should be outcomes-driven and, where possible, risk should be managed off-shore. At the very least, goods presented at the Australia's border should meet the required import conditions.

This reality requires a new view of phytosanitary risks and their management. It will also drive change and enable the department to focus on higher risk pathways.

Arguably, the highest risk plant pathways are those that present a direct pathway to the establishment of quarantine pests. This includes seed, nursery stock and carriers of risk materials such as soil and used farming equipment. Indirect pathways to establishment present a lower risk and include: processed products; goods for human consumption, including fresh produce and nuts etc.; diversion from intended use; manufactured products such as furniture and raw products for further processing. Conveyances (including passengers, mail, containers, ships, airplanes and unregulated cargo) represent a different but no less important pathway to the establishment of organisms such as invasive ants, weeds, spiders, soil-borne pests and mosquitoes.

Taken together, there are numerous pathways for the international movement of plant pests. Logistically we need to apply a 'risk return' discipline to focus border intervention on the things that matter most or give us the greatest return on investment.

A universal intervention by NPPOs is phytosanitary inspection. Inspection is used to verify that import conditions have been met sufficiently to reduce the risk of entry of quarantine pests.

Inspection:

- Provides evidence that a consignment has met the required import conditions;
- Provides confidence in the phytosanitary certification provided by the exporting country;
- Confirms the presence of pests that are expected on the goods as assessed in the risk analysis;
- Detects any unexpected or new pests in a pathway that may have resulted from a change in pest status in the country of origin;
- Provides information and data to trigger and inform reviews of import conditions and pathways, to ensure measures are set appropriately to manage risk.

Inspection does not, of itself, change the phytosanitary status of the goods and only works as a verification tool if you can see the pest or the damage it causes.

Risk-based sampling

Since 1 January 1999, Australia has applied a 95% confidence level on imports to detect a 0.5% infection or infestation of pests in a homogeneous lot using:

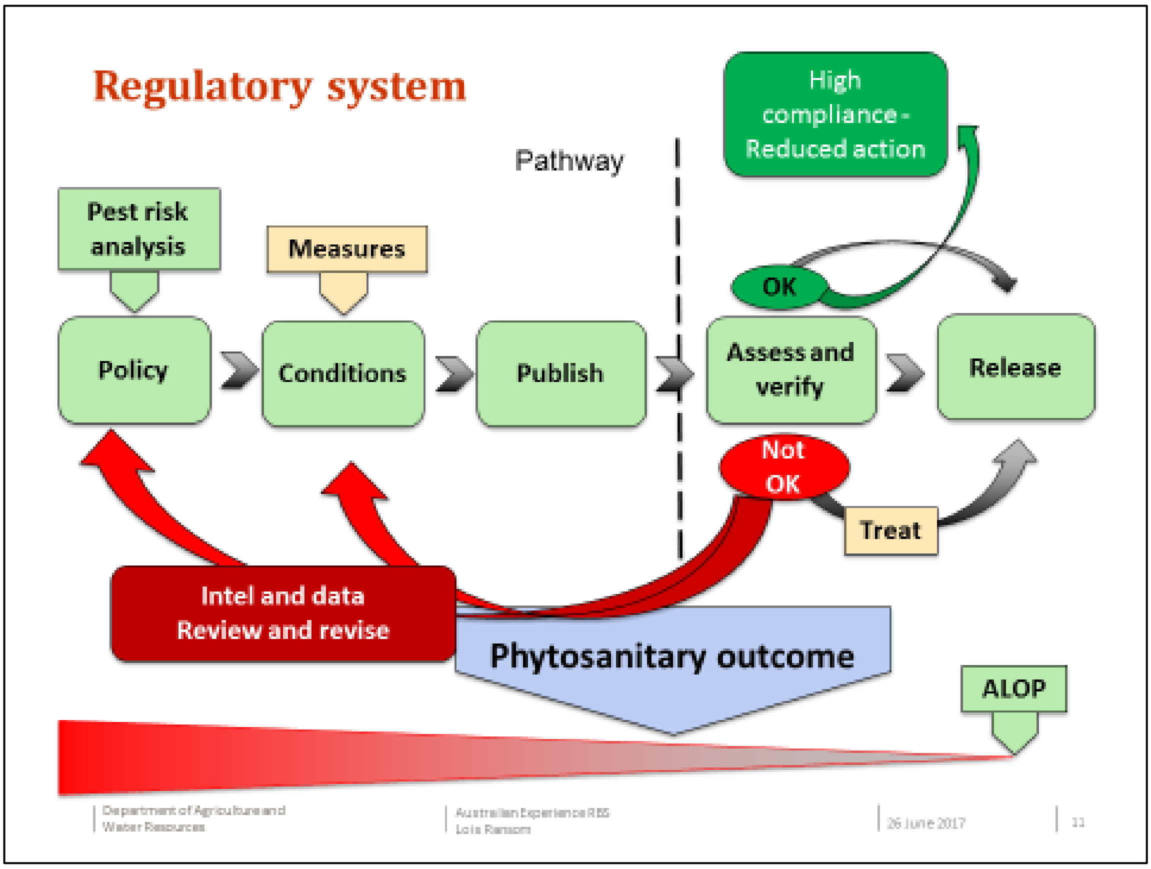
- A 600-unit sample size for inspection as a standard for consignments with more than 1,000 units
- A 450-unit sample size for consignments with less than 1,000 units or
- Alternative equivalent rates if continuous sampling occurs due to the nature of the product, such as grains.

This approach is statistically based and is recognised under ISPM 31 – Methodologies for sampling of consignments. Sampling for verification of export consignments is set by the importing country and may be a percentage (2%) or a defined sample size (600-unit). Applying this approach in practice is not without challenges. Defining the unit is critical, applying this consistently across goods and a changing inspectorate workforce requires standardized work instructions and effective training. How do you compare cherries and melons when defining a unit? Homogeneity of the consignment is also important. How does an inspector assess this? The information accompanying the consignment can provide clues – a single lot from a single source can be assumed to be more homogenous than a consignment made up of different lots from different sources. Do you inspect all 600 units or stop at the unit when an actionable pest is detected? This depends on the data you want to collect. The full 600 sample will provide the greatest confidence in the pest status of the lot, and provides both information on the degree of infestation, as well as on the nature of the pests present, if they are fully identified. This can provide confirmation of the organisms we expect to see on the pathway and also help to detect pests we had not expected and can be used to alert early changes in phytosanitary risk.

Australia's regulatory system for phytosanitary risk management is summarised in Figure 1. A pest risk analysis establishes risk management policy, which is applied as published import conditions. Goods are assessed on arrival in Australia and their phytosanitary status is verified. If they meet the import conditions the goods are released. If they do not and the phytosanitary risks need to be managed to achieve Australia's appropriate level of protection or ALOP, then the goods may be directed for an appropriate treatment, which can cause significant delays. Otherwise the goods may be directed for export or destruction. Australia's ALOP is defined in our operating legislation, the *Biosecurity Act 2015*, as being 'very low but not zero'.

Where goods are consistently compliant, consideration can be given to reducing border intervention. Where they are not, collected data may be used to trigger and inform a review and adjustment of the import conditions.

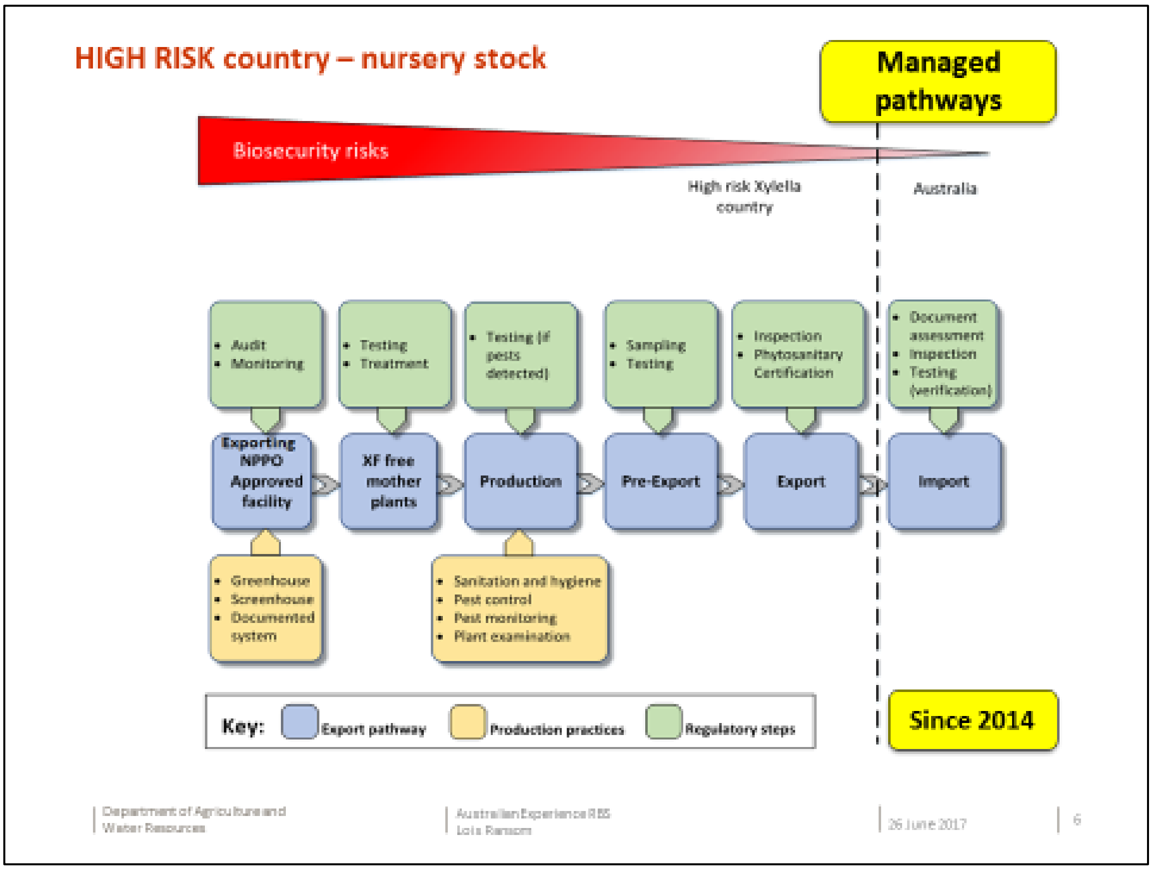
Figure 1. Australia's regulatory system for phytosanitary risk management.



Managed pathways

We can achieve greater confidence in the compliance of consignments if we know more about their likely phytosanitary status. This can come from intelligence gained through inspection of many consignments from the same source but can also be achieved by understanding and considering the production and export system of the imported goods. In Australia we have been developing an approach to better understand production and export systems. We consider the export pathway and production practices, including pest controls in the field, and define regulatory steps that contribute to managing risk. The diagram in Figure 2 helps us visualize these measures and determine the evidence we might need to verify that critical controls have been applied. This is effectively a Hazard Analysis Critical Control Point (HACCP) approach, similar to the approach used to manage and provide assurance for food safety.

Figure 2. Pathway for imports of *Xylella fastidiosa* nursery stock from a known infected country.



Managed pathways provide greater opportunities to optimize and reward compliance. They consider the entire production chain and export/import system and can simplify, streamline and standardize import risk analysis and the development of import conditions. Managed pathways also allow us to incorporate industry systems and processes that assist phytosanitary risk management. Critical phytosanitary controls can be integrated into other quality and regulatory systems, such as food safety or Global GAP. This can provide the importing NPPO with a greater level of confidence that phytosanitary measures have been applied and can significantly reduce pest loads. Systems that consistently achieve a high level of compliance can be rewarded through reduced intervention on import. This can reduce costs and clearance delays for the importer and allow the NPPO to allocate inspection resources to higher risk stakeholders and pathways.

Compliance-Based Inspection Scheme (CBIS)

Australia has implemented the CBIS through the application of continuous sampling plan methodology (CSP). CBIS uses historical data on selected pathways to reward consistently compliant importers through reduced inspections. This is an evidence-led and risk-based approach that allows the targeted re-allocation of inspection resources to higher risk pathways without compromising overall biosecurity outcomes.

CBIS Case study -- Green Coffee Beans

Australia imports large volumes of green coffee beans, mostly for further processing in metropolitan areas into roasted or granulated products.

Analysis indicated that over time, green coffee beans were imported into Australia from 195 suppliers in 63 countries. Only 66 of 2,827 consignments were found to be non-compliant, establishing a fail rate of 2.3%. Taking this into consideration with the intended end use, green coffee beans represent a low residual phytosanitary risk.

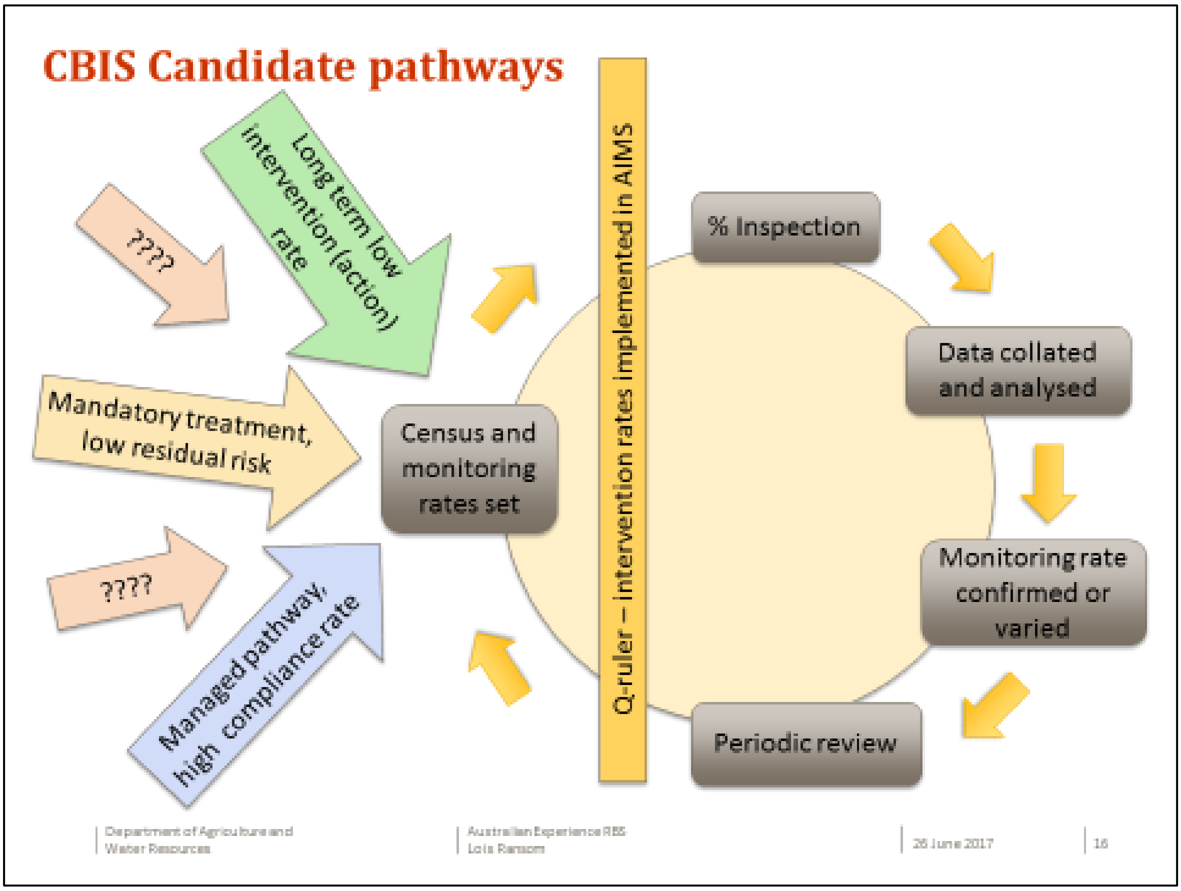
The Australian Import Management System (AIMS) can identify imported consignments of coffee beans and by applying the CSP through a counting function in the system, can direct consignments for inspection or release. A baseline number of compliant consignments to qualify for risk-based inspection was established through statistical analysis and a monitoring rate of subsequent inspections was also set. The CBIS operates on product lines against either the importer or overseas supplier. After qualifying, further imported consignments are randomly selected within AIMS for risk-based intervention. Selected consignments still receive the full inspection, but the frequency of lines being directed for inspection is reduced, provided continuous compliance is maintained. More information on the scheme and the plant products eligible can be found on the department website.

[CBIS webpage](#)

In 2017, inspections on low risk plant products reduced by 11,608, saving compliant importers more than AU$ 1.05M, and the department over 5,500 inspection hours.

Since its introduction in 2013, the majority of CBIS products have continually recorded good compliance resulting in long term low intervention rates. More recently CBIS has been expanded to include inherently higher risk plant products where the residual level of phytosanitary risk is very low, as a result of the application of a mandatory treatment or from a highly managed pathway. The mechanics of the CBIS are summarized in Figure 3.

Figure 3. The mechanics of the CBIS.



Ongoing research into CBIS, including social and economic analysis, has validated this risk-based approach but there are challenges:

- Targeting consignments must be identifiable by tariff or unique codes.

- Feedback to importers is critical to enable them to make decisions on their supply lines, i.e., source from compliant suppliers, is critical. This can be difficult where imports are brokered by an agent as reports are directed back to the importer rather than the supplier.
- There is a perception among staff and domestic production industries that this approach lets pests through the border even though goods are continually monitored.
- To reward compliance, inspection services must accurately record actionable pests. Applying sanctions on non-actionable pests penalizes importers and undermines the system.
- Quality and quantity of data can impact confidence in the risk outcome. Addressing data quality can provide benefits to the NPPO, but quality needs to be defined, staff need to be trained to collect and record quality data, and IT systems need to be able to capture and enable its analysis.

The ongoing evolution of risk-based sampling and intervention in Australia is critical to ensure that the allocation of inspection resources is targeted to the areas of greatest phytosanitary and biosecurity risk. This targeting is informed by data that informs and continues to support risk-based interventions.

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Katsar *et al*. - Risk-Based Sampling: The United States NPPO (USDA-APHIS-PPQ) Perspective

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Summary

The USDA-APHIS-PPQ (PPQ) began the implementation of Risk-Based Sampling (RBS) on shipments of propagative plant material on October 1, 2013. Implementation was staggered, with fourteen of the sixteen PPQ Plant Inspection Stations employing RBS by September 2014. The goal of the program was to develop an operationally feasible inspection system that was both statistically sound and scientifically defendable. During the pilot, RBS sampling parameters were set to detect a 5% infestation rate with 95% confidence, assuming 80% efficiency. More than three years of inspection data is now available. This data will be used to refine the sampling parameters based on field observations and predicted risk to formulate categories for ranking that can be used to adjust inspection frequency and/or intensity in the future.

Data Availability and Quality

The predicted risk of commodities from a specific country of origin are derived from data collected during the RBS import and inspection process. Processing of most imported propagative plant materials occurs immediately upon import at one of the 16 PPQ plant inspection stations (PIS) around the USA. Imported plants are determined to be admissible as is, require treatment as a condition of entry, or are prohibited entry. Prohibited plant materials are refused entry into the US and are either re-exported or destroyed. Any required condition of entry treatments must take place before releasing a commodity into US commerce.

Those country/commodity combinations that are admissible are then visually inspected to ensure that they meet all US entry requirements and that they are free from any quarantine-significant plant pests. Any plant pest intercepted during an inspection must be identified and its quarantine status determined. The shipment is released if intercepted plant pest(s) are not determined to be of quarantine significance. If a pest is quarantine significant, the shipment or commodity must undergo remedial action such as fumigation. Final shipment disposition and any associated plant pest information are assigned based on regulatory action taken as a result of inspection and thus, is also derived from the inspection process. The paperwork review and inspection processes provide additional shipment-related information, including commodity/shipment weights, units of measure, country of origin, and importer/shipper.

The import process results in a vast amount of information. However, historically data was not collected for subsequent analysis, but rather to track work accomplishments. As a result, the existing data elements needed to be carefully examined for meaning and context to be clearly understood, and then evaluated to determine if they would be useful for RBS analysis, either as is or with minor adjustments.

An attempt was made to predict any additional types of information required for RBS analysis. In doing so, seventeen new data elements were characterized. Over time, some of these data elements were found to be more useful than others. Others are still being evaluated. The process to identify current and new data elements necessary for RBS is a process that continues.

Having a data system in place that ensured high-quality and consistent data before implementing the RBS protocol would have been ideal. Starting with clean data would have been far simpler than attempting to clean it up after collection and storage. Without clean data the quality control (QC) process became labor intensive and complex. Identifying data discrepancies, determining root causes, and developing modifications to correct for data errors took a great deal of time. The QC process also involved merging disparate datasets, identifying duplicate entries, standardizing ontologies and values, and normalizing the data.

Some of the more common QC issues encountered included disposition codes, quarantine policy effects, quantity, and identification codes. Disposition codes enumerate inspection results and subsequent quarantine actions. QC routinely identified records possessing incorrect disposition codes. These types of errors can dramatically affect risk calculations.

Quarantine policies can also affect calculations. Quarantine policies define the regulatory action(s) required to mitigate the risk of a given plant pest, commodity, and/or origin. These policies sometimes leave artifacts in the data that require revision before performing data analysis. For example, artifacts often occur when multiple plant genera are commingled together in a single shipment, and an interception of a mobile pest occurs with only one genus. In this case, a quarantine action is carried out on all genera within the shipment, and the inspection record reports the quarantine action for all plant genera within the shipment. In this case, the recorded data indicate a quarantine action rather than an actual pest association or the probability of intercepting a quarantine significant pest species on a particular commodity.

The quantity of imported material is another data element that has many QC issues. Errors in quantity are often due to human error. However, sometimes errors occur as a result of ambiguous definitions or improper coding of data attributes. Another issue associated with quantity is the meaning of the actual value. Historically, inspection records included the total number of plants in a shipment, but we have only just recently started recording the actual number of plants that were subject to inspection.

Formerly, the data required to analyze RBS resided in several different databases. These databases were not developed to be aligned with one another. Unique identification codes were not always present. Consequently, it was not always possible to relate all the necessary information. A relational data structure has since been implemented and has mitigated most of these issues.

A pest action rate is defined as the number of quarantine actions performed on a commodity divided by the total number of inspections performed on that commodity. Action rates for some commodities changed by 10% or more as a result of the QC process. QC and the subsequent analysis of this data are essential to RBS as it provides the base for the implementation of non-biased sampling schemes.

Sampling & Sample Size Calculator

Implementing RBS at the PIS was a significant change. To be successful, RBS required a fundamental change in inspection operations. It also required buy-in from the inspectors, and a shift in thinking as the assumptions underlying the inspection methodology changed. Historically, PPQ inspections utilized fixed rate sampling. Inspection of the designated sample usually continued until the first detection of a quarantine-significant pest species. Fixed rate sampling ensured that the sampling rate was consistent, and the sample size was easy to calculate. However, it did not provide any information on the sample size or the ability to compare shipments as pest detection level varied with sample size. It also meant that the actual number and types of pests present in the shipment could not be determined. Action rates, approach rates, and infestation rates could not be effectively estimated and used to demonstrate program value, before RBS instituted a consistent detection level.

Additionally, population size affects the number of samples required to achieve a set level of statistical accuracy. Smaller shipments require a higher proportion of the population to be sampled to obtain the same level of accuracy. The converse is true for larger shipments. Consequently, if there is a desire to set a desired confidence level, fixed rate sampling is inconsistent. It results in undersampling smaller shipments and oversampling larger ones. In contrast, in RBS, the sample size varies, according to the desired detection level. By providing a consistent level of pest detection, inspection results are comparable across shipments of variable size.

Before RBS, sample selection was an arbitrary process that could be influenced by the inspector's knowledge and or perceptions. RBS utilizes random sampling to identify inspection samples. The RBS inspection method requires that samples always be randomly selected. Moreover, RBS is technically defendable whereas, percentage sampling is not.

For RBS, changing the desired detection level will change the sample size. Such changes are necessary because the sample size must be operationally feasible to process. Detection levels can be modified to account for operations. Modifications to sample size are also achievable by changing the frequency with which an inspection occurs. In either case, plant inspection stations need to be agile and able to quickly determine how many and which samples to inspect both quickly and efficiently. Sample-size calculators based on the risk associated with specific country/commodity combinations and propagative material type were developed to facilitate sample selection.

Statistical analysis and risk ranking

All RBS inspection data was subject to a rigorous QC process before being analyzed. Quarantine action counts and shipment numbers were summarized using predefined criteria. Plant genus, country of origin, and propagative material (PM) type are some of the criteria initially used. After the data were summarized, logistic regression was used to investigate the relationship of selected variables to action rate. Computer simulation was subsequently used to generate predicted action rates and their corresponding 95% confidence intervals. The calculated confidence interval ranges represented an index of the uncertainty for the predicted action rates. Cluster analysis was then used to categorize country/commodity combinations into low uncertainty and high uncertainty groups with 95% confidence. The high compliance group had low predicted action rates and relatively shorter confidence range.

Preselected cut-off points were then applied to categorize further "low" and "high" variance or uncertainty groups into high, medium, low, or poor compliance categories. The data was used to determine the cut-off points for each compliance group. These compliance groupings could be modified as needed to meet operational and or other program considerations. Both Bayesian generalized linear models (GLM) and generalized linear mixed effects models (GLMM) were tested to predict action rate of the country /commodity combinations. The results varied substantially depending on the modelling method employed. A comparison of pre- and post-RBS quarantine action rates demonstrated that inspectors had a grasp of the risk associated with many of the top 20 country/commodity combinations. However, the relative relationships among 20 country/commodity combinations differed considerably, with some combinations no longer appearing.

Operational challenges and enforcement framework

Many operational challenges were encountered during the RBS program development and trial. One of the more considerable operational challenges involved propagative material (PM) type. There is a great deal of variability in the types of live plant material imported. Initially, inspection records omitted propagative material type information, so we were forced to assume that the risk associated with different types of live plant material were equivalent. PM type was identified as a necessary data element and is now recorded along with the other inspection-related data elements. As a result, the entry risk associated with different plant material types is now calculable as it can be for different country commodity combinations.

Comingling of different plant genera within a single shipment has presented many challenges and continues to be a substantial hurdle. Comingling can occur at multiple levels. It can occur at the shipment level where different taxa and or plant material types are mixed within a single container or on a single bill of lading. It can also occur at the inspectional unit level, where imported plant genera are mixed within a carton/box or another type of inspectional unit. Comingling can also take place concurrently at both levels. It is not usually operationally feasible to separate commodities comingled at the inspectional unit level, and entry risk levels among the comingled commodities may differ substantially. PM types, rather than plant genus as the criteria for summarizing quarantine action counts and shipment numbers, may partially alleviate the operational challenges associated with comingling. The efforts in this area are ongoing.

Some locations, for one reason or another, were unable to fully de-van their shipments and were therefore restricted to performing tailgate inspections. Computer simulations were run to determine how vital randomness was to the RBS process in order to determine the utility of tailgate or other non-randomly sampled inspection data for RBS calculations. The simulations involved comparing random versus clustered pest populations present in shipments with the computer identifying boxes for inspection either randomly or just from the tailgate. The simulation demonstrated that, for clustered pests, a high proportion of infested shipments are more likely to be accepted when only inspecting commodities in the tailgate region. Tailgate inspections did not appear to be a problem for randomly distributed pests. This exercise supported the need for randomness as an essential component to RBS since in reality we do not know what pests are present or their distribution.

Conclusion

Risk-based sampling is still very much a work in progress. Current efforts are focused on developing and deploying an enforcement framework to support the RBS program. Additional work is being performed to define compliance levels through risk thresholds for high, medium, low, and poor compliance. The required data elements are still being evaluated.

There is now an understanding of the RBS inspection system and the data generated from it. Actual RBS data, where all inspections occurred with the same intensity, have been used to rank the entry risk of propagative plant materials. The PIS sampling tool, used to identify which samples to inspect, has been evaluated in the field and is being further refined based on those results. The evaluation and enhancement of operational procedures continue as the structure to support the operational, analytic, and policy management aspects of the program are implemented. The final step is to deploy the commodity risk rankings in an operationally feasible manner in the field.

Cazier-Mosley – Status Check – Plant Inspection Stations in the United States

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Summary

For successful implementation of Risk Based Sampling (RBS), it is important to understand the data history, the availability of statistical baseline information, and the variety of ways cargo arrives and is inspected at Plant Inspection Stations (PIS). This understanding helps to successfully adjust inspection intensity in cases where shipments contain mingled or commingled taxa and where risk is linked to taxa and country of origin. When Plant Protection and Quarantine first introduced RBS, flexibility was needed to address the concerns of industry. As RBS is expanded in future its successful implementation will require building on the expertise of the workforce and providing feedback to them to promote understanding of the program's goals.

History of "Risk Based Sampling" at PPQ's Plant Inspection Stations

Program Managers for Plant Inspection Stations spent several years exploring different ways to evaluate the historical data collected on shipments to determine if the collected data could yield information about specific country/commodity combinations; and if that information could support adjustments to inspection intensity and/or frequency based on risk of imported plant taxa and origins. While the historical data provided a record of inspection activities and actions, for reasons discussed previously in Katsar, *et al*., the data could not be used to establish a statistical baseline for comparison.

In 2007, the PIS Program Managers engaged with managers of the Agriculture Quarantine Inspection Monitoring (AQIM) program to develop a statistically valid sampling design for Plant Inspection Stations. AQIM was widely used to conduct sampling and inspection on random cargo shipments using consistent, statistically designed sampling, but it focused exclusively on non-propagative material. Recognizing the vast difference in cargo makeup across the Plant Inspection Stations, AQIM was attempted at five of the sixteen PIS locations. Although sample selection was adjusted for local conditions at respective locations, the differences in cargo makeup did not allow for successful AQIM sampling.

In 2010, PPQ's PIS Working Group and the new Director of Plant Safeguarding and Pest Identification met with data analysts and statisticians to launch two initiatives: 1) a potential expedited release program for propagative material; and 2) a sampling program for propagative material arriving at Plant Inspection Stations.

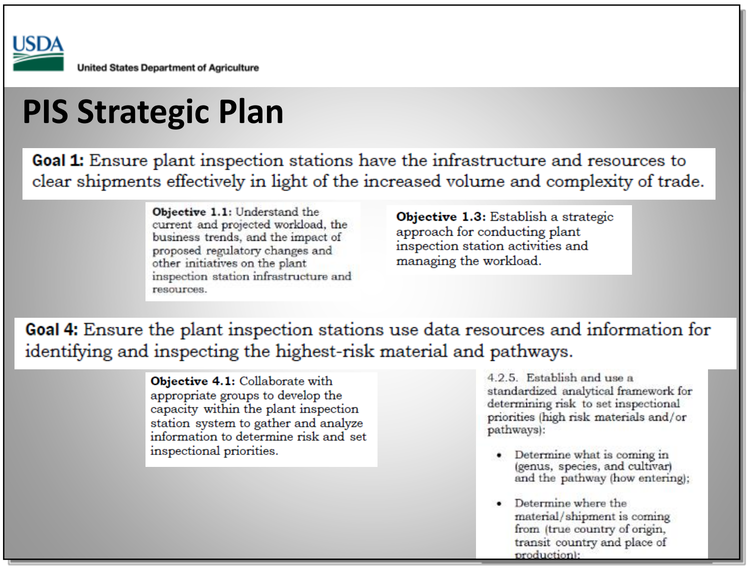
1) The Propagative Monitoring Release Program was launched using parameters similar to the National Agriculture Release Program (NARP) that was already being used for other agricultural cargo. Based on NARP parameters, the list of eligible materials was limited to 23 country/commodity combinations. In order to be part of the release program, shipments could only include those 23 combinations. This requirement became problematic for industry because these combinations were mainly observed at only two of the sixteen PIS locations. As a result, a propagative monitoring release program based on the NARP cargo program proved unsuccessful in the PIS environment.

2) However, the work to develop a sampling program for cargo arriving at Plant Inspection Stations (PIS) looked promising, and the group agreed to the following set of principles for sampling:

a. Statistically robust
b. Operationally feasible
c. Random and representative throughout the shipment
d. Able to Establish a Statistical Baseline (a starting point)
e. Aligned with the goals of the PIS Strategic Plan.

Plant Inspection Station Strategic Plan

The need for a sampling program was highlighted in Goals 1 and 4 of the Plant Inspection Station Strategic Plan, which called for a statistically-based sampling program to provide program managers with information to help set inspectional priorities, assess staffing needs, manage workload and evaluate trends. (See figure below)



Rollout to PPQ's Plant Inspection Stations

The new PIS sampling program was launched at the beginning of fiscal year (FY) 2014, after several months of work by data analysts, statisticians and the program working group. A sampling plan was developed, a sampling tool was designed, and sampling rates were established. PPQ trained staff engaged with industry, communicated with stakeholders, and then implemented the new sampling program through a staggered rollout. By the start of FY 2015, all PIS locations were using the following process:

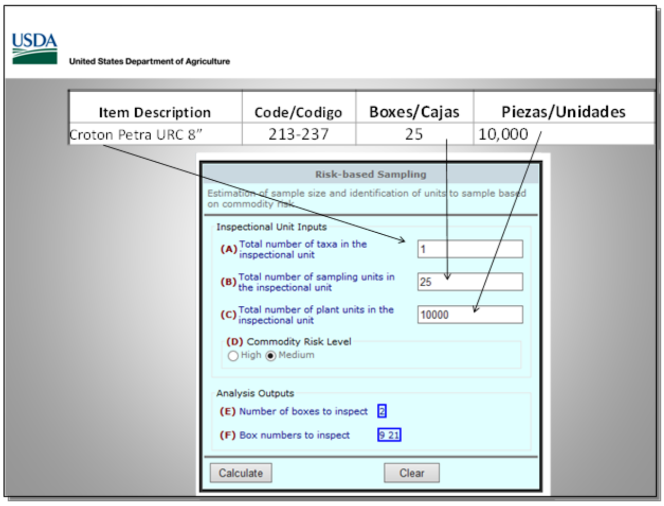
- sample the shipment using the sampling tool;
- allow the tool to determine the number of sample units from the shipment;
- the sample units will be representative throughout the entire shipment; and
- 100 percent of all samples pulled to be inspected.

Terminology: As part of the rollout, program managers provided training that included consistent terminology for using the sampling tool:

- *Inspection Unit:* The single lowest, readily- distinguishable (a) taxon, cultivar, or variety that is clearly defined as being from (b) one source (from the same farm or grower), and in (c) similar condition (e.g., air layer (AL), bare root (BR), callus cutting (CC), rooted cutting (RC), unrooted cutting (URC), etc.) on the invoice, packing list, or phytosanitary certificate
- *Sample Unit:* The smallest, most convenient element of an inspectional unit available for selection during the sampling process (e.g., bag, box, bundle)."

- *Plant Unit:* The smallest unit in the inspectional unit (e.g., cutting, plant, stem)."

Sampling Tool: As part of the rollout, program managers provided training that showed how to use these elements in the sampling tool. The figure immediately following shows a single line from an invoice.



Simple example of using the Risk-based Sampling tool delivered to PPQ's Plant Inspection Stations in 2014

- 1 single taxa
- 25 boxes (sampling unit)
- 10,000 plant units

Enter the numbers in and the Analysis outputs:

- Number of boxes (or sample units) to inspect
- Determines which numbers to inspect

This example appears straight-forward, however when dealing with cargo, there are some real- world challenges.

Reality Check: RBS in the Real World

As straight-forward as using this sampling tool may appear, it is important to understand that specific cargo can present challenges, and that flexible parameters contribute to the successful use of the tool. Shipments arriving at any one of the 16 PPQ Plant Inspection Stations can vary widely in the type of cargo, the volume of cargo, and the way industry packages and ships the cargo. There is a tendency to focus on large volume importers or the PIS locations that receive the largest shipments, however smaller volume shipments are important to the trade as well. Adjustments in inspection intensity or frequency need to be made in consideration of all the ways cargo is packaged and imported. Examples follow below.

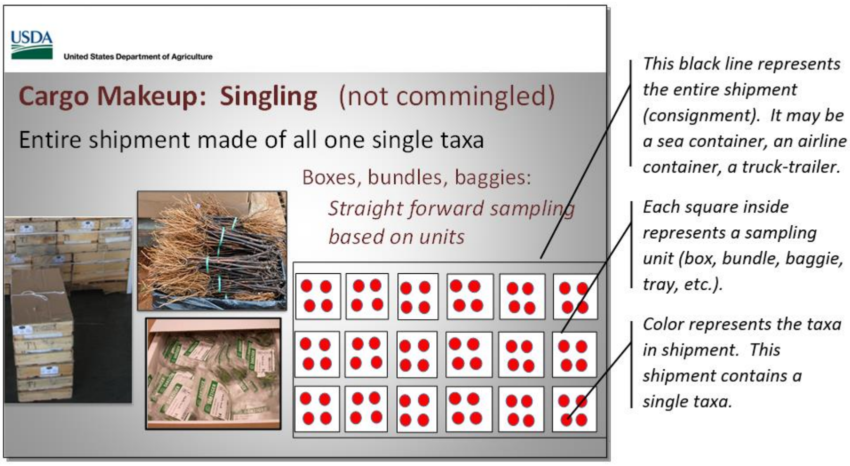
Singling, Mingling, and Comingling

Cargo packaging and shipment configurations created some challenges during implementation of the sampling tool. The three configurations commonly seen include singling, mingling and comingling. The singled shipment is one where the entire product in the shipment is the same taxa. The mingled shipment is one where product is the same taxa within sample units but there is a mixture of taxa in the shipment. The commingled shipment is one where there is a mixture of taxa both within the sample units and throughout the shipment.

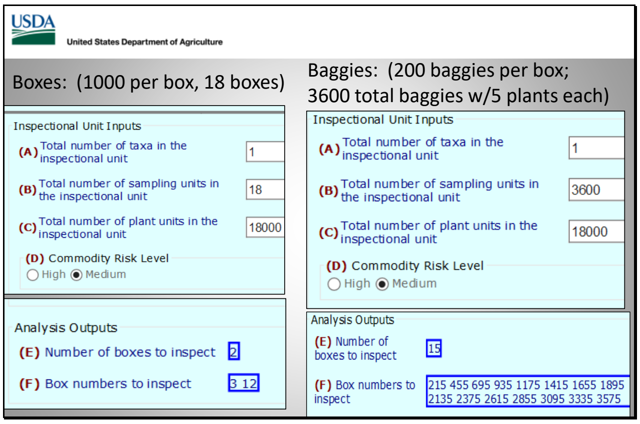
Different operational challenges arise when using the sampling tool for each of these three configurations. Allowing inspectors the flexibility to address these real-world challenges is the key to successfully using the sampling tool.

"Singling" – The Singled Shipment

The picture below shows a "singled" shipment which is comprised of a single taxon. There are no other products in the shipment. The red color represents the taxa in the shipment. The taxa are distributed among 18 different boxes within the shipment.



In this example of 18 boxes, each dot represents 250 plant units for a total of 18,000 plant units in this shipment. Boxes may contain a smaller sample unit (i.e., baggies within the box). The inspector chooses which sample unit to use and then enters the appropriate information into the sampling tool.



In the example above, titled Boxes, the inspector uses the 18 boxes as the sampling unit. After the taxa (1), sampling units (18), and plant units (18,000) are entered, the tool provides the numbers of boxes to be inspected. In this illustrative case, two boxes (box 3 and 12) would be inspected for a total of 2,000 plant units.

In the example above, titled Baggies, the inspector determines there is a small sample unit available. Each box contains 200 baggies. Each baggie contains 5 plant units. After the taxa (1), sampling units (3,600), and the plant units (18,000) are entered, the tool provides the number of baggies to be inspected: 15 baggies will be inspected for a total of 75 plant units.

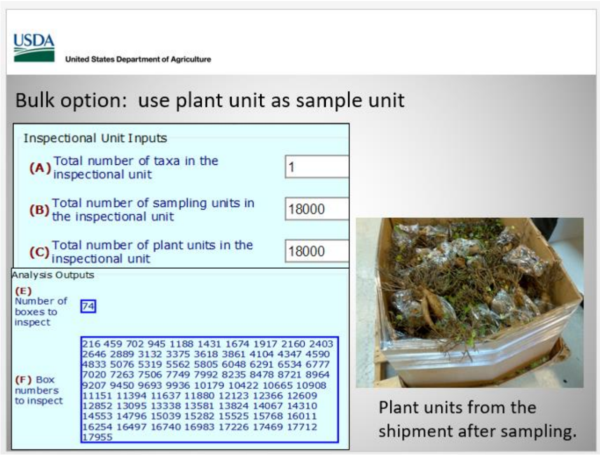
In both examples, the tool specifies which sampling unit(s) to inspect to ensure a distribution of sampling. The smaller sample units allow for fewer plant units for inspection.

What challenge does a "singled" shipment present? In the real world of cargo, not everything is packed into neat boxes, or bundles, or baggies. Some shipments of plant material arrive on towers and some arrive in bulk crates. On towers (Picture 1, below left), the inspector has flexibility to determine the sample unit. Each shelf may represent a sample unit, however to get a better distribution of the sample throughout the shipment, inspectors will look for dividers on the shelves. This increases the number of sample units thus potentially decreasing the actual plant units in the sample; but it creates a better distribution of the sample from the shipment. In bulk crate shipments (Picture 2, below right) there are no dividers, yet the inspector still needs to ensure representative sampling throughout the shipment.

Picture 1: Tower shipment of single taxa

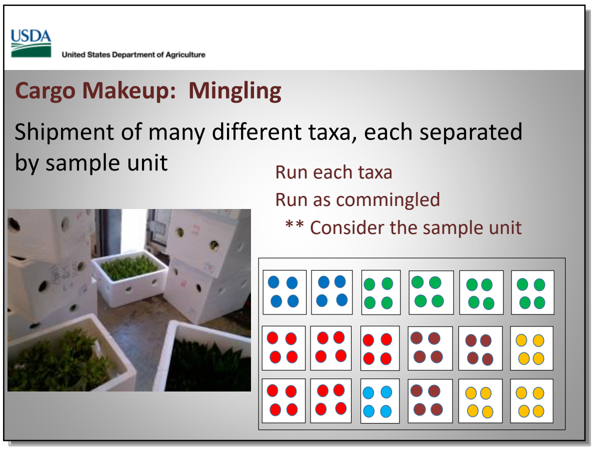
Picture 2: Bulk shipment of single taxa

Bulk shipments may also arrive at the Plant Inspection Station floor loaded in the shipping container. In both bulk and tower shipments, the plant unit may be used as the sample unit:



"Mingling" – The Mingled Shipment

This picture shows a shipment filled with several boxes of material. Each color represents a different taxon in the shipment. While there are six different taxa in the shipment, each one is separated from the others, therefore creating six inspectional units in the shipment. In order to distinguish this type of shipment from a shipment mixed within the boxes (commingled), this will be called a mingled shipment.



This is a typical shipment received at many Plant Inspection Stations. The overall shipments are not necessarily large by volume. They can be different propagative material types, different origins, or in most cases, different taxa. For simplicity, the same number of plant units are assumed in this shipment, with the same number in each box and baggie. Each color represents a different taxon in the shipment. Under the current use of the sampling tool there are a few ways to handle this shipment.

1) Run each individual taxon with box as the sample unit.
    a. Tool output per taxa reflects number of boxes for each taxa pulled for inspection.
    b. Smaller number of sample units reflects inspection of greater number of plant units.
2) Run each individual taxon by a smaller sample unit (i.e., baggies) within each box.
    a. Tool output per taxa reflects number of baggies for each taxa pulled for inspection
    b. Baggies increase the number of sample units resulting in a better sample distribution.
    c. Better sample distribution results in fewer plant units needed for inspection.
3) Run each individual taxon using the plant unit as sample unit.
    a. Tool output per taxa reflects number of plant units for inspection.
    b. Better sample distribution results in fewer plant units needed for inspection.

USDA United States Department of Agriculture

Mingled shipment options:

TAXA	# Boxes	# Plant Units	Tool Output per Taxa		
			By box	By baggies	By plant unit
	2	2000	1 box	15	73
	4	4000	1 box	15	73
	5	5000	2 boxes	15	73
	1	1000	1 box	15	71
	3	3000	1 box	15	73
	3	3000	1 box	15	73
Totals:	**18**	**18000**	**7 boxes** (7000 plants)	**90 bags** (450 plants)	**436 plants**
Tool output if ran as whole commingled shipment			**Boxes: 6** (6000 plants) **Baggies: 92** (460 plants)		

4) This shipment may also be run as a whole commingled shipment as reflected at the bottom on the chart.

    To do this, the total number of taxa changes to "6" to reflect the different taxa in the shipment.

Risk-based Sampling

Estimation of sample size and identification of units to sample based on commodity risk

Inspectional Unit Inputs

(A) Total number of taxa in the inspectional unit: 6

(B) Total number of sampling units in the inspectional unit: 15

(C) Total number of plant units in the inspectional unit: 18000

(D) Commodity Risk Level: ○ High ◉ Medium

Analysis Outputs

(E) Number of boxes to inspect: 6

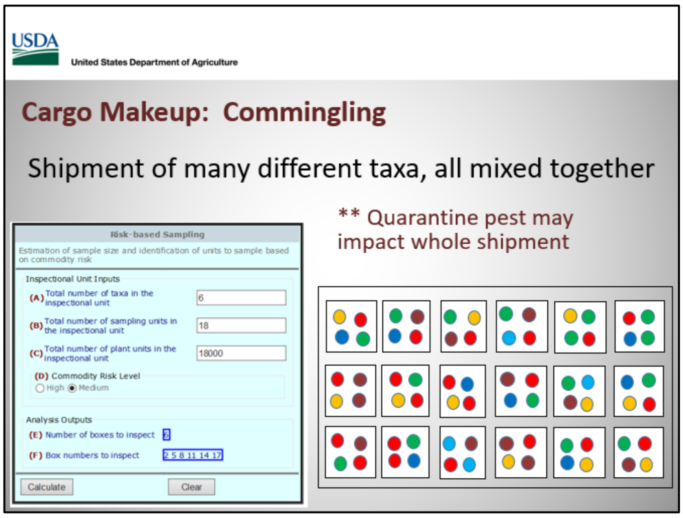
(F) Box numbers to inspect: 4 6 8 10 12 14

In the examples above, there is no adjustment in inspection intensity based on an assigned risk level. However, each taxon in the separate inspection units in a mingled shipment will have a different risk level. It would be appropriate to adjust inspection intensity to account for different risk levels for each taxon in the shipment.

Operationally, there may be other common elements to find in a mingled shipment. For example, the propagative material type and origin may be the same in a mingled shipment even when there are multiple taxa.

"Comingling" – The Comingled Shipment

The picture below shows a shipment with several boxes of material. Each color represents a different taxon in the shipment. The different taxa are mixed within the boxes and mixed throughout the shipment. This is a comingled shipment.



In most cases, these shipments are boxed and packaged ready for distribution. Operationally, the most efficient way to use the sampling tool for this shipment is to run all taxa together. If the boxes contain baggies, the sampling tool can be run using the baggies as the sample unit as previously demonstrated with both a singled and mingled shipment. If the shipment is commingled, then it needs to be sampled to account for the various risk levels of taxa in the shipment. A quarantine pest in a taxon may lead to decisions that impact the whole shipment.

Keys to successful implementation

Workforce

Successful introduction and use of a new tool or adjustment to an existing tool relies on the understanding and participation of PIS inspection workforce and sharing follow-up information and analysis.

Communication and training was an important part of planning for the rollout of the sampling tool. The PIS workforce requested feedback on data analysis results, which in many cases, validated inspectors' experiential knowledge of product risks. Initial analysis feedback was presented to all Plant Inspection Stations in September 2016. Following the presentation, PIS Program Managers received expressions of appreciation from the workforce for the data that was being used and analyzed for future adjustments. This acknowledgement of the workforce will add to the success of using the tool.

Providing inspectors with options regarding the appropriate sample unit for different cargo configurations (e.g., singled, mingled, commingled) allows flexibility for inspectors to work with the various importers at the Plant Inspection Stations.

Collaboration and feedback with the PIS staff is key to developing and using a sampling tool effectively. Input from inspectors with real world knowledge and experience of packaging and distribution of cargo provides program managers with valuable information to refine the sampling tool and use it more efficiently. To summarize, collaboration not only increases the buy-in of the workforce, but also contributes to more accurate use of the sampling tool and inspection process.

Industry

Engaging with industry is also key to success. This includes engagement at all levels. Inclusion of both the local staff and local industry in discussing sampling options for specific cargo provides an opportunity to assess challenges while considering all industry, regardless of the size of the operation and the way the product is packaged and imported into the Plant Inspection Station. This effort contributes to the overall success of implementation and adjustment to RBS.

Risk based sampling offers the ability to focus a higher level of inspection on higher risk product while providing incentives for lower risk importations. When considering incentives to industry, the differences in the shipment configuration needs to be considered so that all importers have an opportunity to meet criteria for those incentives. There may be several ways to look at how to create incentives and thus include the various types of shipments.

In a "singled" world that is very simple. If the shipment if "mingled" or "commingled" the challenges increase. The time it takes for inspection also includes the time it takes for industry to unload the shipment in order to pull the samples from the product. The use of the tool helps provide the proper distribution throughout the shipment.

Data Facts

Collecting data into systems made to minimize errors is important to ensure clean data for the analyst. At the Plant Inspection Stations, the Risk-Based Sampling tool was delivered during a time when data collection systems were changing. Providing the history of implementation dates for both statistical sampling and the data systems helps the analysts to work with the most accurate data available at this time.

- 2014 staggered implementation of sampling tool to stations; data limited by database
- 2015 full implementation of sampling tool at all stations; data limited by database
- 2016 sampling tool in full use; new database staggered implementation at all stations
- 2017 sampling tool in full use; new database fully implemented at all stations

Program Managers and data analysts continue to work together to adjust data elements to ensure more accurate data collection not only to support future adjustments for RBS but also to support other goals of the program.

Vision for the future

The rollout of the Risk-Based Sampling tool at the Plant Inspection Stations followed by changes to data collection systems has provided information for Program Managers and analysts to evaluate and adjust for the program in the future. It is important they work together to evaluate proposals based not only on the data, but also the operational feasibility. Future adjustments may be made based on the taxa, the origin, the propagative material type, or other criteria.

Ormsby - International Developments in Determining Levels of Intervention in Risk Pathways

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Keywords: treatments; phytosanitary; IPPC; wood packaging material; efficacy

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 the Brown Marmorated Stink Bug (*Halyomorpha halys*). Tools used include Bayesian statistics (Bayes Network) and risk models that include biological attributes such as Allele effects, propagule pressures, and pest epidemiology. This paper describes how these methods can be used to determine the performance requirements for risk-based sampling and inspection.

Background

Inspection of plant products before sale has been occurring for as long as humans have bartered goods. While for most of history such inspections would occur at the point of sale, at the end of a simple supply chain, and relatively close to the place of production; modern trade is more likely to be international, involve more complex supply chains, and occur extended distances for the place of production. For New Zealand it was not until the late 1980's, that more integrated systems began to be developed that moved interventions, such as inspections and treatments, back along the supply chain away from the point of sale in the country of import toward the place of production in the country of origin (exporting country).

In the early 1990's, Baker *et al*. (1990) and Cowley *et al.* (1993) developed an approach to estimate the level of protection required for fruit fly host material from Australia. The model developed by these authors formed the basis of New Zealand's fresh produce trading system established with Australia and other countries at that time. Baker *et al*. (1990) proposed a maximum pest limit that indicated the maximum number of juveniles of a pest species that are needed at the point of entry into a country, to enable enough adults to develop and subsequently establish a population in the new area. The model described by Baker *et al*. (1990) and Cowley *et al.* (1993) determined the sampling size required for accurate assessment of the pre-treatment infestation level to ensure any phytosanitary measure will mitigate the risk appropriately. The model relied on seven assumptions (Baker *et al*.,1990):

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 basic equation to determine the required pre-treatment sample detection sensitivity (***DS***):

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

This equation was applied by New Zealand to determine the size of the sample required before any treatment of known efficacy is applied (Cowley *et al.,* 1993). The pre-treatment sample ensured that the infestation rate did not overwhelm the efficacy of the treatment (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 (***μ***) 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). These estimates provided a target sample detection sensitivity of 0.5%, or no more than 1 in 200 fruits 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 compliance requirements. A 600-sample needed 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 on inspection the lot would be rejected for export to New Zealand. In this case the results of each sample are independent of all other samples.

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. Further emphasis for this work has arisen since the adoption of the international phytosanitary standard on methodologies for sampling of consignments (ISPM 31). The focus has been to remove a number of the assumptions that have underpinned the calculations of sample size and the required efficacy of measures, and to improve the versatility of phytosanitary measures throughout the supply chain.

Two assumptions that have generated particular analysis are 'inspection detection rates' and 'natural pest mortality', and these are discussed below.

Assumption 1: The detection rate per inspection is 100%

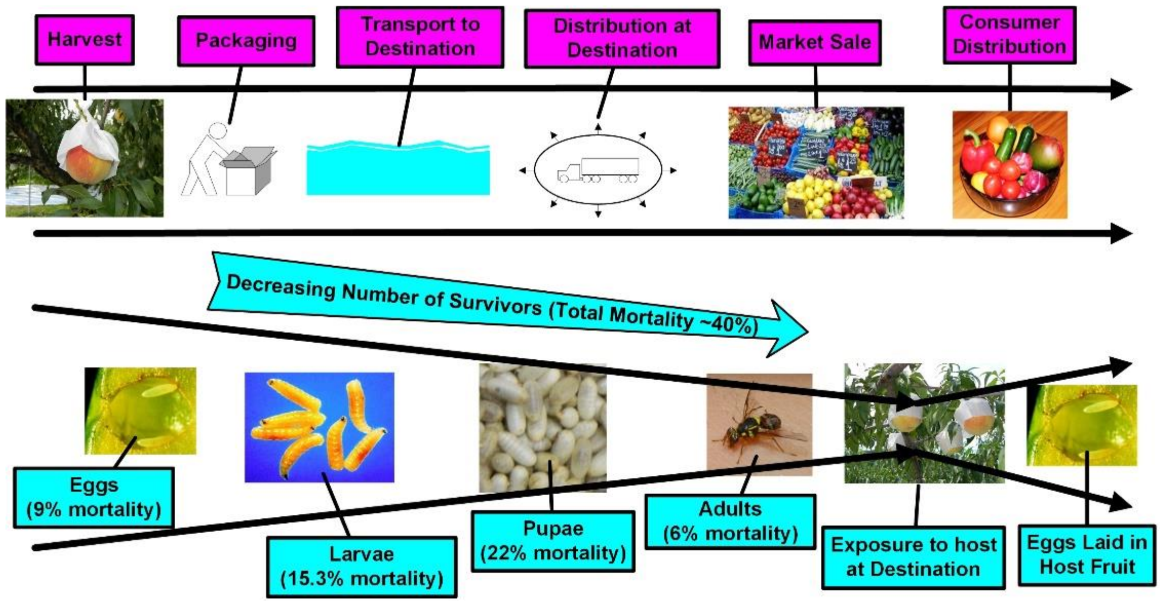
It has been customary to assume that inspection methods are always (100%) likely to detect pests when they are present on the commodity. This assumption is apparent in the almost universal application by several countries of a standard sampling rate (e.g. 60 or 600 units) across many commodities and pathways, irrespective of the type or nature of the pest or its association with the commodity. This assumption is not necessarily supported by information on pest detection efficacy by trained and experienced fruit inspectors. Gould (1995) determined that inspectors using destructive inspection methods (fruit dissection) found fruit fly infestations in fruit 18% to 84% of the time (depending on fruit type and on the inspector), with an average of around 44%. Perrone *et al*. (2013) designed trials in which fresh produce was artificially infested at various prevalence levels with several surface-dwelling arthropods of variable size and mobility, to test if these pests are reliably detected on inspection. They found that pests (or marks) that were big enough to be clearly 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.

Assumption 2: Pest infestations are only reduced by phytosanitary measures

The number of viable pests infesting the plant produce at its origin before packaging and transport is unlikely to be the same by the time it reaches the point of exposure at its destination, even without any phytosanitary measures being applied. It is well known that natural mortality occurs as the pests develop through their lifecycle, during transport to a new area, and when exposed to a new environment (e.g. due to climate, predation etc.) (Ormsby 2012). With natural mortality occurring on the pathway, for a male and female to have a reasonable chance of emerging and surviving to breed when the infested plant produce arrives at the point of sale (e.g. in New Zealand), we need to start with more than the MPL in the fresh produce at the time of infestation (e.g. before harvest). Figure 1 provides an example of a supply chain where natural mortality reduces pest infestations by at least 40% before the point of exposure at destination.

Figure 1: The example of reduction in the level of pest infestation due to natural mortality

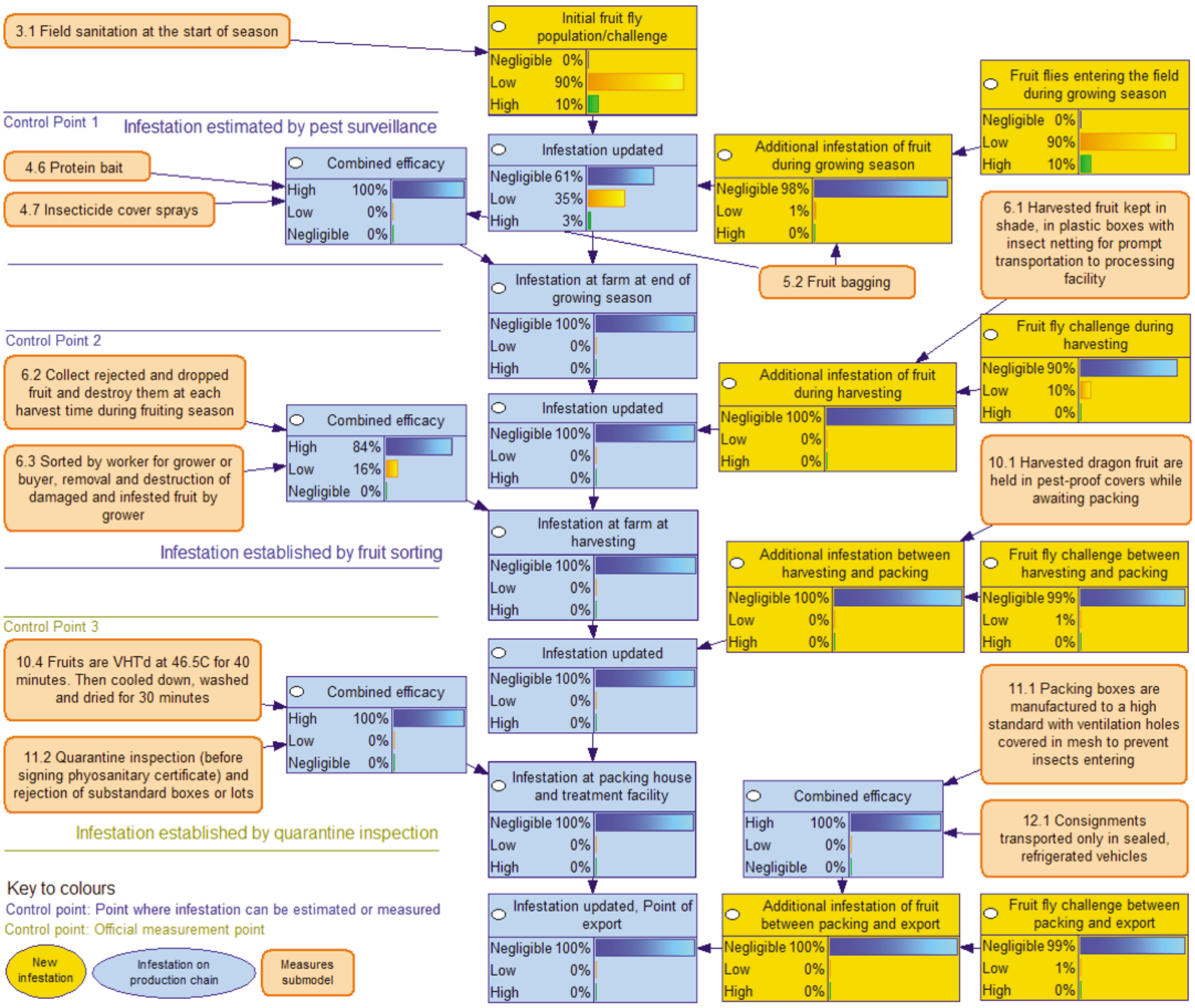


Considering the effect of natural or trade-induced mortality of pests in international trade has significantly reduced the levels of intervention required for risk mitigation (Ormsby 2012). Research in New Zealand is currently underway on the use of Bayesian Networks to develop decision support models to evaluate biosecurity risks (Jamieson *et al*., 2016). In the same manner the European Food Safety Authority (EFSA) Plant Health Panel is currently 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).

Improving the versatility of phytosanitary measures throughout the supply chain

Linking the post-production storage and transport pathway with the production chain offers opportunities to identify further mitigation steps, including the use of statistical sampling methods. Quinlan *et al*. (2016), from the Beyond Compliance research programme, demonstrated the use of a Control Point–Bayesian Network (CP-BN) to present the collated phytosanitary risk-based knowledge about a system. Each CP-BN shows the stages along the process pathway, for example planting, growing, harvesting, packing and export. Arrows link these points to the associated control measures, for example, treatment of planting materials, sprays, pest surveillance, bagging fruit and inspection. Objectives of each of these measures, and verification measures, are also identified and linked via arrows (Quinlan *et al.*, 2016). An example of a CP-BN for fruit fly management on dragon fruit is provided in Figure 2.

Figure 2. Beyond Compliance Bayesian Network example with all measures applied, giving an effective acceptable result at the point of export (the last box in the Production Chain, the blue box in the centre at the bottom) (from Quinlan *et al.*, 2016) (VHT = vapor heat treatment)



Using statistical sampling methods

Statistical sampling can be usefully employed at a number of intervention points in the production and supply chain. Where inspection relies on human eyesight and mental dexterity however, there are practical limitations on the size of samples that can be taken if overall performance is to be maintained, even when instruments such as magnifying glasses are employed. Repetitive activities that produce rare successes are likely to reduce sampling performance over extended periods even when relatively small samples are taken.

Use of small samples to detect pest populations above an MPL threshold after phytosanitary measures have been applied should be considered less than optimal. In the example provided 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 600 sample (assuming 100% detectability) would have only 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 phytosanitary measures are applied) has clear and simple decision criteria (e.g., rejection), failure of a sample after phytosanitary measures could theoretically occur under two circumstances:

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

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

Conclusions

The use of statistical sampling methods has allowed New Zealand to establish relatively straight-forward compliance requirements. As statistical sampling provides the same level of detection sensitivity across all samples, the decision criteria of lot rejection or acceptance is also simple when the sample is used appropriately.

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 pathway compliance over an extended period such as a production season.

The use of production and supply chain 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 extended periods.

Risk-based sampling can provide a consistent measure of the threshold of pest infestation. When implementing risk-based sampling into quarantine inspection systems, care should be taken to ensure any limitations in detection sensitivity are understood and the implications for any resulting failure fully acknowledged and imbedded in any associated decision criteria.

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Dikin - Perspectives on Risk-based Sampling Emerging from the Sampling Workshop in Indonesia

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Summary

A workshop on phytosanitary inspection techniques conducted in 2016 in Indonesia identified strengths, weaknesses, and issues around sampling for inspection that needed attention by the Asia Pacific Plant Protection Commission (APPPC) member countries. Technical limitations and capacity deficiencies were identified as a key issue for APPPC countries. The workshop recognized that the provision of adequate resources and expertise for the inspection of consignments is the first step to establishing credible inspection systems to determine whether phytosanitary measures are necessary. Sampling was identified as an important aspect of the inspection design for both imports and exports. The workshop agreed that decisions about sampling designs depend on the appropriate level of protection established by each country, the target pests, intended use of the commodity, existing sampling techniques, and the history of industry compliance.

Background

The harmonization of phytosanitary measures is central to facilitating the trans-boundary movement of plants, plant products and other regulated articles. Each country has a sovereign right to protect itself against quarantine pests; each country determines its own appropriate level of protection for maintaining the health of plants in their country. Appropriate sampling techniques for the inspection of consignments is important to provide confidence that consignments meet the appropriate level of protection determined for quarantine pests. Following inspection with laboratory testing may further inform the process for determining compliance and whether additional phytosanitary measures are warranted.

Several agencies and industry associations provide information on different approaches, techniques, and procedures for sampling commodities for phytosanitary purposes. The application of these depends on each country's concern about certain quarantine pests, the presence of pests in the consignment (including seed borne pathogens), and the type of pests that are the targets for inspection. This creates a complex situation that may involve different sampling procedures.

The implementation of the World Trade Organization (WTO) Trade Facilitation Agreement (TFA) requires that customs clearance, including inspection of consignments for phytosanitary purposes at ports of entry, be an efficient and risk-based process that does not incur extended demurrage costs due to inefficient and time-consuming procedures. Strategic approaches in the application of sampling techniques based on risk for target quarantine pests are consistent with this objective.

Sampling Application and Constraints

There are number of consequences associated with selecting different inspection designs and sampling procedures. The requirements established by the importing country often define the inspection parameters for issuing a phytosanitary certificate for export. When specified, these import requirements need to be understandable and practical. Phytosanitary certification requirements often do not specify either the target pests or an inspection design. Many notices of non-compliance can be linked to the lack of specifications in import requirements.

Incorrect sampling for export inspection of consignments may cause phytosanitary certification to fail due to contamination by regulated pests found in the consignment on arrival. Inspection procedures in the port of entry of importing country may be rigid to assure consignments meet the national protection level against certain quarantine pests. The intensity of this inspection is balanced by time and costs associated with physical inspection in the port of entry.

Quarantine inspection procedures in the port of entry also confirm the identity and integrity of each consignment by verifying documentation in addition to physical inspection. Live quarantine pests may be found that would initiate a non-compliance notification to the exporting NPPO. Communication about non-compliance between NPPOs is an important part of the strategy to mitigate the entry, establishment and spread of quarantine pests. An established notification process is commonly used for these communications, or bilateral expert meetings may also provide a venue for the evaluation of pests and programs to prevent introducing quarantine pests.

The application of sampling techniques should have a specified tolerance for quarantine pests for both physical inspection and laboratory testing, and for regulated non-quarantine pests associated with the inspection of seed or any propagation material. The tolerance level for intercepted pests should be notified to the NPPO of the exporting country to avoid the rejection of consignments on arrival.

Documentation of the sampling procedure is needed to trace any non-compliance as well as to identify the critical points in the supply chain of the plant or plant product from producing, processing, and packaging to certification. Small industries involved in exporting plants or plant products are encouraged to document any critical activities that avoid pest contamination.

Plant health officials attempt to prevent the incursion of quarantine pests from exporting countries to the importing country without unnecessarily impeding trade. The WTO TFA requires that sampling of consignment(s) after arrival in the port of entry be carried out efficiently and without protracted delays for plant health inspection purposes. Effective and efficient sampling techniques can be established by WTO Member countries based on acceptable risk and through collaboration of both countries on the application of pre-clearance of phytosanitary certification programs.

ISPM 32 (*Categorization of commodities according to their pest risk*) is also helpful for sampling because it identifies commodities by risk categories (high, medium, or low risk). Commodities categorized as lower risk generally require less extensive sampling as long as the consignment is not mixed with other commodities with a different risk category. This allows for more time to be devoted to the inspection of high-risk commodities.

Sampling techniques described in ISPM 31 promote confidence in the detection of quarantine pests in the consignment. However, not all consignments can be sampled using the same statistical approach. The sampling technique to be used also depends on the target pest, volume of commodity, and conditions for sampling. Sampling that is biased for detection may be needed for specific circumstances such as the detection of storage insects in a bulk shipment, due to the live insects mostly hiding in dark areas with temperature around 24-28^{o}C.

Export certification processes (e.g., inspection, treatment, other mitigations undertaken by and described by the exporting country in an additional declaration) may complement or affect intensity of import sampling. However, the capacity of exporting countries to provide such certifications varies and past experience can affect decisions by the importing country regarding the type and intensity of inspection to be applied on import.

Recognition of the intended use for a commodity may also effect the sampling technique. Commodities for consumption or processing have inherently lower risk because sorting, grinding, heating, and other processes mitigate pest risk. Wheat or corn grain in bulk for flour or animal feed is a good example. Sampling can be done in a processing facility or retail outlet to avoid delaying unloading, particularly where port facilities have limited area. Grains for consumption, animal feed, or milling may also be inspected for seed borne pathogens (e.g., *Tilletia* spp). Inspection and sampling from bulk bags of commodity may be difficult to carry out and require more staff resources and time.

The physical location of inspection and sampling may be in an open area or a closed facility. The location is important to consider due to the possibility of escape by live pests during inspection and sampling. Certain target pests will require laboratory identification depending on the life stage of the insect, such as fruit fly larvae in fresh fruits.

Sampling small consignments of particularly high risk and high value plants or propagative materials can be difficult. The International Seed Trade Association (ISTA) provides guidance on sampling techniques for seed to detect seed borne pathogens on small consignments. An alternative is post-entry grow-out followed by observation of seedling symptoms.

Harmonization of WTO Trade Facilitation Agreement with Plant Health Principles

There are strategic initiatives in sampling techniques for plant health inspection that can avoid delays in the custom clearance and facilitate trade, namely:

- Monitoring industries' compliance with phytosanitary requirements of the importing country and providing reward or punishment as appropriate based on performance.
- Importers demonstrating a history of compliance could earn the privilege of less frequent/intensive inspection in the port of entry, and would be subject to random monitoring at the premises of importer following import.
- Electronic integrated single risk management systems in the custom clearance process could identify risky consignments, historically compliant consignments, and the appropriate levels of sampling needed for plant health purposes prior to arrival in the port of entry.

Conclusions

Sampling techniques have an essential role in the proper implementation of phytosanitary measures based on inspection to assure that plants and plant products meet the entry requirements of the importing country. Sampling may be done in the port of entry for import inspection or prior to export for the phytosanitary certification of exports according to relevant ISPMs. The sampling technique needs to be flexible to take account of the appropriate level of protection, target quarantine pests, intended used consignment of commodity, existing sampling technique and industry compliance performance.

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Lee - Risk-Based Sampling – A View From the Canadian Horticulture Sector

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The Canadian Horticultural Council (CHC) is an Ottawa-based voluntary, not-for-profit, national association that represents fruit and vegetable growers across Canada involved in the production of over 120 different types of crops on over 27,500 farms, with farm cash receipts of C$6 billion in 2016.

Since 1922, in collaboration with members and the government, CHC has advocated on important issues which impact Canada's horticultural sector, promoting healthy, safe and sustainable food, and ensuring the continued success of our industry while providing nutritious food to our communities. CHC facilitates the collection of sectorial comments to government consultations and coordinates research projects and funding in answer to prioritized needs. CHC focuses on five core areas: labor; trade and marketing; industry standards and food safety; finance and business management; and crops, plant protection and the environment. While the impacts are considered broadly across horticulture, CHC may also focus on specific concerns for five commodity groups: apple & tree fruits; potatoes; greenhouse vegetables; berries and field vegetables.

Current Inspections in Horticulture: Exports and Imports

Main exports from Canada are currently to the United States, for which there are minimal phytosanitary requirements for most exported fruits and vegetables. The exceptions are potatoes and plants for planting. International agreements and bilateral agreements need to be considered, as specific import requirements have been negotiated which often involve a systems approach (best management practices; ISPM14) and inspection. In the case of plants for planting, inspections are conducted during the growing season, which then allow for movement of nursery stock during the winter. Industry has been requesting lower levels of inspection when there is reduced risk.

Currently, there are targeted inspections upon importation. A new commodity/origin combination has 100% inspection during a trial period to ensure that the agreed-upon requirements mitigate the phytosanitary risk. Inspection rates return to normal at the end of the trial period. Different rates of inspection for different types of imports range between high (100%), medium (15-20%), and low (5-10%). For specific food sectors, the Canadian Food Inspection Agency (CFIA) has begun to use establishment-based risk assessments.

Bacterial Ring Rot (*Clavibacter michiganensis* subsp. *sepedonicus*) Testing Program for Seed Potatoes

Bacterial Ring Rot (BRR) is present in many countries around the world. The Canadian Seed Certification Program (CSCP) is under federal jurisdiction (CFIA) and is applied on a national basis. All seed potatoes grown in Canada are certified under the CSCP. Testing of seed lots for the BRR causal agent is required under the federal legislation *Seeds Regulations* Part II (2). The objective is to move towards the functional eradication of BRR from the Canadian seed certification system and the Canadian potato system in general. This is dependent upon multiple interventions or testing at multiple steps along the seed certification process. Considered together, these varied points of testing along the seed certification system provide enhanced likelihood of the detection of BRR.

Every farm producing seed potatoes is required to test at least two seed lots annually for BRR. Seed lots to be tested are determined based on priority i.e., seed lots intended to be grown for increase next season on that farm OR seed lots with the highest number of generations (e.g. Foundation vs. Elite III). Samples can be from stems in the field or from harvested tubers.

All seed lots shipped belonging to Elite II, Elite II, Elite IV and Foundation classes must be tested for BRR. A grower may be allowed to ship seed potatoes of Pre-Elite, Elite I and Certified classes without further testing if the annual minimum two seed lots has been completed and they were found to be negative for BRR. As above, seed lots are selected based on priority if intended for planting in seed growers' farms next season and lots with highest number of generations.

When Canada had a more widespread problem with BRR in the 1960s, sampling was very intensive. Once the incidence of BRR was significantly reduced, Canada moved to a "maintenance" level of testing based on seed lot size. A normal testing regime is based on acreage. For example, for 4 to 40 hectares, 400 stems or tubers must be sampled. For larger areas (more than 40 ha), 800 stems or tubers must be sampled.

If BRR has been detected in a farm unit within the last six years, sample collections are done by the CFIA and an Intensified Testing Regime for BRR is used for the next three years. This means that for fields of 1 ha or greater, a minimum of 1000 tubers or stems must be tested. These intensified testing regimes are accompanied by additional measures, including sampling of all other seed lots on the farm, loss of seed status for all seed potatoes produced on the farm, trace-back and trace-forward investigations, and further CFIA restrictions and close monitoring of the farm for several years afterwards.

There is much debate around probability of detection and sampling size. The cost of achieving high detection levels can be prohibitive when the event is very rare. For example, the probability of detecting BRR at an incidence of 0.1% is approximately 33% in a sample of 400 tubers or stems and approximately 70% in a sample of 1,200 tubers or stems. Multiple testing points increase the probability of detection of BRR in the seed certification system.

From production through export and import, there are many steps taken to reduce BRR in the seed potato certification program. First, potato production is based on a flush-through system for seed certification. In this system, most planted seed must either originate from farms tested annually for BRR or be tested. There is also multi-point testing of seed through the certification system. The inspection of seed fields adds to BRR surveillance through detection of visual symptoms on the seed crop, and tuber inspection provides a secondary visual inspection for BRR symptoms prior to shipment. Finally, when seed is imported through non-U.S. or Canadian sources, post-entry quarantine eliminates introduction of BRR. Overall, the Canadian approach has resulted in a highly effective system for detecting and managing BRR, with only one seed farm in Canada found to be positive for BRR in the past 5+ years.

Perspectives from Partner Organizations

Sampling methods are different for ornamentals. When inspections are to be undertaken in bulbs, the importer is notified first and then a random number generator is used to determine which boxes will undergo inspection. The number of bulbs to inspect is based on the lot size and compliance history of the exporter.

For Canadian seeds (excluding seed potatoes), alternate sampling strategies are employed. Current requirements include the sampling of small seed lots, which has become a problem associated with export certification and movement of seed for research and breeding programs, primarily where there is a requirement for a molecular testing method. Sampling based on hypergeometric approaches also calls for sample sizes that are often as large or larger than the entire seed lot (ISPM 31). The Canadian Seed Trade Association (CSTA) supports choosing sample sizes based on the epidemiology of the pathogen (infection unit concept), which might result in much smaller sample sizes (there is a protocol in preparation by the *American Seed Trade Association [ASTA]* and the *International Seed Federation*

[ISF] [ISHI-Veg]). CSTA also supports the use of systems approaches to mitigate phytosanitary risk. Sample sizes could be adjusted to detect pests at a lesser level of detection than a zero level (Probit 9).

Further opportunities for risk-based sampling could be used as part of the inspection process when required in new export markets. RBS could, however, be challenging to implement because it would need to be negotiated with the trading partner, most likely on a country- by- country basis.

The CHC is creating other opportunities by collaborating in national initiatives. These include:

- National Plant Health Network
    - Network of laboratories to work on clean plants, starting with strawberries and grapes.
- Canadian Plant and Animal Health Strategy.
    - Broad consultations nationwide 2016-17, with a final proposal approved July 2017.
    - A system founded on prevention, collection and sharing of information, coordination through partnerships, and influencing behaviour. Details and implementation will be worked on over the next years.

Epanchin-Niell and Liebhold - Informing cost-effective strategies for reducing pest risk from live plant imports

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Abstract

Live plant imports are a key input to domestic horticultural industries, but also a primary pathway for non-native invertebrate and pathogen introductions. A variety of biosecurity measures – ranging from off-shore mitigation to inspection and phytosanitary treatment at the border to post-entry quarantine and monitoring – are available to reduce the risk of plant pest imports. How can these policies and measures be designed to reduce the pest risks from live plant imports while also maintaining the benefits from trade? Here we report on the findings of on-going work from a collaborative research effort that is focused on designing cost-efficient policies for reducing pest risk from live plant imports. Research findings include development of risk-based inspection approaches and highlight how accounting for stakeholder interests can enhance the cost-effectiveness of invasion prevention policies.

Background

The United States imports more than a billion live plants annually. Live plants are a key input to the domestic horticultural industry, providing domestic consumers access to diverse and low-cost plants for their homes and gardens. However, live plant imports also are an important pathway for the introduction of damaging non-native invertebrates and pathogens. For example, Light brown apple moth (*Epiphyas postvittana*), white pine blister rust (*Cronartium ribicola*), Citrus long-horned beetle (*Anoplophora chinensis*), and Sudden oak death (*Phytophthora ramorum*) are examples of damaging pests believed to have been introduced on imported live plants. Understanding how to efficiently manage risk from this invasion pathway is an important global challenge that must balance the benefits and costs of different policies, as well as the incentives and possible unintended consequences posed by those policies.

Recognizing the challenges from live plant importation, we convened a collaborative research effort, supported by the National Socio-Environmental Synthesis Center (SESYNC), aimed at understanding the live plant pathway and designing cost-efficient policies for reducing pest risk from plant imports. This working group brought together stakeholders, policymakers, and diverse researchers (including economists, ecologists, entomologists, plant pathologists) to examine this pathway and the available policy options. We considered the range of safeguarding policies available, from managing plant production practices off-shore to inspection and control of imports at the border, and we explored the costs and benefits of different policies, the incentives that they induce in producers and importers, and how effective targeting of policies may reduce risks while maintaining benefits. This effort has produced new knowledge and policy-insights, and a variety of completed and forthcoming outputs that may help inform more effective management.

Recognizing that the present can often be better understood by studying the past, one paper from this effort explores the history of phytosanitary policy in the United States, recounting how entomologists first came to identify the problem of plant pest invasions and describing the attempts to reduce pest introductions through regulatory efforts (Liebhold and Griffin, 2016). In the early and mid-1800s there was little recognition that plant movement could be harmful, and Acclimatization Societies – whose purpose was to add to mother nature through species introductions – were common. However, there grew to be increasing concern about non-native organisms in the late 1800s following outbreaks of species such as the San Jose scale, *Quadraspidiotus perniciosus*, which was introduced to San Jose, California on trees imported from China. Following several early regulatory efforts, Quarantine 37 – the first major United States policy regulating plants for planting – was finally implemented in 1919, but not without push-back from horticultural interests. This policy, while substantially altered since its inception, remains a key safeguarding policy today, and the tensions between trade interests and desires to reduce pest risk continue to influence policy.

While great strides have been made to reduce pest risk from imports over the past century, long time lags often exist between when invading species establish and when their damage occurs, such that the lax regulatory protections of a century ago remain a source of current damages to the landscape (Liebhold and Griffin, 2016; Epanchin-Niell and Liebhold, 2015). Furthermore, the benefits of new policies for reducing pest risk may not be felt for decades, while the costs are more immediate, adding challenges to effective policy design.

A variety of measures are available for reducing pest risk, ranging from regulation of plant production, to prohibitions or restrictions on imported goods, to pre- and post-entry treatments. The U.S. requires that countries apply for a permit to import new plant commodities, and an issued permit may place certain conditions on imports, such as seasonal or geographic restrictions, certification of pest-free areas, and specification of mandatory pre-entry treatments. In addition, the exporting country must issue a phytosanitary certificate stating that the required conditions for export have been met and that the plants have been inspected and are free of pests. Pest risk assessments, typically completed by the importing country, assess the risk of plant imports, and provide the technical justification for import requirements. Upon entry into the U.S., all plant imports pass through one of 17 plant inspection stations where shipments are inspected for the presence of actionable pests. If a pest is found, shipments may be treated, rejected, or destroyed to avoid pest introduction. If a pest successfully evades detection, early detection and rapid response may be the next line of defence. Voluntary measures and traceability procedures have been put in place by industry for some imported commodities. Importantly, off-shore producers often gain benefits from ensuring clean production practices and shipments, as such practices increase the quality of the exported product while reducing risk of loss from damaging infestations in production greenhouses, pest interceptions on consignments at the border, or recalls on infested material already in the distribution chain.

The stringency and types of safeguarding policies in place vary substantially among importing countries. Another paper stemming from our collaborative working group conducted a country comparison of phytosanitary legislation and regulations governing importation of live plants (Eschen *et al*., 2015). Of the ten countries/regions compared, the authors found that Australia and New Zealand have the most stringent requirements, including a white list approach to importing, that only allows imports of plant species that have been placed on a "safe" list. In comparison, Europe has perhaps the most open approach, not even requiring an import permit for new commodities – providing a single, blanket permit for all plants for planting. Eschen *et al*. (2015) also sought evidence for the effectiveness of various measures but found that a lack of appropriate data hindered assessment. Most countries lack inspection data, especially on negative outcomes. More comprehensive data on imports and detections would better allow assessment of the risks and trends associated with live-plant imports and the effectiveness of phytosanitary measures.

Because of the pest risk associated with live plant imports, various advocates have called for bans on live plant importation, largely citing the benefits that would be provided from reducing pest risk, but often providing little discussion of potential policy costs (e.g., Roy *et al*., 2014). However, an economic assessment of such a policy would need to weigh the potential costs of such a ban relative to the expected benefits, as well as the distribution of those values. Our group is working currently on such an analysis for woody plant imports. This study will compare the welfare benefits from live plant importation to the risks posed by such imports, and how the relative costs and benefits may vary dependent on the relatedness of imports to U.S. plant genera that would be susceptible to newly introduced pests. This type of analysis is challenged by a variety of data limitations, such as lack of data needed to estimate rates of pest introduction on plant imports as well as data on the value of potential damages caused by these pests. Accounting for these uncertainties is a key feature of this analysis.

Another underappreciated complication of large-scale import bans is that while such a policy would eliminate legal imports, it likely also would have the consequence of increasing unauthorized imports, as demand for new plant material would remain. Thus, while the volume of imported plants would decrease, the riskiness of imported material would likely increase because it would not be subject to the range of measures (from phytosanitary certification to inspection) that are required for authorized imports. Such unintended consequences must be considered in effective policy design. Indeed, unauthorized plant imports, in mail and courier shipments, passenger baggage, and cargo are important sources of pests, both those that have already been introduced and those at risk of future introduction. Quantification of the diversity and volume of unauthorized plant imports is another topic currently being researched by our working group.

Border inspections of imported material provide another key means for preventing pest introduction. The three main goals of border inspections are: 1) to gain information about pest risk in different pathways immediately and over time (used to inform other measures or requirements), 2) to prevent the introduction of pests through detection and mitigation of infested consignments, and 3) to deter (via the threat of consignment refusal, destruction or costly treatments) the shipment of infested material by exporters. While inspections provide these key benefits, inspection of all imported plant material is not possible due to capacity and resource constraints. Furthermore, inspections are imperfect. As such, an important policy question arises: How can limited inspection resources be allocated across diverse shipments to minimize pest risk? Our research group published two papers addressing this question. Specifically, the papers consider optimal design of a risk-based inspection strategy to address the problem of allocating scarce border inspection resources across consignments to minimize acceptance of infested consignments or infested plants units. While it makes intuitive sense that greater inspection resources should be directed to riskier shipments than less risky shipments, exactly how many resources should be allocated is a key policy challenge.

One paper (Springborn *et al*., 2016) considers a risk-based inspection system in which the regulator categorizes each commodity (i.e. a plant genus from a given origin) into either a low or high-risk group based on its historical inspection record. The high-risk group is inspected more intensively, and commodities can be moved to a different group as their inspection record is updated. To implement this policy, the regulator must specify the interception rate threshold that differentiates the low and high-risk groups, as well as the frequency with which each group is inspected. The exporters then respond to this policy by deciding how much to abate pest risk in order to minimize their long term expected costs from inspections, interceptions, and abatement efforts (recognizing that inspections, interceptions, and abatement are all costly to exporters). To inform policy design, Springborn *et al*. (2016) modelled live plant import inspections using a state-dependent monitoring and enforcement model to identify the policy (i.e. group membership rules and inspection intensity across risk groups) that minimizes entry of infested consignments, accounting for exporters' abatement responses. The model was calibrated using historic inspection data.

Springborn *et al*. (2016) found that a shift to this form of risk-based inspection could cut the rate of infested consignments that are accepted into the U.S. by one-fifth without any additional inspection resources. This reduction in pest risk results both from targeting more surveillance resources at the riskiest commodities and increasing the incentives for exporters to conduct more pest abatement to reduce their long-term costs from inspection and interceptions. Specifically, producers with commodities in the high-risk group have an increased incentive to clean up their shipments because they are inspected more frequently and interceptions are costly. Also, by cleaning up their shipments, they have a greater chance of moving to the lower risk group where they would be inspected less frequently (reducing inspection and interception costs). Interestingly, exporters in the low risk group also are expected to mitigate more under this risk-based policy than under a uniform inspection policy, even though they are inspected less intensively. This occurs because they want to ensure that they remain in the low risk group where they incur fewer costs associated with inspection. Thus, exporters in both the high and low risk groups face higher incentives to abate under a risk-based inspection policy than under uniform inspections. Springborn et al (2016) provide insights for how such a policy might be deployed.

The group's second paper on risk-based inspection (Chen *et al*. forthcoming) focuses less on the incentives that such a program poses for exporters, but rather on how different types of sampling plans (i.e. number of plants inspected per consignment) can minimize the risk of accepting infested plant units. The paper uses the number of infested plant units as a proxy for pest propagule pressure, recognizing that propagule pressure is a key determinant of successful pest introduction. The paper theoretically and empirically identifies strategies for allocating inspection effort across shipments – based on their underlying infestation rates and differences in shipment size – to minimize the expected number of infested plant units accepted into a country, given the inspectors' capacity constraints. The authors developed a statistical approach for estimating underlying commodity infestation rates based on historic inspection data, using data on sample sizes and outcomes. The authors also derive a formula to calculate the expected number of accepted infested plant units (expected leakage) based on a shipment's size, the size of the inspected sample, the commodity's underlying infestation rate, and the efficacy of inspection. The question then is how to allocate a sampling budget among incoming shipments of live plants to minimize the total costs of leakage (i.e. infested plants that are accepted into the country). In other words, how many plants should be sampled from each shipment to minimize the number of accepted infested plant units?

When applied to historical plant import and inspection data, Chen *et al*. found that to achieve this objective, inspections should optimally target the largest consignments with the highest plant infestation rates, and some consignments may be left uninspected. This inspection strategy (targeting the largest and dirtiest consignments) substantially reduced expected leakage relative to two other inspection strategies considered: inspection of two percent (2%) of plant units in each consignment and hypergeometric sampling to ensure a 95% chance of detecting an infestation if at least 5% of the plant units in a consignment were infested. Under the optimal risk-based sampling strategy developed in this paper, expected leakage was reduced by 29% to 59% as compared to the alternative sampling strategies. The paper also considers that inspecting all consignments at a baseline level may be desired (e.g., to gather data and provide deterrence), rather than leaving some consignments unsampled. The authors find that when implementing a comprehensive baseline inspection, allocating any additional capacity to the largest consignments with the highest plant infestation rates can enable inspectors to meet the dual goals of minimizing the costs of leakage and maintaining baseline sampling without substantial compromise.

Conclusions

Together, the studies highlight both the complexity and trade-offs inherent in managing the risks from trade. A forthcoming paper will synthesize the group's findings and highlight how policy design can affect how costs and benefits accrue across different stakeholders – from off-shore producers to importers to consumers and the public more generally, including those who benefit from the resources at risk from non-native pest introductions. As highlighted here, well-designed border inspections offer key opportunities for better understanding and managing risks, and recognition of stakeholder interests can improve the effectiveness of biosecurity design. Continued and improved data collection – including of both authorized and unauthorized imports – will enable further refinement to more effectively manage risk from live plant imports.

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Springborn *et al*. - Risk-based Inspection: Setting policy parameters to harness enforcement leverage

Michael R. Springborn, Amanda R. Lindsay, and Rebecca S. Epanchin-Niell

In this report we describe our recent research to inform the design and evaluate the gains of a risk-based inspection (RBI) program for examining imported goods at the United States border (Springborn *et al*., 2016). The importation of live plants has long been a pathway for the unintentional introduction of non-native insect pests and pathogens to the U.S. This international trade vector has been growing fast: over the past four decades, the dollar value of plants for planting imports to the U.S. has grown at 68% per decade (MacLachlan et al., 2017). Because resources for inspecting these goods have not grown at the same rate, there is a growing need to reexamine the efficiency of shipment inspection strategies.

Recently USDA-APHIS has explored moving from a relatively uniform approach for inspecting shipments to an RBI approach that concentrates effort on sources of imports that have more problematic inspection histories. While the basic idea of RBIs is simple, designing the actual system is complicated by the involvement of thousands of offshore producers, each likely to adapt their behavior to any change in the border inspection strategy. In the research presented in Springborn *et al*. (2016) we evaluate how to effectively design such a system: how should producers be categorized into high versus lower risk groups and how differently should these groups be treated (e.g. in intensity of inspections)?

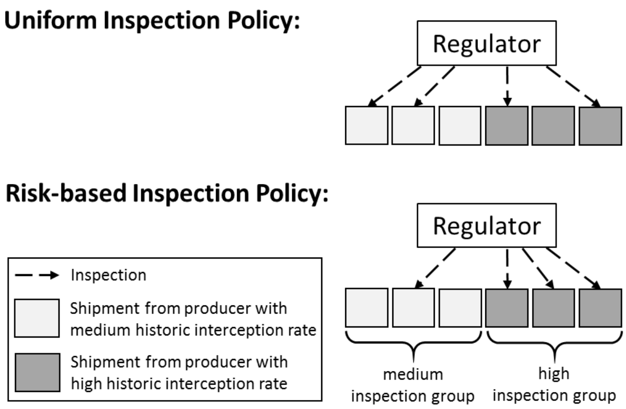
Using a numerical model calibrated to U.S. imports and inspection data, we find that adopting RBI can provide a *greater* incentive for producers to clean up their shipments, even for producers inspected with *less* intensity than under a uniform inspection approach. We estimate that shifting to an RBI approach can cut the expected rate of infested shipments entering the U.S. by one-fifth, simply by reallocating existing resources.

Overview of the Inspection Procedures

Inspection of live plant imports involves an inspector examining individual plants within a shipment for signs of pests or pest damage. Inspected shipments that are found to be infested —we refer to these as 'intercepted' shipments—may be either treated, destroyed, or returned, imposing a cost on the producer and preventing entry of the associated pests. Infested shipments may enter the U.S. if pests are not detected by inspection or a shipment is not inspected. When shipments are not intercepted, they continue on to their intended destination. Because the inspection process takes time, inspected shipments that are not intercepted still generate costs for producers due to delay and use valuable inspection resources.

Following the approach of APHIS, we differentiate shipments by their origin-commodity combination, where the origin is the country of export and commodity is the genus of plant. We refer to these unique origin-commodity combinations as 'producers'.

Figure 1: Under uniform inspection, all shipments face the same probability of inspection. Under risk-based inspection, higher risk shipments are inspected more frequently than lower risk shipments.



As illustrated in Figure 1, under a uniform approach, the regulator inspects all producers with equal likelihood. In contrast, under an RBI policy, producers are divided into medium- and high-risk groups based on their historic interception rates—a record characterizing previous inspection performance. Producers with a high historical interception rate are assigned to the high-risk group and receive more frequent inspections. Historic interception rates are continuously updated to incorporate outcomes from recent inspections, capturing either deterioration or improvement in the cleanliness of a producer. As such, producers can move from the medium to high group and vice versa, based on performance.

Modeling Risk-based Inspection

In our RBI model, the regulator announces a cut-off that determines how producers will be treated—those with interception rates above the cut-off are placed in the high-risk group with the remainder falling in the medium-risk group. The regulator also announces how inspection frequencies will differ between groups. Producers respond by choosing their level of phytosanitary effort to reduce infestations in their shipments with the goal of minimizing their expected losses. These potential losses come from the costs of phytosanitary effort, border inspection delays, costs from intercepted shipments, and being banned from the market entirely if interception rates are extreme. Phytosanitary effort is costly but reduces the anticipated level of all other losses.

It is typically impossible for producers to control infestations with certainty. Nor is it possible for border inspections to intercept all infested shipments. Thus, we model uncertainty in both of these components. We empirically ground the analysis by using data on live plant imports and shipment inspection outcomes to estimate parameters in the model. We also calibrate our model of producer behavior so that the model replicates overall inspection outcomes observed in the data.

Inspection policy aims to minimize the number of infested shipments that enter past a given national border. We identify the policy that minimizes the expected rate of these accepted infested shipments. The policy's focus on inspection highlights the role of border interceptions in preventing pest introductions. However, in reality—and in our model—reductions of accepted infested shipments come mainly from incentivizing producers to clean up shipments at the source, and only secondarily from interceptions at the border. A comprehensive model captures the threat of the latter on the former.

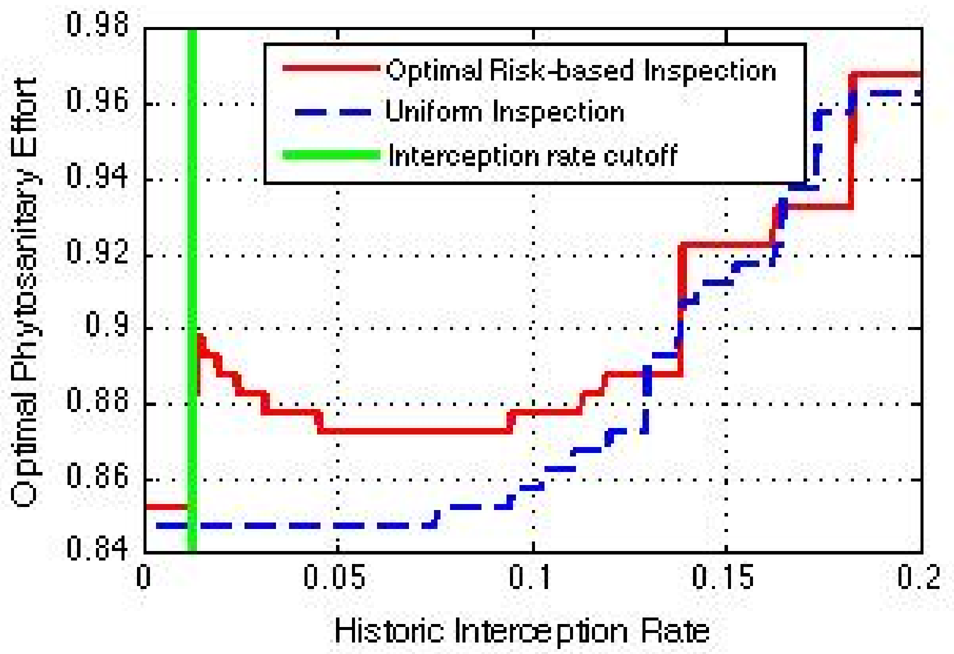
Benefits and Design of an RBI Policy

We compare an RBI policy to a uniform inspection policy to evaluate the potential gains. Under an RBI policy, shipments from high-risk offshore producers are inspected *more* frequently and those from medium-risk producers are inspected *less* frequently.

Figure 2 illuminates the phytosanitary benefits of an RBI policy by comparing the predicted phytosanitary effort response (vertical axis) of a producer as a function of the producer's historic interception rate (horizontal axis) for both the baseline uniform inspection policy (dashed line) and the optimal RBI policy (solid line). Producers in both the medium and high-risk groups generally exert higher phytosanitary effort under a risk-based policy than under a uniform inspection approach.

While producers falling into the medium-risk group—below the interception rate cut-off (thick vertical line) —are inspected *less* frequently under the RBI policy relative to the uniform approach, they nonetheless exert *higher* phytosanitary effort than under the uniform policy; these producers have a stronger incentive to provide cleaner shipments to avoid being transferred into the high-risk inspection group in which they would be inspected more frequently.

Figure 2: Optimal phytosanitary response for a representative producer (homogenous producer model). Phytosanitary effort is normalized to take a value between zero and one. When a producer's historic interception rate moves above 0.20, their shipments are banned from entry.



We also see that producers in the high-risk group, with interception rates close to the cut-off exert substantially more phytosanitary effort than under the uniform inspection policy. These producers are motivated to increase phytosanitary effort to increase the chance of transitioning to the medium inspection group, where they would be inspected less frequently.

These two features of producer response under RBI, in which producers exert enhanced effort on either side of the interception rate cut-off, illustrate an idea known as 'enforcement leverage'. This enforcement leverage—combined with the direct effect of higher inspection frequency in the high group (relative to the uniform approach) —led to reductions in the expected rate of infested shipments entering the country.

Accounting for the behavioral response of producers (as above) the optimal RBI policy involves inspecting 100% of shipments from high-risk producers using approximately 82% of the available inspection budget. Shipments in the medium-risk group are inspected with a probability equal to 0.28, almost one quarter of the rate of high-risk shipments. The interception rate cut-off, determining group assignment, is set such that just over half (57%) of shipments entering the U.S. are assigned to the high inspection group.

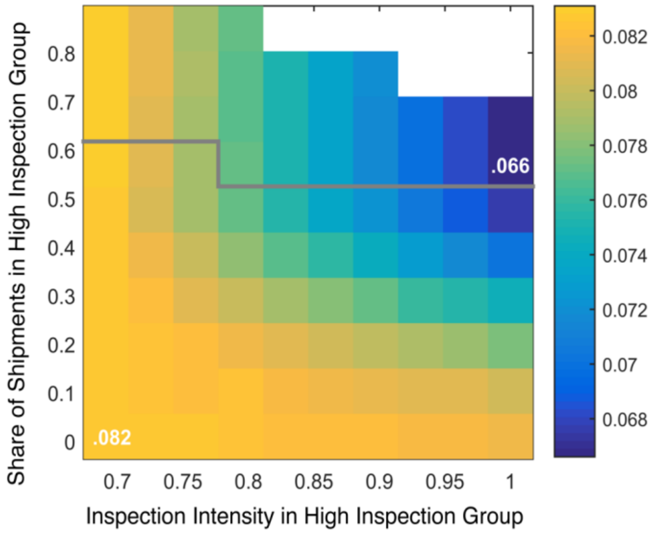
We estimate that—relative to uniform inspection policy—the optimal RBI policy cuts the expected rate of infested shipments entering the U.S. by one-fifth. It does so by increasing inspection frequency in the high-risk group and decreasing inspection frequency in the medium-risk group—both by roughly 50%. This improvement is substantial, especially given that it results simply from reallocation of existing inspection effort.

To generate the results discussed above we considered a model based on a single representative producer type. We considered a model that incorporated four different producer types as characterized by shipping frequency and phytosanitary effort costs. Incorporating this heterogeneity did not affect the results reported above but did affect the level of the interception rate cut-off (vertical line in Figure 3), a policy parameter that must be announced by the regulator so producers know how their historic interception rate maps into the medium- or high-risk group.

In Figure 3, we show the resulting expected accepted infested shipment rates (color bar) from the set of feasible policy alternatives. Uniform inspection policies (equal inspection frequency in high and medium groups) are located on the left-most column of cells. We find that this uniform approach performs worse in comparison to non-uniform inspection policies to the right, as indicated by cooler colors. As noted in the figure, the expected accepted infested shipment rate under a uniform inspection policy is equal to 0.082 and falls to 0.066 under the optimal RBI policy.

Figure 3: Expected accepted infested shipment rate resulting from feasible inspection policies, generated from the heterogeneous model. Each square represents a different inspection policy, with uniform inspection policies located along the left most column. The y-axis indicates the proportion of shipments allocated to the high inspection group, and the x-axis represents the high inspection group's inspection intensity. As the colors move from bright yellow to dark blue, the expected accepted infested shipment rate decreases.

Figure 3: Expected accepted infested rate resulting from feasible inspection policies



In reality there is substantial heterogeneity, with thousands of producers that vary along a continuum. Fully capturing this heterogeneity is not possible in the optimization model we use with strategic interactions between the regulator and producers. However, this is a design parameter that the regulator can settle on through trial and error, starting with high values--fewer producers in the high category translating to little risk that inspection resources will be overwhelmed--and iterating towards lower cut-off values until inspection resources are fully utilized.

Discussion

Given the substantial ecological and economic damages that can result from unintentional introduction of invasive pests via trade, measures to safeguard our natural resources are critical. But resources for implementing such measures are limited. Our research shows how shifting from a uniform policy to an RBI policy for imported shipments of live plants can reduce the number of infested shipments accepted into the U.S., and hence the likelihood of pest introduction, simply by reallocating existing inspection resources.

Our modelling results also help support effective design of an RBI program in the complex setting of international trade inspections, involving many more targets for inspection than considered by previous studies. We estimate that this approach would substantially enhance the performance of monitoring and enforcement efforts, even though the overall level of effort does not change, by targeting riskier shipments more intensively and incentivizing producers to clean up their shipments.

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Caton - Analysis and data challenges associated with risk-based sampling programs

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Introduction

Anyone interested in trying to develop, implement, monitor, and maintain risk-based sampling (RBS) programs face some significant analysis and data challenges. Some of the issues are universal, while some are specific to the type of RBS plan being used. For example, in every RBS program, some kind of approach rate will need to be defined in order to set up or monitor the programs. In contrast, some plan types require data collection before implementation and some do not, and some require methodologies for estimating rates while some do not. We will go through these issues, by phase and plan type, assessing advantages and disadvantages of the two major plan types when appropriate.

Issues Common to All Inspection Programs

Regardless of plan type or sampling scheme, some issues are common to all inspection programs. The two issues considered here are quantifying approach rates, and the efficacy of inspection.

Approach rates

If we are considering how to analyze inspection data to identify lower or higher risk commodities, or even just monitoring the outcomes of our basic inspection operations, one has to consider approach rates. Approach rates are the measure of how often a commodity or pathway is infested or contaminated by pests. Different versions of approach rates can be calculated, depending on the available data. We'll evaluate the approach rate possibilities below from the perspective of having a goal of reducing overall leakage rates (annual number of undetected pests on cleared goods), which is one useful metric for evaluating the worth of a RBS plan (e.g., Robinson *et al.*, 2015).

Action rate

The simplest approach rate calculation is the 'action rate,' which is the proportion of consignments found to have one or more pests. Action rate (or non-compliance rate) is defined as the number of actions (i.e., consignments with detected pests) divided by the total number of consignments inspected (e.g., PPQ, 2017). It is a coarse calculation because the numerator is the sum of consignments with pests, rather than the number of pests actually found, while the denominator takes no account of the unit quantities in each consignment and treats all consignments as if they were equal in volume. Action rates are also the least useful for predictive purposes, since one can only use it to estimate the number of infested consignments arriving in a given time frame, but with no information about how many total pests might be arriving. This hinders the ability to target inspections, from a consignment size perspective, and affects leakage.

For example, if two commodities have action rates of 0.1, and we expect 1,000 consignments of each to arrive, the mean estimate for the number of infested consignments, 100 (=1000 × 0.1), is the same for both. However, if commodity A has mean quantity of 20,000 units while commodity B has a mean quantity of only 1000 units, this has significant implications for biosecurity. First, without knowing the infestation rate, but assuming both are non-zero, we know pests will be easier to sample for in B, because of the smaller quantities involved. But because the quantities in A are so much larger, the potential for leakage is much greater than in B. Minimizing leakage by prioritizing inspections between A and B is very difficult if we only know action rates. Despite these issues, most agencies at least can calculate and use action rates, because the data requirements are so low. Action rates should be considered an entry-level metric for working with RBS, however, rather than a goal or end point.

Infestation rate

The ideal approach rate is 'infestation rate,' which is defined as the number of infested units per unit inspected. The numerator is the total number of units found with pests, and the denominator is the total number of units inspected. Note that the denominator is not the total number of units *imported*. Infestation rates are much more informative because they account for the quantities of pests, infested units, and total units. Predictions using infestation rate are much more useful, since we can explicitly estimate the likely number of infested units in a consignment, given the expected volume, and even the number of pests if we know a little about the number of pests per infested unit. Minimizing leakage then becomes much simpler, because we can estimate both the number of infested units in a consignment, and the likelihood of finding those units (pests).

Coming back to the example from above, if Commodity A, with about 20,000 units, has an infestation rate of 0.01, then we estimate 200 infested units in an average infested consignment (recall only 10 percent of consignments are likely to be infested). If Commodity B, with only 1,000 units, has an infestation rate of 0.001, then we estimate only 1 infested unit in an average infested consignment. The base likelihood of sampling an infested unit is an order of magnitude greater with Commodity A (= 0.01 = 200/20,000) than Commodity B (= 0.001 = 1/1,000), and the likely number of pests in the consignment is also much greater (unless pest incidence in A is greater than 200 pests per unit). So, having infestation rate information allows us to determine that inspecting Commodity A is much higher priority, and more likely to lead to pest detection, than inspecting Commodity B. When we only knew action rate, above, we could not determine this. The reason more agencies do not seem to rely on infestation rates, though, is that the data collection requirements are much more severe, including capturing the number of units infested by pests, and documenting or estimating sample sizes.

Inspection Efficiency

Inspection efficiency, or pest detection rate is defined as the likelihood of finding a pest or pests that are present on a commodity (e.g., Hauser *et al*., 2015). 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. Two issues around this factor are that it is sensitive information, since it has implications for how well inspectors are performing, and because Plant Protection Organizations (PPOs) do not seem eager to study the issue or share information about it. Frankly, inspection efficiency cannot and should not be described by a single number. That is because it should vary by inspection technique (e.g., visual-only versus using diagnostic equipment), by pest and stage (e.g., adult insect versus asymptomatic pathogen), and perhaps other factors as well (Hauser *et al*., 2015). Until PPOs do research on this issue, it will remain uncertain.

Issues Specific to Implementation Phases and RBS Plan Types

It is useful to discuss analytical issues that occur before implementation of an RBS plan, and after implementation, since the objectives vary greatly. In addition, depending on whether a ratings-based plan or acceptance sampling plan is chosen, the analytical challenges vary greatly.

In ratings-based plans data is used to calculate rates for the regulated goods, and assign ratings based on determined thresholds to separate goods into low and high categories (at least) for differential sampling. Ratings-based plans are very data intensive, during all phases.

In an acceptance sampling plan, the cumulative results of inspections of lots dynamically determine inspection status (e.g., reduced or standard). As a result, most of the analytical challenges associated with acceptance sampling plans are post-implementation. Acceptance sampling plans have recently demonstrated successful use by other plant protection organizations (PPOs) (e.g., Robinson *et al.*, 2012). In addition, acceptance sampling plans have a long history of use in manufacturing and other processes (e.g., veterinary health) (Shmueli, 2016). Plan specifications can vary, depending on whether the lots arrive in batches (lot-by-lot sampling) or are continuously produced (continuous sampling).

Pre-Implementation Phase

Before implementation, the major tasks are to determine how best to implement a RBS plan, and to estimate the impacts on inspection operations. We've identified up to seven different analytical tasks that need to be completed before a risk-based sampling plan can be implemented (Table 1). Brief descriptions of the objective of each are as follows:

1. Consignment/commodity analysis: understanding pathway volume and characteristics, and their impact on operations
2. Specifying incentives: determining the number of levels which may be eligible for incentives (e.g., low/high versus low/medium/high)
3. Sampling scheme(s): specifying the confidence and risk levels for inspection, and if frequency or intensity or both will be reduced
4. Collect risk data for rating: ensuring that enough good, relevant inspections data is available for needed analyses
5. Ratings development/validation: specifying the risk metric or modelling approach and the risk categorization thresholds, and—ideally—validating those results against out-of-sample data or by some other means
6. Ratings revision/update plan: specifying how and when changes will be made to the plan in the future based on inspection results
7. Estimating the impact of the proposed plan(s) on inspection operations: modelling outcomes to provide insight into whether or not the proposed plan will accomplish program goals

Table 1. Analytical tasks that need to be completed before implementation of a risk-based sampling plan, depending on plan type: acceptance sampling plan or ratings-based plan. Absence of a checkmark indicates the plan does not require that task.

Task	**Acceptance Sampling Plan**	**Ratings-Based Plan**
1. Consignment/commodity analysis	✓	✓
2. Specify incentive levels	✓	✓
3. Specify sampling scheme(s)	✓	✓
4. Collect inspections data for rating		✓
5. Ratings development/validation		✓
6. Ratings revision/update plan		✓
7. Estimating impacts on operations	✓	✓

Acceptance sampling plans. Because acceptance sampling plans require no ratings, only four of seven tasks described above need to be completed before implementation. The first task is essential to understand the pathway being inspected and determine all necessary information for making planning decisions. The second, specifying incentives, is in many ways the heart of the risk-based sampling plan, as it determines how the plan will operate, and how simple or complicated it will be in terms of number of levels of inspection enacted. For example, the number of threshold and failure parameters need to be defined for plan operation, and those depend on how many switching rules are invoked (Robinson *et al*., 2012). The sampling scheme is fundamental and refers to the frequency and intensity of sampling for each level specified in Task 2. It determines the confidence level and infestation (or action) rate that can be found at the standard and reduced inspection levels and is therefore critical to understanding and monitoring outcomes.

Ratings-based Plans. All seven of the tasks described above need to be accomplished before a ratings-based plan can be implemented. Note that one cannot implement this plan until they all are complete. This is especially significant for the 'collecting data' task, since time periods of up to a year may be required to generate enough characterization and validation data.

Two tasks are particularly difficult, yet critical to program success. The first is 'ratings development/validation,' because no standard accepted approach to characterizing commodity risk exists, and because validation is simply difficult to accomplish. This task is likely to take significant amounts of time and effort, and perhaps be very contentious.

The second is the 'ratings revision/update plan.' Program managers need to be transparent about how and when the current ratings will be updated. The technical challenges associated with this include determining how much and what kind of data is needed to support revisions and specifying the process to be used. The former is important because it determines how long ratings will be 'locked in place' for producers/shippers. Also note that analysis time further delays updating. The timing considerations around getting a sufficient amount of data to trust re-rankings while not making the period between updates too long, will be important to determining how responsive the program is for industry. The process used is important because if ratings are calculated with a dynamic modelling approach, then categorical thresholds become unknown, moving targets, which complicates the communication with industry members about how to become eligible. This is discussed further below. Technically this task could be done post-implementation, but there are significant downsides to that approach, such as not being able to tell industry members when they could next become eligible for reduced inspections, nor what it would take to achieve that.

Estimating Plan Impacts on Operations (Task 7). This should always be done, regardless of plan type, for a few reasons. First, if the estimated impacts on operations do not meet our goals, then we have the chance to adapt and improve the plan before implementation. Second, it will help set expectations, so that we can better understand and report on observed outcomes. Third, if we are considering multiple plans, this analysis becomes a critical piece of information for plan selection.

Rate model considerations. For any ratings-based plan we know that risk characterization is required, but different methods can also have large effects on program operation and potential success. Two modelling methods considered here are 'empirical' and 'fitted.' By empirical modelling we mean methods that use a standard arithmetical approach that is repeated every time a new summary rate is calculated; that is, ratings change only because of the underlying data. An example of this is the empirical Bayes method for estimating rates and confidence bounds, with rates updated as new inspection data are gathered (Bolstad and Curran, 2016). By fitted modelling, on the other hand, we mean using a dynamic statistical approach with new data, factors that can vary from period to period, and even different methodologies. An example is statistically fitting a Bayesian generalized linear model to the ratings data, along with some method for determining the confidence limits (e.g., uncertainty simulations).

Choice of modelling approach has important implications for the ratings-based plan, as described by several factors that it affects, especially how the program parameters are determined and communicated to producers and shippers, and in flexibility in administration of the program (Table 2).

Table 2. Important factor differences between modelling methods that affect ratings-based plans.

Factor	Empirical modelling	Model fitting
Specificity	Each combination separately	All combinations at once
Dependency	Independent	Dependent
Ratings derivation	Direct	Indirect
Explicability	Standardized	Ambiguous/Ever-changing
Revisions/updates	By single combinations	All combinations at once
Data pooling	Cumulative data available	Only period-specific data
Connectivity	Bayesian updating possible	Restricted
Rating factors	Standardized	Dynamic / variable
Uncertainty	Integrated into method [a]	Separate/additional approach

[a] E.g., true for empirical Bayes

For example, using an empirical approach lets one communicate to producers and shippers exactly what rate of pest freedom they need to become eligible for inspection reductions in the next iteration. This is not necessarily possible when one uses a fitted approach, however, because with dynamic results is becomes difficult to guarantee particular outcomes. For example, the thresholds determined previously may change in the next iteration, so that producers/shippers never know the goal from iteration to iteration. Also, the significance of modelling factors can change from iteration to iteration. Perhaps last time the factor 'origin' was not significant, but becomes so in this iteration, which would cause some producers/shippers to remain in the ineligible category, despite improving their approach rates. Fairness becomes an issue in such cases, and these occurrences seem very likely to lead to complaints from producers and shippers and to difficult conversations with them.

The model fitting approach can greatly reduce flexibility in program administration, because all estimated rates are dependent upon all others. It becomes impossible to evaluate possible changes in the rate of any single commodity combination, and therefore impossible to make status adjustments for single producers and shippers. If an empirical fitting method is used, however, updating can be done for single commodity combinations at any time. Thus, producers and shippers could become eligible for reduced inspections as soon as they meet the threshold criteria, rather than waiting for fitted model ratings to be updated after some arbitrary time.

Another critical impact of model choice is upon the data used for analysis. Under the model fitting approach, each iteration is performed only upon the most recent segment of data, however long that might be (e.g., annual, semi-annual). The exclusion of old data means that uncertainties stay relatively high over time, and we lose the ability to integrate historical performance information. In the empirical modelling approach, all data collected from the start of the RBS program are potentially available. With the empirical Bayes method, for example, updated rates are explicitly calculated from the prior estimate—which reflects historical performance from the start—by simply adding the new information. In this manner, producers and shippers get appropriate credit for demonstrating low approach rates over the long-term.

Finally, empirical approaches that explicitly incorporate or facilitate uncertainty estimates are preferable. Empirical Bayes, for example, allows this to be simply estimated by finding the 99th percentiles (or whatever is deemed appropriate) of the rate distribution. By comparison, we have seen fitted model approaches that use separate simulations to generate estimates for the confidence limits. These simulations add further caveats and assumptions to the mix, may add variance, and perhaps need validation themselves.

Overall, model fitting approaches present serious constraints on program capability by reducing flexibility of administration and the ability to use historical data, and perhaps by presenting ever-changing standards. They also seem likely to be more difficult for stakeholders to understand, and therefore may be subject to greater criticism and scepticism. This might all be justified if the fitting procedure could be demonstrated to achieve much greater accuracy in predictions. To date, however, we have not seen that happen within our own program analyses. Recent studies, moreover, concluded that more complicated optimization approaches did not outperform simpler approaches (DeMiguel *et al*., 2009; Powell, 2015). Consequently, we recommend using simpler estimates in the absence of clear evidence that more complicated estimates perform markedly better.

Post-Implementation Phase

After implementation, the major tasks are monitoring outcomes and making any needed revisions or updates to the RBS program. We listed up to five analytical activities that the different types of plans may require (Table 3). Two of these (Incentives and sampling scheme adjustments) are optional, for both plan types, because they are required only if changes are made to either the incentives specifications or sampling scheme. Typically, the changes would require some rationale or evidence for justification, such as program improvement. Possible examples are if managers decide the monitoring data support the addition of a "very low risk" incentive level with even greater reduction in inspections, or if availability of additional resources enables sampling intensity to be increased.

Under both types of plans, collecting data and monitoring outcomes are key tasks, especially for demonstrating improvements in safeguarding. Data collection has additional importance for ratings-based plans, since new data will become the basis for the next iteration of ratings. Monitoring is essential to evaluate the impact of the RBS program on inspection efforts and safeguarding and provides feedback to producers and shippers that would facilitate any needed improvements. Common metrics for monitoring and evaluating program success may include inspection effort, number of cleared versus inspected consignments, total pest detections, status/ratings changes and proportions, and especially estimated leakage rates. Ratings-based plans would probably also be calculating metrics for performance by rating and accuracy of ratings.

Table 3. Analytical tasks that need to be completed after implementation of a risk-based sampling plan, depending on plan type: Acceptance sampling or Ratings-based.

Task	**Acceptance Sampling**	**Ratings-Based**
Collect inspections data	✓ (monitoring)	✓ (monitoring/re-rating)
Evaluate outcomes	✓	✓
Ratings revisions/updates	—[a]	✓
Incentives adjustment	?	?
Sampling scheme adjustment	?	?

[a] In this plan type, inspection statuses (i.e., ratings) are automatically updated

The revision or updating task for ratings-based plans is significant; ideally it occurs as specified in the plan created before implementation (Task 6). Following an established protocol for the estimation of rates would also be ideal --the process would be complicated by testing models or rate functions that differ from the previous version.

Note that the ratings revision/update process would almost certainly have two additional (non-analytical) tasks tied to it. The first is communicating any changes in methodologies, estimated rates, and ratings to producers and shippers. The second is operationalizing those changes.

Conclusions

All RBS programs need to consider approach rates and inspection efficiency. The advantages to developing the capability to use infestation rates should be apparent, but it remains to be seen if agencies will make the changes necessary for implementation, including resource costs. We think those costs are more than justified by the program gains that result. Meanwhile, many agencies will be forced to rely on action rates, which is acceptable given that we understand the limitations in those rates, not become too dependent on them, and continue to try to move toward infestation rates or other better metrics.

Similarly, agencies seem unlikely to quickly develop alternatives to using rough estimates of inspection efficiency (detection rate; non-compliance rate). This area seems ripe for collaborative research. Third party efforts may be necessary, however, because sensitivities toward inspectors may make it difficult for NPPOs to tackle.

The number and kinds of analytical issues faced within RBS programs varies significantly depending on the type of plan that is implemented. Acceptance sampling plans require far fewer analytical tasks than ratings-based plans, both pre- and post-implementation, which means data and analytical needs are much reduced. In addition, because inspection status (i.e., ratings) is determined dynamically, acceptance sampling plans require fewer maintenance, revision, and updating tasks. Instead, efforts can focus on monitoring and communication to enhance the chances that producers and shippers understand successes and failures and can act to take full advantage of incentives.

For ratings-based plans, all seven tasks in the pre-implementation phase must be completed before they can be started, and at least three of the post-implementation tasks are required—in each succeeding iteration, according to whatever updating schedule is formulated—to maintain and revise the operational plan. Data and analytical needs in each phase are maximized in this scheme.

Ratings-based plans also introduce challenges by requiring model estimates to be formulated and validated before use. Data needs and restrictions are maximized when a model fitting approach is used, and that also maximizes the analytical needs and difficulty of communication, while minimizing RBS program flexibility. Empirical approaches seem much preferable to maintain program flexibility and maximize the worth of historical data. Using a model fitting approach is really only suitable if the accuracy gains justify it, but expert reviewers believe that more complicated rate estimates are unlikely to outperform simpler approaches.

Finally, the post-implementation phase is largely similar for each RBS plan type, with a strong emphasis on data collection and monitoring. Plus, any RBS program has some likelihood of needing course adjustments at different times, so tweaks to incentive levels or sampling schemes are expected. The main difference between plan types in this phase is the express need to periodically update the ratings in ratings-based plans, which also necessitates associated special review and communication tasks.

Overall, acceptance sampling plans appear to minimize analytical and data challenges, compared to ratings-based plans, while delivering associated benefits like greater flexibility in program administration, and simpler communications. Acceptance sampling plans also have a demonstrated successful record of use in other industries. While either type of RBS program can likely be made to work, given that the relevant expertise and resources are available, the analysis and data challenges faced by ratings-based plans are considerable.

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Church *et al*. - A risk-based sampling approach to phytosanitary inspection

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Summary

As the pace of global trade in plant commodities accelerates, plant health regulators must become more agile and efficient in the execution of their mandate to prevent the introduction and spread of plant pests and to ensure the sustainability of the planet's valuable plant resources. National Plant Protection Organizations (NPPOs) are challenged to uphold this mandate with minimal impact on trade. Phytosanitary inspections are among the most significant regulatory pressures experienced by industry as certain regulated products are subject to phytosanitary inspection prior to entering trade.

In response to this pressure, many NPPOs are exploring the potential of a risk-based sampling approach to enhance the efficiency of phytosanitary inspections. A risk-based sampling approach to inspections would prescribe sampling frequencies based on risk factors, including compliance history, origin and intended end use of the commodity.

In 2015, the Canadian Food Inspection Agency (CFIA) developed a risk-based sampling approach model for *Listeria monocytogenes* in ready to eat meat and poultry products. The CFIA is now evaluating the feasibility of adapting this approach for phytosanitary inspections. The CFIA's risk-based sampling approach model was based on developing relative ratings for the risks associated with a range of commodities or production facilities in relation to their potential to transmit a single pathogen of concern - *Listeria monocytogenes*.

The approach calculates the relative risk of the commodity or production facility and allocates the frequency of inspections per year that should be associated with the commodity or facility. The model is based on a series of algorithms that tailor the inspection frequencies to each commodity or facility based on risk factors including;

- the inherent risk presented by the commodity;
- the mitigated risk resulting from particular process-control measures;
- the volume of material entering the at-risk area; and,
- the compliance history of the commodity/ origin combination.

From a phytosanitary perspective, we are often concerned about a range of pathogens, arthropods and other contaminants in association with a single commodity. A fairly complex manipulation of the existing model may be required to rank a range of pests on a single commodity; however, the risk-based sampling approach model offers a solid framework upon which to expand. With only a few modifications, this model could be used to produce relative risk index of commodities from particular producers or exporters. This application would be very useful for commodity inspections as well as inspections and audits of facilities under systems approaches and certification programs as it would provide incentive for importers to do business with facilities with a lower risk index.

There are some challenges associated with the phytosanitary application of the risk-based sampling approach model. For example, in the risk-based sampling approach model, the production volume rating refers to the kilograms per year of production for a particular commodity. There is no consistent unit of measure that is used to calculate this for plant commodities: some commodities are measured in units or bunches, while others are measured in weight or volume. Even within a particular

commodity, there is variation in the units of measurement that are recorded. The basic principle behind the production volume rating is that relative risk increases with the production volume.

Compliance rating is another factor that could pose a challenge; however, NPPOs could determine this value based on the number of shipments of a particular commodity that are cleared versus the number of notifications of non-compliance that are issued for that commodity.

There is potential to develop various risk-based sampling approach models for different categories of phytosanitary scenarios. In some situations, the data that would be required to populate these models is not currently being tracked by NPPOs; however, in most cases, data such as volume, origin and exporter could be extrapolated from shipping documents. These risk-based sampling approach models could be applied as part of the existing plant health risk assessment process to support a more efficient inspection and sampling protocol.

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Hester *et al*. - What about the incentive properties of biosecurity inspection rules?

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The Australian Government has replaced mandatory inspection requirements on selected low-risk plant-product pathways with arrangements where the frequency of inspection is based on an importer's compliance history. These protocols posit that the likelihood of biosecurity risk material being present in a consignment is related to past compliance – importers with a good history of complying with biosecurity requirements face fewer inspections. Such schemes offer the potential to reduce regulatory compliance costs to businesses that adhere to biosecurity requirements while also freeing up resources, so biosecurity regulators can reallocate resources towards activities more critical to maintaining national biosecurity standards.

While the progression to risk-based and compliance-based regulatory regimes may appear to offer system efficiencies, it is important to recognise that humans behave strategically and respond to incentives in all domains of the economy including biosecurity – all inspection rules, by default, possess incentives for stakeholder compliance. Changes to rules are likely to provide impetus for behaviour change among import-supply chain participants and these changes may or may not meet the regulator's biosecurity objective: the rules could encourage importers to decrease the approach rate of biosecurity risk material in their consignments to reduce future inspection costs; or they could encourage compliance only until lower inspection frequency and intensity is achieved. A major challenge when designing adaptive, flexible and 'strategy-proof' protocols is to understand how importers and others in the supply chain may respond to the changes. If potential behavioural responses are not considered, the outcomes of rule changes may not align with the regulator's expectations.

A series of Australian government-initiated projects have been investigating the way compliance-based sampling regimes affect the incentives facing importers. While economic theory clarifies the incentive and information architecture needed to design appropriate inspection rules, designing implementable, incentive-compatible rules in the biosecurity context is complex and not well understood. Interviews with import-supply chain participants, statistical analysis of administrative data, laboratory experiments and a field trial have been used to assess a range of inspection protocols that harness importers' private information, utilize incentives and draw upon insights from behavioural economics to improve compliance with biosecurity objectives and reduce system costs.

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Ramirez Guzmán - Predictive phytosanitary model for quarantine pests

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Some relevant questions to guide the search for predictive phytosanitary models for quarantine pests are:

- What pests are likely to exceed zero detections?
- What are the high risk and low risk pests?
- What are the high risk geographical areas where the pest detections exceed expected detections?
- What is 100% sampling inspection?
- How to perform sampling inspection of high-risk and low-risk exporters involved in international trade?
- Is it worthwhile to perform a skip-lot sampling?
- Is the risk different at different ports, airports and land border ports?
- What high risk products are associated with pest detections?
- What phytosanitary inspection locations are hotspots for pest detections?

To answer these questions we propose an approach that consists of three steps:

1. Define risk statistically in order to establish a statistical methodology to estimate the probability of risky pests (ports, inspection offices, commodities, and geographical areas).

2. Establish two types of sampling – sampling 100% of shipments for high risk exporters/products, and continuous sampling (CSP-3) for low-risk importers/products.

3. Measure changes. To the extent that this approach focuses inspectional resources on the riskiest pests and develops more reliable/low risk exporters, it should result in cost and staff savings.

Statistical methods to estimate quarantine risk

The following regression models (see Appendix) are proposed for modeling count data with asymmetrical distribution and excess zeros, which characterize quarantine pest data (Figure 1). Poisson regression will be used for identifying the risky ports (McCullagh and Nelder, 1989). Negative binomial regression (NB) will be used to compare the incidence rate of several types of quarantine pests, and also to predict the expected number of detections as a function of the volume of imported products (Mullahy, 1986, McCullagh and Nelder, 1989). Hurdle regression will be used to identify the type of pests that exceed zero detections and the type of pests that have a probability of zero detections (Zeileis *et al*., 2008, Zeilis and Croissant, 2010). Several empirical Bayes estimates, structured additive Bayesian regression model (STAR) and conditional autoregressive model (hierarchical) will be used for producing a quarantine risk map (Marshall, 1991, Cressie, 1992, Best *et al*., 2005, Hodges and Reich, 2010, Klein *et al*, 2014).

Figure 1. Quarantine pest interception histograms for bacteria, fungi, insects, mites, mollusks, nematodes, protozoa, viroids, viruses, and weeds. Fifty four percent of data were zeros.

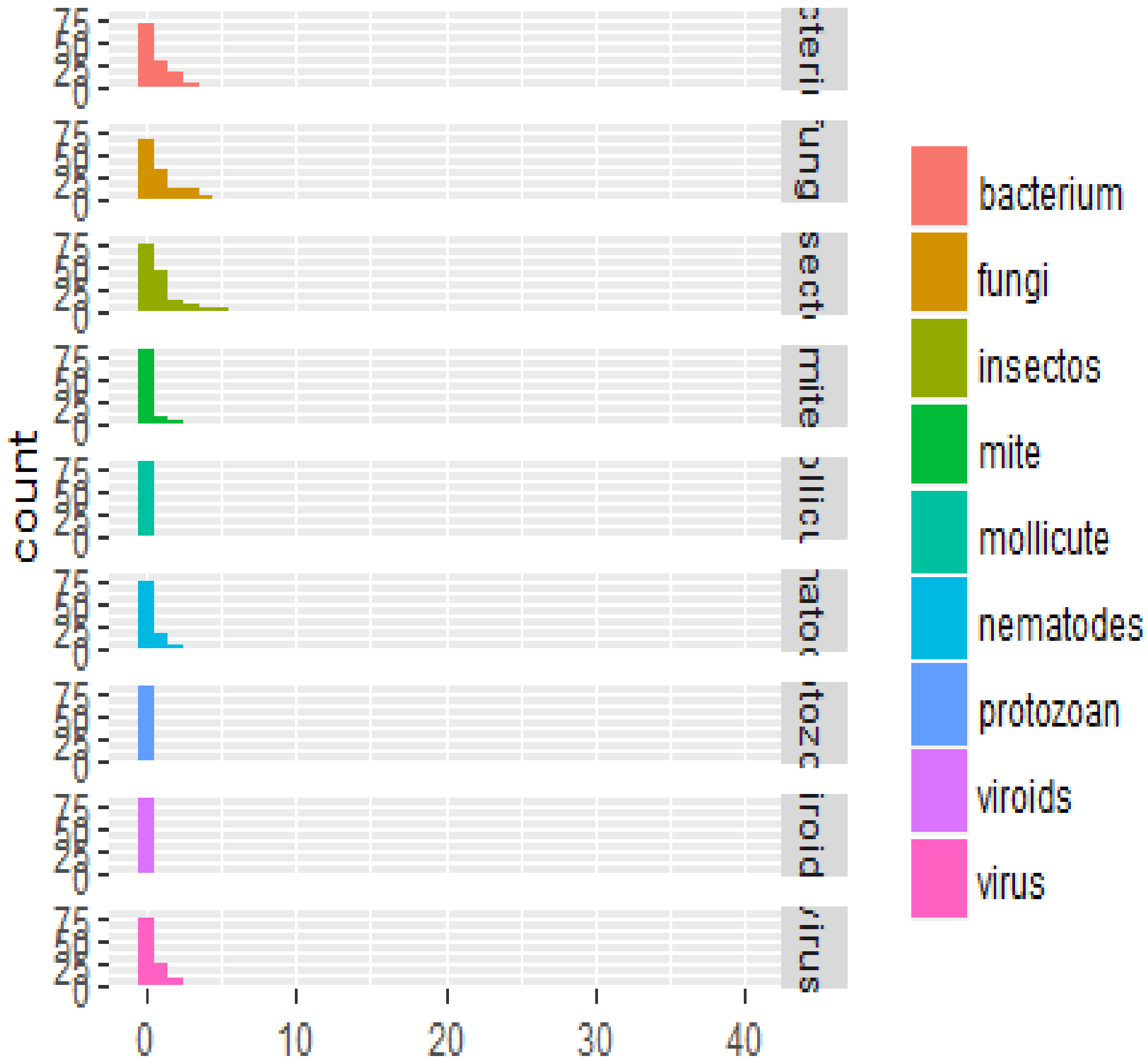
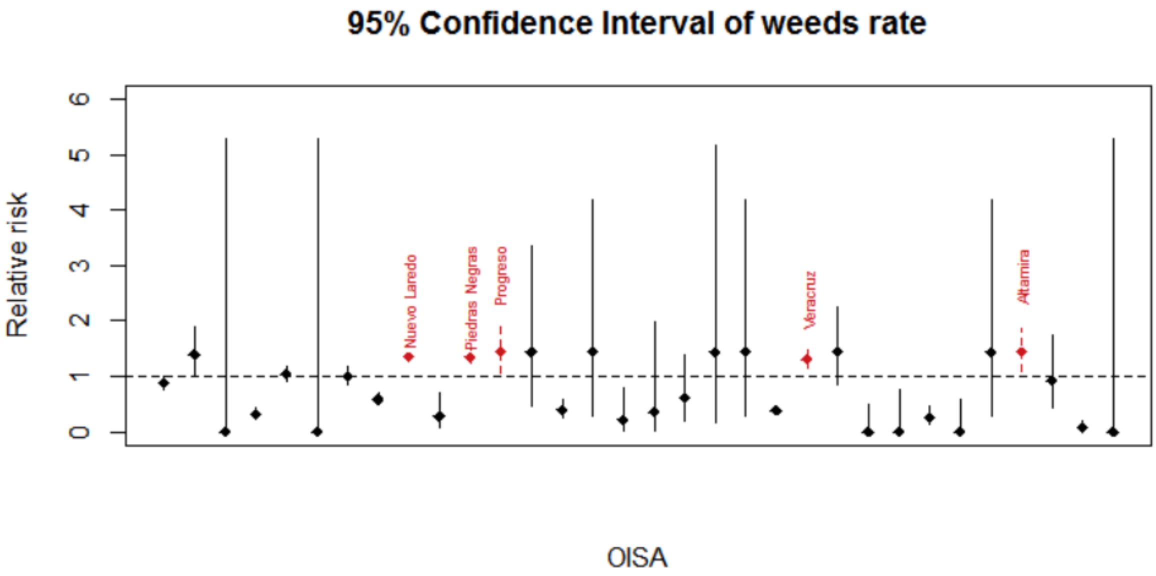


Figure 2. Relative risk =O/E where O= observed total detections and E= expected detections with Poisson distribution.



Sampling methods

Two types of sampling methods are proposed: a) 100% shipment inspection by sampling, for high-risk importers/products (at least one pest detection in the last three years); b) continuous sampling (CSP-3) for low risk importers/products (zero detections in the last three years or more) (Shilling, 1982).

Improvement measurement

In order to measure the effect of the first two steps of the methodology, it is proposed to compare the number of detections before and after application of the steps. Expected results are staff and cost savings that would result from a focus on risky pests, the development of reliable/low risk exporters, and the use of continuous sampling plan (CSP-3) for low risk exporters.

Results

Figure 2 above shows that Nuevo Laredo, Piedras Negras, Progreso, Veracruz y Altamira are the hot spot ports, given that the lower confidence limit exceeds 100% relative risk. This estimation was done with ***Poisson distribution***.

Table 1 below shows incidence rates for pathogens, type of entry and product based on ***NB regression***. Rates can be read as follows: The incidence rate for weeds is 6.55 times the incidence rate for the reference group of viruses, mites and mollusks (1.1). The incidence rate for entries is 17.43 times the incidence rate of airports (0.27). The incidence rate for barley is 8.93 times the incidence rate of garlic (1).

Table 1. Incidence rates for pathogens, type of entry and product.

Pathogens	
weeds	6.55
nematodes	2.04
fungi and bacteria	1.5
Viruses, mites and insects (reference group)	1.1
protozoa, viroids and mollusks	0.02

Type of entry	
Land border port	17.43
seaport	8.19
Airport (reference group)	0.27

Product	
barley	8.93
potato	7.81
linseed	7.72
lentil	7.11
oats	6.48
Garlic (reference group)	1

Hurdle regression (see Appendix) reported that weeds, fungi, insects, bacteria, viruses and nematodes had a probability of greater than zero P[Y>0], which indicates that a pest will be present. Once this probability is achieved, the expected intensity of detections is $E(Y)=\exp(X'\beta)$ which determines how many cases will be detected. Expected cases for these pests were 2.043, 1.668, 0.552, 0.499 and 0.481 for weeds, nematodes, bacteria, fungi and viruses, respectively.

In particular, weed relative risk maps (RR=O/E, O: observed pest detections, E: expected count detections) were elaborated with several empirical Bayes estimators (EB): EBPG (empirical Bayes estimator with Poisson distribution for likelihood and gamma for priori, without considering the spatial configuration) (Clayton and Kaldor, 1987), EBLN (empirical Bayes estimator with both likelihood and prior with lognormal distribution) (Clayton and Kaldor, 1987), EBMarshal (Marshall, 1991, who proposed an EB estimator without considering the spatial configuration of the small areas, only priors for mean and variance, EBMrshloc (Marshall, 1991, who proposed an EB estimator with considering the spatial configuration of the small areas). The last two consider the regional pattern of data through a neighborhood matrix (W). CarBayes, conditional autoregressive model with a neighborhood matrix (Lee and Richard Mitchell, 2012) and PGBayesX (Fahrmeir *et al.*, 2013 with spline functions with Poisson model for likelihood and gamma for a priori). The last one could be used to include climatic variables. Figure 3 shows that the best model is PGBayesX, given that it shows lower deviance information criterion (DIC) in contrast with CarBayes. Also, RR predictions of PGBayesX show a symmetrical distribution and the smallest mean square error (MSE). If RR exceeds 1 a high risk pest area has been identified. A risk map from the PGBayesX model shows that the Mexican states with a high risk of weed infiltration are Chihuahua and Sinaloa (40% of risk) and BCS, Tamaulipas and Sonora (35% of risk).

Figure 3. Prediction risk rates derived from empirical estimators, structural regression model and conditional autoregressive model.

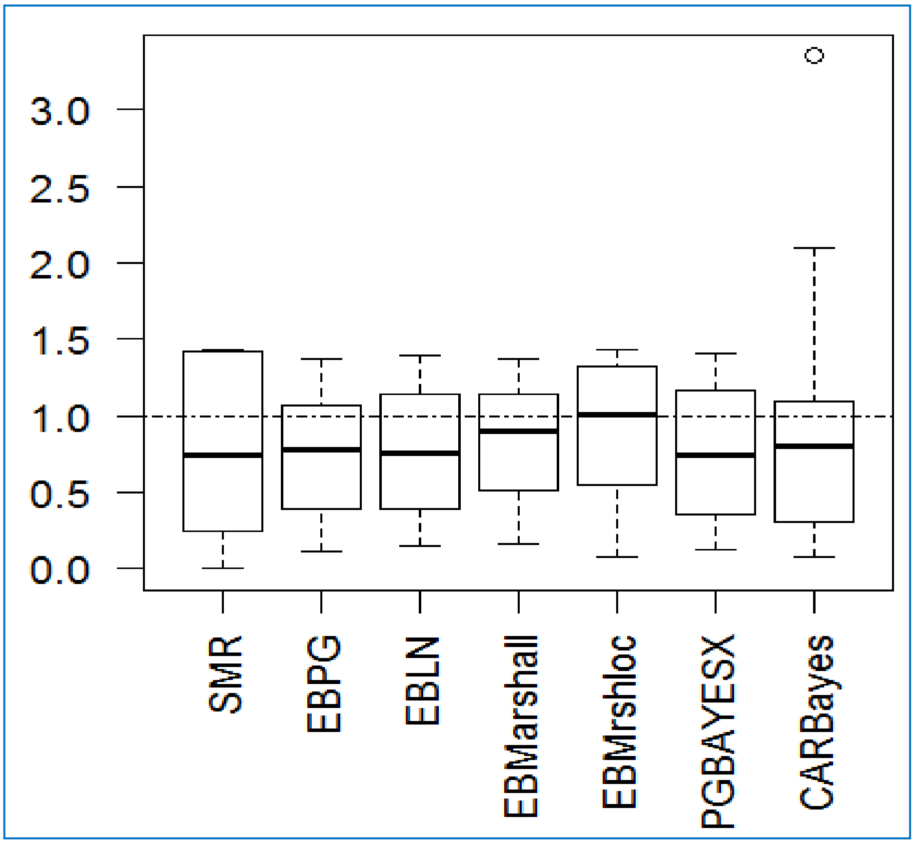
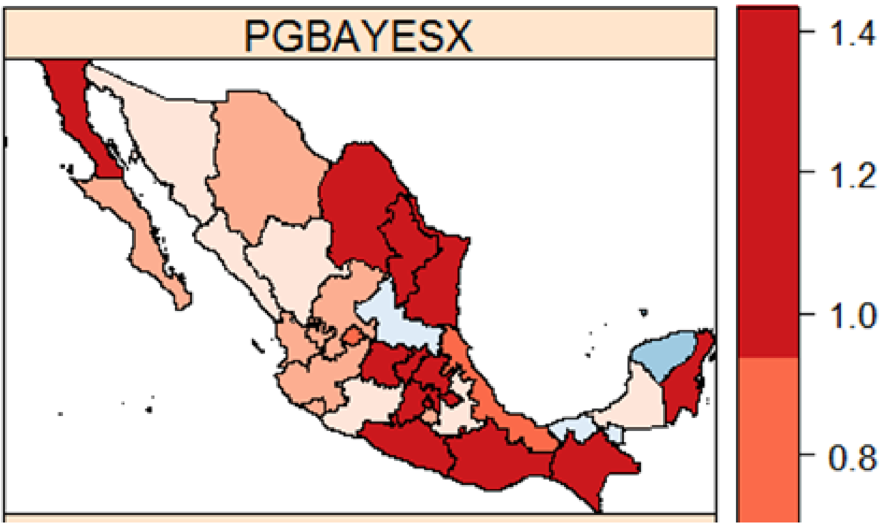


Figure 4. Prediction risk map for weeds.



Examples of sampling methods

Manuals for inspecting seeds, grains, fruits and vegetables, dehydrated products, cut flowers and fresh foliage, and propagative plant material can be found in Ramírez Guzmán and López Tirado (2006 and 2007). A Montecarlo simulation analysis based on implementing a CSP-3 scheme (Schilling, 1982) for low/risk importers in Mexico in 2013, demonstrated roughly 49.78% cost savings (in pesos). The analysis assumed continuous sampling for importers with at least 3 years of zero quarantine pest detections.

Conclusions

NB regression is recommended to estimate risk probability for quarantine pests. Hurdle regression would be useful to estimate the probability risk of exceeding a threshold of zero detections and to estimate the intensity of expected detections once the zero threshold has been crossed. Hurdle regression could be useful to measure effectiveness of stricter inspection controls. STAR models are a good option to represent graphical variation of the phytosanitary risk. It could be useful to propose a new norm in the Diario Oficial of Mexico to include NB, Hurdle and STAR regression models to monitor and represent quarantine pest risk geographically.

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- Poisson:
  $f(y_i/\underline{x_i}^T, \mu_i) = \frac{exp(-\mu_i)\mu_i^{y_i}}{y_i!}$; $E(y_i/\underline{x_i}^T) = \mu_i$
- BN:
  $f(y_i/\mu_i, \theta) = \frac{\Gamma(y_i+\theta)}{\Gamma(\theta)y_i!} \frac{\mu_i^y \theta^\theta}{(\mu_i+\theta)^{y+\theta}}$; $E(y_i/\underline{x_i}^T) = \mu_i$
- RIC:
  $f_{zero\_inflation}(y_i/\underline{x_i}^T, \underline{z_i}^T, \beta, \gamma) =$
  $f_{zero}(0/\underline{z_i}^T, \gamma)I_{\{0\}}(y_i) + (1 - f_{zero}(0/\underline{z_i}^T, \gamma)) \cdot f_{count}(y_i/\underline{x_i}^T, \beta)$
  $E\,(y_i/\,\underline{x_i}^T) = \pi_i \cdot 0 + (1 - \pi_i) \cdot exp(\underline{x_i}^T\beta); \pi_i = f_{zero}(0/\underline{z_i}^T, \gamma)$
- Hurdle:
  $f_{hurdle}(y_i/\underline{x_i}^T, \underline{z_i}^T, \beta, \gamma) =$
  $\begin{cases} f_{zero}(0/\underline{z_i}^T, \gamma), \text{ if } y_i = 0 \\ \frac{(1-f_{zero}(0/\underline{z_i}^T,\gamma))\cdot f_{count}(y_i/\underline{x_i}^T,\beta)}{(1-f_{count(0/\underline{xi}^T,\beta)})}, \text{ si } y_i > 0 \end{cases}$
  $E\,(y_i/\,\underline{x_i}^T) =$
  $exp\left[\underline{x_i}^T\beta + log(1 - f_{zero}(0/\underline{z_i}^T, \gamma)) - log(1 - f_{count}(0/\underline{x_i}^T, \beta))\right]$

- $SMR_i = O_i/E_i$ where $O_i \backsim P(E_i\theta_i)$, E_i is the number of cases in region i and θ_i is relative risk. $Var(SMR_i) = O_i/E_i^2$ It is less efficient for little population areas.

- EBPG: With Poisson model for likelihood and Gamma for apriori distribution to estimate the parameters: ν and α which smooths rr: $(O_i + \nu)/(E_i + \alpha)$

- EBLN: with log-Normal Model for both likelihood and apriori (Cressie, 1992). Same failure as EBPG.

- EBMarshall: It considers the regional patron of the data, however it has the same failure that the EBPG model.

- EBMarsloc: It considers the local regional pattern of the data.

- PGBAYESX (a Structured Additive Regresion models: STAR). A nonlinear GAM model for spatially correlated data with two-dimensional surfaces and heterogeneity among individuals.
  $\eta_r = X\beta + f_{spat}(AREA)$
  r Is a generic variable. Function f can contain non linear,spatial,global and local effects. Local effects as:
  $f_{spat}(AREA) = \beta_x$ where $\beta_x \sim N(0, \tau^2)$
  It does not include W.
- CARBayes: Conditional autoregresive model (hierarchical): Uses W of neighbors.
  $\eta(\mu_k) = X\beta + \phi_k + O_k$
  ϕ_k random effect, O_k offset (observations). This model captures the spatial local correlation of the data yet after removing the covariables effect. Conditioning is over random effects of the adjacent areas by means of (W).

Chunhua - Plant Quarantine Methodologies for Sampling utilized by the NPPO of China

Chunhua Dong

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The NPPO of China is organized into three main sections: General Administration of Quality Supervision, Inspection and Quarantine, China Inspection and Quality (AQSIQ – CIQ), the Ministry of Agriculture (MOA) and the State Forestry Administration (SFA). AQSIQ - CIQ) is the branch responsible for national import and export commodity inspection according to the laws of the People's Republic of China.

According to the guidance and methodologies contained in ISPM 23 and ISPM 31, China has developed sampling protocols for different plant commodities. Risk analysis informs pest tolerance levels. For seeds and plants for propagation, tolerance levels for regulated non-quarantine pests are negotiated bilaterally.

Inspectors in China are assigned to inspect commodities that have different levels of risk. Highest risk commodities are inspected by those that have more extensive professional background, a higher educational level, have deep knowledge of the rules and regulations and have ability to speak English

China has relevant laws and regulations, continually provides on-the-job inspection training for inspectors, develops sampling protocols that follow international standards, and employs a rigorous science-based sampling system.

García-Figuera and McRoberts - Cognitive mapping

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The keynote address was used to introduce a range of ideas that might be useful in studying barriers to the adoption of risk-based Sampling (RBS). The presentation drew in ideas from classical innovation diffusion theory, behavioral economics, and original research on information theory and its use in understanding trade-off functions between accuracy and simplicity in models of reality. This leads, naturally, to consider the mental models people construct to understand bits of the world, and the second half of the session was used for an audience participation exercise in cognitive mapping.

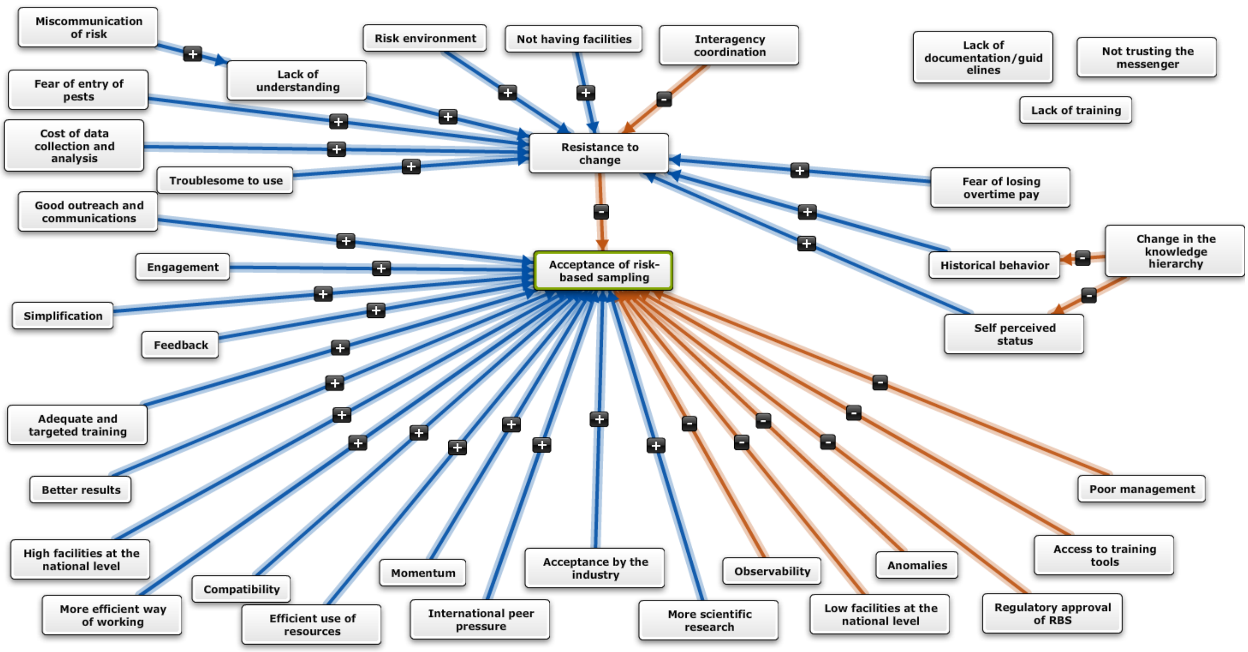
The audience was invited to participate in the development of a Fuzzy Cognitive Map (FCM) of drivers and constrains on the adoption of RBS. FCMs are graphical representations of complex systems based on people's perceptions, in which nodes represent events or concepts in the world, and edges represent causal connections between the nodes. The numerical values of the edges, usually in the interval [-1, 1], are the fuzzy weights, fuzzy degrees of belief or fuzzy entailments. Therefore, a FCM is a graphical summary of a set of causal statements ('if…then…') that can also be represented by a matrix, in which the elements e_{ij} would be the fuzzy weights of the edges between nodes n_i and n_j on the FCM (Kafetzis, McRoberts et al. 2010). Interestingly, the FCM matrix can then be used to analyse the system's behaviour through scenario simulations using matrix multiplications.

The FCM of RBS adoption was built live during the session with the aid of the software Mental Modeler (http://www.mentalmodeler.org/#home). After creating the central node 'Acceptance of risk-based sampling', the audience was invited to suggest any concepts (other nodes) that they thought would increase or decrease RBS adoption.

Original fuzzy cognitive map of the adoption of risk-based sampling

The original FCM that was created during the session (Figure 1) contained 37 nodes connected by 34 edges. Orange edges represented negative interactions ("if node A increases, node B decreases"); and blue edges represented positive interactions ("if node A increases, node B increases"). Positive edges were given a fuzzy weight of +1 and negative edges were given a fuzzy weight of -1. The FCM had a density of 0.026, with an average of 0.919 connections per component. The closeness of this last number to 1 reflects the fact that most nodes were connected to only one node, predominantly to one of the two central nodes: '**Acceptance of risk-based sampling**'; and '**Resistance to change'**, which was quickly identified as a key constraint in the adoption of RBS. Most of the nodes (29) were driver components, or nodes that cause an increase/decrease in other nodes but are not subject to any causal effect themselves. The emergence of so many driver nodes lacking connections among them was probably encouraged by the way the workshop was conducted. As people raised their hands in an open session, their suggestions for nodes that could be connected to RBS were captured on the FCM, leaving little time for thinking about possible connections between those nodes. The central node '**Acceptance of risk-based sampling'** was the only receiver component (not causing any increase/decrease on any other node, but receiving those interactions), and there were only 4 ordinary components (nodes driving and receiving interactions). These were '**Resistance to change**', '**Self perceived status'**, '**Historical behavior**' and '**Lack of understanding**'. Also due to the quick rate at which people suggested new nodes, there was barely enough time to capture all the suggested interactions, and three nodes were left without any connection: '**Lack of documentation/guidelines**'; **'Not trusting the messenger**' and '**Lack of training'**.

Figure 1: Original fuzzy cognitive map of the acceptance of risk-based sampling, built during the workshop. Orange edges represent negative interactions and blue edges represent positive interactions.



The cognitive map of RBS adoption shown on Figure 1 was left on the screen to stimulate group discussions, while the matrix associated with the FCM was downloaded to conduct a simulation. This matrix, which comprised the fuzzy weights of the edges between nodes, was multiplied by a vector of initial node states, in which nodes that were active corresponded to a 1 and nodes that were inactive corresponded to a 0. Subsequent matrix multiplications simulated the dynamics of the system (Kafetzis, McRoberts et al. 2010, Ortolani, McRoberts et al. 2010). The objective of this simulation was to predict the impact that the nodes would have on the acceptance of risk-based sampling.

Within the time available in the session, the first simulation (Figure 2) considered a scenario in which all of the nodes were initially active, except for the central node '**Acceptance of risk-based sampling**'. The aim of this simulation was to test whether the existence of all the nodes related to RBS, and their associated causal interactions, predicted an activation of the acceptance of RBS, indicated by a positive value in its corresponding cell; or a rejection, indicated by a negative value. The vector of initial states (the blue column on Figure 2) was multiplied by the FCM matrix, and the result vector is shown on the third column on Figure 2, labelled as Cycle 1. In the following step, the vector from Cycle 1 was multiplied by the FCM matrix, and the result vector is shown under Cycle 2. Subsequent matrix multiplications were repeated until a limit cycle (a repetitive pattern) was reached, in this case on Cycle 4. For easier interpretation, any value above 0 in the cells of the result vectors (representing an increase in the activity of the corresponding node, or an upregulation) was converted to a value of 1, and the cells were green. Negative values (decrease in activity or downregulation) were converted to a value of -1 and the cells were red. Cells with a value of 0, corresponding to nodes that were deactivated for that cycle, are shown in grey.

Figure 2: Results of the first simulation using the original version of the FCM of RBS adoption. All of the nodes except for 'Acceptance of RBS' are activated in the vector of initial states (blue column) and the system is allowed to freely change according to the interactions captured in the model. Nodes that are upregulated in a specific cycle are shown in red and nodes that are downregulated are shown in red. Nodes that are deactivated are shown in grey.

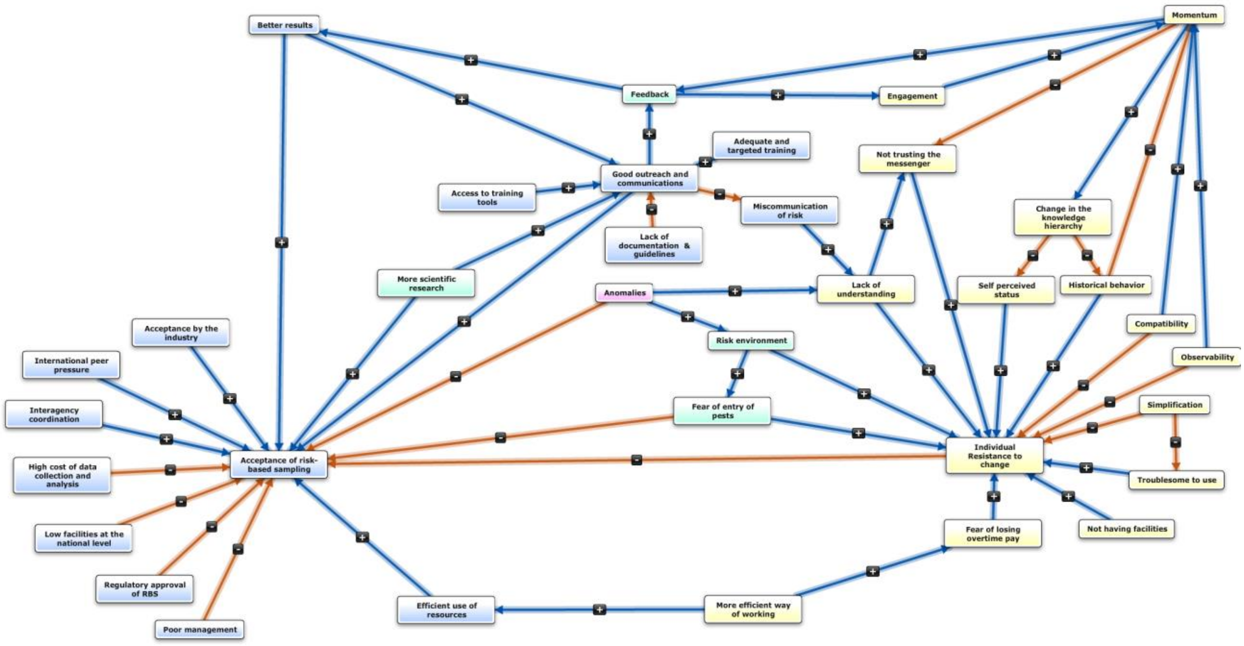
		Cycle 1	Cycle 2	Cycle 3	Cycle 4	Cycle 5	Cycle 6	Cycle 7	Cycle 8	Cycle 9	Cycle 10
Acceptance of risk-based sampling	0	1	-1	1	0	0	0	0	0	0	0
Resistance to change	1	1	-1	0	0	0	0	0	0	0	0
Lack of understanding	1	1	0	0	0	0	0	0	0	0	0
Adequate and targeted training	1	0	0	0	0	0	0	0	0	0	0
Fear of losing overtime pay	1	0	0	0	0	0	0	0	0	0	0
Troublesome to use	1	0	0	0	0	0	0	0	0	0	0
Miscommunication of risk	1	0	0	0	0	0	0	0	0	0	0
Not having facilities	1	0	0	0	0	0	0	0	0	0	0
Historical behavior	1	-1	0	0	0	0	0	0	0	0	0
Change in the knowledge hierarchy	1	0	0	0	0	0	0	0	0	0	0
Compatibility	1	0	0	0	0	0	0	0	0	0	0
Observability	1	0	0	0	0	0	0	0	0	0	0
Self perceived status	1	-1	0	0	0	0	0	0	0	0	0
Cost of data collection and analysis	1	0	0	0	0	0	0	0	0	0	0
Fear of entry of pests	1	0	0	0	0	0	0	0	0	0	0
Not trusting the messenger	1	0	0	0	0	0	0	0	0	0	0
Lack of training	1	0	0	0	0	0	0	0	0	0	0
Lack of documentation/guidelines	1	0	0	0	0	0	0	0	0	0	0
Better results	1	0	0	0	0	0	0	0	0	0	0
More efficient way of working	1	0	0	0	0	0	0	0	0	0	0
Feedback	1	0	0	0	0	0	0	0	0	0	0
Engagement	1	0	0	0	0	0	0	0	0	0	0
International peer pressure	1	0	0	0	0	0	0	0	0	0	0
More scientific research	1	0	0	0	0	0	0	0	0	0	0
High facilities at the national level	1	0	0	0	0	0	0	0	0	0	0
Low facilities at the national level	1	0	0	0	0	0	0	0	0	0	0
Acceptance by the industry	1	0	0	0	0	0	0	0	0	0	0
Poor management	1	0	0	0	0	0	0	0	0	0	0
Access to training tools	1	0	0	0	0	0	0	0	0	0	0
Good outreach and communications	1	0	0	0	0	0	0	0	0	0	0
Regulatory approval of RBS	1	0	0	0	0	0	0	0	0	0	0
Anomalies	1	0	0	0	0	0	0	0	0	0	0
Momentum	1	0	0	0	0	0	0	0	0	0	0
Risk environment	1	0	0	0	0	0	0	0	0	0	0
Interagency coordination	1	0	0	0	0	0	0	0	0	0	0
Simplification	1	0	0	0	0	0	0	0	0	0	0
Efficient use of resources	1	0	0	0	0	0	0	0	0	0	0

The results of the first simulation, shown on Figure 2, suggest that, if all of the concepts represented by the nodes do exist, and cause the positive or negative effects captured in the model, the acceptance of RBS would be initially activated in Cycle 1, then deactivated for the following cycle, activated once more on Cycle 3, and then it would be deactivated, as the rest of the nodes, from Cycle 4 onwards. Therefore, the simulation suggests that positive interactions leading to the activation of RBS predominate over negative interactions, but there are not enough connections between the nodes to prevent the inactivation of the whole system after Cycle 4. In order for the model to closer match reality, and provide more valuable predictions, the FCM would have to be refined, possibly grouping related nodes and establishing causal connections between them.

Second version of the fuzzy cognitive map of the adoption of risk-based sampling

Consequently, the original FCM of the adoption of risk-based sampling was refined into a second version after the workshop. The nodes and causal relations that were suggested during the session were rearranged to better reflect the interactions that exist between concepts related to the adoption of RBS. The new version is shown on Figure 3.

Figure 3: Second version of the fuzzy cognitive map of the acceptance of risk-based sampling. Orange edges represent negative interactions and blue edges represent positive interactions. Concepts that operate on individual perceptions/behavior are represented by yellow nodes; on an institutional level by blue nodes; and on both by green nodes. The pink node was identified as an emergent property.



Nodes were separated into two main groups, based on expert judgement, on whether they operated on individual perceptions/behavior (yellow nodes) or at an institutional level (blue nodes). Some concepts (green nodes) applied to both, and one node (‘**Anomalies**’, or spurious sampling results) was identified as an emergent property (pink node). The number of nodes was reduced from 37 in the original FCM (Figure 1) to 35 in this new version (Figure 3); and the number of edges was increased from 34 to 52, resulting in a density of 0.044 (instead of 0.026 in the original version) and an average of 1.486 connections per component (as opposed to 0.919). Thus, this second version of the model had more connections between nodes than the original. Also, the new model had 17 driver components, 1 receiver component (the central node ‘**Acceptance of risk-based sampling**’) and 17 ordinary components. The complexity score in this second version was 0.059.

Again, a simulation was run in order to test whether the second version of the model predicted an activation of the acceptance of risk-based sampling, if the rest of the nodes were initially active. Results are shown on Figure 4, and indicate that under these conditions, RBS acceptance would be inactive in Cycle 1, downregulated in Cycle 2, deactivated in Cycle 3; and then it would be irreversibly upregulated from Cycle 4 onwards. Therefore, the simulation with the second version of the model suggests that, even if it might take some time, risk-based sampling would finally be adopted if all of the nodes and the interactions captured in the model existed and were all operating from the onset of the regulation. Interestingly, the simulation also predicts that seven additional nodes would be constantly upregulated after Cycle 4, corresponding to ‘**Change in the knowledge hierarchy**’, **‘Better results**’, ‘**Feedback**’, ‘**Engagement**’, ‘**Good outreach and communications**’ and ‘**Momentum**’. Therefore, these might be important elements to consider when trying to promote the adoption of risk-based sampling. On the other hand, six nodes are predicted to be constantly downregulated from Cycle 3 onwards: ‘**Individual resistance to change**’, ‘**Lack of understanding**’, ‘**Miscommunication of risk**’, ‘**Historical behavior**’, ‘**Self perceived status**’ and ‘**Not trusting the messenger**’. Consequently, it might be important to act on these nodes to favor the adoption of RBS. Finally, an elevated number of nodes were only connected by one causal relation to another node and they were deactivated after one cycle. This could indicate either that they would not have any relevant influence on the adoption of RBS; or that the model is still missing connections between nodes that are present.

Summarizing, we interpret these results as confirming that adoption of RBS (in the collective opinion of workshop participants) is likely to depend on an active process of communicating its benefits, while changing the existing culture within the target populations. Crucially, this is not the sort of thing that can be achieved simply by filling a knowledge gap. It requires active engagement with the adopting populations.

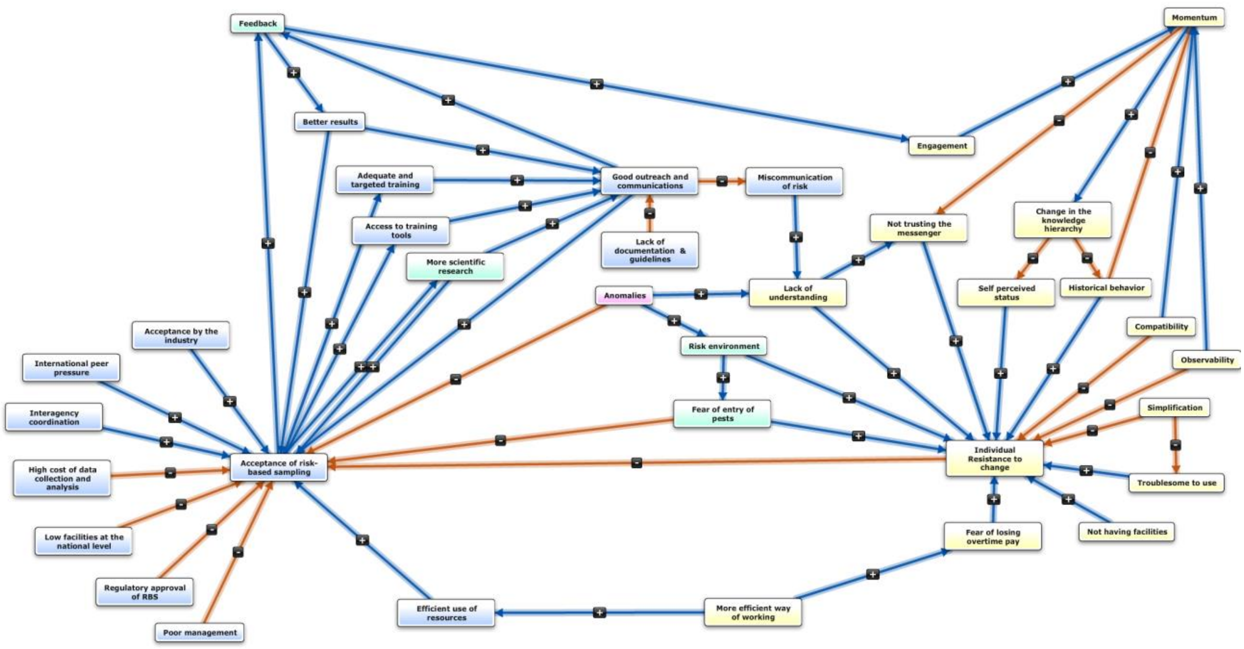
Figure 4**:** Results of the first simulation using the second version of the FCM of RBS adoption. All of the nodes except for 'Acceptance of RBS' are activated in the vector of initial states (blue column) and the system is allowed to freely change according to the interactions captured in the model. Nodes that are upregulated in a specific cycle are shown in green and nodes that are downregulated are shown in red. Nodes that are deactivated are shown in grey.

		Cycle 1	Cycle 2	Cycle 3	Cycle 4	Cycle 5	Cycle 6	Cycle 7	Cycle 8	Cycle 9	Cycle 10
Acceptance of risk-based sampling	0	0	-1	0	1	1	1	1	1	1	1
Individual Resistance to change	1	1	1	-1	-1	-1	-1	-1	-1	-1	-1
Lack of understanding	1	1	-1	-1	-1	-1	-1	-1	-1	-1	-1
Adequate and targeted training	1	0	0	0	0	0	0	0	0	0	0
Fear of losing overtime pay	1	1	0	0	0	0	0	0	0	0	0
Troublesome to use	1	-1	0	0	0	0	0	0	0	0	0
Miscommunication of risk	1	-1	-1	-1	-1	-1	-1	-1	-1	-1	-1
Not having facilities	1	0	0	0	0	0	0	0	0	0	0
Historical behavior	1	-1	-1	-1	-1	-1	-1	-1	-1	-1	-1
Change in the knowledge hierarchy	1	1	1	1	1	1	1	1	1	1	1
Compatibility	1	0	0	0	0	0	0	0	0	0	0
Self perceived status	1	-1	-1	-1	-1	-1	-1	-1	-1	-1	-1
High cost of data collection and analysis	1	0	0	0	0	0	0	0	0	0	0
Fear of entry of pests	1	1	1	0	0	0	0	0	0	0	0
Not trusting the messenger	1	0	0	-1	-1	-1	-1	-1	-1	-1	-1
Lack of documentation & guidelines	1	0	0	0	0	0	0	0	0	0	0
Better results	1	1	1	1	1	1	1	1	1	1	1
More efficient way of working	1	0	0	0	0	0	0	0	0	0	0
Feedback	1	1	1	1	1	1	1	1	1	1	1
Engagement	1	1	1	1	1	1	1	1	1	1	1
International peer pressure	1	0	0	0	0	0	0	0	0	0	0
More scientific research	1	0	0	0	0	0	0	0	0	0	0
Low facilities at the national level	1	0	0	0	0	0	0	0	0	0	0
Acceptance by the industry	1	0	0	0	0	0	0	0	0	0	0
Poor management	1	0	0	0	0	0	0	0	0	0	0
Access to training tools	1	0	0	0	0	0	0	0	0	0	0
Good outreach and communications	1	1	1	1	1	1	1	1	1	1	1
Regulatory approval of RBS	1	0	0	0	0	0	0	0	0	0	0
Anomalies	1	0	0	0	0	0	0	0	0	0	0
Momentum	1	1	1	1	1	1	1	1	1	1	1
Risk environment	1	1	0	0	0	0	0	0	0	0	0
Interagency coordination	1	0	0	0	0	0	0	0	0	0	0
Simplification	1	0	0	0	0	0	0	0	0	0	0
Efficient use of resources	1	1	0	0	0	0	0	0	0	0	0
Observability	1	0	0	0	0	0	0	0	0	0	0

Third version of the fuzzy cognitive map of the adoption of risk-based sampling

In a further attempt to refine the model, a third version of the FCM was created to incorporate drivers from the institutional side to the individual side, as shown on Figure 5.

Figure 5**:** Third version of the fuzzy cognitive map of the acceptance of risk-based sampling. Orange edges represent negative interactions and blue edges represent positive interactions. Concepts that operate on individual perceptions/behavior are represented by yellow nodes; on an institutional level by blue nodes; and on both by green nodes. The pink node was identified as an emergent property.



This third version of the model had the same 35 nodes of the second version, but the total number of edges was increased from 52 to 55, and edges were rearranged to favor more connections, resulting in a slightly higher density (0.046) and a higher number of connections per component (1.571) than the second version. The number of ordinary components (driving and receiving interactions) was increased from 17 to 21; and consequently, the number of driver components was reduced from 17 to 14. The central node '**Acceptance of risk based sampling**' was transformed from a receiving to an ordinary component.

Simulations were run again to test whether this third version of the model predicted an activation of the **Acceptance of risk-based sampling** if the rest of the nodes were initially active. An additional objective was to identify what other nodes would be constantly up- or down-regulated once RBS is irreversibly upregulated. The results of this simulation, shown in Figure 6, were very similar to those shown in Figure 4. '**Acceptance of RBS**' was upregulated from Cycle 4 onwards, together with '**Change in the knowledge hierarchy'**, '**Better results**', '**Feedback', 'Engagement**', '**Good outreach and communications**' and '**Momentum**'. Interestingly, three additional nodes followed the same pattern: '**Adequate and targeted training**', '**More scientific research**' and '**Access to training tools**', highlighting the importance of these concepts for the acceptance of RBS. As in Figure 4, '**Individual resistance to change**', '**Lack of understanding**', '**Miscommunication of risk**', '**Historical behavior**', '**Self perceived status**' and '**Not trusting the messenger**' were constantly downregulated once the system reached a repetitive pattern. However, unlike in Figure 4, this did not happen until Cycle 9. A plausible interpretation of this delay is that it might take longer than was estimated in the second version of the model to downregulate some of the obstacles to the adoption of risk-based sampling. A significant number of nodes were again deactivated after Cycle 1. Some of these inactive nodes, including '**Not having facilities**', '**High cost of data collection and analysis**' and **'Lack of documentation and guidelines**' might be useful targets for intervention to favor the acceptance of risk-based sampling.

Figure 6: Results of the first simulation using the third version of the FCM of RBS adoption. All of the nodes except for 'Acceptance of RBS' are activated in the vector of initial states (blue column) and the system is allowed to freely change according to the interactions captured in the model. Nodes that are upregulated in a specific cycle are shown in green and nodes that are downregulated are shown in red. Nodes that are deactivated are shown in grey.

		Cycle 1	Cycle 2	Cycle 3	Cycle 4	Cycle 5	Cycle 6	Cycle 7	Cycle 8	Cycle 9	Cycle 10
Acceptance of risk-based sampling	0	0	-1	-1	1	1	1	1	1	1	1
Individual Resistance to change	1	1	1	-1	-1	-1	-1	-1	1	-1	-1
Lack of understanding	1	1	-1	-1	-1	-1	1	1	-1	-1	-1
Adequate and targeted training	1	0	0	-1	-1	1	1	1	1	1	1
Fear of losing overtime pay	1	1	0	0	0	0	0	0	0	0	0
Troublesome to use	1	-1	0	0	0	0	0	0	0	0	0
Miscommunication of risk	1	-1	-1	-1	-1	1	1	-1	-1	-1	-1
Not having facilities	1	0	0	0	0	0	0	0	0	0	0
Historical behavior	1	-1	-1	-1	-1	-1	-1	-1	-1	-1	-1
Change in the knowledge hierarchy	1	1	1	1	1	1	1	1	1	1	1
Compatibility	1	0	0	0	0	0	0	0	0	0	0
Self perceived status	1	-1	-1	-1	-1	-1	-1	-1	-1	-1	-1
High cost of data collection and analysis	1	0	0	0	0	0	0	0	0	0	0
Fear of entry of pests	1	1	1	0	0	0	0	0	0	0	0
Not trusting the messenger	1	0	0	-1	-1	-1	-1	1	-1	-1	-1
Lack of documentation & guidelines	1	0	0	0	0	0	0	0	0	0	0
Better results	1	1	1	1	-1	0	1	1	1	1	1
More efficient way of working	1	0	0	0	0	0	0	0	0	0	0
Feedback	1	1	1	-1	0	1	1	1	1	1	1
Engagement	1	1	1	1	-1	0	1	1	1	1	1
International peer pressure	1	0	0	0	0	0	0	0	0	0	0
More scientific research	1	0	0	-1	-1	1	1	1	1	1	1
Low facilities at the national level	1	0	0	0	0	0	0	0	0	0	0
Acceptance by the industry	1	0	0	0	0	0	0	0	0	0	0
Poor management	1	0	0	0	0	0	0	0	0	0	0
Access to training tools	1	0	0	-1	-1	1	1	1	1	1	1
Good outreach and communications	1	1	1	1	-1	-1	1	1	1	1	1
Regulatory approval of RBS	1	0	0	0	0	0	0	0	0	0	0
Anomalies	1	0	0	0	0	0	0	0	0	0	0
Momentum	1	1	1	1	1	1	1	1	1	1	1
Risk environment	1	1	0	0	0	0	0	0	0	0	0
Interagency coordination	1	0	0	0	0	0	0	0	0	0	0
Simplification	1	0	0	0	0	0	0	0	0	0	0
Efficient use of resources	1	1	0	0	0	0	0	0	0	0	0
Observability	1	0	0	0	0	0	0	0	0	0	0

Additional simulations were run with the third version of the model to test the influence that the initial activation or deactivation of certain nodes would have on the dynamics of the system. For example, if RBS is not assumed to produce better results from the beginning (i.e., **'Better results'** is not activated in the vector of initial states), the dynamics of the system are completely changed. As Figure 7 shows, '**Acceptance of risk-based sampling**' and the other 'favorable' nodes that were upregulated in Cycle 10 of Figure 6 are downregulated in Figure 7, and the 'unfavorable' nodes that were downregulated in Figure 6 are upregulated in Figure 7. This highlights the importance of the early and effective communication of the advantages of RBS and could lead to a discussion about how results are measured, and the criteria that are used to evaluate whether results are 'better' or 'worse'.

Figure 7: Results of the second simulation using the third version of the FCM of RBS adoption. All of the nodes except for 'Acceptance of RBS' and 'Better results' are activated in the vector of initial states (blue column) and the system is allowed to freely change according to the interactions captured in the model. Nodes that are upregulated in a specific cycle are shown in green and nodes that are downregulated are shown in red. Nodes that are deactivated are shown in grey.

		Cycle 1	Cycle 2	Cycle 3	Cycle 4	Cycle 5	Cycle 6	Cycle 7	Cycle 8	Cycle 9	Cycle 10
Acceptance of risk-based sampling	0	-1	-1	-1	-1	-1	-1	-1	-1	-1	-1
Individual Resistance to change	1	1	1	-1	-1	-1	-1	1	1	1	1
Lack of understanding	1	1	-1	-1	-1	1	1	1	1	1	1
Adequate and targeted training	1	0	-1	-1	-1	-1	-1	-1	-1	-1	-1
Fear of losing overtime pay	1	1	0	0	0	0	0	0	0	0	0
Troublesome to use	1	-1	0	0	0	0	0	0	0	0	0
Miscommunication of risk	1	-1	-1	-1	1	1	1	1	1	1	1
Not having facilities	1	0	0	0	0	0	0	0	0	0	0
Historical behavior	1	-1	-1	-1	-1	-1	-1	0	1	1	1
Change in the knowledge hierarchy	1	1	1	1	1	1	0	-1	-1	-1	-1
Compatibility	1	0	0	0	0	0	0	0	0	0	0
Self perceived status	1	-1	-1	-1	-1	-1	-1	0	1	1	1
High cost of data collection and analysis	1	0	0	0	0	0	0	0	0	0	0
Fear of entry of pests	1	1	1	0	0	0	0	0	0	0	0
Not trusting the messenger	1	0	0	-1	-1	-1	1	1	1	1	1
Lack of documentation & guidelines	1	0	0	0	0	0	0	0	0	0	0
Better results	0	1	1	1	-1	-1	-1	-1	-1	-1	-1
More efficient way of working	1	0	0	0	0	0	0	0	0	0	0
Feedback	1	1	1	-1	-1	-1	-1	-1	-1	-1	-1
Engagement	1	1	1	1	-1	-1	-1	-1	-1	-1	-1
International peer pressure	1	0	0	0	0	0	0	0	0	0	0
More scientific research	1	0	-1	-1	-1	-1	-1	-1	-1	-1	-1
Low facilities at the national level	1	0	0	0	0	0	0	0	0	0	0
Acceptance by the industry	1	0	0	0	0	0	0	0	0	0	0
Poor management	1	0	0	0	0	0	0	0	0	0	0
Access to training tools	1	0	-1	-1	-1	-1	-1	-1	-1	-1	-1
Good outreach and communications	1	1	1	-1	-1	-1	-1	-1	-1	-1	-1
Regulatory approval of RBS	1	0	0	0	0	0	0	0	0	0	0
Anomalies	1	0	0	0	0	0	0	0	0	0	0
Momentum	1	1	1	1	1	0	-1	-1	-1	-1	-1
Risk environment	1	1	0	0	0	0	0	0	0	0	0
Interagency coordination	1	0	0	0	0	0	0	0	0	0	0
Simplification	1	0	0	0	0	0	0	0	0	0	0
Efficient use of resources	1	1	0	0	0	0	0	0	0	0	0
Observability	1	0	0	0	0	0	0	0	0	0	0

During the discussions, the establishment of a feedback loop from the practice of risk-based sampling at the borders to the regulatory authorities was stressed as one of the key elements for the acceptance and success of RBS. Therefore, we simulated a scenario in which the node **'Feedback'** was initially inactive, to test the influence that it would have on the acceptance of RBS. The results of this simulation are shown on Figure 8. According to our model, if feedback is not provided from the beginning of the program (i.e., the vector of initial states), the system fluctuates between the up- and downregulation of the acceptance of RBS, but ultimately reaches a repetitive pattern on Cycle 21. From this cycle onwards, RBS is downregulated together with other 'favorable' nodes. Therefore, the establishment of feedback loops seems to be crucial for the long-term adoption of RBS, according to the model.

RBS is also irreversibly downregulated on Cycle 8 if the node **'Good outreach and communications'** is not initially active (results not shown).

Additional simulations showed that if risk-based sampling were understood from the beginning ('**Lack of understanding'** is initially inactive), the acceptance of RBS would be still upregulated from Cycle 4 onwards, as if all of the nodes were initially active (shown on Figure 6).

Figure 8: Results of the third simulation using the third version of the FCM of RBS adoption. All nodes except for 'Acceptance of RBS' and 'Feedback' are activated in the vector of initial states (blue column) and the system is allowed to freely change according to the interactions captured in the model. Nodes that are upregulated in a specific cycle are shown in green and nodes that are downregulated are shown in red. Nodes that are deactivated are shown in grey.

		Cycle 1	Cycle 2	Cycle 3	Cycle 4	Cycle 5	Cycle 6	Cycle 7	Cycle 8	Cycle 9	Cycle 10	Cycle 11	Cycle 12	Cycle 13	Cycle 14	Cycle 15	Cycle 16	Cycle 17	Cycle 18	Cycle 19	Cycle 20	Cycle 21	Cycle 22
Acceptance of risk-based sampling	0	0	-1	-1	1	-1	0	1	-1	-1	1	-1	-1	1	-1	-1	-1	-1	-1	-1	-1	-1	-1
Individual Resistance to change	1	1	1	-1	-1	-1	-1	-1	1	-1	1	1	-1	1	1	-1	1	1	-1	1	1	1	1
Lack of understanding	1	1	-1	-1	0	-1	1	1	-1	1	1	-1	1	1	-1	1	1	-1	1	1	-1	1	1
Adequate and targeted training	1	0	0	-1	-1	1	-1	0	1	-1	-1	1	-1	-1	1	-1	-1	-1	-1	-1	-1	-1	-1
Fear of losing overtime pay	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Troublesome to use	1	-1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Miscommunication of risk	1	-1	-1	0	-1	1	1	-1	1	1	-1	1	1	-1	1	1	-1	1	1	-1	1	1	1
Not having facilities	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Historical behavior	1	-1	-1	-1	-1	-1	-1	1	-1	-1	1	-1	-1	1	-1	1	1	-1	1	1	-1	1	1
Change in the knowledge hierarchy	1	1	1	1	1	1	-1	1	1	-1	1	1	-1	1	-1	-1	1	-1	-1	1	-1	-1	-1
Compatibility	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Self perceived status	1	-1	-1	-1	-1	-1	-1	1	-1	-1	1	-1	-1	1	-1	1	1	-1	1	1	-1	1	1
High cost of data collection and analysis	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Fear of entry of pests	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Not trusting the messenger	1	0	0	-1	-1	-1	1	1	1	1	0	1	-1	-1	1	1	1	1	1	1	1	1	1
Lack of documentation & guidelines	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Better results	1	0	1	1	-1	-1	-1	-1	1	1	-1	1	-1	-1	1	-1	-1	1	-1	-1	-1	-1	-1
More efficient way of working	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Feedback	0	1	1	-1	-1	-1	-1	1	1	-1	1	-1	-1	1	-1	-1	1	-1	-1	-1	-1	-1	-1
Engagement	1	0	1	1	-1	-1	-1	-1	1	1	-1	1	-1	-1	1	-1	-1	1	-1	-1	-1	-1	-1
International peer pressure	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
More scientific research	1	0	0	-1	-1	1	-1	0	1	-1	-1	1	-1	-1	1	-1	-1	-1	-1	-1	-1	-1	-1
Low facilities at the national level	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Acceptance by the industry	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Poor management	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Access to training tools	1	0	0	-1	-1	1	-1	0	1	-1	-1	1	-1	-1	1	-1	-1	-1	-1	-1	-1	-1	-1
Good outreach and communications	1	1	0	1	-1	-1	1	-1	-1	1	-1	-1	1	-1	-1	1	-1	-1	1	-1	-1	-1	-1
Regulatory approval of RBS	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Anomalies	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Momentum	1	1	1	1	1	-1	1	1	-1	1	1	-1	1	-1	-1	1	-1	-1	1	-1	-1	-1	-1
Risk environment	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Interagency coordination	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Simplification	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Efficient use of resources	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Observability	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Finally, we conducted '**press experiments'**, in which nodes in the vector that is multiplied by the FCM matrix are artificially maintained in an active or inactive state, instead of being free to change state according to the inherent dynamics of the system. As a first approach, these press experiments focused on those nodes that became inactive after one cycle on Figure 6 and tested whether their permanent activation would change the dynamics represented on Figure 6.

For example, if '**High cost of data collection and analysis**' were forced to be permanently activated (Figure 9, the node '**Acceptance of risk-based sampling**' would not be permanently upregulated until Cycle 18, representing a significant delay from Figure 6 (in which this happened on Cycle 4). Therefore, the simulation suggests that it would be important to reduce the costs associated with the implementation of RBS as soon as possible to promote an earlier acceptance.

Figure 9**:** Results of the press experiment using the third version of the FCM of RBS adoption. All of the nodes except for 'Acceptance of RBS' are activated in the vector of initial states (blue column) and the node 'High cost of data collection and analysis' is kept in an active state. Nodes that are upregulated in a specific cycle are shown in green and nodes that are downregulated are shown in red. Nodes that are deactivated are shown in grey.

		Cycle 1	Cycle 2	Cycle 3	Cycle 4	Cycle 5	Cycle 6	Cycle 7	Cycle 8	Cycle 9	Cycle 10	Cycle 11	Cycle 12	Cycle 13	Cycle 14	Cycle 15	Cycle 16	Cycle 17	Cycle 18	Cycle 19	Cycle 20	Cycle 21	Cycle 22	Cycle 23	Cycle 24	Cycle 25
Acceptance of risk-based sampling	0	0	-1	-1	1	-1	1	1	-1	0	1	-1	1	1	-1	1	1	-1	1	1	1	1	1	1	1	1
Individual Resistance to change	1	1	1	-1	-1	-1	-1	-1	1	0	1	1	-1	1	1	-1	1	1	-1	1	-1	-1	-1	-1	-1	-1
Lack of understanding	1	1	-1	-1	-1	-1	1	1	-1	1	1	-1	1	1	-1	1	-1	-1	1	-1	-1	1	-1	-1	-1	-1
Adequate and targeted training	1	0	0	-1	-1	1	-1	1	1	-1	0	1	-1	1	1	-1	1	1	-1	1	1	1	1	1	1	1
Fear of losing overtime pay	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Troublesome to use	1	-1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Miscommunication of risk	1	-1	-1	-1	-1	1	1	-1	1	1	-1	1	1	-1	1	-1	-1	1	-1	-1	1	-1	-1	-1	-1	-1
Not having facilities	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Historical behavior	1	-1	-1	-1	-1	-1	-1	0	-1	-1	1	-1	-1	1	-1	-1	1	-1	1	1	-1	1	1	-1	-1	-1
Change in the knowledge hierarchy	1	1	1	1	1	1	0	1	1	-1	1	1	-1	1	1	-1	1	-1	-1	1	-1	-1	1	1	1	1
Compatibility	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Self perceived status	1	-1	-1	-1	-1	-1	-1	0	-1	-1	1	-1	-1	1	-1	-1	1	-1	1	1	-1	1	1	-1	-1	-1
High cost of data collection and analysis	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Fear of entry of pests	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Not trusting the messenger	1	0	0	-1	-1	-1	-1	1	1	1	-1	-1	-1	-1	1	-1	-1	-1	-1	-1	-1	-1	-1	-1	-1	-1
Lack of documentation & guidelines	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Better results	1	1	1	1	-1	-1	-1	-1	1	1	-1	1	1	-1	1	-1	-1	1	-1	1	1	1	1	1	1	1
More efficient way of working	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Feedback	1	1	1	-1	-1	-1	-1	1	1	-1	1	1	-1	1	-1	-1	1	-1	1	1	1	1	1	1	1	1
Engagement	1	1	1	1	-1	-1	-1	-1	1	1	-1	1	1	-1	1	-1	-1	1	-1	1	1	1	1	1	1	1
International peer pressure	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
More scientific research	1	0	0	-1	-1	1	-1	1	1	-1	0	1	-1	1	1	-1	1	1	-1	1	1	1	1	1	1	1
Low facilities at the national level	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Acceptance by the industry	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Poor management	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Access to training tools	1	0	0	-1	-1	1	-1	1	1	-1	0	1	-1	1	1	-1	1	1	-1	1	1	1	1	1	1	1
Good outreach and communications	1	1	1	1	-1	-1	1	-1	-1	1	-1	-1	1	-1	1	1	-1	1	1	-1	1	1	1	1	1	1
Regulatory approval of RBS	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Anomalies	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Momentum	1	1	1	1	1	0	1	1	-1	1	1	-1	1	1	-1	1	-1	-1	1	-1	-1	1	1	1	1	1
Risk environment	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Interagency coordination	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Simplification	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Efficient use of resources	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Observability	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Additionally, if it were proven early that RBS is definitely a '**More efficient way of working**' (i.e., if that node is constantly kept active), the press experiment (Figure 10) shows that this would drive the activation of the node '**Efficient use of resources**'. However, it would also activate the node '**Fear of**

losing overtime pay', which would be an undesired outcome, even if the experiment suggests that this node would not prevent the acceptance of risk-based sampling.

Figure 10**:** Results of a press experiment using the third version of the FCM of RBS adoption. All of the nodes except for 'Acceptance of RBS' are activated in the vector of initial states (blue column) and the node 'More efficient way of working' is kept in an active state. Nodes that are upregulated in a specific cycle are shown in green and nodes that are downregulated are shown in red. Nodes that are deactivated are shown in grey.

		Cycle 1	Cycle 2	Cycle 3	Cycle 4	Cycle 5	Cycle 6	Cycle 7	Cycle 8	Cycle 9	Cycle 10
Acceptance of risk-based sampling	0	0	-1	0	1	1	1	1	1	1	1
Individual Resistance to change	1	1	1	-1	-1	-1	-1	-1	0	-1	-1
Lack of understanding	1	1	-1	-1	-1	-1	1	1	-1	-1	-1
Adequate and targeted training	1	0	0	-1	0	1	1	1	1	1	1
Fear of losing overtime pay	1	1	1	1	1	1	1	1	1	1	1
Troublesome to use	1	-1	0	0	0	0	0	0	0	0	0
Miscommunication of risk	1	-1	-1	-1	-1	1	1	-1	-1	-1	-1
Not having facilities	1	0	0	0	0	0	0	0	0	0	0
Historical behavior	1	-1	-1	-1	-1	-1	-1	-1	-1	-1	-1
Change in the knowledge hierarchy	1	1	1	1	1	1	1	1	1	1	1
Compatibility	1	0	0	0	0	0	0	0	0	0	0
Self perceived status	1	-1	-1	-1	-1	-1	-1	-1	-1	-1	-1
High cost of data collection and analysis	1	0	0	0	0	0	0	0	0	0	0
Fear of entry of pests	1	1	1	0	0	0	0	0	0	0	0
Not trusting the messenger	1	0	0	-1	-1	-1	-1	0	-1	-1	-1
Lack of documentation & guidelines	1	0	0	0	0	0	0	0	0	0	0
Better results	1	1	1	1	-1	1	1	1	1	1	1
More efficient way of working	1	1	1	1	1	1	1	1	1	1	1
Feedback	1	1	1	-1	1	1	1	1	1	1	1
Engagement	1	1	1	1	-1	1	1	1	1	1	1
International peer pressure	1	0	0	0	0	0	0	0	0	0	0
More scientific research	1	0	0	-1	0	1	1	1	1	1	1
Low facilities at the national level	1	0	0	0	0	0	0	0	0	0	0
Acceptance by the industry	1	0	0	0	0	0	0	0	0	0	0
Poor management	1	0	0	0	0	0	0	0	0	0	0
Access to training tools	1	0	0	-1	0	1	1	1	1	1	1
Good outreach and communications	1	1	1	1	-1	-1	1	1	1	1	1
Regulatory approval of RBS	1	0	0	0	0	0	0	0	0	0	0
Anomalies	1	0	0	0	0	0	0	0	0	0	0
Momentum	1	1	1	1	1	1	1	1	1	1	1
Risk environment	1	1	0	0	0	0	0	0	0	0	0
Interagency coordination	1	0	0	0	0	0	0	0	0	0	0
Simplification	1	0	0	0	0	0	0	0	0	0	0
Efficient use of resources	1	1	1	1	1	1	1	1	1	1	1
Observability	1	0	0	0	0	0	0	0	0	0	0

Conclusions

The main objective of this activity was to give the audience of the International Symposium for Risk-Based Sampling an opportunity to express their concerns and motivations for the adoption of risk-based sampling, and to show how Fuzzy Cognitive Mapping could be used as a first approach to analyzing the impact that this new protocol could have on border inspections. We think that this objective was clearly fulfilled, and the models derived from the session will be provided to the participants and the regulatory authorities for reference.

In addition, we used the original model and two refined versions to conduct several simulations aimed at analyzing the impact that the different nodes would have on the acceptance of risk-based sampling. Overall, it seems like Risk-Based Sampling would finally be adopted under most scenarios, but several nodes that were suggested during the session might be important targets for intervention in order to secure an early adoption of RBS. If there is interest in further refinement of the models or additional simulations, the model files and the spreadsheets will be provided upon request.

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Appendix 1 Glossary of Acronyms

Acronym	*Explanation*
AIMS	*Australian Import Management System*
APPPC	*Asian Pacific Plant Protection Commission*
AQIM	*Agriculture Quarantine Inspection Monitoring (US)*
AQSIQ-CIQ	*General Administration of Quality Supervision, Inspection and Quarantine (China)*
ASTA	*American Seed Trade Association*
CFIA	*Canadian Food Inspection Agency*
CHC	*Canadian Horticultural Council*
CSCP	*Canadian Seed Certification Program*
CSTA	*Canadian Seed Trade Association*
DAWR	*Australian Department of Agriculture and Water Resources*
DS	*Detection Sensitivity*
FCM	*Fuzzy cognitive map*
IPPC	*The International Plant Protection Convention*
ISF	*International Seed Federation*
ISPM	*International Standard for Phytosanitary Measure*
ISTA	*International Seed Technology Association*
MOA	*Ministry of Agriculture (China)*
MPL	*Maximum pest limit*
NARP	*National Agriculture Release Program (US)*
NPPO	*National Plant Protection Organization*
NSF	*National Science Foundation*
OISA	*Phytosanitary Inspection Office (Mexico)*

PIS	*Plant Inspection Stations (US)*
PM	*Propagative material*
QC	*Quality Control*
SESYNC	*National Socio-Environmental Synthesis Center*
SFA	*State Forestry Administration (China)*
SPS Agreement	*World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures*
USDA	*United States Department of Agriculture*
USDA –APHIS-PPQ	*USDA - Animal Plant Health Inspection Service - Plant Protection and Quarantine*
VHT	*Vapor Heat Treatment*
WTO TFA	*World Trade Organization Trade Facilitation Agreement*

Appendix 2 Glossary of Terms

Term	*Definition*
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).*
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. Actions for other non-compliance reasons (not necessarily pest risk-related) are included to be compliance-based.*
Approach rate	*The number of times a specific pest (or pest group/type) is found associated with a particular volume in a specified pathway.*
Comingled Shipment	*Shipment comprised of a mixture of taxa both within the sample units and throughout the shipment.*
Compliance Based Inspection Scheme (CBIS)	*An Australian program for the importation of plant products that rewards importers who have demonstrated consistent compliance with Australia's biosecurity requirements.*
Continuous sampling	*An approach used in acceptance sampling plans where data are continuously produced.*
Disposition codes	*Codes that describe inspection results and subsequent quarantine actions.*
Fixed rate sampling	*Inspection based on consistently sampling the same proportion of consignments (e.g., 2% of every consignment regardless of size or risk).*
Hazard Analysis Critical Control Point (HACCP)	*A management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product.*
Infestation rate	*The total number of units estimated to have actionable pests in a specific volume (usually a consignment) based on sampling results.*
Inspection efficiency (or pest detection rate)	*The likelihood of finding a pest or pests that are present on a commodity.*
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).*

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 released without action.*
Lot-by-lot sampling	*An approach used in acceptance sampling plans where data arrive in batches.*
Mingled Shipment	*Shipment comprised of multiple taxa, with the same taxa within sample units.*
Pest action rate	*Number of quarantine actions performed on a commodity divided by the total number of inspections performed on that commodity.*
Ratings-based plan	*A type of RBS plan that uses data to calculate rates for the regulated goods, and assign ratings based on determined thresholds to separate goods into low and high categories (at least) for differential sampling.*
Risk return	*The extent to which actions maximize the likelihood of detecting and managing biosecurity risks and reducing the risk of pest incursion.*
Risk-based Inspection (RBI)	*A specific approach to inspections that concentrates inspectional effort on sources of imports with problematic inspection histories.*
Risk-based sampling approach (RBSA)	*An approach to inspections that prescribes sampling frequencies based on compliance history, origin, and intended use of the commodity.*
Risk-based Sampling (RBS)	*An approach to inspections that prescribes sampling frequencies based on the relationship of actionable pest detections with specific inspection variables (e.g., type of commodity, origin, consignee, etc.).*
Singled shipment	*Shipment comprised of a single taxon.*
Skip lot sampling	*Inspection designs that allow for consignments to be released without inspection.*