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SAMPLE SIZE CALCULATOR FOR PHYTOSANITARY SAMPLING PLANS BASED ON CONSUMER RISK

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ABSTRACT

The international flow of agricultural products is a key factor in the spread of potentially harmful species. Pests and non-native organisms that spread between countries in commercial transport can establish themselves and significantly alter biodiversity, the functioning of agroecosystem services, human health, and the economy. Between 1970 and 2017, the economic cost of biological invasions and control methods represented an estimated global investment of USD 1.288 trillion; in Mexico alone, the cost on the agricultural sector represented an estimated investment of USD 1.01 billion. Because of the volume and diversity of imported products, as well as the economic and environmental damage caused by pest species, sanitary inspection must explicitly incorporate the concepts of producer risk (rejecting a lot with an acceptable sanitary level) and consumer risk (accepting a lot with a minimum sanitary level) to decide whether to accept or reject a lot. This paper introduces the main features of risk-based sampling, defines the acceptable and minimum sanitation levels, discusses how changes in parameters affect the behavior of the characteristic operating curve, and presents the user interface of an interactive web calculator that was programmed in R to automate the development of sampling plans and calculate the risk-based sample size. The estimates obtained compared to other sources indicate that the computation performed with the calculator is accurate and determines sample sizes and acceptance numbers. The inspection should explore sampling methods that explicitly include risk and coin its own concepts that fit its information needs and objectives.

Key words: inspection, R programming, quarantine pests.

INTRODUCTION

The international exchange of food and raw materials of animal and plant origin has increased in recent decades, and with this, the risk of introduction of pests, diseases, and non-native organisms of quarantine importance (NAPPO, 2020; Diagne *et al.*,

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2021; SENASICA, 2024). The economic-environmental impact of invasive species on a product system and the impact derived from the cost of applying targeted measures for their control (Villanueva-Jiménez *et al*., 2017) represent annual investments estimated in billions of dollars (Pimentel *et al*., 2000; Jáquez-Mata *et al*., 2022). Hoffmann and Broadhurst (2016) estimated a multinational investment (USA, UK, India, South Africa, Australia, and Brazil) of USD 306 billion in damages, plus USD 30 billion in management and handling costs; Warziniack *et al*. (2021) reported an approximate annual global cost of half a trillion dollars between 1999 and 2000. Diagne *et al*. (2021) estimated that the global economic losses associated with border biosecurity programs between 1970 and 2017 totaled approximately USD 1.288 trillion. In Mexico, the estimated cost was USD 5.33 billion between 1992 and 2019; during this time, the agricultural sector generated the highest costs with USD 1.01 billion; the second place was occupied by fisheries with USD 517.24 million, while the rest was invested in unspecified sectors (Rico-Sánchez *et al*., 2021).

To safeguard the health of agricultural resources and reduce the economic-environmental cost, each country developed and implemented protection systems or border biosecurity programs that inspect products to determine if they meet the sanitary standard (Lane *et al*., 2019; Trouvé and Robinson, 2024). These programs change depending on the country, its geographical position, socio-economic condition, commercial needs, and the stages associated with control actions. Regardless of the particular conditions, Warziniack *et al*. (2021) classified the general strategies common to all protection systems or border biosecurity programs into stages. The first stage corresponds to actions that prevent the introduction of pests, diseases, and non-native organisms. This stage includes the rules and procedures for the review of goods at the point of origin, the set of documentary and legal obligations to carry out the purchase and sale of the product, and the inspection at the point of entry. The second category is surveillance and eradication programs, which are activated when the first records of the organism's presence within the national territory are identified; these practices include monitoring programs for free zones and national mobilization. Finally, the third category is what authors call optimal control to stop the spread, consisting of quarantine programs and integrated control methods.

Inspection is the measure most used by national agencies to prevent the entry of a pest, disease, or non-native organism; therefore, regardless of the country where it is carried out, operational and regulatory responsibilities guarantee the standards that ensure the sanitation of products. These responsibilities are closely related, since the documentary and physical review or inspection and the set of laboratory tests that provide empirical, technical, and scientific support for the sanitary status of a product (NAPPO, 2020; IPPC, 2005, 2008) are supported and delimited to the guidelines defined by international standards and treaties, for example, the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization (WTO), for free, fair, and safe trade between countries.

In addition to being important, inspection is complex and faces multiple challenges. Due to the volume, it is impractical to completely review the products, so the inspection and determination of the sanitary status of a lot is done from the study of a sample; the diversity of the commodities requires that different probability functions be used to study it (SIICEX, 2024). Due to the complex nature of the biology of the species, some pests cannot be detected without special diagnostic procedures, while others have different levels of detection (NAPPO, 2020). Inspections, on the other hand, are carried out in places with their own infrastructure, which do not always have the best lighting, equipment, and spaces, and are carried out by officers with particular needs, behaviors, and attachments (NAPPO, 2022); that is, the particular differences of each inspection point and the methods used in each of them promote that the unit of effort, cost, and time invested are heterogeneous (Follett and Hennessey, 2007; Decrouez and Robinson, 2013).

As a rule, each country is free to define the sampling plan, the development of inspection guidelines (IPPC, 2005), and methodologies for sampling consignments (IPPC, 2008); however, different inspection designs and methods produce different results. To standardize phytosanitary inspection sampling plans, it is necessary to investigate sampling methods that explicitly incorporate the concept of risk and estimate sample sizes based on parameter relationships, as opposed to other inspection sampling design methods such as fixed proportion and acceptance sampling. The most common sanitary inspection sampling designs are fixed proportion sampling and acceptance sampling. In the former, the sample size is estimated as a percentage; however, with the increase in the flow of goods, the larger the volume, the larger the sample size.

Acceptance sampling depends on the definition of the consumer risk. The probability function is estimated from the producer risk, the consumer risk, and the definition of the acceptance number and volume; this type of sampling allows the inclusion of the risk concept but depends on volume and, in particular, on the acceptance number (C): the lower the acceptance number, the larger the sample size. The problem with this type of sampling is the effect of the acceptance number, which determines very rigorous programs when $C = 0$, as occurs with quarantine pests. The definition of the acceptance number does not reflect the sanitation level of a lot, and the goal is to determine the quality of a product rather than its health.

Risk-based sampling includes risk levels but differs from acceptance sampling in that the sample size and acceptance number are determined by the definition of an acceptable or desired sanitation level and a minimum or limit sanitation level. The sample size and acceptance number depend on the definition of risk and sanitation levels, rather than the tolerance or acceptance limit, with the goal to estimate sampling units as small as possible in order to reduce inspection time, costs, unit of effort, handling of goods, and the introduction of products that do not meet sanitary standards.

This paper presents consumer risk-based sampling derived from simple attribute acceptance sampling schemes (McWilliams *et al*., 2001; Chen *et al*., 2017). The objectives are to present the elements that define risk-based sampling, the advantages of its implementation, the definition of the acceptable sanitation level, and the minimum sanitation level. A free open-source calculation was developed in R and Shiny to create an interactive web application that computes sampling plans with a minimum sample size and a given acceptance number based on two types of risk (consumer risk and producer risk). Based on the review, unlike the dynamic tables of the North American Plant Protection Organization (NAPPO) and the National Service for Health, Safety, and Food Quality (SENASICA), which are programmed in commercial software for the estimation of sample size through acceptance sampling or fixed proportion, the calculator presented in this work is the first record with technical-scientific support of a free interactive web application, open-source and with internet access, which aims to estimate sampling plans based on the risk of introduction of pests and diseases of agricultural products.

MATERIALS AND METHODS

The proposed risk-based sampling model is derived from a simple attribute acceptance sampling scheme, which consists of defining a sample size and an acceptance value such that the following conditional probability relationships are met (McWilliams *et al*., 2001):

$$P\ (x \leq\ C \mid n, ASL) = 1 - \alpha$$

$$P\ (x \leq\ C \mid n, MSL) = \beta$$

where $P(x)$ is the probability of acceptance under two risk criteria: 1-α is the producer risk and α (type I error) represents the probability of not accepting a lot that has a satisfactory sanitation level; β is the consumer risk and represents the probability of accepting a lot that has a minimum sanitation level (Gutiérrez-Pulido and de la Vara-Salazar, 2009; Schilling and Neubauer, 2009). x is the attribute representing the number of defective items in the sample, where a defective item is one that evidences the presence of a pest or disease. C is the acceptance number or the number of items not meeting the sanitary standard in the sample. A lot will be rejected if, under certain levels of consumer and producer risk, the number of units not meeting the standard exceeds C. n is the sample size, ASL is the acceptable sanitation level, and MSL is the minimum sanitation level.

For many years, phytosanitary inspection sampling and risk-based sampling programs adopted two concepts from industrial activities: the acceptable quality level (AQL) and the tolerable lot defective ratio (LTPD) (Chen *et al*., 2017; NAPPO, 2020). Although both represent the upper and lower limits of the quality of a lot, multiple names for these concepts were found in the literature. For example, McWilliams *et al*. (2001) defined them as p_1 and p_2, two probabilities related to an acceptance sampling program, while Kiermeier (2008) refers to them as the producer risk point (PRP) and consumer risk point (CRP). The differences in the use of concepts and the lack of terms applied in healthcare lead us to assume that risk-based sampling is in a moment of expansion, where disciplines other than industry have identified the advantages of using this type of sampling. The AQL and LTPD concepts present clear conceptual limitations in the sanitary field, since what an inspector evaluates is not the quality of the product but the sanitary status.

Therefore, the terms of acceptable sanitation level (ASL) are proposed, which is calculated equal to p_1 (AQL or PRP) and refers to the sanitation level where the lot presents such a low infestation that the probability of acceptance will be high; and minimum sanitation level term (MSL), which is estimated equal to p_2 (LTPD or CRP), which refers to the sanitation level associated with the lowest level of the probability of acceptance, i.e., a lot that does not comply with the standard and will be rejected (Gutiérrez-Pulido and de la Vara-Salazar, 2009).

Because one or more probability functions are used based on the characteristics of a lot, the calculator included a variety of these functions. Small, isolated lots, as well as shipments transported by air or in small boxes, can be modeled with the hypergeometric distribution (type A plan) because they are size dependent. Using the binomial distribution (type B plan), large batches of continuous supply can be modeled (McWilliams *et al*., 2001; Gutiérrez-Pulido and de la Vara-Salazar, 2009), such as cargo vans or ships. The Poisson distribution was included, which allows modeling situations with low infestation probabilities in very large lot sizes (Thomson, 2012) and can be used in records with low infestation proportions. The differences between the probability functions or the type of plan (A and B) depend on the sample size; if the sample size is approximately 5 to 10 % of the lot, the differences of the curves are small and statistically significant, and the lot size can be considered negligible (Gutiérrez-Pulido and de la Vara-Salazar, 2009).

The calculator was programmed using the R language (R Core Team, 2023) with the objective of programming an interactive web application with remote access via mobile devices and personal computers. The R package Shiny was used to create a user interface that allows for quick capture of the producer risk level, consumer risk level, ASL, and MSL through editable fields. Using the *AcceptanceSampling* package (Kiermeier, 2008), the calculations can be performed to obtain the sampling plans by defining the sanitation and risk levels, plotting the characteristic operating curve, and estimating the sample size and acceptance number based on the conditional probabilities. Therefore, by entering values for 1-α, β, ASL, and MSL, the calculator provides the minimum sample size that complies with $P\,(x \leq C \mid n, ASL) = 1 - \alpha$ and $P\,(x \leq C \mid n, MSL) = \beta$ (McWilliams *et al*., 2001).

When the program is run, the graphical interface (Figure 1) is displayed with its input components: A) Title of the calculator; B) selection of the probability function, depending on the nature and type of batch; C) data entry section: 1-α (producer risk), β (consumer risk), ASL (acceptable sanitation level), and MSL (minimum tolerable sanitation level); and D) three tabs with the program results: the first (Figure 1) shows the sampling plan with acceptance probabilities for different product infestation proportions, sample size (n), and acceptance number (C); the second (Figure 2) presents the characteristic operating curve; and the third (Figure 3) presents the main characteristics of the sampling plan.

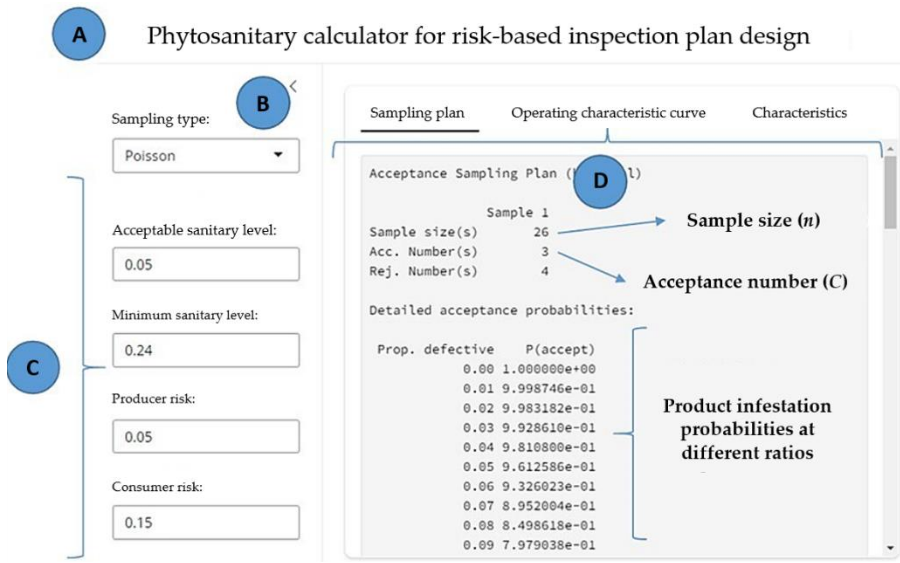

Figure 1. Risk-based sample size calculator user interface for phytosanitary sampling. A: Calculator title; B: probability function selection; C: data entry section; D: program results.

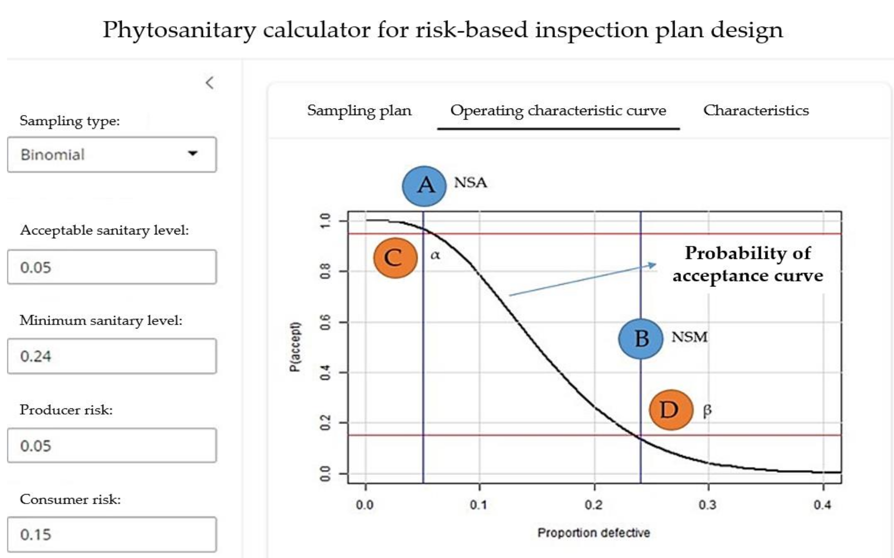

Figure 2. Characteristic operating curve estimated by the calculator. A: acceptable sanitation level; B: minimum sanitation level; C: producer risk; D: consumer risk.

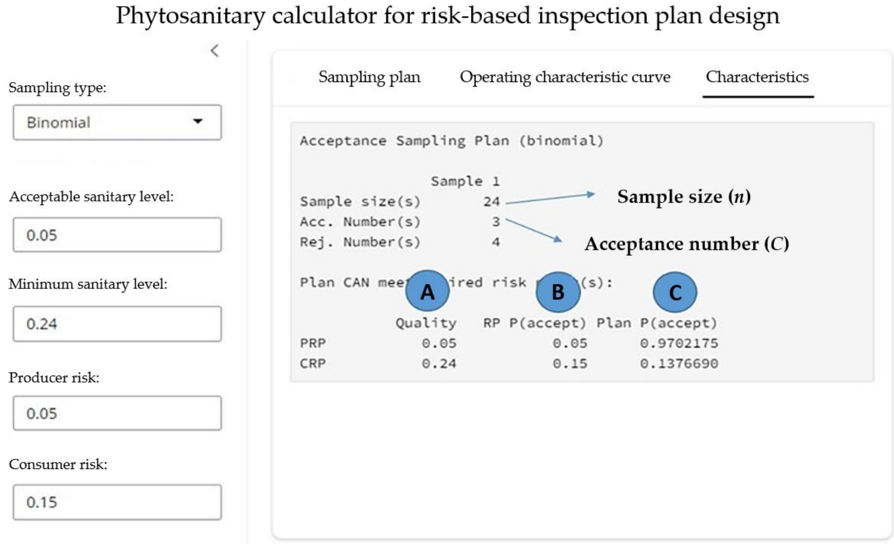

Figure 3. Characteristics proposed by the calculator for the sampling plan for phytosanitary inspection. **A:** Quality values according to the sanitation levels related to the producer risk point (PRP) and the consumer risk point (CRP); B: acceptance probability values of producer risk (1-α) and consumer risk (β); C: acceptance probabilities estimated using an optimization function included in the *AcceptanceSampling* R library.

The interface is intuitive and easy to use (Figure 1), as the user only has to enter four numerical values in the editable fields to define the ASL, MSL, producer risk, and consumer risk. For the type of sampling, the user must only decide on one of the selection fields with the options Poisson, hypergeometric, and binomial. The system automatically calculates the acceptance number and sample size. The tabbed arrangement of options allows the user to quickly select between sampling plan, characteristics, and operating curve.

The characteristic operating curve (Figure 2) shows a pair of blue and red lines; the blue lines represent the acceptance probability levels associated with the user-defined ASL and MSL, while the red lines represent the producer risk (1-α) and the consumer risk (β). These lines make the graph easier to read. The plan can be considered to meet the user conditions if the characteristic operating curve (black line) passes exactly at the intersection of the red and blue lines at the top left of the graph, as well as the intersection of the red and blue lines at the bottom right of the graph.

The calculator determines the smallest sampling plan that meets the specifications given for the producer and consumer risks. Increasing the producer risk increases the probability that lots that meet the sanitary standard will be rejected, while increasing the consumer risk increases the likelihood that lots that do not meet the standard will be introduced into the country. It is important to keep both levels of risk low, so the inspection plan is a compromise that maintains a balance between the two types of risk with a minimum sample size so that the operational part of the inspection can be carried out quickly. For this reason, it is common for the characteristic operating curve to pass above the A-B intersection or below C-D (Figure 2) because the calculator is conservative towards the consumer risk. It is important to emphasize that the sampling plans generated, as evidenced by the characteristic operating curve or the plan characteristics, always reduce both producer and consumer risks for the stipulated ASL and MSL.

The characteristics of the sampling provide information on the proposed plan. The first column labeled "Quality" (Figure 3) reads the values related to the sanitation of the lot, the acceptable sanitation level in the PRP column, and the minimum sanitation level in the CRP column. In the next column, "RP P(accept)," the values of producer risk (1-α) in the PRP column and consumer risk (β) in the CRP column are read. In the "Plan P(accept)" column, the acceptance probabilities are estimated using an optimization function included in the *AcceptanceSampling* library (Kiermeier, 2008); for example, the data-driven probability of acceptance yields a probability of 0.9702 for producer acceptance and 0.137 for consumer acceptance.

To determine the degree of precision of the calculator, the results obtained with this tool were compared with those presented by McWilliams *et al*. (2001), who compared the sample size and acceptance number of some simple attribute acceptance sampling plans with the approximate and exact estimation methods programmed in FORTRAN. The approximate estimation method is used once there are multiple results that comply with $P(X \leq C \mid n, p)$, so the acceptance probability of the hypergeometric distribution (p_h) was calculated with the following expression:

$$P(X \leq C \mid n, p_h) = \sum_{d=0}^{c} \frac{\frac{D!}{d!\,(D-d)!}\frac{(N-D)!}{(n-d)!\,(N-D-n+d)!}}{\frac{N!}{n!\,(N-n)!}}$$

where N is the lot size, d is the number of infested units in the sample, and $D = Np$ is the number of infested units in the lot. Meanwhile, the estimation of the probability of acceptance of the binomial distribution (p_b) was estimated as:

$$P(X \leq C \mid n, p_b) = \sum_{d=0}^{c} \frac{n!}{d!\,(n-d)!} p^d (1-p)^{n-d}$$

RESULTS AND DISCUSSION

Fixed ratio sampling and acceptance sampling are methods commonly used in phytosanitary inspection; however, increasing lot flow and volumes pose challenges to these methods. With fixed proportion, the larger the lot volume, the larger the sample size; however, with acceptance sampling, the limitations of the acceptance number to determine the level of sanitation, as well as the lack of concepts specific to sanitary activities, independent of the concept of quality, require research into other sampling methods used in inspection. Risk-based sampling is an alternative that has gained importance in inspection in recent years (NAPPO, 2020, 2024) due to the conceptual and operational benefits implied by the explicit inclusion of the concept of risk, as well as the change in the relationship between parameters for the estimation of sample size and the acceptance number based on risk and sanitation levels.

The calculator for risk-based sample size estimation in phytosanitary inspection sampling programs is versatile and allows to quickly obtain the number of units to be taken and the acceptance number of a lot with user-defined producer risk (1-α), consumer risk (β), acceptable sanitation level (ASL), and minimum sanitation level (MSL). The instrument can be tailored to the characteristics of the lot, as it includes three functions for risk-based probability of acceptance estimation. Therefore, it can be used for sampling designs of lots with small volumes (hypergeometric, type A plan), large volumes (binomial, type B plan) (Gutiérrez-Pulido and de la Vara-Salazar, 2009; Schilling and Neubauer, 2009), and lots with low probability of finding a pest (Poisson) (Thomson, 2012). The behavior of the curves and sample sizes estimated by the calculator are consistent with those reported in the literature (Gutiérrez-Pulido and de la Vara-Salazar, 2009; Schilling and Neubauer, 2009). As ASL increases, the sample size increases; as MSL increases, the sample size decreases; in both cases, the characteristic operating curve shifts to the right.

To check the veracity of the computation and results obtained by the calculator, they were compared with the sample size and acceptance number presented by McWilliams *et al*. (2001). The check (Tables 1 and 2) indicates that using fixed values of 1-α = 0.05 and β = 0.1 results in higher decay of the acceptance probability and stiffer sampling design, while lower values produce smaller sample sizes. With fixed levels of ASL and MSL, the same results for sample size (n) and acceptance number (C) were obtained as those estimated by McWilliams *et al*. (2001), both by the exact method (Table 1) and the approximate method (Table 2).

Although the acceptance number and sample size were the same in both tables, the α and β values captured in the calculator tended to be equivalent or very close to those obtained by the exact method. The approximate method produced cases with varying β values, while the others had consistent results. The calculator produced the same results as McWilliams *et al*. (2001), who used the exact method programmed in FORTRAN, while differences in the value of the consumer risk were identified. The differences are minimal and could be attributed to rounding of the calculations.

The calculator could be improved by incorporating a diagram into the code that identifies the units in the lots to be sampled based on any inspection sampling plan generated and displaying the information as a written or printed report. Finally, there is a lack of research on machine learning as an aid in determining the level of risk for a particular sampling program from historical grower data. However, it is worth noting that there are scenarios where the plan is not practical, as may occur on very small lots; in such cases, an installment-based inspection plan may be used.

Table 1. Sample size and acceptance number results comparison to the exact method presented by McWilliams *et al*. (2001), taking into account producer and consumer risks with fixed values of acceptable sanitation level (ASL) and minimum sanitation level (MSLT).

Example	Type	ASL	MSL	α_e	α_c	β_e	β_c	C	n
1	A/10000	0.01	0.025	0.0450	0.046	0.0863	0.0864	10	620
2	A/5000	0.01	0.035	0.0442	0.0443	0.0974	0.0975	5	261
3	A/1000	0.01	0.04	0.0546	0.0547	0.1085	01086	3	155
4	A/500	0.01	0.06	0.0332	0.0334	0.1023	0.1024	2	82
5	A/500	0.01	0.10	0.0463	0.0464	0.0949	0.095	1	37
6	B	0.01	0.028	0.0499	0.05	0.0884	0.0089	8	471
7	B	0.01	0.02	0.0491	0.05	0.0936	0.0937	18	1244
8	B	0.01	0.03	0.0445	0.045	0.0999	0.10	7	390
9	B	0.01	0.05	0.0443	0.044	0.0992	0.0993	3	132
10	B	0.01	0.07	0.0424	0.0425	0.087	0.0876	2	77

Type: probability function/N (lot size); A: hypergeometric function; B: binomial function; α_e: producer risk by exact method in FORTRAN; α_c: producer risk by calculator; β_e: consumer risk by exact method in FORTRAN; β_c: consumer risk by calculator; C: acceptance number; n: sample size.

Table 2. Sample size and acceptance number results comparison to the approximate method presented by McWilliams *et al*. (2001), taking into account producer and consumer risks with fixed values of acceptable sanitation level (ASL) and minimum sanitation level (MSLT).

Example	Type	ASL	MSL	α_e	α_c	β_e	β_c	C	n
1	A/10000	0.01	0.025	0.0445	0.0449	0.1211	0.122	9	543
2	A/5000	0.01	0.035	0.0442	0.04	0.0974	0.073	5	261
3	A/1000	0.01	0.04	0.0302	0.0302	0.0783	0.08	4	197
4	A/500	0.01	0.06	0.0332	0.034	0.1023	0.1023	2	82
5	A/500	0.01	0.10	0.0439	0.0439	0.1038	0.114	1	36
6	B	0.01	0.028	0.0491	0.0499	0.1305	0.132	7	398
7	B	0.01	0.02	0.049	0.049	0.1102	0.111	17	1163
8	B	0.01	0.03	0.0494	0.0445	0.1347	0.154	6	329
9	B	0.01	0.05	0.0495	0.0495	0.2164	0.223	2	82
10	B	0.01	0.07	0.0503	0.042	0.2721	0.2228	1	36

Type: probability function/N (lot size); A: hypergeometric function; B: binomial function; α_e: producer risk by exact method in FORTRAN; α_c: producer risk by calculator; β_e: consumer risk by exact method in FORTRAN; β_c: consumer risk by calculator; C: acceptance number; n: sample size.

CONCLUSIONS

The sanitary inspection should explore other sampling methods that explicitly include risk and coin concepts of their own that fit the information needs and objectives of sanitary inspection. Risk-based sampling is advantageous because it allows obtaining a sample size and acceptance number from the definition of the producer and consumer risks and the acceptable and minimum sanitation levels. Using the R software, a remote access interactive web calculator was designed to provide the user with a quick way to develop and design risk-based import product acceptance sampling plans, plot the characteristic operating curve, and provide information that can be used to make product inspection easier and more efficient.

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