TECHNICAL REPORT

Update on EFSA's activities on Emerging Risks 2012-2013[1]

European Food Safety Authority[2, 3]

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ABSTRACT

EFSA has statutory obligations to identify emerging risks. In 2012-2013, an approach for emerging risk identification was piloted and follow-up activities on the issues identified were carried out. The engagement with Member States and civil society Stakeholders was extended to international partners. To further engage the Panels, the Scientific Committee's Standing Working Group on Emerging Risks was established. Overall, 45 issues were evaluated. Issues prioritised for further investigation include the first European-wide survey on energy drinks consumption, an inventory of EFSA activities on bees, a study on omics technologies, and a report on the international frameworks for human risk assessment of chemical mixtures. Ongoing activities include further projects on chemical mixtures and bee health, human biomonitoring for risk assessment, non-monotonic-dose-response effects of chemical substances, and cyanobacteria toxins in food. After a few years of activity, the approach has now shown its potential to anticipate some issues that may give rise to emerging risks. Issues previously identified have recently been addressed by the Scientific Committees of the European Commission or by EFSA. These include three questions of the European Commission to EFSA (caffeine intake, lumpy skin disease, pollen importation as a source of plant health risks), one from a Member State (micro-plastic particles in marine animals), and one to the Scientific Committee on Emerging and Newly Identified Health Risks (synthetic biology). Activities on emerging risks allowed EFSA to provide relevant contributions to Horizon 2020. Overall, our experience confirms that emerging risk identification requires a high level of expertise and knowledge networks for sharing information. Effective networking is essential for exchanging methods, data and evaluations. Next steps include the completion of the expert consultations on emerging biological hazards, the continuation of the engagement with Member States and Stakeholders, the appraisal of the approach, and the completion of the ongoing activities on the issues identified.

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KEY WORDS

Emerging risks, emerging issues, stakeholders, network, standing working group, foresight, horizon 2020;

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SUMMARY

EFSA has statutory obligations to identify and share information on emerging risks. In 2012-2013, the approach was fully implemented and follow-up activities on specific issues identified were completed. The streamlined approach includes three main steps: 1) preliminary identification of priority emerging issues, 2) identification of appropriate data sources and data collection, 3) final evaluation and emerging risk identification.

Overall, EFSA, the Network and the Stakeholders Group on emerging risks have evaluated 45 issues, covering a wide range of biological and chemical areas. Relevant issues have been selected for further investigation and self tasking mandates have been started. Issues prioritised for further investigation include the first European-wide survey on energy drinks consumption, an internal task force and a scientific workshop on the holistic approach to bee risk assessment, and a foresight study on the potential impact of omics technologies on food and feed safety risk assessment. Ongoing activities include chemical mixtures (i.e. a task force on human risk assessment of chemical mixtures, a systematic review on the combined toxicity of multiple chemicals, a toxicological modelling study on exposure to multiple chemicals in bees), two reviews of the scientific literature (i.e. one on human biomonitoring for risk assessment, and one on non-monotonic-dose-response effects of chemical substances for human risk assessment), and one project on cyanobacteria toxins in food. In addition, EFSA activities on emerging risks has allowed EFSA to provide DG-Research and Innovation with relevant contributions to Horizon 2020.

After a few years of activities, the approach has now shown its potential to anticipate issues that may give rise to emerging risks. Issues previously identified have recently been addressed by Scientific Committees of the European Commission or by EFSA as self-tasking activities. These include four questions of the European Commission to EFSA (one on caffeine intake, one on lumpy skin disease, and one on pollen importation as a source of plant health risks), one from a Member State (micro-plastic particles in marine animals), and one to the Scientific Committee on non-food Emerging and Newly Identified Health Risks on synthetic biology.

The engagement with Member States and Stakeholders has now been reinforced and extended to international partners. In order to further engage the EFSA scientific Panels, the Standing Working Group on Emerging Risks has been established and has started its activities in 2013. The Standing Working Group is now coordinating an expert consultation for the identification of biological emerging risks involving members of the BIOHAZ and AHAW Panels. With respect to chemicals, the Standing Working Group is drafting a procedure for the identification of chemical emerging risks starting from available lists of chemicals of potential concerns from the REACH and other databases, selecting substances of concern on the basis of their production volumes, persistence, bioaccumulation, use and toxicity.

Overall, our experience confirms that emerging risks identification is an iterative process characterised by a high level of uncertainty due to substantial data gaps, which requires several rounds of expert consultations and well established knowledge networks for sharing information. Effective networking has proven to be essential for exchanging methods, data and evaluations of emerging risks.

Next steps include the finalisation of the expert consultations on biological emerging risks through the Scientific Committee's Standing Working Group on Emerging Risks, the conduction of a pilot study to test the proposed procedure for the identification of chemical emerging risks, the continuation of the engagement with Member States and civil society Stakeholders, an appraisal of the efficacy of the overall approach for emerging risks identification, and the completion of the ongoing activities on the issues identified.

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BACKGROUND AS PROVIDED BY EFSA

The successful identification of risks at their early inception is at the heart of public health and environmental protection. Improved identification of emerging risks may become a major preventive instrument at the disposal of the Member States and the Community[4].

According to EFSA's Founding Regulation[5], the Authority is required to *"undertake action to identify and characterise emerging risks"* in the field of food and feed safety. The Scientific Committee and Emerging Risks Unit (SCER) contributes to this mission by supporting the development, establishment and operation of structures for the screening and analysis of information sources with a view to identifying emerging risks.

Over the last few years, EFSA has started to implement its programme to develop an effective and transparent approach to identify emerging risks. This consists of a definition of emerging risks and an overall strategy for the collection, analysis and evaluation of the relevant data and information (EFSA, 2006, 2007, 2009).

Whilst EFSA has a unit dedicated to the early identification of emerging risks, the task is a horizontal one, implicating not only SCER, but also all of EFSA's science units and their associated Panels.

TERMS OF REFERENCE AS PROVIDED BY EFSA

The SCER Unit will draft a report on emerging risks in food and feed. The report will include an update on the EFSA's activities and approach on emerging risks in food and feed.

[4] Recital 50, Reg. 178/2002/EC
[5] Article 23(f) Reg. 178/2002/EC

1. Introduction

The successful identification of risks at their early inception is at the heart of public health and environmental protection. According to Art. 34 of Regulation (EC) 178/2002, the EFSA shall "*undertake action to identify and characterise emerging risks*" in the field of food and feed safety, and "*to establish a system of networks of organisations*"[6] in the field of food and feed related emerging risks. The authority is required to establish "*monitoring procedures for systematically searching for, collecting, collating and analysing information and data with a view to the identification of emerging risks in the fields within its mission*" (i.e. human, animal and plant health in relation to the food and feed chain)[7].

Such a pro-active approach is intended to provide an opportunity for risk assessors to undertake further investigations, possibly leading to a full risk assessment to support risk managers to put in place preventative and mitigating measures. It is not surprising, therefore, that next to EFSA the task of emerging risk identification has been assigned to a number of different bodies in the EU and in third countries (ECDC, 2011; EEA, 2011; International Risk Governance Council, 2009; JRC IPTS Team Working in European Foresight, 2010; Kocharov, 2010; OECD, 2003).

As mentioned in the Regulation, the Authority shall forward the evaluation and information collected on the emerging risks identified to the European Parliament, the Commission and the Member States. This prescription has two main objectives: (i) the first one being the adoption of specific measures justified according to the precautionary principle (see Art. 7 of Reg. (EC) 178/2002); and (ii) the second one being the adoption of decisions to gather and/or to produce the additional missing data to enable a full risk assessment. Therefore, it is important that information on each emerging risk identified is provided by EFSA with a clear indication of additional data needed for the full risk assessment. To this end, information on emerging risks should be shared with the relevant EFSA Panels, to check for additional data requirements, before reporting to the European Parliament, Commission and Member States.

This technical report on emerging risks takes stock of the experience acquired in 2012-2013, presenting the results obtained so far, paving the way for the further development of the EFSA strategy and activities on emerging risks. In particular, the report includes the results obtained in terms of issues identified and follow-up actions, an update of the developments in the EFSA's strategy for emerging risk identification, the knowledge networks established, and indications on next steps and future direction of EFSA's work in this area.

2. Developing an approach for Emerging Risk Identification

Since its inception in 2003, EFSA has worked intensively to develop an approach to identify emerging risks. According to EFSA's definition of "emerging risk" adopted in 2007[8], an emerging risk is understood to be associated with the probability of a harm (i.e. injury or damage or adverse response) to human, animal and/or plant health, resulting from a newly identified hazard which may be an agent of physical, chemical or biological nature to which a significant exposure of the target organism may occur, or from an unexpected new or increased significant exposure and/or susceptibility to a known hazard through the food chain for humans, through the feed chain for animals and through the environment for plants.

A preliminary important step in such a process is identified when a new exposure of human beings, animals and/or plants is discovered or suspected to an agent of unknown toxicity/pathogenicity or a new toxicity/pathogenicity is discovered for a hazard with unknown human, animal and/or plant

[6] Art. 23(g) Reg. 178/2002/EC.
[7] European Union (2002). REGULATION (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
[8] http://www.efsa.europa.eu/en/scdocs/doc/escoemriskdefinition.pdf

exposure. Such a condition is operationally defined in the present context as an "emerging issue" that conceptually corresponds to the suspicion of serious emerging risk mentioned in the second paragraph of Art. 34 of Reg. (EC) 178/2002. In fact, it clearly points to the need of getting more toxicity/pathogenicity or exposure data, which could lead to the identification of an emerging risk. Emerging risks or issues can be identified in association with a variety of biological, chemical and/or physical hazards of natural or industrial origin, as well as for a variety of target organisms, including human beings, animals and/or plants. In addition, the mandate of EFSA on emerging risks strives for the early identification of new and emerging research or methodological issues that may have implications for food and feed safety.

Principles and methods for emerging risk identification have been rarely formalised in the context of food and feed risk assessment (Altieri et al., 2011). As data leading to the identification of risks at their early inception are characterised by considerable limitations and uncertainties, emerging risk identification is typically based on expert judgment and qualitative or semi-quantitative priority setting methods.

The current EFSA approach for emerging risk identification includes three main steps: 1) preliminary identification of priority emerging issues, 2) identification of appropriate data sources and data collection, 3) final evaluation and emerging risk identification (EFSA, 2012). Priority emerging issues should be identified preferably through expert consultations with EFSA staff, EFSA's Scientific Panels, the Member States Network on Emerging Risks (EREN) and the Stakeholders Consultative Group on Emerging Risks (StaCG-ER) and via exchange of information with qualified organisations (e.g. sister Agencies and other competent organisations). Within the three steps a structured expert judgment approach is applied to filter and prioritise the relevance of the information. In 2013, the Standing Working Group (SWG) of the Scientific Committee on Emerging Risks has been established to support EFSA in the selection of most relevant issues identified in the previous steps and providing recommendations on the formalisation of the outputs (e.g. self-task mandate) and follow-up actions (EFSA, 2012).

3. Update on the activities of the Emerging Risks Exchange Network (EREN) and the Stakeholder Consultative Group on Emerging Risks (StaCG-ER)

Effective networking has proven to be essential for exchanging methods, data and evaluations of emerging risks. EFSA established EREN to exchange information with Member States on possible emerging risks for food and feed safety in 2010. The Network is currently composed of delegates from 21 Member States and an EFTA country (Norway) designated through the Advisory Forum of EFSA and observers from the European Commission, EU pre-accession countries, the Food and Drug Administration of the USA (FDA) and the Food and Agricultural Organisation of the United Nations (FAO).

The Network met six times in 2012-2013, and discussed a total of 35 issues (see Table 1 on the next page). Out of these, 21 originated from EFSA, 13 from Member States, and 1 from the Stakeholders. The issues discussed included a broad range of areas, such as microbiological hazards, chemical contaminants, biotoxins, new technologies and dietary habits, illegal activity, among others. Selected issues deemed to merit further consideration have been submitted to the EFSA Scientific Committee's SWG on Emerging Risks (see Table 1). More detailed information on the activities of the Network and the issues evaluated in 2012 can be found in Appendix A. The report on the activities of EREN of 2013 is in preparation and will be published in 2014.

StaCG-ER was established by EFSA to facilitate the exchange of information on emerging risks with other civil society stakeholders. Members of StaCG-ER were selected by EFSA from nominations made through EFSA's Stakeholder Consultative Platform (SCP). The Platform is composed of EU-wide stakeholder organisations working in areas related to the food chain, and assists EFSA in the development of its overall relations and policy with stakeholders. The selection of members for StaCG-ER was based on the individual expertise of the nominees, and to ensure a balanced

representation of both industry and consumers. In 2012-2013, StaCG-ER met six times and discussed 22 issues (Table 1). Out of these, 16 originated from EFSA, 3 from the Stakeholders and 3 from a Member State. The issues brought to the attention of StaCG-ER were a selection of issues of particular relevance to the stakeholders involved, for which EFSA was seeking further data or was interested in the group's opinion thereon. The issues discussed were from the areas of novel foods, packaging, pesticides, marine biotoxins, environmental contamination, chemical contaminants and dietary habits, among others. More information on the activities of StaCG-ER of 2012 and 2013 can be found in Appendix B and C.

Selected issues deemed to merit further consideration have been submitted to the EFSA Scientific Committee SWG on Emerging Risks (Table 1).

Table 1: List of issues discussed by SCER, EREN, StaCG-ER and the Scientific Committee SWG on Emerging Risks in 2012-2013.

	Issue[8]	Presented by	SCER	EREN	StaCG-ER	SWG	Follow-up
1	Potential chemical contamination of food from recycled paper	EFSA	X	X	X	X	
2	Zoonotic viruses associated with illegally imported wildlife products	EFSA	X	X			
3	First report on indigenous ciguatera fish poisoning in the EU	EFSA	X	X	X	X	
4	*Salmonella* in paan (betel) leaves	MS	X	X			
5	Indian milk adulteration	MS	X	X			
6	Increased use of banned, unauthorised and counterfeit pesticides	MS	X	X	X		
7	Increased cancer risk in meat and poultry workers	EFSA	X	X	X		
8	Combined toxicity of melamine and cyanuric acid	EFSA	X	X	X		
9	Import of stray dogs and new parasitic diseases	MS	X	X			
10	Mycotoxins in Swedish crops[9]	MS	X	X			
11	Undereporting of foodborne norovirus in older adults	MS	X	X			
12	Drivers and pathways of antimicrobial resistance: foodborne extended-spectrum beta-lactamase (ESBL)	MS	X	X			
13	Zoonotic potential of Usutu virus	EFSA	X	X			
14	Colorectal cancer and possible link with dietary and cooking habits of red meat consumption	EFSA	X	X	X	X	
15	Animal illnesses linked to jerky pet treats	EFSA	X	X	X		
16	Pharmaceuticals and personal care products (PPCPs) in the environment and possible human exposure through the food chain	EFSA	X	X	X	X	
17	Potential contamination of the food/feed chain from industrial and environmental chemical contaminants with certain characteristics (i.e. volume of production, dispersive use, persistence in the environment, bioaccumulation and toxicity).	EFSA	X	X	X	X	Self-tasking mandate to be started in 2014.
18	Insects used as food and feed[10]	EFSA	X	X	X	X	
19	Food packaging residues in feed[11]	StaCG-ER	X		X		
20	Alternatives to bisphenol A for food contact material applications	EFSA	X	X	X	X	
21	Food chain contamination from environmental pollution of micro plastic particles	MS	X	X		X	MS request to EFSA.
22	Possible applications of synthetic biology in the food chain	EFSA	X	X		X	Mandate of the EC to the SCENIHR.
23	*Clostridium difficile* as a potential zoonotic or foodborne pathogen	EFSA	X	X	X		
24	Increase of *Cryptosporidium* infections in the Netherlands, the UK and Germany in 2012	EFSA	X	X	X		
25	Lumpy skin disease	StaCG-ER	X	X	X		Mandate from the EC to EFSA.
26	Cyanotoxins contamination in food	EFSA	X	X	X		Self-tasking mandate to be started in 2014.
27	Potential synergistic toxicity: cadmium and chlorpyrifos	EFSA	X	X	X		
28	Wheat crop: low quality and poor yield	MS	X	X	X		
29	Fish substitution and mislabelling	MS	X	X	X		
30	Masked mycotoxins	EFSA	X	X	X		Mandate from the EC to EFSA.
31	Epigenetic endpoints in chemical risk assessment regulatory testing	EFSA	X	X	X		
32	Presentation of nutritional information to consumers	StaCG-ER			X		

[9] The issue was discussed for the first time in 2011.
[10] This issue was discussed in 2010.
[11] The issue was shared for information only, without the use of the standard briefing note template; no comments received from other members.

	Issue[8]	Presented by	SCER	EREN	StaCG-ER	SWG	Follow-up
33	3d-food printing	MS	X	X			
34	Extraintestinal pathogenic *Eschericia coli* (ExPEC)	MS	X	X			
35	*Opisthorchis felineus* in Italy	EFSA	X	X			
36	Cinnamon challenge: consumption of large quantities of cinnamon within a short time	MS	X	X			
37	Increased norovirus activity associated with emergence of a new variant of genotype II	EFSA	X	X			
38	Imported flowers as a vector for spreading honey bees infectious Diseases	EFSA[12]	X				Mandate of the EC to EFSA on the risks posed by Prunus pollen, and pollen from seven additional plant genera, for the introduction of viruses and virus-like organisms into the EU.
39	Chemical mixtures[13]	EFSA	X			X	• Systematic review on metabolic interactions and synergistic effects of chemical mixtures for human risk assessment. • Internal science project on international frameworks dealing with the human risk assessment of chemical mixtures. • Development of a framework for the risk assessment of chemical mixtures and a toxicological database on relevant chemical mixtures to food safety.
40	Human biomonitoring[13]	EFSA	X			X	Review of human biomonitoring for chemical substances and its applications to human exposure assessment for food safety.
41	Non-monotonic-dose-response chemical effects[13]	EFSA	X			X	Review of non-monotonic dose-responses of substances for human risk assessment.
42	Bee health	EFSA	X			X	• Procurement on toxicity of exposure to multiple chemicals in bees and modelling the effects on bee population dynamics using DEB-TOX models. • Internal Bee Task Force for the pre-screening and assessment of the information collected outside EFSA. • Scientific Colloquium XVIII "Towards approaches for a holistic risk assessment of multiple stressors in bees".

[12] The issue was discussed in 2011.
[13] The issue was shared for information only, without the use of the standard briefing note template

	Issue[8]	Presented by	SCER	EREN	StaCG-ER	SWG	Follow-up
							• Inventory of studies conducted on bees, inside and outside EFSA, to identify cross-cutting issues and further research needs for a more integrated approach on the evaluation of risks to bees and their ecosystem services.
43	Omics technologies in food safety risk assessment[13]	EFSA	X			X	A foresight study on emerging technologies: state of the art of Omics technologies and potential applications in food and feed safety.
44	Energy drinks	EFSA	X			X	• European-wide survey on energy drinks consumption. • Mandate of the EC to EFSA on caffeine intake, including caffeine from energy drinks.
45	Emerging methodologies and tools for hazard assessment of chemicals in humans	EFSA	X			X	Self-tasking mandate to prepare a scientific report comprising a critical review of the state of the science of the modern and emerging methodologies and tools: biologically-based models, omics, for the hazard identification and characterisation of chemicals in humans.

4. Standing Working Group on Emerging Risks

The SWG on Emerging Risks was created in 2013 under the umbrella of the Scientific Committee, and sought the participation of all EFSA scientific Panels to emphasise the multidisciplinary effort needed to identify and appraise emerging risks. The remit of the SWG on Emerging Risks is to support EFSA throughout the emerging risk identification process, from the identification of priority issues that merit further consideration to the final identification of emerging risks. Thus, one of the major tasks of the Working Group (WG) is to provide recommendations on the issues identified by EFSA, EREN and StaCG-ER. The WG started its scientific activities in 2013, and has only recently started to evaluate the issues identified by EFSA and its WGs. Thus, not all the issues submitted by EREN and StaCG-ER have been evaluated by the end of 2013.

In its first year of activities the WG focused on chemical and biological hazards. In the chemical area, the activities focussed on the use of existing information on chemical production/use in its widest sense with a view to identifying potential contamination of the food and feed chain (Table 1, issue 17) by chemicals that have not yet been considered in formal food/feed chain risk assessments. In fact, once released into the environment, these substances could find their way into the food and feed chain. In particular, industrial contaminants with certain characteristics such as high volume of production, dispersive use, persistence in the environment, bioaccumulation and toxicity could have a higher likelihood of being detected in the food and feed chain. Thus, the WG proposed a systematic procedure for the identification of emerging chemical risks in the food and feed chain (EFSA, 2014). The proposed framework uses a variety of data sources as an input relating to industrial chemicals as well as software models that can be used to predict the environmental behaviour and potential toxicity of chemical substances from their structural features and physico-chemical properties. The procedure consists of a multi-step selection process that starts with a list of chemicals to which a sequence of selection criteria is applied to identify the substances of potential concern. The selection criteria take into account a number of parameters such as volumes of production or import, persistence in the environment, potential for bioaccumulation, dispersive uses, toxicity, and any available outcomes of risk assessments. The WG recommended to test and further developed the proposed procedure using specific examples of chemical substances, preferably through a pilot project. The results of the pilot project should inform on additional activities that might be needed for further refinement of the proposed approach.

In the domain of biological risks, relevant expertise is found in EFSA in different Panels, such as the BIOHAZ and AHAW Panels. This field is very broad and characterized by dynamic interactions between many factors. A series of forces – or drivers of emerging risks – can be identified, ranging from developments in global trade flows, to new food chain technologies, to changes in consumer behaviour, which could all potentially develop into or trigger an emerging risk. There is a need to identify and focus on the most important factors that may drive the (re-)emergence of risks in the remits of those Panels. Thus, the SWG of the Scientific Committee decided to conduct an expert consultation with the relevant Panels. The objective of the consultation is to bring together experts to identify priority drivers of biological emerging risks to human and animal health. This exercise will support EFSA in the identification of emerging biological risks to human and animal health.

The SWG of the Scientific Committee on Emerging Risks is also mandated to prioritise issues identified by EFSA and its other WGs and Network, indicating those for which further action is warranted. In 2013, the WG evaluated 9 issues, which were all selected by EFSA, StaCG-ER, or EREN and presented by EFSA in plenary meeting (see Table 1). The issues discussed were related to areas of environmental contamination, nutrition, new technologies, and chemical contamination. Among the different issues evaluated, the one identified for follow-up action was the one on the potential contamination of the food chain from industrial and environmental chemical contaminants. Follow-up action resulted in the report described above and in an outsourced project to test the proposed procedure. For the other issues, either no follow-up actions were recommended or follow-up actions already initiated by EFSA were deemed to be appropriate.

5. Monitoring activities of the SCER Unit

In addition to the coordination activities of its WGs and Network, the SCER Unit, comprised of a multidisciplinary team of scientific officers with expertise in microbiology, animal health, ecology, toxicology, food chemistry, and epidemiology, is also performing active monitoring of other selected sources of information (e.g. scientific literature, conferences, and other scientific events). Issues of potential interest in terms of emerging risks are also selected by EFSA staff members through these active monitoring activities. More information on the approach and the criteria used to select relevant issues can be found in a previous report (EFSA, 2012).

6. Issues identified and follow-up activities

In 2012-2013, the approach for the identification of emerging risks was implemented and follow-up activities on specific issues identified have been carried out. A total of 45 issues were evaluated by SCER, EREN, StaCG-ER or the Scientific Committee's SWG on Emerging Risks. Twenty-nine were identified by EFSA, 13 by the Network, and 3 by StaCG-ER. Out of the 45 issues evaluated, 14 have been prioritised for follow-up actions (Table 1). The following paragraphs summarise completed and on going activities on the issues identified. More details on the specific projects can be found on the reports published on the EFSA website.

Completed activities

These includes a European-wide survey on energy drinks consumption[14], an inventory of EFSA activities on bees[15] and a scientific colloquium on the holistic approach to bee risk assessment[16], a foresight study on the potential impact of omics technologies on food and feed safety risk assessment[17], and a report on the international frameworks dealing with human risk assessment of combined exposure to multiple chemicals[18]. In 2013, the EFSA PLH Panel issued an opinion on the risks posed by Prunus pollen, and pollen from seven additional plant genera, for the introduction of viruses and virus-like organisms into the EU.

Ongoing activities

Ongoing activities include further projects on chemical mixtures (i.e. a systematic review on metabolic interactions and synergistic effects of chemical mixtures for human risk assessment, the development of a framework for the risk assessment of chemical mixtures and a toxicological database on relevant chemical mixtures to food safety), one study on human biomonitoring for risk assessment (i.e. review of human biomonitoring for chemical substances and its applications to human exposure assessment for food safety), one study on non-monotonic-dose-response effects of chemical substances for human risk assessment (i.e. a review of non-monotonic dose-responses of substances for human risk assessment), further activities on bee health, including a procurement on toxicity of exposure to multiple chemicals in bees and modelling the effects on bee population dynamics using DEB-TOX models, an internal Bee Task Force for the pre-screening and assessment of the information collected outside EFSA, an inventory of studies on bees conducted outside EFSA to identify cross-cutting issues and further research needs for a more integrated approach on the evaluation of risks to bees and their ecosystem services.

For lumpy skin disease, the Animal and Plant Health Panel has received a mandate from the EC and the opinion is estimated to be published by the end of 2014.

[14] http://www.efsa.europa.eu/en/supporting/pub/394e.htm
[15] http://www.efsa.europa.eu/en/supporting/pub/358e.htm
[16] http://www.efsa.europa.eu/en/events/event/130515.htm
[17] http://www.efsa.europa.eu/en/supporting/pub/495e.htm
[18] http://www.efsa.europa.eu/en/efsajournal/pub/3313.htm

7. Horizon 2020

Emerging risk identification is often characterised by important knowledge and data gaps and, therefore, it may have important implications in terms of future research needs. In 2011, the European Commission drafted proposals for a Regulation to establish Horizon 2020, the next Framework Programme for Research and Innovation (2014-2020). The European Commission has agreed the proposals for Horizon 2020 and it is expected to have a final agreement of the European Parliament with the launch of the first calls by 2014. The ongoing activities on emerging risk identification, allowed EFSA to provide relevant contributions for DG-Research and Development for Horizon 2020.

In 2012-2013[19], the SCER Unit has conducted a consultation with the EFSA Advisory Forum, Advisory Forum Consultation WG, and EFSA's Scientific Panels and Units and the Scientific Committee, and EFSA Panels with the objective to identify priority research areas (in general and not restricted to the emerging risks area *senso stricto*).

Fifty-six research priority areas were identified by EFSA under the Horizon 2020 headings. Following dialogue with DG-Research and Innovation and DG-Research Agriculture and Rural development. These priority research topics have been communicated to these DGs and DG-Health and Consumers to further support the prioritisation of research within the Horizon 2020 context. A comprehensive list of the 56 priority research topics identified by EFSA is listed in Appendix D.

8. "Validation" of the approach

Principles of the verification and validation of the proposed approach should be considered in a stepwise process and should be based on the practical experience gained through at least a few years of implementation. The validation of the efficacy of the approach for emerging risks identification is a challenging issue to be seriously considered by taking into account not only the evaluation of the ability of the system to identify new and re-emerging risks earlier than traditional systems, but also the usefulness of other types of outputs coming from the process, such as the establishment of networks, the generation of new knowledge and new paradigms, and the fostering of innovation and technologies.

Follow-up activities can contribute to the determination of whether the issues identified are indeed emerging risks. Some issues previously identified during the first years of activity have recently been followed up by European Commission, MSs or by EFSA as self-tasking activities. These include a question of the EC to EFSA on caffeine intake with reference to energy drinks, one on pollen importation as a source of plant health risks, one on lumpy skin disease, one question to EFSA from a MS on micro-plastic particles in marine animals, and one on synthetic biology for the SCENIHR.

Thus, the approach has shown its potential to be able to anticipate issues that may give rise to emerging risks.

[19] EFSA-Q-2010-00922 Report of the Task Force on identifying research priorities for submission to DG Research (IN18)

CONCLUSIONS

Over 2012-2013, the process for emerging risk identification was piloted and considerably improved in terms of efficiency. This effort lead to a more focused monitoring and targeted follow-up actions, the consolidation of knowledge networks for sharing information, and the further development of a methodological framework. Emerging risks activities encompass a broad range of issues ranging from the identification of new hazards to the early identification of emerging research or methodological issues that may have implications for food and feed safety.

More than 40 issues were evaluated using an expert judgment approach. Specific issues were identified for which follow-up activities have been completed and others have been initiated. After a few years of activities, the approach has now shown its potential to anticipate issues that may give rise to emerging risks. Issues previously identified have recently been addressed by the Scientific Committees of the European Commission or by EFSA as self-tasking activities. These include a question of the EC to EFSA on caffeine intake with reference to energy drinks, a question of the EC on pollen importation as a source of plant health risks, one on synthetic biology now being addressed by the SCENIHR, and a request from a MS to EFSA on micro-plastic particles in marine animals.

Completed activities include a European-wide survey on energy drinks consumption, an inventory of EFSA activities on bees, a foresight study on the potential impact of omics technologies on food and feed safety risk assessment, and a report on the international frameworks dealing with human risk assessment of combined exposure to multiple chemicals. Ongoing activities include further projects on chemical mixtures and bee health, one study on human biomonitoring for risk assessment, and one on non-monotonic-dose-response effects of chemical substances for human risk assessment.

Whilst EFSA has a unit dedicated to emerging risks identification, the task is a horizontal one. Thus, the Scientific Committee and Panels have now a more prominent role in the process. Involving experts already working with EFSA in the selection of priority issues is a particularly efficient approach, as it allows to take into account issues already covered by current EU Food Safety Regulations and related EFSA's activities. Effective networking of experts was confirmed to be essential for exchanging experience, methods, data and evaluation of emerging issues. In particular, networking with stakeholders, MS, EU and international agencies has proven to be a key step in the effectiveness of this process, and the structures for carrying this out effectively have been further developed. In 2012-2013, the focus of their activities has shifted from the description of existing systems and methodologies used to identify emerging risks to the evaluation of specific emerging issues. Considering the broad spectrum of areas under the remit of EFSA and the nature of emerging risk identification, characterised by large data gaps and uncertainties, a structured expert judgment approach has proven to be an efficient approach for emerging risks identification. Expert advice is now further deployed through the Scientific Committee's SWG on Emerging Risks, the enlarged Network and the Stakeholders Consultative Group.

Based on this hands-on experience, the system has shown the potential in the identification of issues that may give rise to emerging risks and considerable knowledge has been gained in the area of expert elicitation related to emerging risks. The development and operation of the current process over a period about 4 years has provided practical experience for the improvement of the efficiency of the approach.

In conclusion, our experience confirms the need of the EFSA Scientific Committee and Panels to play a key role. It is, thus, important to continue the activities of the Scientific Committee's SWG on Emerging Risks. Given the key role of networking activities, it is recommended to further encourage Stakeholder and MS engagement to share information on the issues identified. Next steps include the further engagement with Member States and Stakeholders, including other European and International agencies, the appraisal of the approach by the SWG on Emerging Risks, and the completion of the ongoing activities on the issues identified.

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ABBREVIATIONS

EREN	Emerging Risks Exchange Network
FAO	Food and Agricultural Organisation of the United Nations
FDA	Food and Drug Administration of the USA
SCER	Scientific Committee and Emerging Risks Unit
StaCG-ER	Stakeholders Consultative Group on Emerging Risks
SWG	Standing Working Group
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
WG	Working Group

APPENDICES

Appendix A. ANNUAL REPORT OF THE EMERGING RISKS EXCHANGE NETWORK 2012

Appendix B. REPORT OF THE STAKEHOLDERS' ACTIVITIES IN THE AREA OF EMERGING RISKS 2012

Appendix C. REPORT OF THE STAKEHOLDERS' ACTIVITIES IN THE AREA OF EMERGING RISKS 2013

Appendix D. HORIZON 2020: 2013 CONSULTATION OF EFSA PANELS, UNITS, THE SCIENTIFIC COMMITTEE AND THE ADVISORY FORUM REGARDING PRIORITY RESEARCH TOPICS

APPENDIX A

TECHNICAL REPORT OF EFSA

Annual report of the Emerging Risks Exchange Network 2012[1]

European Food Safety Authority (EFSA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

EFSA established an Emerging Risks Exchange Network (EREN) to exchange information between EFSA and the MSs on possible emerging risks for food and feed safety in 2010. The Network is currently composed of delegates from 20 Member States and an EFTA country (Norway) designated through the Advisory Forum of EFSA and observers from the European Commission, EU pre-accession countries, the Food and Drug Administration of the USA (FDA) and the Food and Agricultural Organisation of the United Nations (FAO). The Network met three times during 2012. The Network discussed a total of 17 signals of potential emerging issues that were presented and assessed using a standard template developed by EFSA. Out of these signals, 10 originated from EFSA and seven from Member States. The issues discussed were from the areas of microbiological hazards, illegal activity, chemical contaminants, biotoxins, new technologies and dietary habits. The issues that merit further consideration will be discussed in the EFSA's Scientific Committee Standing Working Group on emerging Risks.

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KEY WORDS

Emerging risks, information exchange, Member States, Stakeholders.

1 On request of EFSA, Question No EFSA-Q-2012-00823, approved on 26 July 2013

2 Correspondence: emrisk@efsa.europa.eu

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SUMMARY

The EFSA wishes to be fully prepared to detect, in a systematic and efficient way, medium- and long-term emerging risks of relevance for the European food and feed chain, animal and plant health. To achieve this purpose, EFSA has promoted the networking of Member States (MSs) and the European Commission active in the field of emerging risks identification.

In 2010 an internal mandate was issued by EFSA for establishing an Emerging Risks Exchange Network (EREN) to exchange information between EFSA and the MSs on possible emerging risks for food and feed safety. The Network is currently composed of delegates from 20 MSs and an EFTA country (Norway), designated through the Advisory Forum (AF) and observers from the European Commission, EU pre-accession countries (Croatia, Former Yugoslav Republic of Macedonia, Serbia, Turkey), the Food and Drug Administration of the USA (FDA) and the Food and Agricultural Organisation of the United Nations (FAO).

The main objectives of the network are: (i) to facilitate the exchange of information and expertise on Emerging Risks in the fields of food and feed safety, and animal and plant health; (ii) to promote the coordination of activities and the development and implementation of joint research projects, and (iii) to build support and commitment of MSs to the emerging risks identification activities of EFSA.

In accordance with EFSA's commitment to transparency and openness, each year EFSA publishes a report on the activities of the EREN. In 2012, EREN discussed a total of 17 signals of potential emerging issues that were presented and assessed using a standard template developed by the EFSA. Out of these signals, 10 originated from the EFSA and 7 from MSs. The issues discussed were from the areas of microbiological hazards, illegal activity, chemical contaminants, biotoxins, new technologies and dietary habits.

The emerging risks identification approach foresees that the EREN works as a pool of knowledge for issues that EFSA brings to the attention of the group and for which EFSA seeks more information and expert consultation on whether an issue merits further follow up.

EREN members can also flag emerging issues to the other members and to EFSA. The next step of the process is that these issues are discussed at the Standing Working Group on emerging Risks (SWG) that is composed by members of EFSA Panels and Scientific Committee. The SWG takes into consideration all the information it has before it and recommends follow up actions for endorsement by the Scientific Committee.

The networking of organisations of MSs active in the field of emerging risks identification has been shown to facilitate the exchange of information and expertise. In 2013, it is anticipated that the Network will provide significant contributions in the identification of new emerging issues and assist to the emerging risks identification process currently in place by EFSA.

The EREN annual report is prepared by the network and reflects the EFSA and MSs' commitment to transparency and accountability.

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BACKGROUND AS PROVIDED BY EFSA

Identifying emerging risks to food and feed safety in a systematic way is a new area, not only within EFSA, but also within Member States as demonstrated by a survey carried out by the Scientific Cooperation (ESCO) Working Group on Emerging Risks. This survey also highlighted the interest of Member States in exchanging information on emerging risks and to be part of a European network on emerging risks involving the EFSA and, potentially, the Commission and other EU-agencies and international organisations (EFSA, 2009).

The networking of organisations of Member States and the EC active in the field of emerging risks identification will facilitate the exchange of information and expertise in this new discipline, the coordination of activities and the development and implementation of joint research projects. Furthermore, it will build support and commitment of Member States to the emerging risks identification activities of EFSA.

TERMS OF REFERENCE AS PROVIDED BY EFSA

The EREN will be the principal body for exchanging information on emerging risks to food and feed safety between EFSA, Member States, Commission, EU-agencies and international organisations.

The Network shall consist of national experts on emerging risks identification nominated by Member States and observers from the Commission (e.g. DG Research, DG SANCO), relevant EU-agencies, e.g. European Centre for Disease Control (ECDC), European Medical Agency (EMEA), European Environment Agency (EEA) or European Chemical Agency (ECHA), JRC and, where possible, international authorities and organisations (e.g. WHO, FAO, OIE) and third countries. The profile of the network members needed is experience in emerging risks identification. English will be the working language of the network.

The exchange on emerging risks shall comprise exchange of information on emerging food safety risks observed or anticipated by network members as well as exchange of information on emerging risk identification activities of network members.

Specifically, this exchange shall include the kind of data network members use in these activities, the methodology applied to analyse this data, the communication practices and strategies and the outputs generated.

The network shall also facilitate the access to and the exchange of relevant databases.

Finally, the network shall comment on reports drafted by the EFSA technical working groups on Emerging Risks as well as on EFSA's Annual Report on Emerging Risks.

The EREN will be chaired by an EFSA staff member, designated by EFSA, and meet three to four times per year. EFSA is responsible for providing the secretarial support, including drafting the Network's comments on documents submitted to the Network and drafting the Network's annual report which collates the emerging risks identification activities of network members and their results as well as recommendations for further research needs and possible joint projects.

A platform for the EREN shall be established on the extranet site of EFSA. This platform shall be accessible to network members and serve as a place for sharing documents and data for the network.

EXPECTED DELIVERABLES

- Comments of the Network on documents prepared by EFSA Working Groups on Emerging Risks.
- Comments of the Network on the Annual Report of the EFSA on emerging risks.
- Annual Report of the EFSA Emerging Risks Exchange Network.

- Emerging Risks Exchange Network platform for exchange of documents and data established and used by network members.

This report is only addressing point three of the terms of reference.

MEMBERS OF THE SCIENTIFIC NETWORK

Members of the network shall be appointed for the term of three years by the relevant organisations of EU Member States in accordance with Articles 2 and 3 of the Decision of the Management Board of EFSA on the establishment and operations of networks[4].

The Network shall consist of 27 national experts in the area of emerging risks identification plus one additional member per third country participating to EFSA's activities in accordance with Article 49 of the 178/2002 Regulation.

ACCESS TO MEETINGS

Representatives of the European Commission are entitled to attend meetings of networks as observers.

The Executive Director may invite representatives of other agencies, bodies or Institutions of the European Union (EU), third countries or international organisations to attend meetings of Networks as observers.

[4] http://www.efsa.europa.eu/en/keydocs/docs/networksoperation.pdf

1. Introduction

EFSA wishes to be fully prepared to detect, in a systematic and efficient way, medium- and long-term emerging risks of relevance for the European food and feed chain, animal and plant health. To achieve this purpose, EFSA has promoted the networking of Member States (MSs) and the European Commission active in the field of emerging risks identification.

In 2010 an internal mandate was issued by EFSA for establishing an Emerging Risks Exchange Network (EREN) to exchange information between EFSA and the MSs on possible emerging risks for food and feed safety. The Network is currently composed of delegates from 20 MSs and an EFTA country (Norway), designated through the Advisory Forum (AF) and observers from the European Commission, EU pre-accession countries (Croatia, Former Yugoslav Republic of Macedonia, Serbia, Turkey), the Food and Drug Administration of the USA (FDA) and the Food and Agricultural Organisation of the United Nations (FAO).

The main objectives of the network are: (i) to facilitate the exchange of information and expertise on Emerging Risks in the fields of food and feed safety, and animal and plant health; (ii) to promote the coordination of activities and the development and implementation of joint research projects, and (iii) to build support and commitment of MSs to the emerging risks identification activities of EFSA.

The emerging risks identification process set in place at EFSA foresees that the EREN, as well as the Stakeholder Consultative Group on Emerging Risks (StaCG-ER), works as a pool of knowledge for issues that EFSA brings to their attention and for which EFSA seeks more information and expert consultation on whether an issue merits further follow up. Both groups can also flag emerging issues to the other members and to EFSA.

The next step of the process is that these issues are discussed at the Standing Working Group on emerging Risks (SWG) that is composed by members of EFSA Panels and Scientific Committee. The SWG takes into consideration all the information it has before it and recommends follow up actions for endorsement by the Scientific Committee.

2. Methods

During 2012, the EREN met three times. Each meeting was organised around three different sessions. The first session was dedicated to presentation and discussion of new emerging issues by members or EFSA. The second session was dedicated to discussion of new information on previously raised topics. The third session was dedicated to updating the network on the EFSA and MSs activities and developments in the area of emerging risks such as upcoming projects, survey results and outcomes of conferences.

Members had the possibility to comment and provide further information on the emerging issues between the meetings.

The emerging issues were presented and assessed using a standard template developed by EFSA (see Appendix).

The issues discussed at EREN was a selection of potential emerging issues for which MSs and EFSA were seeking further data or were interested in the group's opinion thereon.

Definitions

According to the definition adopted by the Scientific Committee of EFSA in 2007, "an **emerging risk** to human, animal and/or plant health is understood 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).

An "**emerging issue**" can be defined as one that has very recently been identified and merits further investigation, and for which the information collected is still too limited to be able to assess whether it meets the requirements of an emerging risk. Thus, emerging issues are identified at the beginning of the emerging risks identification process as subjects that merit further investigation and additional data collection. Emerging issues can include specific issues (e.g. a specific chemical substance or pathogen, or a specific genetically susceptible group of the population), as well as general issues such as drivers of change or megatrends (e.g. climate change) (EFSA, 2012).

3. Results

3.1. Overview

Overall, 7 and 10 emerging issues were presented by MSs and EFSA to the EREN in 2012 respectively, whereas in 2011, 7 and 19 emerging issues were presented by MSs and EFSA respectively (Figure 1). These issues were originated from MSs food and animal health surveillance systems and from the EFSA own identification activities. The overall decrease in issues presented represents a desire to discuss the issues in more detail, and also to have time to deal with additional information received concerning issues previously discussed.

The emerging issues considered in 2012 were classified in seven categories (Figure 2). The most frequently evaluated issues were microbiological hazards with six issues. The next categories most reported were illegal activity and chemical contaminants with three issues each. Finally, two issues were presented in the category of biotoxins and one in the categories of new technologies and dietary habits, while there was one issue considered without being possible to identify the potential hazard of concern.

In 2011, the most frequently evaluated issues were chemical contaminants with 13 issues, followed by microbiological hazards with 7 issues (Figure 3).

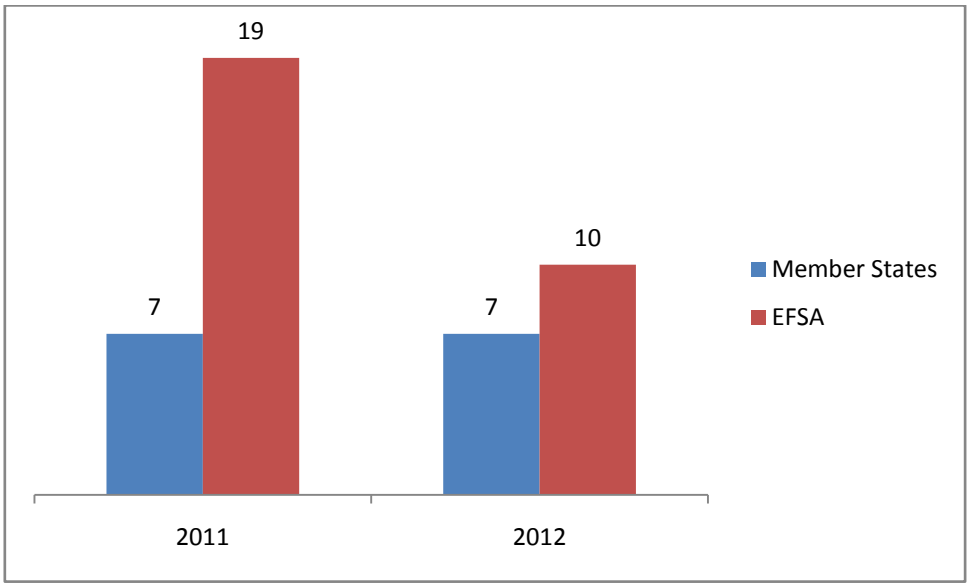

Figure 1: Number of issues presented by MSs and EFSA to EREN in 2011 and 2012.

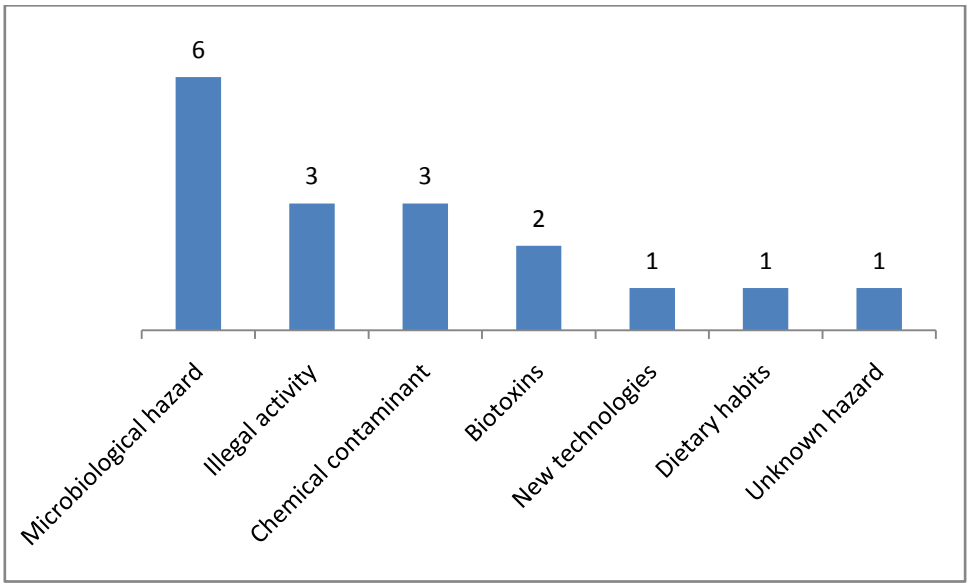

Figure 2: Number of issues presented by MSs and EFSA to EREN by hazard category in 2012.

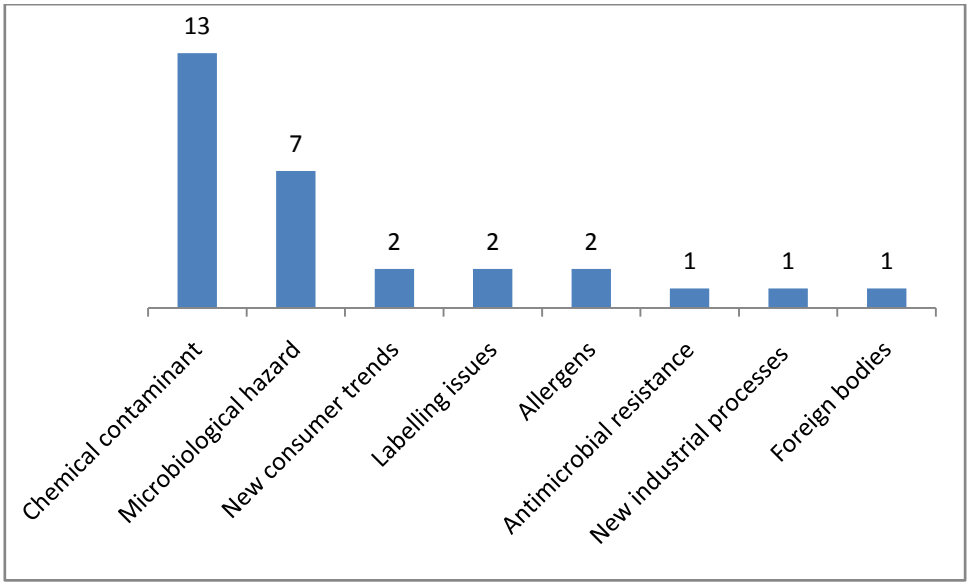

Figure 3: Number of issues presented by MSs and EFSA to EREN by hazard category in 2011.

3.2. Methodologies for emerging risks identification

In 2012, EREN members shared methodologies applied for emerging risks identification. These were:

- A multidisciplinary and evidence-based methodology applied to prioritize diseases of food-producing animals and zoonoses[5] in Belgium;
- Emerging risk detection & identification; developments in the Netherlands[6];
- The identification of future food safety risks in the UK[7];
- Briefing from France on the Colloquium "Internationalized agri-food systems: new risks, new regulations" held in Paris on 25 June 2012.

3.3. Issues[8]

The 17 signals of potential emerging issues discussed by EREN in 2012 are given in Table 1. A summary of each issue, together with the key points of the discussions and the conclusions follows.

Table 1: List of issues discussed by EREN in 2012.

	Issue[8]	Presented by
1	Potential chemical contamination of food from recycled paper	EFSA
2	Zoonotic viruses associated with illegally imported wildlife products	EFSA
3	First report on indigenous ciguatera fish poisoning in the EU	EFSA
4	*Salmonella* in paan (betel) leaves	MS
5	Indian milk adulteration	MS
6	Increased use of banned, unauthorised and counterfeit pesticides	MS
7	Increased cancer risk in meat and poultry workers	EFSA
8	Combined toxicity of melamine and cyanuric acid	EFSA
9	Import of stray dogs and new parasitic diseases	MS
10	Follow-up on mycotoxins in Swedish crops 2011	MS
11	Undereporting of foodborne norovirus and older adults	MS
12	Drivers and pathways of antimicrobial resistance: Foodborne extended-spectrum beta-lactamase (ESBL)	MS
13	Zoonotic potential of Usutu virus	EFSA
14	Colorectal cancer and possible link to dietary and cooking habits of red meat consumption	EFSA
15	Animal illnesses linked to jerky pet treats	EFSA
16	Pharmaceuticals and personal care products (PPCPs) in the environment and possible human exposure through the food chain	EFSA
17	Potential contamination of the food/feed chain from industrial and environmental chemical contaminants with certain characteristics. The use of the ECHA 's Candidate List of Substances of Very High Concern to identify emerging chemical risks.	EFSA

[5] For more information see: Humblet M-F, et al., 2012. Multidisciplinary and evidence-based method for prioritizing diseases of food-producing animals and zoonoses. Emerg Infect Dis. http://dx.doi.org/10.3201/eid1804.111151

[6] http://vwa.nl/onderwerpen/risicobeoordelingen/dossier/bureau-risicobeoordeling-en-onderzoeksprogrammering/nieuwe-risico-s/signaleren-nieuw-opduikende-risico-s

[7] http://www.efet.gr/images/efet_res/docs/EFSA/donohoe.pdf

[8] The definition of "emerging issue" is given under section 2 "Methods"

3.3.1. Potential chemical contamination of food from recycled paper

Description of the issue

Various types of contaminants have been reported in recycled paper, including printing inks, adhesives, trace elements, waxes, fluorescent whitening agents and dyes, sizing agents, organochlorine substances, plasticizers, aromatic hydrocarbons, volatile organic compounds, curing and grease-proofing agents, amines, biocides and surfactants (Binderup et al., 2002; Castle et al., 1997; Damant, 1999; EFSA, 2011; Fauris et al., 1998; Grob et al., 1991; Sipilainen-Malm et al., 1997; Vinggaard et al., 2000; Ziegleder, 2001).

There are no specific migration limits (SMLs) for many of these compounds, including printing inks and mineral oils in carton-board food packaging. However, packaging materials, must meet the requirements of Regulation (EC) No. 1935/2004; this requires that under normal and foreseeable conditions of use, packaging materials do not transfer their constituents to food in quantities which could endanger human health.

Many of these contaminants have not been specifically evaluated for their safety at the EU level with the exception of printing ink related compounds (e.g. benzophenone and 4-methylbenzophenone) and mineral oil hydrocarbons that have been evaluated by EFSA[9]. Thus, recycled paper and board used as food contact material could potentially represent a new route of exposure to these other contaminants.

Key points from the discussion and the conclusions

The network considered that this maybe an emerging issue and recommended (i) generation of data on the migration of these compounds from recycled packaging into food; (ii) a review of what types of food may be in contact with this type of packaging material; and (iii) promotion of standardised migration test methods.

3.3.2. Zoonotic viruses associated with illegally imported wildlife products

Description of the issue

Illegal bushmeat (i.e. the meat of terrestrial wild animals, killed for subsistence or commercial purposes throughout the humid tropics of the Americas, Asia, and Africa) importation could act as a vehicle for pathogen introduction into the EU. Smith et al. (2012) reported retroviruses (simian foamy virus (SFV)) and herpesviruses (cytomegalovirus and lymphocryptovirus) in nonhuman primate samples, including baboon, chimpanzee, mangabey and green monkey confiscated at five US airports.

Whilst this is a study in the US, the same or different pathogens could be present in bushmeat illegally imported into Europe. The finding of mangabey, guenon, and cane rat bushmeat in this study is consistent with that reported by Chaber et al. (2010) who found these and bushmeat from nine other species entering Paris-Charles de Gaulle Airport, without however testing for the presence of pathogens on the inspected bushmeat.

Uncertainties and limitations of the study include: (i) illegally imported shipments were confiscated opportunistically and thus the study established only the presence and not the prevalence of zoonotic agents in the specimens; (ii) the restricted number of samples were tested for a limited range of pathogens only and thus presence of additional pathogens not screened could not be ruled out; (iii) virus isolation was not performed to determine the infectiousness of the specimens at the time of confiscation.

[9] http://www.efsa.europa.eu/en/efsajournal/pub/2704.htm

Key points from the discussion and the conclusions

The network considered that this maybe an emerging issue, acknowledging at the same time that more information is needed in order to better understand the extent of it, for example by having data from customs controls.

3.3.3. First report on indigenous ciguatera fish poisoning in the EU

The issue was raised at the 42nd EFSA AF meeting on 30 November 2011[10] and no immediate action was requested from EFSA. EFSA prepared a briefing note and presented the issue to EREN in March 2012.

Description of the issue

Boada et al. (2010) reported for the first time multiple and confirmed outbreaks of Ciguatera Fish Poisoning (CFP) in EU, in the Canary Islands Archipelago. Again, in late 2011, new cases of CFP poisoning coming from consumption of local seafood were reported from the Canary Islands.

CFP is a seafood-borne illness that is rare outside tropical and subtropical coral reef regions. When reported outside these regions, it is often related to consumption of imported toxic fish. However, due to human activities (e.g. transport by ship ballast water; nutrient loading, changes in sea surface temperature, habitat alteration), the algae *(Gambierdiscus* spp.) producing the ciguatera toxins (CTXs) as well as the ciguatoxic fish may expand their biogeographical range.

In addition, in recent years the presence of *Gambierdiscus* sp. has been recorded in the eastern Mediterranean Sea. The first report on occurrence of *Gambierdiscus* sp. in Crete is from 2003 (Aligizaki and Nikolaidis, 2008), however, CFP has not been reported in this area.

Given the geographic expansion of the distribution of the algae (*Gambierdiscus* spp.) capable of producing the toxins CTXs, it is anticipated that CFP becomes more frequent in Europe through new and increased exposure to ciguatoxins produced in fish contaminated in local waters. The example of ciguatoxin represents the broader issue of emerging marine biotoxins since a number of these compounds are now detected in European waters e.g. pinnatoxins, ovatoxin A, microcystin LR and sporidesmines.

Key points from the discussion and the conclusions

The network assessed the available information and noted that:

- There is a lack of rapid analytical techniques and that chemical standards should be made available in order to be able to test for ciguatera toxins particularly in fish imported into the EU.
- There are no human cases of CFP reported from Mediterranean caught fish so far. This may be an indication that the species adapted to the Mediterranean may grow without producing toxins.
- There is an increase in biotoxin incidents in general in EU waters. A potential common link to this reporting could be climate change that could result in alien algae species establishing themselves in EU waters.
- Illegal fishing or fraudulent labelling could be a separate driver for increased human cases of marine biotoxin intoxications. Illegally fished produce could enter into the EU[11] and be declared

[10] Minutes of the 42nd meeting of the Advisory Forum: http://www.efsa.europa.eu/en/events/event/111130-m.pdf

[11] For example see a BBC article: http://www.bbc.co.uk/news/world-africa-19905709

to be of different origin; testing will not be applied to these fish as it is focused on fishes originated from areas or species known to be at risk from ciguatera toxins.

EREN considered that this maybe an emerging issue and recommended to:

- Monitor the geographical distribution of *Gambierdiscus* sp. in European waters, particularly in the Mediterranean.
- To promote research to determine the conditions for growth and toxin production of *G. excentricus* in the European environment.
- To increase awareness of the medical profession on this emergent food toxin to better detect the symptoms and report the cases.

3.3.4. *Salmonella* in paan (betel) leaves

Description of the issue

An unusual trend in the reported cases of human salmonellosis in the UK was traced to Paan (betel) leaves imported from Bangladesh and India. Paan leaves are traditionally chewed in Asia and valued as a mild stimulant. The fresh paan leaves are consumed as a ready-to-eat product. A potential link to flooding in the region was raised, and that this might be an indicator of other related problems.

The Food Standards Agency (FSA) of the UK conducted a risk assessment which stated that the presence of *Salmonella* in a ready to eat food is considered unacceptable and potentially hazardous and that consideration should be given to withdrawing and recalling the affected batches. The Health Protection Agency of the UK detected 37 different serotypes of *Salmonella* from paan leaves.

Key points from the discussion and the conclusions

The network considered that this is not an emerging issue, as Paan were not consumed in significant quantity in other MS and the risks associated with *Salmonellae* have been characterised so management of the source of the contamination would have been for the risk managers to deal with. However, several members expressed interest in receiving additional information.

3.3.5. Indian milk adulteration

Description of the issue

An informal survey that was conducted by the Food Safety & Standards Authority of India (FSSAI) to determine the quality of milk led to the discovery of widespread adulteration and contamination[12]. The milk was surveyed from 33 Indian states. The non-conforming samples were found to be 68.4% of the total which were adulterated/ contaminated with water, skim milk powder, detergents, vegetable oil and urea.

No reports from the EU appeared to have been made concerning detection of contaminants from Indian milk, however, powdered milk in particular might be incorporated into a variety of other products.

Key points from the discussion and the conclusions

The network considered that this maybe a potential emerging issue and agreed to share information on trade routes/uses of milk and milk products coming from India.

[12] FSSAI executive summary on national survey on milk adulteration: http://fssai.gov.in/Portals/0/Pdf/sample_analysed(02-01-2012).pdf

3.3.6. Increased use of banned, unauthorised and counterfeit pesticides

Description of the issue

Some MSs reported an increased number of cases of pesticide residues (primarily Monocrotophos) which are either banned in EU or inappropriately administered e.g. in okra imported from India.

Europol issued a press release[13] on 13 January 2012 concerning the growth in the trade of illegal and counterfeit pesticides. Such illegal and counterfeit pesticides were reported as potentially threatening to public health (both of farmers and consumers) and pose a risk to crops and the environment, and linked to organised crime.

Key points from the discussion and the conclusions

It was noted that routine testing is not directed towards detecting such contaminants. The members reported that the main problem is re-packaging and re-labelling of counterfeit copies, where the active substance is the same to the legal products, but the other components are not.

Following EREN recommendation, EFSA presented the issue to StaCG-ER to collect more information and the issue was re-discussed at a subsequent meeting. The network could not conclude if this was an emerging issue as legislation is in place and, therefore, it is primarily a risk management issue.

3.3.7. Increased cancer risk in meat and poultry workers

Description of the issue

A review of more than 60 studies was published investigating lung cancer risk in meat and poultry workers (Johnson and Choi, 2012). The overwhelming majority of studies of different designs (including all the cohort mortality and cancer incidence studies) indicate at least a 30% excess risk of lung cancer in meat and poultry plant workers, even after controlling for smoking. Moreover, at least one cohort study, including 30,411 poultry workers and 16,408 non-poultry workers reported an increased risk of pancreatic and liver cancers in poultry workers (Felini et al., 2011).

Food animal oncogenic microorganisms have been postulated as being one possible cause. Laboratory and in vivo studies in primates, and serological evidence in humans, indicate that food animal oncogenic viruses show potential for causing cancer in humans. Some, but not all, studies reported the presence of antibodies to these viruses in the sera of poultry workers and subjects in the general population.

These reported associations, if confirmed, could have public health implications because the general population might also be exposed. Studies carried out so far have had limited statistical power, due to the rarity of these types of tumours, especially in non-smokers, and limited evidence seems to be available on the detection of specific viruses in cancer patients. Thus, larger studies that can adequately control for occupational and non-occupational confounding factors are needed, before any conclusions can be drawn.

Key points from the discussion and the conclusions

EREN commented that there is the risk of misinterpretation and passing the message that meat products can be a vehicle of these viruses to consumers, when there is currently no information to

[13] https://www.europol.europa.eu/content/press/europol-warns-growing-trade-counterfeit-pesticides-worth-billions-euros-year-1237

support this hypothesis. Any additional activity should focus on the risk for the workers (if any) rather than on consumers, for whom the postulated risk would be much lower.

The network believed that there is not enough evidence to characterise this as a food safety emerging issue. It recommended EFSA to monitor the issue, also, in the context of the revision of meat inspection.

3.3.8. Combined toxicity of melamine and cyanuric acid

Description of the issue

After the adulteration of milk in China with melamine (September 2009), an action level of 2.5 mg/kg was set by the Commission to distinguish between the unavoidable background presence of melamine and possible adulteration. The current specific migration limit (SML) for melamine in the EU legislation for plastics is 2.5 mg/kg food.

The toxicity of melamine leads to kidney failure resulting from the formation of crystals in the urinary tract as non-covalent complexes of melamine with uric acid or of covalent complexes when co-occurrence with cyanuric acid occurs.

Recent studies in rats have shown that co-administration of melamine and cyanuric acid for 7, 28 and 90 days, in groups of male and female F344 rats showed higher toxicity compared with melamine alone, with No-Observed Adverse Effect Levels (NOAEL) or Benchmark Dose Limits ($BMDL_{10}$) of 8.6 and 8.4-10.9 mg/kg b.w per day for the 7 day study respectively, NOAEL of 2.1-2.6 mg/kg b.w per day for males and females for the 28 day study ($BMDL_{10}$ 1.6 mg/kg bw/day for both sexes) and a NOAEL of 0.63 mg/kg b.w per day for the 90 day study.

In terms of toxicity, these NOAEL and $BMDL_{10}$ values for melamine-cyanuric acid for the 7, 28 and 90 days study were approximately 7-fold, 24-39-fold and a 100-fold and 2-fold, 7-12 fold and 30-fold below the NOAEL of 63 mg/kg b.w per day and the $BMDL_{10}$ of 19 mg/kg b.w per day established for melamine alone by the FDA and EFSA respectively and both based on a 13 week study (Jacob et al., 2011; Gamboa-da Costa et al., 2012 a,b).

These new toxicological studies show that melamine-cyanuric acid toxicity increases with exposure time and suggests that the Tolerable Daily Intake values (TDI) derived by WHO and EFSA (0.2 mg kg.b.w per day by both) derived from studies conducted with melamine alone may underestimate the risk from co-exposures to melamine and cyanuric acid.

Key points from the discussion and the conclusions

The network considered that this maybe an emerging issue and recommended EFSA to monitor scientific publications on this issue and present it to the SWG.

3.3.9. Import of stray dogs and new parasitic diseases

Description of the issue

Importation of stray dogs into Norway from south-east Europe is increasing. Some of these dogs were found to be infected with three diseases not existing in Norway: Tongue Worm (*Linguatula serrata*), heartworm (*Dirofilaria immitis*) and brown dog tick (*Rhipicephalus sanguineus*). In terms of severity, none of these diseases pose deadly threat to the Norwegian pet population.

Key points from the discussion and the conclusions

Several MSs reported cases of dogs originating from other MSs or from third countries infected with rabies. It was highlighted that there is legislation in place obliging the vaccination of dogs (including

rabies) and treatment against tapeworms. It is difficult to estimate the proportion of legal versus illegal movement and illegal trade of dogs and domestic animals in general.

The network considered that this is not an emerging issue as such, as some aspects are related to risk management, for example vaccination of dogs according to the legal requirements. They highlighted two drivers of emerging risks: (i) changes in the movement of domestic animals within the EU and between MSs and third counties and (ii) illegal trade of domestic animals as they are not examined at the borders by the authorities.

3.3.10. Follow-up on mycotoxins in Swedish crops 2011

Description of the issue

During the summer of 2011, the weather conditions in Sweden varied rapidly, changing between extremely dry and wet conditions. At harvest, widespread mould contamination was observed, leading to a more detailed study of the crops. The Swedish National Veterinary Institute conducted a field survey that revealed widespread occurrence of Fusarium spp and highly elevated levels of deoxynivalenol (DON) and zearalenon (ZON). The industry acknowledged the problem and took action to avert grain with high mycotoxin levels to enter the market. Swedish authorities did not identify any alarming trends in the official controls of food products placed on the market. Overall, there is high uncertainty regarding the causes for high variations in mycotoxin levels or potentially new strains/variants (chemotypes) of Fusarium.

Key points from the discussion and the conclusions

Several MSs reported elevated levels of DON in wheat, corn and oat in 2009 and/or 2010. It was also mentioned that there is no clear trend identified so far confirming an increase occurrence of mycotoxins in food.

A project was outsourced by EFSA to model, predict and map the emergence of aflatoxins in cereals in the EU due to climate change, where influencing factors for the production on aflatoxins were discussed[14].

The network considered that this is not an emerging issue as the risk is already known and relative well characterised.

It recommended that (i) the issue should be monitored with a view to identify if there is a trend of increased prevalence of mycotoxins in cereals (in which case it could fall under the definition of emerging issue) and (ii) an external project could be started on the DON production in wheat and oat in Europe in order to identify different influencing factors and model them.

3.3.11. Undereporting of foodborne norovirus and older adults

Description of the issue

Studies pointed to the underestimation of morbidity and mortality of norovirus among older adults (over 65 years old); recently the burden of disease estimate for norovirus was doubled (Verhoef et al, 2012). In the US, norovirus caused about 800 deaths annually, with 50 percent more deaths in years with epidemics caused by new strains of the virus (Hall et al, 2012).

Overall, illness and outbreaks due to spread of norovirus among older adults, in particular in elderly care, may pose a more serious health threat than previously believed.

[14] http://www.efsa.europa.eu/en/supporting/pub/223e.htm

Key points from the discussion and the conclusions

According to the EFSA definition on emerging risks, this issue is related to the increased susceptibility of the elderly as they are more vulnerable to diseases. The drivers behind could be (i) the aging of the population; (ii) nowadays, care facilities for elderly are used more often; and (iii) polymedication applied to the elderly reduces their immune systems.

The BIOHAZ panel of EFSA adopted two opinions related to the issue in 2011: on foodborne viruses[15] and norovirus in oysters[16].

The network considered that this maybe an emerging issue, especially with the view of the increased use of care facilities for elderly.

3.3.12. Drivers and pathways of antimicrobial resistance: Foodborne extended-spectrum beta-lactamase (ESBL)

Description of the issue

The presence of extended-spectrum beta-lactamase (ESBL)-producing bacteria is increasingly being reported in humans and in food-producing animals and food may be a possible link between the two populations. According to the scientific literature, there is a large knowledge gap of antibiotic resistance risks along the food chain, both across and within countries. Further studies of the genetic overlap of isolates from animal reservoirs (cattle, pigs and broilers), food vehicles, and human cases are needed to assess the emerging public health risk of foodborne spread of antibiotic resistant bacteria, in particular ESBL, including a more detailed comparison of ESBL genes and *E. coli* isolates from meat and patients. There is also a need for assessing the impact of food trade and import on the spread of potential foodborne outbreaks of antibiotic resistant bacteria, for addressing systematic surveillance methods.

Key points from the discussion and the conclusions

EFSA has addressed antimicrobial resistance, including ESBL, and has published several opinions on this issue[17].

The network considered that this issue is being extensively addressed elsewhere and so, unless new aspects come to light, should not be a priority for this network.

3.3.13. Zoonotic potential of Usutu virus

Description of the issue

For the first time in Germany, human infection with the tropical Usutu virus was detected[18]. It was confirmed in donor blood, when a total of 4,200 blood samples were analyzed for antibodies. The information was released by the Bernhard Nocht Institute (BNI) for Tropical Medicine in Hamburg on 20 August 2012. The affected man claims to have experienced no symptoms of illness. Usutu virus was found in mosquitoes (Culex pipiens) in Germany and can be transmitted to humans. According to the BNI the donor blood was collected in January 2012 from the outbreak region between Frankfurt and Freiburg. According to experts, the infection of the man at that time was rather recent. The disease

[15] EFSA, 2011. Scientific Opinion on an update on the present knowledge on the occurrence and control of foodborne viruses. Available from: http://www.efsa.europa.eu/en/efsajournal/pub/2190.htm
[16] EFSA, 2011. Scientific Opinion on Norovirus (NoV) in oysters: methods, limits and control options Available from: http://www.efsa.europa.eu/en/efsajournal/pub/2500.htm
[17] http://www.efsa.europa.eu/en/topics/topic/amr.htm
[18] PRO/AH/EDR> Usutu virus - Germany (03) 1st case: http://www.promedmail.org/direct.php?id=20120821.1255556

can only be transmitted through a mosquito bite; the mere touch of a diseased bird does not cause infection.

Outside Africa, the virus had appeared for the first time in 2001 in the Vienna area; in 2009, two immunocompromised patients in Italy became infected. The Usutu virus was already found in the summer 2011, when it infected and killed hundreds of thousands of blackbirds. During the 2012 summer, thousands of birds died in Southwest Germany. The affected area this year seems to be much larger than in 2011.

Key points from the discussion and the conclusions

It was highlighted that, so far, this is an animal health issue and not a human health issue.

The members reported that surveillance data indicate that Usutu virus seems to be established and experts believe that Usutu virus is not relevant as a health problem for healthy people, but can be a threat for immunocompromised people. Other arboviruses specifically Tahyna and Batai viruses of the Orthobunyavirus genus were detected during arbovirus surveillance conducted on mosquitoes in recent years. These findings are indicators of the likelihood of introduction into Europe of potentially pathogenic exotic arboviruses.

In its report on "Health effects of Climate Change in the UK"[19] (October 2012), the Health Protection Agency (HPA) identified Usutu as being an exotic mosquito-borne arbovirus that was imported into Europe and was involved in local transmission to humans. It is mentioned with regards to potential mosquito-borne risks as a result of climate change.

Chvala et al. (2005 and 2006), studied the pathogenicity of Usutu virus for chickens and geese; they reported that domestic chickens and geese were not at risk of developing clinical disease following Usutu virus infection.

The network considered that this maybe a potential emerging issue and suggested that EFSA should monitor the issue.

3.3.14. Colorectal cancer and possible link to dietary and cooking habits of red meat consumption

The issue was discussed in the 44th EFSA AF meeting on 17-28 June 2012[20]. Following this, EFSA brought it to the attention of EREN for consultation and to collect more information.

Description of the issue

A large body of epidemiological evidence shows that red[21] and processed meats are strongly associated with an increased risk of colorectal cancer (World Cancer Research Fund (WCRF) and American Institute for Cancer Research (AICR); 2007, 2011). The risk appears to be higher for long-term consumption of cooked and processed red meat. The conclusions of those reports are strongly based on epidemiological studies of different design and populations. Epidemiological studies are generally used to assess associations, but have limited power in proving causality.

Potential mechanisms of carcinogenesis linked to red meat consumption include chemical carcinogens arising during the cooking process of meat (i.e. polycyclic aromatic hydrocarbons (PAHs), nitrosamine derivatives during broiling, barbecuing or processing of red meat) (Sugimura T. et al,

[19] http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1317135969235

[20] Minutes of the 44th meeting of the Advisory Forum: http://www.efsa.europa.eu/en/events/event/120627a.htm

[21] Generally red meat includes beef/veal, pork and sheep meat/goat meat

1977, 2004; Yano M. et al, 1988). More recently, a hypothesis on a possible role of one or more thermo-resistant potentially oncogenic bovine viruses (e.g., polyoma-, papilloma- or possibly single-stranded DNA viruses) has been brought forward (zur Hausen H, 2012). However, the exact mechanism by which red meat could be involved in cancer aetiology is under debate.

The association between red meat consumption and colorectal cancer is not an emerging issue, as it has been addressed by a large body of epidemiological evidence over the last decades. However, the available evidence does not allow establishing a causal link. EFSA has not addressed this issue, and it is not clear whether EFSA should deal with issues linked to providing recommendations to the public on dietary habits.

Key points from the discussion and the conclusions

Although the network agreed that this is an important issue, in particular as colorectal cancer is one of the most common cancer in the EU[22], it was highlighted that the available evidence does not allow establishing a causal link.

Some members believed that it is the role of MSs as risk managers to provide nutritional advice at national level implementing, for example, the dietary guidelines of EFSA or other bodies. Other members considered that EFSA could make recommendations on the consumption habits (including of red meat) as well as on risks related to cooking habits, for example cooking meat at high temperatures (barbeque).

3.3.15. Animal illnesses linked to jerky pet treats

Description of the issue

Since 2007, the U.S. Food and Drug Administration (FDA) has become aware of increasing numbers of illnesses in pets associated with the consumption of jerky (dried meat) pet treats and released several consumer alerts about treats. On 14 September 2012, the FDA published a communication that "investigates animal illnesses linked to jerky pet treats"[23].

Although the FDA has been investigating the reports of illnesses, no definitive cause has been determined. The FDA tested product samples for factors known to cause the symptoms and illnesses reported in pets including, *Salmonella*, heavy metals, furans, pesticides, antibiotics, mycotoxins, rodenticides, nephrotoxins (including melamine) with negative results (however, no information on the number of samples analysed was given). In 2011, samples were also submitted for nutritional composition. The FDA is now expanding its testing to include irradiation by-products.

The majority of the cases in dogs report primarily gastrointestinal signs, including vomiting and diarrhoea, and can involve severe signs such as pancreatitis or gastrointestinal bleeding. The next most common signs relate to kidney function, including frequent urination, increased urine, severe thirst, kidney failure and some cases resemble a rare kidney related illness called Fanconi's syndrome.

Whilst there is no scientific evidence confirming that the jerky pet treats are the cause of the illnesses, this case could be a potential signal for adulteration of pet food at present, and for food in the future.

Key points from the discussion and the conclusions

The network was not sure if this is an emerging issue; although there is no cause-effect relationship identified so far, it could be an indicator of a potential issue.

[22] http://ec.europa.eu/health/major_chronic_diseases/diseases/cancer/

[23] http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm319463

The ingredients from which jerky treats are produced need to be examined. A consequence step is to map the trade in ingredients and products made in and outside Europe.

There is the potential to introduce exotic species of pathogens into the European feed chain both from third counties' as well as from European pet treats.

Members reported that *Salmonella* is typically found in jerky treats (in 5-50% of the samples); it is paradoxical that the FDA did not identify *Salmonella* in the samples.

Possible causes could include:

- Illegal irradiation of ingredients e.g. yeast; there are no registered irradiation plants in China;
- Hypervitaminosis of dogs with vitamin D;
- A contaminant from the tanning process, if gelatine extracted from leather is used;
- With regards to microbiological hazards, contamination routes for these products can be insufficient thermal processing and/or post process contamination; a recent incident is described in the RASFF notification 2012/1424.

EREN recommended that EFSA should monitor the issue.

3.3.16. Pharmaceuticals and personal care products (PPCPs) in the environment and possible human exposure through the food chain

Description of the issue

An increasing number of publications in the scientific literature report the presence of Pharmaceuticals and Personal Care Products (PPCPs) in the food-chain (e.g. Clarke et al., 2011; Stuart et al., 2012). Residues of PPCPs present in wastewater and sewage sludge are of concern due to their transfer to aquatic and terrestrial food chains and possible adverse effects on non-targeted organisms. The distribution to biota and accumulation throughout the food chain is poorly understood, in particular because of limited number of studies on this topic and lack of adapted models (EAHC, 2012).

In general, there is scarcity of data on human health effects at environmental levels, effects on aquatic organisms, and other harmful effects and therefore it is difficult to predict which health effects PPCPs may have on humans, terrestrial and aquatic organisms, and ecosystems. Interest in studying toxicological and eco-toxicological profiles of medicines and their likely impacts on the environment and human health via the environment was only raised recently, and has had to cope with scientific and technical challenges of assessing the impacts of chronic exposure at low concentrations to a mixture of pharmaceuticals (Boxall et al., 2012).

Human exposure can derive from the increasing amount of PPCPs residues present in sewage sludge, wastewater and ground water used in agriculture, and the possible subsequent contamination of or even accumulation in leaf crops, root crops, fish, dairy products, and meat. Presence of PPCPs in drinking water highlights the concern of potential health risk with long-term low-level exposures.

Key points from the discussion and the conclusions

The network considered that this maybe a potential emerging issue, in particular related to potential health risks with long-term low-level exposures and groups of compounds like endocrine disruptors. However, the data available do not clearly show that the exposure to PPCPs is high enough to be of concern.

EREN recommended that attention should be taken when informing the consumers about the potential hazards related to the use of purified waste water for irrigation, as for some MSs and other countries having lack of ground water this is a common practise.

EREN recommended that EFSA should monitor the issue and consult EMA (as the medicine producers have to evaluate the disposal of their products) and EEA (for environmental contamination).

3.3.17. Potential contamination of the food/feed chain from industrial and environmental chemical contaminants with certain characteristics. The use of the ECHA 's Candidate List of Substances of Very High Concern to identify emerging chemical risks

Description of the issue

A potential approach for anticipating environmental and consequentially food chain contamination with emerging chemical contaminants is to monitor chemical production, irrespective of intended use. A source of information for this data at European level is the REACH Regulation (Regulation (EC) No 1907/2006).

Substances of very high concern are defined in Article 57 of the REACH Regulation and classified as:

- Carcinogenic, Mutagenic or toxic to Reproduction (CMR);
- Persistent, bioaccumulative and toxic (PBT) or very Persistent and very Bioaccumulative (vPvB);
- Identified, on a case-by-case basis, from scientific evidence as causing probable serious effects to human health or the environment of an equivalent level of concern as those above (such as endocrine disrupters).

A list of 145 substances, published between 30/06/2008 and 03/09/2012, is accessible on the ECHA website[24].

These lists may provide a starting point for identifying chemicals of concern that may enter the food/feed chain and for which EFSA has not already carried out a risk assessment. A number of these Substances of Very High Concern have not been assessed by EFSA and could potentially constitute new hazards for the food and the feed chain. However, new or increased exposure to these substances is unknown for the food and feed chain.

Key points from the discussion and the conclusions

EREN considered that there maybe a potential to identify emerging risks from the list. The difficulty is the exposure estimation; a possible approach would be to take into account these compounds in the dietary daily studies.

The network commented that some compounds included in the REACH are used as food contact materials; there is a risk for misinterpretation by the consumers.

EREN recommended EFSA to monitor the issue and to interact with ECHA.

[24] http://echa.europa.eu/web/guest/proposals-to-identify-substances-of-very-high-concern-previous-consultations

4. Conclusions and recommendations

The emerging risks identification process set in place at EFSA foresees that the EREN works as a pool of knowledge for issues that EFSA brings to their attention and for which seeks more information and expert consultation on whether an issue merits further follow up.

EREN members can also flag emerging issues to the other members and to EFSA. The next step of the process is that these issues are discussed at the Standing Working Group on emerging Risks (SWG) that is composed by members of EFSA Panels and Scientific Committee. The SWG takes into consideration all the information it has before it and recommends follow up actions for endorsement by the Scientific Committee.

The network discussed 17 potential emerging issues during 2012, two of which had been previously presented in the Advisory Forum. This report includes a summary of each issue, together with the key points of the discussions and the conclusions drawn by EREN.

Members shared expertise and information on these issues, for example surveillance reporting and assessments performed at national level, as well as recommendations for follow up actions, such as (i) EFSA should monitor the issue, (ii) generation of data is needed, (iii) EFSA should consult other bodies such as European agencies or the StaCG-ER and (iv) the issue should not be considered as an emerging issue.

The networking of organisations of MSs active in the field of emerging risks identification has been shown to facilitate the exchange of information and expertise. In 2013, it is anticipated that the Network will provide significant contributions in the identification of new emerging issues and assist to the emerging risks identification process currently in place by EFSA. In addition, and in particular for addressing the data and research gaps identified through the emerging risks identification process, the Network will promote the development of joint research projects among MSs and between MSs and EFSA.

APPENDIX

BRIEFING NOTE TEMPLATE

(This is a template for "Briefing notes on emerging issues" identified by EFSA for EREN)

BRIEFING NOTE ON EMERGING ISSUES[25]

Lasty updated by EFSA on DD MM YYYY

Presented to EREN MTG on DD MM YYYY

The scope of this briefing note is to present emerging issues to EREN. EREN is requested to (i) evaluate the relevance of the issue presented and (ii) facilitate the exchange of any relevant information. The information provided in this briefing note is not comprehensive and is intended as a quick summary and a point of departure.

Title and ID

DESCRIPTION OF THE ISSUE

Include a short description of the issue, mentioning the hazard under evaluation (e.g. which virus, bacteria, parasite, chemical, driver etc). Use the following criteria to explain why EFSA considers this an emerging issue. Evaluation criteria to be considered include at least one of the three criteria listed below.

ADDITIONAL SUPPORTING INFORMATION

Provide any additional background information you believe is important in order to support the evaluation of the issue. For example:

- *Any additional information on the source of information (scientific or grey literature, inputs from AF, EFSA's Units, Experts, surveillance systems…);*
- *Limitations of the analysis/study;*
- *Toxicological information of this (or similar) agents/compounds;*
- *Any other information you believe is important.*
- *Has this related to any other issues already discussed by EFSA.*

LEGAL AND INSTITUTIONAL ASPECTS

- *Report the results of a basic search for EFSA risk assessment or action, and Commission documents or legislation on the subject.*

EVALUATION

Main criteria

- **Driver:** *(e.g. is this a new driver?)*

[25] "*Emerging issues"* are identified at the beginning of the Emerging Risk Identification process as issues that may merit further investigation and additional data collection. Emerging issues can include specific issues (*e.g.* specific chemical substance or a pathogen), as well as general issues such as drivers of change (*e.g.* climate change). Risk management issues resulting from a lack of compliance with existing regulations should be excluded.

The information provided in this briefing note is not comprehensive and is intended as a quick summary and a point of departure.

- **New hazard:** *(e.g. Has a new hazard been identified? If so, which one and how?)*
- **New or increased exposure:** *(e.g. Has a possible exposure through food/feed to the new hazard been identified?)*
- **New susceptible group:** *(e.g. Has a new vulnerable group been identified?)*

Other qualifying criteria

In addition, the following criteria can be addressed if you have information readily available

- **Soundness:** *(e.g. What is the reliability of sources of information? e.g. peer-reviewed journals)*
- **Severity:** *(e.g. What could be the severity of the health effects in terms of morbidity and/or mortality?)*
- **Imminence:** *(e.g. how soon it is estimated that the potential hazard will manifest in the food, feed, environment? How soon is it estimated that this health risk will manifest in the population?)*
- **Scale:** *(e.g. number of people and Member States potentially exposed?)will IT, e.g. days, months, years)*

Conclusions: *Enter a brief summary of the reasoning that led to identify this as an emerging issue.*

QUESTIONS FOR EREN

Have you already identified this issue before? □ Yes □ No □ Not sure

Do you have any additional information/data on this issue? □ Yes □ No □ Not sure

Do you believe that this is an emerging issue? □ Yes □ No □ Not sure

Should EREN start exchanging information on the issue? □ Yes □ No □ Not sure

[*other*]

EREN COMMENTS: _____

EREN RECOMMENDATIONS (*EXAMPLES*)

1. EFSA should keep monitor the issue.
2. EFSA should start a review of this issue aiming at publishing a report.
3. EFSA should start a project to generate data on this issue (e.g. outsourcing).
4. EFSA should start a risk assessment.
5. EFSA should consult other bodies (e.g. the Stakeholder consultative group).
6. [*other*]

ABBREVIATIONS

AF	Advisory Forum of EFSA
CFP	Ciguatera fish poisoning
ECDC	European Centre for Disease Control
ECHA	European Chemical Agency
EEA	European Environment Agency
EMA	European Medical Agency
EREN	Emerging Risks Exchange Network
EU	European Union
MSs	Member States
StaCG-ER	Stakeholder Consultative Group on Emerging Risks
SWG	EFSA's Standing Working Group on emerging risks

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APPENDIX B

OUTCOME OF THE STAKEHOLDERS' CONSULTATIVE GROUP ON EMERGING RISKS SUBMITTED TO EFSA

Report of the Stakeholders' activities in the area of emerging risks[1]

ABSTRACT

EFSA has established the Stakeholder Consultative Group on Emerging Risks (StaCG-ER) in order to improve the exchange of ideas and methods on the identification of emerging risks, but also for openness and transparency, information and data sharing, communication and dialogue on issues pertaining to emerging risks. During 2012, the StaCG-ER met three times. The group discussed a total of 11 issues that were presented and assessed using a standard template developed by EFSA. Out of these issues, ten originated from the EFSA and one by a stakeholder member. The issues brought to the attention of StaCG-ER were a selection of potential emerging issues of particular relevance to the stakeholders involved, for which EFSA was seeking further data or was interested in the group's opinion thereon. The issues discussed were from the areas of novel foods, packaging, pesticides, marine biotoxins, environmental contamination, chemical contaminants and dietary habits.

KEY WORDS

Emerging risks, emerging issues, stakeholders;

[1] Question No EFSA-Q-2011-01204; Accepted for publication on 18 February 2013.

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SUMMARY

For EFSA, the term "stakeholder" describes an individual or group that is concerned or stands to be affected, directly or indirectly, by EFSA's work in scientific risk assessment. EFSA has established the Stakeholder Consultative Group on Emerging Risks (StaCG-ER) in order to improve the exchange of ideas and methods on the identification of emerging risks, but also for openness and transparency, information and data sharing, communication and dialogue on issues pertaining to emerging risks.

Members of StaCG-ER were selected by EFSA from nominations made through EFSA's Stakeholder Consultative Platform (SCP). The Platform is composed of EU-wide stakeholder organisations working in areas related to the food chain, and assists EFSA in the development of its overall relations and policy with stakeholders. The selection of members for StaCG-ER was based on the individual expertise of the nominees, and to ensure a balanced representation of both industry and consumers.

The first StaCG-ER mandate summarised stakeholders' activities in their respective sectors and proposed some potential drivers of emerging risks. Stakeholders reported that the identification of emerging risks is an essential part of the daily activities in food and feed sector organisations and is undertaken through regular monitoring of various data sources combined with information received through organisations' networks and experts.

The work of this group (second StaCG-ER mandate) built on the experience of the first and is an integral part of the emerging risks identification approach of EFSA.

An "*emerging issue*" can be defined as one that has very recently been identified and merits further investigation, and for which the information collected is still too limited to be able to assess whether it meets the requirements of an emerging risk. Thus, emerging issues are firstly identified as subjects that merit further investigation and additional data collection.

During 2012, the StaCG-ER met three times. The group discussed a total of 11 issues that were presented and assessed using a standard template developed by EFSA. Out of these, ten originated from EFSA and one by a stakeholder member. The group had the possibility to comment and provide further information on the emerging issues between the meetings.

Members brought to the attention of EFSA additional data and information on these issues, for example prioritisation criteria and additional scientific evidence, as well as recommendations, such as consultation with other organisations and areas for further scientific research.

The issues discussed were: (i) potential contamination of food from recycled paper; (ii) insects used as food and feed; (iii) increased use of banned, unauthorised and counterfeit pesticides; (iv) first report on indigenous ciguatera fish poisoning in the EU; (v) Increased cancer risk in meat and poultry workers; (vi) combined toxicity of melamine and cyanuric acid; (vii) food packaging residues in feed; (viii) colorectal cancer and possible link to dietary and cooking habits of red meat; (ix) animal illnesses linked to jerky pet treats; (x) pharmaceuticals and personal care products in the environment and possible human exposure through the food chain; (xi) Potential contamination of the food/feed chain from industrial and environmental chemical contaminants with certain characteristics. ECHA's candidate list of substances of very high concern.

The approach for identifying the issues was not systematic. The issues discussed at StaCG-ER were a selection of potential emerging issues of particular relevance to the stakeholders involved, for which EFSA was seeking further data or was interested in the group's opinion thereon.

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BACKGROUND AS PROVIDED BY EFSA

Networking with stakeholders, MSs, EU and international agencies is seen as a key step in developing the effectiveness of the emerging risks identification approach as described in EFSA's Annual Report on Emerging Risks[2].

The EFSA's Management Board formed a Stakeholder Consultative Platform (SCP) in 2005 and renewed its Terms of Reference in 2010[3]. The current platform is composed of EU-wide stakeholder organizations working in the food chain and organizations representing consumers, food and feed operators, food industry, food trade and NGOs.

A Stakeholder Consultative Group on Emerging Risks (StaCG-ER) was established in 2010, which worked with EFSA on emerging risks. The mandate of this Group expired in May 2011 and its report on Stakeholders' activities in the area of emerging risks was published in June 2011[4]. The report confirms that the identification of emerging risks is an essential part of the daily activities in food and feed sector organisations and is undertaken through regular monitoring of various data sources combined with information received through organisations' networks. A common approach among stakeholders is the use of multidisciplinary expert groups to discuss the relevance and importance of signals of potential emerging risks.

In the same report, it is also suggested that in order to strengthen the capability to identify emerging risks of public health importance, a multidisciplinary and multi-stakeholder approach is essential for both vision and interpretation, as is a means for sharing information and accumulated knowledge. Therefore, the development of a common language with shared definitions, terminology, and methodology is necessary.

From experience gained trialling EFSA's approach for identifying emerging risks[2], it is clear that an important data source are stakeholders. In order to continue to exchange in a constructive way with stakeholders on both signals of potential emerging risks and also on data concerning potential identified risks, it is proposed that EFSA should establish a "second Stakeholder Consultative Group on emerging risks".

TERMS OF REFERENCE AS PROVIDED BY EFSA

The StaCG-ER will be coordinated by the Emerging Risks Unit (now Scientific Committee and Emerging Risks Unit) that will also provide the chair, rapporteur and secretariat and be responsible for drafting the minutes of the meetings, the report of the StaCG-ER, and reporting back to the SCP. The StaCG-ER shall meet three times in one year period.

StaCG-ER members shall present to the group information and data concerning identified emerging risks and/or signals, the methods used to detect them and for the analysis of the collected data. Members shall give access to these data and justify the reporting emerging risks/signals based on scientific evidence. The data shall be presented and assessed using a standard template developed by EFSA.

As emerging risks may concern all areas of the food and feed chain, a group of approximately 15 to 20 experts with a wide range of expertise shall be selected from nominations made by the EFSA SCP to participate in the StaCG-ER.

The experts shall be selected on the basis of their expertise and their strong motivation.

[2] Development and implementation of a system for the early identification of emerging risks in food and feed; http://www.efsa.europa.eu/en/efsajournal/pub/1888.htm

[3] http://www.efsa.europa.eu/en/consultativeplatform/docs/cptor.pdf

[4] Outcome of the stakeholders' consultative group on emerging risks; http://www.efsa.europa.eu/fr/supporting/doc/170e.pdf

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The StaCG-ER shall be composed of a group representing, as far as possible, the whole food chain, from primary production to retail. In particular, experts shall be selected according to the following:

- Expertise in current and novel industrial and agricultural practices, in food and feed technology, primary production, food and feed import, novel foods, food and feed additives, food supplements, food contact materials;
- Expertise and participation in ongoing activities in the area of emerging risks identification.

The selection will also ensure a balanced representation of both industry and consumer concerns. Members of the first StaCG-ER are welcome to participate in the group to be established.

Scope in EFSA's work and outsourcing programme

This work will build on the experience of the previous Stakeholders' Consultative Group and is an integral part of the emerging risks identification approach.

Timeline

i) January 2011: composition of the StaCG-ER to be finalised.

ii) March 2012: first meeting of the StaCG-ER to discuss about the EFSA's activities on emerging risks and adopt the work plan for 2012. Presentation of emerging signals/issues by EFSA.

iii) May to July 2012: one meeting of the StaCG-ER to discuss emerging risks/signals identified by the members of the StaCG-ER through their own networks or organisation they represent and those signals presented by EFSA. Feedback on the issues presented in previous meetings. Preliminary drafting of the StaCG-ER report.

iv) October 2012: final meeting of the StaCG-ER to discuss emerging risks/signals and review the report of the StaCG-ER. The report should be finalised by February 2013.

The points ii to iv to be repeated in 2013.

After the second year of operation, the usefulness of this activity will be reviewed.

Expected deliverables (e.g. scientific output, scientific article)

- Feedback of members on issues presented by EFSA and by StaCG-ER.
- Report on signals reported by the StaCG-ER, the data exchanged and latest developments in the area of emerging risks, i.e. methods, data sources and drivers of emerging risks not described in the report of the first StaCG-ER.

Publication plan:

It is proposed to publish the StaCG-ER reports of 2012 and 2013 as soon as they are finalised and approved.

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1. Introduction

For EFSA, the term "stakeholder" describes an individual or group that is concerned or stands to be affected – directly or indirectly - by EFSA's work in scientific risk assessment. EFSA has established the StaCG-ER in order to improve the exchange of ideas and methods on the identification of emerging risks, but also for openness and transparency, information and data sharing, communication and dialogue on issues pertaining to emerging risks.

The first StaCG-ER mandate summarised stakeholders' activities in their respective sectors and proposed some potential drivers of emerging risks (EFSA, 2011). Stakeholders reported that the identification of emerging risks is an essential part of the daily activities in food and feed sector organisations and is undertaken through regular monitoring of various data sources combined with information received through organisations' networks and experts.

The work of this group (second StaCG-ER mandate) built on the experience of the first and is an integral part of the emerging risks identification approach of EFSA (EFSA, 2012).

The definition of emerging risk (ER) currently in use in EFSA is that developed by its Scientific Committee in 2007: "an *emerging risk* to human, animal and/or plant health is understood 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's (EFSA, 2007).

An "*emerging issue*" can be defined as one that has very recently been identified and merits further investigation, and for which the information collected is still too limited to be able to assess whether it meets the requirements of an emerging risk. Thus, emerging issues are firstly identified as subjects that merit further investigation and additional data collection. Emerging issues can include specific issues (*e.g.* a specific chemical substance or pathogen, or a specific genetically susceptible group of the population), as well as general issues such as drivers of change or megatrends (*e.g.* climate change) (EFSA, 2012).

A distinction has been made between emerging risks and emergency (or crisis) situations (EFSA, 2007). The first has a clear prevention and anticipation scope, the latter is related more to risk management and risk communication often involving well known and characterised hazards. The term "emerging risks" does not include issues relating to non-compliance with recognised safety requirements (i.e. risk management issues), although immediate action may be needed to prevent further exposure or damage to the health of consumers.

As part of the development of EFSA's approach for identifying emerging risks, this report includes the issues discussed at StaCG-ER in 2012 and summarises the feedback that the group gave to EFSA.

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2. Methods

Members of StaCG-ER were selected by EFSA from nominations made through EFSA's Stakeholder Consultative Platform (SCP). The Platform is composed of EU-wide stakeholder organisations working in areas related to the food chain, and assists EFSA in the development of its overall relations and policy with stakeholders.

The selection of members for StaCG-ER was based on the individual expertise of the nominees, and ensuring a balanced representation of both industry and consumers.

During 2012, the StaCG-ER met three times. Each meeting was organised around three different sessions. The first session was dedicated to presentation of topics by members or EFSA on emerging issues. The second session was dedicated to the evaluation of emerging issues presented; members were requested to provide additional information or feedback on those issues. The third session was designated to update the Group on the EFSA activities and developments.

Members had the possibility to comment and provide further information on the emerging issues between the meetings.

The emerging issues were presented and assessed using a standard template developed by EFSA (see Appendix).

The approach for identifying emerging issues was not a systematic one. The issues discussed at StaCG-ER was a selection of issues of particular relevance to the stakeholders involved, for which EFSA was seeking further data or was interested in the group's opinion thereon.

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3. Results

3.1. Issues

The group discussed a total of 11 signals of potential emerging issues (see Table 1).

A summary of each issue, together with the key points of the discussions and the conclusions follows. All the feedback provided by StaCG-ER to the issues presented will be captured in detail in the annual report on emerging risks.

Table 1: List of issues discussed by the Stakeholder Consultative Group on Emerging Risks in 2012.

	Issue[5]	**Presented by**
1	Potential chemical contamination of food from recycled paper	EFSA
2	Insects used as food and feed	EFSA
3	Increased use of banned, unauthorised and counterfeit pesticides	EFSA
4	First report on indigenous ciguatera fish poisoning in the EU	EFSA
5	Increased cancer risk in meat and poultry workers	EFSA
6	Combined toxicity of melamine and cyanuric acid	EFSA
7	Food packaging residues in feed*	FEFAC
8	Colorectal cancer and possible link to dietary and cooking habits of red meat consumption	EFSA
9	Animal illnesses linked to jerky pet treats	EFSA
10	Pharmaceuticals and personal care products (PPCPs) in the environment and possible human exposure through the food chain	EFSA
11	Potential contamination of the food/feed chain from industrial and environmental chemical contaminants with certain characteristics. The use of the ECHA 's Candidate List of Substances of Very High Concern to identify emerging chemical risks.	EFSA

*The issue was shared for information only, without the use of the standard template.

3.1.1. Potential chemical contamination of food from recycled paper

Description of the issue

Various types of contaminants have been reported in recycled paper, including printing inks, adhesives, trace elements, waxes, fluorescent whitening agents and dyes, sizing agents, organochlorine substances, plasticizers, aromatic hydrocarbons, volatile organic compounds, curing and grease-proofing agents, amines, biocides and surfactants (Binderup et al., 2002; Castle et al., 1997; Damant, 1999; EFSA, 2011; Fauris et al., 1998; Grob et al., 1991; Sipilainen-Malm et al., 1997; Vinggaard et al., 2000; Ziegleder, 2001).

There are no specific migration limits (SMLs) for many of these compounds, including printing inks and mineral oils in carton-board food packaging. However, packaging materials, must meet the requirements of Regulation (EC) No. 1935/2004; this requires that under normal and foreseeable

[5] The definition of "emerging issue" is given under section 1 "Introduction".

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conditions of use, packaging materials do not transfer their constituents to food in quantities which could endanger human health.

Many of these contaminants have not been specifically evaluated for their safety at the EU level with the exemption of printing ink related compounds (e.g. benzophenone and 4-methylbenzophenone) and mineral oil hydrocarbons that have been evaluated by EFSA[6]. Thus, recycled paper and board used as food contact material could potentially represent a new route of exposure to these other contaminants.

Key points from the discussion and the conclusions

There is a lack of standardised methods that can be used to assess the total and specific migration of chemical substances from paper.

Contamination can also occur by the use of recycled paper or carton as secondary packaging material, as volatile compounds of the packaging can be absorbed by the food.

Overall, there is no differentiation regarding the original material used and the final specifications of recycled paper or board used for different purposes e.g. packaging of food, electronic equipment or furniture. However, the existence of recycling chains specifically for producing food-use material was mentioned. Further information will be sought on this.

Other potential food-chain relevant uses of recycled paper include: (i) paper can be used together with other organic material for the production of compost[7]. In some cases, compost can be used as a fertilizer with the potential of contaminants originating from recycled paper passing into crops, fruits and vegetables. However, no scientific evidence was identified to support this hypothesis. (ii) Recycled paper can be used as animal bedding. If animals eat the bedding, they are exposed to contaminants potentially being present in the paper.

The group provided reports and guidance documents on recycled paper:

- The European Food Industry issued in 2012 a guidance document for the safe Use of Paper and Board made from recycled Fibres for Food Contact Use.
- The Confederation of European Paper Industry (CEPI) has developed a good manufacturing practice guide for the manufacture of paper and board for food contact[8]. CEPI has also produced a complementary industry guideline for the compliance of paper and board materials and articles for food contact[9]. This guideline includes an Annex on the requirements for recovered paper which refers to the European standard EN643.
- The European Carton Makers Association (ECMA) has issued a good manufacturing practice guide in September 2011.
- The German Federal Institute for Risk Assessment (BfR) issued Recommendation XXXVI on paper and board for food contact on 1 June 2007. It lists a number of requirements and specifications as well as the raw materials, additives, fillers and production aids, which may be used in paper and board for food contact.
- Final report of the FP5 BIOSAFEPAPER project: application of bioassays for safety assessment of paper and board for food contact. This document relates to the toxicological assessment of food contact paper and board.

[6] http://www.efsa.europa.eu/en/efsajournal/pub/2704.htm
[7] http://www.jhl.si/en/snaga/separate-waste-collection/Biowaste
[8] http://www.cepi.org/docshare/docs/2/NLAPOMACMAJEOPMKKIMHNKCML8KCM6U9Y3PDWDBGW19D/CEPI/docs/DLS/GMP_final-20100915-00027-01-E.pdf
[9] http://www.cepi.org/docshare/docs/1/NLAPOMACMAJEOPMKKIMHNKCM774A6OYB46864DY6UD9Q/CEPI/docs/DLS/Industry_guideline-final-printer-20100503-00005-01-E.pdf

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- International Life Sciences Institute (ILSI) packaging report[10] (on paper, not on recycled paper).

The group was of the opinion that this could be an emerging issue because of the increasing pressure to use recycled paper and board whenever possible, for instance under the EU packaging and packaging Waste Directive (94/62/EC), and people not necessarily being aware of the necessity to conduct a specific risk assessment. However, if current Industry guidance would be fully disseminated, the probability of this risk being realised should be lower.

3.1.2. Insects used as food and feed

Description of the issue

A number of drivers such as population growth, increasing animal protein demand, and ecological concerns may modify European cultural prejudices and induce the use of edible insects as food or feed.

Insect consumption is widespread in many parts of the world; FAO[11] estimates that approximately 2.5 billion people, mainly in Africa, Asia and Latin America, eating insects is part of their common diets, in a similar way as eating meat or fish.

Potential uses of edible insects in the EU include (i) their use as feed (insects or their protein extracts) and (ii) it is less likely to be included in the human diet, but cannot be excluded (already on the market as novelty/niche foods, e.g. chocolate with ants, worm lollypop).

Potential safety issues may arise by the use of insects as food and feed as (i) new hazards in terms of pathogens (for humans, plants and animals) or introduction of pests, animal and plant diseases into the EU, (ii) new or increased exposure to contaminants (e.g. pesticides, natural toxins like venoms and stings, heavy metals, processing/veterinary residues) and (iii) allergenicity (e.g. by the presence of chitin, which has been associated to asthma).

Key points from the discussion and the conclusions

StaCG-ER believed that this could be an issue in terms of (i) invasive insect species or (ii) biosecurity and carriers of plant pathogens. The group does not believe that insects are likely to be used as food or feed in the next five years, with the existing exceptions of specialised pet food and as feed in aquaculture.

In case of future importation of live insects into the EU, either for reproduction or consumption purposes, environmental risk assessment should be carried out, as the insects could escape to the environment and establish themselves as invasive species.

The group concluded that this issue should not be considered as a priority for EFSA.

3.1.3. Increased use of banned, unauthorised and counterfeit pesticides

Description of the issue

Europol issued a press release[12] on 13 January 2012 concerning the growth in the trade of illegal and counterfeit pesticides. Such illegal and counterfeit pesticides were reported as potentially threatening to public health (both of farmers and consumers) and pose a risk to crops and the environment.

[10] http://www.ilsi.org/Europe/Publications/R2004Pac_Mat.pdf
[11] http://www.fao.org/forestry/65422/en/

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According to the European Crop Protection Association (ECPA), seven to 10 percent by volume of Europe's plant protection products (PPP) are estimated to be illegal and this number is increasing annually. Counterfeit and illegal pesticides come in several forms: (i) sophisticated counterfeits (packaging and labelling copies identical to legitimate products) (ii) illegal pesticides which are low quality copies, often with plain or no labelling or with different formulation, unregistered and untested and (iii) illegal products masquerading as legitimate, but containing illegal, unregistered and potentially inferior materials (ECPA web sites[13]).

Due to the uncertain composition (active substances, metabolites, carriers, bulking agents and contaminants and their concentration) and/or false labeling or no labeling of these illegal pesticides, which are unregistered and might be untested, this can potentially pose severe health risks to farmers applying them and ultimately consumers. It can also potentially damage or even destroy the crop treated or leave unknown pesticide residues and metabolites which are not permitted in that particular crop. Synergistic effects of mixtures could also be of concern.

Key points from the discussion and the conclusions

Official controls should prioritize monitoring at the earliest point possible throughout the entire pesticide life cycle (production /distribution/ sale/ use at farm level /residues in primary production/ residues in processed products). In this way, illegal and counterfeit pesticides can be more easily targeted and the negative impact to the food chain will be reduced. It should be considered useful to further establish qualitative screening methods for illegal pesticides to rapidly identify samples for further analysis.

Criminal activity is difficult to address. A comprehensive response addressing the different aspects of the problem, including cooperation of law enforcement with relevant pesticide authorities, is therefore key. It should involve the relevant competent authorities and stakeholders i.e. custom authorities, pesticide regulatory authorities, prosecutors and judiciary, food chain partners including PPP industry.

Europol and the Office of Harmonization for the Internal Market (OHIM) organized an awareness raising conference on illegal and counterfeit pesticides in November 2012 bringing together relevant representatives of MS enforcement stakeholders, authorities and EC representatives to discuss the threat posed by these illegal products, and ways to counteract them[14].

StaCG-ER believes that this is an emerging issue; however, most aspects of the issue are related to risk management. The group could not identify trends on the use of specific compounds in illegal pesticides and trends on specific crops, but noted that counterfeit and illegal pesticide producers can try to mimic in principle any pesticide authorised on the market and particularly would be expected to target those recognised as high-value products.

Recognising that this issue was one principally of risk management, the group felt that in order to make progress, other bodies such as EC and MSs, should be consulted to gather and share more information, including on pesticide formulation testing and to map the pesticide production/distribution chain to identify intervention points. ECPA and the food industry could consider holding a conference on best practice of pesticides, highlighting the risks associated by the use of illegal pesticides.

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[12] https://www.europol.europa.eu/content/press/europol-warns-growing-trade-counterfeit-pesticides-worth-billions-euros-year-1237

[13] http://www.ecpa.eu/page/counterfeit-pesticides, www.illegalpesticides.eu see in particular: http://youtu.be/dLYEFaG1Iog

[14] http://oami.europa.eu/ows/rw/news/item2663.en.do and http://oami.europa.eu/ows/rw/resource/documents/OHIM/pressRoom/pesticides_press_release_en.pdf

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3.1.4. First report on indigenous ciguatera fish poisoning in the EU

Description of the issue

Boada et al. (2010) reported for the first time multiple and confirmed outbreaks of Ciguatera Fish Poisoning (CFP) in EU, in the Canary Islands Archipelago. Again, in late 2011, new cases of CFP poisoning coming from consumption of local seafood were reported from the Canary Islands.

CFP is a seafood-borne illness that is infrequent outside tropical and subtropical coral reef regions. When reported outside these regions, it is often related to consumption of imported toxic fish. However, due to human activities (e.g. transport by ship ballast water; nutrient loading, changes in sea surface temperature, habitat alteration), the algae *(Gambierdiscus* spp.) producing the ciguatera toxins (CTXs) as well as the ciguatoxic fish tend to expand their biogeographical range.

In recent years the presence of *Gambierdiscus* sp. was recorded in the eastern Mediterranean Sea. The first report on occurrence of *Gambierdiscus* sp. in Crete Island is from 2003 (Aligizaki and Nikolaidis, 2008).

Given the geographic expansion of the distribution of the algae (*Gambierdiscus* spp.) producing the toxins CTXs, it is expected that CFP becomes more frequent through new and increased exposure to ciguatoxins. The example of ciguatoxin represents the broader issue of emerging marine biotoxins since a number of these compounds are now detected in European waters e.g. pinnatoxins, ovatoxin A, microcystin LR and sporidesmines.

Key points from the discussion and the conclusions

The group noted that:

- There is a lack of reference methods for the detection of marine biotoxins as well as lack of reference material;
- There is the risk of transmission of the marine biotoxins throughout the food chain if contaminated fish is used as feed;
- In addition, food fraud could be a driver for CFP, if imported fish is sold under different species name or of different provenance; testing will not be applied to these fish as it is focused on fishes known for CTX.

StaCG-ER provided a recent review for *Gambierdiscus* by Parsons et al. (2012); according to this review:

- More recent studies (Aligizaki et al., 2009; 2010) have documented the presence of *Gambierdiscus* spp., in other eastern Mediterranean areas at approximately the same latitude as Crete (approximately 35^{o}N), e.g., Cyprus and Rhodes, but also in northern Greek coastal waters, such as Saronikos Gulf. The authors highlighted that it is unknown whether the presence of *Gambierdiscus* is a recent phenomenon (i.e., range expansion), or recent detection (i.e. more intensive sampling).
- As summarized by Litaker et al. (2010), *Gambierdiscus* is likely to grow in shallow water habitats (<50 m) where annual temperatures range between 21 and 31.8^{o}C (optimum between 25 and 29.8^{o}C), with high, stable salinities, light levels 10% of incident light, and housing adequate substrate (algae, biofilms). A review of the literature, however, indicates that there is a good deal of variability in these characteristics, likely reflecting species-specific differences;

StaCG-ER believes that this is an emerging issue. Moreover, the issue of marine biotoxins merits further scientific research. Regarding CTX, the influencing factors for the establishment of the toxin

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producing algae as well as for the production of toxins should be studied (e.g. water temperature, salt concentration).

StaCG-ER recommended that EFSA should keep monitor and bring the issue on CTX, but also the broader issue of marine biotoxins, to the EFSA Standing WG on emerging risks.

3.1.5. Increased cancer risk in meat and poultry workers

Description of the issue

A review of more than 60 studies was published investigating lung cancer risk in meat and poultry workers (Johnson and Choi, 2012). The overwhelming majority of studies of different designs (including all the cohort mortality and cancer incidence studies) indicate at least a 30% excess risk of lung cancer in meat and poultry plant workers, even after controlling for smoking. Moreover, at least one cohort study, including 30,411 poultry workers and 16,408 non-poultry workers reported an increased risk of pancreatic and liver cancers in poultry workers (Felini et al., 2011).

Food animal oncogenic microorganisms were postulated as one possible cause. Laboratory and in vivo studies in primates, and serological evidence in humans, indicate that food animal oncogenic viruses show potential for causing cancer in humans. Some, but not all, studies reported the presence of antibodies to these viruses in the sera of poultry workers and subjects in the general population.

These reported associations, if confirmed, could have public health implications because the general population might also be widely exposed. Studies carried out so far have had limited statistical power, due to the rarity of these types of tumours, especially in non-smokers, and limited evidence seems to be available on the detection of specific viruses in cancer patients. Thus, larger studies that can adequately control for occupational and non-occupational confounding factors are needed, so that the possible role of food animal oncogenic viruses in the occurrence of human cancer can be clearly defined.

Key points from the discussion and the conclusions

StaCG-ER commented that the review is conducted on studies of different design that makes it difficult to derive inferences. The fact that a low number, but of different types of cancer, are reported weakens the hypothesis of a direct causal relationship. More indications are needed to show that this issue is not due to social confounders that explain the increase in the risk (e.g. heavy smoking and/or drinking by meat workers).

If the reported association is limited due to the low statistical power because cases are rare, then it will be difficult to control for important confounders such as age, social status, eating habits, alcohol consumption. This implies that one will not be able to explain the increased risk; however, a lot of unreasonable negative attention to meat and poultry sector may be created.

The group could not decide if this is a food safety emerging issue; they suggested that EFSA should keep monitoring the issue and that more information is needed to explain if there is occupational risk only or if there is a food safety issue as well. With regards to the protection of slaughterhouse workers, other hazards such as *Campylobacter*, *Salmonella* and ESBL-producing bacteria should merit higher attention than this issue.

3.1.6. Combined toxicity of melamine and cyanuric acid

Description of the issue

After the adulteration of milk in China with melamine (September 2009), an action level of 2.5 mg/kg was set by the Commission to distinguish between the unavoidable background presence of melamine

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and possible adulteration. The current specific migration limit (SML) for melamine in the EU legislation for plastics is 2.5 mg/kg food.

The toxicity of melamine leads to kidney failure resulting from the formation of crystals in the urinary tract as non-covalent complexes of melamine with uric acid or of covalent complexes when co-occurrence with cyanuric acid occurs.

Recent studies in rats have shown that co-administration of melamine and cyanuric acid for 7, 28 and 90 days, in groups of male and female F344 rats showed higher toxicity compared with melamine alone, with No-Observed Adverse Effect Levels (NOAEL) or Benchmark Dose Limits ($BMDL_{10}$) of 8.6 and 8.4-10.9 mg/kg b.w per day for the 7 day study respectively, NOAEL of 2.1-2.6 mg/kg b.w per day for males and females for the 28 day study ($BMDL_{10}$ 1.6 mg/kg bw/day for both sexes) and a NOAEL of 0.63 mg/kg b.w per day for the 90 day study.

In terms of toxicity, these NOAEL and $BMDL_{10}$ values for melamine-cyanuric acid for the 7, 28 and 90 days study were approximately 7-fold, 24-39-fold and a 100-fold and 2-fold, 7-12 fold and 30-fold below the NOAEL of 63 mg/kg b.w per day and the $BMDL_{10}$ of 19 mg/kg b.w per day established for melamine alone by the FDA and EFSA respectively and both based on a 13 week study (Jacobs et al., 2011; Gamboa-da Costa et al., 2012 a,b).

These new toxicological studies show that melamine-cyanuric acid toxicity increases with exposure time and suggests that the Tolerable Daily Intake values (TDI) derived by WHO and EFSA (0.2 mg kg.b.w per day by both) derived from studies conducted with melamine alone may underestimate the risk from co-exposures to melamine and cyanuric acid.

Key points from the discussion and the conclusions

Apart from new insights of the combined melamine and cyanuric acid toxicity, exposure data would need to be collected to eventually proceed with full risk assessment. Monitoring activities should define a cut-off point and the levels above which there should be a concern. FoodDrinkEurope shared their data on melamine occurrence with EFSA in 2009; there are new data for tests performed after 2009, including for cyanuric acid.

Other sources of cyanuric acid than food should be monitored and evaluated, in particular exposure via plant protection products, food contact materials and sanitising agents. When establishing maximum levels for melamine and cyanuric acid in food and feed products, there is a need to distinguish fraudulent activities from levels resulting due to unavoidable presence from sources other than food.

Dominquez-Estevez M. et al. (2010) reported that the presence of 1 ppm of melamine and cyanuric acid each in infant formula is unlikely to be of significant health concern.

StaCG-ER was not sure if this is an emerging issue; combined melamine and cyanuric acid toxicity is known and not new. Moreover, the European food and feed industry is aware of the issue and performs controls on imports of raw material for further processing. The group suggested that EFSA should monitor the issue, but not as a high priority.

3.1.7. Food packaging residues in feed

Description of the issue

Minimising and recycling of food waste is on the top of the Commission working programme. A significant proportion of produced food does not meet the technical product specifications and cannot be placed on the market as food and drink or is removed from the food chain as "past the sell by-date" or surplus products. Using these "former foodstuffs" as feed material is a recognised and useful means of good usage of these products and a way to prevent waste generation, which is the top priority in the waste hierarchy as defined in Directive 2008/98/EC.

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Examples of these products include ones initially destined for food use, but which are not placed on the market for technical reasons (e.g. biscuits which are the wrong size, packaging error) or the production process of food was interrupted (e.g. raw dough); surplus products meet the food specifications, but miss a market (e.g. Easter eggs unsold by Easter) or may not have been sold before the expiry of the sell-by date (e.g. fruits and vegetables, bread).

Former foodstuffs are mostly bread, biscuits, snacks, chocolate and confectionery products. According to data collected by FEFAC from former foodstuffs processors from five EU Member States (UK, Belgium, The Netherlands, Italy and Germany), the volume of former foodstuffs that undergoes a process (e.g. unwrapping) before being placed on the market as feed in these five countries is estimated around two million tonnes per year.

Regulation (EU) No 767/2009 on the placing on the market and use of feed introduces a ban on the use of packaging materials for use in feed (Annex III, chapter 1, par. 7). However, former foodstuffs may be packed and in practice, the total absence of residues of packaging materials in former foodstuffs having undergone an unwrapping process is not technically achievable. Best available techniques for unwrapping enable reduction in the amount of packaging down to 0.15 %.

FEFAC considers that the chemical hazards related to this issue should be identified and evaluated; moreover, the exposure of animals to packaging residues should be evaluated. As a following step, a tolerance limit should be set with regards to the presence of packaging residues in processed former foodstuffs to be used as feed.

Key points from the discussion and the conclusions

The issue was shared for information only, without the use of the standard template; no comments received from other members.

3.1.8. Colorectal cancer and possible link to dietary and cooking habits of red meat consumption

Description of the issue

A large body of epidemiological evidence shows that red[15] and processed meats are strongly associated with an increased risk of colorectal cancer (World Cancer Research Fund (WCRF) and American Institute for Cancer Research (AICR); 2007, 2011). The risk appears to be higher for long-term consumption of cooked and processed red meat. The conclusions of those reports are strongly based on epidemiological studies of different design and populations. Epidemiological studies are generally used to assess associations, but have limited power in proving causality.

Potential mechanisms of carcinogenesis linked to red meat consumption include chemical carcinogens arising during the cooking process of meat (i.e. polycyclic aromatic hydrocarbons (PAHs), nitrosamine derivatives during broiling, barbecuing or processing of red meat) (Sugimura T. et al, 1977, 2004; Yano M. et al, 1988). More recently, a hypothesis on a possible role of one or more thermo-resistant potentially oncogenic bovine viruses (e.g., polyoma-, papilloma- or possibly single-stranded DNA viruses) has been brought forward (zur Hausen H, 2012). However, the exact mechanism by which red meat could be involved in cancer aetiology is under debate.

The association between red meat consumption and colorectal cancer is not an emerging issue, as it has been addressed by a large body of epidemiological evidence over the last decades. However, the available evidence does not allow establishing a causal link. EFSA has not addressed this issue, and it is not clear whether EFSA should deal with issues linked to providing recommendations to the public on dietary habits.

[15] Generally red meat includes beef/veal, pork and sheep meat/goat meat.

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Key points from the discussion and the conclusions

StaCG-ER noted that WCRF/AICR received negative comments for these reviews (e.g. see below Truswell S., 2009; Alexander and Cushing, 2010). The evidence is not clear and sometimes contradicting. The risk for colorectal cancer related to red meat consumption is relatively low compared to other potential causative factors e.g. smoking. The review can be biased by other factors not taken into account, including dietary habits (low intake of vegetables, high energy intake) and food preparation techniques e.g. cooking meat at high temperatures (barbeque), which creates polycyclic aromatic hydrocarbons. Moreover, the role of other non-food related factors should also be considered e.g. physical exercise.

Truswell S. (2009) commented on the WCRF/AICR report (2007):

- The WCRF report omitted 13 cohort studies involving approximately 1.6 million people - including a large study conducted by the American Cancer Society- in which 11 of the studies found no significant association between eating red meat and cancer;
- The report omitted a comparison of several groups of socially matched meat-eating consumers and vegetarians in which there was no difference in mortality from colorectal cancer between the two groups;
- The report did not refer to follow-up work by certain of its research sources that drew different conclusions;
- The report did not refer to recent work by researchers that involved more subjects and reached different conclusions.

Alexander and Cushing (2010) identified limitations of the WCRF/AICR report as well. They noted that the epidemiologic associations across the consortium of studies were relatively weak in magnitude (i.e. relative risk below 1.5), most individual studies did not observe statistically significant associations, there was no clear evidence of dose–response, and patterns of associations varied by study characteristics.

Alexander D. et al. (2011) conducted a review of 34 studies on red meat consumption associated with colorectal cancer. They calculated summary relative risk estimates (SRREs) of high versus low intake and dose–response relationships. They concluded that the SRREs for colon cancer and rectal cancer were 1.11 (95% Confidence Interval (CI): 1.03–1.19) and 1.19 (95% CI: 0.97–1.46) respectively. The SRREs among men and women were 1.21 (95% CI: 1.04–1.42) and 1.01 (95% CI: 0.87–1.17) respectively. According to the authors, the available epidemiologic data are not sufficient to support an independent and unequivocal positive association between red meat intake and colorectal cancer.

The WCRF/AICR report (2007) took into account the European Prospective Investigation into Cancer and Nutrition (EPIC[16]) study that included 520,000 subjects from ten European countries. EPIC investigated the relationships among diet, lifestyle, genetic and environmental factors, and the incidence of different forms of cancer. According to the results of this study, the combination of four dietary factors i.e. fibre, fish, red and processed meats plays a major role in colorectal cancer etiology in addition to alcohol intake, obesity and low physical activity. Moreover, the hypothesis that consumption of red and processed meat increases colorectal cancer risk was supported by the EPIC results, however, the hazard ratio [HR] for highest [>160 g/day] versus lowest [<20 g/day] intake level was 1.57 and the 95% CI was 1.13 to 2.17 (Norat et al., 2005).

StaCG-ER members reflected different opinions on the question of whether EFSA should deal with issues related to nutritional habits. Some members believed that this is more a risk management issue and it is the role of Member States to implement the dietary guidelines of EFSA or other bodies at national level. Other members considered that EFSA could make recommendations on the

[16] http://epic.iarc.fr/about.php

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consumption of red meat as well as on cooking habits, for example as risk-benefit analyses on these issues.

StaCG-ER believed that this is neither an emerging issue nor a priority for EFSA to take action on.

3.1.9. Animal illnesses linked to jerky pet treats

Description of the issue

Since 2007, the U.S. Food and Drug Administration (FDA) has become aware of increasing numbers of illnesses in pets associated with the consumption of jerky (dried meat) pet treats and released several consumer alerts about treats. On 14 September 2012, the FDA published a communication that "investigates animal illnesses linked to jerky pet treats"[17].

Although the FDA has been investigating the reports of illnesses, no definitive cause has been determined. The FDA tested product samples for factors known to cause the symptoms and illnesses reported in pets including, *Salmonella*, heavy metals, furans, pesticides, antibiotics, mycotoxins, rodenticides, nephrotoxins (including melamine) with negative results (however, no information on the number of samples analysed was given). In 2011, samples were also submitted for nutritional composition. The FDA is now expanding its testing to include irradiation by-products.

The majority of the cases in dogs report primarily gastrointestinal signs, including vomiting and diarrhoea, and can involve severe signs such as pancreatitis or gastrointestinal bleeding. The next most common signs relate to kidney function, including frequent urination, increased urine, severe thirst, kidney failure and some cases resemble a rare kidney related illness called Fanconi's syndrome.

Whilst there is no scientific evidence confirming that the jerky pet treats are the cause of the illnesses, this case could be a potential signal for adulteration of pet food at present, and for food in the future.

Key points from the discussion and the conclusions

StaCG-ER noted that during the melamine adulteration incident in China, first reporting was in pet food particularly in the USA, whereas adulteration in milk and infant formula was reported later on.

Regarding the FDA communication:

- The diversity of symptoms reported by the FDA does not point to a single pattern related to a specific toxicity or composition or microbial contamination of the treats of concern; the cause of illness may be more than one.
- The sampling size during testing is not reported; this is important in order to understand the negative findings.
- There are no epidemiological data reported connecting the different cases.

Possible causes could include:

- The use of an oilseed having a toxic substance as an ingredient.
- Inappropriate use of treats. Treats should be used as a supplement only and cannot substitute dog food. For some treats, it is recommended to only give two to three pieces a day as high consumption might cause nephropathy to dogs.

[17] http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm319463

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The group could not decide if this is an emerging issue as there is neither a specific hazard identified so far, nor a confirmed connection between product consumption and symptoms. They suggested that EFSA should monitor the issue.

3.1.10. Pharmaceuticals and personal care products (PPCPs) in the environment and possible human exposure through the food chain

Description of the issue

An increasing number of publications in the scientific literature report the presence of Pharmaceuticals and Personal Care Products (PPCPs) in the food-chain (e.g. Clarke et al., 2011; Stuart et al., 2012). Residues of PPCPs present in wastewater and sewage sludge are of concern due to their transfer to aquatic and terrestrial food chains and possible adverse effects on non-targeted organisms. The distribution to biota and accumulation throughout the food chain is poorly understood, in particular because of limited number of studies on this topic and lack of adapted models (EAHC, 2012).

In general, there is scarcity of data on human health effects at environmental levels, effects on aquatic organisms, and other harmful effects and therefore it is difficult to predict which health effects PPCPs may have on humans, terrestrial and aquatic organisms, and ecosystems. Interest in studying toxicological and eco-toxicological profiles of medicines and their likely impacts on the environment and human health via the environment was only raised recently, and has had to cope with scientific and technical challenges of assessing the impacts of chronic exposure at low concentrations to a mixture of pharmaceuticals (Boxall et al., 2012).

Human exposure can derive from the increasing amount of PPCPs residues present in sewage sludge, wastewater and ground water used in agriculture, and the possible subsequent contamination of or even accumulation in leaf crops, root crops, fish, dairy products, and meat. Presence of PPCPs in drinking water highlights the concern of potential health risk with long-term low-level exposures.

Key points from the discussion and the conclusions

The detection of PPCPs in food and feed *per se* does not lead to the conclusion that there is an increased exposure to a hazard, as the analytical techniques become more advanced and the limits of detection lower. Furthermore, exposure to very low amounts of such contaminants may not represent a health risk.

Prioritisation of PPCPs of concern could be done by estimating the expected use of these products, e.g. a specific diabetic medicine is expected to be used only by a small group of the population and so the possibility of having residues in the environment and subsequently in the food chain is lower than a common antibiotic.

Contamination of the food chain by PPCPs could be prevented or reduced by taking measures as high as possible in the chain i.e. safeguard water used for irrigation and food production from contamination.

The group could not identify specific PPCPs of concern. However, the increased use of sewage in agriculture could be a vehicle for the introduction of PPCPs into the food and feed chains.

It was also indicated that water treatment processes by municipalities can significantly lower the exposure to PPCP's.

StaCG-ER concluded that this is a potential emerging issue, whilst noting that there are limited data on exposure and diversity in bioaccumulation in different food and non-food organisms of the low doses analysed. They recommended to EFSA to monitor the issue

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3.1.11. Potential contamination of the food/feed chain from industrial and environmental chemical contaminants with certain characteristics. The use of the ECHA 's Candidate List of Substances of Very High Concern to identify emerging chemical risks

Description of the issue

A potential approach for anticipating environmental and consequentially food chain contamination with emerging chemical contaminants is to monitor chemical production, irrespective of intended use. A source of information for this data at European level is the REACH Regulation (Regulation (EC) No 1907/2006).

Substances of very high concern are defined in Article 57 of the REACH Regulation and classified as:

- Carcinogenic, Mutagenic or toxic to Reproduction (CMR);
- Persistent, bioaccumulative and toxic (PBT) or very Persistent and very Bioaccumulative (vPvB);
- Identified, on a case-by-case basis, from scientific evidence as causing probable serious effects to human health or the environment of an equivalent level of concern as those above (such as endocrine disrupters).

A list of 145 substances, published between 30/06/2008 and 03/09/2012, is accessible on the ECHA website[18].

These lists may provide a starting point for identifying chemicals of concern that may enter the food/feed chain and for which EFSA has not already carried out a risk assessment. A number of these Substances of Very High Concern have not been assessed by EFSA and could potentially constitute new hazards for the food and the feed chain. However, new or increased exposure to these substances is unknown for the food and feed chain.

Key points from the discussion and the conclusions

StaCG-ER proposed that another starting point for identifying emerging chemical risks could be counterfeit veterinary drugs.

The group noted that the ECHA list is a hazard list without data on the exposure to these hazards.

The group noted that cobalt salts are in the ECHA list, however, at the same time there are used as feed additives as a source of vitamin B12 in cows and their use and efficacy has been assessed by EFSA[19].

StaCG-ER proposed that criteria to prioritise substances from the list related to the food/feed chain could include:

- Physicochemical characteristics of the substances like volatility, stability in food/feed matrixes and bioaccumulation in food/feed;
- Consequences specifically from oral exposure to these substances, as the data used for the selection of chemicals included in the ECHA lists is based on overall exposure i.e. ingestion, inhalation and dermal contact.

StaCG-ER suggested to EFSA to assess the ECHA lists in more detail, as there is a potential to use this list to identify emerging chemical risks, once one is able to use the list as a risk assessment tool, rather than only a hazard identification tool.

[18] http://echa.europa.eu/web/guest/proposals-to-identify-substances-of-very-high-concern-previous-consultations
[19] http://www.efsa.europa.eu/it/scdocs/doc/1383.pdf

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3.2. Update on drivers and new methodology applied

StaCG-ER did not report additional drivers of emerging risks and methodology applied for emerging risks identification in the food and feed sector organisations other that of what is already described in the report of the first StaCG-ER mandate (EFSA, 2011).

CONCLUSIONS

The group discussed 11 potential emerging issues during 2012. Members brought to the attention of EFSA additional data and information on these issues, for example prioritisation criteria and additional scientific evidence, as well as recommendations, such as consultation with other organisations and areas for further scientific research.

Whilst the objective of StaCG-ER is to exchange data and information, the emerging issues discussed in StaCG-ER in 2012 originated from the EFSA with an exception of one issue presented by a stakeholder member, however, without using the standard template. Using this year as a learning experience, the StaCG-ER members agreed to commit to raise more potential issues for discussion in 2013.

In summary, the group provided useful information on issues raised by EFSA, as well as enriching the discussion on the relevance and importance of the issues addressed.

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ABBREVIATIONS

AICR	American Institute for Cancer Research
BMDL	Benchmark Dose Limits
CEPI	Confederation of European Paper Industry
CFP	Ciguatera Fish Poisoning
CI	Confidence Interval
CTXs	Ciguatera Toxin
EC	European Commission
ECHA	European Chemical Agency
ECPA	European Crop Protection Association
EPIC	European Prospective Investigation into Cancer and Nutrition
EU	European Union
FAO	Food and Agricultural Organisation of the United Nations
FDA	The U.S. Food and Drug Administration
FEFAC	European Feed manufactures' Federation
MS	Member State of the European Union
NOAEL	No-Observed Adverse Effect Levels
PAHs	Polycyclic Aromatic Hydrocarbons
PPCPs	Pharmaceuticals and Personal Care Products
PPP	plant protection products
SCP	EFSA's Stakeholder Consultative Platform
SML	Specific Migration Limit
SRREs	Summary Relative Risk Estimates
StaCG-ER	Stakeholder Consultative Group on Emerging Risks
TDI	Tolerable Daily Intake
WCRF	World Cancer Research Fund
WHO	World Health Organisation

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APPENDIX

BRIEFING NOTE TEMPLATE

Stakeholder Consultative Group on Emerging Risks (StaCG-ER)

(This is a template for "Briefing notes on emerging issues" identified by a member of the StaCG-ER)

BRIEFING NOTE ON EMERGING ISSUES[20]

Updated by [NAME] on DD MM YYYY

Presented to StaCG-ER MTG on DD MM YYYY

The scope of this briefing note is to present priority emerging issues identified by a member of StaCG-ER or EFSA to the Group. StaCG-ER is requested to (i) evaluate the relevance of the issue presented and (ii) facilitate the exchange of any relevant information. The information provided in this briefing note is not comprehensive and is intended as a quick summary and a point of departure.

Title and ID

DESCRIPTION OF THE ISSUE

Include a short description of the issue, mentioning the hazard under evaluation (e.g. which virus, bacteria, parasite, contaminant, driver etc). Use the following criteria to explain why do you consider this an emerging issue. Evaluation criteria to be considered include at least one of the four main criteria listed under "Evaluation".

ADDITIONAL SUPPORTING INFORMATION

Provide any additional background information you believe is important in order to support the evaluation of the issue. For example:

- *Any additional information on the source of information (scientific or grey literature, , experts, surveillance systems…);*
- *Limitations of the analysis/study;*
- *Toxicological information of this (or similar) agents/compounds;*
- *Any other information you believe is important.*
- *Is this related to any other issues already discussed in StaCG-ER meetings?*

[20] "*Emerging issues"* are identified at the beginning of the Emerging Risk Identification approach as issues that may merit further investigation and additional data collection. Emerging issues can include specific issues (*e.g.* specific chemical substance or a pathogen), as well as general issues such as drivers of change (*e.g.* climate change). Risk management issues resulting from a lack of compliance with existing regulations should be excluded.

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LEGAL AND INSTITUTIONAL ASPECTS

- *Report the results of a basic search for (i) EFSA risk assessment or action, (ii) legislation on the subject or (iii) institutional reporting (e.g. documents from the European Commission, and European or international food safety authorities/risk assessment bodies).*

EVALUATION

Main criteria

- **Driver:** *(e.g. is this a new driver?)*
- **New hazard:** *(e.g. Has a new hazard been identified? If so, which one and how?)*
- **New or increased exposure:** *(e.g. Has a possible exposure through food/feed to the new hazard been identified?)*
- **New susceptible group:** *(e.g. Has a new vulnerable group been identified?)*

Other qualifying criteria

In addition, the following criteria can be addressed <u>if you have information readily available</u>

- **Soundness:** *(e.g. What is the reliability of sources of information? e.g. peer-reviewed journals)*
- **Severity:** *(e.g. What could be the severity of the health effects in terms of morbidity and/or mortality?)*
- **Imminence:** *(e.g. how soon it is estimated that the potential hazard will manifest in the food, feed, environment? How soon is it estimated that this health risk will manifest in the population?)*
- **Scale:** *(e.g. number of people and Member States potentially exposed?), e.g. days, months, years)*

Conclusions: *Enter a brief summary of the reasoning that led to identify this as an emerging issue.*

QUESTIONS FOR STACG-ER

Have you already identified this issue before? □ Yes □ No □ Not sure

Do you have any additional information/data on this issue? □ Yes □ No □ Not sure

Do you believe that this is an emerging issue? □ Yes □ No □ Not sure

Should StaCG-ER start exchanging information on the issue? □ Yes □ No □ Not sure

[other]

STACG-ER COMMENTS:

_____

STACG-ER RECOMMENDATIONS (EXAMPLES)

1. EFSA should monitor the issue.

2. EFSA should consult other bodies (please indicate which).

3. The issue should be addressed by the Standing WG on emerging risks with a view to:

- reviewing this issue aiming at publishing a report;
- starting a project to generate data on this issue (e.g. outsourcing);
- starting a risk assessment.

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APPENDIX C

OUTCOME OF THE STAKEHOLDERS' CONSULTATIVE GROUP ON EMERGING RISKS SUBMITTED TO EFSA

2013 Report of the Stakeholders' activities in the area of emerging risks[1]

ABSTRACT

EFSA has established the Stakeholder Consultative Group on Emerging Risks (StaCG-ER) in order to improve the exchange of ideas and methods on the identification of emerging risks, but also for openness and transparency, information and data sharing, communication and dialogue on issues pertaining to emerging risks. During 2013, the StaCG-ER met three times. The group discussed a total of 11 issues that were presented and assessed using a standard template developed by EFSA. Out of these signals, nine originated from EFSA and two from stakeholder members. The issues brought to the attention of StaCG-ER were a selection of potential emerging issues of particular relevance to the stakeholders involved, for which EFSA was seeking further data or was interested in the group's opinion thereon. The issues discussed were from the areas of microbiological hazards, food contact materials, animal diseases, biotoxins, chemical mixtures, changes in crop production, food fraud, new methods for risk assessment and changes in the regulatory framework.

KEY WORDS

Emerging risks, emerging issues, stakeholders;

[1] Question No EFSA-Q-2011-01236; Accepted for publication on 28 February 2014.

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SUMMARY

For EFSA, the term "stakeholder" describes an individual or group that is concerned or stands to be affected - directly or indirectly- by EFSA's work in scientific risk assessment. EFSA has established the Stakeholder Consultative Group on Emerging Risks (StaCG-ER) in order to improve the exchange of ideas and methods on the identification of emerging risks, but also for openness and transparency, information and data sharing, communication and dialogue on issues pertaining to emerging risks.

Members of StaCG-ER were selected by EFSA from nominations made through EFSA's Stakeholder Consultative Platform (SCP). The Platform is composed of EU-wide stakeholder organisations working in areas related to the food chain, and assists EFSA in the development of its overall relations and policy with stakeholders. The selection of members for StaCG-ER was based on the individual expertise of the nominees, and to ensure a balanced representation of both industry and consumers.

The first StaCG-ER mandate summarised stakeholders' activities in their respective sectors and proposed some potential drivers of emerging risks. Stakeholders reported that the identification of emerging risks is an essential part of the daily activities in food and feed sector organisations and is undertaken through regular monitoring of various data sources combined with information received through organisations' networks and experts.

The work of this group (second StaCG-ER mandate) built on the experience of the first and is an integral part of the emerging risks identification approach of EFSA.

An "*emerging issue*" can be defined as one that has very recently been identified and merits further investigation, and for which the information collected is still too limited to be able to assess whether it meets the requirements of an emerging risk. Thus, emerging issues are firstly identified as subjects that merit further investigation and additional data collection.

During 2013, the StaCG-ER met three times. The group discussed a total of 11 issues that were presented and assessed using a standard template developed by EFSA. Out of these signals, nine originated from EFSA and two by stakeholder members. The group had the possibility to comment and provide further information on the issues between the meetings.

The issues discussed were: (i) *Clostridium difficile*; (ii) Increase of *Cryptosporidium* infections in the Netherlands, the UK and Germany in 2012; (iii) Alternatives to Bisphenol A for food contact material applications; (iv) Lumpy Skin Disease; (v) Cyanotoxins in food supplements; (vi) An example of potential synergistic toxicity: cadmium and chlorpyrifos; (vii) Wheat crop: low quality and poor yield; (viii) Fish substitution and mislabelling; (ix) Masked mycotoxins; (x) Epigenetic endpoints in chemical risk assessment regulatory testing; (xi) Information to consumers.

Members brought to the attention of EFSA additional data and useful information on these issues, for example prioritisation criteria and additional scientific evidence, as well as recommendations, such as consultation with other organisations and areas for further scientific research. These contributions have added to the overall approach established in EFSA for the identification of emerging risks, concretely;

- For Lumpy Skin Disease, an issue raised by the StaCGER, the EC has since sent a mandate to EFSA to address this in detail.
- Mandates from the EC on masked mycotoxins are already with EFSA.
- Information on fish mislabelling has been forwarded to the newly formed food fraud team at the EC.
- *Clostridium difficile* as a potential food borne zoonoses has been monitored by EFSA's BIOHAZ unit, and will continue to be monitored for new developments by EFSA.
- The issue of epigenetic endpoints in risk assessment will be raised with the EFSA's standing working group on Emerging Risks, as will alternatives to BPA.
- The risk assessment of chemical mixtures is being addressed through a series of outsourced data gathering activities, aimed at building on the approach being developed at EFSA in the area of pesticides, with a view to having a horizontal approach applicable to all areas of chemical risk assessment.
- Outsourcing of a review on presence of cyanotoxins in food supplements is being considered.

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- The issues of increased *Cryposporidium* infections, and reduced quality and yield of wheat crops will be considered under the activity on the identification of drivers of emerging risks (in both these cases, there appears to be a link to climate and potentially climate change), of the standing working group.
- The implications of the introduction of Regulation (EU) 1169/2011 on information to consumers were considered as being outside the remit of EFSA.

The mandate of this group expired in end 2013. Following the recommendation of the Stakeholder Consultative Platform and in order to continue to exchange in a constructive way with stakeholders on both signals of potential emerging risks and also on data concerning potential identified risks, the Scientific Committee and Emerging Risks Unit renewed the mandate of the StaCG-ER for another two years (2014-2015).

The approach for identifying emerging risks is not a systematic one. The issues discussed at StaCG-ER were a selection of issues of particular relevance to the stakeholders involved, for which EFSA was seeking further data or was interested in the group's opinion thereon.

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BACKGROUND AS PROVIDED BY EFSA

Networking with stakeholders, MSs, EU and international agencies is seen as a key step in developing the effectiveness of the emerging risks identification approach as described in EFSA's Annual Report on Emerging Risks[2].

The EFSA's Management Board formed a Stakeholder Consultative Platform (SCP) in 2005 and renewed its Terms of Reference in 2010[3]. The current platform is composed of EU-wide stakeholder organizations working in the food chain and organizations representing consumers, food and feed operators, food industry, food trade and NGOs.

A Stakeholder Consultative Group on Emerging Risks (StaCG-ER) was established in 2010, which worked with EMRISK on emerging risks. The mandate of this Group expired in May 2011 and its report on Stakeholders' activities in the area of emerging risks was published in June 2011[4]. The report confirms that the identification of emerging risks is an essential part of the daily activities in food and feed sector organisations and is undertaken through regular monitoring of various data sources combined with information received through organisations' networks. A common approach among stakeholders is the use of multidisciplinary expert groups to discuss the relevance and importance of signals of potential emerging risks.

In the same report, it is also suggested that in order to strengthen the capability to identify emerging risks of public health importance, a multidisciplinary and multi-stakeholder approach is essential for both vision and interpretation, as is a means for sharing information and accumulated knowledge. Therefore, the development of a common language with shared definitions, terminology, and methodology is necessary.

From experience gained trialling EFSA's approach for identifying emerging risks[2], it is clear that an important data source are stakeholders. In order to continue to exchange in a constructive way with stakeholders on both signals of potential emerging risks and also on data concerning potential identified risks, it is proposed that EMRISK should establish a "second Stakeholder Consultative Group on emerging risks".

TERMS OF REFERENCE AS PROVIDED BY EFSA

The StaCG-ER will be coordinated by EMRISK that will also provide the chair, rapporteur and secretariat and be responsible for drafting the minutes of the meetings, the report of the StaCG-ER, and reporting back to the SCP. The StaCG-ER shall meet three times in one year period.

StaCG-ER members shall present to the group information and data concerning identified emerging risks and/or signals, the methods used to detect them and for the analysis of the collected data. Members shall give access to these data and justify the reporting emerging risks/signals based on scientific evidence. The data shall be presented and assessed using a standard template developed by EMRISK.

As emerging risks may concern all areas of the food and feed chain, a group of approximately 15 to 20 experts with a wide range of expertise shall be selected from nominations made by the EFSA SCP to participate in the StaCG-ER.

The experts shall be selected on the basis of their expertise and their strong motivation.

The StaCG-ER shall be composed of a group representing, as far as possible, the whole food chain, from primary production to retail. In particular, experts shall be selected according to the following:

[2] Development and implementation of a system for the early identification of emerging risks in food and feed; http://www.efsa.europa.eu/en/efsajournal/pub/1888.htm

[3] http://www.efsa.europa.eu/en/consultativeplatform/docs/cptor.pdf

[4] Outcome of the stakeholders' consultative group on emerging risks; http://www.efsa.europa.eu/fr/supporting/doc/170e.pdf

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- Expertise in current and novel industrial and agricultural practices, in food and feed technology, primary production, food and feed import, novel foods, food and feed additives, food supplements, food contact materials;
- Expertise and participation in ongoing activities in the area of emerging risks identification.

The selection will also ensure a balanced representation of both industry and consumer concerns. Members of the first StaCG-ER are welcome to participate in the group to be established.

Scope in EFSA's work and outsourcing programme

This work will build on the experience of the previous Stakeholders' Consultative Group and is an integral part of the emerging risks identification approach.

Timeline

i) January 2011: composition of the StaCG-ER to be finalised.

ii) March 2012: first meeting of the StaCG-ER to discuss about the EFSA, EMRISK activities on emerging risks and adopt the work plan for 2012. Presentation of emerging signals/issues by EFSA.

iii) May to July 2012: one meeting of the StaCG-ER to discuss emerging risks/signals identified by the members of the StaCG-ER through their own networks or organisation they represent and those signals presented by EMRISK. Feedback on the issues presented in previous meetings. Preliminary drafting of the StaCG-ER report.

iv) October 2012: final meeting of the StaCG-ER to discuss emerging risks/signals and review the report of the StaCG-ER. The report should be finalised by December 2012.

The points ii to iv to be repeated in 2013.

After the second year of operation, the usefulness of this activity will be reviewed.

Expected deliverables (e.g. scientific output, scientific article)

- Feedback of members on issues presented by EFSA and by StaCG-ER.
- Report on signals reported by the StaCG-ER, the data exchanged and latest developments in the area of emerging risks i.e. methods, data sources and drivers of emerging risks not described in the report of the first StaCG-ER.

Publication plan:

It is proposed to publish the StaCG-ER reports of 2012 and 2013 as soon as they are finalised and approved.

ACKNOWLEDGEMENTS

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1. Introduction

For EFSA, the term "stakeholder" describes an individual or group that is concerned or stands to be affected – directly or indirectly - by EFSA's work in scientific risk assessment. EFSA has established the StaCG-ER in order to improve the exchange of ideas and methods on the identification of emerging risks, but also for openness and transparency, information and data sharing, communication and dialogue on issues pertaining to emerging risks.

The first StaCG-ER mandate summarised stakeholders' activities in their respective sectors and proposed some potential drivers of emerging risks (EFSA, 2011). Stakeholders reported that the identification of emerging risks is an essential part of the daily activities in food and feed sector organisations and is undertaken through regular monitoring of various data sources combined with information received through organisations' networks and experts.

The work of this group (second StaCG-ER mandate) built on the experience of the first and is an integral part of the emerging risks identification approach of EFSA (EFSA, 2012). The mandate of this group expired in end 2013. Following the recommendation of the Stakeholder Consultative Platform and in order to continue to exchange in a constructive way with stakeholders on both signals of potential emerging risks and also on data concerning potential identified risks, the Scientific Committee and Emerging Risks Unit renewed the mandate of the StaCG-ER for another two years (2014-2015).

The definition of emerging risk (ER) currently in use in EFSA is that developed by its Scientific Committee in 2007: "an *emerging risk* to human, animal and/or plant health is understood 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's (EFSA, 2007).

An "*emerging issue*" can be defined as one that has very recently been identified and merits further investigation, and for which the information collected is still too limited to be able to assess whether it meets the requirements of an emerging risk. Thus, emerging issues are firstly identified as subjects that merit further investigation and additional data collection. Emerging issues can include specific issues (*e.g.* a specific chemical substance or pathogen, or a specific susceptible group of the population), as well as general issues such as drivers of change or megatrends (*e.g.* climate change) (EFSA, 2012).

A distinction has been made between emerging risks and emergency (or crisis) situations (EFSA, 2007). The first has a clear prevention and anticipation scope, the latter is related more to risk management and risk communication often involving well known and characterised hazards. The term "emerging risks" does not include issues relating to non-compliance with recognised safety requirements (i.e. risk management issues), although immediate action may be needed to prevent further exposure or damage to the health of consumers.

As part of the development of EFSA's approach for identifying emerging risks, this report includes the potential emerging issues discussed at StaCG-ER in 2013 and summarises the feedback that the group gave to EFSA.

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2. Methods

Members of StaCG-ER were selected by EFSA from nominations made through EFSA's Stakeholder Consultative Platform (SCP). The Platform is composed of EU-wide stakeholder organisations working in areas related to the food chain, and assists EFSA in the development of its overall relations and policy with stakeholders.

The selection of members for StaCG-ER was based on the individual expertise of the nominees, and ensuring a balanced representation of both industry and consumers.

During 2013, the StaCG-ER met three times. Each meeting was organised around three different sessions. The first session was dedicated to presentation of topics by members or EFSA on emerging issues. The second session was dedicated to the evaluation of emerging issues presented; members were requested to provide additional information or feedback on those issues. The third session was designated to update the Group on EFSA activities and developments.

The emerging issues were presented and assessed using a standard template developed by EFSA (see Appendix A). Members had the possibility to comment and provide further information on the emerging issues between the meetings.

The approach for identifying emerging issues is not a systematic one. The issues discussed at StaCG-ER were a selection of potential emerging issues of particular relevance to the stakeholders involved, for which EFSA was seeking further data or was interested in the group's opinion thereon.

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3. Results

3.1. Issues

The group discussed a total of 11 issues (see Table 1). A summary of each issue, together with the key points of the discussions and the conclusions follows.

Table 1: List of issues discussed by the Stakeholder Consultative Group on Emerging Risks in 2013.

	Issue[5]	**Presented by**
1	*Clostridium difficile* as a potential zoonotic or foodborne pathogen	EFSA
2	Increase of *Cryptosporidium* infections in the Netherlands, the UK and Germany in 2012	EFSA
3	Alternatives to Bisphenol A for food contact material applications	EFSA
4	Lumpy Skin Disease	CELCAA
5	Cyanotoxins in food	EFSA
6	Potential synergistic toxicity: cadmium and chlorpyrifos	EFSA
7	Wheat crop: low quality and poor yield	EFSA
8	Fish substitution and mislabelling	EFSA
9	Masked mycotoxins	EFSA
10	Epigenetic endpoints in chemical risk assessment regulatory testing	EFSA
11	Presentation of nutritional information to consumers	Copa Cogeca

3.1.1. *Clostridium difficile*

Description of the issue

C. difficile is an anaerobic spore forming bacterium, widely distributed in soil and intestinal tracts of animals. The clinical spectrum of *C. difficile* infection (CDI) ranges from mild diarrhoea to severe life threatening pseudomembranous colitis. The disease is not always associated with previous antibiotic use, although this is often indicated as a risk factor. The transmission of *C. difficile* can be patient-to-patient, via contaminated hands of healthcare workers or by environmental contamination[6].

ECDC funded a hospital based survey on *C.difficile* infection in Europe (Bauer et al., 2011). According to it, the most common PCR ribotypes in Europe were 014 and 020 (found in 19 countries), 001 (in 13 countries) and 078 (in 18 countries); PCR-ribotype 027 ranked sixth and was reported in 6 countries.

Although previously considered as a primarily hospital- or health-care acquired infection, since the 1990's community acquired *C. difficile* infections have been increasingly reported (Jones et al., 2012). *C. difficile* has been isolated from food producing animals (Keel et al,. 2007) and different kinds of food, raising concerns that it might also be a zoonotic or foodborne pathogen (Metcalf, 2010),

[5] The definition of "emerging issue" is given under section 1 "Introduction"

[6] http://ecdc.europa.eu/EN/HEALTHTOPICS/CLOSTRIDIUM_DIFFICILE_INFECTION/BASIC_FACTS/Pages/basic_facts.aspx

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although, to date, direct transmission from animals and food products to humans has not been proven (Hensgens et al., 2012).

In the Netherlands, an overlap between the location of pig farms and the occurrence of human *C. difficile* ribotype 078 infections, which were increasing in prevalence, was observed by Goorhuis et al. (2008). Whilst surveillance data on pig farms were lacking and a zoonotic transmission was never demonstrated, the fact that infections with ribotype 078 in humans occurred in a younger population and were more frequently community-acquired than infections with ribotype 027 strains, together with the fact that 078 was the predominant PCR ribotype in piglets, suggested a common source (Goorhuis et al., 2008). Hensgens et al. (2012) commented that this common source is likely to be the environment.

Key points from the discussion and the conclusions

StaCG-ER commented that this is a public health issue and was not sure if it is a food safety issue as the role of food as vehicle for infection is not clear. *C. difficile* was identified in the gastrointestinal track of a fraction of the total human population asymptomatically (2-4%).

In a poster presented at European Society of Clinical Microbiology and Infectious Diseases conference in London in 2012[7], Søes and co-workers presented the results of a case-control risk factor study about community-acquired CDI. The results of the study suggest at least weekly intake of beef as a possible risk factor for CDI, but further studies are needed to confirm this finding and clarify whether there is a causal relation between beef consumption and CDI.

The group believed that the following areas should be monitored:

- Typing of the isolates among the community acquired infections;
- Survival of *C. difficile* and toxin production in different food matrixes and packaging conditions;
- Establishment of *C. difficile* in the gut flora.

The group believed that there are not enough data for a risk assessment. Instead, EFSA could consider preparing a position paper describing the available information and if *C. difficile* posses a risk for foodborne or zoonotic transmission.

3.1.2. Increase of *Cryptosporidium* infections in the Netherlands, the UK and Germany in 2012

Description of the issue

Fournet et al. (2013) reported an "unprecedented increase of *Cryptosporidium* infections" in the Netherlands, as well as an "unexpected excess of cases" in parts of the UK (England, Wales and Scotland) and Germany in August 2012, compared to former years. This observed increase in cryptosporidiosis notifications is likely to be real, and not due to surveillance or notification artefacts

[7] Narrow spectrum penicillins and exposure to beef as risk factors for C. difficile infection in community. A case-control study among patients attending general practice in Denmark. Lillian Marie Søes Copenhagen, Denmark. L. M. Søes, H. M. Holt, S. Ethelberg, K. Mølbak, B. Böttiger, H. V. Nielsen, V. Andreasen, M. Kemp, K. E. P. Olsen (Copenhagen, Odense, Roskilde, DK). 03 April 2012; Abstract (poster session); Clostridium difficile; ECCMID 2012, London, United Kingdom. http://www.escmid.org/escmid_library/online_lecture_library/?search=1&current_page=1&search_term=S%C3%B8es&entrytitle%5B%5D=1597

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(ECDC, 2012). Finland also reported two ongoing outbreaks caused by *C. parvum* (Fournet et al., 2013). No other European countries reported an increase of *Cryptosporidium* infections.

The available information from investigations in the three countries does not indicate that there is a single common source, and suggests a combination of causes. These may include climatic drivers, such as the increased rainfall in summer 2012 in these countries or a widely distributed commonly consumed product. However, there is no evidence for it so far and further investigations are ongoing (ECDC, 2012).

Faecal-oral transmission of the parasite can occur directly through person-to-person and animal-to-person routes or indirectly through environmental vehicles (e.g. contaminated water and food) (HPA, 2012).

Ingestion of contaminated drinking water and recreational water is the most common mode of *Cryptosporidium* transmission (ECDC, 2012). Food-borne outbreaks on the other hand, are less often detected and described than water-borne outbreaks (Gherasim et al., 2012).

Food-borne outbreaks of cryptosporidiosis infections have been documented in association with raw or insufficiently pasteurised milk, unpasteurised apple juice, and raw produce, including parsley, green onions, and chicken salad as well as transmission via food handlers. *Cryptosporidium* oocysts have been detected in bottled water in Brazil and Mexico, but at a low concentration as well as in shellfish, vegetables and fruit (ECDC, 2012).

The overall threat for citizens in the EU due to this incident is considered to be low (ECDC, 2012). However, the increased number of cryptosporidiosis infections in three EU countries in the same period of time is unusual and might indicate an increasing trend that could be of public health concern (Fournet et al., 2013). This concern is particularly associated with altered climatic patterns potentially leading to water-borne outbreaks, as well as specific food vehicle(s) potentially implicated and not yet identified.

Key points from the discussion and the conclusions

The group provided the following information:

- On occurrence, outbreaks in the UK and internationally, disinfection methods, inactivation in food and beverages, and control in water and food production.
- In the UK, the HPA published[8] on 19 March 2013 findings of an investigation into an outbreak of *Cryptosporidium* infection that affected around 300 people in England and Scotland in May 2012. The findings "showed strong evidence of an association with eating pre-cut bagged salad products which are likely to have been labelled as 'ready-to-eat'. The outbreak was short lived and the numbers of cases returned to expected seasonal levels within a month of the first cases being reported. Most of those affected had a mild to moderate form of illness and there were no deaths associated with the outbreak".
- In Ireland, the source of the infections is more often related to contamination of drinking water through access to water from private wells rather than being foodborne.
- In Denmark, *Cryptosporidium* is not notifiable and is not considered as high risk, because ground water is used primarily instead of surface water.
- In Slovenia, testing for *Cryptosporidium* is part of the official drinking water control, but is not included in regular food testing.

[8] http://www.hpa.org.uk/NewsCentre/NationalPressReleases/2013PressReleases/130319Investigationintoanoutbreakofcryptosporidium/

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- According to a report of Havelaar et al. on the disease burden of food-related pathogens in the Netherlands (2012), the disease burden caused by *Cryptosporidium spp* was estimated as 76 DALY (Disability Adjusted Life Years) in the Netherlands in 2010. This estimation was extrapolated from trends until 2007 representing the second lowest disease burden (after Hepatitis E) compared to other 13 enteric pathogens included in the report (including thermophilic *Campylobacter* spp, Shiga-toxin *Escherichia coli* O157, etc.).
- A possible source of infection could be drinking water contaminated by manure.

The group concluded that more data are required to confirm a trend, as *Cryptosporidium* is established in these countries and infections are not always related to food. Increased reporting may be linked to increased surveillance.

It recommended that EFSA could examine the effect of flooding as a driver of introducing chemical and biological hazards into the food chain.

3.1.3. Alternatives to Bisphenol A for food contact material applications

Description of the issue

Currently, there is considerable debate regarding the toxicity of Bisphenol A (BPA) below threshold levels set by public health agencies. Consequently, decision makers may further restrict the use of BPA in Europe or manufacturers may cease its use and as a consequence a number of alternative chemicals are being investigated. Two documents were recently published regarding alternatives to BPA and the available hazard/toxicological data for these substances by ANSES (June 2012) and the US-EPA (July 2012):

- ANSES published a note on alternatives to BPA after consulting national and international experts from (i) a call for data to agencies, industry and academia (September 2011); (ii) literature searches (up until February 2012) and (iii) phone interviews with representatives from industry. In the note, 73 alternatives of BPA were identified.
- Tables summarising available toxicity/hazard data for the alternatives can be found in the report (Annex 2) and a more detailed analysis was published in March 2013[9].
- The US-EPA published a hazard assessment summarising the toxicological and environmental hazards of BPA itself and each of 20 alternative chemicals that were identified as potential functional substitutes for BPA in thermal paper. Criteria were used for mammalian and environmental toxicity to classify the chemicals from very high to very low toxicity (very high, high, moderate, low, very low). It is noted in the report that the hazard profiles include the assessment of unchanged starting materials, by-products, and impurities.

Key points from the discussion and the conclusions

The group noted that:

- According to the Regulation on plastic materials and articles intended to come into contact with food, a substance may be used in the manufacture of plastic materials and articles only if it is authorised. New substances, such as alternatives of BPA, have to undergo a scientific evaluation first. The use of substances in other applications (such as paper, coatings etc.) is not covered by the above Regulation and thus alternatives of BPA for such use are not subject to a mandatory scientific evaluation at EU level, but would need to comply with the Framework Regulation 1935/2004/EC.

[9] http://www.anses.fr/fr/documents/CHIM2009sa0331Ra-3.pdf

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- BPA has been checked for decades, whereas information and data for alternatives will not be available in the near future. Moreover, due to data ownership, it is difficult to find data on specific substances.
- The discussion on replacing BPA is hazard based and not risk based. Alternatives could introduce other food safety issues e.g. higher migration, problems with the integrity of the packaging, microbial contamination. Overall, there are uncertainties on the potential risks that these alternatives can introduce into the food chain.

The group believed that information is lacking in the following areas:

- Criteria for selecting alternatives to BPA taking into consideration both food safety issues and technological characteristics important for packaging material, e.g. being less estrogenic than BPA, but at the same time having reasonable stability during processing and ensuring the integrity of the food product throughout its shelf life.
- Preparation of food contact materials using these alternatives.

StaCG-ER recommended that EFSA should monitor the issue, consult the packaging industry and bring it to the Standing Working Group on emerging risks.

3.1.4. Lumpy Skin Disease

Description of the issue

Lumpy skin disease (LSD) is an infectious, occasionally fatal disease of cattle characterized by nodules on the skin and other parts of the body. Traditionally, it is found in southern and eastern Africa but, in recent years, has extended northwest through the continent into sub-Saharan West Africa, however two outbreaks have been confirmed in Israel in 2007 and 2012, one in Lebanon in 2013 and three in Turkey in 2013[10]. Although the mortality rate is usually low, the disease is of major economic importance due to production losses resulting from severe emaciation, lowered milk production, abortion, secondary mastitis, loss of fertility, extensive damage to hides, and a loss of draft from lameness.

LSD is not a zoonosis and is a compulsorily notifiable disease according to the EU legislation[11].

Key points from the discussion and the conclusions

The group recommended that EFSA should monitor the issue i.e. the spread of the outbreaks and information on the role of the vectors. It suggested experts that EFSA could consult on the subject as well as relevant scientific papers.

3.1.5. Cyanotoxins in food supplements

Description of the issue

Food supplements containing cyanobacteria also called "blue-green algae products" (BGAS products) are sold as nutraceuticals. *Aphanizomenon flos aquae* (*A. flos aquae*) is one of the most commonly used species for the production of BGAS, usually collected from the natural environment, where other potentially toxic cyanobacteria as *Microcystis sp.* can be present, causing BGAS contamination by

[10] http://www.oie.int/wahis_2/public/wahid.php/Reviewreport/Review?page_refer=MapFullEventReport&reportid=14174

[11] Council Directive 92/119/EEC introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease.

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cyanotoxins, such as microcystins (MCs). MCs are hepatoxic and classified by the International Agency for Research and Cancer (IARC) as possibly carcinogenic to humans (group 2B).

Different brands (17) of BGAS products available on the Italian market were sampled to detect and quantify MCs (Vichi et al., 2012). Almost all of the *A. flos aquae*-containing products were contaminated, with approximately 40% having total MCs levels exceeding 1 μg/g, the guidance value for BGAS proposed by Oregon Dept. Agriculture (Gilroy et al., 2000) from a provisional TDI (0.04 ug/kg BW/day) set by WHO for drinking water (WHO, 1998 and 2006).

Cyanobacterial toxin exposure is also known to occur through the consumption of contaminated drinking water or food (mainly due to bioaccumulation in fishes and shellfishes living in toxin-rich waters), and through oral, inhalation or dermal contact with contaminated waters during recreational activities (Dietrich and Hoeger, 2005; Ibelings et al., 2007).

Many gaps in the area of risk assessment need to be investigated, including the toxicological profile of the different cyanotoxins produced by cyanobacteria used in BGAS, as well as exposure scenarios in general and susceptible population from contaminated food supplements.

Key points from the discussion and the conclusions

The group commented that BGAS product manufacturers should have in place good manufacturing practices and HACCP plans in order to ensure that the products they bring on the market are safe for consumption. Importation of fish from warm water areas into the EU may represent another route of exposure.

The group concluded that more data on this issue need to be generated on chronic and acute toxicity for the different congeners, as well as on supporting an exposure assessment.

3.1.6. An example of potential synergistic toxicity: cadmium and chlorpyrifos

Description of the issue

Risk assessment of chemical mixtures is a complex topic that has received increased attention in the scientific literature and the media, particularly with regards to the potential environmental and human risks associated with combined exposures to multiple chemicals via the diet and other routes of exposure (e.g. inhalation, dermal absorption). This topic is of high priority for EFSA, as indicated in the Science Strategy 2012-2016 and has been identified as an area that would need further development and harmonisation.

A recent study reports the formation of a complex between chlorpyrifos (used as plant protection product) and cadmium together with *in vitro* evidence for synergistic toxicity. The complex was shown to exhibit synergistic *in vitro* hepatoxicity due to the complex-facilitated intracellular transport associated with oxidative stress leading to cell death (Chen et al., 2013). However, no *in vivo* toxicological study has been performed to investigate whether the complex between cadmium and chlorpyrifos forms *in vivo* and whether it consequently leads to synergistic toxicity.

Chlorpyrifos is approved in the EU[12]. Authorisations for specific crops are delivered at national level based on risk assessment on MS level.

[12] EU pesticides database: http://ec.europa.eu/sanco_pesticides/public/index.cfm?event=activesubstance.detail

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Key points from the discussion and the conclusions

The group noted that chlorpyrifos has high sales in EU, due to the fact that it offers a wide application and has relatively low cost. According to the group, from laboratory tests, chlorpyrifos is usually detected in vegetables (e.g. cucumbers, lettuce), fruit (e.g. peaches, citrus), oils and olives. The usual detected concentration in these products is around 0,05mg/kg.

The group commented that it is difficult to extrapolate the results of one *in vitro* study and assess if this is an emerging issue or perform a risk assessment of this mixture. Synergistic toxicity of heavy metals and pesticides may be an emerging issue, however, more data (including *in vivo* studies) need to be available in order to assess whether this specific combination of cadmium and chlorpyrifos could be an of importance.

If synergistic toxicity of cadmium and chlorpyrifos is proven, then consideration should be given to geographical areas where chlorpyrifos is applied and at the same time the water used for irrigation or the water used to prepare the pesticide solution is contaminated with cadmium.

StaCG-ER suggested that EFSA should monitor the issue of synergistic effects of chemical mixtures.

3.1.7. Wheat crop: low quality and poor yield

Description of the issue

Unfavourable weather conditions in some MSs affecting wheat harvests leading to low yields in 2012 and 2013, were producing shortages and potentially poor quality material reaching the market. There was evidence to suggest that manufacturers are using alternative sources of wheat and are, in some cases, halting the production of particular products.

StaCG-ER was requested to reflect on the subject in order to assess potential emerging issues, that could be rising, for example, from mycotoxins, adulteration of raw materials, from the types of alternatives to be used, fraud issues, quality issues and the changes of agricultural practises that may be needed in order to address these consequences in long-term.

Key points from the discussion and the conclusions

The group noted that:

- Issues related to the quality and availability of raw materials is something that food and feed manufacturers always have to deal with. In such cases, another source has to be found or another substitute ingredient has to be used. In both cases, the manufacturers have to ensure that the raw materials and the final products meet the legal requirements on food safety.
- Whilst feed production substitution is done on the basis of maintaining the nutrient balance, substitution in food production needs testing prior to its implementation as other characteristics have to be considered such as texture and flavour.
- Substitution of ingredients may alter the dietary intake of nutrients; moreover, substitution of foods may add to uncertainty as the data used for exposure assessment might no longer reflect the actual consumption patterns of the given population and/or previous exposure assessments may no longer be valid.
- Climate change leading to warmer climate would be more favourable for the proliferation of insect pests, because many insects can then complete a greater number of reproductive cycles. Warmer winter temperatures may also allow pests to overwinter in areas where they are now limited by cold, thus causing greater and earlier infestation during the following

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crop season. A similar situation may be seen for plant diseases leading to an increased demand for pesticide control (Bindi and Olesen, 2011).

- The toolbox for farmers allowing prevention of mycotoxin development is reduced by the fact that the number of authorised active ingredients has been decreased.
- An assessment of the socio-economic importance of azole active substances (fungicides) in European agriculture considering the specific case study of wheat was published recently (Nomisma, 2012). According to it, the yield of wheat would decrease in the hypothesis that the use of azoles ceased, resulting in a loss of production (leaving all other variables constant) of 9.8 millions of tons in 2013 (from 141.1 to 131.3) and 18.6 millions of tons in 2020 (from 152.4 to 133.8). This scenario of decreasing production would mean that the EU would be unable to satisfy its internal demand and maintain a 100% self-sufficiency rate for wheat, if alternatives are not found.
- This season, the price of wheat is decreasing (as for July 2013).

The group recommended that more research is needed on the effect of climate change on mycotoxin production, as well as on practical, applicable and economic tools that farmers/food producers could use in order to minimise mycotoxin production.

3.1.8. Fish substitution and mislabelling

Description of the issue

Official figures show that global consumption of fish and seafood per person is rising steeply, but research also reveals frequent mislabelling of fish and fish products.

Some examples are:

- Scientific testing reveals that the traditional cod or haddock and chips, as sold in the UK, are often something else entirely. Research reveals that 7% of cod and haddock - the deep-fried staples of British fish and chips - actually turn out to be cheaper fish, substituted to cut costs[13].
- In the United States, a study showed that 25% of the fish served in restaurants in New York were not what they were said to be on the menu. In Europe, about a quarter to a third of fish products tested turned out to be not what was described on the packet or menu[14].
- The Food Safety Authority of Ireland issued the results of its labelling survey of fish and fish products, which found that 19% of products sampled were labelled incorrectly (FSAI, 2011). Out of the 111 samples analysed (100 un-smoked fish products and 11 smoked fish products), a total of 20 were found to be mislabelled as cod and one was mislabelled as smoked haddock.

Miller et al. (2011) tested 226 cod products purchased from Ireland and the UK and compared them against product labels. Cod mislabelling proved more severe in Ireland than in the UK (28.4% vs. 7.4%). Moreover, whereas data show that in Ireland, cheaper species are sold as cod, in the UK, threatened Atlantic cod (*Gadus morhua*) may be sold as 'sustainable sourced' Pacific cod.

Commission Regulation (EC) No 2065/2001 laying down detailed rules for the application of Council Regulation (EC) No 104/2000 as regards informing consumers about fishery and aquaculture products.

In addition, two regulations addressing Illegal, Unreported and Unregulated (IUU) fishing and fisheries control have been implemented; Council Regulation (EC) No 1005/2008 establishing a Community system to prevent, deter and eliminate illegal, unreported and unregulated fishing, the so-

[13] http://www.bbc.co.uk/news/uk-northern-ireland-22203709
[14] http://www.bbc.co.uk/news/world-europe-21993684

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called 'IUU regulation', introducing a catch certification scheme, and Regulation (EC) No 1224/2009 which overhauls the preceding control scheme, and puts emphasis on traceability in support of fisheries control and control along the supply chain.

Drivers such as expected higher profit, consumer demand for specific fish species and increasing scarcity of certain fish species lead to economically motivated substitution of fish and fish products. This phenomenon increases the uncertainty of exposure to known hazards due to loss of traceability.

Key points from the discussion and the conclusions

The Group commented that food fraud is a risk management issue; more information is needed to confirm whether food safety issues are involved with fish substitution and mislabelling, such as the species used, their origin and past incidents related to these species and origin. For example, RASFF data show that *Pangasius* catfish from Vietnam or Tilapia species from China were found to be contaminated with antibiotics and chemical contaminants.

Whilst no specific hazards were identified due to fish mislabelling, this practise is proposed as a driver of emerging risks.

DG SANCO has recently created a Food Fraud Team and established an EU Food Fraud Network with Member States to reinforce cooperation on food fraud matters.

The group recommended that EFSA could:

- Consider likely scenarios of fish substitution and mislabelling with a view to identifying which species are expected to be involved; the next step would be to characterise the hazards and likelihood of occurrence behind the substitution and mislabelling;
- Bring this issue to the Food Fraud Team of DG SANCO for discussion in order to avoid duplication of efforts.

3.1.9. Masked mycotoxins

Description of the issue

Mycotoxins are secondary fungal metabolites, toxic to human and animals. Toxigenic fungi often grow on edible plants, thus contaminating food and feed. Plants, as living organisms, can alter the chemical structure of mycotoxins. The extractable conjugated or non-extractable bound mycotoxins formed remain present in the plant tissue, but are currently neither routinely screened for in food nor regulated by legislation, thus they may be considered masked (Berthiller et al., 2013).

Fusarium mycotoxins (deoxynivalenol (DON), zearalenone, fumonisins, nivalenol, fusarenon-X, T-2 toxin, HT-2 toxin, fusaric acid) are prone to metabolisation or binding by plants. Risk assessment studies of parent mycotoxins make no or limited reference to the masked form of these *Fusarium* toxins. A number of *in vivo* and *in vitro* studies suggest that cleavage of masked mycotoxins back to their toxic parents, e.g. during mammalian digestion, may possibly be contributing to the exposure of humans and animals to these substances (for example: Dall' Erta et al., 2013; Gratz et al., 2013; Berthiller *et at.*, 2011; De Nijs et al., 2012; Nagl et al., 2012; Versilovskis et al., 2012).

EFSA received two requests[15&16] from the European Commission for scientific opinions on the risks for public health and animal health related to the presence of metabolites and the masked or bound forms of certain mycotoxins (DON, zearalenone, fumonisins, nivalenol, T-2 toxin, HT-2 toxin) in food and feed. The opinions should be delivered by December 2014.

[15] EFSA mandate M-2013-0260
[16] EFSA mandate M-2013-0258

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Key points from the discussion and the conclusions

The group suggested experts that EFSA could consult on the subject as well as relevant scientific papers. It also considered that this is an issue of concern and encouraged EFSA to continue working in this area.

3.1.10. Epigenetic endpoints in chemical risk assessment regulatory testing

Description of the issue

New insights into the long-term health effects of exposure to chemical hazards show that a previously underestimated endpoint may merit taking into consideration for risk assessment. Epigenetic[17] modulations underlie critical developmental processes and contribute to determining adult phenotype. Alterations to the phenotype, due to exposure to environmental insults (e.g. chemical hazards) during sensitive periods of development, are mediated through alterations in epigenetic programming in affected tissues, the outcome of which can have lifelong health implications for current and subsequent generations.

In their reviews, the OECD (2012) and Greally and Jacobs (2013) included an evaluation of the potential role of chemical-induced epigenetic modifications to endocrine signalling pathways, during sensitive windows of exposure, as a mechanism of endocrine disruption, along with the examination of potential methods for assessing such disruption. Many food and feed ingredients, contaminants, packaging materials, pesticides and biocides are putatively endocrine active substances, and some are potentially also endocrine disruptors.

Key points from the discussion and the conclusions

The group commented that the scientific community is divided on this issue and a lot of debate is ongoing since it is new territory and more research is needed, for example, to improve knowledge on the links between the modulation of the epigenome and associated phenotypes. In order to use such biomarkers for predicting alteration to endocrine activity, more knowledge needs to be developed. However, it may be a promising tool for evaluating endocrine activity.

StaCG-ER suggested that in general, EFSA should follow the development of new methods for chemical risk assessment, including assessment of endocrine disruption, with a view to integrating them into its palette of risk assessment approaches.

3.1.11. Presentation of nutritional information to consumers

Description of the issue

Regulation (EU) 1169/2011[18] is the major piece of EU food legislation on information to the end consumers. It repeals previous Directives on food labelling and harmonises aspects such as health claims and nutritional information among the Member States. It was brought for discussion as it was felt that some aspects of it could potentially mislead consumers, such as the possibility of using

[17] The word "epigenome" is derived from "epigenetics "the branch of biology which studies the causal interactions between genes and their products, which bring the phenotype into being." The term "epigenetic" was resurrected more recently as a broad description of heritable processes that do not depend on changes in DNA sequence, to include phenomena such as genomic imprinting and X chromosome inactivation. "Epigenome" represents the collective noun to describe the sum of the epigenetic modifications throughout the genome. See Greally and Jacobs, 2013.

[18] Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004.

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different methods of risk communication at national level and the way that nutritional information is presented on the label.

Key points from the discussion and the conclusions

The group recognised that changes in the regulatory framework have been identified as a potential driver of emerging risks in the scientific literature. However, in this example, no specific emerging issue could be identified. Moreover, the implementation of the Regulation at national and European level is a risk management issue, whereas EFSA's role is on risk assessment and risk communication.

3.2. Update on drivers and emerging risks identification methodology

StaCG-ER did not report additional drivers of emerging risks and methodology applied for emerging risks identification in the food and feed sector organisations other than what is already described in the report of the first StaCG-ER mandate (EFSA, 2011).

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CONCLUSIONS

The group discussed 11 potential emerging issues during 2013, two of which originated from the group. Members brought to the attention of EFSA additional data and useful information on these issues, for example prioritisation criteria and additional scientific evidence, as well as recommendations, such as consultation with other organisations and areas for further scientific research. These contributions have added to the overall approach established in EFSA for the identification of emerging risks, concretely;

- For Lumpy Skin Disease, an issue raised by the StaCGER, the EC has since sent a mandate to EFSA to address this in detail.
- Mandates from the EC on masked mycotoxins are already with EFSA.
- Information on fish mislabelling has been forwarded to the newly formed food fraud team at the EC.
- *Clostridium difficile* as a potential food borne zoonoses has been monitored by EFSA's BIOHAZ unit, and will continue to be monitored for new developments by EFSA.
- The issue of epigenetic endpoints in risk assessment will be raised with the EFSA's standing working group on Emerging Risks, as will alternatives to BPA.
- The risk assessment of chemical mixtures is being addressed through a series of outsourced data gathering activities, aimed at building on the approach being developed at EFSA in the area of pesticides, with a view to having a horizontal approach applicable to all areas of chemical risk assessment.
- Outsourcing of a review on presence of cyanotoxins in food supplements is being considered.
- The issues of increased *Crypospordium* infections, and reduced quality and yield of wheat crops will be considered under the activity on the identification of drivers of emerging risks (in both these cases, there appears to be a link to climate and potentially climate change), of the standing working group.
- The implications of the introduction of Regulation (EU) 1169/2011 on information to consumers were considered as being outside the remit of EFSA.

The mandate of this group expired in end 2013. Following the recommendation of the Stakeholder Consultative Platform and in order to continue to exchange in a constructive way with stakeholders on both signals of potential emerging risks and also on data concerning potential identified risks, the Scientific Committee and Emerging Risks Unit renewed the mandate of the StaCG-ER for another two years (2014-2015).

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ABBREVIATIONS

ANSES	French Agency for Food, Environmental and Occupational Health Safety
BGAS	Blue-green algae products
BPA	Bisphenol A
CDI	*Clostridium difficile* infection
DG SANCO	Directorate General for Health and Consumers
DON	deoxynivalenol
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
ECPA	European Crop Protection Association
EPA	US Environmental Protection Agency
EU	European Union
FSAI	Food Safety Authority of Ireland
HACCP	Hazard Analysis Critical Control Points
HPA	Health Protection Agency of the UK
LSD	Lumpy Skin Disease
MCs	Microcystins
MS	Member State of the European Union
NOAEL	No-Observed Adverse Effect Levels
OECD	Organisation for Economic Co-operation and Development
SCER	Scientific Committee and Emerging Risks unit of EFSA
SCP	EFSA's Stakeholder Consultative Platform
StaCG-ER	Stakeholder Consultative Group on Emerging Risks
WHO	World Health Organisation

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APPENDIX

BRIEFING NOTE TEMPLATE

Stakeholder Consultative Group on Emerging Risks (StaCG-ER)

(This is a template for "Briefing notes on emerging issues" identified by a member of the StaCG-ER)

BRIEFING NOTE ON EMERGING ISSUES[19]

Updated by [NAME] on DD MM YYYY

Presented to StaCG-ER MTG on DD MM YYYY

The scope of this briefing note is to present emerging issues identified by a member of StaCG-ER or EFSA to the Group. StaCG-ER is requested to (i) evaluate the relevance of the issue presented and (ii) facilitate the exchange of any relevant information. The information provided in this briefing note is not comprehensive and is intended as a quick summary and a point of departure.

Title and ID

DESCRIPTION OF THE ISSUE

Include a short description of the issue, mentioning the hazard under evaluation (e.g. which virus, bacteria, parasite, contaminant, driver etc). Use the following criteria to explain why do you consider this an emerging issue. Evaluation criteria to be considered include at least one of the four main criteria listed under "Evaluation".

ADDITIONAL SUPPORTING INFORMATION

Provide any additional background information you believe is important in order to support the evaluation of the issue. For example:

- *Any additional information on the source of information (scientific or grey literature, , experts, surveillance systems…);*
- *Limitations of the analysis/study;*
- *Toxicological information of this (or similar) agents/compounds;*
- *Any other information you believe is important.*
- *Is this related to any other issues already discussed in StaCG-ER meetings.*

[19] "*Emerging issues"* are identified at the beginning as issues that may merit further investigation and additional data collection. Emerging issues can include specific issues (*e.g.* specific chemical substance or a pathogen), as well as general issues such as drivers of change (*e.g.* climate change). Risk management issues resulting from a lack of compliance with existing regulations should be excluded.

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LEGAL AND INSTITUTIONAL ASPECTS

- *Report the results of a basic search for (i) EFSA risk assessment or action, (ii) legislation on the subject or (iii) institutional reporting (e.g. documents from the European Commission, and European or international food safety authorities/risk assessment bodies).*

EVALUATION

Main criteria

- **Driver:** *(e.g. is this a new driver?)*
- **New hazard:** *(e.g. Has a new hazard been identified? If so, which one and how?)*
- **New or increased exposure:** *(e.g. Has a possible exposure through food/feed to the new hazard been identified?)*
- **New susceptible group:** *(e.g. Has a new vulnerable group been identified?)*

Other qualifying criteria

In addition, the following criteria can be addressed <u>if you have information readily available</u>

- **Soundness:** *(e.g. What is the reliability of sources of information? e.g. peer-reviewed journals)*
- **Severity:** *(e.g. What could be the severity of the health effects in terms of morbidity and/or mortality?)*
- **Imminence:** *(e.g. how soon it is estimated that the potential hazard will manifest in the food, feed, environment? How soon is it estimated that this health risk will manifest in the population?)*
- **Scale:** *(e.g. number of people and Member States potentially exposed?), e.g. days, months, years)*

Conclusions: *Enter a brief summary of the reasoning that led to identify this as an emerging issue.*

QUESTIONS FOR STACG-ER

1. Have you already identified this issue before? □ Yes □ No □ Not sure
2. Do you have any additional information/data on this issue? □ Yes □ No □ Not sure
3. Do you believe that this is an emerging issue? □ Yes □ No □ Not sure
4. Should StaCG-ER start exchanging information on the issue? □ Yes □ No □ Not sure
5. [other]

STACG-ER COMMENTS: _____

STACG-ER RECOMMENDATIONS (EXAMPLES)

1. EFSA should monitor the issue.

2. EFSA should consult other bodies (please indicate which).

3. EMRISK should bring the issue to the Standing WG on emerging risks (primary filter) with a view to:

- reviewing this issue aiming at publishing a report;
- starting a project to generate data on this issue (e.g. outsourcing);
- starting a risk assessment.

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APPENDIX D

INTERNAL REPORT

Horizon 2020[1]: 2013 Consultation of EFSA panels, Units, the Scientific Committee and the Advisory Forum Regarding Priority Research Topics

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

[1] Follow up of EFSA Question Number EFSA-Q-2012-00227. Approved on 30/08/2012.

[2] Correspondence: scer@efsa.europa.eu

SUMMARY

In 2011, the European Commission drafted proposals for a Regulation to establish Horizon 2020, the next Framework Programme for Research and Innovation (2014-2020) bringing together three separate programmes/initiatives: the 7th Research Framework Programme (FP7), Innovation aspects of Competitiveness and Innovation Framework Programme (CIP) and an EU contribution to the European Institute of Innovation and Technology (EIT). The European Commission has agreed the proposals for Horizon 2020 and the final agreement of the European Parliament and the launch of the first calls is expected by the end of 2014.

Horizon 2020 has three main research priorities (corresponding to three "Parts" in the programme document) namely: Part I: Excellent Science; Part II: Industrial Leadership; Part III: Societal Challenges.

EFSA's activities and the related research areas fall under **Part III of Horizon 2020 "Societal Challenges"** under the following headings:

1. ***Health, Demographic change and wellbeing***
   1.1 Understanding determinants of health, improving health promotion and disease prevention.
   1.3 Improving surveillance and preparedness
   1.4 Understanding disease
   1.11 Improving scientific tools and methods to support policy making and regulatory needs

2. ***European Bioeconomy Challenges: Food Security, Sustainable Agriculture and Forestry, Marine and Maritime Research***
   2.1 Sustainable Agriculture enhancing food security and the provision of public goods
   2.2 Sustainable and competitive agri-food sector for a safe and healthy diet
   2.2.1 Informed consumer choices
   2.2.2 Health and safe foods and diets for all
   2.2.3 A sustainable and competitive agri-food industry

   (Note: numbering refers to numbering of Horizon 2020 topic headings.)

In 2012[3], 8 research priority areas were identified by EFSA after consulting with the Advisory Forum (AF), Advisory Forum Consultation Working Group (AFCWG), and EFSA's Scientific Panels and Units and the Scientific Committee (SC). Following dialogue with Director-General Research and Innovation (DG-R&I) and Director-General Research Agriculture and Rural development (DG-AGRI), these 8 thematic research priorities were rearranged under the appropriate Horizon 2020 headings and communicated on the 7th September 2012 in the form of an internal report and a letter to DG- DG-R&I, DG-AGRI and Director General health and Consumers (DG-SANCO).

Between February and April 2013, further consultation of EFSA panels and units, the SC, the AF reaffirmed the 8 topics of priority and identified all together 56 topics under the Horizon 2020 headings and sub-headings. Since Horizon 2020 objectives are closely linked to the Europe 2020 strategy, the 56 priority proposals identified during this consultation exercise for the food safety area need to be aligned with the broad principles of the Europe 2020 strategy.

In the development of the specific work programme for Horizon 2020, it is expected that the EC will further detail how food safety is relevant in the different activity areas. These priority research topics should be communicated to DG R&I, DG-AGRI and DG-SANCO to further support the prioritisation of research within the Horizon 2020 context. Finally, a similar yearly consultation exercise is foreseen at EFSA to provide timely support to DG R&I, DG-AGRI and DG-SANCO and priority areas for the launching of the first specific Horizon 2020 calls.

[3] EFSA-Q-2010-00922 Report of the Task Force on identifying research priorities for submission to DG Research (IN18)

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BACKGROUND AND INTRODUCTION

In 2011, the European Commission drafted proposals for a Regulation to establish Horizon 2020, the next Framework Programme for Research and Innovation (2014-2020) bringing together three separate programmes/initiatives: the 7th research Framework Programme (FP7), innovation aspects of Competitiveness and Innovation Framework Programme (CIP) and an EU contribution to the European Institute of Innovation and Technology (EIT). The European Commission has agreed the proposals for Horizon 2020 and it is expected that final agreement of the European Parliament will be reached in 2013, with the launch of the first calls expected in 2014.

Horizon 2020 has three main research priorities (corresponding to three "Parts" in the programme document) namely:

- Part I: Excellent Science
- Part II: Industrial Leadership
- Part III: Societal Challenges

All official documents for the establishment of Horizon 2020, including a Communication of the Commission, proposals for regulation by the European parliament and Council and an impact assessment report, can be found under: http://ec.europa.eu/research/horizon2020/index_en.cfm?pg=h2020-documents

The identification of research priorities and the communication of such priorities to Commission services (Director-General Research and Innovation (DG-R&I) and Director-General Research Agriculture and Rural development (DG-AGRI), Directorate General health and Consumers (DG-SANCO) and the Joint Research Centre (JRC) as well as the Member States is an important aspect of EFSA Science Strategy for the strengthening of the scientific evidence for risk assessment and risk monitoring.

Within the proposal ***Part III, Societal Challenges*** relates directly to the policy priorities and societal challenges identified in the Europe 2020 Strategy including EFSA's remit: food safety. One of the main objectives in this part focuses on *Food security, sustainable agriculture, marine and maritime research, and the bio economy* with the specific objective t*o secure sufficient supplies of safe and high quality food and other bio-based products, by developing productive and resource-efficient primary production systems, fostering related ecosystem services, along side competitive and low carbon supply chains.* This is the only direct reference to safe food in the proposal. The broad lines of activities under this part include *sustainable and competitive agri-food sector for a safe and healthy diet*. It is anticipated that most of the food safety priorities will need to relate to this main line activity.

In developing the specific work programme implementing Horizon 2020, it is understood that the Commission will more directly address food safety in a number of areas. Relating to *Health, Demographic Change and Wellbeing*, there is an expectation that in *understanding the determinants of health, improving health promotion and disease prevention* (Area 1.1) linkages will be made to data derived from 'omics' and other methodologies and in the area of *improving surveillance and preparedness* (Area 1.3) there is recognition of the threats from new and emerging diseases from drug resistance to existing pathogens and from other direct and indirect consequences of climate change. Omics are also referenced in the development of new tools and approaches for understanding disease.

Food safety will also be dealt with in the context of *sustainable and competitive agri-food sector for a safe and healthy diet* (Area 2.2), where food safety innovations, risk communications tools and improved food safety standards are to be linked with consumer trust and protection in Europe in achieving healthy and safe foods and diets for all.

Overall, part III of Horizon 2020 " Societal challenges" of high relevance to EFSA's remit is structured under two main headings and sub-headings as follows:

1. ***Health, Demographic change and wellbeing***

   1.1 Understanding determinants of health, improving health promotion and disease prevention.
   1.3 Improving surveillance and preparedness
   1.4 Understanding disease
   1.11 Improving scientific tools and methods to support policy making and regulatory needs

2. ***European Bioeconomy Challenges: Food Security, Sustainable Agriculture and Forestry, Marine and Maritime Research***

   1.2 Sustainable and competitive agri-food sector for a safe and healthy diet
   2.2.1 Informed consumer choices
   2.2.2 Health and safe foods and diets for all
   2.2.3 A sustainable and competitive agri-food industry

   (Note – numbering refers to numbering of Horizon 2020 topic headings)

The approach being taken with Horizon 2020 is one which involves cross cutting actions which will lead to interactions between the areas of ***Excellent Science, Industrial Technologies and Societal Challenges***. Nanotechnologies, for example, will be addressed generally in the area of industrial leadership, though there will be cross over with the Societal Challenges in relation to food related application of the technology.

The continuation of identifying research priorities and communicating these priorities to DG R&I, DG-AGRI, DG-SANCO is an important aspect of EFSA's Science Strategy relating to strengthening the scientific evidence for risk assessment and risk monitoring. In order to support the Commission in this activity, EFSA has consulted on a number of occasions the Advisory Forum (AF), Advisory Forum Communication Working Group (AFCWG), the Scientific Committee (SC), and EFSA's Scientific Panels and Units. The first consultation of EFSA with the AF, AFCWG, the SC, EFSA's Scientific Panels and Units was performed in 2010 and followed by another consultation in 2012.

In order to prioritise research topics, each proposal was considered against five specific criteria:

1) High/Unclear Risk Level
2) Broad/Europe Wide Perspective (The issue would be relevant across the EU)
3) 'Popularity' of Issue (More than one submission on the same issue)
4) Limited Previous Research/Knowledge (The issue has not been dealt with by previous calls and/or there are gaps in the available knowledge)
5) Links to Europe 2020/Horizon 2020 Strategy issues

Overall, 8 priority areas were identified and re-affirmed by the SC in June 2012[4]. Following dialogue with the DG-R&I and the DG-AGRI, these 8 thematic research priorities were rearranged under the appropriate Horizon 2020 headings and communicated on the 7th September 2012 in the form of an internal report and a letter to DG- DG-R&I, DG-AGRI and Directorate General health and Consumers (DG-SANCO). These eight priority areas rearranged under the appropriate Horizon 2020 headings are presented in Appendix A.

Building on this, a new round of consultation was performed at EFSA in 2013 as described below in order to update EFSA's research priorities.

[4] EFSA-Q-2010-00922 Report of the Task Force on identifying research priorities for submission to DG Research (IN18)

PROCESS

In light of the 8 thematic topics identified in 2012 and the imminent launching of Horizon 2020, EFSA launched another consultation with scientific experts through its panels and SC (many of which were renewed after June 2012), Member States through the AF, between February and April 2013. This consultation aims to provide further support to DG-R&I, DG-AGRI and DG-SANCO to by indicating priority thematic areas of interest within EFSA's remit for consideration under Horizon 2020.

RESULTS: PRIORITY RESEARCH TOPICS AT EFSA

Fifty five priority research topics resulting from the EFSA 2013 consultation are presented below and have been rearranged under the appropriate headings of Horizon 2020 to provide greater clarity on how these work areas and themes link to the overall structure of Horizon 2020. In addition, it is noted that from discussions with DG-AGRI a new header (and corresponding sub-headers) "*2.1 Sustainable Agriculture enhancing food security and the provision of public goods* has been included in the consultation and priority research topics have been identified.

Part III "Societal Challenges"

1. Health, Demographic change and wellbeing

- Use of **whole genome sequencing** data for **epidemiology, outbreak investigation, surveillance and risk assessment**. This could also include an evaluation of the possibility of moving from an isolate-based surveillance to surveillance based on metagenomes – benefits and draw backs.

1.1 Understanding determinants of health, improving health promotion and disease prevention

- Better understanding of the impact of **major drivers potentially affecting the food chain in the next 10 years** (1.1 and 1.3)(priority identified in 2012 and reconfirmed in 2013)
- Change of **food consumption habits**, e.g. exposure and intake assessment in children, elderly, vegans, ethnic groups
- Urbanisation and sufficient food supply, e.g.: food safety and security of **urban agriculture**, risks of organic and local food, quality, consumption and nutritional effect
- Food safety implications linked to **increased recycling** of materials through the food and feed chain, including packaging, animal bedding and feed materials and composting and sewage disposal
- Food safety implications of trends in food production, e.g. **increased aquaculture** and farming of new aquatic species
- **Combined exposures to chemicals**: exposure to newly formed compounds, metabolites, additives from processed food products
- **Risk benefit analysis**: interdisciplinary approach and dialogue for risk assessment of food production (e.g. risk-benefit analysis of fresh vegetables)

1.3 Improving surveillance and preparedness

- Improved methodologies for the **detection of food borne pathogens**
- **Post-market monitoring of regulated substances** including combined exposures (pesticides, food additives, feed additives, food contact materials) in food producing animals and humans, e.g monitoring milk, blood, urine (1.3 and 1.11)
- **Biomonitoring of contaminants in food producing animals and humans** including combined exposures, e.g. monitoring milk, blood, urine (1.3 and 1.11).
- **Prioritisation and risk ranking** of both chemical and biological hazards based on epidemiology aspects and linkage to disease burden (1.3 and 1.11)(priority identified in 2012 and reconfirmed in 2013).

1.4 Understanding disease

- **Antimicrobial resistance**: quantifying the relative contribution of resistance genes in the food chain on the public health impact of antimicrobial resistance in general (priority identified in 2012 and reconfirmed/reformulated in 2013)
- **Variability in types and prevalence of foodborne pathogens** among geographical regions and climatic conditions as well as food handling practices among member states in the European Union
- Multidisciplinary approaches for identifying characteristics of pathogens and host-

pathogen responses associated with organisms with the potential for **international epidemics**
- **Epigenetic and epidemiology of diseases in Europe**

1.11 Improving scientific tools and methods to support policy making and regulatory needs

- Development of methods to **reduce the burden of food-borne disease** in the European Union
- Statistical basis and detection thresholds for **monitoring programmes** from theoretical and practical perspectives.
- Research on the development of new risk assessment strategies using **Omics technologies, mathematical models, QSARs, PB-PK, TTC** (priority identified in 2012 and reconfirmed in 2013)
- Methodology and approach to assess **health risks of combined exposures of the population to chemicals** (single/multiple routes of exposure, single/multiple modes of action) (priority identified in 2012 and reconfirmed in 2013)
- Methods for measuring the **fate of chemical migrants** in the food chain (including analytical techniques for measuring multiple residues, complex mixtures, impurities and thermal/chemical degradation products)
- Methods for the screening and rapid identification of **potential contaminants in regulated substances** (including food additives, in food contact materials and pesticides) including endocrine active substances/endocrine disrupters
- Implementation and validation of novel study models for the **risk assessment of nanomaterials** in Europe
- Development of methods to assess the safety of products generated by emerging plant breeding techniques, (i.e. site-directed nuclease techniques, oligonucleotide directed mutagenesis, cis- and intragenesis)
- Development of methods to identify and **characterise uncertainty in risk assessment** in the food chain
- Development of **methods to incorporate metabolism into *in vitro* tests** for both humans and test species in order to provide tools for better prediction of in vivo toxicity and alternatives to animal testing
- Development of **methods for the study of endocrine disrupters** in mammals during the complete life cycle of mammals from development exposure to old age including mechanistic assays
- Methodologies for the testing of **epigenetic toxicity and carcinogenesis of chemicals**
- Development of methods to investigate non-monotonic dose response

2 European Bioeconomy Challenges: Food Security, Sustainable Agriculture and Forestry, Marine and Maritime Research

2.1 Sustainable Agriculture enhancing food security and the provision of public goods

2.1.1 Increasing production efficiency and coping with climate change, while ensuring sustainability and resilience

- Development and validation of effective, practical and environmentally sustainable **low cost microbial food safety solutions** in the farm to fork chain
- Develop **low input and higher efficiency plant varieties and animal breeds** through conventional and modern breeding approaches (including approaches such as varietal associations, genomic selection, and new plant breeding techniques, such as cisgenesis that can introduce useful genes from cross-able sexually compatible species (i.e., breeder's gene pool) into existing plant varieties etc.)
- Research into **"orphan" / minor crops and breeds** which have been neglected in recent years (e.g. horticultural crops, ancestral varieties of commodity crops, abandoned crop types)
- Development of **animal breeds and plant varieties adapted to climate change** and/or that show greater tolerance of diseases and pests

2.1.2 Providing ecosystem services and public goods

- Develop **integrated risk assessment methodologies at the landscape level** to protect ecosystem services and wildlife in the aerial, terrestrial and aquatic environment. This includes setting protection goals for the species providing ecosystem services
- Monitor the **impact of climate change on spreading of pests and diseases**, increase risk assessment, protection and develop climate-informed crop and animal protection
- Develop detection and diagnostic tools for **monitoring plant and animal pests and diseases** (including threshold values and warning systems)
- **Improve pest and disease surveillance**, risk assessment (including develop new strategies and tools to identify and prioritise emerging risks such as new pests and pathogens of crops and animals) and control strategies (suppression, containment and eradication) for crops and animals
- Develop **test methods for endocrine disrupters in amphibians, birds and other taxa**
- Develop methods and tools to evaluate the **efficiency and effectiveness of pest and disease control** (including controls at border inspection posts)
- Investigate causes of health problems in honey bees, bumblebees and solitary bees at the individual and colony level. These include the assessment of potential interactions between multiple stressors (e.g. diseases and nutrition status) and exposure to various chemicals used in agriculture and bee keeping (e.g. pesticides, acaricides, fungicides, contaminants etc.)
- **Combined effects of chemicals (**including pesticides and contaminants) **on test species and wildlife in the aerial,** (including bees) **terrestrial and aquatic environment** in the laboratory and in the field. This includes investigation of recovery in relation to protection goals for ecosystem services

2.1.3 Empowerment of rural areas, support to policies and rural innovation

- Design suitable plant pest management strategies, in particular for the so-called minor use crops and non-traditional (e.g. biomass) crops
- Develop methods for a **holistic approach on the environmental impact of farming practices,** crop threats (e.g. plant pests and diseases, climate change effects as drought, desertification, floods etc.) and threat mitigation measures (e.g. plant protection products, resistant plant varieties, fertilisers, irrigation, etc.) to biodiversity and ecosystem services.

2.2 Sustainable and competitive agri-food sector for a safe and healthy diet

- Methodological developments for **pro-active and sustained control of animal diseases and improved animal welfare** on European farms
- Research towards an **understanding of emerging animal diseases**. These include vector-borne pathogens and diseases originating from intensified production systems. This would also involve methodological developments to assess the impact on animal health and welfare and their zoonotic potential (priority identified in 2012 and reconfirmed/reformulated in 2013)
- Methods for the **improvement of transboundary disease control** (e.g. Classical Swine Fever (CSF), Foot and Mouth Disease (FMD), African Swine Fever (ASF), Avian Influenza (AI)).

2.2.1 Informed consumer choices

- **Risk perception by and communication of priorities to stakeholders** (priority identified in 2012 and reconfirmed in 2013)
- Towards an understanding of **factors that influence risk perception of key target audiences** (e.g. complexity of the science and issues, communication strategies, impact of media, severity of effects, risk quantification, risk benefit)
- Explore the **food acceptability of crops derived from new plant breeding techniques in consumers**

2.2.2 Health and safe foods and diets for all

- **Sustainability of plant and animal production** moving away from non-renewable resources (fuel, arable area, water, minerals etc..) towards less limited resources such as sunlight, carbon dioxide, nitrogen, genetic pool etc… (2.2.2 and 2.2.3).
- **Reducing food waste** through the development of new methodologies to increase the shelf-life of perishable goods (e.g. development of chemical markers that enable prediction of durability during storage of fruits and vegetables).
- **Post market surveillance on nutritional behaviour** in relation to authorised health claims and use of food supplements, and subsequent health consequences.

2.2.3 A sustainable and competitive agri-food industry

- **Competitive food processing methods**: holistic approach involving the whole food chain/cycle i.e. environmental fate (e.g. consideration of developments of maize biofuels and impact of resultant waste) (priority identified in 2012 and reconfirmed in 2013)
- Motivational drivers, incentives, penalties, social science attitude studies etc. relating to **enhancing compliance with regulations and best practice in food production**
- **Alternate protein production** for feed and food consumption, e.g. use of insects as source of protein for animal feed (and human food)
- Development of **alternative methods for pest management** supporting the implementation of Integrated Pest Management under the Directive 2009/128/EC on the sustainable use of pesticides

CONCLUSIONS

The European Commission proposals for Horizon 2020 which are expected to be agreed by the European Parliament in 2013 set out a number of priority areas including a main objective relating to food under the heading Societal Challenges. Horizon 2020 objectives are closely linked to the Europe 2020 strategy and therefore the 56 priority research topics identified during this consultation exercise for the food safety area need to be aligned with the broad principles of the Europe 2020 strategy.

In the development of the specific work programme for Horizon 2020, it is expected that the EC will further detail how food safety is relevant in the different activity areas. In anticipation of this, the priority topics identified by EFSA, its panels, SC, AFC and AFWG have been considered under the appropriate Horizon 2020 headings. These priority research topics should be communicated to DG R&I, DG-AGRI and DG-SANCO to further support the prioritisation of research within the Horizon 2020 context. Finally, a similar yearly consultation exercise is foreseen at EFSA to provide timely support to DG R&I, DG-AGRI and DG-SANCO and priority areas for the launching of the first specific Horizon 2020 calls.

APPENDIX

Appendix A: Priority thematic research proposals identified by EFSA during the 2013

1. Health, Demographic change and wellbeing

1.1 Understanding determinants of health, improving health promotion and disease prevention.
1.3 Improving surveillance and preparedness
1.4 Understanding disease
1.11 Improving scientific tools and methods to support policy making and regulatory needs'

- Better understanding of the impact of major drivers of change potentially affecting the food chain in the next 10 years (1.1; 1.3).
- Research on the development of new risk Assessment strategies using 'omics' technologies, mathematical models, QSARs and TTC (1.4; 1.11).
- Research on a better understanding of the major origin and transmission of antimicrobial resistance and/or virulence traits in animals and the food chain (1.1;1.3).
- Research and methodology to assess health risks of combined exposures of the population to toxic substances (single/multiple routes of exposure, single/multiple modes of action) (1.11).
- Prioritisation and risk ranking based on epidemiology aspects and linkage to disease burden (1.3; 1.11).

2. European Bioeconomy Challenges: Food Security, Sustainable Agriculture and Forestry, Marine and Maritime Research

2.3 Sustainable and competitive agri-food sector for a safe and healthy diet
2.2.1 Informed consumer choices
2.2.2 Health and safe foods and diets for all
2.2.3 A sustainable and competitive agri-food industry.

- Informed consumer choices: Risk perceptions and communication of priorities to stakeholders (2.2; 2.2.1; 2.2.2).
- Competitive food processing methods: A holistic approach involving the whole food chain/cycle, *i.e.* environmental fate (for example, consideration of the development of maize biofuels and the impact of the resultant waste) (2.2; 2.2.3).
- Non-foodborne zoonoses and emerging diseases at the animal–human interface (2.2).