Report of the Scientific Committee of the Spanish Agency for Consumers Affairs, Food Safety and Nutrition (AECOSAN) on the programming of official controls on biological 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 biological 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 the consideration of, on the one hand, the impact on health, considering the frequency and severity, and on the other hand, the prevalence, consisting of data from non-compliant samples and alert notifications.

The Scientific Committee concludes that the Document for the prioritisation and distribution of official control samples aimed at determining the biological 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.

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Key words

Official control, sampling, biological 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 official control samples directed at determining biological hazards" (hereinafter, prioritisation Document) in which the risks are prioritised and the official control samples directed at determining biological 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, biological 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 11 and 14 (control of food safety microbiological criteria and control of marine biotoxins in food products, 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 biological 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 biological hazards

2.1 General considerations

The AECOSAN request refers only to those biological hazards for which limits have been established in the legislation, Regulation (EC) No 2073/2005 (EU, 2005a) and Regulation (EC) No 853/2004 (EU, 2004), for which control is in laboratory. Consequently, hazards such as Anisakis are excluded from the terms of reference as these are not controlled in laboratories.

2.2 Definition of the hazards

The comments of the Scientific Committee are given below with respect to some of the hazards which have been included in the list of hazards to be prioritised and some which are regulated or close to regulation but have been omitted from this list.

2.2.1 Marine biotoxins

The prioritisation Document includes marine biotoxins which have maximum limits per kilogram of molluscs in the Regulation (EC) No 853/2004 (PSP, ASP, okadaic acid, dinophysitoxins and pectenotoxins, yessotoxins and azaspiracids).

The prioritisation Document does not refer to certain marine biotoxins such as the brevetoxins and the ciguatoxins. The brevetoxins are not explicitly mentioned in Regulation (EC) No 853/2004 and moreover, although referenced in some cases in the United States (Visciano et al., 2016), no bibliographic or epidemiological data has been found regarding their presence in Spain, and therefore the risk can be deduced to be insignificant. However, the ciguatoxins are mentioned in Regulation (EC) No 853/2004 ("fishery products containing biotoxins such as ciguatoxin must not be placed on the market..."), but without specifying maximum limits. In addition, the epidemiological data available reports 5 outbreaks of marine biotoxins and 6 of ciguatoxin in Spain in the period 2008-2011, with 35 and 45 cases respectively (Espinosa et al., 2014) and the joint report of the European Food Safety Authority and the European Centre for Disease Prevention and Control (EFSA/ECDC) in 2014 reported 2 outbreaks due to marine biotoxins (1 in Spain and 1 in Ireland; the one in Spain is specifically listed as "muscle-paralysing toxin") and 5 outbreaks due to ciguatoxin in France (EFSA/ECDC, 2015). The studies published suggest that the number of cases of ciguatera is increasing in Europe (Mattei et al., 2014).

In accordance with Community legislation (Regulation (EC) No 2074/2005) (EU, 2005b), the valid method of liquid chromatography tandem mass spectrometry (LC-MS/MS) should be applied as

a method of reference for the detection of lipophilic toxins and used as standard for the official controls at any stage of the food chain. Any other recognised method instead of LC-MS/MS may be used provided that the effectiveness criteria established by the European Union Reference Laboratory (EURL) for marine biotoxins are satisfied, but in the case of discrepancy, the reference method used should be the LC-MS/MS method of the EURL.

The traditional biological method of reference for the detection of biotoxins, bioassays on mice or rats, due to ethical and technical reasons (high variability, low detection and specificity) is no longer considered suitable although it may be used for a limited period of time. Other alternative detection methods used include HPLC-FLD (pre- or post-column oxidation) and receptor binding assay for PSP; HPLC-UV and ELISA for domoic acid; and radioligand receptor binding assay for ciguatoxins (Ajani et al., 2017).

To sum up, marine biotoxins may be considered together, as in this way they are usually reported epidemiologically (although the severity of the syndromes is very variable, depending on the toxin type and there is no defined test method which permits the joint detection of all of them) and it would appear necessary to include the ciguatoxin.

2.2.2 *Campylobacter*

At the time of the request, *Campylobacter* was not considered in Regulation (EC) No 2073/2005 but it has now been published in Regulation (EU) 2017/1495 (EU, 2017), amending the previous regulation as regards *Campylobacter* in broiler carcases, and therefore, at the request of the AECOSAN, it is included in the terms of reference.

Campylobacter is of great significance as a food-borne pathogenic agent. The European Union report on zoonotic agents and outbreaks of food-borne diseases in 2014 describes 236 851 confirmed cases of campylobacteriosis in the European Union, with a notification rate of 71/100 000 inhabitants. In particular for Spain the figures given in the same report are for 11 481 confirmed cases (a rate of 82.3/100 000 inhabitants; moreover this is an estimated partial rate based on a cover of 30 %). It also lists 444 food-borne outbreaks, equivalent to a rate of 0.11/100 000 inhabitants which produced 571 cases; eight of these outbreaks occurred in Spain, with 95 cases and a rate of 0.02/100 000 inhabitants (EFSA/ECDC, 2015). The Epidemiological Surveillance Network at the Carlos III Institute of Health in 2014 listed 11 415 cases of campylobacteriosis and 13 outbreaks, affecting a total of 93 people; of these outbreaks, 7 were food-borne (CIBERESP, 2016). It should also be noted that the plans of some autonomous communities include *Campylobacter* in the biological hazards to be controlled; for example, Andalusia maintains a *Campylobacter* control programme in poultry slaughterhouses (Consejería de Salud, 2016). Commission Regulation (EU) 2017/1495, amending Regulation (EC) No 2073/2005 establishes *Campylobacter* as the micro-organism process hygiene indicator on broiler carcases using a methodology similar to that defined for *Salmonella* in this category of food and a sampling plan with n= 50 (samples taken from 10 consecutive sampling sessions; at each session random neck skin samples are taken from a minimum of 15 poultry carcases in order to obtain five collective samples from three 26 g carcases), c= 20 and m= M of 1 000

CFU/g. The reference method is the EN ISO 10272-2, based on the count in a modified CCDA medium. In addition, the analysis of *Campylobacter* may also be considered in poultry-based minced meat, meat preparations and meat products (categories 1.5 and 1.9 of Regulation (EC) No 2073/2005), as is done for *Salmonella*.

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 (EFSA, 2012). In a subsequent report, written with the aim of designing and developing a tool for the prioritisation of risks for the Panel on Biological Hazards (BIOHAZ), the EFSA assessed the operation and data requirements of the available tools from a statistical/theoretical perspective (EFSA, 2015). None of the tools assessed consider, in the current state, the uncertainty in the prioritisation of risks, which has led the BIOHAZ Panel of the EFSA to design a new tool prototype which includes, separately, variability and uncertainty. This prototype is currently at the development stage. In the same report, the EFSA recommends that, wherever possible, a quantitative approximation is made, indicating that when data, time or resource limitations do not permit this quantitative approach, semi-quantitative models may be used (EFSA, 2015). Consequently, until the new EFSA tool is completely developed, there is no obvious reason for not using a semi-quantitative model if this is considered more appropriate given the available information.

2.4 Methodology of the hierarchical model

The hierarchical methodology involves an arbitrary classification system of up to 16 points on an increasing scale of risk (the higher the score, the greater the risk). Two aspects are considered when calculating the risk:

I. Impact on health, with two variables:
   a) Incidence from the available epidemiological information.
   b) Severity considering the disability-adjusted life years (DALY).

II Prevalence, in turn consisting of:
   a) Health surveillance. The percentage of non-compliant samples in Spain in the last 3 years is used.
   b) SCIRI notifications considering the last 3 years (annual mean number of notifications).
   c) The prevalence is corrected according to the treatment given to the food using a disabling treatment correction factor (FCTI) which is multiplied by 0.5 if the food is intended to be cooked and by 1 in all other cases.

To correctly interpret the incidence data, a correction is made according to the percentage of cases which can be attributed to dietary intake, principally using the data proposed by Havelaar et al. (2008) and other studies included in the EFSA (2008) report and which appear in the table.

The biological hazards which are not considered in the above papers have been estimated from bibliographic data.

Table 1. Estimated percentage of cases of disease caused by biological hazards which can be attributed to dietary intake

Pathogen	Cases attributable to food (%)
Staphylococcus aureus (toxin)	100
Listeria monocytogenes	69
Salmonella spp.	55
Escherichia coli STEC O157	40
Escherichia coli STEC No- O157	42
Escherichia coli	0[(1)]
Cronobacter	78[(2)]
Histamine	92[(3)]
Marine biotoxins	100[(4)]

[(1)] *E. coli* is included in the food safety criteria for live bivalve molluscs and echinoderms, tunicates and live marine gastropods, as an indicator of faecal contamination, and will therefore not be a direct cause of human disease.

[(2)] The transmission paths of *Cronobacter* spp. are not totally clarified and it is considered that the oral path, through powdered formulae, is the main route (AECOSAN, 2015). The figure of 78 % is attributed based on the review of the epidemiology of *Cronobacte*r spp. in infants, which analyses nine outbreaks of disease and detects seven in which the powdered formulae may possible be involved (Bowen and Baden, 2008).

[(3)] Histamine intoxication is mainly linked to fish and fish products, but may also be present in other fermented food. Analysis of outbreaks of histamine intoxication in Europe reveals that between 2010 and 2015 there were 191 outbreaks, of which 176 (92 %) were due to fish and fish products (EFSA, 2017).

[(4)] Exposure to marine biotoxins considered in the European legislation is through the intake of contaminated fish and fish products. Although non-dietary intake is described for some of the syndromes (ciguatera), these are very sporadic cases (FAO, 2005).

The DALY values are generally used to estimate the importance of the diseases (for example, they are used by the World Health Organisation), but they have certain disadvantages when it comes to assessing, for example, diseases which may affect certain groups (for example, Listeria monocytogenes does not have the same importance in pregnant women as in the general population).

The FCTI is only applied to raw food intended to be cooked. That is, it separates food which is going to be cooked from food which is to be eaten raw, but there may be other possibilities which consider disabling (for example, fermented products, raw food with a certain water activity…). In addition, this factor may be very different depending on whether vegetative cells of bacteria or microbial toxins are considered, due to the different resistance to heat of each one.

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

1. With respect to the definition of biological hazards, the Document includes the suggestions of the Scientific Committee on the combined consideration of marine biotoxins.
2. The Document expressly mentions the non-inclusion of *Campylobacter* in the official control plans, as it is considered as process hygiene criteria in Regulation (EU) 2017/1495. The Scientific Committee understands the reasons for not including *Campylobacter* in the prioritisation of samples for the official control and offers to conduct a more detailed assessment of this hazard.

With respect to the prioritisation of the hazards

1. The Document includes the suggestions of the Scientific Committee with respect to the attribution to dietary intake of the cases of disease in those hazards for which there is no previous scientific opinion. It also considers the opinion to not limit the disabling factors of the hazards to cooking food alone.

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

The Document for the prioritisation and distribution of official control 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.

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