

Report of the Scientific Committee of the Spanish Agency for Food Safety and Nutrition (AESAN) on the classification of food establishments on a risk basis within the Spanish National Plan for Official Control of the Food Chain (PNCOCA 2021-2025) framework

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Working group

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Abstract

The National Plan for the Official Control of the Food Chain (PNCOCA) 2021-2025 lists the directives for conducting risk-based inspections in accordance with current European legislation. In this regard, AESAN (Spanish Agency for Food Safety and Nutrition) and the autonomous communities have drawn up a “Guidance Document for the Risk-Based Classification of Food Establishments within the Framework of PNCOCA 2021-2025” whose main objective is to establish a common system for the risk-based assessment and classification of food establishments, setting certain basic criteria of risks, as well as its objective assessment in accordance with standardised criteria.

Based on this Guidance Document, the AESAN Scientific Committee has drafted an assessment report including various recommendations, especially regarding risk criteria, risk assessment and the risk-based classification of establishments.

The Scientific Committee concludes that the Guidance Document for the risk-based classification of food establishments within the framework of the PNCOCA 2021-2025 is currently suitable for the intended purpose. Nevertheless, the guidance document must be periodically updated considering the experience of its application, scientific progress, legislative changes and new directives, and tools for the risk-based prioritisation of inspection frequency which may be developed at the national or European Union level.

Overall, the criteria used to establish the risk-based classification of food establishments in the Guidance Document are deemed to be accurate. Other criteria have been suggested for consideration such as the adherence of each establishment to the self-monitoring system and good hygiene and handling practices or correct training of the establishment's employees.

Among other issues, a pilot study is recommended in order to detect potential difficulties that may lead to the modification of the selected criteria.

Key words

Official control, food establishments, risk criteria, classification.

Suggested citation

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1. Introduction

The National Plan for the Official Control of the Food Chain (PNCOCA) describes the official controls conducted in Spain by different competent authorities at the national, regional and local levels to ensure regulatory compliance throughout the food chain, from primary production to the points of sale to end consumers. Article 9 of Regulation (EU) 2017/625 establishes that the competent authorities must perform official checks on a regular basis, according to risk and with the appropriate frequency, of all sectors and for all operators, activities, animals and goods to which European Union legislation on the food chain is applicable (EU, 2017).

After the audits conducted in Spain by the European Commission until 2019, it became evident that the risk-based classification of the establishments and the frequency of the official controls varied between autonomous regions. This issue also emerged during visits by third-party delegations for exports. This evidence, along with the health alerts declared in 2019 for *Listeria monocytogenes*, led to the proposal for establishing a series of common criteria for the risk-based classification of establishments.

The Institutional Committee of the Spanish Agency for Food Safety and Nutrition (AESAN) agreed to standardise these criteria for all Spain, in line with the provisions of Regulation (EU) 2017/625. Firstly, the various regional criteria for the risk-based classification of establishments were studied and a Working Group was created to develop the National Plan for the Official Control of the Food Chain (PNCOCA) 2021-2025, consisting of the autonomous regions and the AESAN. The Group drafted the Guidance Document which is being assessed in this report (PNCOCA, 2021-2025).

2. Legislative considerations regarding official risk-based control

With regard to the directives mentioned in Regulation (EC) No. 178/2002, food establishment operators are responsible for guaranteeing the safety of foods placed on the market (EU, 2002). Management systems such as the ISO (International Organization for Standardization) standards and HACCP (Hazard Analysis and Critical Control Points) systems have been applied with the primary goal of preventing and monitoring the presence of hazards that compromise food safety (Gil et al., 2017).

In spite of this, there may be physical, chemical and biological hazards in the final product. The use of preventive approaches facilitates the implementation of measures for control throughout the production chain and the development of rapid response systems, which enable correct and effective decision-making. Given the limitation of existing resources, official control programmes must be as effective as possible and geared towards those hazards and foods that pose a greater risk (Presi et al., 2008) (Focker and van der Fels-Klerx, 2020).

The well-known Food Safety Modernisation Act (FSMA) implemented in the United States since 2011 (FDA, 2015) seeks to make these preventive approaches the norm in order to provide an effective response to problems of food safety. Its goals are to improve public health protection by reinforcing food chain safety, focusing more on incident prevention rather than action after alerts are raised. This law requires the presence of a new figure, the Preventive Controls Qualified Individual (PCQI) who is in charge of preparing and implementing the Food Safety Plan, apart from correctly managing preventive controls. Within the foods considered high risk, the Food and Drug Administration (FDA)

has developed a model for the prioritisation of foods and hazards considered high risk, based on a series of formulating criteria, involvement in food outbreaks, processing, consumption, and cost of the disease. This developed model is the basis on which the frequency of inspection programmes is established (FDA, 2020).

Equally, the European Union is calling for risk-based inspection programmes, the directives being included in Regulation (EU) 2017/625 (EU, 2017). In this regard, risk must be understood as the combined probability that a certain hazard may cause an adverse effect to public health, as well as the seriousness of said effect (Codex Alimentarius, 2015).

Regulation (EU) 2017/625 mentions some articles in relation to risk-based inspection (EU, 2017). Article 32 establishes that “the competent authorities must perform official checks on a regular basis, according to risk and with the appropriate frequency, of all sectors and for all operators, activities, animals and goods to which EU legislation on the food chain is applicable (EU, 2017). The frequency of official controls must be established by the competent authorities keeping in mind the need to adapt the control efforts to the risk and level of compliance provided for in different situations, including possible violations of EU agri-food chain legislation committed through fraudulent or misleading practices”. Additionally, Article 76 states that “each Member State should be required to set up and regularly update a Multi-Annual National Control Plan (MANCP) covering all the areas governed by Union agri-food chain legislation and containing information on the structure and organisation of its system of official controls. This MANCP is the instrument through which each Member State must ensure that the official controls are conducted on the basis of risk and are effective in all the territory and in the entire agri-food chain of the Union, and pursuant to this Regulation”.

In relation to this last point, the National Plan for the Official Control of the Food Chain (PNCOCA) describes the official controls conducted in Spain by different competent authorities at the national, regional and local levels to ensure regulatory compliance throughout the food chain, from primary production to the points of sale to end-consumers.

The PNCOCA 2016-2020 (PNCOCA, 2016-2020) already described a series of principles for scheduling risk-based controls, in the part dedicated to the official control in stages subsequent to the primary production, in the “System for the control of food establishments and foods produced or marketed in the intra-Community market with implications for food safety”, area which covers the Guidance document assessed in this report and which is included as the most detailed and standardised guidance in the new PNCOCA 2021-2025 (PNCOCA, 2021-2025).

In this part of the PNCOCA 2021-2025, Programme 1 on the General control of food establishments looks at different aspects that had to be fulfilled by food establishment operators and which consequently must be subjected to official controls by the competent authorities (PNCOCA, 2021-2025).

Firstly, it establishes the need to register food establishments and foods based on Regulation (EC) No. 852/2004 on the hygiene of food products, which establishes that the food establishment operator must notify the competent authority of the establishments under their control and which perform any activity of food production, processing and distribution, in order to register it (EU, 2004a). This Regulation sets the added requirement of authorisation by the competent authority for those cases that are provided for in Regulation (EC) No. 853/2004 laying down specific hygiene rules for food of

animal origin (EU, 2004b). Similarly, Royal Decree 191/2011 establishes the General Health Registry for Food Companies and Foods at the national level (BOE, 2011).

Food establishments must also comply with certain general hygiene requirements based on Regulations (EC) No. 852/2004 and 853/2004 (EU, 2004a, b). Likewise, fulfilling the requirement of efficient traceability understood as the continuous system of product identification throughout the food chain in accordance with Regulation (EC) No. 178/2002 (EU, 2002).

In this area, it is also necessary to monitor the training to be received by food establishment workers. Regulation (EC) No. 852/2004 establishes the personal hygiene conditions for workers. According to this, the food establishment must supervise the workers' activity, and they must also educate or train these workers on food hygiene issues according to their work activity.

Finally, it is worth highlighting the need to perform product checks, either raw material or the final product, such that there is control of the food and food product characteristics (for example, physicochemical and organoleptic characteristics, temperature characteristics, etc.), verifying their suitability.

The Guidance Document assessed in this report seeks to include all of these aspects such that a common system for the risk-based classification of food establishments may be established in Spain.

3. Objective of the report and application to the AESAN Scientific Committee

On 16 December 2020, the AESAN Institutional Committee approved the "Guidance Document for the Risk-Based Classification of Food Establishments Within the Framework of PNCOCA 2021-2025" (hereafter "Guidance Document") whose main objective is to establish a common system for the risk-based assessment and classification of food establishments, setting certain basic criteria of risks, as well as its objective assessment in accordance with standardised scales (PNCOCA, 2021-2025).

The AESAN Scientific Committee has been requested to draft a report assessing this Guidance Document and to make the recommendations it deems necessary, especially with regard to the following points:

- Risk criteria.
- Risk assessment.
- Risk-based categorisation.

4. Assessment of the proposal to classify risk-based food establishments

4.1 General establishments

The Guidance Document is applicable to food establishments located within national territory that intervene in any stage of the manufacturing, processing, preparation, packaging, storage, transport and distribution of foods. It does not include retail trade which shall be governed by a different procedure for this activity.

The main intention behind drafting the Guidance Document, apart from standardising criteria for the risk-based classification of establishments, is that it may be updated when required, given the complexity of the different official control plans of the autonomous regions.

4.2 Defining risk criteria

The Guidance Document defines a series of criteria, classifying them as general and specific.

General criteria are defined as those inherent to the particular nature of each establishment and display little or no variation over time. They may therefore be assessed without visiting the establishment and are sub-divided into:

- Type of food product and intended use.
- Establishment activity.
- Marketing scope.
- Company size.

On the other hand, specific criteria are those that depend on the functioning and/or infrastructure of the establishment itself, as well as the food safety management that is performed in it. Specific criteria may be sub-divided into:

- Registration and authorisation.
- Results of the last official control of the establishment: inspection or audit.
- Company history, company collaboration and measures taken in the event of serious non-compliances.

Once the different criteria used in the Guidance document have been assessed, their suitability is determined on the basis of current legislation, in consonance with the PNCOCA 2021-2025.

4.3 Risk assessment

Next, the Guidance Document provides a series of sub-categories within each of the risk criteria defined in Section 4.2. It proposes a semi-quantitative model where a point is assigned to each sub-category to obtain a final score. Higher scores are associated with greater risk and therefore, greater frequency of inspection.

The European Food Safety Authority (EFSA) has reviewed several modelling tools and has concluded that there is none that may be universally applied (EFSA, 2012). The development of available tools, as well as the criteria for their selection has been widely discussed from a statistical/theoretical perspective (EFSA, 2015) (Van der Fels-Klerx et al., 2017, 2018). Similarly, the Food and Agriculture Organization of the United Nations (FAO) has published guidelines for the prioritisation of risks to food safety at the national level (FAO, 2020). However, the development of these tools is more geared towards prioritising chemical or biological risks rather than one related to food establishment classification criteria.

As a matter of fact, the EFSA recommends that when information, time or sufficient resources are lacking, semi-quantitative approximations may be made for the development of risk prioritisation models. Therefore, based on the available information, the approach used is considered adequate.

Next, we evaluate the relevance of different prioritisation criteria and their assigned scores.

4.3.1 General criteria

The Guidance Document proceeds to assess the following general criteria:

4.3.1.1 Type of food product and intended use

4.3.1.1.1 Origin of the food

The Guidance Document assigns greater weight to foods of animal origin (POAO) as the cause of a greater number of outbreaks, as well as their severity. Although the number of food poisonings associated with foods of plant origin is not negligible, according to several opinions published by the EFSA in this regard (EFSA, 2013) as well as the number of alerts notified by the RASFF (Rapid Alert System for Food and Feed), it is true that in 2019, most poisonings were associated with foods of animal origin, in accordance with the latest zoonosis report published (EFSA, 2021). Assigning a higher score to foods of animal origin is deemed appropriate.

4.3.1.1.2 Inherent characteristics of the food

The Guidance Document mentions the physicochemical characteristics linked to the formulation and composition of foods; environmental and process-related contaminants. The Document categorises foods according to high, medium and low risk levels, depending on the presence and/or growth or proliferation of pathogenic biological agents or physical or chemical hazards. To apply this criteria, a table (Annex I of the Guidance Document) of food products classified under each of these categories is included.

After assessing the table, there remains a certain ambiguity regarding the classification of some food groups in the high, medium or low risk categories, therefore the Scientific Committee recommends the following food categories be reviewed:

- Several food poisonings have been reported in recent years associated with cured-matured meat products where most of the cases do not include microbicidal treatment during their preparation (Hennekinne et al., 2015) (Pizzolato Montanha et al., 2018). Given that these are ready-to-eat foods that may also have a long shelf life, it is recommended that the Guidance Document revise this classification. Likewise, it is suggested that the name be modified to cured-matured meat products, according to the stipulations of Royal Decree 474/2014 (BOE, 2014).
- Fish as medium-risk food. in this case, the “fish” category is insufficiently defined, requiring clarification in this regard. Additionally, only cold smoked fish is included within high-risk foods, not hot smoked fish.
- Likewise, clarification is required for the classification of pasteurised honey as medium risk, and raw honey as low risk.
- The categorisation of hardboiled eggs, regardless of their form of marketing, may be established as medium risk.
- Some precooked foods, such as omelettes, if refrigerated, may be labelled as medium risk.
- It is suggested that flavoured dairy drinks, when subjected to UHT treatment, may be listed as low risk.
- Cheeses prepared with thermally treated milk may be classified as medium risk.

- *Gazpacho*, in the event that it is thermally treated, may be classified as medium risk.
- It is suggested that vegetable creams and purees be classified as medium risk, similar to pasteurised juices.
- Whole chillies (fresh) may be classified as medium risk, similar to whole pieces of fruits.
- Intermediate preparations for industrial use (base of ready-to-eat POAO foods) when involving refrigeration, may be classified as medium risk.
- Ice, when manufactured from controlled hygienic water, may be classified as low risk.
- The category “pasteurized soy, almond-based drinks...” appears twice in Sections 21 and 29 of the Annex. It is recommended to classify them as medium risk.
- Finally, it is suggested that additives and processing aids be classified as medium or low risk.

While the risk-based classification for different foods is deemed accurate, there may be situations where a food may undergo changes in its formulation that may lead to its classification in one category or another. In this regard, the application of this criterion must include a “worst case” scenario based on the existing information.

4.3.1.1.3 *Intended use*

The Guidance Document is in line with current legislation on the growth of *L. monocytogenes* in ready-to-eat foods (Regulation (EC) No. 2073/2005) (EU, 2005). A distinction is drawn between a food that undergoes subsequent processing by the consumer and food that is intended for direct consumption.

This criterion is accurate since *L. monocytogenes* continues to be the microorganism considered when assessing the safety of ready-to-eat foods. Nevertheless, it is suggested that for those establishments that prepare foods whose inherent characteristics enable the growth of *L. monocytogenes*, if demonstrated to the competent authority that the food is safe against the pathogen following the guidelines established in the Guidance Document for the Verification of Shelf Life Studies (AESAN, 2019), it may be catalogued as unfavourable to growth.

4.3.1.1.4 *Consumer population at risk*

The Guidance Document distinguishes between children, adults > 65 years and sick persons. A series of activities linked to these consumers, including whether it hails from the preparation of ready-to-eat meals for mass caterers. The application of this criterion is considered ideal as the Document covers the population sectors that are considered high risk. Children for whom the foods are intended include newborns and children under school age to the extent that it is possible to differentiate in the General Health Registry for Food Companies and Foods (RGSEAA).

The scores assigned in this section (*Type of food product and intended use*) award greater values (20 points) to high risk foods and ready-to-use foods that may favour the growth of *L. monocytogenes*.

4.3.1.2 Establishment activity

The Guidance document grades the following activities from high to low risk: Manufacturing (M) > Packaging (P) > Warehousing for distribution (W) > Distribution without storage (D) = Importing (I). A document classifying the establishments based on their activity is annexed to this document (Annex II).

The final score assigns a higher value to manufacturers (20), and with regard to storage activity, it distinguishes between those establishments that conduct temperature control and those that do not. It is worth highlighting that establishments with food temperature control have a higher score, which is valued as ideal, since it implies the storage of more perishable foods which, in the event of contamination, may greatly compromise consumer health.

Equally, for those establishments that perform more than one activity within the RGSEAA, the activity that is of higher risk, is scored.

Manufacturers who prepare or process foods have a higher score in this category (20 points). The criterion for awarding a higher score to manufacturers is deemed correct since they are agents who intervene to a greater degree in food processing and therefore, may entail greater risk to the consumer.

4.3.1.3 Scope of marketing

In this regard, the Guidance Document distinguishes between those establishments that conduct activities beyond the scope of the local territory, according to Royal Decree 191/2011 (BOE, 2011) which may be assigned higher scores (10 points). This scoring is pertinent according to different studies published in this regard which indicate that establishments that cover a larger channel of marketing display greater risk since they must be subjected to a greater number of controls and must maintain food safety for a longer period of time (Van der Fels-Klerx et al., 2017).

4.3.1.4 Establishment size

The Guidance Document distinguishes between companies according to the number of employees. Scores are assigned based on the number of employees: micro-company, small and medium enterprise and large enterprise, with the score being the highest for the third (20 points). Although it is true that company size is used as a criterion to assess inspection frequency (European Commission, 2018, 2019), several published studies point out that smaller companies have a higher probability of non-compliance with hygienic-sanitary regulations, owing to technical and economic limitations (Herath et al., 2007) (Mercado et al., 2018). On the other hand, it may be said that a smaller establishment would have lower production and therefore, a lower probability of any incidents. Therefore, based on the literature available on this topic, there is insufficient evidence to support a change in the criterion, thus it is recommended to maintain it, until subjected to a pilot study by the autonomous regions.

4.3.2 Specific criteria

Specific criteria are those that must be assessed after the official control visits to the establishments. Therefore, their scoring is based on the results of the previously conducted inspections, as well as

all the historical data of the establishments.

4.3.2.1 Registration and authorisation

The scores are related to the detection of deficiencies or the performance of activities without the relevant authorisation. The scores awarded in this document are consistent and give higher scores to those establishments where the unauthorised performance of activities is detected.

4.3.2.2 Results of the last official control of the establishment

The assessment of this result is based on the latest inspections and audits, awarding different values according to the number and severity of the detected non-compliances. A higher score is assigned to those establishments where Type 1 non-compliances or critical non-conformances are detected.

4.3.2.3 Company history. Company collaboration and measures taken in the event of serious non-compliances

The Guidance Document takes into consideration the establishment's record for the past 2 years, as well as their willingness to collaborate with the health authorities.

Firstly, the establishments are scored according to their diligence in resolving deficiencies, non-compliances or non-conformances over the last 2 years. In the event that the unresolved issues are of a serious nature, a higher score is given, specifically, 30 points for Type 1 non-compliances or critical non-conformances.

Secondly, an additional score is awarded where the company's data history is taken into account. The use of the historical dataset provided by the companies regarding the implementation of the in-house control systems and analyses performed is an effective tool for prioritising inspection frequency (Lee et al., 2009) (Govindaraju et al., 2010). As a matter of fact, several European agencies use this criterion where the inspection frequency is increased for establishments with a larger number of non-compliances (BEUC, 2019).

Establishments with a correctly implemented food safety management system have a greater possibility of fulfilling sanitary regulations in the future (Ramalho et al., 2015). Therefore, the use of historical data is considered relevant for prioritising the inspection frequency of the establishments such that if the establishment demonstrates a high level of compliance and adherence to the in-house control system based on the historical data set, it may be incentivised with a lower score.

Finally, an additional score is given for the management's attitude to the official control agents. A series of scoring systems based on the establishment's non-compliances or involvement in alerts of food poisoning outbreaks is established.

Generally, the specific criteria proposed in the Guidance Document are deemed accurate based on the currently available literature and actions of other national agencies.

4.4 Risk categorisation

Risk categorisation is based on the sum of all the scores and classification into high (>150 points), medium (101-150 points), low (50-100 points) and very low (<50 points) levels of risk. The minimum

frequency of the control visits to be made is determined on this basis.

The risk assignment system is dynamic and must be continuously updated in accordance with the real hygienic-sanitary conditions and activities of each establishment.

The minimum control frequencies have been included in Programme 1 of the National Plan for the Official Control of the Food Chain 2021-2025, but it seems appropriate to include them in the Guidance Document, and they are the following (Table 1):

Category	Level of risk	Minimum control frequency
1	High	Every 6 months
2	Medium	Every 18 months
3	Low	Every 36 months
4	Very low	Every 60 months

Additionally, it may also be updated every time any of the following situations occur:

- When there are changes in the type of foods handled by the establishment.
- When there are modifications to the company's in-house control system.
- When there are modifications to the directives mentioned in Article 109 of the Regulation on official controls (EU, 2017).
- When new hazards or food risks appear that may affect the establishment.
- Each time information is received regarding a change of activity by the operator.

5. Cases of use of the Guidance Document for the Risk-Based Classification of Food Establishments within the Framework of PNCOCA 2021-2025

With the goal of putting into practice the classification system proposed in the Guidance Document, two examples of establishment types to determine inspection frequency are given below.

Establishment 1 is a large company that cold smokes fish, whereas Establishment 2 is a small company that manufactures cured-matured meat products.

Different scenarios for each establishment are described below, in order to award their corresponding scores:

General criteria:

- Type of food product and intended use:
 - Origin of the food: in this case, both establishments process foods of animal origin, therefore they are given a score of 5.
 - Inherent characteristics of the food: based on Annex I, cured-matured meat products are classified as low risk foods, whereas cold smoked fish would be a high risk food. Therefore, the score assigned to Establishment 1 would be 20 points, whereas for Establishment 2, it would be 0 points.
 - Intended use: both food types are ready-to-eat meals and due to their formulation and processing

in the company, tolerate the growth of *L. monocytogenes*. Therefore, both establishments have a score of 20.

- Population group: in this case, the foods are not intended specifically for groups at risk, but for the general population. The score of both establishments would be 0 points.
- Establishment activity: as both are manufacturers, i.e., the highest risk category, they are awarded a score of 20.
- Marketing scope: Establishment 1 is a large company and markets outside its local scope (10 points), whereas Establishment 2 markets within its territory (0 points).
- Company size: Establishment 1 would be a large company with >100 workers (20 points), whereas Establishment 2 would correspond to a micro-company, with <10 workers (0 points).

Specific criteria:

- Registration and authorisation: Authorisation 1 has no incidence in this regard (0 points), while deficiencies or non-compliances were detected in Establishment 2 (5 points).
- Results of the last official control: non-compliances were not detected for Establishment 1 (0 points), while Type 2 non-compliances were detected for Establishment 2 (20 points).
- Company history. Company collaboration and measures taken in the event of serious non-compliances: Incidences were not detected for Establishment 1 (0 points), while Type 1 non-compliances were detected for Establishment 2 (30 points). Additionally, Establishment 2 was implicated in a complaint within the last 2 years (5 points), therefore the sum total in this section would be 35 points.

Finally, the sum of the score for each establishment is as follows (Table 2).

Table 2. Score of two examples of establishment types to determine inspection frequency		
General criteria	Establishment 1	Establishment 2
	Score	
Type of food product and intended use:		
a. Origin of the food	5	5
b. Inherent characteristics of the food	20	0
c. Intended use	20	20
d. Consumer population group at risk	0	0
Establishment activity	20	20
Marketing scope	10	0
Establishment size	20	0
Specific criteria		
Registration and authorisation	0	5
Results of the last official control of the establishment: inspection or audit	0	20
Company history. Company collaboration and measures taken in the event of serious non-compliances	0	35
Total score	95	105
Risk categorisation	Low	Medium
Inspection frequency	Every 36 months	Every 18 months

Based on the results of both establishments, it is demonstrated that Establishment 1 has a higher score than Establishment 2 in general criteria. Nevertheless, Establishment 1 has implemented good hygiene practices, and therefore there are no incidents related to the results of the inspection visits. On the contrary and in spite of a lower score in general criteria, Establishment 2's series of non-compliances in specific criteria gives it a slightly higher score than Establishment 1 and therefore, the inspection frequency is higher.

In spite of the consistency of these results, the scores for both establishments are quite similar and as a matter of fact, there may be cases where an establishment with several incidents or non-compliances is subjected to the same inspection frequency as another where no incidents or non-compliances are detected. Therefore, it is suggested that the scores be revised in the pilot stage so that possible difficulties in assigning the inspection frequencies of establishment may be detected.

Conclusions and recommendations of the Scientific Committee with regard to the Guidance Document for the Risk-Based Classification of Food Establishments within the Framework of PNCOCA 2021-2025

1. On general lines, the criteria used to establish the risk-based classification of food establishments, within the framework of the provided Guidance Document are deemed to be accurate. Although criteria such as the results of inspection visits to establishments or their data history are useful tools for their risk-based classification, a future assessment of the adherence of each establishment to the in-house control system and good hygiene and handling practices may be considered. Although the dynamic nature of in-house control systems is recognised, for future versions of the Document, it is recommended to take into consideration the correct training of the establishment's workers, it being especially important for those who process foods, as many studies have highlighted that better training, knowledge and good handling practices lead to safer food production for consumers (Zanin et al., 2017).
2. With regard to the classification model proposed, it is considered that the definition of the criteria and the awarding of scores for risk categorisation and subsequent determination of the inspection frequency of food establishments is correct, albeit complex, essentially due to the heterogeneous nature of the official control programmes conducted in different autonomous regions. A pilot period is recommended in order to detect possible difficulties that may lead to the modification of the selected criteria. Likewise, it must be clarified that there is no numerical correlation, that is to say, the fact that an establishment obtains double the score of the other, does not mean double the risk.
3. The classification of foods into categories of high, medium or low risk is subject to a series of ambiguities reflected in this report which must be clarified in future discussions with the autonomous regions and revisions of the Guidance Document.
4. The Scientific Committee recommends that establishments with a sufficient and satisfactory history with regard to the implemented in-house control system, or which apply and validate corrective measures based on prior official control actions should have a positive consideration for their activity.
5. In the case of manufacturing establishments that prepare ready-to-eat meals for consumption which due to their inherent characteristics enable the growth of *L. monocytogenes*, and which demonstrate by means of the steps described in the Guidance Document for the Verification of Shelf Life Studies (AESAN, 2019) that the food is safe against pathogens, they may be classified as not favouring their growth.
6. The Scientific Committee concludes that the Guidance Document for the risk-based classification of food establishments within the framework of the PNCOCA 2021-2025 is currently suitable for the intended goal. Nevertheless, the Guidance Document must be periodically updated in light of the experience of its application, scientific progress, legislative changes and new directives, and tools for the risk-based prioritisation of inspection frequency which may be developed at the State or European Union level.

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