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EFSA's activities on emerging risks in 2020

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Abstract

The main objectives of EFSA's activities on emerging risks are: (i) to carry out activities to identify emerging risks; (ii) to develop and improve emerging risk identification (ERI) methodologies and approaches; and (iii) communicate the issues and risks identified. The outcome of these activities also allows EFSA to prepare for future risk assessment challenges. The current technical report summarises the activities of all groups involved in the ERI procedure, the issues identified in the course of 2020, a description of the methodologies that have been considered, and collaborative activities. EFSA networks of knowledge contributing to the ERI activity include the Emerging Risks Exchange Network (EREN), the Stakeholder Discussion Group on Emerging Risks, EFSA's scientific units, scientific panels and the Scientific Committee. In total, 13 potential emerging issues were discussed in 2020. Six were concluded to be emerging issues. The potential issues were organised according to the hazard or driver identified. In addition, in 2020, EREN network members presented and discussed a total of 35 signals/potential emerging issues that had been identified by their own horizon-scanning activities. Member State representatives shared their work on signal identification with the objective of collecting additional information that could be used for better characterisation. It is crucial to introduce more dynamic and interactive approaches to gather and disseminate knowledge, while also taking into consideration the potential risks that may arise in new areas.

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Keywords: emerging issues, emerging risks, drivers, networks of knowledge, methodologies

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1. Introduction

1.1. Background

The successful identification of risks at their early inception is at the heart of public health and environmental protection. Improved identification of emerging risks has the potential to be a major preventive instrument at the disposal of the Member States and the European Union $(EU)^1$.

The European Food Safety Authority (EFSA) must put in place procedures to search for, collect, collate and analyse information and data with a view to the identification of emerging risks in the fields within its mission (Regulation (EC) No. 178/2002/EC, Article 34). To achieve this objective, EFSA has developed a working definition for emerging risks² (EFSA, 2020), carried out consultations with experts and developed a practicable approach to the identification of emerging risks in collaboration with its networks of knowledge (EFSA, 2018).

1.2. Terms of reference

The main objectives of EFSA's activities on emerging risks are: (i) to carry out activities to identify emerging risks; (ii) to develop and improve emerging risk identification (ERI) methodologies and approaches; and iii) communicate the issues and risks identified. The outcome of these activities also allows EFSA to prepare for future risk assessment challenges.

This technical report summarises the activities of all groups involved in the ERI procedure, the issues identified in the course of 2020, a description of methodologies being developed and collaboration activities.

2. Knowledge networks

2.1. Emerging Risks Exchange Network

The Emerging Risks Exchange Network (EREN) was established in 2010 to exchange information with Member States on possible emerging risks for food and feed safety.

The role of the network is to provide a platform for scientific cooperation in the area of ERI between risk assessors in the EU Member States and EFSA and to enhance risk assessment practices in the area of ERI methodologies. Specifically, the aims of the network are the following:

1. Present information, data and knowledge on identified emerging issues and risks.



¹ Recital 50, 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. OJ L 31, 1 February 2002, pp. 1–24.

² 'An emerging risk to human, animal and/or plant health and the environment is understood as a risk resulting from a newly identified hazard to which significant exposure may occur or from an unexpected new or increased significant exposure and/or susceptibility to a known hazard.' (EFSA, 2020, page 14).



- 2. Provide advice on and share experience of ERI methodologies used at national level to identify emerging issues and risks.
- 3. Give access to data and substantiate the reported emerging issues and risks based on scientific evidence or theoretical derivation of a possible health risk. The data should be presented and assessed using a standard briefing note template developed by EFSA.
- 4. Share potential emerging issues and risks identified through countries' own scanning systems at every meeting as a way to prioritise which issues to prepare a briefing note for.
- 5. Provide additional data on the issues and risks previously discussed by the EREN.
- 6. Provide recommendations for further research and possible joint projects among Member States.
- 7. Commit to liaise at national level by circulating background documents before and after each EREN meeting with relevant stakeholders to collect and share information covering the whole food chain, from primary production to retail, and to gather additional evidence on the emerging issues identified.
- 8. Collaborate with EFSA's national focal points to facilitate an exchange of information on emerging issues and to maintain a link with EFSA's Advisory Forum.
- 9. Avoid duplication of work to ensure that activities between Member States, between EFSA and the Member States and other existing EU systems involved in the ERI process are complementary.

Following its establishment in 2010, the EREN terms of reference have been revised twice: first at the Advisory Forum meeting in Oslo (18–19 June 2014) and then again at the Advisory Forum meeting in Parma (5–6 December 2017). The network comprises national experts on ERI, analysis and processing of data on emerging issues and risks. Members of the network are appointed in accordance with Articles 2 and 3 of the Decision of the Management Board of EFSA on the establishment and operations of networks. The network is currently composed of delegates from 27 EU Member States, Norway and Switzerland³ and observers from the European Centre for Disease Control (ECDC), the European Chemicals Agency (ECHA), the European Environment Agency (EEA), the World Health Organization (WHO), the Food and Agriculture Organization of the United Nations (FAO), Food Standards Australia New Zealand, the US Food and Drug Administration (FDA) and the Directorate-General for Health and Food Safety. The members of the network are required to act as a communication point for relevant organisations and stakeholders within their respective Member State, ensuring the

³ <u>https://www.efsa.europa.eu/sites/default/files/assets/emrisknetworkerenlist.pdf</u>



timely exchange of scientific information between these national organisations and EFSA.

The work of EREN is fully integrated into EFSA's ERI procedure. The group is consulted to identify emerging issues and to add information and further prepare briefing notes that describe previously identified emerging issues. To strengthen the overall ERI procedures, the activities of EREN are presented to EFSA's Stakeholder Discussion Group on Emerging Risks (StaDG-ER), to EFSA's Scientific Committee and Panels and to the Advisory Forum. Member State representatives in this network commit to liaise as appropriate at national level before and after each network meeting to make sure that all the necessary information is shared subject to Article 10 of the Decision of the Management Board on the establishment and operation of European Networks of scientific organisations operating in the field of the Authority's mission.

2.1.1. Emerging Risks Exchange Network meetings

EREN met twice in 2020 in virtual mode, using the Microsoft Teams collaborative platform. The agendas of the two meetings are summarised in Table 1. A short description of the issues discussed, conclusions and recommendations are presented in Tables 4 and 5. Signals identified by different EREN members as part of their own horizon-scanning activities are listed in Table 6.

Discussion area	Items	Meetings in 2020
Presentation and discussion of emerging issues	ID 0422 – Potential risks of introducing Oxo-degradable plastic into the environment ID 0423 – Emerging risks associated with feed and products of feed production technologies of increasing relevance (novel feeds)	23rd (26–27 March)
	ID 0426 – Toys and occupying materials in animal husbandry ID 0427 – Steroidal selective androgen receptor modulators (SARMs) in food supplements ID 0418 – Health concerns about flowers in food and feed by Stakeholder Discussion Group on Emerging Risk ID 0428 – Risk of tick-borne encephalitis due to raw goat milk consumption in France ID 0429 – Possibility for Chagas disease in Europe due to climate change	24th (23–24 November)
Further information on previous emerging issues	ID0156 – The use of insects as a raw material for animal feed	23rd (26–27 March)

Table 1: Summary of EREN discussions in 2020



	ID 0374 – BfR overview on a risk assessment of STEC in flour and flour products ID0332 – Fluorinated alternatives to per- and polyfluoroalkyl substances ID0352 - Fertiliser from waste and the risk to human health ID0409 – Results from Ireland on cannabidiol/tetrahydrocannabinol official controls on hemp-based supplements	
	ID0369 – Possible contamination of foods with residues of pesticides used to control Zika virus vectors in South America ID 0336 – Results of the EFSA grant on risk assessment for influenza D in Europe ID 0330 – Emulsifier and microbiome: Microbiome: the missing link? – FAO's work, with a focus on food safety ID 0076 – Results on the risk characterisation of ciguatera food poisoning in Europe project and outcome of the final workshop ID 0351 – Seaweed Scientific Opinion on cadmium in algae used for food	24th (23–24 November)
Feedback on EREN/EFSA activities	DEMETER: Emerging risks knowledge exchange platform prototype demonstration Applicability of a food chain analysis to identify and monitor vulnerabilities and drivers of change for the identification of emerging risks – Atlantic salmon (aquaculture) (AQUARIUS) project) Prioritisation of livestock transboundary diseases in Belgium using a multicriteria decision analysis tool based on drivers of emergence Project results on climate change as a driver of emerging risks for food and feed safety, plant, animal health and nutritional quality in the EU (CLEFSA) A pilot study on the usefulness of MedISys for the monitoring of adulteration in beeswax	23rd (26–27 March)
	CLEFSA event and upcoming project on circular economy Drivers on the emergence of COVID-19 in pets Upcoming project on new technologies Phyto pharmacovigilance in France DEMETER	24th (23–24 November)



2.2. Stakeholder Discussion Group on Emerging Risks

EFSA is committed to increasing public and stakeholder involvement in the process of risk assessment. The approach to stakeholder engagement (EFSA, 2016) enables EFSA to interact with a larger range of stakeholders through permanent and targeted platforms. Targeted platforms are established by the set of interests and the specific knowledge that stakeholder communities bring to the various phases of EFSA's work. Discussion groups are 'learning systems' that allow EFSA to capitalise on stakeholders' specialist knowledge in specific areas, such as developing efficient and harmonised data collection systems, methodological approaches and identification of new or emerging issues.

The role of stakeholders is essential to increase EFSA's capacity to anticipate emerging scientific or societal issues. Established in 2011, StaDG-ER is an efficient tool to engage with EFSA-registered stakeholder organisations. The group's composition (Table 2) was reviewed following the adoption of a new policy to ensure a more representative distribution of all stakeholder categories. These categories are consumer organisations, business and food industry, environmental/health non-governmental organisations and/or advocacy groups, farmers and primary producers, distributors and hotels, restaurants, and catering (HORECA), practitioners and academia.

Registered Stakeholder category	Organisation
Academia	Global Harmonisation Initiative
Associations of Practitioners	Association of Veterinary Consultants (AVC)
	FoodDrinkEurope
Business and food	The Primary Food Processors of the EU
industry	Union of European Beverages Associations (UNESDA)
	European Chemical Industry Council
Consumer associations	Safe Food Advocacy Europe (SAFE)
	European Liaison Committee for Agricultural and Agri-Food Trade
Distributors and HORECA	Euro Commerce
	FoodServiceEurope
	Serving Europe

Table 2: StaDG-ER member organisations



	EU agri cooperatives
Farmers and primary producers	EU farmers
	European Federation for Animal Health and Sanitary Security (FESASS)
	Association of Natural Medicine in Europe
Non-governmental organisations and	Federation of Veterinarians of Europe (FVE)
advocacy groups	Eurogroup for Animals
	Pesticide Action Network Europe

2.2.1. Stakeholder Discussion Group meetings

The group met twice in 2020 in virtual mode, using Microsoft Teams. The agendas of the two meetings are summarised in Table 3. A short description of the issues discussed, conclusions and recommendations are presented in Tables 4 and 5.

Table 3: Summary of StaDG-ER discussions in 2020

Discussion area	Items	Meetings in 2020
Presentation and discussion of emerging issues	ID0421 – SDHI fungicides – an overview on research and assessments in Europe ID0424 – Update on potential health risks linked to a large intake of collagen powder ID 0425 – COVID-19 impact on food safety	23rd (11 June)
	ID-430 – COVID-19 in animals ID-0431 – Potential risks associated with the excessive use of disinfectants during the COVID-19 pandemic ID-0432 – Besnoitiosis: a re-emerging disease in Europe? ID-0433 – SARS-CoV-2 and food contamination	24th (9–10 December)
Further information on previous emerging issues	ID0411 – Food-borne invasive infections with <i>Streptococcus agalactactiae</i>	23rd (11 June)
	ID0423 – Emerging risks associated with feed and products of feed production technologies of increasing relevance (novel feeds)	24th (9–10 December)
Feedback on StaDG-ER/EFSA activities	Technical Report on adulterated beeswax and follow-up on previous issues by EFSA	23rd (11 June)



* A framework for assessing food fraud as a driver of food safety emerging risks.

3. Identification of emerging issues, trends and drivers

3.1. Potential emerging issues evaluated

In total, 13 potential emerging issues were discussed in 2020. Each issue was presented in the form of a standard briefing note and given a unique identifier (ID No.). When information was available, the issues were classified according to the hazard or driver identified (hazards: microbiological (5), chemical (2), microbiological and chemical (1), other (4); drivers: illegal activity (0), new consumer trends (0), new process or technology (1), climate change (0), other (0)).

The issues were assessed against a set of predefined criteria: (i) new hazard; (ii) new or increased exposure; (iii) new susceptible group; and (iv) new driver. The criteria are based on EFSA's definitions of emerging risk and emerging issue.

Six issues were considered as emerging issues (summarised in Table 4) and six issues were not considered to be emerging issues or not enough information was available to reach a conclusion, i.e. no new hazards, no new or increased exposures and no new susceptible groups were identified (summarised in Table 5).

The conclusions and recommendations proposed to EFSA by EREN and/or StaDG-ER are recorded in the common briefing notes. They reflect the views of EREN and/or StaDG-ER, as indicated. They do not represent EFSA's view and position but reflect the discussions in the networks.

In addition, 35 issues (Table 6) within the remit of EFSA resulting from Member States' own horizon-scanning activities were presented to EREN. A standard template in which to submit information has been developed and each issue discussed is given a unique identifier (M No.). The issues are brought forward for discussion with the aim of collecting further information from EFSA's emerging risk knowledge networks.



Table 4: Emerging issues (a new hazard, new or increased exposure or new susceptible group was identified)

(IDO430^(a)) COVID-19 in animals

SARS-CoV-2 virus infection has been reported in various animal species including dogs, cats, zoo felids, American mink and a pet ferret. Farmed mink, which were probably infected by humans, have shown contagiousness to other mink and humans, resulting in new random mutations of the virus. Infections in farmed mink have been reported in Denmark, Italy, Spain, Sweden and the United States, as well as a wild mink infection in the USA. The COVID-19 outbreak in Denmark (the cluster 5 variant linked to mink farms) died out on its own after contingency measures were implemented. However, at least 12 people in northern Jutland were exposed to a mink variant of SARS-CoV-2 (different from cluster 5) and transmitted these variants in the local community (see https://www.who.int/emergencies/diseaseoutbreak-news/item/2020-DON301).

The available scientific evidence suggests that poultry and wild birds are generally not susceptible to SARS-CoV-2 infection (attempts to experimentally infect chickens, ducks and turkeys with SARS-CoV-2 have been unsuccessful (El Masry, et al., 2020)). It is still uncertain whether birds can transmit the disease to humans, and whether infected birds can carry and excrete the virus, which would pose a risk to humans and wildlife. Human-to-human transmission via shellfish contaminated with sewage or coastal water run-off (a known route for norovirus, hepatitis virus and other food-borne infections (Hassard et al., 2017)) could be an additional possible source (not associated with pets or farmed animals) but requires further investigation.

Author	Classification(^b)	New driver (^c)	New hazard(^c)	New/ increa sed expos ure ^(c)	New/sus ceptible group ^(c)	Recommendations of the emerging risk knowledge networks(^d)
StaDG- ER AVC	Microbiological hazard	Y	Y	Y	Y	StaDG-ER Recommendations: Diagnostics and monitoring tools should be developed for pets (similar to those developed for humans), but also for farm animals and the fishing sector. Risk management recommendations: animal vaccines should be developed to protect people at risk, protective gear for animals could be an option; however, this is not possible in many cases. On the other hand, more drastic solutions such as e.g. euthanising cats will be very ethically contested.



(ID0428) Risk of tick-borne encephalitis due to raw goat milk consumption in France

Tick-borne encephalitis (TBE) is a zoonotic arbovirosis caused by the tick-borne encephalitis virus (TBEV), a flavivirus. The disease is characterised by acute and chronic neurological infections in humans and is primarily transmitted by ticks, particularly *Ixodes* spp., which feed on small mammals such as rodents that serve as virus-amplifying hosts (Valarcher et al. 2015). TBEV is endemic in central, northern and eastern Europe, with 3,212 cases reported in 2018 (ECDC, 2019) and has been a growing concern in Europe. Although vaccination campaigns have led to a significant decrease in TBE incidence in some areas of Europe, it has expanded in other areas, such as in Scandinavia, Austria, Germany and Switzerland (Valarcher et al. 2015). TBE is particularly present in the Alsace and French alpine regions (Velay et al. 2018). The virus can also be transmitted by consumption of unpasteurised milk and milk products from infected animals, primarily goats, and food-borne TBE outbreaks have been reported in central and eastern European countries, including Germany (EFSA BIOHAZ Panel, 2015; Valarcher et al., 2015; Brockmann et al. 2018). However, in France, food-borne transmission of TBEV had not been reported until April/May 2020, when a cluster of 44 cases of lymphocytic meningitis, encephalitis and infectious syndromes was identified in the Ain department in the Rhone-Alpes region (Santé publique France, 2020) and TBE infection was confirmed for these cases by the French National Centre for the Arbovirus

Author	Classificatio n(^b)	New driver (^c)	New hazard (^c)	New/ increase d exposur e ^(c)	New/sus ceptible group ^(c)	Recommendations of the emerging risk knowledge networks(^d)
EREN FRANCE	Microbiolog ical hazard	Y	N	Y	Ν	EREN Recommendations:1. EFSA to update AHAW and BIOHAZ units2. EFSA to discuss the human health implications with ECDC3. EREN to do some ranking on the possible influence of drivers.

(ID0427) Steroidal selective androgen receptor modulators (SARMs) in food supplements

SARMs are a class of therapeutic performance and image-enhancing drugs that have similar properties to anabolic agents, but are claimed to have reduced androgenic properties (USDA, 2020). This property facilitates the advantage of androgen receptor specificity, tissue selectivity and the lack of some steroid-related side effects. Due to their therapeutic potential, SARMs are under development for medical purposes and some have entered clinical trials to test their efficacy at treating human disease. The US FDA has issued a number





of warnings for products containing SARMs (mainly ostarine, andarine and lingandrol (LGD-4033)). In a general warning against using SARMs in body-building products issued in 2017, the FDA raised safety concerns on the basis of post-marketing safety reviews of adverse event reports for products containing SARMs (Meyer, 2017). The reported adverse events included life-threatening reactions, including liver toxicity, and occurred in people taking products containing SARMs. SARMs also have the potential to increase the risk of heart attack and stroke, and the long-term effects on the body are unknown (Meyer, 2017). Products which have been found to contain SARMs are mainly dietary supplements in capsule form, accompanied by claims relating to increased muscle mass, reduced body fat, improved recovery from exercise and enhanced performance. Bottles usually contain 30–90 capsules and often do not make reference to the anabolic agent in the ingredients list (Van Wagoner et al., 2017). In addition, an obscure trivial reference to the substance (i.e. LGD, MK, STEN, etc.) or a misspelt scientific name is often used on the label to alert the user to the presence of the active ingredient, while evading regulatory oversight (Cohen et al., 2015). A study performed in 2016 analysed the content on body-building forums and demonstrated that anabolic androgenic steroids were the most discussed type of product for body image enhancement and performance (Pineau et al., 2016). Despite this finding, the study identified a downward trend in discussions on popular anabolic androgenic steroids and an increased trend related to discussions on other supplements which can illicit anabolic effects. On a separate, but similar, note, the Food Safety Authority of Ireland has detected SARMs (and other stimulants) in dietary supplements.

Author	Classificatio n(^b)	New driver	New hazard ⁽ c)	New/inc reased exposur e ^(c)	New/sus ceptible group ^(c)	Recommendations of the emerging risk knowledge networks(^d)
EREN Ireland	Other	Y	Y	Y	Y	 EREN Recommendations: 1. EFSA to contact the European Medicines Agency to enquire about the known status of adverse health effects. 2. EFSA to contact the European Monitoring Centre for Drugs and Drug Addiction to enquire about recreational drug use. 3. EFSA to contact the new Head of agencies food supplements working group to bring the issue to the attention of the Member States so that they can coordinate their risk reduction strategies and harmonise how food supplements are risk assessed at Member State level



Animal welfare measures are becoming more important in industrial animal husbandry. Materials for play are introduced into stables to occupy animals and reduce abnormal behaviour such as tail-biting or feather-pecking. Some toys and products are specifically designed for livestock farming. Examples are bite blocks, pecking stones, metal chains, perches, sisal play ropes, jute bags, straw baskets, brushes for scratching and rubber balls. Sometimes, used children's toys are given to the animals. As animals in primary production may lose interest in the objects within a few days, replacement or renewal of toys frequently occurs (Godyn et al. 2019). Some occupying materials like metal chains, brushes or sisal ropes may have a longer lifespan than a group of fattening animals in primary production. Hence, toys and occupying materials may move from one group of animals or housing to another. Next to objects, substrates are added to stables to provide animals with possibilities for exploration and occupation. These include a variety of bedding materials and litter such as sawdust, wood shavings, sand, peat and straw (Schreiter et al. 2019). Alongside these classic materials, sustainability approaches lead to the introduction of re-used or recycled materials to stables. For example, peanut shells or shredded paper are used as enrichment material for pigs (Godyn et al. 2019; Bracke et al. 2013). Moreover, some combinations of objects and feed are in use, like alfalfa bales or straw pellets. Mouthing and chewing behaviours of animals with toys can leach out chemical contaminants. A study by Wooten and Smith (2013) with chewing materials for dogs showed a potential for the uptake of the chemical contaminants phthalates and bisphenol A. Contaminants introduced by edible occupation material like straw may enter the food chain directly. Specific risks might be associated with recycled materials. Peanut shells, for instance, could introduce mycotoxins to stables and shredded printed paper could introduce Mineral Oil Saturated Hydrocarbons (MOSH)/Mineral Oil Aromatic Hydrocarbons (MOAH) into the food chain. Bedding materials derived from treated timber were found to be contaminated with persistent organic pollutants (Brambilla et al. 2009). Fernandes et al. (2019) demonstrated the potential for contaminant uptake from recycled materials used in livestock farming to result in contaminated foods. A further point of concern is the possible introduction of pathogenic microorganisms with enrichment or bedding materials. This has been described for peat (Matlova et al. 2012; Wagner et al. 2018) and recycled sand (Kristula et al. 2005). Little is known about the movement of animal toys between stables and their re-use for different flocks or herds. Some of the materials like brushes or sisal ropes seem difficult to disinfect. A transfer of pathogenic microorganisms via toy vehicles cannot be excluded. To date, there are only a few studies on the occurrence of chemical contaminants or pathogenic microorganisms in materials introduced into animal husbandry to enhance animal welfare. The movement of toys in primary production has not yet been sufficiently studied.

$ \begin{array}{ c c c } \mbox{Author} & \mbox{Classificatio} \\ n(^{b}) & \mbox{arive} \\ r(^{c}) & \mbox{arian} \\ \mbox{d(c)} & \mbox{New/inc} \\ \mbox{reased} \\ \mbox{exposur} \\ e^{(c)} & \mbox{exposur} \\ \mbox{exposur} \\$	Recommendations of the emerging risk knowledge networks(d)
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EREN	Microbiolo	Y	Ν	Y	N	EREN Recommendations:
GERMA NY	gical and chemical hazard					 EREN to share more evidence: on ongoing work on children's toys by the Scientific Committee on Health, Environmental and Emerging Risks; on animal mouthing behaviour; on the kind of material used in these toys used for animal husbandry; on patents on animal toys/materials for animal toys.
						2. SCER to raise awareness on these potential risks to animal health colleagues

ID 0424 Potential health risks linked to a large intake of collagen powder

The briefing note is a follow-up of the short issue (M112) identified by the German Federal Institute for Risk Assessment (BfR) scanning activities and presented to EREN at its past meeting in April 2020. A publication by J. Knight et al. (2006) revealed the fact that the high content of hydroxyproline in collagen (about 13.5%) may increase the risk of kidney stones. There is no EFSA claim on the anti-ageing properties of collagen powder, however its consumption as a dietary supplement is increasing in Europe. The early signal was brought up by the BfR for which the concern was the following: 'Because of claimed anti-age properties, consumption of collagen powder as a dietary supplement is increasing either in pure form or added to smoothies, coffee etc.' Not much is known about the long-term effects of high collagen intake, but certain properties of collagen powder raise potential concerns. With the high content of hydroxyproline (about 13.5%), collagen may increase the risk of kidney stones. Significant changes in plasma hydroxyproline and urinary oxalate were observed after intake of 5 g of gelatin (25% hydroxyproline content). High oxalate concentrations are one of the main causes of kidney stones. Most collagen powder products are made from marine sources and include large amounts of calcium, so allergies and hypercalcaemia are also potential risks to be assessed. The discussion concerns a potential health risk to consumers in developing kidney stones associated with a large intake of collagen powder products. The concern originates from the concept that the amino acid hydroxyproline, present in collagen, is a potential precursor of glyoxalate, who in its turn is believed to be a precursor of oxalate, and calcium oxalate is the most common form of kidney stone. Central to this issue is the study from Knight et al. (2006) where the authors observed increases in urinary oxalate levels induced by a daily intake of 5–10 g of collagen in the diet.





Author	Classificati on(^b)	New drive r(^c)	New hazar d(^c)	New/in crease d exposu re(^c)	New/su sceptibl e group(^c)	Recommendations of the emerging risk knowledge networks(^d)
StaDG- ER Europea n Chemical Industry Council on behalf of the Associati on of all the Leading Europea n Gelatine Manufact urers	Other	Y	Ν	Y	Y	StaDG-ER recommendations: Risk assessment for collagen power has already started as part of the current discussions and studies are underway in the context of kidney stones and high intake of proteins. However, the group identified the need for consumption data on collagen powder as a food supplement and the relevance of obtaining data related to total exposure to perform meaningful risk assessments on high protein intake. The group identified the need for consumption data on collagen powder as food supplements. In addition, it was highlighted the relevance of obtaining data related to total exposure to perform meaningful risk assessment on high protein intake.

ID 0423 Emerging risks associated with feed and products of feed production technologies of increasing relevance (novel feeds)

Conventional feed includes products and by-products of plant and animal origin, considered traditional parts of an animal's diet (e.g. soybean meal, fishmeal, cereals and dairy products). However, new sources of alternative feed ('novel feed') are increasingly being used





to cope with the growing demand for food and feed products, as a consequence of increased globalisation, the progressive increase in the global population, and the need to reduce the high pressure on natural resources and the negative impact on the planet attributable to the current conventional agro-zootechnological practices. Under the definition of novel feed falls a wide category of ingredients such as insects, aquatic products of plant and animal origin, former food products and food processing by-products, and by-products of other industrial processes (e.g. the biofuel industry). These alternative feed sources, compared with traditional ones, can present new challenges to the risk assessment and management process, requiring clear identification and characterisation of hazards that can potentially be introduced. Thus, a tiered approach to assess new insights into potential hazards and emerging risks attributable to novel feed should be proposed (FAO & WHO, 2019): (a) identifying all incoming material used to produce the novel feed and their potential hazards (mapping); (b) understanding the manufacturing process to identify and characterise potential hazards introduced via processing (knowing); and (c) performing a risk characterisation of the final product itself (concluding). The purpose of this briefing note was to set the scene for the EREN endorsement to: (i) complete a comprehensive mapping of the potential emerging risks posed by novel feed to set up a suitable risk assessment paradigm; (ii) expand the identification of the potential emerging risks posed by novel feed to also cover scenarios of global environmental changes (climate change), technological and public perception change (sustainability, circular economy, etc.); (iii) establish harmonised partner activities with those actors directly or indirectly interested in the risk assessment and management of novel feed (industry, academia, governmental authorities and farmers are key players in the development of a more holistic risk assessment model); (iv) remark that early cooperation will avoid redundancies or diverging positions and that, in the event of a future revision of sectoral legislation impacting the risk assessment of feed, a further attempt at better harmonisation might benefit from this fruitful cooperation.

Author	Classificati on ^(b)	New drive r ^(c)	New hazar d ^(c)	New/ increas ed exposu re(^c)	New/su sceptibl e group(^c)	Recommendations of the emerging risk knowledge networks ^(d)
EFSA	New process or technol ogy	Y	Y	Y	N	EREN Recommendations: No recommendations

(a) Each issue is presented using a standard briefing note template and given a unique identifier number (ID No.).

(b) Classification by hazard and/or driver: microbiological hazard, chemical hazard, illegal activity, new consumer trends, new process or technology.

(c) Yes (Y), No (N), Not concluded (NC).



(d) The conclusions and recommendations were produced and adopted by EREN and StaDG-ER as indicated. They may not be considered as EFSA's view and position as regards the issues addressed, subject to the rights of the authors.

Table 5: Not concluded/Not an emerging issue (no new hazard, no new or increased exposure and no new susceptible groups were identified)

(ID 0433^(a)) SARS-CoV-2 and food contamination

Several reported episodes of food contamination with SARS-CoV-2, such as imported salmon meat or seafood shows that food is likely to have been contaminated at the producer, seller or customer level. Under certain conditions, SARS-CoV-2 can survive on surfaces for a limited time, including food packaging. European and worldwide institutions with competence in food safety currently state that, to date, there is no evidence that food or food packaging has been a source or vehicle of COVID-19 infection for people. There is consistent evidence that sewage contaminated by SARS-CoV-2 from the faeces of infected patients goes into the natural aquatic environment. The events recognise the transmission from human faeces, through municipal wastewater treatment plant effluents (given that it can survive the wastewater treatment process) and ultimately the introduction into the natural aquatic environment where wildlife and harvested food might be contaminated.

Autho r	Classificati on ^(b)	New drive r ^(c)	New haza rd ^(c)	New/ increa sed expos	New/ suscep tible group(Recommendations of the emerging risk knowledge networks ^(d)
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StaDG- ER	Microbiologi cal hazard	Y	Ν	N	Ν	StaDG-ER Recommendations:
FVE						 To regularly monitor scientific literature to prove evidence that food is not associated with the transmission of the virus. To develop fast sensitive tests (e.g. ELISA) to check and monitor SARS-CoV-2 in the feed and food chain. To identify safe ways to trade (e.g. pork) based on scientific risk assessment e.g. by EFSA. RNA monitoring in sludge can be used as an indicator of the prevalence of COVID-19 infection in a population. The raw wastewater and sludge-based surveillance of COVID-19 in the community would be an innovative tactic to support COVID-19 epidemic surveillance.

(ID 0432) Besnoitiosis

Besnoitiosis is serious for cattle, but it is not a zoonotic disease, and therefore there is no risk to humans. The disease's natural vectors are horseflies and *Stomoxys* (the stable fly), but it can also be transmitted by vet needles. So far there is neither a vaccine available nor an effective treatment. Besnoitiosis was first described in Europe at the end of the 19th century in France and in the 1990s expanded in Spain, Portugal and the Massif Central. In 2010, EFSA published a statement considering Besnoitiosis to be an emerging disease in Europe. Belgium was free of this disease as of 2015 but monitoring of imported cattle needed to be implemented to avoid imported cases. As a result of systematically testing cattle imported from countries at risk, in 2018 three other cases were diagnosed, two from Spain and one from France. In 2019, the first case of a non-imported animal in Belgium was diagnosed and the number of outbreaks slowly started to raise. The outbreaks in 2019–2020 originated in animals imported from affected areas (southern France). Only one herd demonstrated local transmission (Evrard and Quinet, 2020). Despite being a vector-borne disease, there is no scientific evidence that its transmission would be influenced by climate change, but it cannot yet be excluded.



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Author	Classificatio n ^(b)	New driver (^c)	New haza rd(^c)	New/ increase d exposure	New/s uscept ible group (^c)	Recommendations of the emerging risk knowledge networks ^(d)
StaDG- ER FESAS S	Microbiologi cal hazard	N	N	Ŷ	Ý	 StaDG-ER Recommendations: Testing all animals coming from affected regions and slaughter of affected animals should be implemented in all EU countries. In collaboration with the AHAW Team/ALPHA Unit, it would be advisable to check the 2010 EFSA publication on Besnoitiosis and look for new publications and data to understand scientific developments and the evolution of the disease since then. Scientific Committee and Emerging Risk Unit (SCER) to contact AHAW/ALPHA, and possibly the European Commission (EC), for further information on how countries at risk, such as Spain and France, are handling the issue. The group agreed that this is not an emerging risk but suggested monitoring for possible increase of the number of cases



(ID0431) Disinfectant COVID-19 pandemic

A summary of the many consequences linked to the problems in distribution and the excessive use and misuse of disinfectants experienced during the COVID-19 pandemic was presented. From the initially limited availability due to the panic leading to stockpiling of sanitation products, manufacturing shutdowns, tighter border controls and lack of coordination in distribution, to the misinformation occasionally provided; where wrong chemicals may have been advertised as sanitation products, wrong advice provided, e.g. to drink hot water, or where some sanitisers that were not safe to be uses in large amounts because they are volatile, toxic or irritating for the skin were marketed to control the pandemic. Documented cases reported in Spain showed an increase in the number of poisonings by hydroalcoholic gels in children during the COVID-19 pandemic. Further, some hydrogels are not completely effective and some of them may damage the skin. The role of 'fake news' on the use of disinfectants during the pandemic misinforming the public may have contributed to increasing the risks.

Author	Classificatio n ^(b)	New driver (^c)	New haza rd(^c)	New/ increase d	New/s uscep tible	Recommendations of the emerging risk knowledge networks ^(d)
StaDG- ER	Chemical hazard	N	N	Y	Y	StaDG-ER Recommendations: The issue might be brought up at the next EREN meeting to share
Food Service Europe & Serving Europe						communication practices between Member State and potentially coordinate the communication strategies (with support from the European Commission).

(ID 0425) COVID-19 impact on food safety

This briefing note presents an overview of the potential medium and long-term impact of the COVID-19 pandemic on food safety in Europe. Possible risks/impacts were identified along the food supply chain (farm to fork) by the StaDG-ER members in anticipation of the meeting and categorised under four different areas (consumer preferences, supply chain, industry, new virus on the horizon). Some of the issues identified were the potential impact of stockpiling of food at home and the risk of temperature fluctuations due to an increased use of domestic fridges compromising the cold chain, or the impact on setting up priorities for research.

Author	Classificatio n ^(b)	New driver (^c)	New haza rd(^c)	New/ increase d	New/s uscep tible	Recommendations of the emerging risk knowledge networks ^(d)
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StaDG- ER	Microbiologi cal hazard	N	Y	Y	Y	St DG-ER Recommendations:
FVE, AVC, UNESD A						There is a need to explore whether a cross-organisation group between organisations such as FoodDrinkEurope, Primary Food Processors of the EU, the food section of EuroCommerce, Hotel & Restaurant association, and animal feed organisations already exits, and if not, whether this should be proposed, and which could be the institution addressing its establishment.

(ID0429) Possibility of Chagas disease in Europe due to climate change

Chagas disease, also known as American trypanosomiasis, is a tropical parasitic disease. It is caused by the protozoan species Trypanosoma cruzi, which is closely related to the species responsible for sleeping sickness. Initial symptoms are relatively mild, but chronic Chagas disease can lead to long-term organ damage, mainly to the heart, and has a 10% fatality rate if left untreated. Chagas is a vector-transmitted disease, with the carriers being members of the Triatominae, a subfamily of kissing bugs located mainly in Latin America. Although transmission of the disease can occur through blood transfusions or from mother to unborn child, transmission mostly occurs directly though contact with the kissing bugs after a blood meal of the host. As the parasites are present in the kissing bug's faeces, transmission though contaminated food or drink is also possible and has been documented in several cases. Chagas disease is currently mainly concentrated in South and Central America, but is common there, with a current estimate of 15 million people infected, and 50,000 new infections as well as 15,000 deaths every year. There are also cases of Chagas disease in other parts of the world, with the main concentrations being in the USA (100,000) and Spain (6,000); these cases mainly being immigrants from Latin America. So far, no cases of infection have been reported in European regions, as they lack the responsible vector species. However, since climate change is a global problem and has already led to the spread of certain vector-borne diseases in Europe (FSME and Lyme disease being prominent examples), scientists have speculated whether the change in climate could lead to certain species of Triatominae being introduced as an invasive species and, as a result, Chagas disease becoming a relevant concern in European countries. A new study by the Senckenberg Biodiversity and Climate Research Centre (Eberhard, et al., 2020) uses climactic modelling to provide a scientific basis for these discussions and shows that certain relevant species of Triatominae might already find suitable living conditions in parts of southern Europe if they were accidently transported here through global trade routes or private travel.



Author	Classificati on ^(b)	New drive r(^c)	New hazard(^c)	New/ increas ed	New/ susce ptible	Recommendations of the emerging risk knowledge networks ^(d)
EREN GERMANY	Other	Y	Ν	Ν	Y	 EREN Recommendations: 1. EFSA to discuss with the Directorate-General for Health and Food Safety in the context of crisis preparedness 2. Monitoring and modelling activities by EREN and the wider research community are encouraged. Within that work potential vectors already present in Europe should be identified.

(ID0422) Potential risks of introducing oxo-degradable plastic into the environment

It has long been a global problem that huge quantities of plastic material are released into the environment. In general, about 12% of plastic material used is mismanaged with the potential to get into the environment, while about 3% ends up in the oceans (Ritchie and Roser,2018). Because plastic polymers are not bio-degradable, they accumulate over time, causing severe environmental issues. Therefore, degradable alternatives have been increasingly used to combat this problem. Among those are 'oxo-degradable' plastics, which use various forms of metallic additives to achieve the desired effect. The usage is manifold, including in packaging and plastic shopping bags, but also as plastic mulch in farming. The market value for oxo-degradable plastic packaging was already at about USD 660 million in 2017, with an estimation of more than USD 1 billion by the year 2026 (Persistence Market Research, 2018). Scientists have raised concerns over this material for some time, considering that degradation products are released into the environment. New research has now shown leachates of these materials to have detrimental effects on various freshwater organisms. Potential negative effects on humans have not yet been intensively studied, but seem at least possible. Potential means of exposure include either direct contact through handling products made from degradable plastic, or indirect contact through consumption of plants grown with plastic mulch. To our knowledge, there have been no studies so far dealing specifically with the detection of oxo-degradable plastic in food.

Author	Classificati on ^(b)	New drive r(^c)	New hazard(°)	New/ increas ed exposur e(^c)	New/ susce ptible group (°)	Recommendations of the emerging risk knowledge networks ^(d)
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EREN GERMANY	Chemical hazard	Y	N	Y	Ν	EREN Recommendations: EFSA to consult the stakeholders to enquire about replacement products currently being tested to plan to replace current products on the market.				
(ID 0421) Succinate dehydrogenase inhibitor (SDHI) fungicides – an overview of research and assessments in Europe										
SDHI fungicides were developed more than 40 years ago. Ten SDHI fungicides are currently approved for use in the EU. The potential risks associated with their use is a hot topic in France and expert groups have become very active. In January 2019 the French Agency for Food, Environmental and Occupational Health and Safety (ANSES) published an opinion that highlighted the difficulties of comparing values obtained <i>in vitro</i> under laboratory conditions with the SDHI concentrations that could result from applying pesticides to crops (ANSES, 2019a). Newly developed SDHI fungicides are very efficient with regards to the development of antifungal resistance and, according to the current regulatory framework, do not raise serious concerns on toxicity to humans under the established maximum residue levels (MRLs). These advantages make them a preferable option for the protection of crops. However, researchers demonstrated that the conditions of current regulatory tests for toxicity mask a very important effect that SDHIs have on human cells: the pesticides induce oxidative stress in cells, leading to their death. Boscalid and fluopyram are the most used SDHI fungicides in Europe. EFSA has assessed these substances, lowering their MRLs for certain uses (EFSA, 2019a; EFSA, 2019b; EFSA, 2019c)										
Author	Classificati on(^b)	New drive r(^c)	New hazard(c)	New/ increas ed exposur	New/s uscept ible group ⁽	Recommendations of the emerging risk knowledge networks(^d)				
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StaDG- ER	Other	Y	N	Y	Y	StaDG-ER Recommendations:
PAN Europe						 EFSA to develop a briefing note. To consult EFSA Unit on pesticides and ANSES (e.g. through our EREN network member representing France) and to inform the StaDG-ER members on any ongoing activities. EFSA to perform a new/reviewed risk assessment on the most used SDHI fungicides.

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Table 6: EREN horizon scan signals

Emerging R	Risk Activities 2020		
able 6: I	EREN horizon scan si	gnals	
ID No.	Title	Author	Description
M112	Health risks from a large intake of collagen powder	Germany	Because of claimed anti-ageing properties, consumption of collagen powder as a dietary supplement is increasing either in its pure form or added to smoothies, coffee, etc. Potential concerns include: the high content of hydroxyproline may increase the risk of kidney stones; most collagen powder products are made from marine sources and include large amounts of calcium, leading to the potential risk of allergies and hypercalcaemia.
M113	Health risks from the consumption of soybean oil	Germany	The use of soybean is increasing in Europe. Studies have shown a greater risk of diabetes in mice, linked to soybean oil intake, compared with either coconut oil or fructose, as well as an increased risk of other diseases, like Alzheimer's.
M114	Global aquaculture supply chains lead to the destruction of wild fish stocks	Germany	There is evidence that the production of fishmeal and fish oil for use in global aquaculture supply chains is precipitating the collapse of fish stocks, compromising food security and destroying the social and economic fabric of communities living adjacent to historic fishing grounds. A lack of traceability and transparency on the origin and supply chain of farmed seafood products was reported, as well as violations of fishing bans and a lack of required food safety certificates.
M115	Shiga toxin- producing <i>Escherichia coli</i> survives storage in wheat flour for two years	Germany	Wheat flour is an exposure vehicle for the food- borne pathogen Shiga toxin-producing <i>E. coli</i> (STEC), see EREN briefing note ID 0374. Two years after milling the flour, the presence of STEC was confirmed with the same genotype and core genome multilocus sequence type as previously found. STEC has the potential to persist in wheat flour for at least up to two years, and possibly in other foods with low water activity.
M116	Chlorinated paraffins in dietary supplements	Germany	Chlorinated paraffins (CPs) are a group of man- made pollutants of growing environmental concern. Short-chain chlorinated paraffins were recently classified as persistent organic pollutants. Foodstuffs are a major pathway for the human CP intake. The study by Sprengel et al, 2019 was the first to investigate the occurrence of CPs in dietary supplements and to evaluate the risk.
M117	Cucurbit aphid- borne yellows virus in Germany	Germany	In the summer of 2019, Cucurbit aphid-borne yellows virus (CABYV) was isolated in cucumbers for the first time in Germany and infected 90% of Bavarian stocks, causing up to 50% yield loss. CABYV is spread by aphids and is present in the Mediterranean region. Scientists fear that the occurrence in Germany is only the beginning of a spread throughout central Europe, supported by
www.efsa.europa.eu/publications EFSA Supporting publication 20YY:EN-8024			



merging R	isk Activities 2020		
			more favourable conditions for the vector insects to survive increasingly warmer winters. The virus has also been detected in Slovakia and Poland.
M118	<i>Listeria</i> <i>monocytogenes</i> in manually treated olives from small producers	Germany	In 2018, high levels of <i>Listeria monocytogenes</i> tha were considered harmful to health were detected in black olives sold loose in Germany that came from small producers, as well as in olive products. In 2019, a coordinated control programme to check loose olives for <i>L. monocytogenes</i> was initiated in Germany.
M119	Atropine in corn/soy meals (super cereals), a fortified blended food	Denmark	Jimsonweed (<i>Datura stramonium</i>), which grows together with harvested soy, caused incidents of food poisoning with illness and death in Uganda from corn/soy meals due to contamination of atropine/scopolamine. According to the Uganda National Institute of Public Health the same kind of food might be sold also in Europe. However, no specific information on this is available.
M120	Safety risks of food supplements containing vinpocetine	France	Animal data support a risk of birth defects with <i>in utero</i> exposure to vinpocetine. This substance is contained in certain food supplements.
M121	Risk assessment of the recovery of former foodstuffs in animal feed for livestock	France	The French law against food waste has explicitly designated the 'valuation for animal feed' as an option to fight against food waste.
M122	Contamination of groundwater by some veterinary drug residues in Ireland	Ireland	Multiple anthelmintic and anticoccidial veterinary drug residues have been detected in raw water in Ireland. Detections were higher nearer to intensive agricultural operations. These veterinary drug compounds are associated with a range of acute and chronic side effects and their transformation products may cause uncharacterised additional effects.
M123	Metabolites of NBPT-protected urea	Ireland	The use of <i>N</i> -(n-butyl) thiophosphoric triamide (NBPT)-protected urea is expected to increase in Ireland due to a strategy aimed at reducing nitrous oxide gas emissions from fertiliser. Limited residue levels of NBPT in bovine tissues and milk were reported from animals fed high doses of NBPT, but little is known about the fate of its metabolites. Analytical methods and standard reference materials are limited for these and other potential metabolites.
M124	Poisoning from high vitamin D content in food supplement	France	Vitamin D drops are increasingly marketed as a food supplement rather than as a drug, because it is vegan or 'more natural'. The dosage of the food supplement drops is 3 to 4 times higher than for the drug, but the prescription (2 to 3 drops per day for the drug) is not adapted to the food supplement. Several cases of severe chronic intoxication have been observed.





Emerging R	lisk Activities 2020		
M125	First evidence of the presence of anatoxin-a in sea figs/violets (<i>Microcosmus</i>) associated with human food poisoning in France	France	From January 2011 to March 2018, in France, 26 patients reported having a cerebellar syndrome after eating sea figs of the genus <i>Microcosmus</i> . Anatoxin-a (ATX-a) was detected in the sea fig samples; this is the first report of human food poisoning involving ATX-a as the possible causative toxin where the cyanotoxin could be unequivocally identified.
M126	Increase of fish parasites	Germany	Anisakis is one of the most common fish parasites whose numbers have greatly increased over the decades. The worldwide COVID-19 outbreak situation is seen as an additional driver for the increase in incidence of Anisakis and other fish parasites, as a result of food fraud (mislabelling of fish species for sale). This is an update on a short issue reported at a previous EREN meeting.
M127	Contaminants in sushi leaves	Germany	High levels of various contaminants in sea algae and especially sushi leaves were reported, mainly heavy metals like cadmium, lead and aluminium, but also organic arsenic compounds. This is an update to the briefing note on seaweed (ID351).
M128	Increase in <i>Vibrio</i> infections through food due to climate change	Germany	As presented during the digital CLEFSA meeting in [2020], <i>Vibrio</i> infections were identified as one of the most relevant issues likely to increase in Europe due to climate change, especially as a result of increased temperatures and an increase in heavy precipitation events. The abundance of <i>Vibrio</i> species has already been shown to rise greatly as a result, mainly in the Baltic Sea due to its naturally low salt content. Although the issue that has emerged first as a consequence relates to wound infections, food-based infections should also be considered, as infections though digestion of raw fish or shellfish can also occur.
M129	An emerging virus is killing farmed fish: Tilapia lake virus	Germany	Tilapia lake virus is a virus that affects wild and farmed tilapines which causes ulcerated skin, internal haemorrhages and death. It has been reported in Asia, Africa and South America and the number of countries is likely to increase. Currently there is no cure and no vaccine. New findings suggest that Nile tilapia (<i>Oreochromis niloticus</i>), the most common kind of farmed tilapia, could be bred to resist the virus.
M130	Seafloor microplastic hotspots controlled by deep-sea circulation	Germany	Although microplastics are known to pervade the global seafloor, the processes that control their dispersal and concentration in the deep sea remain largely unknown. Thermohaline-driven currents, which build extensive seafloor sediment accumulations, can control the distribution of microplastics and create hotspots with high concentrations, which provides a new mechanism of microplastic transport next to vertical settling. Thermohaline-driven currents are known to supply oxygen and nutrients to deep-sea benthos,
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			suggesting that deep-sea biodiversity hotspots are also likely to be microplastic hotspots.
M131	The proportion of soil-borne pathogens increases with warming at the global scale	Germany	Global warming will lead to an increase of soil- borne pathogens for plants, including diseases of important food and medicinal plants, which could endanger food security. The study offers a global atlas of soil-borne plant pathogens and calculates where they will occur under different conditions in the future. This makes it possible to predict which regions will be particularly susceptible to microbial pest crises in future.
M132	Squid instead of sprats	Germany	While populations of tuna, cod and swordfish decrease due to climate change, the population of squid such as <i>Illex coindetii</i> grows and spreads due to climate change. The advantages of squid are to grow quickly and to have short lives, which allows them to adapt to a changing environment within a comparatively short time. The increase of squid can reinforce the decrease of some kinds of fish, but it can also turn out to be an advantage for predatory fish when the food supply of squid increases.
M133	New salmonid hosts for <i>Tenacibaculum</i> species: expansion of tenacibaculosis in Chilean aquaculture	Germany	The fish pathogen <i>Tenacibaculum</i> has been detected for the first time in rainbow trout (<i>Oncorhynchus mykiss</i>) and in coho salmon (<i>Oncorhynchus kisutch</i>) in Chile. The diseased fish exhibit cutaneous haemorrhages, tail peduncle rot and damage to the mouth and tongue.
M134	Hepatitis E virus genome detected in commercial pork liver and pork meat products in Germany	Germany	The prevalence of hepatitis E virus RNA in pork liver and pork meat products was investigated and overall, 10% of the samples were positive. The prevalence of hepatitis E virus in foods containing pork liver has remained relatively stable and very high in Germany for the last 10 years. The infectivity of the virus was not investigated, and so it is not possible to say whether the detected viruses had been inactivated by heating processes during food production.
M135	Bis(4- chlorophenyl) sulfone (BCPS) concentrations found in Austrian freshwater fish and cormorants (<i>Phalacrocorax</i> <i>carbo sinensis</i>) indicating trophic transport and biomagnification	Austria	BCPS is used as a monomer for the production of polymers like polysulphones and polyethersulphones. Residual amounts migrate from the polymer and were found in various fish tissues. Comparing these results with concentrations measured in 2002–2005, an increasing trend of BCPS levels was observed.



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M136	US court blocks sales of dicamba weedkiller in the United States	Hungary	A US appeal court has blocked Bayer AG from selling a dicamba-based agricultural weedkiller in the United States, and also condemned the US Environmental Protection Agency for substantially understating the risks when it approved the weedkiller in 2016. Dicamba-based weed killers are among the trending patents in recent years. The case is in progress but might affect the pesticide's usage and the target for pesticide residues.
M137	Exposure to environmental levels of pesticides stimulates antibiotic resistance	Hungary	Antibiotics often coexist with pesticides in some environments. Using <i>an E. coli K-12</i> model strain, a connection between nonantibiotic pesticides and the development of antibiotic resistance was proven in different settings.
M138	Shiga toxin- producing <i>Escherichia</i> albertii (STEA)	Hungary	<i>Escherichia albertii</i> , an emerging human pathogen, has been historically misidentified as <i>E. coli</i> or other enterobacteria due to their similar biochemical properties. STEA strains isolated from wild birds in a leafy greens-growing region of California possessed genes encoding type II cytolethal distending toxin.
M139	New hypervirulent <i>Listeria monocytogenes s</i> erovar 4H reported	Hungary	HSL-II isolates that caused severe ovine listeriosis outbreaks are highly virulent and exhibit higher organ colonisation capacities than well- characterised hypervirulent strains of Lm in an orogastric mouse infection model. Its unusual properties, particularly its rhamnose-negative phenotype, would have precluded their recognition as bona fide members of the species Lm and may have resulted in them being overlooked. The discovery of isolates harbouring pan-species virulence genes of the genus <i>Listeria</i> warrants global efforts to identify further hypervirulent lineages of Lm.
M140	Some Salmonella strains can enter lettuce leaves by opening up the plant's breathing pores	Hungary	Wild strains of <i>Salmonella</i> can circumvent a plant's immune defence system and enter the leaves through reopening stomata. A beneficial strain UD1022 was developed and licensed by BASF to protect and strengthen plant root systems
M141	SARS-CoV-2 survives on meat	Hungary	SARS-CoV-2 can survive the time and temperatures associated with transportation and storage conditions in the international food trade: there is no decline in infectious virus after 21 days at 4°C (standard refrigeration) or at -20°C (standard freezing) in chicken, salmon and pork pieces, and longer survival has been reported on stainless steel. The WHO advises that it is very unlikely that people can contract COVID-19 from food or food packaging. While transmission via contaminated food is not a major infection route, the potential for movement of contaminated items



			to a region with no COVID-19 to initiate an outbreak is an important hypothesis.
M142	Barcoded microbial system for tracking agricultural products	Hungary	Genetically engineered microbes (<i>Bacillus subtilis</i> and <i>Saccharomyces cerevisiae</i>) with unique DNA 'barcodes' can track items, e.g. agricultural products, across the world. Decoding these barcodes takes less than an hour and these microbes can last on surfaces for months and ever throughout food preparation. By mixing and matching how these codes were injected, researchers were able to design a nearly infinite number of unique barcodes. The microbes are put in a vegetative state (spore form). By simply spraying these engineered microbes on plants throughout the growing process, researchers found they could still be traced back to their places of origin even months later. The technology also can be used to trace the spread of food-borne illnesses.
M143	Transgenic <i>Aedes</i> <i>aegypti</i> mosquitoes transfer genes to a natural population	Hungary	To control the mosquito-borne diseases yellow fever, dengue, chikungunya and Zika fevers, a strain of genetically modified <i>Aedes aegypti</i> mosquitoes (OX5034) containing a dominant letha gene has been developed by Oxitec Ltd. If lethality is complete, releasing this strain should only reduce population size and not affect the genetics of the target populations, but there is clear evidence that portions of the transgenic strain genome have been incorporated into the target population by creating viable hybrids. In May 2020, the OX5034 strain has received approval to be released into the Florida Keys until 2022, against the objection of many local residents and a coalition of environmental advocacy groups.
M144	Cell-based milk development	Hungary	Stem cells from sources such as milk are transferred into an environment where they convert into mammary gland cells and are treated with the special formula that causes them to lactate. The end product – milk – is obtained through a filtration process.
M145	MicroRNA in breast milk	Hungary	So far more than 1,400 miRNAs (short, fragile strands of RNA made up of around 22 nucleotides) have been identified in breast milk, according to a 2019 review. miRNAs might regulate important aspects of infant development, such as immune function. Data are needed to determine whether they can survive in the gut and whether they have potential as an additive to infant formulas. Their introduction might be difficult because miRNAs were first discovered in relation to cancer research
M147	First identification of <i>Sulcascaris</i> <i>sulcata</i> in edible scallops in Italy	Italy	Sulcascaris sulcata is a nematode parasite of sea turtles, whose larvae were found within the adductor muscle of <i>Pecten jacobeus</i> and <i>Aequipecten opercularis</i> collected from the northern Adriatic Sea in 2017–19. Infection in edible scallops justifies the exclusion of the product from the market and the zoonotic potentia



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		of larvae of this <i>anisakis</i> nematode are yet to be completely excluded.

4. Emerging risk identification activities reported by the knowledge networks

The improvement and adoption of methodologies that support the identification of emerging issues is a priority for EFSA but collaboration between EFSA and its stakeholders, including other EU or Member State institutions, academia and industry, should be improved to avoid any duplication of effort. A summary of presentations on existing systems is included in this section.

4.1. Prioritisation of livestock transboundary diseases in Belgium using a multicriteria decision analysis tool based on drivers of emergence

Belgium shared with EREN the outcome of a ranking exercise using a multicriteria decision analysis tool based on drivers of emergence to prioritise livestock transboundary diseases in Belgium. During the past decade, livestock diseases have (re-)emerged in areas where they had been previously eradicated or never been recorded before. Certain drivers (i.e. factors of (re-)emergence) have been identified. Livestock diseases spread irrespective of borders and therefore reliable methods are required to help decision-makers to identify potential threats and try to stop their (re-) emergence. Ranking methods and multicriteria approaches are cost-effective tools for this purpose and were applied to prioritise a list of selected diseases (N = 29 including six zoonoses) based on the opinion of 62 experts in accordance with 50 driver-related criteria. A total of 50 criteria were identified and classified under eight different domains: (1) pathogen/disease characteristics (N = 9 criteria); (2) distance from Belgium (N = 3 criteria); (3) ability to monitor, treat and control the disease (N = 7 criteria); (4) farm/production characteristics (N = 7 criteria); (5) changes in climate conditions (N = 3 criteria); (6) wildlife interface (N = 6 criteria); (7) human activity (N = 6 criteria); and (8) economic and trade activity (N = 9 criteria). Diseases appearing in the upper ranking were porcine epidemic diarrhoea, foot-and-mouth disease, low pathogenic avian influenza, African horse sickness and highly pathogenic avian influenza. The tool proposed uses a multicriteria decision analysis approach to prioritise pathogens according to drivers and could be applied to other countries or diseases.

4.2. EU foresight system for the systematic identification of emerging environmental issues (FORENV)

FORENV⁴ is a collaborative process for the early detection, characterisation and assessment of emerging environmental issues. A long-term approach that brings together EU knowledge, expertise and practice, its aim is to encourage appropriate and timely actions, enabling decision-makers and stakeholders to manage risks to the environment and health, and to take best advantage of any opportunities. FORENV was established in 2017 in response to the need for improved understanding of emerging

⁴ https://op.europa.eu/en/publication-detail/-/publication/4a9b705f-55d0-11e9-a8ed-01aa75ed71a1/languageen/format-PDF/source-93380080



environmental and climate risks, set out in the seventh Environmental Action Programme. Through a collaborative process, combining expert knowledge and deskbased research, each year FORENV identifies, characterises and communicates 10 priority emerging issues and their associated risks and opportunities for Europe's environment and environmental policy. In its first full cycle (autumn 2018 to autumn 2019), FORENV focused on emerging issues at the environment-social interface. The 10 issues are diverse in nature and broad in focus, and links can be drawn between some issues. These include digitalisation and mobile communications as drivers of changes in citizen activism, consumption behaviours and the way that people connect with nature; new patterns of consumption; the implications of populism and protectionism for international cooperation on environmental issues; and environmental and climate change as a driver of conflict and migration; niche activities at the environment-social interface such as using small areas in cities as 'living labs' to test social and technological innovations; the implications of such transitions for different social groups; and the need for new forms of knowledge and skills to support sustainability transitions (FORENV, 2019).

4.3. Drivers for the emergence of COVID-19 in pets

Belgium presented EREN with the results of an expert elicitation of knowledge on the drivers of emergence of the COVID-19 in pets. Its probable animal origin, along with recent case reports among pets, make it crucial to understand the drivers of emergence in domestic carnivorous pets, especially cats, dogs and ferrets. Few data are available for these species. First, 46 possible drivers of emergence of COVID-19 were listed in pets, regrouped into eight domains (i.e. the pathogen/disease characteristics, the spatial-temporal distance of outbreaks, the ability to monitor it, disease treatment and control, the characteristics of pets, changes in climate conditions, the wildlife interface, and human activity and economic and trade activities). Secondly, a scoring system for each driver was developed, then scientific experts (N = 33) were asked to: (a) allocate a score to each driver, (b) weight the drivers' scores within each domain, and (c) weight the different domains. Thirdly, an overall weighted score per driver was calculated; drivers were ranked in decreasing order. Fourthly, a regression tree analysis was used to group drivers with a comparable likelihood of playing a role in the emergence of COVID-19 in pets. Finally, the robustness of the expert elicitation was verified. Five drivers were ranked with the highest probability of playing a key role in the emergence of COVID-19 in pets: the availability and quality of diagnostic tools, the human density close to pets, the ability of preventive/control measures to avoid the disease's introduction or spread in a country (except treatment, vaccination and reservoir control), current species specificity of the disease-causing agent and current knowledge on the pathogen. As scientific knowledge on the topic is scarce and still uncertain, expert elicitation of knowledge, in addition with clustering and sensitivity analyses, is of prime importance to prioritise future studies, starting from the top five drivers. The present methodology is applicable to other emerging pet diseases (Saegerman et al., 2020).



4.4. Phytopharmacovigilance in France

ANSES presented EREN with the French phytopharmacovigilance scheme for monitoring the adverse effects of plant protection products. Nineteen partners are part of the monitoring networks covering the surveillance of the environment, pest resistance, sales and uses of plant protection products, animal and human health effects. In addition to these information sources the scientific literature is monitored. Information gathered by the network and the literature are analysed to issue reviews, trends, signals or alerts. Two examples picked up by the network were shown to illustrate the various possible outcomes of a signal analysis: prosulfocarb residues in apples (and other nontarget crops) resulted in strengthening the monitoring and drift controls, and a cluster of paediatric cancers in the Bordeaux vineyard area resulted in two research studies one exposure study among residents living close to a vineyard (PestiRiv) and one epidemiological study on the association between the proximity to crops and the occurrence of paediatric cancers (GEOCAP-Ag). The phytopharmacovigilance scheme has proven a successful way to share the results of the data analyses that support the review of the active substance in the context of authorisation renewal, and also at triggering alerts that can conclude in management measures, risk assessment method reviews or further research studies being commissioned.

4.5. Emerging risk identification system for Tesco

Retailers are the interface between producers and customers at all levels of the supply chain and therefore they need to be at the forefront of providing a robust emerging risk identification system.

Supply chains are continually increasing in complexity with the need for strong quality systems to ensure food safety. Horizon-scanning is key to ensuring emerging issues and regulatory changes are identified, allowing appropriate action to be taken in the business to mitigate the impact in the short, medium and long term. Reputable businesses and their trade associations carry out horizon-scanning and risk-monitoring as an integral part of their management systems.

The scope of Tesco's emerging risk identification system at retail level is broader than just food safety, as it should also cover the scanning of risks associated with changes in legislative frameworks such as competition law. Therefore, the Tesco ERI team is composed of experts from a wide variety of backgrounds which also include law.

With the purpose of collecting signals on potential emerging issues, the Tesco ERI team scans a huge variety of information and data sources. From food safety authorities and other relevant institutions' websites, such as the World Organization for Animal Health and ECHA, to data collection and analysis from testing labs or peer-reviewed publications.

The Tesco ERI team uses new methodologies to filter relevant information from this vast amount of data, from structured scanning of key publication databases to trialling new systems such as SGS Digicomply or by exploring external providers to develop structured news scanning services tailored to their needs.



All the activities conducted by the Tesco ERI team are supported by a robust communication plan within the organisation that includes, ad hoc alerts via email and communications at the technical director's forum.

4.6. International Featured Standards database and emerging risk identification

The International Featured Standards (IFS) certification⁵ on food standards is a recognised standard for audits of food industries. IFS food standards are applicable when products are 'processed' or where there is a risk of contamination of the product during primary packaging. A recent pilot exercise was conducted by IFS to test the usefulness of the information collected on non-compliance identified at unannounced IFS audits for the identification of emerging food safety issues. The information on non-compliance is collected in the form of a report and transferred to the IFS database for further analysis. The IFS tool, data and audit reports are open to the respective local authorities to support regular official inspections of IFS-certified premises.

The outcomes of this pilot exercise identified as the most relevant non-compliance incidents were those related to labelling issues (e.g. missing information, wrong labelling), allergens (e.g. not declared allergens, failure of adequate cleaning), critical limits for hazard analysis and critical control points and the condition of equipment and facilities. A comparison between these outcomes and the Rapid Alert System for Food and Feed notifications at country level was made to correlate the deficiencies identified at the premises with officially reported food safety scares.

4.7. SAFE campaign 'We value true natural'

SAFE is an independent non-profit organisation lobbying for consumer rights in EU policy. Within SAFE's activities, the recent campaign 'We value true natural' aims to highlight the misleading use of the term 'natural' on food packaging. Such campaigns may be interpreted as a way to raise awareness and to identify potential risks for consumers.

Several examples were presented to illustrate the use of the label 'natural' on different food products and how this practice could lead to misinterpretation. This is the case for highly processed food still labelled as natural. Mislabelling a product as 'natural' may increase consumer trust towards high intakes, and therefore increase exposure to certain chemicals in their composition.

5. Emerging risk identification methodologies and data collection by EFSA

5.1. DEMETER 1

The project was finalised and the scientific report published (Meijer, et. al, 2020). The objectives and research proposed in the DEMETER project were specifically designed to support EFSA's procedures for emerging issue and risk identification by providing a

⁵ <u>https://www.ifs-certification.com/index.php/en/</u>



community resource that would allow EFSA and EU Member State authorities to share data, data-mining knowledge and methods in a rapid and effective manner over a new technical platform. This was done by developing a prototype Emerging Risks Knowledge Exchange Platform (ERKEP), based on a content management system and KNIME data analysis workflows. The prototype ERKEP can assist EFSA and the EREN members to share knowledge more effectively, contributing to earlier identification of emerging risks. In particular, the content management system component provides a platform to share data, data-mining knowledge and methods in an easy and effective manner. The KNIME infrastructure and data analysis workflows that were developed as part of the project provide the ERKEP users with methods to analyse data and develop these methods collaboratively. In conclusion, the output of the DEMETER project illustrates how EFSA's and EREN members' interactions for the identification and analysis of emerging risks could look in the future.

5.2. Screening for emerging chemical risks in the food chain (SCREENER)

Emerging chemical risks can arise from intentional or unintentional contamination of the food chain either by anthropogenic or 'natural' chemicals. A systematic framework for the identification of emerging chemical risks in the food chain using data generated under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation⁶ was published in 2014. The methodology proposed was further developed and tested on 100 substances registered under REACH (project report on REACH 1). The tested screening procedure was then applied to the 15,021 substances registered in REACH (project report on REACH 2). Substances were assessed and scored for environmental release (tonnage and use information from REACH registration dossiers), biodegradation (predictions from BIOWIN models 3, 5 and 6 evaluated in a battery approach), bioaccumulation in food/feed (ACC-HUMAN steady modelling) and chronic human health hazards (classification according to the Classification, Labelling and Packaging Regulation⁷ for carcinogenicity, mutagenicity, reproductive toxicity and repeated dose toxicity as well as the International Agency for Research on Cancer's classification for carcinogenicity). Prioritisation based on the scores assigned and additional data curation steps identified 212 substances that were considered to be `potential emerging risks' in the food chain. А follow-up project (OC/EFSA/SCER/2020/02) was launched in 2020 with the following specific objectives: (a) to apply a suspect screening approach to 212 chemicals currently registered under the REACH legislation that were assigned high priority as potential unrecognised contaminants in European food and feed; (b) to concurrently apply non-target screening for halogenated organic chemicals which may have been introduced unintentionally through industrial and/or anthropogenic sources and have not previously been

⁶ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. OJ L 396, 30.12.2006, p. 1–849.

⁷ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1–1355.



recognised as contaminants in the food chain; (c) to fully quantify the occurrence of a limited number of chemicals in food and feed; (d) to evaluate the significance of the occurrence levels of analysed chemicals to characterise the risk from them. The project was awarded to a consortium of Wageningen University & Research, University of Chemistry and Technology Prague and Fraunhofer Item.

5.3. Food fraud

The FFRAUD Project envisages developing a framework to detect food fraud as a driver of emerging risks in food and feed safety. This will include the development of tools to collect food fraud incident data, methodologies for data analysis, and establishing partnership/networking activities to characterise and prioritise signals of food fraud incidents. The project aims to analyse and incorporate the many different initiatives dealing with the monitoring and analysis of food fraud in Europe.

5.4. Circular economy

EFSA envisaged a two-year project on food safety vulnerabilities in the circular economy. The project had two specific objectives:

- To conduct a literature survey and monitor ongoing research projects to gather and evaluate the evidence for vulnerabilities of the circular economy for food and feed safety, plant and animal health, and the environment. As a new driver, implementation of the circular economy might bring about a set of emerging risks, understood as risks resulting from a newly identified hazard to which significant exposure might occur, or from an unexpected new or increased significant exposure or susceptibility to a known hazard.
- To build a network of stakeholders from various relevant international organisations (EEA, FAO, the Joint Research Centre (JRC), the European Commission's Directorates-General for Health and Food Safety; Environment; Research and Innovation; Agriculture and Rural Development) and Member States and engage them to explore future developments and possible synergies, opportunities, conflicts and trade-offs between environmental and food safety considerations.

The first work package of the project was based on an extensive literature search and monitoring of ongoing research projects, having three specific objectives:

1. to describe the current degree of uptake of different circular economy practices in Europe;

2. to identify emerging risks to plant, animal health and the environment related to the circular economy, resulting from new hazards and new exposure pathways leading to increased exposure;

3. to characterise the identified emerging risks by providing the available information justifying the definition of emerging risk, in the context of EFSA's prioritisation and risk assessment activities.



The literature review was outsourced through a negotiated procedure. The contract entered into force in December 2020 and the duration was one year.

5.5. New food and feed sources and production technologies (innovation activity)

Innovation is one of the key drivers accelerating the transition to sustainable, healthy and inclusive food systems from primary production to consumption and can contribute to developing and testing solutions, and overcome barriers, but at the same time can lead to the emergence of new risks. Innovation in the food and feed production sector has been substantial over the last two decades, both in terms of the production technologies it employs as well as the products it brings forward. Changes in production technologies and global supply chains, along with the growing need to secure food and feed, to ensure the sustainable use of resources and to address societal concerns provide key drivers for future developments. Technologies from a wide range of sectors are applied to food and feed production, while new food and feed production methods are under development. Innovative production technologies can drive a new generation of new food and feed sources, necessitating multifaceted pre-market evaluation to protect the health and interests of consumers. Innovation in general may lead to potential complex problems involving multiple actors. That's why we should act proactively and not repressively.

The objective of this project is the identification of weak signals in the field of new food and feed sources and production technologies and the piloting of appropriate stakeholder engagement methods in order to harvest relevant knowledge. The deliverables of the project are: (a) the customisation of automatic tools to extract and visualise information in the respective fields; (b) the piloting of engagement methods that have not yet been used by EFSA and in this way creating a bridge of knowledge between all the involved parties; (c) the potential enrichment of EFSA's stakeholder list; (d) the customisation of appropriate methodology for characterisation reasons; and (e) the production of a technical report on the potential weak signals in the area of new food and feed sources and production technologies, which could be shared as part of EFSA's emerging risk identification process and enrich the repository of emerging risks or the platform that we will use in the future.

5.6. Data intelligence tool for emerging chemical risks – JRC tool for the innovation monitoring project

The European Commission's JRC has developed two data intelligence tools: Medisys for real-time news analysis of medical and health-related topics and the tool for innovation monitoring (TIM) technology for extracting data visualisation and knowledge from scientific publications, patents and EU projects. None has been evaluated for its ability to identify emerging chemicals in the food chain in the EU. Both tools will be customised and tested in an initial pilot phase over a two-year period for this purpose. The project kicked off in September 2020 and will run until the end of 2022. Its overall objective is to apply data intelligence tools from JRC (TIM and Europe Media Monitor) to support the identification of emerging chemical risks in food and feed. They will be applied to: (a)





unknown emerging chemical issues or risks; and (b) a set of known priority chemicals with emerging risk potential (Oltmanns et al, 2019; Oltmanns et al., 2020).

5.7. EuroCigua

As a follow-up from emerging issue ID No. 76 – First report of indigenous ciguatera fish poisoning in the EU (EREN), a framework partnership agreement (the EuroCigua project) was signed between EFSA and a consortium of 14 Article 36 partners (coordinated by the Spanish Authority for Food Safety – AESAN) in April 2016 and four different specific agreements were signed in June 2016. The project ended in January 2021.

The overall objective of the project was to characterise the risk of European ciguatera food poisoning. The main tasks were to determine the incidence of ciguatera in Europe and the epidemiological characteristics of cases, to assess the presence of ciguatoxin in fish and phytoplankton (dinoflagellates *Gambierdiscus* and *Fukuyoa* spp.) in Europe, and to develop and validate methods for the detection, quantification and confirmation of the presence of ciguatoxin-contaminated specimens.

Annual reports have been produced accompanied by a case definition, surveillance protocol, a database for collecting cases and outbreaks, a list of fish associated with ciguatera, extraction procedures, sampling strategies for *Gambierdiscus*, *Fukuyoa* and fish, evaluation of the presence of ciguatoxin in different fish tissues and the development, optimisation and validation of analytical procedures (liquid chromatography coupled with mass spectrometry) for the identification and confirmation of ciguatoxin. A website⁸, leaflets and factsheets have also been produced.

An end-of-project workshop was held in October 2020⁹. The EuroCigua project recorded a total of 34 outbreaks and 209 cases in Europe between 2012 and 2019. It found *Gambierdiscus* and *Fukuyoa* spp. not only on the Spanish and Portuguese Atlantic islands but also on several Mediterranean islands including Crete, Cyprus and, for the first time, the Balearics. EuroCigua confirmed that ciguatera fish poisoning is becoming endemic in the Macaronesia area. Climate change and globalisation of trade are the main drivers of the spread of ciguatera in Europe, which is intensified by travel to tropical areas. The project ended with a call for further data collection, standardisation of analytical methods and development of predictive modelling to inform appropriate risk management of ciguatera in Europe

For further information on ciguatoxins and other marine biotoxins, see https://www.efsa.europa.eu/en/topics/ciguatoxins-and-other-marine-biotoxins

5.8. CLEFSA – climate change and emerging risks to food safety

The objectives of the CLEFSA project were: (i) to develop a methodological approach for identifying, characterising, analysing and visualising emerging issues related to the effects of climate change on food and feed safety, plants, animal health and nutritional

⁸ http://www.aesan.gob.es/AECOSAN/web/ciguatera/home/aecosan_home_ciguatera.htm

⁹ http://www.aesan.gob.es/AECOSAN/web/ciguatera/ampliacion/seminario.htm



quality in the EU; and (ii) to bring together existing EFSA initiatives in the area of climate change, providing more transparency to the way EFSA is contributing to addressing this global problem.

The CLEFSA project explored the possibility of: (a) using the specific driver, climate change, for long-term anticipation of multiple emerging risks, using scenarios of climate change; (b) using horizon-scanning and crowdsourcing to collect a broad range of signals from a variety of information sources; (c) using a knowledge network of experts from international organisations in the EU and the United Nations; (d) designing a multicriteria decision analysis tool to characterise signals through a participatory process, in which expert knowledge is used to identify relevant issues from vast and often incomplete information; and (e) developing methodologies and indicators for the analysis and visualisation of the information collected during the characterisation and to address uncertainty in a data-poor environment.

A transparent and reproducible procedure was designed: (1) building the CLEFSA network; (2) definition of the identification criteria; (3) identification of emerging issues; (4) definition of the characterisation criteria; (5) designing the methods and tools for expert characterisation; (6) characterisation of the identified emerging issues; (7) analysis and visualisation of the results.

An interdisciplinary CLEFSA network was created constituted by experts from international EU and UN institutions and the coordinators of large EU projects involved with climate change. The task of this network was to support the identification of emerging issues, design a multicriteria decision analysis tool for characterisation purposes and to support the building of the characterisation group.

The criteria for identifying emerging issues potentially affected by climate change were drawn up based on those used in the EFSA emerging risks identification process and adapted to the specific driver under analysis.

A survey was launched to collect a broad range of issues potentially affected by climate change, including weak signals. The scope of the survey covered all of EFSA's areas of work. More than 600 people responded, yielding over 240 issues. The issues identified in the survey were complemented by literature search, using online search tools developed by other EU institutions, EFSA's EREN (and the stakeholder discussion group) and information stemming from EFSA's activity related to the subject.

CLEFSA concluded that climate change has the potential to cause, increase or change the occurrence and intensity of some food-borne diseases and the establishment of invasive alien species harmful to plant and animal health. It has an impact on the occurrence, intensity and toxicity of blooms of potentially toxic marine and freshwater algae and bacteria, on the dominance and persistence of various parasites, fungi, viruses, vectors and invasive species that are harmful to plant and animal health. Climate change is likely to drive the emergence of new hazards, increase the exposure or the susceptibility to known hazards and change the levels of micronutrients and macronutrients in food and feed items.





The project ended in June 2020 and in October 2020 a final information session¹⁰ was held to communicate the results of the project. It concluded that CLEFSA was successful in bringing together the expertise of different stakeholders to address a complex, multidisciplinary problem, characterised by a high level of uncertainty. As a follow-up, EFSA should strive to engage a wider variety of stakeholders, such as citizens, farmers and local authorities, in the implementation of systemic approaches to its emerging risk identification process, strengthen its collaboration with international bodies such as the Intergovernmental Panel on Climate Change to disseminate its work on climate change and focus on a more detailed risk characterisation of priority issues.

6. Networking and international cooperation

Exchange of information and knowledge is a key priority in the EFSA strategy for ERI. EFSA knowledge networks are not limited to EREN and StaDG-ER but include EFSA's units, networks, panels and the Scientific Committees, Member State national scientific networks, European institutions and international organisations. Data are shared between EFSA knowledge networks and the EC to collect additional information and communicate identified issues. The agenda and minutes of EREN meetings are also shared with Member State focal points. All outputs (technical reports, meeting agendas and minutes, and annual activity reports) are available on EFSA's website¹¹. Presentations to EFSA panels and the Scientific Committee during plenary meetings to discuss potential emerging risks are regularly organised. In addition, a series of collaboration and dissemination activities were organised in 2020:

- Participation in the International Food Chemical Safety Liaison Group meeting, 4 February 2020
- Participation in the FORENV meeting, 5 February 2020
- Participation in the Heads of Agencies Working Group on Food Supplements meeting at the Federal Office of Consumer Protection and Food Safety,20 March 2020
- Presentation given to the International Liaison Group on Methods for Risk Assessment of Chemicals in Food, 25 June 2020
- Presentations given to the European Environment Information and Observation Network Ad Hoc Expert Group on Chemicals, 29 June 2020 and 15 September 2020
- Presentation given at PROTECT, Marie Sklodowska-Curie Innovative Training Network, 9–10 October 2020
- Presentation given at the third International Congress on Food Safety and Quality, 10–13 November 2020
- Participation in the fourth meeting of the Spanish National Network of Emerging Risks, AESAN, 17 November 2020



¹⁰ https://www.efsa.europa.eu/en/events/event/info-session-climate-change-driver-emerging-risks-food-and-feedsafety

¹¹ https://www.efsa.europa.eu/en/topics/topic/emerging-risks



 Presentation given to Operation OPSON X – Targeted action on honey, Europol, 1 December 2020.

EFSA also contributed to training on the emerging risk identification process in the context of the EFSA summer school and EU-FORA (risk assessment capacity development).

7. Discussion

In total, 13 potential emerging issues were discussed in 2020. Six were concluded to be emerging while in seven cases no conclusion was reached. The potential issues were classified according to the hazard and/or driver identified (hazard identified: microbiological (5), chemical (2), microbiological and chemical (1), other (4); driver identified: illegal activity (0), new consumer trends (0), new process or technology (1), climate change (0), other (0)) (Figure 1).

The classification adopted by EFSA allows for comparison of trends and hazards identified over the years (Figure 1).

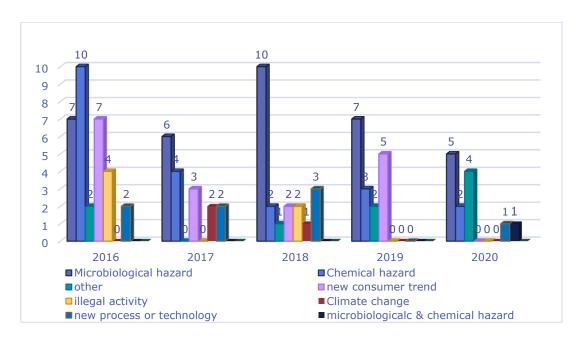


Figure 1: Potential emerging issues and drivers 2016–2019

In addition, in 2020 the EREN network members presented and discussed a total of 35 signals and potential emerging issues identified by their own horizon-scanning activities. Member State representatives shared their work on signal identification with the objective of collecting additional information to be used for better characterisation. EFSA has updated its template to collect the information and a unique identifier is now attributed to each of the signals and potential emerging issues within EFSA's remit to allow for traceability of the issue and the possibility to update of the information over time. A new EUSurvey-based system has also been developed to characterise and analyse emerging issues without having to wait for an EREN or StaDG-ER meeting.



Emerging risk identification and analysis activities between EFSA and its partners require the development of an effective digital collaboration tool and a flexible knowledge management system beyond the existing emerging risks knowledge repository. The ERKEP prototype developed under the DEMETER project is an illustration of such a digital solution. ERKEP was designed for the interaction between EFSA and EREN but the variety of parties involved in emerging risk identification in and outside of Europe requires a collaborative platform for broader participation.

Communication is a fundamental part of the ERI procedure. Presentations on identified emerging issues and risks and supporting projects were given to EFSA's scientific panels (e.g. the Panel on Biological Hazards, 9 July 2020). Communication with the relevant Commission services is also ensured by the participation of a EC representative during the EREN and StaDG-ER meetings. The low frequency of EFSA communication on its emerging risks identification/analysis activities to the general public, through the publication of the EREN/StaDG-ER meeting minutes, and once a year with the publication of an annual activity report, is acknowledged; alternative solutions will be considered by EFSA to improve this.

8. Conclusion and recommendations

The landscape of emerging risks is constantly changing and evolving. As in previous years, EFSA continues to improve its methodology and tools to address the responsibility conferred by the EU General Food Law¹² regarding the anticipation of possible emerging risks in food and feed. With this objective, EFSA decided to become more proactive in identifying emerging issues and envisaged a series of pilot projects for the identification of emerging risks associated with areas of specific interest, such as emerging chemicals, new food and feed sources and production technologies, food fraud, the circular economy, etc. (see Section 5). These project proposals, if prioritised by EFSA would complement the issues brought up by EREN and StaDG-ER members and enrich the discussion.

By increasing its emerging issues identification capacity, EFSA will need an operational platform, centralising all emerging risk identification and characterisation activities. The ERKEP prototype resulting from the DEMETER project is an example of how such a platform might look, but it has already been identified that EFSA needs a broader, more collaborative platform, allowing the participation of all interested parties, whether Member State competent authorities, stakeholders or international organisations. Possibilities to further develop ERKEP and make it operational will therefore be explored.

The emergence of COVID in 2020 has highlighted the need for EFSA to change its working methods, relying less on physical meetings and instead develop alternative solutions to continue its mission. The incremental use of Microsoft Teams and the development of smart solutions such as surveys to gather information on and analyse emerging issues electronically have been part of the solution and avoided the disruption

¹² Regulation (EC) No. 178/2002/EC.



of the emerging risk identification activities. These alternative approaches will be further developed and improved, with the experience accumulated overtime.

It is essential to remain vigilant and proactive in the area of emerging risks in order to address and tackle all the challenges in this demanding field.





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Glossary

Driver	Generally, the energy providing impetus to a development. In futures research, drivers are frequently referred to as internal/external factors influencing developments, decisions, policies etc., helping to define possible future scenarios. Often used in parallel to, or overlapping with, the term 'trend', but a driver can be observed as having a direct or indirect impact on the system while a trend reflects change within the system. Hence, a driver is more specifically used to describe the phenomena underlying trends and other developments that eventually lead to the emergence of risks.
Emerging issue	An issue that could be a food or feed safety risk that has very recently been identified and merits further investigation, or 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 risk 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 susceptible group of the population), as well as general issues, called drivers (e.g. climate change), that could result in emerging risks.
Emerging risk	An 'emerging risk' to human, animal or plant health and the environment is understood to be a risk resulting from a newly identified hazard to which a significant exposure could occur or from an unexpected new or increased significant exposure or susceptibility to a known hazard.



Abbreviations

AHAW	EFSA Panel on Animal Health and Welfare
ANSES	French Agency for Food, Environmental and Occupational Health and Safety
AVC	Association of Veterinary Consultants
ATX-a	Anatoxin-a
BCPS	Bis(4-chlorophenyl) sulfone
BfR	German Federal Institute for Risk Assessment
BIOHAZ	EFSA Panel on Biological Hazards
BIOWIN	Biodegradation Probability program
CABYV	Cucurbit aphid-borne yellows virus
CLEFSA	Climate change and emerging risks for food safety
CPs	Chlorinated paraffins
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
EEA	European Environment Agency
EFSA	European Food Safety Authority
EREN	Emerging Risks Exchange Network
ERI	Emerging risk identification
ERKEP	Emerging Risks Knowledge Exchange Platform
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FDA	US Food and Drug Administration
FESASS	European Federation for Animal Health and Sanitary Security
FORENV	EU Environmental Foresight System
FVE	Federation of Veterinarians of Europe
HORECA	Hotels, Restaurants and Catering
IFS	International Featured Standards
JRC	Joint Research Centre
MRL	maximum residue levels



NBPT	N-(n-butyl) thiophosphoric triamide
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RNA	Ribonucleic acid
SAFE	Safe Food Advocacy Europe
SARMs	Selective androgen receptor modulators
SCER	Scientific Committee and Emerging Risk Unit
SDHI	Succinate dehydrogenase inhibitor
StaDG-ER	Stakeholder Discussion Group on Emerging Risks
TBE	Tick-borne encephalitis
TBEV	Tick-borne encephalitis virus
TIM	Tool for Innovation Monitoring
STEC	Shiga toxin-producing Escherichia coli
UNESDA	Union of European Beverages Associations
WHO	World Health Organization