

Emerging chemical risks in food and feed

European Food Safety Authority (EFSA),
Alexandros Georganas, Angelo Maggiore, Bernard Bottex

Abstract

The EFSA process of Environmental Scanning and Strategic Options Definition aims at identifying knowledge gaps and opportunities to fulfil EFSA's mission more efficiently and contribute to the definition of EFSA's work programme and long-term strategy. The identification of trends, drivers of change and emerging risks in the fields within EFSA's mission is one of the objectives of this process. The Member States and stakeholders in the EFSA knowledge networks for emerging risks, namely the Emerging Risks Exchange Network (EREN) and the Stakeholder Discussion Group on Emerging Risks (StaDG-ER), have identified several emerging chemical issues/risks and analysed them according to the EFSA definition of emerging risks and characterisation criteria. In addition, various EFSA projects have been conducted for the identification of emerging chemical issues/risks using a wide range of methodologies and tools, like text and data mining, drivers' analysis, foresight and chemical analysis (suspect screening, non-target analysis). In these projects, a variety of specific emerging chemical issues/risks have been identified and drivers of emerging risks explored (climate change, blue economy, circular economy). This technical report provides an overview of EFSA's activities related to emerging chemicals in the period 2020-2023. Identified emerging chemicals as well as the analysis of the strengths and weaknesses of the overall identification process in place, with a particular focus on its sustainability in the long term, are reported. In the context of the latest regulatory developments related to the set-up of an early warning system for emerging chemicals, actions to maximise opportunities and minimise weaknesses are described. They focus on collaborative efforts with a wide range of organisations for a permanent and sustainable emerging chemical risks identification system and developments to support the exchange of information on emerging chemical risks via specialised platforms.

© European Food Safety Authority, 2024

Key words: emerging risks, chemicals, food, suspect screening, non-target screening

Requestor: EFSA

Question number: EFSA-Q-2024-00477

Correspondence: know@efsa.europa.eu

Acknowledgements: EFSA wishes to thank the following people for the support provided to this scientific output: Members of EFSA Working Group on Emerging Chemicals: Peter Fürst and Matthew MacLeod; EFSA staff and trainees: Aurore Czerwiek, Raquel Garcia Matas, Milen Georgiev, Roberta Giarnecchia and Georgia Gkrintzali.

Suggested citation: EFSA (European Food Safety Authority), Georganas A, Maggiore A and Bottex B, 2024. Emerging chemical risks in food and feed. EFSA supporting publication 2024:EN-8992 42 pp. doi:10.2903/sp.efsa.2024.EN-8992

ISSN: 2397-8325

© European Food Safety Authority, 2024

Reproduction is authorised provided the source is acknowledged.

Copyright for non-EFSA content: EFSA may include images or other content for which it does not hold copyright. In such cases, EFSA indicates the copyright holder and users should seek permission to reproduce the content from the original source.

Map Disclaimer: The designations employed and the presentation of material on any maps included in this scientific output do not imply the expression of any opinion whatsoever on the part of the European Food Safety Authority concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries.

Table of Contents

Abstract	1
1 Introduction	4
1.1 Background and terms of reference	4
1.2 The EFSA Environmental scanning and strategic options definition process	4
2 Emerging chemical risks identified in EFSA projects	8
2.1 Screening for emerging chemical risks in the food chain (SCREENER Project)	8
2.2 Testing the JRC TIM tool to identify emerging chemical risks in food	10
2.3 Climate change and emerging risks for food safety (CLEFSA project)	12
2.4 EuroCigua I and II projects	16
2.5 Future challenges for the safety of food and feed from the oceans: A foresight study	18
2.6 Food and feed safety vulnerabilities in the circular economy	19
3 Emerging chemical risks identified within the EFSA's knowledge networks	20
4 Evaluation of EFSA's approach for identification of emerging chemicals: a SWOT analysis	28
5 Future developments	29
5.1 Policy developments on emerging chemical risks	30
5.2 Platforms for the exchange of information on emerging risks	31
5.3 Cooperation at EU and international level	32
5.4 Workshop on "Emerging chemical risks for public health and the environment"	33
6 Conclusions	33
7 Recommendations	34
References	37
Glossary	41
Abbreviations	42

1 Introduction

1.1 Background and terms of reference

Strategic Objective N°2 of the EFSA Strategy 2027 is about ensuring preparedness for future risk assessment needs (EFSA 2021). To address it, EFSA has developed the “Environmental Scanning and Strategic Options Definition” process. This process aims at identifying both knowledge gaps and opportunities to fulfil EFSA's mission more efficiently. As such, the process contributes to the definition of EFSA's work programme and long-term strategy. The identification of trends, drivers of change and emerging risks in the fields within EFSA's mission is one of the aims of such process.

Emerging chemical risks may arise from intentional or unintentional contamination of the food chain either by anthropogenic or ‘natural’ chemicals. Several projects have been or are being developed by EFSA, in collaboration with other European Union (EU) agencies and partner organisations (Article 36 of Regulation (EC) No 178/2002), for the collection of data and the development of methodologies for the identification of emerging chemical risks. This report aims to provide a comprehensive overview and analysis of the main results of the projects run during the period 2020-2023. This overview includes:

- a) the SCREENER project on “Screening for emerging chemical risks in the food chain”;
- b) the TIM project on “Testing the JRC Tool for Innovation Monitoring (TIM) to identify emerging chemical risks”;
- c) the CLEFSA project on “Climate change as a driver of emerging risks for food and feed safety, plant, animal health and nutritional quality”
- d) the EUROCIGUA (EuroCigua I and II projects) projects on “An integrated approach to assess the human health risks of ciguatoxins in fish in Europe”;
- e) the OCEANS project on “Future challenges for the safety of food and feed from the oceans: a foresight study”;
- f) the CIRCULAR ECONOMY project on “Identification of vulnerabilities of circular economy for food/feed safety, plant and animal health and the environment”;
- g) emerging chemical issues/risks discussed at the knowledge networks on emerging risks (Emerging Risks Exchange Network (EREN) and Stakeholder Discussion Group on Emerging Risks (StaDG-ER)).

The report also describes the ongoing policy developments related to the set-up of an early warning system for emerging chemicals and provides recommendations on next steps.

An Emerging Chemical Risks Identification Working Group (ECRI WG) has been established to (1) carry out activities to identify emerging chemical risks in food and collect additional data regarding identified emerging chemical issues; and (2) develop, test, and improve current horizon scanning methodologies and approaches. The ECRI WG has supported both activities by participating in the SCREENER, the TIM project and in the design of priority follow-up activities.

1.2 The EFSA Environmental scanning and strategic options definition process

The newly implemented process of “Environmental scanning and strategic options definition” aims at:

Emerging chemical risks in food and feed

- Identification/anticipation of any gaps/opportunities that would prevent EFSA to fulfil its mission/allow EFSA to fulfil its mission more efficiently.
- Contribution to the definition of EFSA's working agenda and long-term strategy.
- Analysis of strategic competencies/skills needed – EFSA's partners ecosystem.
- Identification of trends, drivers of change and emerging risks in the fields within EFSA's mission.

It consists in two workflows:

- Horizon Scanning workflow
- Emerging risks analysis workflow

Horizon scanning workflow

The horizon scanning workflow is summarised in Figure 1. The collected topics, signals, trends or upcoming policy developments are subject to a gap analysis by the Knowledge, Innovation and Partnership Management (KNOW) Unit and the Chief Scientist Office (CSO). If the topics are not falling under existing programmes or covered by the current strategy, and if relevant for EFSA, they are further analysed with the aid of various EFSA Units and Panels. The submitted topics are assessed on the basis of the following aspects: (a) whether they have already been addressed by EFSA or its Partners, (b) whether EFSA possesses the in-house expertise to address the topics and if not, where the required expertise is available, (c) whether the submitted topics are consensual enough to be considered in regulatory science. All information collected is summarised in a factsheet that is brought to the attention of the EFSA Preparedness Council. If confirmed relevant for EFSA future work programme and/or strategy, the topic is prioritised.

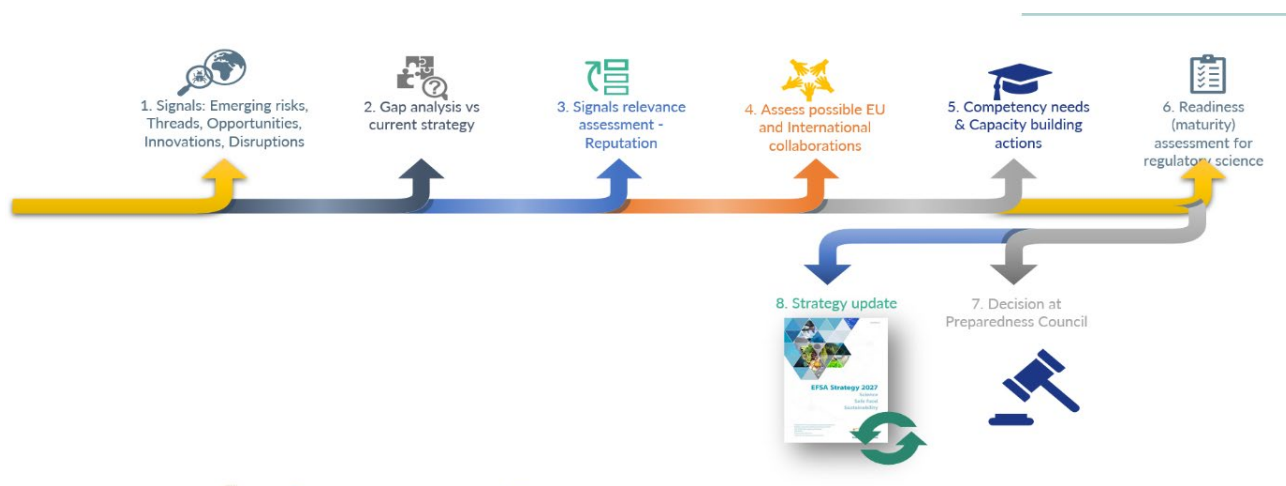


Figure 1: Horizon Scanning Workflow

Emerging Risks Analysis Workflow

In accordance with the EFSA's Founding Regulation (EC) No 178/2002 (Article 34)¹, EFSA establishes procedures to systematically search for, collect, collate, and analyse information and data aiming to identify emerging risks in the fields within its mission.

¹ <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32002R0178>

The emerging risks identification (ERI) process aims to raise awareness and to improve preparedness to future food/feed safety challenges as well as to identify future data and assessment methodology needs to keep EFSA's work relevant (EFSA 2020). A definition for emerging risk was developed and agreed by the EFSA Scientific Committee in 2007. A revision of the definition was proposed by the EFSA Standing Working Group on Emerging risks (EFSA 2018) by adding the "environment" in the definition, which was endorsed by the EFSA Scientific Committee in 2019. The addition of the component "environment" in this definition underlines the importance of the One Health approach in preserving not only the health of humans, animals, and plants, but also of the environment. Thus, the revised definition of emerging risk is as follows:

'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.'

In the chemical realm, emerging risks may also result from changed composition of food items or environmental matrices, determining the possibility of a changed intake of micro- and macronutrients. Emerging issues are identified at the beginning of the ERI process as issues that may deserve further investigation and additional data collection. Emerging issues can include specific hazards (e.g., specific chemical substances) as well as general issues such as drivers of change (EFSA 2012a). A commonly used classification for categories of drivers is the STEEPLE framework (Social, Technological, Economic, Environmental, Political, Legal and Ethical) (EFSA 2018). Examples of drivers include population growth, globalisation, resource, and energy scarcity, slowing agricultural productivity, increasing concentration of the supply chain, price volatility, changing diet trends and waste crisis. These can cause complex and interlinked changes that could put the European food and feed system under severe stress.

The identification of emerging issues tends to focus on the short- and medium-term time horizons whereas the long-term anticipation of future food and feed safety challenges and risk assessment needs (data, knowledge, methodologies) may be based on the identification of drivers and the development of future scenarios in the context of foresight exercises. The emerging risks analysis workflow is focusing on the identification and characterisation of issues from weak signals arising from surveillance activities, screening of scientific publications, media monitoring, foresight, experts' networks and analytical screening. Automatic identification tools such as text (MediSys and the TNO Emerging Risk Identification System – ERIS) or data mining (Bitsch et al., 2016) are also being used.

Following pre-screening by EFSA, the analysis of emerging risks is conducted through the EREN and the StaDG-ER, supported by the EFSA scientific units, other EU institutions and international parties like the World Health Organization (WHO) or the Food and Agriculture Organization of the United Nations (FAO), giving access to a broad range of expertise in all fields related to EFSA's remit (EFSA 2015). The objective of EREN is to increase EFSA's capacity to anticipate emerging scientific or societal issues through the cooperation between EFSA and risk assessors of the EU Member States and countries of the European Free Trade Association (EFTA), as well as observers from the European Commission (EC), the European Centre for Disease Prevention and Control (ECDC), the European Chemicals Agency (ECHA), the European Environment Agency (EEA), WHO, FAO, the Food Standards Australia New Zealand, and the US Food and Drug Administration (FDA). The StaDG-ER on the other hand is facilitating exchange of information between EFSA and registered stakeholder organisations from the private sector, consumers' associations, and non-governmental organisations. The information related to an

emerging issue is structured into the so-called 'briefing notes'. They are handled through the emerging risks analysis workflow summarised in Figure 2 below.

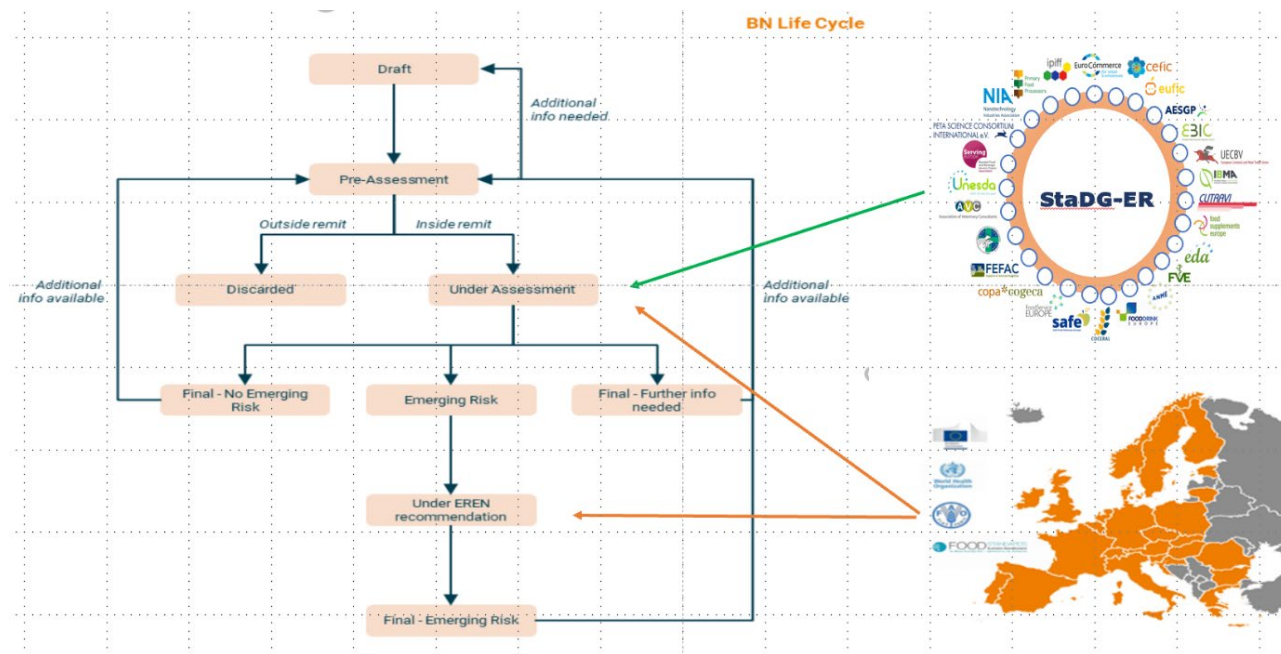


Figure 2: The process of production and discussion of briefing notes in the two established networks for emerging risks. *Acronym:* briefing note (BN).

The emerging issues are assessed based on a set of predetermined criteria according to the EFSA's definitions of emerging issue and emerging risk: (a) new hazard; (b) new or increased exposure; (c) new susceptible group; and (d) new driver.

In addition, a defined set of criteria (Novelty, Soundness, Imminence, Severity and Scale) (EFSA 2012b, 2015) are used for the 'characterisation' of the identified issue through an iterative process within the established emerging risks networks. Additional information on the nature of the hazard identified, or associated drivers and trends is also included. No action is undertaken if the issue is deemed as not compliant with the definition of emerging issue/risk and relevant criteria. The process of characterisation of emerging issues is often based on limited and ambiguous data and expert knowledge, with high levels of uncertainty and low reproducibility.

Based on the available evidence, three decisions may be made for an emerging issue:

- concluded as emerging risk;
- impossibility to conclude due to insufficient information;
- not an emerging risk.

The emerging issues and risks discussed in the two networks are summarised in annual reports on EFSA's activities on emerging risks (EFSA 2023a, 2023b).

The process developed by EFSA for identifying emerging risks in the food and feed chain has a predictive and anticipatory nature (EFSA 2014b) by identifying risks pro-actively before they have any impact or at an early stage of development. This approach is distinct from the responsive nature of detecting known risks leading to emergency (or crisis) situations, and that are usually detected by rapid alert systems such as the Rapid Alert System for Food and Feed

(RASFF) or by the Early Warning Response System (EWRS). These risks are dealt through specific procedures established by the EC. These systems are useful to support decision makers in implementing control and mitigations measures (EFSA 2012b).

2 Emerging chemical risks identified in EFSA projects

2.1 Screening for emerging chemical risks in the food chain (SCREENER Project)

It is in the EFSA's remit to identify emerging chemical risks through systematic processes. Oltmanns et al. (2019) applied a procedure for the identification of potential emerging chemical risks in the food chain associated to substances registered under the Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals² (REACH) that was previously developed and tested in an EFSA-sponsored pilot study (EFSA 2014b). The overall objective was to identify substances potentially introduced into the food chain unintentionally through industrial and anthropogenic activities, which were previously unrecognised or unreported in the food chain.

The selection of the substances was limited to those that (a) were fully registered, (b) met eligibility criteria (e.g., availability of a CAS number and a SMILES notation) and (c) were considered to be inside the applicability domain of the biodegradation and bioaccumulation models used in the study. By using these criteria, the selection of the substances was reduced from 15000 to 2336. Subsequently, the 2336 substances were assessed according to four criteria (Oltmanns et al., 2019):

- environmental releases (based on tonnage and environmental release categories);
- biodegradation (using BIOWIN predictions assessed in a battery approach);
- bioaccumulation in food and feed (using ACC-HUMAN steady modelling); and
- chronic toxicity (based on classification for carcinogenicity, mutagenicity, reprotoxicity and repeated dose toxicity).

The prioritisation resulted in 212 potential emerging chemicals.

As a follow-up of this previous EFSA project, the SCREENER project (see EFSA 2024) aimed at carrying out an in-depth evaluation of the 212 priority substances which were identified. These substances, registered under the REACH Regulation, were considered as 'potential emerging risks', or emerging issues using EFSA's terminology. In addition, the SCREENER project aimed at detecting unknown halogenated organic chemicals not included in the previous list.

Multi-residue high-resolution mass spectrometry-based analytical methods were developed and validated for qualitative screening (presence/absence) applied to the above-mentioned REACH chemicals in plant- and animal-based matrices: wheat flour, carrots, kale, potatoes, peas, strawberries, oranges, chicken, pork, beef, trout, herring, salmon, cow milk, and hen eggs. The detection of the halogenated organic chemicals was performed through non-target screening in the same food items.

Fifteen chemicals (twelve REACH chemicals and three halogenated organic compounds) were prioritised for quantitative analysis, which was carried out in the same samples. The rest of the REACH chemicals from the list of the initial 212 prioritized chemicals were excluded mainly

² <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20140410>

due to reactivity or insolubility in common extraction solvents or unavailability of commercial analytical standards.

Following quantitative analyses of the fifteen chemicals, no signals were detected for the three halogenated organic compounds. Finally, hazard characterisation, exposure assessment, and a preliminary risk characterisation were performed for the remaining 12 REACH chemicals (Table 1).

Table 1: List of chemicals (with CAS numbers in brackets) prioritised for quantitative analysis and for which exposure estimation, hazard and risk characterisation were performed.

Chemical (CAS Number)	# findings of residues ^(a)	HR ^(b) L1 infants max 95 th (µg/kg/day)	Initial LEL ^(b) (µg/kg/day)	Refined LEL (µg/kg/day)	Initial MoE ^(b)	Refined MoE
N-methylacetamide (CAS 79-16-3)	32 ^(c)	2.372	1.5	-	0.6	-
N-methylpyrrolidone (CAS 872-50-4)	30 ^(d)	2.065	15	850	7	412
diethyltoluenediamine (CAS 68479-98-1)	0	0.064	0.0025	100	0.04	1553
N-isopropylmethacrylamide (CAS 13749-61-6)	0	0.064	1.5	830	23	12893
p-toluidine (CAS 106-49-0)	4	0.065	1.5	4	23	62
o-toluidine (CAS 95-53-4)	0	0.064	0.0025	3400	0.04	53125
quinoline (CAS 91-22-5)	20	0.067	0.0025	32.55	0.04	486
TDCPP (CAS 13674-87-8)	1	0.064	0.18	20	3	311
methyl-2-benzoylbenzoate (CAS 606-28-0)	14	0.129	1.5	52	12	403
IPPP (CAS 68937-41-7)	1	0.066	1.5	8	23	121
piperonyl butoxide (CAS 51-03-6)	16 ^(e)	0.481	22	160	46	333
3,4-dimethylaniline (CAS 95-64-7)	3	0.088	0.0025	-	0.03	-

(a): number of measurable findings (i.e., above limit of quantification)

(b): highest residue (HR); lowest effect level (LEL); Margin of Exposure (MoE)

(c): 24 in chicken and eggs samples

(d): 23 in chicken and eggs samples

(e): 12 in wheat flour samples

Source: EFSA (2024).

The preliminary characterization of the potential risk posed by the chemicals found in the samples during quantitative analysis indicated no concern to human health in all but three cases:

- (i) 3,4-dimethylaniline,
- (ii) quinoline,
- (iii) n-methylacetamide.

For these, additional analysis on occurrence and detailed evaluation of the hazard was recommended.

2.2 Testing the JRC TIM tool to identify emerging chemical risks in food

The TIM Analytics tool³ developed by the Joint Research Centre (JRC) was assessed for its efficiency and relevancy in identifying emerging chemical risks in the food chain. More specifically, the TIM Analytics tool consists of the 'TIM Technology' tool, which was tested for extracting knowledge from structured data such as scientific publications (Scopus database, Elsevier), patents (European Patent Office-PATSTAT) and EU funded projects (CORDIS), and the 'TIM News' tool, for analysing media aggregated by the Europe Media Monitor (EMM) system^{4,5} (EFSA 2023c).

During a 2-year exercise, a subset of 60 chemicals of the top scored 212 considered as potential emerging risks in the REACH2 project (Oltmanns et al., 2019) as well as newly identified chemicals were assessed using 'TIM Technology' and 'TIM News' (EFSA 2023c). Of the above-mentioned 60 chemicals, bisphenol A (BPA), tetrabromobisphenol-A (TBBPA), 9,10-anthraquinone, and hexabromocyclododecane did not qualify as emerging since these compounds were well studied at the time of the study. Thus, these chemicals were excluded from the screening procedure.

By using different search strings for each chemical in 'TIM Technology', the title and the abstract of the resulting articles were screened by EFSA and the ECRI-WG in two phases. The first screening was performed by two EFSA reviewers, and the second screening by one EFSA reviewer and two members of the ECRI WG. The experts conducting the second screening had expertise in environmental science, food and analytical chemistry and toxicology. Furthermore, the second screening was assisted by using the screening tool 'DistillerSR'⁶. The same approach was followed for the results retrieved from 'TIM News'. The eligibility criteria and the detailed methodology can be found in the technical report of the project (EFSA 2023c).

For 'TIM Technology', approximately 3000 articles per year were retrieved for the known 60 top scored REACH chemicals and about 1000 articles per 3 years for the newly identified chemical risks. For 'TIM News', the timeframe for the news articles collected was restricted to 427 days. Very few relevant news articles were retrieved via 'TIM News', all relative to known chemicals, such as paracetamol and melamine. Overall, the time required for the screening was about 3 hours per expert for 150 references.

The efficiency and relevance of the two TIM Analytics tools in identifying emerging chemical risks was evaluated based on the number of articles flagged as relevant. For this purpose, the total number of retrieved articles and the number of articles selected in the first and second screening were considered (Tables 2 and 3).

³ https://knowledge4policy.ec.europa.eu/text-mining/topic/tim_analytics_en

⁴ https://knowledge4policy.ec.europa.eu/online-resource/europe-media-monitor-emm_en

⁵ <https://emm.newsbrief.eu/>

⁶ <https://www.distillersr.com/>

For the evaluation of 'TIM Technology', the chemicals shown in Table 2 were randomly selected from the list of the 60 known REACH chemicals and 1363 scientific articles published in 2020 were retrieved. Among these publications, 148 passed the first screening and then, 4 of the 148 passed the second screening. Overall, 0.29% (4/1363) of the articles retrieved initially from 'TIM Technology' were considered relevant to be assessed in EREN (Table 2).

Table 2: Summary of the output of the screening of selected chemicals retrieved from scientific publications in 'TIM Technology' with restricted search strings for the year 2020.

Chemical	Ref ID	Total number of articles retrieved in TIM ^(a)	Relevant hits 1 st screening	Relevant hits 2 nd screening	% relevant (for EREN)
Paracetamol	79-124	336	46	0	0%
Melamine	68-78	481	13	0	0%
Diuron	36-67	128	32	1	0.78%
4-Aminophenol	5-9	135	5	0	0%
Antioxidant 2246	-	10	0	0	0%
Butylated hydroxyanisole	125-136	131	18	0	0%
Cyclonite	11-24	70	14	2	2.8%
Chlorinated paraffins LC	137-148	12	12	0	0
Dicyclohexyl phthalate	25-35	15	11	1	6.7%
Bis 2,4-dichlorobenzoyl peroxide	10	2	1	0	0%
4,4'-Oxybis(benzenesulfonyl hydrazide)	-	4	0	0	0%
4_4_-Methylenebis_2_chloroaniline	-	9	0	0	0%
4-Chloro-2_5-dimethoxyacetanilide	-	0	0	0	0%
2_Chloroaniline	4	22	1	0	0%
2,5-Diaminotoluene	1-3	8	3	0	0%
SUM		1363	148	4	0.29%

(a): Not fully reviewed.

Source: EFSA (2023c).

Moreover, regarding the search conducted on chemicals considered as 'newly identified chemicals' in 'TIM Technology', 831 scientific articles published between 2019 and November 2021 were retrieved. From those publications, 171 were marked as relevant in the first screening. In the second screening, 22 of the 171 publications were considered relevant, which represents a 2.65% (22/831 publications) of the initial output.

For the news articles retrieved from 'TIM News', the two screening phases were conducted for 5 of the known REACH chemicals as shown in Table 3. The first screening phase was conducted for the rest of the known chemicals (excluding BPA, TBBPA, 9,10-anthraquinone, and hexabromocyclododecane) and the percentage of relevant articles was low for many of them. No articles were retrieved for 24 of the chemicals screened. Furthermore, for the search on newly identified chemicals, using the final optimised search, the percentage of relevant articles was about 15%.

Table 3: Screening summary of selected chemicals for the outputs on news articles retrieved from 'TIM News'^(a).

Chemical	Total number of articles retrieved in TIM	Relevant hits 1st screening	% relevant 1st screening	Relevant hits 2nd screening	% relevant 2nd screening
Paracetamol	336	25	7.44%	2	0.60%
Melamine	191	25	13.09%	12	6.28%
Melamine_cyanurate	50	3	6.00%	3	6.00%
Butylated hydroxyanisole	246	19	7.72%	6	2.44%
Chlorinated paraffins	58	14	24.14%	0 ^b	-

(a): Articles collected from 1 July 2021 to 31 August 2022

(b): not fully reviewed.

Source: EFSA (2023c).

Overall, the percentage of relevant hits for newly identified chemicals to be evaluated in EREN was higher than the percentage for the known REACH chemicals presented in Table 2 (2.65% vs 0.29%). Furthermore, the efficiency of identifying emerging chemical risks through searching news media articles is low. Although the relevancy of articles retrieved from the 'TIM News' could be enhanced by further adapting the search strings, the margin of improvement is probably not significant since significant efforts have been already made. The TIM tools offer useful quantitative analysis and visualisation functionalities e.g., time series analysis, cluster effects and the possibility to export data for further analysis. Moreover, user-friendly dashboards have been developed for monitoring trends in publications and news for the different chemicals. This testing phase of the TIM tools have identified a few limitations. First of all, significant resources (both in terms of number of experts and expertise coverage) are necessary to review articles (both from news and from scientific literature). The low number of relevant hits both from scientific publications and from news articles also questions the adequateness of this type of data sources for identifying emerging risks related to chemicals. External outsourcing of the screening, supported by the implementation of machine learning could enhance the efficiency of the screening. However, at this stage, the number of articles is not considered enough to train a machine. A briefing note for an emerging issue identified during the project, entitled 'Analysis of samples of explosives excavated from the Baltic Sea floor and explosives degradation products in dab (*Limanda limanda* L.) from a munition dumpsite in the Baltic Sea' was discussed at the 29th EREN meeting which took place in May 2023. It was concluded that more information is needed to characterise the aforementioned emerging issue (section 3, Table 7).

2.3 Climate change and emerging risks for food safety (CLEFSA project)

Climate change is a relevant driver of emerging risks. The aim of the 'Climate change as a driver of emerging risks for food and feed safety, plant, animal health and nutritional quality (CLEFSA)' project was to develop and test new methodologies for the identification, characterisation and analysis of emerging risks linked with climate change. Several emerging issues in relation to contaminants and nutritional quality were identified, scored, and characterised based on the impact of scenarios of climate change that are projected to take place in the "near-future", which corresponds to the period 2021-2050 (EFSA 2020).

The impact of each issue was defined as the severity, duration and frequency of the potential effects of the hazard considered in the identified issue considering 'reference' (period 1981-2010) and 'near-future' (period 2021-2050) conditions.

Emerging chemical risks in food and feed

The likelihood of emergence of an issue was defined as the likelihood of emergence of the risk in Europe in terms of emergence of a new hazard, or increased exposure/susceptibility to a known hazard or variation in micro/macronutrient content in environmental matrices or food items, considering 'reference' and 'near-future' conditions.

The emerging issues in the category of 'contaminants' were analysed with respect to their impacts on human health. The interlinkages with plant and animal health were also identified for several issues. A total of 19 emerging issues were characterised. Those scored by the highest number of experts (at least 5) include deoxynivalenol (DON) and zearalenone (ZON), ciguatoxins, β -methylamino-L-alanine (BMAA), cyanotoxins, domoic acid, palytoxin, okadaic acid, pinnatoxins, tetrodotoxin (TTX) and TTX analogues (Table 4). For communication purposes, scoresheets were generated for the above-mentioned contaminants. The sources used for identifying and characterising the emerging issues potentially affected by climate change included CLEFSA experts, EFSA experts, a crowdsourcing CLEFSA survey, EREN, StaDG-ER, TIM tool, MediSys tool and the literature.

Table 4: List of characterised emerging issues belonging to the 'contaminants' category of the CLEFSA project.

Issue ID	Issue name ^(a)
101	Deoxynivalenol (DON) and zearalenone (ZON)
102	Aflatoxins
103	Ochratoxin A
104	Ciguatoxins
105	β-Methylamino-L-alanine (BMAA)
106	Cyanotoxins
107	Domoic acid
108	Palytoxin
109	Okadaic acid
110	Pinnatoxins
111	Tetrodotoxin (TTX) and TTX analogues
112	Hormones
115	Pyrrolizidine alkaloids
116	Mercury
118	Plastic debris
120	Heavy metals as As, Pb, Cd
121	Polycyclic aromatic hydrocarbon
128	Saxitoxin
129	Azaspiracid

(a): Emerging issues in bold were scored by 5 to 8 experts and are described in scoresheets, which are available in the supporting information of EFSA (2020).

Source: EFSA (2020).

Figure 3 illustrates the emerging issues listed in Table 4 related to contaminants, visualised as circles in a bidimensional impact-likelihood diagram. The axes of the bidimensional diagram represent the probability weighted average score in the near-future scenario.

As depicted in figure 3, no issues with extremely low or high impact were identified in the area of contaminants under the near-future climate scenario. The scores were distributed in a clustered manner, with issues 105 (BMAA) and 115 (pyrrolizidine alkaloids) as notable exceptions characterised by considerably lower likelihood of emergence. Among the characterised issues, the marine biotoxins with issue ID 104 (ciguatoxins), 107 (domoic acid),

Emerging chemical risks in food and feed

ID 128 (saxitoxin), and ID 129 (azaspiracid) constitute the issues with the highest likelihood of emergence.

The issues scored by at least five experts (deoxynivalenol and zearalenone, ciguatoxins, BMAA, cyanotoxins, domoic acid, palytoxin, okadaic acid, pinnatoxins, TTX and TTX analogues) are clustered together and are likely to emerge, with moderate impacts. All nine issues are related to toxins produced by microorganisms (bacteria, fungi, algae) whose growth is strongly affected by climate change, like extensively described harmful algal blooms.

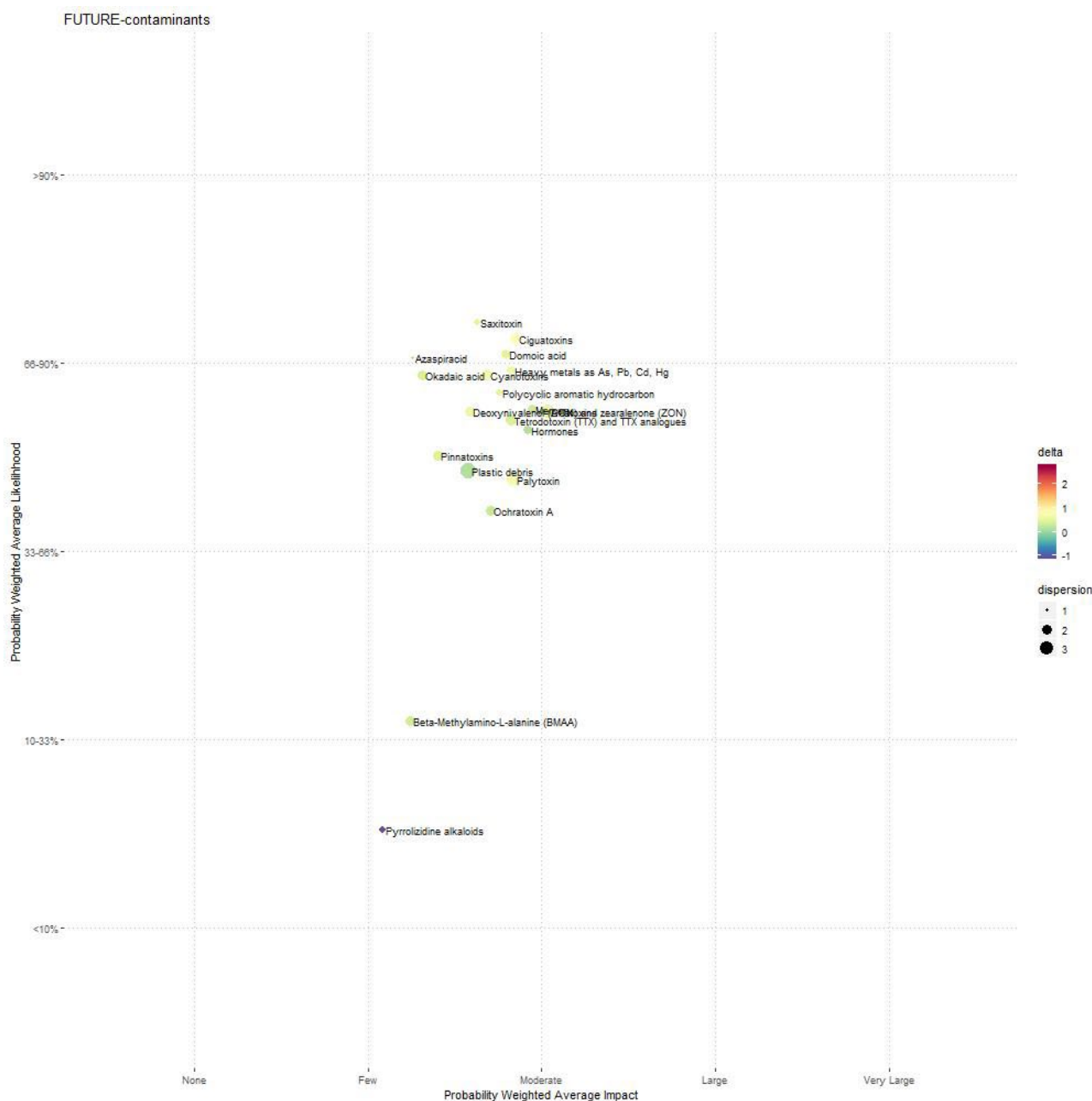


Figure 3: Graphical comparison of all issues belonging to ‘contaminants’ category under the near-future climate scenario. Probability weighted average values for impact are plotted on the x-axis, and those for likelihood on the y-axis. Colours of the circles correspond to delta values and their sizes to variance values. The numbers correspond to the ID numbers of issues listed in Table 4. Source: EFSA (2020).

Emerging chemical risks in food and feed

Apart from the above characterised emerging issues, the CLEFSA project identified some issues related to contaminants which were not characterised due to expert's unavailability. These uncharacterised issues include cyanogenic glucosides and cucurbitacin (macrophytes biotoxins), perchlorates, and acids (H_2SO_4 , H_2CO_3 and HNO_3) of acid rains generated by pollution. Details can be retrieved from Appendix C of the CLEFSA report (EFSA 2020).

In the category of 'nutritional quality' a total of six emerging issues were identified (Table 5).

Table 5: List of characterised emerging issues belonging to 'nutritional quality' category of the CLEFSA project.

Issue ID	Issue name ^(a)
122	Selenium content
123	Gluten content
124	Manganese content
125	Protein content
126	Zinc content
127	Iron content

(a): Issues in bold were scored by four experts and are described in scoresheets, which are available in the supporting information of EFSA (2020).

Source: EFSA (2020).

Figure 4 shows all the issues related to nutritional quality, visualised as circles in a bidimensional impact–likelihood diagram. The issues and corresponding ID numbers used in Figure 4 are listed in Table 5. As depicted in Figure 4, no issues were characterised with extremely low or high impact under the near-future climate scenario. Overall, the issues were characterised as "about as likely as not" to emerge with moderate impacts, with the exception of issue ID 123 (gluten content) which was scored as less likely to emerge than other issues from this area.

The four high-scored issues namely selenium content (ID 122), manganese content (ID 124), zinc content (ID 125), and iron content (ID 127) are related to micronutrient deficiency, which corresponds to the lower micronutrient contents observed in plants, as a result of elevated atmospheric CO_2 concentrations (Myers et al., 2014; EFSA 2020).

Overall, climate change is likely to drive the (re)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. Moreover, climate change may elevate severity, duration and/or frequency of the potential effects of the hazard considered in the identified issue. A notable effect appears on the likelihood of emergence, for which the confidence level is higher.

In the area of contaminants, an impact on the occurrence, intensity, and toxicity of blooms of potentially toxic marine and freshwater algae and bacteria was identified. Furthermore, climate change may affect transport pathways in the environment, fate (including bioaccumulation and elimination), and toxicity of and exposure to toxic compounds. The importance of extreme weather events (heat waves, drought, heavy rainfall, and flooding) as driver of emerging chemical issues was emphasised.

Finally, an interdisciplinary CLEFSA network was established which consisted of experts from international EU agencies and United Nations organisations, together with the coordinators of large EU projects involved with climate change. The objectives of the CLEFSA network were to support the identification of emerging issues and design a Multi-Criteria Decision Analysis tool for characterising them (EFSA 2020).

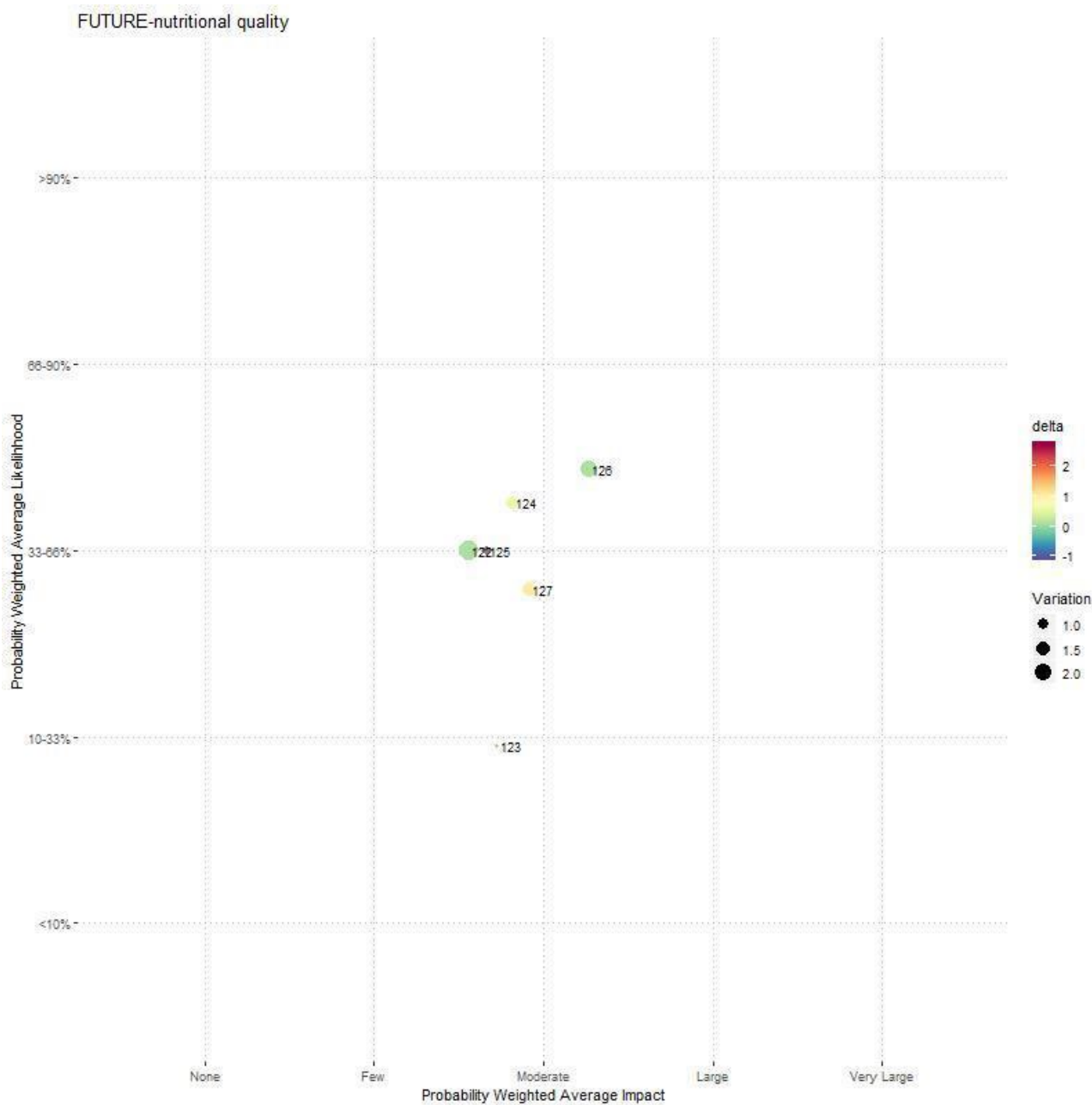


Figure 4: Graphical comparison of all issues belonging to 'nutritional quality' category under the near-future climate scenario. Probability weighted average values for impact are plotted on the x-axis, and those for likelihood on the y-axis. Colours of the circles correspond to delta values and their sizes to variance values. The numbers correspond to the ID numbers of issues listed in Table 5. Source: EFSA (2020).

2.4 EuroCigua I and II projects

Ciguatoxins are marine biotoxins that occur in fish as a result of bioaccumulation and biotransformation of precursor toxins produced by the benthic dinoflagellate genera *Gambierdiscus* spp. and *Fukuyoa* spp. (EFSA Panel on Contaminants in the Food Chain, 2010; EFSA 2020). Following the EREN briefing note 'First report of indigenous ciguatera fish poisoning in the EU' (ID No. 76) discussed in March 2012 (EFSA 2014a), the EuroCigua project was launched in April 2016 and lasted until January 2021. The main objectives of the EuroCigua

project were to determine the incidence of ciguatera in Europe and the epidemiological characteristics of cases (Varela Martínez et al., 2021), to assess the presence of ciguatoxin in fish and phytoplankton (dinoflagellates *Gambierdiscus* spp. and *Fukuyoa* spp.) in Europe (Diogène et al., 2021), and to develop and validate methods for the detection, quantification and confirmation of the presence of ciguatoxin-contaminated specimens (Gago-Martinez et al., 2021).

The EuroCigua project recorded a total of 209 cases in 34 ciguatera outbreaks in EU Member States between 2012 and 2019. A summary of the findings of the EuroCigua project is provided by Canals et al. (2021). EuroCigua recorded 34 outbreaks (2012-2019). The overall incidence rate of ciguatera in the EU and the European Economic Area is low (0.0054 cases per 100,000 inhabitants per year, excluding tropical overseas territories). However, it is higher in the Canary Islands (0.47 cases/100,000 inhabitants), more than twice the incidence rate reported in Florida from 2000 to 2011 (0.2 cases/100,000 inhabitants). Moreover, cases and outbreaks are largely underdiagnosed and underreported. EuroCigua found *Gambierdiscus* not only in the Spanish and Portuguese Atlantic islands but also in several Mediterranean islands including, for the first time, the Balearic Islands (see Figure 5 below).

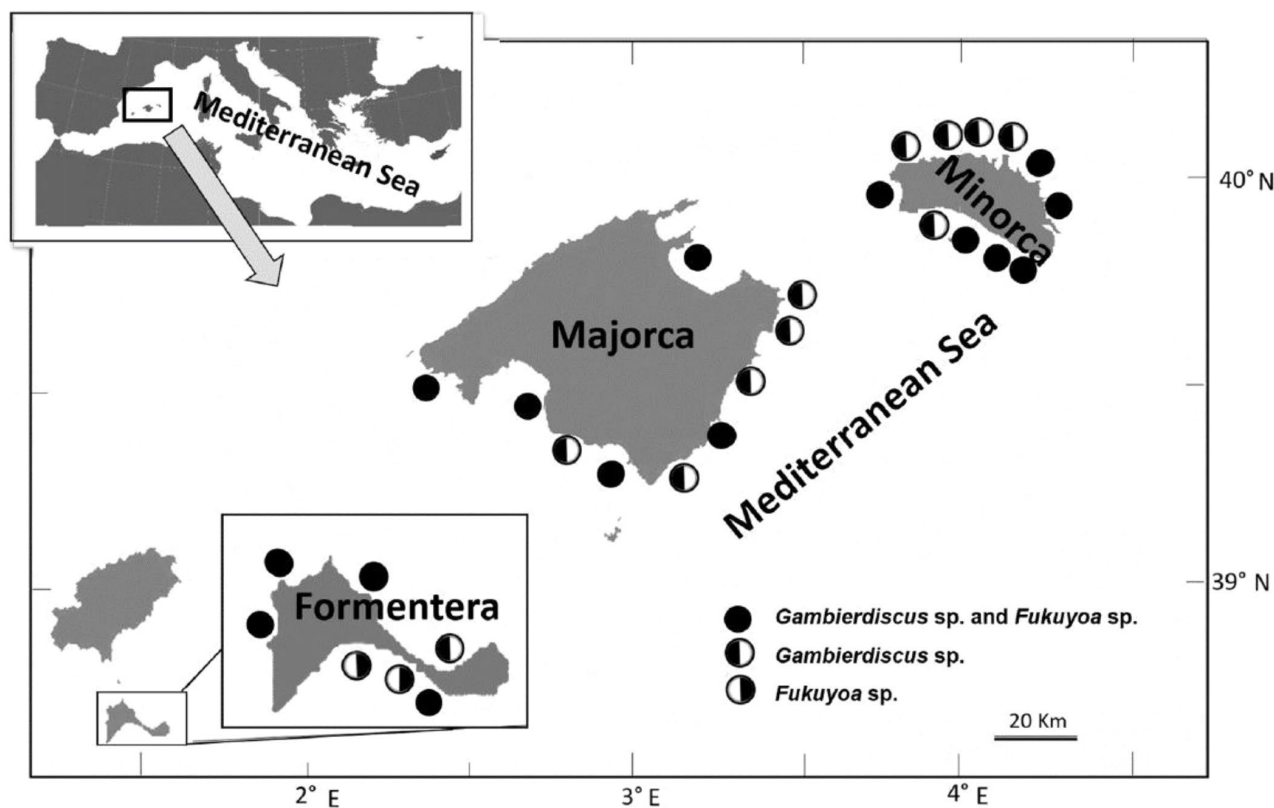


Figure 5: Presence of the *Gambierdiscus* and *Fukuyoa* genera in the sampling stations in the Balearic Islands (Mediterranean Sea) during 2016-2019. Source: Canals et al. (2021).

It developed analytical methods for the quantification of ciguatoxins. It confirmed that ciguatera is becoming endemic in the Macaronesia but also that the problem is largely underestimated because of current gaps and weaknesses in epidemiological data collection in existing reporting systems. Further data collection was considered needed to inform adequate risk management of ciguatera, including quantitative data on microalgae abundance

(concentration), toxicity and their link with changing environmental parameters, analytical method standardisation and development of predictive modelling under climate change.

The results of the CLEFSA project, presented in section 2.3, indicated ciguatoxins as one of the issues with the highest likelihood of emergence (Figure 3). Climate change and globalisation of trade are considered the primary drivers of the spread of ciguatera in Europe, which is intensified by travel to tropical areas.

A follow-up project, EuroCigua II, was therefore launched in August 2022 and is expected to end in September 2025. This project aims to (a) deepen the characterisation of the epidemiology of ciguatera fish poisoning in the EU; (b) characterise the risk of the ciguatera fish poisoning due to imported fish in the EU; (c) fully characterise the ciguatoxins profiles in microalgae and fish from European Risk Areas; (d) initiate the work for predictive modelling on ciguatera in Europe under climate change scenarios; and (e) stimulate capacity building by establishing training programmes for the detection and quantification of ciguatoxins in fish and microalgae.

2.5 Future challenges for the safety of food and feed from the oceans: A foresight study

An 18-month project 'Future challenges for the safety of food and feed from the oceans: a foresight study' was launched in late 2022 with the aim to identify and characterise emerging risks for the safety of food and feed from the oceans by exploring the future uses of the ocean's resources in a context of global changes.

The project consists in the following three parts:

- i. scoping study to look at the future uses of the ocean and its resources that may impact the food and feed systems, in a context of global changes;
- ii. mapping existing expertise and engaging experts within a knowledge network in a foresight exercise;
- iii. identification and characterisation of strategic options relevant for EFSA and emerging risks for food and feed safety.

Three areas were prioritised in the foresight study, namely coastal- and open-sea mining, marine aquaculture, and sea transport and trade. Following a series of processes (see Figure 6) including:

- (a) in-depth interviews with experts,
- (b) a participatory horizon scanning exercise which took place with a broad stakeholder group in late 2023 (September – October 2023),
- (c) online workshops (January 2024),

scenarios and accompanying narratives were developed for each area. Subsequently, an in-person workshop entitled 'Navigating Tomorrow's Tide: Exploring the Future of Ocean Resources and Their Impact on Food and Feed Safety' involving external experts took place in Lisbon between 20 and 21 March 2024. During the workshop, the scenarios and narratives previously developed were discussed in relation to potential implications for the safety of food and feed from the oceans including (a) emerging risks; (b) elements and considerations useful for risk-benefit assessments of dietary inclusion of food and feed from the oceans; and (c) implications,

challenges, and opportunities for EU sustainability objectives. The final results of the project will be published in the second half of 2024 and will enter the environmental scanning process.

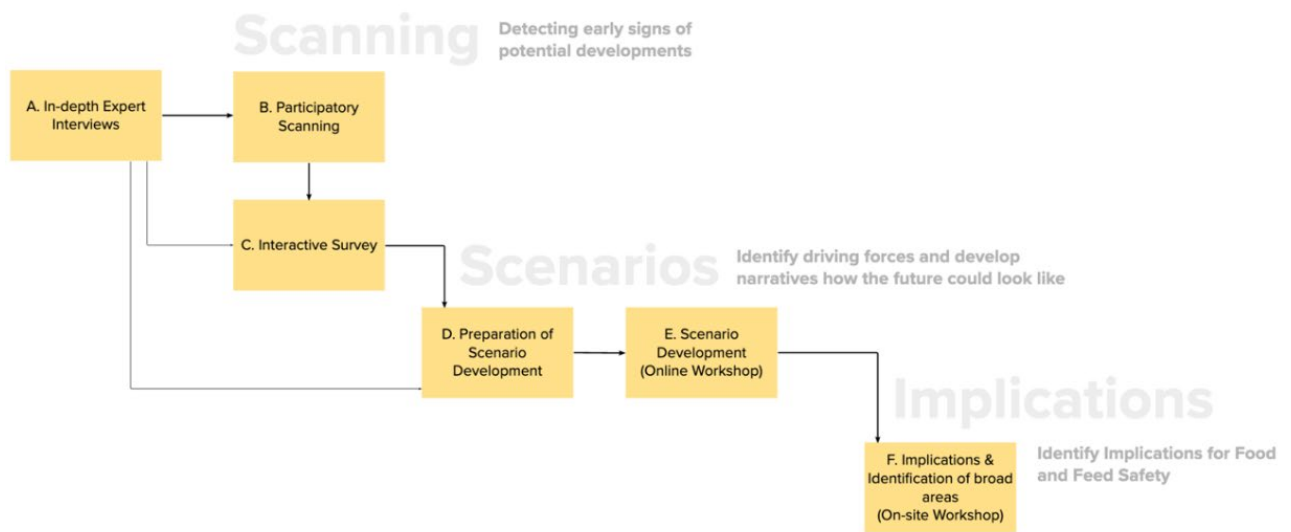


Figure 6: Overview of the foresight process. Kindly provided by Prospex bv.

2.6 Food and feed safety vulnerabilities in the circular economy

The project on 'Food and feed safety vulnerabilities in the circular economy' aimed at identifying potential emerging risks for plant, animal and human health and the environment which may arise due to the transition to a circular economy.

As a first step of the project, an outsourced extensive literature review and monitoring of research Horizon 2020 projects was performed (start February 2021, one year duration) (EFSA 2022). Four broad macro areas of envisaged or currently used circular economy practices in Europe were identified:

- (i) primary production of food and feed;
- (ii) reducing industrial/manufacturing/processing waste;
- (iii) reducing food and feed waste in wholesale, food retail, catering and households;
- (iv) reducing food and feed packaging waste.

Following consultation with stakeholders, a focused literature search was carried out to identify emerging risks to plant, animal, human health and the environment from novel foods and feeds within the framework of circular economy.

The literature showed that most of the research investigations in novel food and feeds focus on the suitability of novel feeds in terms of animal productivity parameters rather than on emerging risks of novel food/feed for animal, human, plant health and the environment. Those few studies that investigated risk were almost entirely focused on the biological and chemical hazards, risks to health, and environmental impacts of insects as food or feed and the substrates that they are reared on. In this area, a wide range of chemical hazards were reported including heavy metals (in particular high levels of the heavy metals Cd and Ni in prepupae), dioxins, polychlorinated biphenyls (PCBs), polycyclic aromatic hydrocarbons (PAHs), mineral oil hydrocarbons, veterinary medicines, pesticides and the uptake of allergens by insects from the substrate, e.g. gluten.

The initial identification and categorization of circular practices relevant for the food and feed chain and the resulting emerging risks led to two conclusions:

- The amount and breadth of circular economy practices impose the need for prioritizing the domain on which EFSA should focus,
- Additional sources of information were needed, as scientific literature only takes stock of existing practices but does not shed light on future drivers.

Based on a series of criteria applied at successive steps, EFSA has therefore decided to narrow the original scope of the project and focus on the identification and characterization of emerging risks from 'circular feed', defined as feed derived from the following three sources:

- Food waste
- Former food products
- Agri-Food processing co/by-products

As literature search alone was not enough to identify emerging risks, it was necessary to implement participatory future-oriented approaches. A foresight workshop on 'Circular Future: emerging feed sources, technologies and related risks'⁷ was therefore organised. Participants jointly discussed and identified, for each of the abovementioned sources, future trends and technologies that may drive the emergence of risks for feed safety, animal health and the environment in the transition to a circular economy in the next 10 years.

The workshop highlighted that in the transition to sustainable animal feed production, it is crucial to recognize emerging risks associated with the use of feed sources and novel technologies in a circular bioeconomy context. Potential new hazards, exposure pathways and knowledge gaps need to be explored, in order to assess the adequacy of the current feed safety framework for assessing the feed of the future. This might contribute to the definition of the EFSA's scientific outlook, and its innovation/transformation agenda. Given the policy pressure to the adoption of sustainable practices, the urgency of addressing this issue was considered high.

The main specific issues discussed at the workshop were assembled in three briefing notes, which were submitted to the EREN:

- Emerging risks to food and feed safety posed by toxins and anti-nutrients from legumes and oilseeds in animal feed formulated with by-products from less familiar legumes and/or obtained through reduced processing as triggered by recent trends towards protein transition, circularity, and energy-efficiency.
- Increased antimicrobial resistance resulting from the use of circular feed.
- Former food products (FFPs).

3 Emerging chemical risks identified within the EFSA's knowledge networks

Tables 6 and 7 present, for the period 2020-2023, the issues discussed in the context of the EREN and StaDG-ER Networks concluded as "emerging risk" and those which could not be concluded as emerging risks due to insufficient evidence, respectively. As the annual activity

⁷ <https://www.efsa.europa.eu/en/events/foresight-workshop-circular-future-emerging-feed-sources-technologies-related-risks>

Emerging chemical risks in food and feed

reports describing the issues related to the period 2022 and 2023 are still pending publication, a brief description is included in Tables 6 and 7.

Emerging chemical risks in food and feed

Table 6: Summary of briefing notes *concluded as emerging risks*^{(a),(b)} related to chemical risks from the evaluation in the Emerging Risk Exchange Network (EREN) and Stakeholder Discussion Group on Emerging Risks (StaDG-ER) meetings in the period 2020-2023. Note: in 2022, the discussed emerging chemical issues were all concluded as “further info needed”. Therefore, they are listed in Table 7.

Year	Network	Briefing Note submitted to EREN or StaDG-ER and relevant chemicals	Classification ^(c)	Description of emerging risk/Reference
2020	EREN (Ireland)	Steroidal selective androgen receptor modulators (SARMs) in food supplements	Other	Description available in EFSA (2023a).
2020	EREN (Germany)	Toys and occupying materials in animal husbandry (phthalates and bisphenol A in chewing materials for dogs, mycotoxins in peanut shells, MOSH/MOAH ^(d) in shredded printed paper, POPs ^(d) in treated timber as bedding material)	Microbiological and chemical hazard	Description available in EFSA (2023a).
2020	StaDG-ER (European Chemical Industry Council on behalf of the Association of all the Leading European Gélatine Manufacturers)	Potential health risks linked to a large intake of collagen powder	Other	Description available in EFSA (2023a).
2021	EREN (France)	Risk of overdosing of vitamin D in food supplements	New consumer trend	Description available in EFSA (2023b).
2021	EREN (Germany)	Health risks of coconut oil (higher LDL ^(d) cholesterol and insulin resistance)	New consumer trend	Description available in EFSA (2023b).
2021	StaDG-ER (COPA-AGRI)	Potential emerging risks associated with decreased use of pesticides and fertilizers (increase of jimsonweed (<i>Datura stramonium</i>) which contains a tropane alkaloid)	Other	Description available in EFSA (2023b).
2021	EREN (France)	Brevetoxins in French shellfish	Chemical hazard	Description available in EFSA (2023b).

Emerging chemical risks in food and feed

Table 6: Continued

Year	Network	Briefing Note submitted to EREN or StaDG-ER and relevant chemicals	Classification ^(c)	Description of emerging risk/Reference
2023	EREN (Ireland)	Z15 nanomaterial used in Wastewater Treatment Plants (WWTPs) in Ireland and EU (relevant chemical: iron oxide coated with folic acid)	Plant health, Biological hazards, Contaminants, Feed	Z15 nanomaterial is used to separate the solids from the liquid fraction in wastewater and thus increase the efficiency of the precipitation step. Z15 nanomaterial consists of iron oxide particles coated with folic acid. Iron nanoparticles conjugated with folic acid have been used for targeted drug delivery in cancer cells. According to the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS Panel, 2015), the genotoxicity of iron oxides cannot be evaluated based on the available data, and no signs of carcinogenicity and reproductive and developmental toxicity were observed in unpublished studies which were not available and thus could not be evaluated by the Panel.
2023	EREN (Denmark)	Potential risk of rare earth elements and other elements present in modern electronics	Contaminants, Feed	Increased exposure to lithium, rare earth elements and other elements in feed and food due to the increased use, and thereby waste, of electronic products containing these substances, may occur. Insufficient data on occurrence and toxicity. It is important that EFSA looks into this partly to perform risk assessments and partly to identify the data gaps.
2023	EREN (Hungary)	Alcohol replacement drinks (relevant chemical: a synthetic compound named alcarelle)	Food innovation	The Briefing Note is about a new alcohol replacement botanical drink made with food grade herbs. This drink could affect the nervous system and lead to dependence and craving because of active compounds. It contains a synthetic compound named alcarelle, which targets the gamma-aminobutyric acid (GABA) receptors in the brain.

(a): The issues were assessed against a set of predefined criteria: (i) new hazard; (ii) new or increased exposure; (iii) new susceptible group; (iv) new driver. The criteria are based on the EFSA's definitions of emerging risk and emerging issue. More information on these criteria can be retrieved by the annual reports on EFSA's activities on emerging risks (EFSA 2023a, 2023b).

(b): The conclusions 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.

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

(d): Low-density lipoprotein (LDL); Mineral Oil Aromatic Hydrocarbons (MOAH); Mineral Oil Saturated Hydrocarbons (MOSH); Persistent Organic Pollutant (POP).

Emerging chemical risks in food and feed

Table 7: Summary of emerging issues^{(a),(b)} related to chemical risks for which further information is needed for their characterisation, discussed in the Emerging Risk Exchange Network (EREN) and Stakeholder Discussion Group on Emerging Risks (StaDG-ER) meetings in the period 2020-2023.

Year	Network	Briefing Note submitted to EREN or StaDG-ER and relevant chemicals	Classification ^(c)	Reference/Description of emerging issue
2020	StaDG-ER (Food Service Europe & Serving Europe)	Disinfectant COVID-19 pandemic (hydroalcoholic gels)	Chemical hazard	Description available in EFSA (2023a).
2020	EREN (Germany)	Potential risks of introducing oxo-degradable plastic into the environment	Chemical hazard	Description available in EFSA (2023a).
2020	StaDG-ER (Pesticide Action Network Europe)	Succinate dehydrogenase inhibitor (SDHI) fungicides	Other	Description available in EFSA (2023a).
2021	EREN (France)	Coumarin: High consumers of food supplements risk exceeding the tolerable daily intake (TDI)	New consumer trend	Description available in EFSA (2023b).
2021	EREN (France)	Is there a risk of severe poisoning from imported Asian morels? (the chemical hazard that led to two lethal poisonings after consumption of morels was unknown)	Other	Description available in EFSA (2023b).
2021	EREN (Germany)	Hypoglycin A in cow milk	Other	Description available in EFSA (2023b).
2022	EREN (Hungary)	Palmitic acid is found to make cancers more aggressive	Chemical	The European Food Safety Authority and the World Health Organization have already declared that glycidol (which is a compound formed by processing of palm oil) is genotoxic and carcinogenic (WHO and FAO, 2017; EFSA CONTAM Panel, 2016). A recent article reported that mice fed with palmitic acid developed oral cancers and deadly skin melanomas (Pascual et al., 2021).
2022	EREN (Estonia)	The contents of minerals, vitamins, heavy metals, and oxalates in chaga mushroom (<i>Inonotus obliquus</i>)	Consumer trend	Chaga mushroom is a fungus growing on trunks of birch and alder trees. Chaga consumption is increasing in Estonia, potentially linked to the advertised health benefits (although not well substantiated), therapeutic actions and richness in vitamins and minerals, thus suggesting an increasing exposure to chaga mushroom and possible harmful effects for identified heavy metals and oxalates presence.

Emerging chemical risks in food and feed

Table 7: Continued

Year	Network	Briefing Note submitted to EREN or StaDG-ER and relevant chemicals	Classification ^(c)	Reference/Description of emerging issue
2023	EREN (Ireland)	Plasticosis in birds (microplastics)	Contaminants	Ingestion of plastic by seabirds and the consequence of this exposure has been reported, in particular the ability of plastic to directly induce severe, organ-wide scar tissue formation or 'plasticosis' in wild, free-living animals (Charlton-Howard et al., 2023).
2023	EREN (Germany)	Correlation between the Contamination of Sesame Seeds with <i>Salmonella</i> and the EU-Regulation on Ethylene Oxide Follow up on "Outbreak caused by <i>Salmonella Typhimurium</i> in Ispaghula seeds husk"	Pesticides, Biological hazards, Contaminants	Sesame seeds can be contaminated with microbiological pathogens like <i>Salmonella</i> . Several countries used ethylene oxide for decontamination. However, the use of ethylene oxide has been banned in the EU and imported foods are increasingly checked for ethylene oxide residues.
2023	EREN (Switzerland)	Insights into the Relevance of <i>Bacillus cytotoxicus</i> as a Foodborne Pathogen and the toxins it produces (relevant chemicals: enterotoxins and cereulide toxins)	Contaminants	<i>B. cytotoxicus</i> as a possible (new) hazard has been found in more traditional food (e.g., potato flakes, potato starch) but also in new products (e.g., insect-based foods). <i>B. cytotoxicus</i> is a member of the <i>Bacillus cereus</i> group. This group comprises closely related organisms of varying pathogenicity including the foodborne pathogen <i>Bacillus cereus sensu stricto</i> (Guinebretière et al., 2013). Some members of the <i>B. cereus</i> group can cause two distinct forms of foodborne illness: Firstly, the diarrheal syndrome that is linked to three enterotoxins - Hbl, Nhe and CytK (Fagerlund et al., 2007; Burtscher et al., 2021) - and secondly, the emetic syndrome caused by cereulide toxin (Rau et al., 2009).
2023	EREN (Ireland)	Blue Algae proliferation (relevant chemicals: toxins produced by blue-green algae)	Contaminants	Observed increase of blue-green algae in several freshwater bodies on the Island of Ireland. Blue-green algae can produce toxins leading to death of animals from drinking contaminated water (due to neurotoxicity or hepatotoxicity) (Paerl et al., 2018). Blue-green algae toxin contaminated fish may also pose a threat to humans.
2023	EREN (Germany)	Oder River fish dieoff_Salt discharges caused mass proliferation of toxic alga (relevant chemicals: toxins produced by brackish water alga)	Contaminants	In August 2022, a massive fish die-off in river Oder was observed. The most probable cause of the fish die-off in the river Oder is the rapid rise in salinity, which together with other factors led to the mass proliferation of a brackish water alga that is poisonous to fish (Umwelt Bundesamt, 2022). In addition to fish, other aquatic organisms such as snails and mussels also died. The brackish water alga <i>Prymnesium parvum</i> produces a toxic substance that is fatal to fish and other aquatic organisms (Free et al., 2023).

Emerging chemical risks in food and feed

Table 7: Continued

Year	Network	Briefing Note submitted to EREN or StaDG-ER and relevant chemicals	Classification ^(c)	Reference/Description of emerging issue
2023	EREN (EFSA)	Analysis of samples of explosives excavated from the Baltic Sea floor and explosives degradation products in dab (<i>Limanda limanda</i> L.) from a ammunition dumpsite in the Baltic Sea (Chemicals or relevance: explosive compounds including 2,4,6-trinitrotoluene, 4-amino-2,6-dinitroloouene, and hexahydro-1,3,5-trinitro-1,3,5-triazine)	Contaminants	A comprehensive study on the contamination status of dab (<i>Limanda limanda</i>) from a munition dumpsite and from reference sites in the Baltic Sea is presented (Koske et al., 2020). Explosive compounds were detected by high-performance liquid chromatography with mass spectrometry (HPLC-MS). Five explosive compounds were identified, including 2,4,6-trinitrotoluene, 4-amino-2,6-dinitroloouene, and hexahydro-1,3,5-trinitro-1,3,5-triazine. 48% of the samples from the dumpsite contained at least one explosive compound (Koske et al., 2020). Toxic explosive compounds from a dumpsite in the Baltic Sea are accumulated by flatfish and may therefore pose a risk to fish health and human food safety.
2023	EREN (Hungary)	Perinatal exposure to foodborne inorganic nanoparticles	Contaminants, Food ingredients	The Briefing Note is about the potential role of inorganic nanoparticle in the development of food allergies. The study highlights that exposure to these nanoparticles may disrupt the beneficial exchanges of the host-intestinal microbiota and interfere with the intestinal barrier and gut-associated immune system development (Issa et al., 2022). As a result, this may impede the induction of oral tolerance, a crucial process of immune unresponsiveness to food antigens, and significantly increase the risk of developing food allergies (Issa et al., 2022).
2023	StaDG-ER (COCERAL)	Impact of the effect of climate change on food security and trade patterns for grains/oilseeds/pulses as a driver to quality and safety issues (relevant chemicals: mycotoxins)	Plant health, Pesticides, Biological hazards, Contaminants, Feed, Nutrition (incl. food supplement)	A decreased trend on grains and oilseeds yields and an increased prevalence and co-occurrence of mycotoxins have been suggested by data collected from COCERAL.
2023	StaDG-ER (Safe Food Advocacy Europe, SAFE)	Potential occurrence of primary sensitisation allergies in insect products and consumer information (allergens like proteins)	Food ingredients	EFSA's opinion on the use of certain insects for human consumption pointed out the danger of potential primary sensitisation allergies in insect products. This is caused by proteins present on the carapace, such as hexamerin-2 which are common to insects and other species with exoskeletons, such as crustaceans (Wang et al., 2022; Pener, 2014).

Emerging chemical risks in food and feed

Table 7: Continued

Year	Network	Briefing Note submitted to EREN or StaDG-ER and relevant chemicals	Classification ^(c)	Reference/Description of emerging issue
2023	StaDG-ER (SAFE)	Concerns on the risk of food contamination by bisphenol A (BPA) through its release from micro- and nano-plastics in soils and irrigation water	Contaminants	Water constitutes a possible route of exposure of BPA via the release from micro- and nano-plastics. BPA is degraded by microflora in the environment (water and soil) (Lu et al., 2015) and has been detected in groundwater, surface water and agricultural soils (Dodgen et al., 2013). Studies have demonstrated that BPA can be uptaken and accumulated by edible crops (Lu et al., 2015) such as lettuce (<i>Lactuca sativa</i>) and collards (<i>Brassica oleracea</i>) through irrigation with reclaimed water (Dodgen et al., 2013; Lu et al., 2013) and exerts negative effects in the roots of soybean seedlings (Sun et al., 2013). BPA can also be released in the marine environment through microplastics.
2023	EREN (Hungary)	Tara flour as potential cause of illnesses (relevant chemical: baikiaian possibly as the causative agent)	Food ingredients	It is hypothesised that baikiaian present in tara flour was responsible for more than 470 illnesses reported in the US since June 2022. Recently, the U.S. Food and Drug Administration concluded that tara flour in human food does not meet the Generally Recognized As Safe (GRAS) standard and is an unapproved food additive (FDA, 2024). Although further information is needed, available evidence seems to indicate an emerging risk.

(a): The issues were assessed against a set of predefined criteria: (i) new hazard; (ii) new or increased exposure; (iii) new susceptible group; (iv) new driver. The criteria are based on the EFSA's definitions of emerging risk and emerging issue. More information on these criteria can be retrieved by the annual reports on EFSA's activities on emerging risks (EFSA 2023a, 2023b).

(b): The conclusions 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.

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

4 Evaluation of EFSA's approach for identification of emerging chemicals: a SWOT analysis

A SWOT analysis was carried out to consider Strengths and Weaknesses of the current system for identification of emerging chemicals as well as Opportunities to improve it and possible Threats.

Strengths

- A definition and criteria for identification and prioritisation of emerging chemical risks are available and operationalised.
- Strong network capacity with broad expertise.
- Use of system-based approaches (drivers for long-term anticipation of emerging risks).
- The TIM tools offer useful quantitative analysis and visualisation functionalities supported by a user-friendly dashboard for monitoring trends in publications, patents registrations and news.
- From an analytical perspective, the SCREENER project has developed a single approach, based on liquid chromatography–high resolution mass spectrometry (LC–HRMS) or liquid chromatography–tandem mass spectrometry (LC–MS/MS), for simultaneous detection of a big number of chemicals with different physico-chemical properties and low limit of detection (LoD). Target-LoD calculated for each compound is calculated on the basis of “Lowest Effect Levels” according to a tiered conservative approach from high-quality data.
- The use of citizen science and crowdsourcing for identifying weak signals, as tested in the CLEFSA project.
- Several projects (Oceans, circular economy and CLEFSA) have piloted the use of a transparent scoring system based on Multi-Criteria Decision Analysis (MCDA) tools. Each criterion has been structured according to different levels. Weights have been applied to prioritise the criteria.

Weaknesses

- Media monitoring and other automatic text mining tools are often not specific or not sensitive enough (i.e., more effective when hazard driven), especially when applied to broad areas like “emerging chemicals”.
- Significant resources (both in terms of number of experts and expertise coverage) are necessary to review articles (both from news and from scientific literature) selected through the TIM tools. The low number of relevant hits both from scientific publications and from news articles also questions the adequateness of this type of data sources for identifying emerging risks related to chemicals.
- Training datasets are not large enough for using machine learning to support literature searches and screening.
- Difficult to track issues over time.
- Selection of food samples in SCREENER: Limited number of food categories and food items, selected on the basis of the high consumption rate in the prioritised countries.
- Exposure assessment in SCREENER:

- at European Level done by merging and averaging consumption data from different surveys (but a weighting system has been used to weight the number of participants of the survey).
- Limited number of samples (only three values per country per food item) and countries (Czech Republic, Poland, Germany and the Netherlands).

Opportunities

- Evaluate the suitability of the process of identification of emerging chemicals to cover innovation in industry and technology.
- Improve the horizon scanning capacity through collaboration with wider audiences than the EFSA Emerging Risks Networks (Units, panels, Scientific Committee and relevant networks).
- Improve the use of Big data and machine learning for identification of emerging chemicals.
- Further explore the potential of citizen science capacity for identification of emerging chemicals.
- Implement search protocols that capture and combine structured and unstructured data from a collection of sources.
- Improve tracking for revisiting issues by better links with Risk Managers and research institutions.
- Develop data sharing agreements with different stakeholders and highlight mutual benefits.
- Explore possible collaborative options for a permanent and sustainable emerging chemical risks identification system.
- Discuss how to optimise the exchange of information on emerging chemicals with relevant institutional stakeholders.
- Explore the potential contribution of the EFSA system for the identification of emerging chemicals to the establishment of an early warning and action system for emerging chemical risks, foreseen in the context of the legislative proposals on chemicals assessment.

Threats

- Increasing complexity of food/feed supply chains.
- Uncertainty inherent in chemical issues/risks emerging in the long-term in complex food systems as an outcome of drivers 'analysis and foresight studies, which reduces the level of confidence in outcomes, impacts, and associated probabilities.
- Lack of trust between stakeholders to share data.
- In the context of systemic approaches to food safety, new stakeholders might show an initial scepticism.
- Improved analytical capacity and methods that will multiply candidates for the emerging chemicals early warning system.

5 Future developments

The SWOT analysis described in chapter 4 leads to a series of developments and follow-up actions aiming at maximising the strengths, capturing the opportunities while at the same time mitigating the weaknesses and threats of the system in place for the identification of

emerging chemicals (sections 5.2-5.4). Such activities need to embark recent policy developments in the area of chemical assessment (section 5.1).

5.1 Policy developments on emerging chemical risks

The European Green Deal⁸ envisages the transition towards a toxic-free environment and zero pollution. For this purpose, the 'Chemicals Strategy for Sustainability Towards a Toxic-Free Environment' (CSS)⁹ adopted by the EC, which is part of the Zero Pollution ambition¹⁰, introduces the 'one substance, one assessment' approach, which aims to enhance the efficiency, effectiveness, coherence, and transparency of safety assessments of chemicals across EU legislation. The 'one substance, one assessment' approach aligns with the EFSA Strategy 2027 to propose solutions that support simplification, cost savings and improved regulatory predictability (EFSA 2021). The Strategy also sets out that the interaction between scientific developments and policymaking should be strengthened by means of an early warning system for chemicals to ensure that Union policies address emerging chemical risks as soon as these are identified by monitoring and research, and that a framework of indicators should be developed to monitor the drivers and impacts of chemical pollution and to measure the effectiveness of chemicals legislation.

On this basis, three legislative proposals were adopted by the EC on 7 December 2023 and further examination from the European Parliament and the Council is expected. These three proposals include:

- streamline assessments of chemicals across EU legislation;
- strengthen the knowledge base on chemicals;
- ensure early detection and action on emerging chemical risks¹¹.

The latter proposal is supported by a new Regulation of the European Parliament and of the Council "establishing a common data platform on chemicals laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals"¹².

In its article 18, the EEA, in collaboration with the ECHA, the EFSA, the European Medicines Agency (EMA), the European Agency for Safety and Health at Work (EU-OSHA) and the EC, shall establish, operate, and maintain a framework of indicators to monitor the drivers and impacts of exposure to chemicals, measure the effectiveness of chemicals legislation and measure the transition towards the production of safe and sustainable chemicals.

In the article 19, the EEA shall establish, operate and maintain a Union early warning system for emerging chemical risks. The article requires that EEA compiles information on early warning signals from a variety of sources including EEA, ECHA, EFSA, EU-OSHA, EMA sources and their networks, literature searches that the EEA carries out, and national early warning systems. This information will be made available in a centralised way on the common data platform, and it is expected to facilitate the identification of early warning signals as soon as they are identified by monitoring and research.

⁸ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2019%3A640%3AFIN>

⁹ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2020%3A667%3AFIN>

¹⁰ https://environment.ec.europa.eu/strategy/zero-pollution-action-plan_en

¹¹ https://ec.europa.eu/commission/presscorner/detail/en/ip_23_6413

¹² <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52023PC0779>

5.2 Platforms for the exchange of information on emerging risks

The exchange of information among different actors is a crucial component in the process of identification and analysis of emerging chemical risks. Few platforms are under development for that purpose. Two ongoing Horizon 2020 research projects of possible use for emerging chemicals identification are briefly introduced below.

The FoodSafeR¹³ project, launched in October 2022, aims at developing a platform (FoodSafeR Open Digital Hub) that will facilitate the identification and characterisation of emerging (chemicals) risks, bringing together a Community of key players (regulators, risk managers, stakeholders) dealing with emerging risks. The resources and tools include:

- (a) science-based Risk Assessment Tools;
- (b) data and information related to emerging food hazards;
- (c) training and education resources in relation to risk assessment and management;
- (d) data visualisation and reporting tools;
- (e) workspaces to facilitate collaboration between risk managers and risk assessors;
- (f) discussion forums and tools for experts.

The HoliFood¹⁴ (Holistic approach for tackling food systems risks in a changing global environment) project, launched in October 2022, aims to (a) improve the integrated food safety risk analysis framework in Europe to meet future challenges arising from Green Deal policy driven transitions in particular in relation to climate change; (b) contribute to the United Nations' Sustainable Development Goals and to support the realization of a truly safe and sustainable food production. In this respect, three supply chains will be studied (chicken, maize, and lentils) for emerging and re-emerging risks, enabling researchers to generate adaptive models that will be applied to the entire food system.

In particular, the specific objectives of the HoliFood project are:

- (a) A systems approach is adopted with the use of Big Data and Artificial Intelligence techniques that will support the delivery of early warning and risk prediction systems.
- (b) Develop and validate targeted and non-targeted detection methods for existing and emerging hazards.
- (c) Develop tools and holistic risk assessment methods (cost-benefit analysis) of the food system that will take into account, not only positive and negative health considerations, but also environmental, and economic dimensions.
- (d) Improve data and knowledge-sharing infrastructures by developing an Integrated European Data and Knowledge Exchange Infrastructure that will be able to power an ecosystem of decision support systems.
- (e) Integrate consumer and user requirements using Living Labs and a multi-actor engagement approach to involve all stakeholders (e.g., authorities, food producers, and citizens).

Overall, the above-mentioned platforms will stimulate the exchange of information, enhance participation, improve capacity building, increase accessibility to cutting-edge resources, and optimally orchestrate the concerted actions of each actor.

¹³ <https://foodsaferr.com/>

¹⁴ <https://holifoodproject.eu/>

5.3 Cooperation at EU and international level

EFSA relies on cooperation for bringing together the sources of emerging chemicals and prioritising them. The exchange of information and knowledge in relation to emerging risks is not limited to the knowledge networks EREN and StaDG-ER. Collaborative efforts expand to EFSA units, EFSA networks, EFSA panels and the Scientific Committees, Member States scientific networks, European institutions, and international organisations. Such cooperation is necessary to avoid potential duplication of activities and optimise the use of the limited resources available.

The collaborative efforts with European institutions have been strengthened recently by the development of a cross-agency One Health task force framework for action¹⁵ with the task force consisting of the ECDC, ECHA, EEA, EFSA and EMA. This framework focuses on five strategic objectives: strategic coordination, research coordination, capacity building, stakeholder engagement and joint inter-agency activities. It is envisaged that this framework will further build capacity for joint risk assessments, promote transdisciplinary research on the impacts of emerging chemicals including microplastics, utilise relevant research outcomes and facilitate the translation of research into actionable outputs.

In relation to international cooperation, EFSA engages in a number of activities related to emerging chemical risks. EFSA is involved in activities carried out by the Emerging Risks Task Group of the WHO Chemical Risk Assessment network. The Task Group provides a forum to participants for information sharing about activities related to emerging risks to human health from chemicals on a global scale.

Similarly, EFSA engages with the International Food Chemical Safety Liaison Group (IFCSLG) which aims to facilitate exchange of information and discuss emerging issues in the area of food chemical risk assessment between a number of countries. Australia, Canada, Japan, New Zealand, the United States, the EC, and some European countries are members of the IFCSLG. The use of the Intelligence and Emerging Issues Register developed by the IFCSLG in which input on emerging issues is provided from members of the group will be explored for the needs of ERI at EFSA.

EFSA is also strengthening potential synergies with the International Liaison Group for Methods of Risk Assessment of Chemicals in Food (ILMERAC). The group aims to support the development of new risk assessment methodologies and to improve the consistency of the methods used for risk assessment of chemicals in food by organisations with a risk assessment mandate at national and international level.

Potential synergies with other existing platforms in use within other agencies for cooperating with authorities and stakeholders (e.g., the ECHA RIME+ Risk Management and Evaluation platform) is constantly explored.

Synergies with the Partnership for the Assessment of Risks from Chemicals (PARC) are strengthening. In this regard, the early warning system on chemical risks developed by PARC could provide a wide range of inputs, including:

- Potential newly identified chemical threats, in the form of, for example, a mass spectrometry signal displayed in many screening samples or an effect-based assay result.

¹⁵ <https://www.ecdc.europa.eu/en/publications-data/cross-agency-one-health-task-force-framework-action>

- Prediction tools for calculating exposure and effect potentials for various exposure scenarios and toxicity endpoints.
- Trend analysis tools to identify an increased presence of a chemical in Non-Target Screening data.

Data retrieved from the PARC early warning system may facilitate the prioritisation of new emerging chemicals based on a number of criteria (persistence, bioaccumulation, mobility and toxicity) which may aid proper risk management measures.

5.4 Workshop on “Emerging chemical risks for public health and the environment”

Actions to maximise opportunities, minimise weaknesses and avoid threats previously listed will be discussed in the workshop on “Emerging chemical risks for public health and the environment”, to be held on 26 and 27 September at EFSA’s premises.

The objectives of the workshop are:

- Present the EFSA’s activities on identification of emerging chemicals.
- Discuss possible collaborative options for a permanent and sustainable emerging chemical risks identification system.
- Discuss how to optimise the exchange of information on emerging chemicals with relevant institutional stakeholders.
- Contribute to the ongoing discussions related to the establishment of an Early Warning and action System foreseen in the art. 19 of the proposal for a Regulation of the European Parliament and of the Council “establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals”.

Particular focus will be devoted to:

- Automatic systems for screening and prioritising emerging chemicals: identification of a common set of algorithms, software, models, technologies and tools for identifying and monitoring emerging chemicals, screening large numbers of substances, prioritising and characterising those of emerging concern or requiring early regulatory action.
- Community creation: Identification of the main contributors of signals and potential emerging chemical risks and design an initial and practical workflow for the exchange of information based on a common terminology and shared understanding of the scope, and draft workflow(s) for exchanging and gathering information.

6 Conclusions

EFSA has implemented a structured process for the identification and characterisation of emerging chemicals. It is underpinned by its networks (EREN, StaDG-ER, Circular Economy, Blue Economy, Climate Change) and tools (crowdsourcing, horizon and Environmental scanning, participatory Foresight, Text & data mining - e.g., TIM, Experts' knowledge, analytical screening). Several EU-funded projects (FoodSafeR, HoliFood, PARC) are also being monitored as solution providers for this purpose.

EFSA is also participating in, or exploring possible interlinkages with, a variety of international networks other than those established in the context of its activities (such as the WHO Chemical Risk Assessment Network and the NORMAN network). They support the identification and characterisation of signals of emerging chemical issues and risks, defined as new hazards, increased exposure to known hazards, increased susceptibility and drivers.

A variety of specific emerging chemical issues/risks have been identified (SCREENER, TIM, and EuroCigua projects) and drivers of emerging risks explored (climate change, blue economy, circular economy). The sources of data for emerging risks for ERI have been expanded beyond the traditional ones, in particular through crowdsourcing (as piloted in the CLEFSA project).

The identification of emerging chemicals is challenging due to the scarce existing information on the hazard they pose and their occurrence in food, feed and environmental compartments. In addition, detection and quantification methods are not developed for most of them. For these reasons, in addition to desk-based sources, analytical methodologies have been developed and tested for chemicals screening purposes (suspect screening for “known unknowns”, non-target analysis for “unknown unknowns”, target analysis for “known”). They have addressed the challenge of developing analytical methodologies flexible enough to detect and quantify in food samples, without prior occurrence data, a large variety of chemicals with different physico-chemical properties (e.g., molecular weight and n-octanol–water partition coefficient) and toxicity, still accurate enough to detect chemicals at very low concentrations.

The issue of prioritisation was addressed by developing modelling approaches supported by the application of pre-established scoring criteria for REACH chemicals (release to the environment, biodegradation, bioaccumulation and toxicity – REACH 1 and REACH 2 projects). The identified emerging issues were further characterised through a set of criteria (Novelty, Soundness, Imminence, Severity and Scale). An attempt to propose parameters useful for a preliminary characterisation of the risk on the basis of the potential effects and exposure to the chemicals has been piloted in the SCREENER project.

The One Health approach is the backbone of the EFSA activities in identifying emerging risks related to human, animal and plant health and the environment. In this respect, the projects described in this report have been devoted to this purpose by following a cross-cutting and interdisciplinary approach. These activities are aiming at ensuring preparedness to future regulatory and policy needs by addressing the EU Farm to Fork¹⁶, Biodiversity strategy for 2030¹⁷, CSS¹⁸ and the Sustainable Blue Economy¹⁹ as stipulated in the EFSA Strategy 2027 (EFSA 2021). More in general, they aim at fostering resilience against current and future challenges, building-in competence and methodologies able of handling unforeseen or poorly understood chemical risks.

7 Recommendations

The risk landscape is rapidly evolving due to global, interconnected economies, societies, environment and the uptake of new technologies. To manage emerging chemical

¹⁶ https://food.ec.europa.eu/horizontal-topics/farm-fork-strategy_en

¹⁷ https://environment.ec.europa.eu/strategy/biodiversity-strategy-2030_en

¹⁸ https://environment.ec.europa.eu/strategy/chemicals-strategy_en

¹⁹ <https://www.unep.org/topics/ocean-seas-and-coasts/ecosystem-based-approaches/sustainable-blue-economy>

risks, it is necessary to anticipate, characterise, and possibly prevent risks, which are transboundary, highly uncertain, and systemic.

Due to the very nature of the challenge of identifying emerging chemical risks, continuous efforts are essential to ensure preparedness for future food safety and risk assessment challenges. These efforts include the application of future-oriented approaches aiming at stretching the time horizon of the investigation from the short- to the long-term and to a more systemic view of the food chain. Future oriented approaches may support the continuous identification of new emerging risks, trends and relevant drivers of change.

These efforts need to be accompanied by a structured and organised tracking of the large number of emerging issues that were not concluded as emerging risks due to insufficient data and those concluded as emerging risks but lacking a defined follow-up.

For this purpose, networking and cooperation with “emerging stakeholders” not previously engaged in the EFSA’s ecosystem can be beneficial. Joint efforts and an efficient flow of information between risk assessors and risk managers is essential to optimise the process of identification of emerging chemicals.

The knowledge gaps that arise from the identification of emerging chemical issues should provide insight for research prioritisation for emerging chemical risks for which information is scant. For example, future research should focus on optimised efforts in detecting the ‘unknown unknowns’, which constitute unknown markers of exposure and for which non-target screening is required for their detection. In order to limit the inherent limitations posed by non-target screening, methodological harmonisation is suggested among laboratories. This is among the most challenging endeavours and is a promising approach to advance our knowledge in emerging chemical risks. Moreover, optimal combinations between bio-based methods (effect-based methods) and chemical screening methods could also be explored in future research.

The screening of emerging chemicals through text and data mining and analytical methodologies has proven to be highly demanding, resource-intensive, with a limited throughput and therefore not sustainable, considering the limited resources and time available. The potential offered by machine learning techniques for this purpose should be further explored.

It is essential to optimise the exchange of information with the other actors involved in the process (e.g., EU and international organisations). Under this perspective, the PARC early warning system will be explored for the needs of the EFSA identification of emerging chemical risks. Possible collaborative options for a permanent and sustainable emerging chemical risks identification system should be discussed with a view to contributing to the ongoing discussions related to the establishment of an Early Warning and action System for emerging chemical risks, foreseen in the context of the legislative proposals on chemicals assessment.

Particular attention should be devoted to the identification of a common set of algorithms, software, models, technologies and tools for identifying and monitoring emerging chemicals, screening large numbers of substances, prioritising and characterising those of emerging concern or requiring early regulatory action. The main challenges suspect screening and non-targeted analysis (blind spots, unidentified chemicals etc) pose to the identification

Emerging chemical risks in food and feed

of emerging chemicals should be discussed and appropriate computational methods identified that could contribute to address them.

It is necessary to set up a community of providers of information and signals on emerging chemicals, based on a common terminology and shared understanding of the scope and draft workflow(s) for exchanging and gathering information. In particular a common understanding of what a relevant signal is, who are the main sources (national Early Warning Systems, Member State agencies and EU sources etc) together with the accompanying temporal and spatial scales.

References

- ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), 2015. Scientific Opinion on the re-evaluation of iron oxides and hydroxides (E 172) as food additives. *EFSA Journal* 2015;13(12):4317, 57 pp. doi:10.2903/j.efsa.2015.4317
- Bitsch A, Bohlen ML, Escher S, Licht O, Oltmanns J, Schneider K and Wibbertmann A, 2016. Final report: Testing a procedure for the identification of emerging chemical risks in the food chain. External Scientific Report. OC/EFSA/SCER/2014/03. doi:10.2903/sp.efsa.2016.EN-1050
- Burtscher J, Etter D, Biggel M, Schlaepfer J and Johler S, 2021. Further Insights into the toxicity of *Bacillus cytotoxicus* based on toxin gene profiling and Vero cell cytotoxicity assays. *Toxins*, 13, 1–7. doi:10.3390/toxins13040234
- Canals A, Varela Martínez C, Diogène J and Gago-Martínez A, 2021. Risk characterisation of ciguatera poisoning in Europe. EFSA supporting publication 2021:EN-6647. 86 pp. doi:10.2903/sp.efsa.2021.EN-6647
- Charlton-Howard HS, Bond AL, Rivers-Auty J and Lavers JL, 2023. 'Plasticosis': Characterising macro-and microplastic-associated fibrosis in seabird tissues. *Journal of Hazardous Materials*, 450, 131090. doi:10.1016/j.jhazmat.2023.131090
- Diogène J, Rambla M, Campàs M, Fernández M, Andree K, Tudó A, Rey M, Sagristà N, Aguayo P, Leonardo S, Castan V, Costa JL, Real F, García N, Fernández Rodríguez AJ, Martín León F, Reis Costa P, Soliño L, Rodrigues S, Silva A, Godinho L, Marques A, Kanari P, Stavroulakis G, Papageorgiou G, Chrysanthou E, Aligizaki K, Nikolopoulou I and Kaliwra A, 2021. Evaluation of ciguatoxins in seafood and the environment in Europe. EFSA supporting publication 2021:EN-6648. 104 pp. doi:10.2903/sp.efsa.2021.EN-6648
- Dodgen LK, Li J, Parker D, Gan JJ, 2013. Uptake and accumulation of four PPCP/EDCs in two leafy vegetables. *Environmental Pollution*, 150-156. doi:j.envpol.2013.06.038
- EFSA Panel on Contaminants in the Food Chain, 2010. Scientific Opinion on marine biotoxins in shellfish – Emerging toxins: Ciguatoxin group. *EFSA Journal* 8(6):1627. 38 pp. doi:10.2903/j.efsa.2010.1627
- EFSA (European Food Safety Authority), 2012a. Piloting a process for Emerging Risks Identification: Lessons learnt and next steps. Supporting publications 2012:EN-310. 39 pp. doi:10.2903/sp.efsa.2012.EN-310
- EFSA (European Food Safety Authority), 2012b. Towards a methodological framework for emerging risk identification. Supporting publications 2012:EN-243. 42 pp. doi:10.2903/sp.efsa.2012.EN-243
- EFSA (European Food Safety Authority), 2014a. Update on EFSA's activities on Emerging Risks 2012-2013. EFSA supporting publication 2014:EN-585. 17 pp. doi:10.2903/sp.efsa.2014.EN-585
- EFSA (European Food Safety Authority), 2014b. A systematic procedure for the identification of emerging chemical risks in the food and feed chain. EFSA supporting publication 2014:EN-547. 40 pp. doi:10.2903/sp.efsa.2014.EN-547

Emerging chemical risks in food and feed

EFSA (European Food Safety Authority), 2015. Identification of emerging risks: An appraisal of the procedure trialled by EFSA and the way forward. EFSA supporting publication 2015;12(6):EN-824, 30. doi:10.2903/sp.efsa.2015.EN-824

EFSA (European Food Safety Authority), Donohoe T, Garnett K, Lansink AO, Afonso A and Noteborn H, 2018. Scientific report on the emerging risks identification on food and feed – EFSA. EFSA Journal 2018;16(7):5359, 37 pp. doi:10.2903/j.efsa.2018.5359

EFSA (European Food Safety Authority), Maggiore A, Afonso A, Barrucci F and De Sanctis G, 2020. Climate change as a driver of emerging risks for food and feed safety, plant, animal health and nutritional quality. EFSA supporting publication 2020:EN-1881. 146 pp. doi:10.2903/sp.efsa.2020.EN-1881

EFSA (European Food Safety Authority), James K, Millington A and Randall N, 2022. Food and feed safety vulnerabilities in the circular economy. EFSA supporting publication 2022:EN-7226. 112 pp. doi:10.2903/sp.efsa.2022.EN-7226

EFSA (European Food Safety Authority), Bottex B, Gkrintzali G, Garcia Matas R, Georgiev M, Maggiore A, Merten C, Rortais A, Afonso A and Robinson T, 2023a. Technical report on EFSA's activities on emerging risks in 2020. EFSA supporting publication 2023:EN-8024. 51 pp. doi:10.2903/sp.efsa.2023.EN-8024

EFSA (European Food Safety Authority), Gkrintzali G, Georgiev G, Garcia Matas R, Maggiore A, Merten C, Rortais A, Giarnecchia, R, Robinson T and Bottex B, 2023b. Technical report on EFSA's activities on emerging risks in 2021. EFSA supporting publication 2023:EN-8233, 41 pp. doi:10.2903/sp.efsa.2023.EN-8233

EFSA (European Food Safety Authority), Steinbach AM, Giarnecchia R, Maggiore A, Eulaerts O and Joanny G, 2023c. Testing the JRC TIM tools to identify emerging chemical risks. EFSA supporting publication 2023:EN-7906. 135 pp. doi:10.2903/sp.efsa.2023.EN-7906

EFSA (European Food Safety Authority), Undas AK, Escher S, Hahn S, Hajslova J, Hrbek V, Kosek V, Licht O, Lommen A, Mol H, Pulkrabova J, Stupak M, Zobl W and Hoogenboom R, 2024. Screening for emerging chemical risks in the food chain (SCREENER). EFSA supporting publication 2024:EN- 8962. 183 pp. doi:10.2903/sp.efsa.2024.EN-8962

EFSA (European Food Safety Authority), 2021. EFSA Strategy 2027 – Science, safe food, sustainability. Luxembourg: Publications Office of the European Union. doi:10.2805/886006

EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2016. Scientific opinion on the risks for human health related to the presence of 3- and 2-monochloropropanediol (MCPD), and their fatty acid esters, and glycidyl fatty acid esters in food. EFSA Journal 2016; 14(5), 4426, 159 pp. doi:10.2903/j.efsa.2016.4426

Fagerlund A, Brillard J, Furst R, Guinebretiere M-H and Granum PE, 2007. Toxin production in a rare and genetically remote cluster of strains of the Bacillus cereus group. BMC Microbiology, 7, 43. doi:10.1186/1471-2180-7-43

FDA, 2024. FDA Update on the Post-market Assessment of Tara Flour Available from: <https://www.fda.gov/food/cfsan-constituent-updates/fda-update-post-market-assessment-tara-flour>

Free G, Van De Bund W, Gawlik B, Van Wijk L, Wood M, Guagnini E, Koutelos K, Annunziato A, Grizzetti B, Vigiak O, Gnechi M, Poikane S, Christiansen T, Whalley C, Antognazza F, Zenger B, Hoeve R and Stielstra H, 2023. An EU analysis of the ecological disaster in the Oder River of 2022. JRC132271. Publications Office of the European Union, Luxembourg, doi:10.2760/067386

Gago-Martinez A, Leão JM, Estevez P, Castro D, Barrios C, Hess P and Sibat M, 2021. Characterisation of ciguatoxins. EFSA supporting publication 2021:EN-6649. 37 pp. doi:10.2903/sp.efsa.2021.EN-6649

Guinebretière M-H, Auger S, Galleron N, Contzen M, De Sarrau B, De Buyser M-L, Lamberet G, Fagerlund A, Granum PE, Lereclus D, De Vos P, Nguyen-The C and Sorokin A, 2013. *Bacillus cytotoxicus* sp. nov. is a novel thermotolerant species of the *Bacillus cereus* Group occasionally associated with food poisoning. International Journal of Systematic and Evolutionary Microbiology, 63, 31–40. doi:10.1099/ijs.0.030627-0

Issa M, Rivière G, Houdeau E and Adel-Patient K, 2022. Perinatal exposure to foodborne inorganic nanoparticles: A role in the susceptibility to food allergy? Frontiers in Allergy, 3, 1067281. doi:10.3389/falgy.2022.1067281

Koske D, Straumer, K, Goldenstein NI, Hanel R, Lang T and Kammann U, 2020. First evidence of explosives and their degradation products in dab (*Limanda limanda* L.) from a munition dumpsite in the Baltic Sea. Marine Pollution Bulletin, 155, 111131. doi:10.1016/j.marpolbul.2020.111131

Lu J, Wu J, Stoffella PJ and Wilson PC, 2013. Analysis of Bisphenol A, Nonylphenol, and Natural Estrogens in Vegetables and Fruits Using Gas Chromatography–Tandem Mass Spectrometry. Journal of Agricultural and Food Chemistry, 61, 84–89. doi:10.1021/jf304971k

Lu J, Wu J, Stoffella PJ and Wilson PC, 2015. Uptake and distribution of bisphenol A and nonylphenol in vegetable crops irrigated with reclaimed water. Journal of Hazardous Materials, 283, 865-870. doi:j.jhazmat.2014.10.018

Myers SS, Zanobetti A, Kloog I, Huybers P, Leakey ADB, Bloom AJ, Carlisle E, Dietterich LH, Fitzgerald G, Hasegawa T, Holbrook NM, Nelson RL, Ottman MJ, Raboy V, Sakai H, Sartor KA, Schwartz J, Seneweera S, Tausz M and Usui Y, 2014. Increasing CO₂ threatens human nutrition. Nature, 510(7503), 139–142. doi:10.1038/nature13179

Oltmanns J, Bohlen M-L, Escher S, Schwarz M and Licht O, 2019. Final Report: Applying a tested procedure for the identification of potential emerging chemical risks in the food chain to the substances registered under REACH - REACH 2. External Scientific Report. OC/EFSA/SCER/2016/01-CT1. EFSA supporting publication 2019:EN-1597. 263 pp. doi:10.2903/sp.efsa.2019.EN-1597

Paerl HW, Otten TG and Kudela R, 2018, Mitigating the Expansion of Harmful Algal Blooms Across the Freshwater-to-Marine Continuum. Environmental Science & Technology, 52 (10), 5519-5529. doi:10.1021/acs.est.7b05950

Pascual G, Domínguez D, Elosúa-Bayes M, Beckedorff F, Laudanna C, Bigas C, Douillet D, Greco C, Symeonidi A, Hernández I, Gil SR, Prats N, Bescós C, Shiekhatar R, Amit M, Heyn H, Shilatifard A and Benitah SA, 2021. Dietary palmitic acid promotes a prometastatic memory via Schwann cells. Nature, 599, 485-490. doi:10.1038/s41586-021-04075-0

Pener MP, 2014. Allergy to locusts and acridid grasshoppers: a review. *Journal of Orthoptera Research*, 23(1), 59–67. <http://www.jstor.org/stable/24367403>

Rau J, Perz R, Klittich G and Contzen M, 2009. Cereulide forming presumptive *Bacillus cereus* strains from food – differentiating analyses using cultural methods, LC-MS/MS, PCR, and infrared spectroscopy in consideration of thermotolerant isolates. *Berl Munch Tierarztl Wochenschr*, 122, 25–36.

Sun H, Wang L and Zhou, Q, 2013. Effects of bisphenol A on growth and nitrogen nutrition of roots of soybean seedlings. *Environmental Toxicology and Chemistry*, 32: 174-180. doi:10.1002/etc.2042

Umwelt Bundesamt, 2022. Oder fish die-off: Salt discharges caused mass proliferation of toxic alga. Available from: <https://www.umweltbundesamt.de/en/press/pressinformation/fish-die-off-salt-discharges-caused-mass>

Varela Martínez C, León Gómez I, Martínez Sánchez EV, Carmona Alférez R, Nuñez D, Friedemann M, Oleastro M and Boziaris I, 2021. Incidence and epidemiological characteristics of ciguatera cases in Europe. *EFSA supporting publication* 18(5):EN-6650. 77 pp. doi:10.2903/sp.efsa.2021.EN-6650

Wang Y, Zhang Y, Lou H, Wang C, Ni M, Yu D, Zhang L and Kang L, 2022. Hexamerin-2 Protein of Locust as a Novel Allergen in Occupational Allergy. *Journal of Asthma and Allergy*, 15, 145-155. doi:10.2147/JAA.S348825

WHO and FAO, 2017. Evaluation of certain contaminants in food. Eighty-third report of the Joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series 1002.

Glossary

Driver	Generally, a driver is the energy that provides 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 for describing 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, and the information collected is still too limited to be able to assess whether it meets the requirements of an emerging risk. Thus, emerging issues are identified at the beginning of the emerging risks identification process as subjects that merit further investigation and additional data collection. Emerging issues can include specific issues (e.g., a specific chemical substance or pathogen, or a specific 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' is understood to be a risk resulting from (a) a newly identified hazard to which significant exposure may occur or (b) an unexpected new or increased significant exposure or susceptibility to a known hazard. For the purpose of emerging chemical risks identification, they may also result from changed composition of food items or environmental matrices, determining the possibility of a changed intake of micro- and macronutrients.

Abbreviations

BMAA	β -methylamino-L-alanine
CLEFSA	Climate change and emerging risks for food safety
CSS	Chemicals Strategy for Sustainability Towards a Toxic-Free Environment
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
ECRI WG	Emerging Chemical Risks Identification Working Group
EEA	European Environment Agency
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EREN	Emerging Risks Exchange Network
ERI	Emerging Risk Identification
EU	European Union
EU-OSHA	European Agency for Safety and Health at Work
FAO	Food and Agriculture Organization of the United Nations
IFCSLG	International Food Chemical Safety Liaison Group
JRC	Joint Research Centre
NORMAN Network	Network of reference laboratories, research centres and related organisations for monitoring of emerging environmental substances
PARC	Partnership for the Assessment of Risks from Chemicals
REACH	An acronym for the Registration, Evaluation, Authorisation and Restriction of Chemicals, acronym of the European Regulation (EC) No 1907/2006
SMILES	Simplified Molecular Input Line Entry System
StaDG-ER	Stakeholder Discussion Group on Emerging Risks
SWOT	Strengths, Weaknesses, Opportunities, and Threats
TIM	Tool for Innovation Monitoring
TTX	Tetrodotoxin
WHO	World Health Organization