



## Report of the Scientific Committee of the Spanish Agency for Consumers Affairs, Food Safety and Nutrition (AECOSAN) on the programming of official controls on chemical hazards

### Section of Food Safety and Nutrition

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## Abstract

The Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN) and the autonomous communities have prepared a Document for the prioritisation and distribution of samples for the official control of chemical hazards with the aim of improving the quality and uniformity of official controls in the framework of the National Food Chain Official Control Plan (PNCOCA). This Document has been based on the programming model of official controls on a risk basis, developed by the General Directorate of Public Health of the Department of Universal Health and Public Health of the Generalitat Valenciana.

The prioritisation Document aims to distribute the sampling for official controls throughout Spain, following prior assessment of the risks and the analytical capacity of the laboratories. It will also serve to provide support and guidance to the autonomous communities in the implementation of their official control programmes.

The prioritisation Document defines a semi-quantitative model which sets out the variables to which a relative numerical value is allocated in order to obtain a final qualification. The hierarchical methodology is based on estimating the extent of the risk depending on the presence of a contaminant in a food, where the risk is the sum of two variables, the impact on the health of the population and the prevalence in consumer products.

The Scientific Committee concludes that the Document for the prioritisation and distribution of official control samples aimed at determining chemical hazards is adequate, at present, for the purpose established. This Document should be regularly updated in light of the experience obtained from its application, progress in scientific knowledge, changes in the legislation and the directives and tools on prioritisation and sampling which may be developed at national or European Union level.

## Key words

Official control, sampling, chemical hazards, prioritisation.

## 1. Introduction

Regulation (EC) No 882/2004 (EU, 2004) in Article 3 lays down that the Member States of the European Union shall ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency.

In order to improve the quality and uniformity of official controls in the framework of the National Food Chain Official Control Plan (PNCOCA), the Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN) and the autonomous communities have prepared a document for the "Prioritisation and distribution of samples for the official control of chemical hazards" (hereinafter, prioritisation Document) in which the risks are prioritised and the official control samples directed at determining chemical hazards are distributed. This Document has been based on the programming model of official controls on a risk basis, developed by the General Directorate of Public Health of the Department of Universal Health and Public Health of the Generalitat Valenciana (Comunitat Valenciana, 2016)\*.

The PNCOCA defines certain high level objectives which are then divided into strategic objectives and, within these, into control programmes. Specifically, chemical hazards are included in strategic objective 2.3 (to reduce as far as possible, and in all cases to acceptable levels, consumer exposure to biological and chemical hazards present in food) and programmes 13 and 15 (control of mycotoxins and plant toxins inherent in food and control of abiotic contaminants in food, respectively).

The prioritisation Document aims to distribute the sampling for official controls throughout Spain, following prior assessment of the risks and the analytical capacity of the laboratories. It will also serve to provide support and guidance to the autonomous communities in the implementation of their official control programmes. However, in any case, the communities will have sufficient flexibility to increase or reduce the number of samples allocated when circumstances warrant this.

The objectives of the prioritisation Document are:

1. To guarantee the performance of sampling for the analysis of every hazard of interest to food safety according to the risk.
2. To establish a minimum number of controls to guarantee compliance with the food safety objectives of the PNCOCA.
3. To distribute sampling throughout Spain according to the risk, ensuring the health of the consumers and control of food industries.
4. To optimise the analytical resources of the laboratories.

At present, there are two baseline documents: one on the prioritisation of the control of biological hazards and the other on the prioritisation of the control of chemical hazards.

\* Correction (15-1-18): the paragraph is modified by adding a reference.

The Section of Food Safety and Nutrition of the Scientific Committee of the AECOSAN has been asked to assess the approach, the factors considered and the prioritisation methodology of the Document for the prioritisation and distribution of official control sampling directed at determining the chemical hazards and making the necessary contributions. These contributions are considered together with those from other interested parties and the resultant document has been submitted to the Scientific Committee for final assessment.

## **2. Assessment of the proposal for prioritisation and distribution of official control samples aimed at establishing chemical hazards**

### **2.1 General considerations**

The request of the AECOSAN only refers to those chemical hazards for which limits have been established in European and Spanish legislation.

The chemical risks present in food may be of varied origin: chemical contaminants, food contact materials, pesticide and veterinary medicine residues. Only the chemical contaminants present in food are considered in the first stage.

### **2.2 Definition of the hazards**

The comments of the Committee with respect to some of the hazards included in the prioritisation Document are listed below.

This document includes the natural and anthropogenic chemical contaminants listed in programmes 13 and 15 of the National Food Chain Official Control Plan, for which the European and Spanish food legislation has established maximum limits or formulated recommendations for values that must not be exceeded.

### **2.3 Hierarchical model**

The prioritisation document defines a semi-quantitative model which sets out the variables to which a relative numerical value is allocated in order to obtain a final qualification.

The European Food Safety Authority (EFSA) has revised several modelling tools and concluded that none of these can be applied universally. It also indicates that, wherever possible, a quantitative approximation should be made, but does not offer further instructions (EFSA, 2012). While EFSA does not offer a proposal, a semi-quantitative model should be used, which responds to the requirements based on the available information.

The qualitative hierarchical models are based on the ratio of the concentration of chemical contaminants in the food and the population's rate of consumption of this food. Therefore, only address those hazards with long-term effects.

The semi-quantitative model proposed is based on the allocation of values to different variables, in addition to considering toxicity and exposure to the chemical contaminant. This results in a discrete numerical score.

## 2.4 Methodology of the hierarchical model

The hierarchical methodology is based on estimating the extent of the risk depending on the presence of a contaminant in a food, where the risk is the sum of two variables, the impact on the health of the population and the prevalence in consumer products.

To assess the impact on health, the exposure to the chemical contaminant is added, weighted by the health-based guide value established by the EFSA and the severity of the effects produced by the contaminant based on the classification of the International Agency for Research on Cancer (IARC).

The formula established to determine the impact on health considers both non-carcinogenic effects (Hazard quotient, HQ) and carcinogenic effects (Severity). Nevertheless, the use of the term "severity" to refer exclusively to carcinogenic effects is not totally correct as there are many other toxic effects induced by the hazards considered which, although they are not carcinogenic, are equally serious (for example, nephrotoxicity from cadmium, neurotoxicity from methylmercury, etc.). These effects are considered in the first addition.

In those cases in which a contaminant has not been classified by the IARC, a different criteria should be applied or, at least, a score to reflect the uncertainty due to the absence of a classification by the IARC.

To quantify the prevalence of the contaminants in food, the half-sum of the score awarded to the health surveillance is used based on the percentage of non-compliant samples collected in Spain in the last 3 years, and on the notifications from the Coordinated System for the Rapid Exchange of Information (SCIRI), weighted by a correction factor depending on the stability of the contaminant to culinary heat treatments.

The final score (from 1 and 10) for the risk of a contaminant in a product serves to prioritise the degree of risk, and depending on the interval in which this value is included, a percentage is allocated to the number of samples to be analysed. This is specified in a table with five allocation intervals.

## 3. Assessment of the prioritisation Document and distribution of official control samples aimed at establishing chemical hazards and conclusions of the Scientific Committee

The Document presented shows a semi-quantitative procedure for the programming of sampling in official controls within the framework of the National Food Chain Official Control Plan. It can be used by the different autonomous communities following a single protocol until a programme is available to be used by all the Member States of the European Union.

The chemical hazards do not include pesticides as a Guide for the Preparation of the Programme for Pesticide Residue Monitoring and Controls was approved in 2016. Nor are veterinary drug residues and components released from packaging included.

The present proposal uses the exposure data taken from the Total Diet study of the Valencian Community for the adult population and in its defect, the data from the EFSA. Nevertheless, and until data obtained in a standardised manner for all the regional communities is available at

national level, the data available for the geographical zone in which the sampling takes place can be used provided that it is relatively recent and can be considered to have not suffered significant variations.

It is difficult to apply the correlation factor applied to the prevalence in order to weight the stability of the chemical contaminants to the heat procedures as there are no tables which provide objective data on its transformation and the bibliography contains limited concordant data, as the temperature applied in relation to the treatment time is not always specified. Therefore, until new contributions are available, the correction factor should be eliminated due to disabling treatment.

The final conclusion of the Scientific Committee is that the Document for the prioritisation and distribution of official control samples aimed at determining chemical hazards is adequate, at present, for the purpose established.

The Document for the prioritisation and distribution of samples should be regularly updated in light of the experience obtained from its application, progress in scientific knowledge, changes in the legislation and the directives and tools on prioritisation and sampling which may be developed at national or European Union level.

## References

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