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Report of the Scientific Committee of the Spanish Agency for Food Safety and Nutrition (AESAN) on the programming of biological hazard sampling at official controls

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Working group

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Abstract

The General State Administration establishes the food safety control and cooperation mechanisms with the competent authorities of the administrations responsible for official controls. In order to improve the quality and homogeneity of official controls related to biological hazards in food, the Spanish Agency for Food Safety and Nutrition (AESAN) and the autonomous communities have a Guidance document for the scheduling of biological hazard sampling within the framework of the National Plan for Official Control of the Food Chain 2021-2025, which establishes a semi-quantitative model that takes into account, on the one hand, the impact on health, considering incidence and severity, and, on the other, the prevalence, composed of data from non-compliant samples and alert notifications.

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At AESAN's request, the Scientific Committee has assessed this Guidance document, and the final conclusion is that this Guidance document is suitable at the present time, for the intended purpose. Specifically, the criteria based on the calculation of the health impact are considered valid for the biological hazards studied. Regarding the prevalence calculation, different percentile levels could be considered for the parameters of percentage of non-compliant samples and number of alert notifications. The use of the correction factor for inactivating treatment for the correction of the score associated with prevalence is positively assessed. Regarding the distribution of food categories and hazards analysed, it is considered suitable and it is recommended to re-evaluate this distribution considering average consumption data of the different food categories in each of the autonomous communities. The procedure to calculate the number of samples and the risk score intervals used for the different hazard-food pairs is also considered suitable for the intended purpose.

Finally, some suggestions are made for revising some criteria in the future in the event that information is available, and it is indicated that the Guidance document should be updated periodically in the light of the experience of its application, progress in scientific knowledge, changes in legislation and guidelines and tools on prioritisation and frequency of risk-based inspection that may be developed at national or European Union level.

Key words

Sampling, official control, biological hazards, prioritisation.

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1. Introduction

Article 9 of Regulation (EU) 2017/625 on official controls provides that "the competent authorities shall carry out official risk-based controls on all operators on a regular basis, and with the appropriate frequency" (EU, 2017).

In order to improve the quality and homogeneity of official controls, in 2016, a working group was created for the scheduling of official sampling controls for analysis within the framework of the National Plan for Official Control of the Food Chain (PNCOCA). Its main objective was to design a national sampling schedule for official controls based on risk. This working group was made up of personnel from different work areas of the Spanish Agency for Food Safety and Nutrition (AESAN) and experts in control planning and analysis from the autonomous communities.

This scheduling aimed to establish a proposal for the distribution of sampling for official control throughout the national territory, after analysis and risk assessment. The resulting scheduling was exclusively intended to provide support and guidance to the autonomous communities to execute their official control programmes, and those communities would have sufficient flexibility to increase the number of samplings when circumstances so warrant.

In 2017, AESAN and the autonomous communities developed a Guidance document for the scheduling of biological hazard sampling within the framework of PNCOCA 2021-2025. This document defined a semi-quantitative model, in which the variables to which a relative numerical value was assigned were established to obtain a final grade. The ranking methodology was based on considering, on the one hand, the impact on health, considering incidence and severity, and, on the other, the prevalence, composed of data from non-compliant samples and alert notifications. The document was evaluated by the AESAN Scientific Committee (AESAN, 2017), which concluded that it was adequate at that time for the intended purpose, and that it should be updated periodically in the light of the experience of its application, the progress of scientific knowledge, changes in legislation and guidelines and tools on prioritisation and sampling that could be developed at national or European Union level.

The AESAN Scientific Committee has been asked to evaluate the suitability of the aspects described below in relation to the scheduling of biological hazard sampling in official controls and make the contributions it deems necessary, in light of the advancement of scientific knowledge:

- Methodology for the calculation of the health impact of biological hazards in food: percentage of cases of disease attributable to food for the calculation of the risk score by incidence and calculation of the risk score by severity.
- Guidance for the scheduling of biological hazard sampling within the framework of PNCOCA 2021-2025: in the proportional allocation of the number of samples of the different hazards for the five-year period, assess the minimum sample size, and in the distribution of samples between autonomous communities, assess the allocation of samples by hazard-food pair.

2. Overview of the methodology for the prioritisation of risk due to the presence of biological hazards in food

Article 15 of Law 17/2011, on food security and nutrition (BOE, 2011), indicates that the General State

Administration will establish food safety control and cooperation mechanisms with the competent authorities of the administrations responsible for official controls, especially with regard to the application of official control plans. These mechanisms aim to ensure that the official control criteria are comprehensive, coordinated, proportionate and the same throughout the national territory. Furthermore, the official controls that are established will be systematic, sufficiently frequent and risk-based. The frequency of official controls must be established by the competent authorities, taking into account the need to adapt the control effort to the risk and the level of compliance expected in different situations.

Official controls are aimed at complying with the provisions of Regulation (EC) No. 2073/2005 (EU, 2005), which establishes microbiological criteria for certain microorganisms and foods, and those of Regulation (EU) 2017/625 on food sampling and analysis that the competent authorities must carry out to verify compliance with current regulations (EU, 2017).

The food safety sampling programs in Spain have been developed by the autonomous regions. The annual reports carried out within the framework of the PNCOCA, as well as the official control audits carried out by the European Commission in Spain and those of third countries, reflect a certain disparity in the verification of compliance with the rules that establish maximum limits of contaminants, residues, microorganisms and other hazards present in food. For this reason, the autonomous communities were proposed a flexible national programming that respects their competences, but that would guarantee a control of compliance at the national level with all the criteria established in food legislation.

To comply with these premises, in 2016 the AESAN Institutional Commission approved the creation of a working group that prepared two documents that establish a methodology for calculating the health impact of biological and chemical hazards, and two other documents that establish a methodology for scheduling sampling for the control of these hazards in food.

2.1 Methodology for prioritising health impact

The risk score in the case of biological hazards has been considered when calculating the health impact using the formula:

$$\text{Health Impact} = \text{Incidence} + \text{Severity} \qquad \textbf{Equation 1}$$

The incidence of a disease is established using epidemiological information (Microbiological Information System (SIM), National Epidemiological Surveillance Network (RENAVE)), based on the number of disease cases for each hazard considered. Once the number of cases associated with each hazard has been obtained, the percentage that the cases represent for each of these hazards is calculated with respect to the total number of cases.

Since some of the cases collected are associated with food-borne diseases, a correction factor is applied, according to the proposal of Havelaar et al. (2008) for the Dutch population. Depending on the number of cases corrected, the following semi-quantitative scale is established on the basis of risk: 4 (>40 %), 3 (40-10 %), 2 (10-5 %), 1 (<5 %), 0 (0 %).

An assessment of the severity of the effects on the health of the population for each hazard is carried out, in accordance with the conclusions of the expert groups of the Spanish agency AESAN and the French ANSES (*Agence nationale de sécurité sanitaire de l'alimentation, de l 'environnement et du travail*) (ANSES, 2014), based on the disability-adjusted life years (DALY-values, Disability Adjusted Life Years) per 1000 cases: 4 (>1000), 3 (101-1000), 2 (10-100), 1 (<10), 0 (0).

The final health impact score results from the sum of the risk scores in the incidence and severity variables.

2.2 Methodology for prioritising prevalence

For the calculation of the risk measure based on prevalence, the following formula is used:

$$\text{Prevalence} = (\text{Health Surveillance} + \text{Notifications in SCIRI}) \times \text{FCTI} \qquad \textbf{Equation 2}$$

The health surveillance score is calculated from the percentage of non-compliant samples in the last 3 years from the data sent to the European Food Safety Authority (EFSA) for the preparation of the annual zoonosis reports. The score awarded is based on a semi-quantitative scale that takes into account the following percentages of non-compliant samples: 4 (>7 %); 3 (5-6.9 %); 2 (1.1-4.9 %); 1 (0.1-1 %) and 0 (0 %).

Furthermore, the score for notifications of alerts in the Coordinated Rapid Information Exchange System (SCIRI) is calculated from the average annual number of notifications in SCIRI with origin or destination in Spain in the last 3 years. The following scale is determined, based on the average annual number of notifications: 4 (>15); 3 (10.1-15); 2 (5.1-10); 1 (0.1-5) and 0 (0).

Depending on the culinary inactivation treatment to which the food is subjected prior to consumption, if yes, a correction factor for inactivating treatment (FCTI) of 0.5 is applied for the calculation of the final risk.

2.3 Proportional allocation of the number of samples for the five-year period

To determine the number of samples to be assigned for each hazard-food pair based on risk, the document of the Food and Agriculture Organisation of the United Nations (FAO, 2009) has been taken as a reference, which establishes a value of 59 samples to detect a positive in a batch with a proportion of 5 % of contaminated units, with a 95 % confidence level.

Taking into account the minimum number of 59 samples for the hazard-food pairs with the lowest score, the number of samples to be taken for each score interval obtained is proportionally calculated taking into account a maximum value of 2065 samples for those hazard-food pairs with scores of 15 and 16. It should be noted that the number of samples by the AESAN is scheduled per five-year period, and is reviewed every year, giving the autonomous communities room to distribute the samples based on their needs and particular situation.

The five-year scheduling for the autonomous communities is established based on the percentage that each food sector represents, with respect to the total of that sector in Spain. The value is determined based on the number of establishments registered with the General Health Registry of

Food Companies and Food (RGSEAA), declared by the autonomous communities in the application of food alert management and official control (ALCON Annual Report) for each food sector. Although the autonomous communities may decide to take samples in any type of establishment based on the criteria they have established, it is considered more relevant to do so with manufacturers to achieve greater effectiveness of official controls.

The five-year scheduling of the number of samples is considered indicative, since consumption data are not taken into account, nor are the size of the establishments, nor the laboratory capacity of each autonomous community.

3. Review of methodologies for prioritising microbiological risk in food

Risk prioritisation is defined as a risk management activity that uses a scientific process to identify food safety priorities and allocate resources accordingly.

Hazards in a food product can be assessed using qualitative (low, medium or high risk) or quantitative approaches. The quantitative approach requires calculating the incidence and severity of a hazard in the food. The incidence of a hazard in a foodstuff (prevalence) is the percentage of samples positive for a pathogen or of samples above the Maximum Residue Limit (MRL) for a substance. However, severity can be defined as the severity of symptoms in health. Severity can also be assessed by qualitative approaches (low, medium or high risk) or using public health data from official national statistics, taking into account the following information: a) health effects related to the pathogen, such as symptoms and sequelae; b) number of outbreaks and cases associated with the pathogen; c) number of hospitalisations associated with the pathogen; and d) number of deaths associated with the pathogen.

There is a wide variety of methods and tools for prioritising risks in food safety (EFSA, 2012, 2015) (van der Fels-Klerx et al., 2015). Likewise, FAO prepared a guide that includes a brief description of the methods selected as most relevant for the classification of food safety risks (FAO, 2020). According to the document published by the Food and Agriculture Organisation of the United Nations/World Health Organization (FAO/WHO, 2006), risk prioritisation methods can be summarised as follows:

3.1 Qualitative methods

These are those based on decision organisation charts and deliberative processes, among others, that require few resources and data (van der Fels-Klerx et al., 2015). They are ideally used as a starting point for the development of strategies that incorporate and evaluate more robust sources of data and information over time. In this sense, decision flow diagrams can be used as a selection tool to identify the parameters that should be included in more complex risk classification models. Another advantage is that the results can be easily used by risk managers or decision-makers. The main disadvantages of qualitative risk classification methods are that they are often not based on quantitative scientific values, and that there may be a greater degree of uncertainty in the results of qualitative methods than quantitative methods.

3.2 Semi-quantitative methods

These methods require moderate resources and some data availability. Scores allow items to be classified, but do not provide an actual quantitative measure of risk or burden of disease, as is the case with quantitative methods.

The Risk Matrix (RM) and the Multicriteria Decision Analysis (MCDA) are the two most common semi-quantitative risk prioritisation methods (van der Fels-Klerx et al., 2015). The risk matrix can be both a qualitative and semi-quantitative method that takes into account a wide variety of data to classify risks. Risks are classified into categories based on their relative severity and probability. The MCDA is a set of decision-analysis techniques that has been used for the prioritisation of food-borne hazards and/or safety issues in which it is necessary to incorporate multiple criteria (or factors), in addition to public health, to support decisions (Ruzante et al., 2010) (FAO/WHO, 2012). The MCDA can aggregate qualitative and quantitative variables into a single metric that allows sorting of the options being classified (e.g., food and/or hazards).

3.3 Quantitative methods

Quantitative risk prioritisation methods produce numerical estimates of the likelihood of food-borne illness and the severity of outcomes with units of measure. Some examples are based on the calculation of metrics such as DALYs, Quality Adjusted Life Years (QALYs), Cost of Illness (COI), and the number of illnesses, hospitalisations, and deaths (total and per ration of a given food). Quantitative methods require the development of mathematical models that can be deterministic (results are single values or score estimates) or stochastic/probabilistic (results are characterised by probability distributions to represent the inherently associated uncertainty and variability). In stochastic models, the calculations are carried out using computer simulations such as the Monte Carlo method (EFSA, 2012). Quantitative methods are robust, can provide estimates of risk, and the magnitude of the differences between each classified element can be more evident if probabilistic methods are used. However, they are usually more complex and require more technical knowledge, resources and data than qualitative or semi-quantitative methods.

Depending on the origin of the data used and the purpose of the prioritisation procedure, quantitative methods can be classified as:

3.3.1 Burden of disease methods

Top-down approaches use epidemiological data, such as the number of diseases reported to national health authorities and detected by surveillance systems, to estimate likelihood and severity. The proportion of cases of food origin, as well as the food vehicle that caused the disease (attribution to the food source) are fundamental data for this approach. Since reported cases are only a small percentage of all diseases, when using these quantitative epidemiological approaches, it will also be necessary to determine the rate of cases that are not reported or diagnosed. Data from other countries and published literature might be useful in some cases, but given differences in surveillance, culture and health systems, they should be carefully evaluated to ensure that they are representative.

3.3.2 Quantitative Microbial Risk Assessment (QMRA)

QMRA is defined as an iterative process where the risk associated with a hazard-food combination is estimated through various data sources and mathematical prediction models. Some of the tools used for QMRA in food are iRISK, sQMRA or MicroHibro, among others (EFSA, 2015) (Possas et al., 2022), which have evolved in recent years to facilitate their use by companies, institutions and health administration. The results obtained from a QMRA provide relevant information for the prioritising risks and, therefore, are very useful in decision-making processes.

4. Review and update of the criteria used for the scheduling of biological hazard sampling within the framework of the PNCOCA

4.1 Adequacy of the hazard-food categories

The categorisation of hazard-food pairs is complex and variable in the different countries of the European Union and outside it. Some systems are based on the FoodEx system, developed by EFSA at the end of 2008 in its first version, and in 2011 as FoodEx2, which is more detailed. The last revision of this system was published in 2015 (FoodEx2, revision 2). This system has made it possible to code foodstuffs and beverages through a basic list of food products or descriptions of generic foods that represent the minimum level of detail necessary for evaluations of intake or exposure, as well as an expanded, more detailed list. The terms of the basic list and the extended list can be aggregated in various ways, depending on the needs of the different areas of food safety (EFSA, 2016).

Based on FoodEx2, in 2020, ANSES established a selection of food-hazard pairs for hierarchy and priority-setting (ANSES, 2020). In it, when the available knowledge and data are sufficient to conclude the absence of hazard in the food, that pair is excluded (for example, if the food is not a potential reservoir of the hazard, or there is a stage that eliminates the risk, there being no significant possibility of secondary contamination). Among the non-excluded pairs, a distinction is made between so-called potential pairs (that present a low risk) and so-called relevant pairs, which would correspond to those that pose a significant risk, obtained from epidemiological data, scientific literature or microbiological criteria contained in legislation (mainly Regulation (EC) No. 2073/2005 (EU, 2005) and its amendments). In addition, for each relevant food-hazard pair, high risk scenarios linked to situations (production processes, risk practices and sensitive populations) have been identified. This system includes bacteria, toxins and metabolites, viruses and parasites. In the United States, the Food and Drug Administration (FDA) has also established different programs for food sampling in relation to the presence of biological hazards. In them, the focus is especially on *Salmonella* spp., *Listeria monocytogenes* and *Escherichia coli*, among others, in food groups such as fruits and vegetables, ready-to-eat foods, cheeses and other groups (FDA, 2022).

There are some differences between the pairs established by ANSES (2020) and the food-hazard categories established in Spain in PNCOCA 2021-2025 (AESAN, 2024a), both in the specified biological hazards and in the established food categories. In the case of the methodology recommended in the latter, for establishing the sampling, a distribution of the food-hazard categories based on the microbiological criteria specified in Regulation (EC) No. 2073/2005 (EU, 2005) has been taken into account, although a different criterion has been followed for *L. monocytogenes*, maintaining cate-

gory 1.1 (Ready-to-eat foods for infants, and ready-to-eat foods for special medical purposes), while categories 1.2 (Ready-to-eat foods that can promote the development of *L. monocytogenes*, other than those intended for infants or for special medical purposes) and 1.3 (Ready-to-eat foods that cannot promote the development of *L. monocytogenes*, other than those intended for infants or for special medical purposes) have been replaced by a distribution based on food sectors, according to the ALCON Annual Report. For example, legislation establishes broad food categories and more detailed ones, and this causes more samples to be scheduled for some types of food. For example, Regulation (EC) No. 2073/2005 (EU, 2005) (and subsequent amendments) considers, in the case of *Salmonella*, six different groups of meat and meat products, with their respective microbiological criteria, while in the case of *L. monocytogenes* only two are established (ready-to-eat meats and derived products that can and cannot support the growth of *L. monocytogenes*), so that in the case of this microorganism the number of samples of meat and meat products analysed is much lower than that of *Salmonella*.

Although the distribution of food categories and hazards analysed is considered suitable for the purpose pursued when carrying out official controls of the food chain, in the autonomous communities, in relation to biological hazards, a review of it could be carried out in the future with the aim of assessing whether it is necessary to modify it. Therefore, it is suggested to re-evaluate this distribution considering additional variables, such as the consumption of the different food categories in each of the autonomous communities to achieve greater uniformity and adequacy in the sampling to be carried out per biological hazard.

4.2 Methodology for calculating the number of samples

Three stages are required to design a risk-based bio-hazard monitoring plan. Firstly, it is necessary to prioritise the hazard-food pairs according to their probability of contamination of the sampled product, its consequences for human health or the combination of one or more of these aspects. Secondly, the food business operators to be sampled must be selected. Selection can be based on historical data, but also on socio-economic factors. These include both internal factors, such as the company's size, the perception of the probability and consequence of producing unsafe food, social pressure, as well as external factors, such as current legislation or the budget available. Thirdly, for the selected hazard-food pairs and food sector operators, it is necessary to determine an optimal sampling strategy. The optimal number of batches to be sampled and the optimal number of samples per batch depend on the prevalence of the pathogen, the distribution of the pathogen among and within the batches, and available resources. In addition, it is important to define the sampling strategy in terms of where and how batch samples should be collected. To date, studies and reviews in this regard have focused on some of these three stages. Devleesschauwer et al. (2015) and van der Fels-Klerx et al. (2018) reviewed the methods available for risk prioritisation, for both chemical and microbiological hazards. Focker et al. (2018) reviewed the methods available for cost-effective monitoring of chemical and microbiological hazards and, on the other hand, van Asselt et al. (2021) described the methods available for selecting food sector operators based on risk. Finally, in a recent review on official control, Focker et al. (2023) recommend further research to develop a me-

thodology to identify hazard-food combinations relevant to risk classification, developing generic models and easy-to-use calculation tools that combine risk classification, food business operator selection and cost-effective sampling.

In the sampling scheduled by AESAN, the number of samples for the corresponding five-year period is scheduled based on the risk scores obtained as a result of the sum of health impact and prevalence.

The calculation of sampling based on the binomial distribution defines the probability of accepting or rejecting a batch following a sampling plan by attributes for microbiological hazards, where n= number of samples, and c= maximum allowable number of positive samples (ICMSF, 2002) (Zwietering et al., 2015) (FAO/WHO, 2016). Therefore, the five-year programming calculates a minimum number of samples (n= 59) from the result returned by the binomial distribution, taking into account a proportion of 5 % of contaminated units in a batch, and assuming a 95 % confidence level. This value is increased in proportion to the score obtained, reaching a maximum of 2065 samples for those food-hazard categories with a score in the range of 15-16, as indicated in section 2.3. Annually, the programming is re-evaluated, taking into account the results of the samples analysed, positive and SCIRI data, following a "moving window" approach. This approach is practical, in addition to offering a good cost-benefit ratio in terms of continuously checking the microbiological functioning of the process or the food safety control system (FAO/WHO, 2016).

Therefore, in view of the available information, it can be concluded that the design of the scheduling of the number of samples is suitable for the intended purpose.

Furthermore, based on the analysis of the latest sampling data collected by the autonomous communities for the period 2019-2021 and AESAN's annual scheduling for the five-year period 2021-2025, it is concluded that, in general, the autonomous communities carry out more intensive sampling for most of the selected hazards and food categories. A comparative analysis has been carried out between the average of samples collected by the autonomous communities and the scheduling by AESAN. The values have been relativised to number of samples/year. In the case of *L. monocytogenes* and *Salmonella* spp., this relationship is shown in Figure 1.

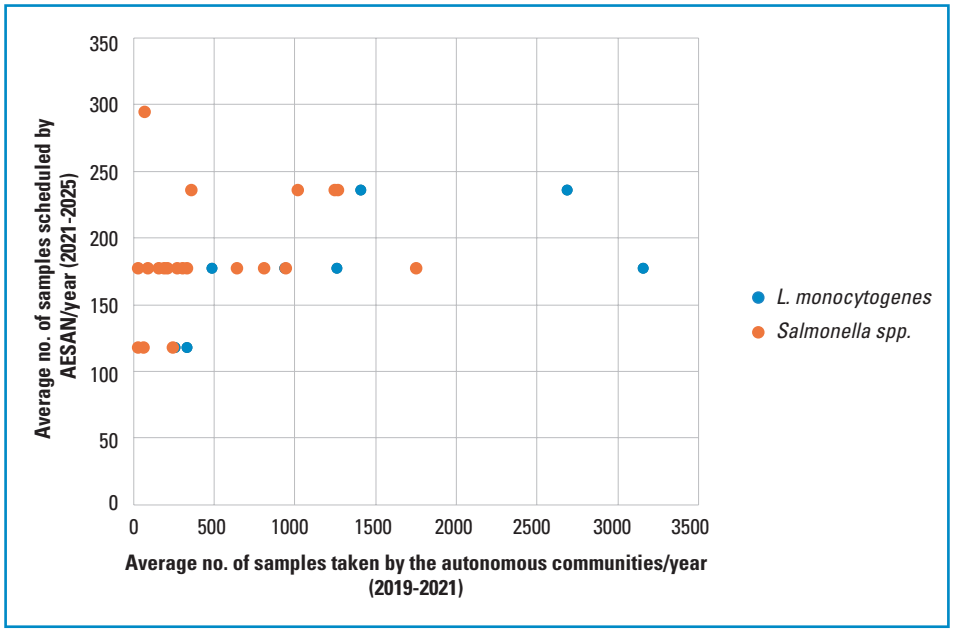


Figure 1. Graphic representation of the average number of samples taken by the autonomous communities/year in the period 2019-2021 versus the average number of samples scheduled by the AESAN/year for the five-year period 2021-2025 for the monitoring of *Salmonella* spp. and *L. monocytogenes*, in each of the selected food categories.

For almost all food categories, the samplings carried out by the autonomous communities sufficiently cover the scheduling carried out by AESAN, except for *Salmonella* spp. in certain food groups (mechanically separated meat, meat products based on poultry meat intended to be consumed cooked, gelatin and collagen, sprouted seeds ready for consumption and dehydrated follow-on preparations).

Similarly, if the biological hazard is taken as a reference, it can also be seen that the autonomous communities intensified sampling to a greater extent for all hazards in the 2019-2021 period, compared to the annual sampling schedule by AESAN.

To assess the adequacy of the sampling schedule, the sampling rate has been calculated as follows:

Equation 3

$$\text{Sampling rate} = \frac{\text{Average No. of samples scheduled by AESAN/year}}{\text{Average of the No. of samples taken by the autonomous communities/year}} \times 100$$

According to the latest data, of the 36 food-hazard combinations included in the five-year scheduling, in 30 of them the sampling rate is below 100 %, which means that the number of samples taken by the autonomous communities is higher than that of the five-year programming by AESAN. Espe-

cially, in the case of the sampling schedule for the pairs *L. monocytogenes* - meat (meat products), *L. monocytogenes* - processed foods not included in the other categories, except foods for infants and young children and histamine - fishery products from fish species associated with a high content of histidine, the percentage is less than 10 %.

Furthermore, for the *Salmonella* spp. pairs in the categories of mechanically separated meat, gelatin and collagen and dehydrated follow-on preparations, the sampling rate is notoriously high, exceeding 400 %, which indicates that the five-year scheduling is well above the sampling by the autonomous communities.

This trend is corroborated through the comparison of the number of samples taken by the autonomous communities and the final risk score associated with each hazard-food pair, established in the Guidance document for the scheduling of biological hazard sampling within the framework of the PNCOCA 2021-2025. According to the five-year schedule, the number of samples is increased proportionally to the final risk score obtained. However, when contrasting the data with the samples taken by the autonomous communities, there is no clear relationship between both parameters, as can be seen in Figure 2.

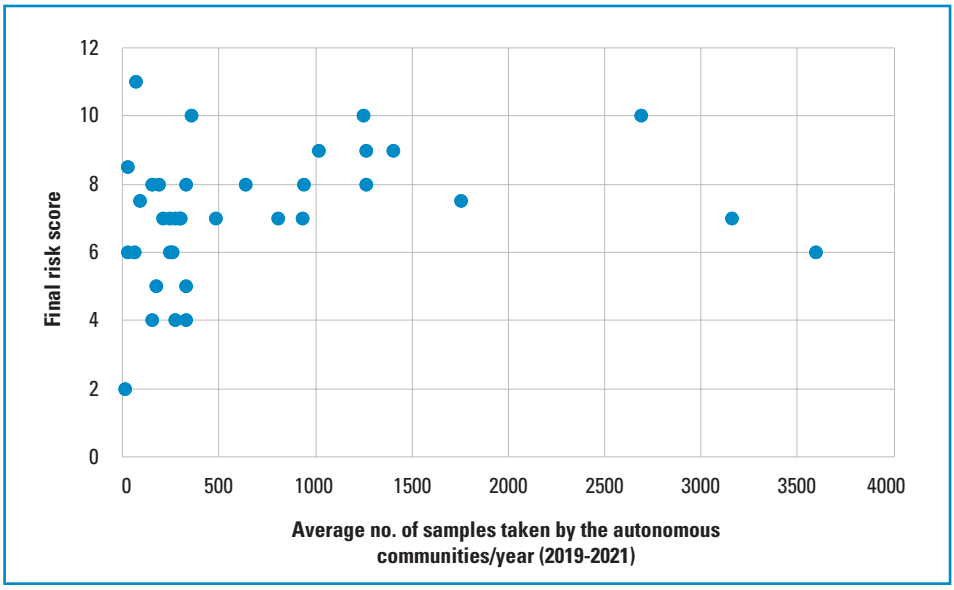


Figure 2. Graphic of the average number of samples taken by the autonomous communities/year in the period 2019-2021 against the final risk score established in the Guidance document for the scheduling of biological hazard sampling within the framework of the PNCOCA for the period 2021-2025.

As mentioned above, the procedure followed to calculate the number of samples, as well as the risk score intervals used for the different hazard-food pairs, are considered suitable for the intended purpose, there being no substantial bibliographic information to suggest a modification of them.

4.3 Criteria used to calculate the health impact and prevalence. Proposal to adapt the programming of the number of samples

As described in sections 2.1 and 2.2, the methodology for calculating the number of samples is based on the sum of the criteria related to health impact and prevalence in food.

4.3.1 Health impact

In relation to the criteria for the calculation of the health impact, they result from the sum of the score for incidence and severity.

With regard to the assessment of incidence, one of the criteria used is the percentage of cases associated with food origin, to which a correction factor is applied (Havelaar et al., 2008). More recently, the Public Health Agency of Canada (PHAC) carried out an expert consultation (expert elicitation) to attribute enteric diseases to their respective routes of transmission (Butler et al., 2015). Expert consultations allow you to explore research issues and the uncertainty associated with them when data collection is expensive or unavailable. The study aimed to improve the understanding of the relative role of transmission pathways in the burden of enteric diseases and focused on 28 pathogens. In addition, the results obtained from the expert consultation were compared with previous works, so it is especially important to compare the combination of hazard-food pairs in several countries (Cressey and Lake, 2005) (Havelaar et al., 2008) (Ravel et al., 2010) (Scallan et al., 2011) (Vally et al., 2014). This study explores a broader range of routes of transmission of enteric pathogens (food, water, animal contact, person-to-person, and others) to reflect the spectrum of all potential exposures. The results of this study confirm the results of previous studies for some pathogens, while showing notable differences in others.

Regarding the calculation of the severity score associated with DALYs, recently, the European Centre for Disease Prevention and Control (ECDC) has developed and made available to the general public a tool for the calculation of DALYs (ECDC, 2024). The programme was developed following a comprehensive review of literature on infection routes of 117 different communicable diseases. This tool facilitates the calculation of DALYs by simply entering age-, gender- and population-specific incidence data, and some adjustment values.

There are fundamentally two types of approaches to the calculation of DALYs:

• Incidence-based approach:

This methodology uses a disease progression pathway to estimate DALYs, a measure that describes the impact of Years Lived with Disability (YLD) after the onset of a disease and Years of Life Lost (YLL) due to premature mortality compared to a standard life expectancy. To determine the standard life expectancy, reference life tables are used (Haagsma et al., 2015), such as those provided by the Global Burden Disease (GBD) (Murray et al., 2012).

The incidence-based approach recognises the current and future sequelae of infections and establishes the basis for estimating the impact that different prevention and control interventions can have (Cassini et al., 2018). The disease progression model links the possible sequelae with the initial infection, which depends on the pathogen in each particular case, and assigns that future burden at the time of infection.

For acute and symptomatic diseases, the key variable to calculate DALYs is incidence. In addition to the number of infections, the calculation of DALYs requires several additional variables specific to each age group and sex. These variables include the risk of developing short-term and long-term complications (health outcomes), their duration, and the weight that reflects their severity. These variables are described through disease models or outcome trees, which represent the progression of a disease over time by ordering the relevant health outcomes after infection and illustrating their conditional dependence (Cassini et al., 2018).

• Prevalence-based approach:

Calculating DALYs based on incidence has three major disadvantages. Firstly, it does not reflect the current burden of disabling sequelae of a disease whose incidence has been substantially reduced. Second, the DALY calculation requires estimates of both the incidence and average duration of disease sequelae, whereas, for many health conditions, what is primarily collected is prevalence data. Third, from an incidence perspective, all DALYs for a condition are assigned to the age groups in which the condition occurs, while risk managers are typically more interested in the groups in which health loss is experienced (WHO, 2020). Finally, the incorporation of comorbidity is simpler in a prevalence approach than in an incidence approach. The main impact of the incidence is that it significantly changes the age distribution of DALYs. Thus, for example, DALYs for congenital hearing loss will be relatively evenly distributed among all age groups in the prevalence perspective, while all will fall at age 0 in the incidence perspective.

Despite this, the criteria used to calculate the health impact are considered stable, since the values of incidence and severity do not undergo significant variations over time. Therefore, in view of the available information, the criteria currently applied for the scheduling of sampling by AESAN are considered valid, although it is recommended to assess the possibility of reviewing the incidence and severity values in the future based on the information and tools described in this report.

4.3.2 Prevalence in food

The prevalence of a hazard in a food is defined as the percentage of positive samples with respect to the total analysed for a hazard in a given food.

$$\text{Prevalence} = \frac{\text{No. of positive samples}}{\text{No. of samples analysed}} \times 100\ (\%) \qquad \textbf{Equation 4}$$

The food prevalence criteria apply a sum of the health surveillance criteria and number of alerts or notifications in SCIRI.

The data of positive samples are obtained both from the reports of non-conforming samples detected in food health surveillance in recent years (AESAN, 2024b), and from the average number of notifications in SCIRI associated with each hazard-food combination in recent years (AESAN, 2024c).

Analysing the relationship between the percentage of non-compliant samples and the number of

alerts or notifications in SCIRI, there is a direct correlation according to the latest data collected by the autonomous communities in the period 2019-2021 (Figure 3).

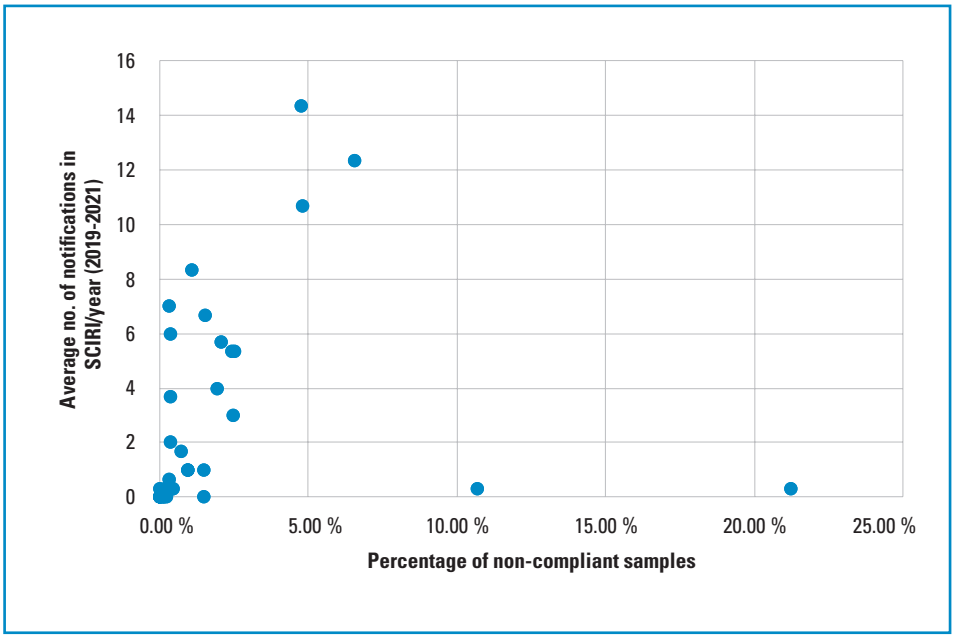


Figure 3. Graphic of the percentage of non-compliant samples compared to the average number of alerts reported in SCIRI/year for the period 2019-2021.

The hierarchy of hazards according to their prevalence is determined on a semi-quantitative scale based on static values, both for the percentage of non-compliant samples (0 % - >7 %) and for the number of notifications in SCIRI (0 - >15).

Based on this positive correlation, in order to achieve a greater adequacy of the five-year sampling schedule to the sampling carried out by the autonomous communities, it is proposed to consider different percentile levels for the parameters of percentage of non-compliant samples and number of notifications in SCIRI as follows:

i. Values <25th percentile: score= 0
ii. Values ≥25th percentile and <50th percentile: score= 1
iii. Values ≥50th percentile and <75th percentile: score= 2
iv. Values ≥75th percentile and <95th percentile: score= 3
v. Values >95th percentile: score =4

Within the five-year schedule, there are biological hazards that are analysed in several food categories, such as *L. monocytogenes*, *Salmonella* spp. and histamine, where the percentile values associated with the data set of all food categories analysed for each of these hazards are considered.

However, other biological hazards (*S.* Typhimurium, *S.* Enteritidis, staphylococcal enterotoxins,

Cronobacter spp., *E. coli*, STEC and marine biotoxins) are analysed for a single food category. In these cases, percentile values are calculated from the entire data set collected for the percentage of non-compliant samples and number of notifications in SCIRI.

Finally, for some hazard-food pairs analysed, there are high values for the percentage of non-compliant samples and number of notifications in SCIRI. For this reason, it is proposed to increase the final risk by 1 point for those combinations where the value resulting from the multiplication of both parameters is higher than that resulting from the multiplication of the 95th percentile values.

Taking into account the data obtained for the period 2019-2021 by the autonomous communities, the percentiles associated with each risk score are shown in Table 1.

Table 1. Associated percentile values for the percentage of non-conformities (NC) and the number of notifications in SCIRI and their relationship with the risk score

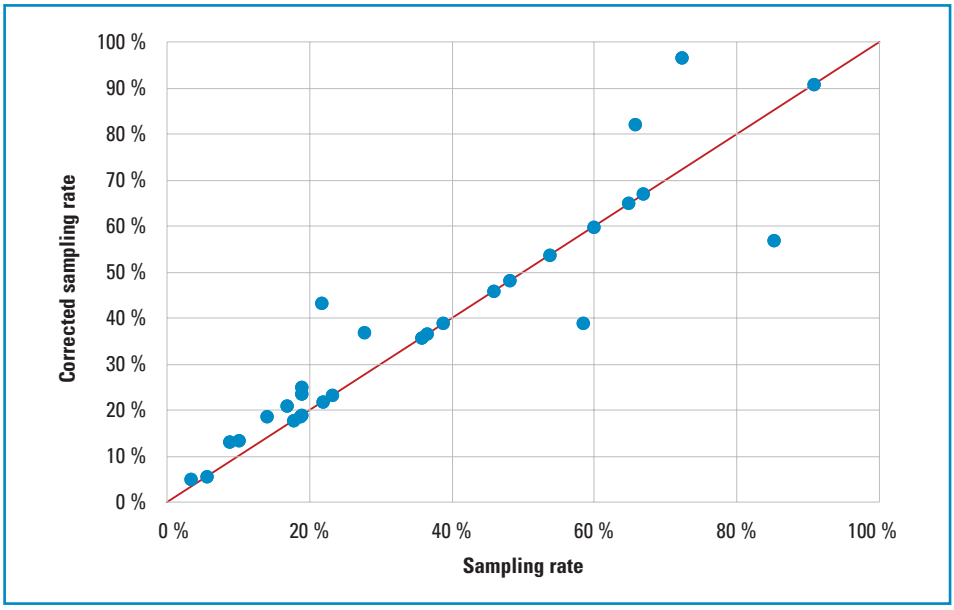
L. monocytogenes				
Percentile	**NC (%)**	**SCIRI**	**Risk score**	**NC x SCIRI***
<25	<0.2	<0.25	0	
25-50	0.2 a <0.6	0.25 a <1.50	1	
50-75	0.6 a <2.0	1.50 a <4.42	2	
75-95	2.0 a 3.9	4.42 a 8.92	3	
>95	>3.9	>8.92	4	34.79 %
***Salmonella* spp.**				
Percentile	**NC (%)**	**SCIRI**	**Risk score**	**NC x SCIRI***
<25	<0.2	<0.01	0	
25-50	0.2 a <0.4	0.01 a <0.67	1	
50-75	0.4 a <2.4	0.67 a <3.33	2	
75-95	2.4 a 11.7	3.33 a 6.63	3	
>95	>11.7	>6.63	4	77.57 %
Histamine				
Percentile	**NC (%)**	**SCIRI**	**Risk score**	**NC x SCIRI***
<25	<0.5	<0.01	0	
25-50	0.5 a <1.1	0.01 a <0.02	1	
50-75	1.1 a <1.3	0.02 a <4.17	2	
75-95	1.3 a 1.4	4.17 a 7.50	3	
>95	>1.4	>7.50	4	10.50 %
Total**				
Percentile	**NC (%)**	**SCIRI**	**Risk score**	**NC x SCIRI***
<25	<0.1	<0.01	0	
25-50	0.1 a <0.42	0.01 a <0.83	1	
50-75	0.42 a <1.96	0.83 a <5.33	2	
75-95	1.96 a 7.58	5.33 a 11.08	3	
>95	>7.58	>11.08	4	83.99 %

*1 additional point is awarded to the final risk in the event that the value is higher for the hazard-food pair. Applies in case that the resulting score is ≤15.

**The values apply for the case of hazards where they are only analysed in a food category: *S.* Typhimurium, *S.* Enteritidis, staphylococcal enterotoxins, *Cronobacter* spp., *E. coli*, STEC and marine biotoxins.

Once these values have been applied, the corrected sampling rate has been estimated, relating to the values obtained without the application of percentiles. The results are shown in Figure 4a and 4b, for the sampling rates below and above 100 %, respectively.

a)



b)

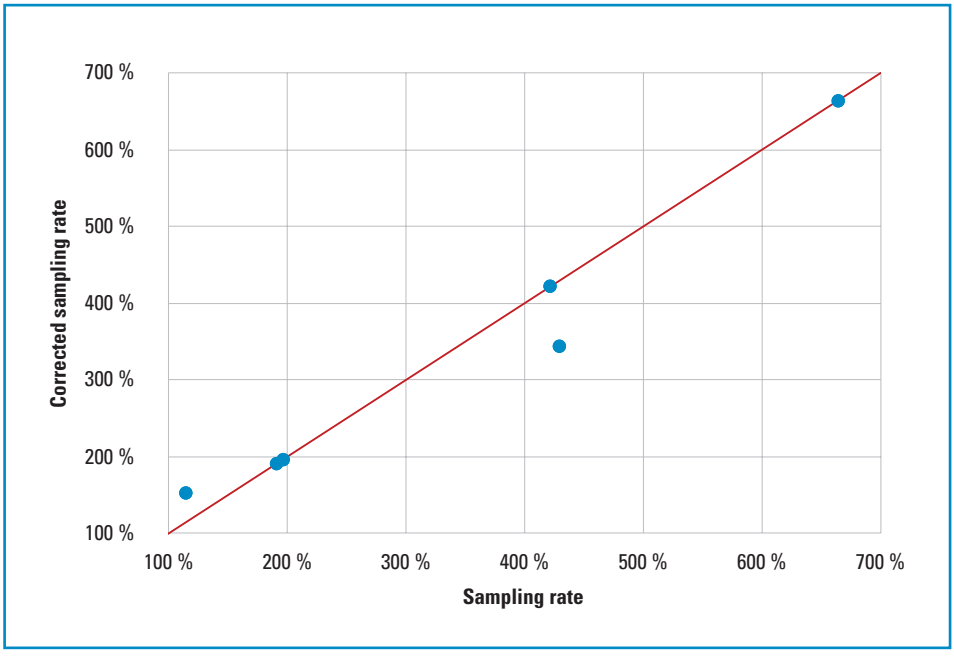


Figure 4. Graphic of the sampling rate values against the corrected sampling rate values obtained for all food-hazard categories analysed, for sampling rates below 100 % (a) and above 100 % (b). The red line represents the equivalence between both rate values.

As can be seen in the graphs, in those values below 100 % of the sampling rate (Figure 4a), that for 12 hazard-food combinations, the corrected values are higher than the uncorrected ones. This means that the percentage of samples scheduled for those combinations is closer to that taken by the autonomous communities. In only two combinations (*Salmonella* spp. - ice cream, excluding products in which the manufacturing process or product composition eliminates the risk of *Salmonella*, and *Salmonella* spp. - dried infant formulae and dried dietary foods for special medical purposes for infants under 6 months of age), the value of the corrected rate was lower (Figure 4a). However, for both combinations, the number of non-conformities and notifications in SCIRI was very low, so they do not represent a significant risk a *priori*.

If sampling rate values greater than 100 % are taken into account, it follows that only in one combination (*Salmonella* spp. - germinated seeds), the corrected value was greater than the uncorrected value. For the rest of the categories, there was no significant change due to the application of the proposed proposal (Figure 4b).

In addition, the prevalence is corrected according to the type of processing that the food goes through in order to consider possible decreases or increases in the risk posed by the hazard-food pair. There are different strategies to take into account the effect of processing:

a) Correction factor for inactivating treatment (FCTI): takes into account the possibility of reducing the presence of the hazard in the food due to handling or cooking by the consumer. The application of regular culinary treatments is often sufficient to reduce the risk associated with the presence of certain hazards to acceptable levels. Therefore, in the case of foods that are analysed raw but consumed cooked, the prevalence value is corrected by multiplying the percentage obtained by 0.5 (AESAN, 2017).

b) Correction factor as a consequence of processing: it is a correction factor on the prevalence, but in a broader sense than the FCTI. It considers the effect of processing not only in reducing the risk, but also takes into account that certain types of processing can lead to an increase in the number of microorganisms and, consequently, in the risk. Such is the case, for example, of certain storage conditions or re-contamination as a result of slicing. Therefore, it corrects the risk value not only downwards (multiplying it by 0, 0.01 or 0.5, for cases in which the processing totally eliminates the risk, eliminates it by 50 %, or 99 % of the cases, respectively), but also increasing it for cases in which there may be microbial growth (multiplying it by 10, 1000 or another value that fits the effect) (Ross and Sumner, 2002) (Food Safety Portal, 2024).

c) Exposure evaluation models: another more complex possibility is to use exposure evaluation models based on predictive models that relate the concentration of the microorganism based on different process parameters (storage temperature, time, heat treatment temperature, etc.), and that allow to accurately estimate the increase or decrease in risk as a result of processing and provide a specific quantitative value of the microorganism-food-process set. This approach is much more precise, but also more laborious and depends on the existence of experimental data describing the process. An example of this type of application is the MicroHibro tool (Cubero-Gonzalez et al., 2019) that allows the quantitative evaluation of the evolution of possible pathogenic microorganisms in food throughout the food chain and their impact on public health.

Of the different strategies described, both that of the correction factor as a consequence of processing and that of the exposure assessment models, require the existence of experimental data that relate more or less quantitatively the effect of processing on risk. Therefore, although these strategies are more precise and allow quantifying both decreases and increases in risk, they are currently difficult to apply in a general way for each hazard-food-process case. Therefore, the strategy of correcting the prevalence through the FCTI is recommended, and considering in subsequent reviews the use of any of the other strategies described based on the availability of information.

Finally, when calculating the final risk score, the fact of applying the FCTI means that some final values do not correspond to whole numbers. Therefore, the proposal to modify the risk score scale to consider those non-integer values is proposed, as shown in Table 2.

Table 2. Proposed semi-quantitative scale of risk score intervals and associated number of samples for five-year programming

Risk score range	Number of samples
1 to 2	59
>2 to 4	295
>4 to 6	590
>6 to 8	885
>8 to 10	1180
>10 to 12	1475
>12 to 14	1770
>14 to 16	2065

Conclusions of the Scientific Committee

This report has reviewed the adequacy of the methodology used for the prioritisation of risk due to the presence of biological hazards in food, as well as the scheduling of sampling for official control. In view of the available information and, after a review and analysis of the most recent data collected, the following conclusions have been reached.

First, given their stability over time, the criteria based on the calculation of the health impact (incidence and severity) are considered valid for the biological hazards studied. However, it is recommended to review them in the future based on the studies cited in this report and assess their possible impact on the final risk score.

The proposal related to the modification of the values of the prevalence criteria significantly affects the relationship between the number of samples calculated and the number of samples finally taken in the sampling schedule aimed at the autonomous communities. However, this proposal could be revised using a more representative data set on health surveillance and notifications in SCIRI to, where appropriate, be implemented in future reviews of the programming. Likewise, the use of the FCTI for the correction of the score associated with prevalence is positively assessed. It is also necessary to point out that the results shown are related to the criteria currently used in the sampling schedule, not considering other variables such as consumption data, size of establishments or laboratory capacity of the autonomous communities, among others.

Regarding the distribution of food categories and hazards analysed, it is considered suitable. Despite this, it is recommended to re-evaluate this distribution considering average consumption data of the different food categories in each of the autonomous communities, so that the design of the sampling schedule is as balanced as possible for each biological hazard considered.

Furthermore, the procedure to calculate the number of samples, as well as the risk score intervals used for the different hazard-food pairs are considered suitable for the intended purpose, there being no substantial bibliographic information to suggest a modification of them.

The final conclusion of the Scientific Committee is that the Guidance document for the scheduling of biological hazard sampling within the framework of PNCOCA 2021-2025 is suitable, at the present time, for the intended purpose. However, the Guidance document should be updated periodically in light of the experience of its application, progress in scientific knowledge, changes in legislation and guidelines and tools on prioritisation and frequency of risk-based inspection that may be developed at national or European Union level.

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