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## **Draft ISPM:**

# ***Sampling of Consignments***

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## OUTLINE of PRESENTATION

- Purpose
- Background
- Objectives of sampling
- Key Concepts (Acceptance Number, Level of Detection, Confidence level, Efficacy of detection, Sample size and Tolerance level)
- Links between Parameters
- Sample Unit
- Lot identification
- Sampling methods
- Selecting a sampling method
- Sample size determination
- Varying levels of detection
- Outcome of Sampling
- Appendices





## Purpose

- The draft ISPM was developed to provide guidance to NPPO policy makers in developing sampling policies that may be applied by inspectors as part of a process for inspection or gathering material for testing to ensure compliance with phytosanitary requirements.
- Key statistical concepts that should be considered by NPPOs in developing a truly statistically based sampling policy are included.
- Different types of statistical and “other” sampling methods are included.





## Background

- The May meeting of the IPPC Standards Committee noted concerns about the understanding of some of the statistically valid concepts included in the draft and requested that a supporting document be produced to accompany the draft (also sent as part of the member consultation process).
- Both statistically based sampling, and other sampling methods, are currently applied by many NPPOs when sampling as part of inspection and/or testing to ensure compliance with phytosanitary requirements.
- Both of these methods are included in the draft ISPM and while truly statistically based methods may be preferable. In the operational environment it is likely that the other sampling methods have been used by many countries.





## Background (Cont')

- While other sampling methods are valid methods they are not "statistically valid" and therefore no statistical inferences can or should be drawn from them.
- By accepting the results of a sample inspection, NPPOs accept that pests not found in the sample may be present in consignment, and make the assumption that the consignment meets phytosanitary requirements.
- Both "other" and statistically based sampling methods can never establish that the pest is truly absent from a consignment. However, statistically based sampling methods can provide confidence that the incidence of a pest is below a certain level.





## Objectives of sampling

Sampling consignments may be done for a variety of purposes, including:

- to detect regulated pests
  - to provide assurance that the number of pests or infested units in a consignment does not exceed a specified level
  - to provide assurance of the general phytosanitary condition of a consignment, in particular the detection of organisms for which a phytosanitary risk has not yet been determined
  - to optimize the probability of detecting specific pests given the available resources
  - to gather information (auditing or determining the proportion of the consignment infested)
  - assurance of compliance with phytosanitary requirements
  - to select units for testing.
- It should be noted that inspection based on sampling always involves a degree of error.
- The acceptance of some degree of risk that the pests are present is inherent in the use of sampling.





## Key Concepts

Key statistical concepts that should be considered by NPPOs in developing a truly statistically based sampling policy are included Confidence level, Acceptance Number, Level of Detection, Efficacy of detection, Sample size and Tolerance level.

### Confidence Level

- Is a basic statistical concept and is the level of certainty to which an estimate can be trusted. The degree of certainty is expressed as the chance that an infested consignment will be detected.





## Key Concepts (Cont.)

### Acceptance Number

- The number of infested units or the number of individual pests that are permissible in a sample of a given size before phytosanitary action is taken.
- The acceptance number is the number of infected/infested units in the sample while "tolerance" refers to the entire consignment.

### Sample size

- A group of units selected from the lot and/or consignment that will be tested and/or inspected.







## Key Concepts (Cont.)

### Level of Detection

- The minimum prevalence of the pest that is intended to be detected and may be based on PRA.

### Efficacy of Detection

- The probability that an inspection or test of an infested unit will detect the pest.
- The sample size required to achieve a desired level of confidence would increase as the efficacy of a non perfect (i.e. not 100%) detection method decreased.





## Key Concepts (Cont.)

### Tolerance level

- The prevalence of a pest in a consignment that is the threshold for phytosanitary action.
- For quarantine pests is commonly zero.
- NPPOs may determine a higher tolerance for a quarantine pest based on pest risk analysis. For example:
  - a quarantine pest may not readily establish and therefore the NPPO may determine a tolerance for the quarantine pest that is greater than zero as small numbers of the pest may be acceptable;
  - fresh fruit and vegetables imported for processing may have a higher tolerance for particular pests than nursery stock;
  - an NPPO may determine that a treatment type may be adjusted depending on the number of pests detected.
- Note that it is not possible to design a sampling system that gives any level of confidence that a tolerance of zero is not exceeded.





## Links between Parameters

- Five parameters (acceptance number, level of detection, confidence level, efficacy of detection and sample size) are statistically related.
- The NPPO should determine:
  - the efficacy of the inspection method used; and
  - the acceptance number in the sample (usually zero);
- Any two of the remaining three parameters can also be chosen, and the third will be determined from the values chosen for the rest.
- For example, where the acceptance number in the sample is 0, the efficacy of detection is 50%, the detection level is 1% and the confidence level is 95% the sample size would be approximately 600 units.





## Sample Unit

- Sampling first involves the identification of the appropriate unit for sampling (for example, a fruit, stem, bouquet, unit of weight, bag etc).
- Determining the sample unit may be related to:
  - the homogeneity in the distribution of pests through the commodity;
  - whether the pests are sedentary or mobile;
  - how the consignment is packaged; and
  - operational considerations.



## Lot identification

- A consignment may consist of one or more lots.
- Section 1.5 of ISPM 23 (*Guidelines for inspection*) should be consulted to determine factors that may influence lot identification.
- A lot to be sampled should be a number of units of a single commodity identifiable by its homogeneity in factors such as: origin; grower; packing facility; species, variety, or degree of maturity; exporter; pests of concern and characteristics of the pests of concern; treatment at origin; type of processing.
- The criteria used by the NPPO to distinguish lots should be consistently applied for similar consignments.





## Sampling Methods

- Both statistically based sampling, and other sampling methods, are currently applied by many NPPOs when sampling as part of inspection and/or testing to ensure compliance with phytosanitary requirements.
- Both of these methods are included in the draft and while truly statistically based methods may be preferable, in an operational environment it is likely that the other sampling methods have been used by many countries.
- In most phytosanitary applications, operational limitations will dictate the practicality of sampling under one or another method.





## Sampling Methods (Cont')

- The sampling method is the process approved by the NPPO to select units for inspection and/or testing.
- If sampling is undertaken to:
  - provide information on the general phytosanitary status of a consignment;
  - to detect multiple quarantine pests;
  - to verify compliance with phytosanitary requirements; or
  - for information gathering.

then one of the statistically based methods will be appropriate.

- If sampling is undertaken to increase the chance of detecting a specific pest, "other" sampling methods may be the preferred option as these methods may be more operationally feasible.





## Sampling Methods (Cont')

### Statistically based methods

- Simple Random Sampling

The use of a predetermined randomization process. The randomization process is what distinguishes this method from haphazard sampling.

- Systematic Sampling

Involves drawing a sample from every  $n$ th unit of the lot. The first selection must be made at random, and the assumption is made that the pest is randomly distributed through the lot.







## Sampling Methods (Cont')

### Statistically based methods (Cont')

- Stratified Sampling

Can be advantageous when strata have different infestation levels or when it can not be assumed that the pest is randomly distributed through the lot

- Sequential sampling

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





## Sampling Methods (Cont')

### Statistically based methods (Cont')

- Clustered sampling

Involves selecting groups of units (for example, boxes of fruit, bunches of flowers) to make up the total number of sample units required from the lot.



## Sampling Methods (Cont')

### Other Sampling methods

May be used for operational considerations or when the goal is purely detection of pests.

- Convenience sampling

Involves selecting the most convenient (e.g. accessible, cheapest, fastest) units from the lot.

- Haphazard sampling

Involves selecting arbitrary units without using a true randomization process.

- Selective or biased sampling

Involves selecting samples from parts of the lot most likely to be infested, or units that are obviously infested, in order to increase the chance of detecting a specific pest.





## Selecting a sampling method

- If sampling is undertaken to increase the chance of detecting a specific pest, biased (other) sampling may be the preferred option, as long as the inspectors can identify the section(s) of the lot with a higher probability of being infested. Without this knowledge, one of the statistically based methods will be more appropriate.
- If sampling is undertaken to provide knowledge about the general phytosanitary condition of a consignment, to detect multiple quarantine pests, to verify compliance with phytosanitary requirements, or for information gathering, one of the statistically based methods will be appropriate.





## Sample size determination

- Ideally, the NPPPO should select a confidence level (e.g. 95%), a level of detection (e.g. 5%) and an acceptance number (e.g. zero), and determine the efficacy of visual inspection or testing (e.g. 80%). From these values and the lot size, a sample size can be calculated.



## Varying levels of detection

The choice of a constant level of detection may result in a varying number of infested units entering with imported consignments because lot size varies (e.g. a 1% infestation level of 1000 units corresponds to 10 infested units, while a 1% infestation level of 10,000 units corresponds to 100 infested units). Ideally the selection of a level of detection will reflect in part the number of infested units entering on all consignments within a particular period of time.





## Outcome of Sampling

The outcome of sampling may result in phytosanitary action being taken (see ISPM No. 23: *Guidelines for inspection*, section 2.5).





## Appendices

The appendices were included to provide information to NPPOs that may not have the resources to develop their own sampling tables. The formulas used to provide the information included in the tables were also provided for information on NPPOs as the tables are limited to the most common sampling levels.







## REVIEW OF PRESENTATION

- The draft ISPM was developed to provide guidance to NPPO policy makers in developing sampling policies.
- Key statistical concepts that should be considered by NPPOs in developing a truly statistically based sampling policy are included.
- Different types of statistical and “other” sampling methods are included.
- Key considerations in the development of a sampling policy are included.

