

Report of the Scientific Committee of the Spanish Agency for Food Safety and Nutrition (AESAN) on the identification of emerging food risks

Section of Food Safety and Nutrition

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Abstract

Emerging risks are those derived from a new hazard for which a significant exposure could be produced, or derived from an exposure and/or new or significantly increased susceptibility to a known hazard.

Identifying these risks may be done using different information sources and tools, which may range from the analysis of the published scientific bibliography, even including what is known as grey literature (documents that are unedited or that are distributed by means of unconventional channels such as doctoral theses, conference proceedings, research reports, etc.), to the study of food alerts.

The assessment of emerging risks is done by specialists in each area of expertise, but in identifying them they may use common tools in such a way that they may detect and characterise them more efficiently prior to their assessment. Therefore, given that Law 17/2011, on Food Safety and Nutrition, establishes a mandate for the Scientific Committee, regarding the identification of emerging food risks, the Section of Food Safety and Nutrition is asked to prepare a report about the applicable strategies for the identification of emerging food risks.

Having as base the definition of the European Food Safety Authority (EFSA) regarding emerging risks it is important to identify if there is a new hazard to which we are exposed, or if a new exposure has come about, or if there has been an increase in the exposure of a known one. At the same time evaluating the increase in susceptibility to a known hazard.

After reviewing the different possible strategies, the Scientific Committee considers the following to be useful:

- Analysis of the scientific bibliography. For this the development or implementation of powerful data management systems and digital collaboration platforms is of use in order to manage the large quantity of available data and information.

- Analysis of grey literature. Just as in the previous case, specific information technology tools would be needed that allow the extraction of interesting information.
- Analysis of the alerts and the results of the official control programmes. These tools are useful for those known risks with existing control legislation. As an example, they could be useful for detecting exposure increases in the presence of some contaminant over time.
- Analysis of the epidemiological monitoring systems, which would help detect increases in susceptibility or exposure.
- Analysis of consumption trends. It would help detect exposure increases, only if the methodology for collecting data is comparable between years.
- Analysis of the information extracted from studies on the risk perception by the population.
- Analysis of information provided by experts and researchers. It would be desirable to improve the collaboration of the scientific community with the national and international institutions and organisations.

Key words

Emerging risks, identification, strategies.

1. Introduction

Law 17/2011, of 5 July, on Food Safety and Nutrition establishes in Article 29 that the Spanish Agency for Food Safety and Nutrition (AESAN) is responsible for coordinating the necessary actions for the identification and evaluation of emerging risks (BOE, 2011). In this respect, Article 31 of the Law on Food Safety and Nutrition assigns this function to the Scientific Committee of the AESAN.

In the food area of the European Union, the term “emerging risk” is defined in Regulation (EC) No. 178/2002. Article 23 of this regulation lays down that the European Food Safety Authority (EFSA) must undertake action to identify and characterise emerging risks, in the fields within its mission (EU, 2002).

These risks may be identified using different strategies, sources of information and tools. Therefore, as Law 17/2011, on Food Safety and Nutrition lays down a mandate for the Scientific Committee in relation to the identification of emerging food risks, the Section of Food Safety and Nutrition has been asked to prepare a report on the applicable strategies for the identification of emerging food risks.

1.1 Definition of emerging risk

The term “Risk” is defined by the United Nations Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO) as a “function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.” (FAO/WHO, 2018a).

In recent years, the term “emerging risk” has been used increasingly, and its assessment or management is considered to belong to advanced systems as it is associated with something new or novel. In 2007, the EFSA defined an emerging risk as a “risk resulting from a newly identified hazard to which a significant exposure may occur, or from an unexpected new or increased significant exposure and/or susceptibility to a known hazard” (EFSA, 2007) (Figure 1).

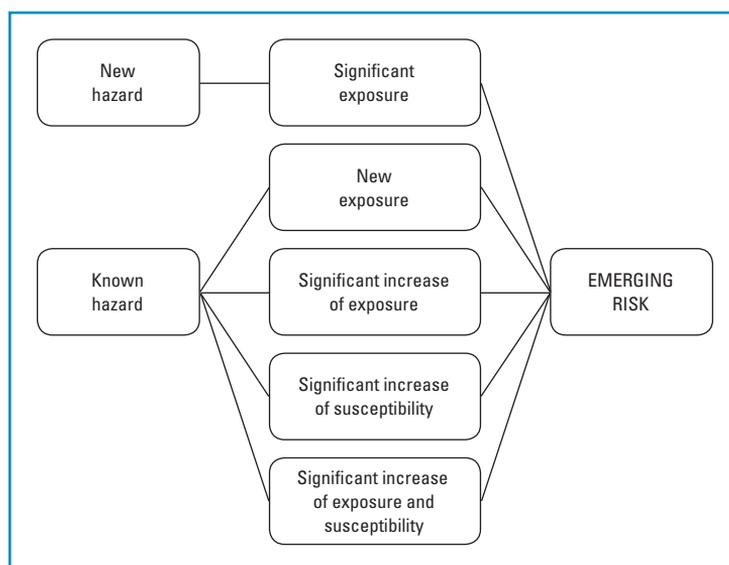


Figure 1. European Food Safety Authority definition of emerging risk. **Source:** (EFSA, 2007).

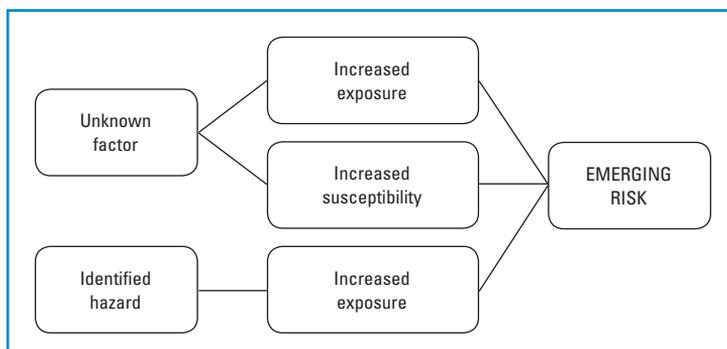


Figure 2. Definition of emerging risk in the Law on Food Safety and Nutrition. **Source:** (BOE, 2011).

In Spain, the Law 17/2011 on Food Safety and Nutrition defines an emerging risk as “the risk resulting from an increased exposure or susceptibility to a factor unknown to date, or that associated with an increase in exposure to a hazard which has already been identified” (BOE, 2011). Unlike the EFSA definition, the Spanish definition does not refer to the increase in the susceptibility of already known hazards (Figure 2).

The EFSA definition does not include risks characterised by a sudden appearance, as for example episodes of food contamination due, to events associated with bioterrorism or the sudden release of a radioactive cloud. Nor does this definition include the risks associated with the involuntary or accidental intake of food or feed that does not comply with the recognised safety requirements, although immediate action may be necessary to prevent greater exposure or harm to consumer health (EFSA, 2007).

In 2015, the Working Group on Emerging Risks of the EFSA Scientific Committee (SWG-ER) assessed the definition of emerging risk and identified certain weaknesses in the definition from the point of view of its practical application. In this respect, they questioned the lack of definition of the concept of severity (“serious risk”) which is mentioned in Regulation (EC) No. 178/2002 as it refers to serious emerging risks. Another important consideration is the difficulty, in practice, of interpreting the concept of novel when using qualifiers such as “new hazard”, “new or increased exposure” (EFSA, 2015a). The term “serious emerging risk” is mentioned but not defined in said Regulation. Nevertheless, there is a definition of “serious risk” given in Directive 2001/95/EC, which defines it as “any serious risk, including those the effects of which are not immediate, requiring rapid intervention by the public authorities” (EU, 2001).

Another question to be considered and which affects the definition of emerging risk is the geographical scope, as a risk may be considered as emerging in one particular geographical zone while in another it has been known for some time. If neither susceptibility nor exposure to the risk has increased, it is not considered as emerging in the second region (Flage and Aven, 2015).

It is also necessary to consider the time for which a risk is considered as emerging and when it stops being emerging. After a certain period of time during which the emerging risk has remained stable, without increase of either exposure or susceptibility, it will be necessary to consider whether it should continue to be considered as emerging or not.

The importance of the perception of the risk by the population must also be considered. All the social and anthropological concepts arising around risk in the last two decades agree that risk is a social construction. As the term risk is understood in very different ways by laypeople and by scientific experts. Whereas the scientific concept of risk is based on evidence and is focussed, laypeople turn towards uncertainty and a broader range of potential problems. On accepting that there are different ways of perceiving risk, and even of defining what is considered to be a risk, it is necessary to consider the different public perceptions of risk and its degree of acceptance (Cámara, 2009).

In any case, when declaring that a risk is emerging, the EFSA definition must always be taken into account and should not be declared as such merely based on its severity, importance or media resonance.

1.2 Identification of emerging food risks at European Union level

In Regulation (EC) No. 178/2002 in which the EFSA is created, the EFSA is required to take actions to identify and characterise emerging risks in the area of food and feed safety. The principal objectives of the EFSA activities on emerging risks include: 1) carry out activities to identify emerging risks in the fields within its mission; and 2) develop and improve emerging risk identification methodologies and approaches.

1.2.1 EFSA Networks and Units, and AESAN

A series of EFSA units and networks with different functions are involved in the identification of emerging risks: the Emerging Risks Exchange Network, the Stakeholder Discussion Group on Emerging Risks, the EFSA Scientific Units, the Scientific Panels and the Scientific Committee and its Working Groups (García Cañas, 2018) (EFSA, 2019).

1.2.1.1 Emerging Risks Exchange Network, EREN

The EREN was set up by the EFSA in 2010, with the aim of enhancing the exchange of information between the European Union Member States in the event of a possible emerging risk for food safety or animal feed. The Network is currently composed of representatives from scientific organisations from 26 Member States, one per country. The organisations are appointed by the EFSA Advisory Forum. The Network also includes representatives from the European Union Free Trade Association (EFTA) (Norway and Switzerland), from the United Nations Food and Agriculture Organisation and the World Health Organisation. The terms of reference of the Network were reviewed in 2017 (EFSA, 2017a). In accordance with these terms, members of the EREN shall:

- Present information, data and knowledge concerning identified emerging issues/risks.
- Provide advice and share experiences on emerging risk identification methodologies used at national level to identify emerging issues and risks.
- Give access to these data and justify the reported emerging issues/risks based on scientific evidence or theoretical derivation of a possible health risk. The data shall be presented and assessed using a standard briefing note template developed by EFSA.

- Share potential emerging issues/risks identified through their respective scanning system as a way to prioritise those issues for which briefing notes can be developed.
- Provide additional data on issues/risks discussed previously by EREN.
- Provide recommendations for further research needs and possible joint projects among Member States.
- Commit to liaise at national level by circulating background documents before and after each EREN meeting with relevant stakeholders in order to collect and share information covering the whole food chain, from primary production to retail and to gather additional evidence on the emerging issues identified.
- Collaborate with EFSA national focal points to facilitate exchange of information on emerging issues and to maintain a link with the EFSA Advisory Forum.
- Avoid duplication of work to ensure activities between Member States, between EFSA and the Member States and other existing EU systems involved in the emerging risk identification process are complementary. Collaboration between the European Union Member States is essential for success in the identification of emerging risks. Consequently, the EFSA plays a role in the coordination of activities to prevent the duplication of effort and to make the best use of the information and available knowledge.

The institution representing Spain in this EFSA Network is the University of Zaragoza, represented by Dr. Juan José Badiola.

1.2.1.2 Stakeholder Discussion group on Emerging Risks (StaDG-ER)

The StaDG-ER was created in 2010 and its current mandate started in 2016. It was set up to promote the exchange of information about the identification of emerging risks and improve communication and dialogue on the issues relevant to emerging risks with the stakeholders. Members of the StaDG-ER are selected by the EFSA and include at least one stakeholder registered in one of these categories: consumers; environmental and health NGO and/or advocacy groups; farmers and primary producers; food industry and businesses; distributors and HORECA (hotel, restaurant and catering), practitioners' associations working under the EFSA mandate and representatives from the academic world. The objectives of the members of the StaDG-ER include (EFSA, 2018a):

- Present to the group information, data and knowledge of the risks and/or emerging issues identified, and the methods used for their identification.
- Provide access to the data related to the risks/emerging issues about which they have been informed.
- Provide additional information about ongoing issues which were discussed at earlier meetings of the StaDG-ER.

Therefore, the role of stakeholders is important for increasing the capacity of EFSA to anticipate emerging social or scientific issues.

1.2.1.3 Scientific Committee and Emerging Risks Unit (SCER)

In 2007, the EFSA set up the Scientific Committee and Emerging Risks Unit (SCER), the function of which is the development, establishment and operation of a screening system and the analysis of sources of information with a view to identifying an emerging risk (EFSA, 2015b). The identification of emerging risks in EFSA is horizontal, involving not only the SCER, but also all the EFSA Scientific Units and their respective Panels (EFSA, 2014). This identification of emerging issues is made through:

- The exchange of information with the national Food Safety Authorities of the Member States, through their representatives in the EFSA Advisory Forum and with industrial sectors.
- Expert consultation, including members of the Scientific Panels and EFSA staff.
- Monitoring of sources of information, including the Rapid Alert System for Food and Feed (RASFF), scientific journals related to food safety, grey literature (includes a set of documents which are unpublished or published through non-commercial channels, including doctoral theses, projects, research reports, standards, reports, etc., which are not easily accessible), databases on the international food trade, and the media. The EFSA uses a series of computer programmes, including MedISys (Medical Information System) and ERIS (Emerging Risk Identification Support) as tools for the monitoring and early detection of food risks. These programmes collect the information provided by the above-mentioned sources to detect signs regarding possible emerging issues. The ERIS programme was developed by the Dutch organisation TNO (Netherlands Organisation for Applied Scientific Research) to identify the new hazards in the food chain (Van de Bruget et al., 2014) (Lucas et al., 2016). MedISys is a media monitoring system providing event-based surveillance to rapidly identify potential public health threats using information from media reports (Rortais et al., 2010) (EFSA, 2017b).

The emerging issues identified are assessed by personnel from the SCER Unit based on certain qualitative criteria including:

- The EFSA definition of emerging risk for 2007.
- Criteria such as: novelty, imminence, legitimacy of information sources, scale (number of people or Member States potentially exposed) and severity.

By applying these criteria, the SCER Unit makes a decision for each issue, and may adopt the following:

- No actions: the issue is dismissed as it is clearly not an indication of an emerging risk.
- To collect further information: further information is required to assess the relevance of the emerging issue.
- It is sent to the EREN and the StaDG-ER: the consultation is made using informative notes, in which a series of questions are proposed with the aim of assessing the relevance of the emerging questions presented and facilitating the exchange of information between the networks and the SCER Unit (EFSA, 2017b).

1.2.1.4 Working Group on Emerging Risks of the Scientific Committee (SWG-ER)

The Working Group on Emerging Risks of the Scientific Committee (SWG-ER) was created in 2013 and its mandate extended to 2018. The group has a multidisciplinary nature as it is formed by members from the different panels of the Scientific Committee with experience in the development of methodologies and the identification of emerging risks (EFSA, 2016a).

The objectives of this working group were to ensure diffusion of the information and coordination between the different panels, to support the collection of new knowledge, the promotion of innovation and technologies, and the generation of data for the emerging risks area.

The function of the SWG-ER was to assess the validity and relevance of the information and the scientific data provided to EFSA by Member States and the stakeholders, presented through marketing authorisation dossiers for different products, collected through public calls for data, and collected by the EFSA. Where applicable, EFSA may subcontract the collection or analysis of scientific information through its subvention and contracting systems to support the SWG-ER (EFSA, 2016a). In this way the task of the SWG-ER is to declare if:

- It is not an emerging risk.
- More information should be obtained on this emerging issue, as a clear response cannot be ruled.
- It is an emerging risk, and it is necessary to proceed to the risk assessment by the corresponding Scientific Panel.

EFSA has recently published a technical report summarising the activities of all the groups involved in the emerging risk identification procedure during 2017, a description of the methodologies which are being developed and the ongoing collaboration activities (EFSA, 2019). The groups involved are as described above, the Emerging Risks Exchange Network, the Stakeholder Discussion group on Emerging Risks, the EFSA Scientific Units, the Scientific Panels and the Scientific Committee.

According to the report, in 2017 a total of 17 potential emerging issues were discussed and assessed, considering four criteria: a) new hazard; b) new or increased exposure; c) new susceptible group; and d) new driver. Following the application of the above criteria, 13 of the 17 issues assessed were considered as emerging risks:

1. Risk associated with the use of black "*cohosh*" in food supplements and tea (phytoestrogen-rich plant).
2. Possible contamination of foods with residues of pesticides used to control Zika Virus vectors in South America.
3. Use of nanoemulsions in the food sector.
4. RNA pesticides.
5. Possible epidemic of wheat stem rust and yellow rust in the 2017 crop season.
6. Shiga toxin-producing *E. coli* O121 in flour.
7. Beta-methylamino-L-alanine.
8. Increase of human infections with *Aspergillus* spp.
9. Organosilicon surfactant adjuvant.

10. First discovery of the Moku virus in invasive Asian hornets.
11. *Brucella suis* in the Netherlands.
12. African swine fever: assessment of biosecurity in pig herds.
13. Potential risk related to high level/content of nutrients in fortified foods.

The identification of an emerging risk may result in the performance of different actions. For example, following the identification of ciguatera as an emerging risk by the EFSA (2014), a framework partnership agreement (FPA) "Risk characterisation of ciguatera food poisoning in Europe" (Euro-cigua) has been set up and is coordinated by the AESAN and signed by EFSA, and also has the collaboration of another 14 organisations from the European Union. The aim is to assess the presence of ciguatoxins in food and phytoplankton (dinoflagellates *Gambierdiscus* spp.) in Europe, and to develop and validate methods for the detection, quantification and confirmation of the presence of ciguatoxin-contaminated specimens (EFSA, 2017b) (AECOSAN, 2018a). Ciguatera causes food poisoning due to the intake of liposoluble toxins from the ciguatoxin group (CTX) via the consumption of fish (Alonso, 2017). The project is for 4 years (until 20 June 2020).

1.2.1.5 National Network on Emerging Risks (AESAN)

In 2013, the EFSA Advisory Forum agreed a series of recommendations, expressly including the intention to incorporate the exchange of information between national representatives in the EFSA Scientific Networks and the Member State into the EFSA Focal Points. As a consequence of the above, the AESAN promoted the creation of a National Network on Emerging Risks which was set up, with a meeting, in November 2014. The Network has a multidisciplinary nature, with representatives from a number of areas, including biological risks, chemical risks and nutritional risks, from universities all over Spain, research centres and other ministries. In the conclusions of the meeting, the participants highlighted the need to support the national representative in the EFSA Scientific Network and to maintain the multidisciplinary nature, establishing *ad hoc* working groups by speciality or multidisciplinary groups. To obtain updated information on the research situation in Spain regarding emerging risks, members of the Network agreed to collect information from projects and research groups in related areas, and to establish a methodology of work with a true exchange of information, considering examples already existing in other countries or in the EFSA itself.

At regional level, there is a Galician Network of Emerging Risks (RISEGAL) funded by the Regional Government of Galicia, in which the Higher Council of Scientific Research (CSIC) and the Universities of Vigo, A Coruña and Santiago de Compostela collaborate. Its mission is to identify emerging risks which compromise food safety in the chain of food produced or marketed in Galicia and to propose actions with the aim of guaranteeing their healthiness (RISEGAL, 2018).

2. Strategies for the identification of emerging food risks

The assessment of emerging risks must be carried out by specialists in each area of knowledge. However, strategies and tools common to all may be used in their identification to enable an efficient detection and characterisation prior to their evaluation. This report identifies a number of stra-

tegies which may permit the identification of emerging food risks, the application of one or another will depend on the information available at national level and the available resources.

Each country in the European Union also has organisations with competencies in risk assessment, management and communication (BfR, 2017). The EFSA conducted a survey in the 28 Member States with the aim of determining whether they had an emerging risk identification system. From this study it was deduced that a total of 11 countries have, on paper, units dedicated to emerging risks, while in another seven countries, staff from the Agency are responsible for emerging risks. The other ten countries, including Spain, do not have units or teams dedicated to emerging risks. This survey reveals the importance held by emerging risks in large number of the European Union Member States, some of which have identified emerging issues (EFSA, 2018b, 2019).

When proposing strategies for the identification of emerging risks, it is important to consider the definition, and according to the definition, aim to detect:

- New hazards for which significant exposure exists.
- Known hazards for which new exposure exists or there has been a significant increase in exposure.
- Known hazards for which a new susceptibility exists or there has been a significant increase in susceptibility.

The principal strategies for the identification of emerging risks are described below.

2.1 Analysis of the scientific literature

Nowadays, every year, thousands of articles are published in scientific journals with JCR (Journal Citation Reports) indexing on food safety and specifically with regard to the risks associated with food. The analysis of the content of these publications may offer information about new hazards or new or increased exposure to a known hazard. The analysis of such a large quantity of information and the detection of signs that may permit the detection of a possible emerging risk is complex, and therefore computer tools are used for this purpose. The tools available for this purpose in different countries are described below.

In the United Kingdom, the Food Standards Agency (FSA) is the leading authority on food safety. The FSA has developed a system for the detection of emerging risks by means of which the available information is analysed to identify any event which may be suspicious, unexpected or unusual. It is managed by a multidisciplinary group under the FSA mandate. Based on prior knowledge of this type of incident and on risk management experience, the FSA decides whether the issue is a potential emerging risk. Three actions may be taken, as already occurs in the EFSA: it may be dismissed, more information may be requested or it is considered as an emerging risk, in which case it will be necessary to establish certain protocols for the emerging risk or draw up guides for industries and the consumer, depending on the severity of the emerging risk (FSA, 2012).

The TNO developed a support system for emerging risk identification (ERIS), with the aim of supporting the identification of new and unexpected hazards in the food chain (Van deBrug et al., 2014). The project called "Testing a text mining tool for the identification of emerging risks (ERIS)", is based on a text mining tool to identify semantic relations between concepts in large document collections,

using as a firm basis the organisation of the concepts and the relations in the food field (ontology) patented by TNO. It is supported by a Network of scientific experts. This project is funded by EFSA and the aims of the project were (Lucas et al., 2016):

- To test and assess the practical applicability and capabilities of the ERIS tool for the identification of emerging chemical and biological risks in the food chain.
- To identify emerging chemical and biological risks for human, animal and environmental health in the sea water fish farming food chain through the ERIS system.

On completion of the project, the ERIS system was considered to be a valuable tool to automatically select the most relevant publications, allowing the identification of potential emerging risks from a trusted and manageable data set after expert evaluation. This system is used for data collection in the EFSA AQUARIUS project on the applicability of the analysis of the global food chain for the identification of vulnerabilities and drivers of change (EFSA, 2017b).

2.2 Analysis of grey literature

Grey literature encompasses a set of documents which are unpublished or published through non-commercial channels, including doctoral theses, projects, research reports, standards, reports, etc., which are not easily accessible, including databases on the international food trade, or media news.

2.3 Analysis of food alerts at national and international level

Globalization in the production and marketing of food products has made it necessary to have rapid alert systems for food at both national and international level, to enable the competent food safety authorities to exchange information and take measures to manage the risk quickly and effectively.

At national level, the rapid food alert network is managed through the Coordinated System for the Rapid Exchange of Information (SCIRI), coordinated by the AESAN which in turn centralises the Rapid Alert System for Food and Feed (RASFF) and the International Food Safety Authorities Network (INFOSAN). The three networks are integrated into a single system.

2.3.1 SCIRI

The SCIRI is a network which monitors and manages any food-related incident or risk. In addition to the AESAN, the competent food safety authorities at national, regional and local level take part, together with other organisations by means of specific collaboration agreements.

An alert case is opened when notification is received of a serious risk associated with a food which may require rapid action in one or more Autonomous Communities or in a Member State of the European Union, provided that the product concerned originates from or is distributed in Spain. In 2017, the SCIRI handled 259 alerts for food products. Of these notifications, 140 were Group 1 alerts implying a severe and immediate risk. Spain was identified as the country of origin of the products involved on 87 occasions (level I), and the other 53 originated in other countries (level II). The remaining 119 notifications were from Group 2 (non-immediate severe risk), with 78 of these

originating in Spain (level III) and 41 outside Spain (level IV). Since 2013, there has been a constant growth in the number of notifications, the highest increase being in 2017.

Of the 259 alert notifications from the SCIRI system in 2017, almost half (45 %) were for chemical hazards and a third (33 %) for biological hazards. With respect to alerts for chemical hazards (118), more than half of these (62) were for heavy metals: mercury (57) and cadmium (5) in fish and fish by-products. These are followed by fungal toxins (19), additives (12), migration of materials in contact with food (10), plant protection products (5), pyrrolizidine alkaloids (3), PAHs (3), mineral oils (2) and acrylamide (2). The majority of the alerts refer to products whose maximum limits are regulated and whose presence in the foods in which they were detected is not new. In other cases, such as acrylamide or pyrrolizidine alkaloids, although these are hazards which do not have specific limits, they are known hazards and they have been detected in matrices where their presence had previously been detected.

The information received from the food alerts reported through the SCIRI is of limited value for detecting emerging risks through the identification of new hazards or new paths of exposure. The analysis of the alerts over the years may contribute to detecting increases in exposure to known hazards provided that the control systems used in those years are comparable.

The AESAN publishes an annual report in which it includes: the alerts, indicating the food products involved, the reasons for the notifications, the origin of the product concerned, the notifying countries and the notifying contact points; follow-up information with the involvement of Spain; and border rejections as well as other information.

2.3.2 RASFF

The RASFF is managed by the European Commission and food safety authorities from the European Union Member States, EFSA and EFTA (Norway, Liechtenstein, Iceland and Switzerland) take part as well as some third countries and international organisations.

The database on food safety notifications (risk identified, product, notifying country and product country of origin) is updated on a daily basis for members, and it can be accessed by consumers, businesses and governments at global level.

RASFF notifications include: alert notifications to identify a problem which requires rapid action (withdrawal of a food product on the market with a serious risk for health) and to inform other members to take the necessary measures in the event of the same problem; follow-up notifications when a problem is identified but does not require rapid action; rejections at a border outside the European Union and the European Economic Area of items that pose a risk to health and thus to reinforce controls; news of interest on food and feed safety.

In 2017, a total of 3 832 original notifications were sent. Of these, 942 were classified as alerts (11 % increase with respect to 2016), 596 follow-up information, 1 588 border rejections and 706 news of interest (EC, 2017). These original notifications led to 9 117 follow-up notifications, equivalent to an average of 2.4 follow-ups per original notification. For example, a food outbreak may be reported in a single notification or there may be several notifications linked to a particular outbreak, in which an incident of this type is identified. This was the case with the outbreaks of histamine

intoxication due to the consumption of vacuum-packed thawed tuna products from two different producers in Spain in 2017.

Every year the RASFF publishes a report which includes: notifications made during the year, notifications by hazard category and classification, notifications by product category and by classification, notifications by hazard category and notifying country, notifications by product category and notifying country, notifications by product category and type of control, non-member countries having provided follow-up, notifications by hazard category and risk decision, etc.

As in the case of the SCIRI, the information currently received from the food alerts reported through the RASSF is of limited value for detecting emerging risks through the identification of new hazards or new paths of exposure. Both of these systems are mainly based on existing knowledge about known hazards and are not designed to identify new or unexpected hazards. For this reason, the analysis of the alerts over the years may contribute to detecting increases in exposure to known hazards provided that the control systems used in those years are comparable.

2.3.3 INFOSAN

INFOSAN is a global network which encompasses competent national authorities involved in ensuring food safety. It is jointly managed by the United Nations Food and Agriculture Organisation and the World Health Organisation (FAO/WHO, 2018).

The objective of INFOSAN is to guarantee the rapid exchange of information of global interest regarding incidents of food safety, and to facilitate the management of food safety emergencies. Briefing notes are prepared at INFOSAN to circulate the information, together with guidance and training tools for managing food-safety emergencies. In 2012, the INFOSAN Community Website was created (INFOSAN, 2019) to improve collaboration between the members of INFOSAN.

As in the case of the SCIRI, the information currently received from the food alerts reported through INFOSAN is of limited value for detecting emerging risks through the identification of new hazards or new paths of exposure. The analysis of the alerts over the years may contribute to detecting increases in exposure to known hazards provided that the control systems used in those years are comparable.

In order to reduce the negative effects of food-safety related emergencies and global public health, and at the request of Member States, in 2010 the FAO established an emergency prevention system for food safety (EMPRES). This system is intended to complement and improve the current work of the FAO in food safety, and in emergency situations linked to animal and/or plant health. The EMPRES system offers guidance to countries and regions on how to improve their early warning capacities with the identification of threats to food safety and the establishment of priorities.

2.4 Analysis of the results of the official control programmes

In accordance with Article 41 of Regulation (EC) No. 882/2004, each Member State shall have a multi-annual national control plan. In Spain, the National Food Chain Official Control Plan (PNCOCA) is the document which describes the official control systems along the food chain in Spain, from primary production to the end consumer points of sale. The purpose of this surveillance programme

is to detect possible risks and vulnerable points in the food chain, and to provide solid data for the prioritisation of improvement measures and decision-making (AECOSAN, 2018b).

The competencies in the official control of the food chain at national level lie with the Ministries of Agriculture, Fisheries and Food and of Health, Consumer Affairs and Social Welfare, who play a mainly coordinating role. With the exception of the border controls, the competencies in the planning and implementation of the official controls lies with the Autonomous Communities.

Together with the PNCOCA (which includes hygiene monitoring throughout primary production, control of animal welfare and feed, control of production, marketing and the application of medicines for veterinary use in food-producing animals, the control of animal by-products not intended for human consumption, the control of plant health, the control of food quality, the control of organic production, use of plant protection products, animal imports...), specific national plans also exist for the monitoring of zoonoses and zoonotic agents, the control of pesticide residues, the monitoring of resistance to antimicrobial agents and the National Residue Investigation Plan. A common feature of these plans is that they control parameters in matrices with established maximum limits or, in some cases, of illegal substances, as occurs with certain animal health product residues.

As currently occurs with food alerts, the results of the application of official control plans are of limited value for detecting emerging risks through the identification of new hazards or changes in the paths of exposure. The regular analysis of these results over the years may contribute to detecting increases in exposure to known hazards or new paths of exposure provided that the control systems used in those years are comparable.

One of the problems of the results reported for the PNCOCA is that the information is available in aggregate rather than individual form, making their analysis more difficult and reducing their value as a source of information for identifying emerging risks. For example, if the type of meat, fish or plant in which the results are obtained was differentiated, this would greatly increase the value of this data as a source of information for detecting emerging risks. In this respect, the information about the presence of contaminants reported to EFSA or the results of the programmes for monitoring zoonoses and zoonotic agents, the control of pesticide residues and the monitoring of resistance to antimicrobial agents are available as individual results for each sample. The development of digital platforms and data repositories which facilitate the transfer and standardisation of the results for their analysis both at national and international level, will also facilitate their applicability in the area of emerging risk detection.

Lastly, the official control laboratories of the Autonomous Communities also take part in prospective studies, aimed at obtaining data with respect to non-regulated matrices and parameters and, therefore, not included in the official control plan. Moreover, the Scientific Committee of the AESAN has also recently put forward proposals for prospective studies (AECOSAN, 2018c, d). In these scenarios it would be possible to detect new hazards or new paths or significant increases of exposure.

2.5 Analysis of the information from the epidemiological surveillance systems

The surveillance systems may be key for the identification of new hazards that may be harmful to health.

In France, the French Agency for Food Safety, the Environment and Work (ANSES) uses a system of nutriviigilance (nutritional monitoring), the purpose of which is to improve consumer safety by rapidly identifying any possible adverse effect related to the consumption of food supplements, enriched food or drink, added substances with nutritional or physiological purposes, novel foods and products intended for special diets. With the nutriviigilance scheme, the ANSES is able to detect potentially emerging hazards, mainly nutritional, and assess them or send them to EFSA (ANSES, 2014).

In Spain, the National Epidemiology Centre (CNE), which belongs to the Carlos III Institute of Health, manages the National Epidemiological Surveillance Network (RENAVE), created in 1995 with Royal Decree 2210/1995 (BOE, 1996). This collects information about the different outbreaks in the country, including foodborne outbreaks. The duties of the CNE, in addition to the management of the RENAVE, include the monitoring of Mandatory Notifiable Diseases (EDO), the development of the epidemiological surveillance and epidemiological investigation of emerging issues. The CNE also reports the diseases which are monitored in the European Union to the European Centre for Disease Prevention and Control (ECDC).

The basic surveillance system of the RENAVE is the Microbiological Information System (SIM), which collects information about infectious diseases confirmed by laboratories which take part in the system, in order to provide specific information for the epidemiological monitoring of the communicable diseases. The monitoring system is based on the declaration of the identifications of the causative agents of the relevant pathology, which includes demographic information about the case, the microbiological description of the causative agent and for some microorganisms the standard of antibiotic susceptibility of the pathogen. The cases of diseases subject to monitoring are reported to the competent authorities at the different territorial levels. This information is used for decision-making in the prevention and control of the diseases and provides operational information for the planning and assessment of the health policies. Only new cases are reported, at monthly intervals. The system currently considers the collection of information from 35 microorganisms.

RENAVE publicises the consolidated information for Public Health projects, especially those concerned with the monitoring and prevention of communicable diseases, through the Weekly Epidemiological Journal (BES), a free publication edited by the National Epidemiological Centre, and annual reports, such as that of the SIM or the results of the epidemiological monitoring of communicable diseases.

2.6 Information from researchers and experts

Researchers investigating emerging risks help to determine to a greater degree the level of exposure and consequently the magnitude of the emerging risk. One example of the importance of the opinion of experts is the Delphi study developed by Kendall et al. (2018) for the identification of factors of impact on existing and emerging risks.

The EFSA, in their most recent report on emerging risks (EFSA, 2018c), concludes that a systemic approach to the identification of emerging risks based on expert networks is the core strength of the procedure today.

2.7 Other sources of information

In the emerging risks identification procedure, the analysis of information about the factors associated with these risks is equally important. These include the following:

- New agricultural, animal and aquaculture production systems.
- Climate change (FACCE strategy - the impact of climate change on agriculture and food safety).
- New food production technologies (technological monitoring).
- New food marketing systems.
- New food consumption guidelines (food consumption tendencies).
- Changes in consumer attitudes, behaviour and knowledge with respect to food safety (studies on the perception of food safety).

According to the FAO/WHO (2018b), the principal emerging food safety challenges are linked to factors of environmental, technological, social and economic change. Considerations which coincide with the conclusions of the study developed by Kendall et al. (2018) who also consider that the emergence of food safety risks must be considered from a global perspective.

Climate change is associated with changes in the frequency and geographical prevalence of hazards related to food safety. The monitoring of climate change and its relation with the prevalence of foodborne diseases is essential for identifying potential emerging risks and introducing effective intervention strategies.

To meet the current growing demand for food, intensification of the agricultural, livestock and aquaculture production is necessary through changes in the production systems. This may result in the introduction of new hazards or an increase in the potential to spread foodborne contaminants and pathogens.

With the rapid evolution of scientific advances, a series of new technologies are emerging with applications in the food production systems which may introduce new risks for health and the environment. In this respect automatic monitoring of the technology and trends is vital to remaining up-to-date with the innovation of each food sector in order to identify potential risk scenarios. Computer tools are available which enable the receipt of alerts personalised by interest.

In addition, growing urbanisation, changes in the purchasing power and new marketing systems have an impact on access to food and consumer habits. These changes in consumer behaviour, motivated by consumer perception of food risks, may create new conditions which favour the development of foodborne diseases.

With respect to new food consumption guidelines, the EFSA considers the absence of tools for the identification of new food consumption guidelines (changes in habits) to be a weakness in the strategies for the identification of priority emerging risks. Moreover, the EFSA underlines the poor representation of consumers and social science experts in those organisations involved in the identification of emerging risks, a factor which is essential for understanding the role of human behaviour in the creation and perception of the risks (EFSA, 2018c).

Possible sources of data for analysis include those which provide information about the consumption of food and drink and about economic data (purchases). Possible sub-analyses include

those linked to consumer trends with respect to local products versus imported products, organic/ environmentally-friendly produce or not, products for people with allergies or intolerances, etc. Other social science methods which analyse behaviour make use of interviews, observations, surveys and experiments.

In 2016, the German Federal Institute for Risk Assessment (BfR) recommended the development of methods and systems for the early identification of emerging risks in the food and feed chain. To this purpose, the DEMETER (*Determination of Metrics of Emerging Risk*) project was created. It is conducted in Germany, as the lead country, with the collaboration of the Netherlands, United Kingdom and Hungary. This platform offers a set of integrated open-code solutions which allow European Union Member States and the EFSA to share knowledge, data and methods for the identification of emerging risks quickly and effectively, through the development of new tools for the collection and automatic validation of data from multiple sources for emerging risk identification (BfR, 2018). The definition of emerging risk used in this project is similar to that provided by the EFSA, but also encompassing communicative factors which influence the development of an emerging risk (EFSA, 2017b).

Another important tool in emerging risk identification is the “Horizon Scanning” programme, a systematic process for the capture and monitoring of changes which includes the identification of changes in consumer habits (EFSA, 2018c). This programme was developed by the FSA in collaboration with the EFSA and is used for the identification of future global tendencies which may have an impact on the world as we know it today. The CERF (Centre for Environmental Risks and Futures) works with the FSA with the aim of leading this tool towards the identification, analysis and prioritisation of transversal and long-lasting global issues, and their impact on food safety (Randles et al., 2014). The results of the “Horizon Scanning” activities and the scenario forecasts are applied as a basis of information for the FSA emerging risk programme (2011).

All these analyses would be particularly associated with a long-term assessment of emerging risks. Other examples include changes in legislation and regulation such as those introduced for the production and marketing of insects, which could entail a change in the epidemiology of allergic reactions (AECOSAN, 2018e).

The EFSA, in their latest report on emerging risks (EFSA, 2018c), establishes the following recommendations: 1) develop a food system-based approach including the integration of social sciences; 2) improve data processing pipelines, implement a data validation system and develop data sharing agreements to explore mutual benefits; that is exploit the development of new technologies; and 3) revise the EFSA procedure for emerging risk identification to increase transparency and improve communication.

In accordance with the EFSA recommendations (2018c), and as part of the concept of citizen science, it is also important to consider the public's perception of the risk. The results of the Eurobarometer survey in 2010 (EC, 2010) revealed that Europeans associate food and eating with enjoyment, and rarely with food safety issues. Given a list of possible risks, they consider that the probability of food damaging your health is low compared to being affected by the economic crisis, environmental pollution or a serious illness. With respect to food-related risks, chemical substances (residues and pollutants) and animal cloning were the most worrying.

Kaptan et al. (2018) consider that the perception of the risk associated with food depends on whether the potential risks are of a natural or technological nature, combined with the acute incident rate compared to the chronic rate at which the potential risk appears. In any case, transparent and honest communication about the benefit and the risk creates increased trust in the responsible institutions.

In Spain, the latest data from the Survey on social perception of science and technology (FECYT, 2018) indicate that the areas that most interest the Spanish population are medicine and health, followed by food and consumption. When it comes to assessing the risk/benefit balance in scientific advances and technological developments, the opinion of the Spanish population remains stable in almost all the areas analysed except with respect to food products and agricultural production in which the positive balance moves back with respect to 2016, clearly a sign of increased perception of the risk.

Conclusions of the Scientific Committee

The Scientific Committee considers that it would be desirable to align the definition of emerging risk included in Law 17/2011 with the EFSA definition to facilitate communication and the effectiveness of the actions to be developed. Taking the EFSA definition as a base in relation to emerging risks, it is important to identify whether there is a new risk to which we are exposed, or if there is new exposure or if exposure to a known risk has increased. At the same time assessing the increase of susceptibility to a known risk.

To this purpose, after reviewing the different possible strategies, the Scientific Committee considers the following to be of use:

- Analysis of scientific literature. The development or implementation of powerful data management systems and digital collaboration platforms would be of use for managing the large quantity of available information and data.
- Analysis of grey literature. As in the above case, specific computer tools which permit the extraction of information of interest would be required.
- Analysis of the alerts and results of official control programmes. These tools control the known risks for which control legislation exists. These may be of value for detecting increases in exposure due to increases in the presence of a certain pollutant over time.
- Analysis of the epidemiological monitoring systems which may serve to detect increases in susceptibility or exposure.
- Analysis of consumer tendencies. This would serve to detect increases in exposure, provided that data collection methodologies are comparable from year to year.
- Analysis of the information collected from studies on the public's perception of risk.
- Analysis of information from experts or researchers. The improvement of collaboration between the scientific community and national and international institutions and organisations would be desirable.

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