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ISPM 31

METHODOLOGIES FOR SAMPLING OF CONSIGNMENTS

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Adoption

This standard was adopted by the Third Session of the Commission on Phytosanitary Measures in April 2008.

INTRODUCTION

Scope

This standard provides guidance to national plant protection organizations (NPPOs) in selecting appropriate sampling methodologies for inspection or testing of consignments to verify compliance with phytosanitary requirements.

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

References

Cochran, W.G. 1977. *Sampling techniques*. 3rd edn. New York, John Wiley & Sons. 428 pp.

ISPM 1. 2006. *Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade*. Rome, IPPC, FAO.

ISPM 5. *Glossary of phytosanitary terms*. Rome, IPPC, FAO.

ISPM 11. 2004. *Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms*. Rome, IPPC, FAO.

ISPM 20. 2004. *Guidelines for a phytosanitary import regulatory system*. Rome, IPPC, FAO.

ISPM 21. 2004. *Pest risk analysis for regulated non-quarantine pests*. Rome, IPPC, FAO.

ISPM 23. 2005. *Guidelines for inspection*. Rome, IPPC, FAO.

Definitions

Definitions of phytosanitary terms used in the present standard can be found in ISPM 5 (*Glossary of phytosanitary terms*).

Outline of Requirements

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

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

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

BACKGROUND

This standard provides the statistical basis for, and complements, ISPM 20:2004 and ISPM 23:2005. Inspection of consignments of regulated articles moving in trade is an essential tool for the management of pest risks and is the most frequently used phytosanitary procedure worldwide to determine if pests are present and/or the compliance with phytosanitary import requirements.

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

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

It is important that sampling procedures established and used by NPPOs are documented and transparent, and take into account the principle of minimum impact (ISPM 1:2006), particularly because inspection based on sampling may lead to the refusal to issue a phytosanitary certificate, refusal of entry, or treatment or destruction of a consignment or part of a consignment.

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

OBJECTIVES OF SAMPLING OF CONSIGNMENTS

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

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

It should be noted that inspection and/or testing based on sampling always involves a degree of error. The acceptance of some probability that the pests are present is inherent in the use of sampling procedures for inspection and/or testing. Inspection and/or testing using statistically based sampling methods can provide a level of confidence that the incidence of a pest is below a certain level, but it does not prove that a pest is truly absent from a consignment.

REQUIREMENTS

1. Lot Identification

A consignment may consist of one or more lots. Where a consignment comprises more than one lot, the inspection to determine compliance may have to consist of several separate visual examinations, and therefore the lots will have to be sampled separately. In such cases, the samples relating to each lot should be segregated and identified in order that the appropriate lot can be clearly identified if subsequent inspection or testing reveals non-compliance with phytosanitary requirements. Whether or not a lot will be inspected should be determined using factors stated in ISPM 23:2005 (section 1.5).

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

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

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

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

2. Sample Unit

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

3. Statistical and Non-Statistical Sampling

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

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

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

3.1 Statistically based sampling

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

3.1.1 Parameters and related concepts

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

3.1.1.1 Acceptance number

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

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

3.1.1.2 Level of detection

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

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

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

3.1.1.3 Confidence level

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

3.1.1.4 Efficacy of detection

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

3.1.1.5 Sample size

The sample size is the number of units selected from the lot or consignment that will be inspected or tested. Guidance on determining the sample size is provided in section 5.

3.1.1.6 Tolerance level

Tolerance level refers to the percentage of infestation in the entire consignment or lot that is the threshold for phytosanitary action.

Tolerance levels may be established for regulated non-quarantine pests (as described in ISPM 21:2004, section 4.4) and may also be established for conditions related to other phytosanitary import requirements (for example, bark on wood or soil on plant roots).

Most NPPOs have a zero tolerance level for all quarantine pests, taking into account probabilities of pest presence in the non-sampled units as described in section 3.1.1.3. However, an NPPO may determine to establish a tolerance level for a quarantine pest based on pest risk analysis (as described in ISPM 11:2004, section 3.4.1) and then determine sampling rates from this. For example, NPPOs may determine a tolerance level that is greater than zero because small numbers of the quarantine pest may be acceptable if the establishment potential of the pest is considered low or if the intended end use of the product (for example, fresh fruit and vegetables imported for processing) limits the potential of entry of the pest into endangered areas.

3.1.2 Links between the parameters and tolerance level

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

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

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

3.1.3 Statistically based sampling methods

3.1.3.1 Simple random sampling

Simple random sampling results in all sample units having an equal probability of being selected from the lot or consignment. Simple random sampling involves drawing the sample units in accordance with a tool such as a random numbers table. The use of a predetermined randomization process is what distinguishes this method from haphazard sampling (described in section 3.2.2).

This method is used when little is known about the pest distribution or rate of infestation. Simple random sampling can be difficult to apply correctly in operational situations. To use this method, each unit should have an equal probability of selection. In cases where a pest is not distributed randomly through the lot, this method may not be optimal. Simple random sampling may require greater resources than other sampling methods. The application can be dependent on the type and/or configuration of the consignment.

3.1.3.2 Systematic sampling

Systematic sampling involves drawing a sample from units in the lot at fixed, predetermined intervals. However, the first selection must be made at random through the lot. Biased results are possible if pests are distributed in a manner similar to the interval chosen for sampling.

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

3.1.3.3 Stratified sampling

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

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

3.1.3.4 Sequential sampling

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

This method can be used when a tolerance level greater than zero is determined and the first set of sample units does not provide sufficient information to allow a decision to be made on whether or not the tolerance level is exceeded. This method would not be used if the acceptance number in a sample of any size is zero. Sequential sampling may reduce the number of samples required for a decision to be made or reduce the possibility of rejecting a conforming consignment.

3.1.3.5 Cluster sampling

Cluster sampling involves selecting groups of units based on a predefined cluster size (for example, boxes of fruit, bunches of flowers) to make up the total number of sample units required from the lot. Cluster sampling is simpler to evaluate and more reliable if the clusters are of equal size. It is useful if resources available for sampling are limited and works well when the distribution of pests is expected to be random.

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

3.1.3.6 Fixed proportion sampling

Sampling a fixed proportion of the units in the lot (for example, 2%) results in inconsistent levels of detection or confidence levels when lot size varies. As shown in Appendix 5, fixed proportion sampling results in changing confidence levels for a given level of detection, or in changing levels of detection for a given confidence level.

3.2 Non-statistically based sampling

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

3.2.1 Convenience sampling

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

3.2.2 Haphazard sampling

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

3.2.3 Selective or targeted sampling

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

4. Selecting a Sampling Method

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

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

If sampling is undertaken to increase the chance of detecting a specific pest targeted sampling (described in section 3.2.3) 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. Non-statistically based sampling methods do not result in each unit having an equal probability of being included in the sample and do not allow for quantification of a confidence level or level of detection.

Statistically based methods will be appropriate if sampling is undertaken to provide information about the general phytosanitary condition of a consignment, to detect multiple quarantine pests or to verify compliance with phytosanitary requirements.

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

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

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

5. Sample Size Determination

To determine the number of samples to be taken, the NPPO should select a confidence level (for example, 95%), a level of detection (for example, 5%) and an acceptance number (for example, zero), and determine the efficacy of detection (for example, 80%). From these values and the lot size, a sample size can be calculated. Appendixes 2–5 set out the mathematical basis for sample size determination. Section 3.1.3 of this standard provides guidance on the most appropriate statistical based sampling method when considering the distribution of the pest in the lot.

5.1 Pests distribution unknown in the lot

Because sampling is done without replacement and the population size is finite, the hypergeometric distribution should be used to determine the sample size. This distribution gives a probability of detecting a certain number of infested units in a sample of a given size drawn from a lot of a given size, when a specific number of infested units exist in the lot (see Appendix 2). The number of infested units in the lot is estimated as the level of detection multiplied by the total number of units in the lot.

As lot size increases, the sample size required for a specific level of detection and confidence level approaches an upper limit. When the sample size is less than 5% of the lot size, the sample size can be calculated using either the binomial or Poisson distribution (see Appendix 3). All three distributions (hypergeometric, binomial and Poisson) give almost identical sample sizes for specific confidence and detection levels with large lot sizes, but binomial and Poisson distributions are easier to calculate.

5.2 Pest distribution aggregated in the lot

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

NPPOs identify that there is a high likelihood that there will be aggregation of infested units in the lot a stratified sampling method may help increase the chance of detecting an aggregated infestation.

When pests are aggregated, the calculation of sample size should ideally be performed using a beta-binomial distribution (see Appendix 4). However, this calculation requires knowledge of the degree of aggregation, which is generally not known and therefore this distribution may not be practical for general use. One of the other distributions (hypergeometric, binomial or Poisson) can be used; however, the confidence level of the sampling will decline as the degree of aggregation increases.

6. Varying Level of Detection

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

7. Outcome of Sampling

The outcome of activities and techniques related to sampling may result in phytosanitary action being taken (further details can be found in ISPM 23:2005, section 2.5).

This appendix is for reference purposes only and is not a prescriptive part of the standard.

APPENDIX 1: Formulae used in Appendixes 2–5

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

This appendix is for reference purposes only and is not a prescriptive part of the standard.

APPENDIX 2: Calculating sample sizes for small lots: hypergeometric-based sampling (simple random sampling)

The hypergeometric distribution is appropriate to describe the probability of finding a pest in a relatively small lot. A lot is considered as small when the sample size is more than 5% of the lot size. In this case, sampling of one unit from the lot affects the probability of finding an infested unit in the next unit selected. Hypergeometric-based sampling is based on sampling without replacement.

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

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

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

Where:

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

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

The confidence level corresponds to: 1- P(X = i)

A = number of infested units in the lot that could be detected if every unit in the lot was inspected or tested, given the efficacy of detection (level of detection × N × efficacy, truncated to an integer)

i = number of infested units in the sample

N = number of units in the lot (size of the lot)

n = number of units in the sample (sample size)

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

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

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

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

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

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

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

Values in Table 1 marked with an asterisk (*) have been rounded down to a whole number because scenarios resulting in a fraction of a unit being infested (for example, 300 units with 0.5% infestation corresponds to 1.5 infested units in the shipment) are not possible. This means that the sampling intensity increases slightly, and may be greater for a shipment size where the number of infested units is rounded down than for a larger shipment where a larger number of infested units are calculated (for example, compare results for 700 and 800 units in the lot). It also means that a slightly lower proportion of infested units might be detected than the proportion indicated by the table, or that such infestation is more likely to be detected than the confidence level shown.

Values in Table 1 marked with a dash (–) refer to scenarios presented that are not possible (less than one unit infested).

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

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

Values in Table 2 marked with an asterisk (*) have been rounded down to a whole number because scenarios resulting in a fraction of a unit being infested (for example, 300 units with 0.5% infestation corresponds to 1.5 infested units in the shipment) are not possible. This means that the sampling intensity increases slightly, and may be greater for a shipment size where the number of infested units is rounded down than for a larger shipment where a larger number of infested units are calculated (for example, compare results for 700 and 800 units in the lot). It also means that a slightly lower proportion of infested units might be detected than the proportion indicated by the table, or that such infestation is more likely to be detected than the confidence level shown.

Values in Table 2 marked with a dash (–) refer to scenarios presented that are not possible (less than one unit infested).

This appendix is for reference purposes only and is not a prescriptive part of the standard.

APPENDIX 3: Sampling of large lots: binomial or Poisson based sampling

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

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

p is the average proportion of infested units (infestation level) in the lot and ϕ represents the percentage inspection efficacy divided by 100.

P(X = *i*) is the probability of observing i infested units in the sample. The confidence level corresponds to: 1- P(X = *i*), i = 0, 1, 2, …, n.

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

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

The probability of observing at least one infested unit is then

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

This equation can be rearranged to determine n:

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

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

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

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

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

The probability of finding no infested units simplifies to

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

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

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

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

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

Tables 3 and 4 show sample sizes when the acceptance number is 0, calculated for different levels of detection, efficacy and confidence levels with the binomial and Poisson distributions, respectively. A comparison of the case for 100% efficacy with the sample sizes in Table 1 (see Appendix 2) shows that the binomial and Poisson give very similar results to the hypergeometric distribution when n is large and p is small.

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

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

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

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

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APPENDIX 4: Sampling for pests with an aggregated distribution: beta-binomial based sampling

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

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

f is the average proportion of infested units (infestation level) in the lot.

P(X = i) is the probability of observing i infested units in a lot.

n = number of units in a lot.

$\prod$ is the product function.

θ provides a measure of aggregation for the *j*th lot where θ is from 0-1.

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

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

and the probability that each of several lots has no infested unit equals $P(X=0)^m$, where *m* is the number of lots. When *f* is low, equation 12 can be estimated by

$$Pr\ (X=0) \approx (1+n\theta)^{-(mf/\theta)} \qquad \text{Formula 13}$$

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

This equation can be rearranged to determine *m*

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

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

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

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

This appendix is for reference purposes only and is not a prescriptive part of the standard.

APPENDIX 5: Comparison of hypergeometric and fixed proportion sampling results

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

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

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

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