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## Emerging risks identification on food and feed – EFSA

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### Abstract

The European Food Safety Authority's has established procedures for the identification of emerging risk in food and feed. The main objectives are to: (i) to carry out activities aiming at identifying, assessing and disseminating information on emerging issues and ensure coordination with relevant networks and international organisations; (ii) promote the identification of data sources and data collection and /or data generation in prioritised emerging issues; and the (iii) evaluate of the collected information and identify of emerging risks. The objective(s) of the Standing Working Group on Emerging Risks (SWG-ER) is to collaborate with EFSA on the emerging risks identification (ERI) procedure and provide strategic direction for EFSA work building on past and ongoing projects related to EFSA ERI procedure. The SWG-ER considered the ERI methodologies in place and results obtained by EFSA. It was concluded that a systematic approach to the identification of emerging issues based on experts' networks is the major strength of the procedure but at present, it is mainly focused on single issues, over short to medium time horizons, no consistent weighting or ranking is applied and clear governance of emerging risks with follow-up actions is missing. The analysis highlighted weaknesses with respect to data collection, analysis and integration. No methodology is in place to estimate the value of the procedure outputs in terms of avoided risk and there is urgent need for a communication strategy that addresses the lack of data and knowledge uncertainty and addresses risk perception issues. Recommendations were given in three areas: (i) Further develop a food system-based approach including the integration of social sciences to improve understanding of interactions and dynamics between actors and drivers and the development of horizon scanning protocols; (ii) Improve data processing pipelines to prepare big data analytics, implement a data validation system and develop data sharing agreements to explore mutual benefits; and (iii) Revise the EFSA procedure for emerging risk identification to increase transparency and improve communication.

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## 1. Introduction

### 1.1. Background

According to the European Food Safety Authority's (EFSA) Founding Regulation (EC) No 178/2002 (Article 34), EFSA is required to establish procedures for the screening and analysis of information with a view of identifying emerging risks in the fields within its mission. To achieve this objective EFSA has carried out, experts' consultations and a testing phase to develop a practicable approach to the identification of emerging risks (EFSA, 2012b, 2014b).

The main objectives of the emerging risks' identification (ERI) procedure are to: (i) carry out activities aiming at identifying, assessing and disseminating information on emerging issues; (ii) ensure coordination with EFSA units, Panels and other relevant EU institutions, Member States (MS) and international organisations and (iii) promote the identification of data sources and data collection and/or data generation in prioritised emerging issues to improve preparedness for EFSA risk assessment needs, and (iv) evaluate of the collected information and identify emerging risks.

The outcome of these activities allows EFSA to identify at an early stage some future challenges and draw conclusions on the approach to emerging risks. The outcome could also be used for strategic planning of EFSA, leading possibly to full risk assessment activities for risk managers to put in place appropriate prevention or mitigation measures.

EFSA coordinates the activities of the Stakeholder Discussion Group on Emerging Risks (StaDG-ER), the Emerging Risks Exchange Network (EREN) and the Scientific Committee's (SC) Standing Working Group on Emerging Risks (SWG-ER). The SWG-ER supports EFSA's activities in the identification of emerging risks and in the development of methodologies and collection of data in the area of emerging risks.

### 1.2. Terms of Reference

The objective(s) of the Standing Working Group on Emerging Risks (SWG-ER) is to collaborate with EFSA on the emerging risks identification procedure, in particular to:

- Ensure dissemination of information and coordination between panels
- Support the generation of new knowledge and the fostering of innovation and technologies as well as the usefulness of data collection and generation.

The specific tasks of the SWG-ER are:

- 1) Assist in the identification and dissemination of information on emerging issues;
  - Contribute to reports on specific issues;
  - Liaise with the Panels in order to both identify new emerging issues as well as to provide feedback on the issues under evaluation;
  - Update the Scientific Committee on the emerging issues identified and follow-up actions.
- 2) Assist EFSA on activities related to methodological development and data collection for prioritised emerging issues;
  - Prevent duplication of initiatives by different panels/units;
  - Ensure scientific quality of projects and deliverables;
  - Promote follow up activities and dissemination in EFSA and through the scientific community.
- 3) Assist in the review of the ERI procedure following experience gained in its operation and recommend further developments.

### 1.3. Aim and scope of the report

The Term of reference (ToR) 3 of the SWG-ER constitutes the objective of the current report, i.e. to provide strategic direction for EFSA work on Emerging Risks building on past and ongoing projects related to EFSA ERI procedure.

This report reviews the work developed by EFSA in the area of emerging risks in food and feed identification. The review will consider the identification, prioritisation and communication of emerging risks as well as feedback and review processes with a view to proposing areas for discussion and development that EFSA can reflect upon.

The potential utility of social science in providing a wider, substantive background and input to ERI, will be considered, examining the relationship between behaviour (or actions) of causal and affected actors and emerging risks for the food system. Public understanding, acceptance and risk perception are also important and will be considered. The behaviours of the people (actors) involved in food systems from farmers to consumers and how their choices may affect food safety need to be more systematically considered. Similarly, consideration will have to be given to how the public's perceptions of risks may impact the decisions that EFSA and others make (Barab and Squire, 2004; Hansena et al., 2013). This understanding will influence how best to communicate emerging issues. Therefore, the report will also include aspects related to digital technologies and citizen engagement and how communication objectives and strategies may be framed for target audiences.

It is the intention, to reflect on the current ERI procedure in a wider context. This will require examining how food systems work and exploring what methods allow for carrying out a more comprehensive assessment of vulnerabilities, drivers and potential impacts related to emerging issues across the short-, medium- and long-term horizons. The report incorporates learning from data sciences and big data disciplines to assess appropriate techniques and tools needed to combine increasing numbers of indigenous and exogenous data sources and to capture spatiotemporal dependent changes in the food system. It is also clear that a proper consideration of EFSA's role is becoming more and more urgent in managing expectations in the remit of ERI.

Recommendations are provided to further improve upon the efficacy of established EFSA procedures for ERI, including innovative or advanced solutions. It is intended that the recommendations can be translated into a longer term strategic policy thinking and concrete action plan(s).

#### 1.4. Relation to other relevant EFSA documents

The report builds on a review of the ERI procedure and recommendations made by the previous SC Standing working group on emerging risks in its final report (EFSA, 2015b).

The conceptual approach for scientific assessments outlined in PROMETHEUS (EFSA, 2015a), which described the overall procedure for dealing with data and evidence, was considered. Transparent reporting of all assumptions and methods used, including expert judgement, is necessary to ensure a robust ERI procedure. 'Open EFSA' (engagement) aspires both to improve the overall quality of available information and data and to comply with normative and societal expectations of openness and transparency (EFSA, 2009a,b, 2014c,d).

EFSA has published closely related guidance on weight of evidence, which provides a general framework for considering and documenting the approach used to evaluate and weigh the assembled evidence. This includes assessing the relevance, reliability and consistency of the evidence (EFSA, 2017a,d). In addition, the report envisages innovations to implement EFSA strategic objective 1 – Prioritise public engagement in the process of scientific assessment – by exploring tools such as 'citizens' science' and 'big data' (EFSA Strategy 2020: trusted science for safe food) (EFSA, 2017c). This report also considers aspects of communicating scientific uncertainty as described in the guidance on uncertainty in EFSA Scientific Assessment (EFSA, 2018).

## 2. Overview of EFSA's activities related to emerging risks identification

The ERI procedure currently in place in EFSA is based on three principal steps:

- 1) Identification of priority emerging issues;
- 2) Identification of data sources and data collection;
- 3) Evaluation of emerging risks.

The procedure follows the requirements established by the EU Food law (Art. 34 Reg. 178/2002) to collect, analyse and disseminate knowledge on possible emerging risks in food and feed that may adversely impact human, animal and plant health (effects on environmental health should also be considered as they may pose an indirect risk to food and feed) (European Commission, 2002).

It was not the legislator intention to establish an emerging risk governance system where roles and responsibilities were defined. EFSA has oriented its ERI procedure to improve preparedness for risk management actions as well as for identifying future data and methodological issues for risks assessment.

The request for action is, however, inherent to the word 'risk' where public health is at stake. In this context, it is understandable that scientists, risk assessors and risk managers have an aversion to the idea of risk identification that is based on scenarios developed from weak signals, narratives and models with high uncertainty (De Ruijter, 2014).

A definition for emerging risk was developed and agreed by EFSA SC while a working definition of emerging issues was introduced in 2012.

*An emerging risk to human, animal and/or plant health is understood as a risk resulting from a newly identified hazard to which significant exposure may occur or from an unexpected new or increased significant exposure and/or susceptibility to a known hazard (EFSA, 2007).*

*Emerging issues are identified at the beginning of the emerging risks identification process as issues that may merit further investigation and additional data collection. Emerging issues can include specific issues as well as general issues such as drivers of change (EFSA, 2012b).*

Currently, emerging issues are identified at the beginning of the ERI procedure (EFSA, 2015b). It is also noted that issues are mainly identified by EFSA networks of knowledge: EREN, StaDG-ER, EFSA SC, Panels or scientific support units, other EU institutions or international parties. The procedure is in agreement with the recommendation of the SWG-ER that priority emerging issues should be preferably identified through expert consultations, and via exchange of information with qualified organisations (e.g. sister agencies and other competent organisations) (EFSA, 2015b). Identified emerging issues are laid out in a briefing note template (EFSA, 2014c; Costa et al., 2017).

Automatic identification tools such as text (MeDYSIS) or data (Bitsch et al., 2016) mining are being used and the potential for screening and prioritising large data sets, by using artificial intelligence, crowd sourcing or other participatory science methods, is being explored by EFSA.

The standardised, structured format of the briefing note supports expert evaluation of emerging issues. The criteria considered are: (i) Novelty, (ii) Soundness, (iii) Imminence, (iv) Scale and (v) Severity (EFSA, 2012a,b). Additional information regarding the nature of the hazard identified, or associated drivers and trends are also included. Briefing notes are not publicly available but constitute working documents for EFSA knowledge networks. The recommendations from the various groups to EFSA regarding the potential interest to monitor the issue, collect more data or information, communicate to relevant stakeholders are recorded.

EFSA evaluates if the particular issues identified are within EFSA risk assessment mission and remit, if risk assessment by EFSA or other Food and Feed safety risk assessment bodies was already performed or if sufficient evidence exists to change the available risk assessment, if research on the issue is ongoing and the recommendations given. The evaluation determines possible follow-up actions.

Important objectives for EFSA procedure for identification of emerging risks are to raise awareness of risk managers for emerging risks and improve preparedness for risk assessment. EFSA has no role in defining possible risk management or risk mitigation measures. Time-effective communication and collaboration with different stakeholders and in particular with risk managers is fundamental to the challenges linked to, the evaluation of possible evidence that an emerging issue evolves into an emerging risks (EFSA, 2015b).

Communication of EFSA's activities in the area of ERI is done: (i) by exchange of briefing notes for review and collection of additional information with EFSA knowledge networks, EREN members and observers (FAO, WHO, ECDC, ECHA, EC, FDA), Scientific panels and scientific support units (different panels depending on the nature of the identified issue) and in some cases the StaDG-ER, (ii) by publication on EFSA web site of agenda and minutes of the various Network and Discussion group meetings, and (iii) by the publication of an EFSA -ERI annual activity report summarising all activities of the various networks, results of methodological development projects and a summary of issues identified and main conclusions and recommendations.

EFSA has established activities in developing methodologies for automatic identification of emerging issues such as text mining (TM), development of automatic evaluation tools for screening of data sets, analysis of commodity and trade data and promoted projects on data collection for identified emerging issues (EFSA, 2009b, 2010a,b, 2012b, 2015b). EFSA website hosts an emerging risks topic<sup>1</sup> that provides easy access to all EFSA scientific and support publications.

Ongoing activities include the development of a prototype exchange collaboration platform for emerging risks with MS food safety authorities 'Development of methodologies and collaborative approaches in emerging risk identification' (DEMETER) to be concluded April 2020, risk characterisation of European Ciguatera (EuroCigua) to be concluded June 2020, a project on global food chain analysis

<sup>1</sup> <https://www.efsa.europa.eu/en/topics/topic/emerging-risks>

of aquaculture, identification of vulnerabilities and drivers of change for the identification of emerging risks (AQUARIUS) to be concluded March 2019, the application of a tested procedure for the identification of potential emerging chemical risks in the food chain to the substances registered under REACH (REACH2) to be concluded January 2019, the development of a methodology for prioritisation of food safety emerging risks linked to climate change (CLEFSA) to be concluded in 2020, the screening of scientific literature for identification of emerging risks in salmon food chain using a adapted ERIS – TNO ontology until 2019 and the use of MediSYS – TM of media and scientific literature for the identification of plant pests.

## 2.1. Evaluation of EFSA's ERI approach: A SWOT analysis

A SWOT analysis was carried out by the SWG-ER at the start of its deliberations to consider the Strengths and Weaknesses of the current system, Opportunities to improve it and possible Threats. The analysis took account of recent reviews of the effectiveness of EFSA working groups and networks (EFSA, 2012a,b, 2014c, 2015b, 2017b) and considered the three steps of the ERI procedure in food and feed implemented by EFSA (EFSA, 2012b). Opportunities and recommendations were highlighted. Actions to maximise opportunities or minimise weaknesses and avoid threats will be described in Section 3 of the report.

### 2.1.1. Identification of priority emerging issues

EFSA has developed a systematic approach to the identification of emerging issues based on collaboration with its networks of knowledge. The networks, both internal to EFSA and at MS and international level give access to diverse expertise in all fields related to EFSA remit. EREN, MS experts, has become a very successful network for the sharing, analysis and dissemination of emerging issues via a strong and committed membership and effective EFSA Secretariat. The procedure is focusing on the identification of issues from the recognition of early signals arising from surveillance activities, scientific publications screening or media monitoring (EFSA, 2017b).

The briefing note template, in use for several years, allows for a standard description of the issue identified. A defined set of criteria (Novelty, Soundness, Imminence and Scale) are in use for the 'characterisation' of the identified issue through an iterative process with a vast range of stakeholders.

At present, ERI focuses on single issues, and is very reliant on the input of its knowledge networks and in particular the expertise from MS. Different approaches to the identification of emerging issues are in place at MS level and often issues may cross the boundaries between the various institutions responsible for food and feed safety and challenge the ability of EREN members to obtain input from the national institutions and fully reflect the views of the MS. As such, emerging issues identification tends to focus on the short and medium term. The EFSA ERI procedure does not perform horizon scanning activities based on 'open searches', which have the capability of capturing a broader range of issues.

EFSA is trialling a system-based approach for the identification of emerging issues looking at food supply chains vulnerabilities and knowledge on drivers of change. The projects AQUARIUS and DEMETER take a whole-chain, medium-term approach and provide platforms and approaches for better understanding of supply chain dynamics as well as improved access to and sharing of information on emerging issues. Successful completion of DEMETER and AQUARIUS therefore offers great potential benefit to both EFSA and MS.

Currently, there is no system or framework in place for using 'big data' in the ERI procedure. The procedure for identification of issues is based mostly on 'second-hand' information from networks of knowledge. There is no system or framework in place for using 'big data' in the ERI procedure. The SWOT analysis (Tables 1–3) highlighted weaknesses with respect to data collection, analysis and integration. Use of big data, insights from social sciences approaches, better data sharing agreements and improved analytical methods provide opportunities for EFSA and its partners to improve further its capabilities and capacity.

Better tracking of issues over longer horizons, combined with a more consistent approach to weighting or ranking of issues and better feedback from EFSA's stakeholder networks could also provide more evidence of the emergence of risks and inform prevention or response strategies.

The poor representation of different groups and in particular consumers in the StaDG-ER can introduce bias into the issues which are identified. The lack of expertise on social sciences constitutes a serious impediment to the ability to understand complex systems and the role of human behaviours in creating and perceiving risks.

The objective of the first step of the ERI procedure is to identify issues that are consistent with the EFSA definition of emerging issues or general issues such as drivers of change. Prioritisation is limited to the decision if an issue can be regarded as an emerging issue or not. The process of characterisation of emerging issues *vis a vis* the criteria: Novelty, Soundness, Imminence and Scale is based on limited data and expert knowledge with high levels of uncertainty and low reproducibility. Making better use of existing frameworks, such as DPSRI (i.e. Drivers, Pressures, States, Response and Impact)<sup>2</sup> analysis, would allow issues to be characterised making it easier to identify and plan response or monitoring over a longer timeframe.

The output of this first step of the ERI procedure is a list of emerging issues (emerging issue: yes or no) with a qualitative description based on criteria such as Novelty, Soundness, Imminence and Scale of potential impact. The responsibility/accountability for follow-up actions is not defined. EFSA publishes details of the issues identified during the year but, at present, do not apply any consistent weighting or ranking to those issues.

Lack of regulatory compliance is a prioritisation criteria in use by EFSA but it may lead to the exclusion of relevant drivers and trends important to consider in ERI.

**Table 1:** Identification of priority emerging issues

| Strengths   | Weaknesses   | Opportunities   | Threats  |
|---|--|---|--|
| <i>Identification of priority emerging issues</i>   |  |   |  |
| Issue-based search  | Limited capacity for carrying out exploratory scans (i.e. open searches).  | A system-based approach for ERI taking into account actors' behaviours; resilience thinking and different time horizons (i.e. short-, medium- and long term)                                | Increasing complexity of food/feed supply chains   |
| Capacity to identify issues related to the re-emergence of known risks and new contexts/areas | Limited use of system (food supply chain)-based approaches.  | Develop protocols for scanning information sources  | There is uncertainty inherent in emerging issues/risks, which reduced the level of confidence in outcomes, impacts, and associated probabilities |
| Strong network capacity with broad expertise and good contacts with scientific networks       | No framework in place for using big data in the ERI process.   | Improve the identification of drivers and trends by understanding different signals, e.g. weak signals, issues at different time frames   | Engaging with complex food systems, severe data gaps, and great uncertainties may take (risk) experts outside their comfort zone                 |
|   | Bias due to poor representation of certain stakeholder groups (e.g. citizen science)   | Improve the horizon scanning capacity through collaboration with wider audiences than the EFSA ER Networks (whole staff, panels, SC and through higher levels of international cooperation) |  |
|   | Lack of use of social sciences analytical approaches, such as the use of indicators derived from economic and behavioural sources              | Improve the use of Big data for emerging issues identification  |  |
|   | Lack of close collaboration between the various institutions responsible for food and feed safety  | Improve the text and data mining capacity by strengthening a world-wide cooperation with Agencies and Institutions already active in this sector  |  |
|   | Media monitoring and other automatic text mining tools are often not specific or not sensitive enough (i.e. more effective when hazard driven) | Explore the potential of citizen science capacity for ERI   |  |

<sup>2</sup> DPSIR framework (i.e. environmental context) used to characterize emerging environmental issues (DG ENV uses this in their FORENV system), available online at: <https://www.ifremer.fr/dce/content/download/69291/913220/.../DPSIR.pdf>

| Strengths  | Weaknesses   | Opportunities  | Threats   |
|--|--|--|---|
| <i>Prioritisation of emerging issues</i>                                   |  |  |   |
| Defined set of criteria<br><br>Iterative process with various stakeholders | <p>Prioritisation is based on expert knowledge which is sensitive to bias</p> <p>The high level of uncertainty makes probability estimates for the various criteria difficult</p> <p>No responsibility/accountability for the prioritisation and follow-up is defined</p> <p>The prioritisation is based on objective risk criteria but ignores human perceptions and or acceptance of risk</p> <p>Lack of regulatory compliance is a characterisation criteria which may lead to the exclusion of relevant drivers and trends</p> | <p>Develop a characterisation process for emerging issues using existing frameworks (e.g. DPSRI)</p> <p>Characterisation helps frame issues in such a way that the data source of the potential threat can be more objectively examined and selected</p> <p>Possible levels for each criteria can be defined along with criteria weights and a transparent scoring systems adopted for prioritisation purposes and MCDA tools developed</p> <p>Develop a prioritised list of issues as an initial output from ERI as a mean to raise awareness of EFSA target audience, especially with regard to pre-emptive responses</p> <p>Issue characterisation offers a rationale for focussing on those issues presenting an emerging food and feed safety risk</p> <p>Effective priority setting in multilateral, international cooperation</p> | <p>Not identifying the big issues</p> <p>No transparency regarding how the evaluation criteria are applied throughout the ERI procedure, resulting in a loss of trust in the ERI procedure</p> <p>Insufficient criteria to prioritise issues prevent assessors and managers from preparing for future risk challenges</p> <p>Lack of support by its stakeholders for EFSA ERI Unjustified scare caused by issues identified (overestimation of risks)</p> |

### 2.1.2. Identification of data sources and data collection

Once a specific emerging issue is identified it is often the case that more data/information is necessary to evaluate the potential emerging risk (novelty, imminence, severity and scale). Access to networks, both internal to EFSA and at MS and international level of diverse expertise in all fields related to EFSA is a considerable advantage and the first steps of the procedure include consultation with the various groups. A system for identification and appraisal of data sources was developed in 2011 by an EFSA WG,<sup>3</sup> and guidance on weight of evidence, biological relevance and uncertainty were recently adopted by the EFSA SC. The application of such guidance to the area of ERI is difficult due to data scarcity and high levels of uncertainty but necessary.

Issues related with data sharing are a major problem. Data confidentiality due to commercial interests or fear to scare consumers, or other actors, complicates the retrieval of information and data.

EFSA has been working on ERI in food and feed since its foundation and a substantial number of issues was identified (EFSA, 2017b) to which follow up activities either in the area of data generation/data collection or formal risk assessments were made. However, a cyclic system to track these activities and revisit identified issues on the basis of new knowledge is not in place.

<sup>3</sup> European Food Safety Authority; Data collection for the identification of emerging risks related to food and feed. EFSA Journal 2011; 9(8):EN-185. [52pp.]<https://doi.org/10.2903/j.efsa.2011.en-185>

**Table 2:** Identification of data sources and data collection

| Strengths   | Weaknesses  | Opportunities  | Threats   |
|---|---|--|---|
| <i>Data identification</i>  |   |  |   |
| <p>Access to diverse scientific expertise networks</p> <p>A system for identification and appraisal of data sources was developed</p> | <p>Guidance for data appraisal not implemented</p> <p>Difficult to integrate concepts of weight of evidence into ERI</p> <p>Sensitivity about data sharing – confidential sources</p> <p>Difficult to manage data and track issues over time. Emerging issues/risks may begin to materialise, while others may not emerge/develop</p> | <p>Implement search protocols (i.e. data retrieval systems) that capture and combine structured and unstructured data from a collection of sources</p> <p>Implement a data governance and validation system to justify selection of data sources</p> <p>Integrate data used in social sciences to capture information on actors behaviour</p> <p>Improve tracking for revisiting issues by better links with RM and research institutions</p> <p>Develop data sharing agreements with different stakeholder (causal actors) to explore mutual benefit</p> <p>Improve data analytics by replicating network structures of food systems to acquire a better understanding of consequences for food and feed safety over time and space</p> | <p>Data reliability</p> <p>Lack of trust between stakeholders to share (sensitive) data</p> <p>Poor algorithm guidance, incomplete data or oversight leads to incorrect conclusions</p> |

### 2.1.3. Evaluation of emerging risks

The final step of the ERI procedure is evaluation of the identified issues and all data/information gathered against the set of pre-established criteria (novelty, severity, imminence, and scale) and its communication. It has been recognised (EFSA, 2015b) that the identification of an 'emerging serious risk' will require a close and time-effective interaction between risk assessors and risk managers. Decisions on follow-up actions need to be carefully considered and are complicated by the high level of uncertainty usually associated with emerging issues. Emerging risks evaluation does not include impact assessments of potential social, economic and environmental aspects in order to assess severity.

The EFSA ERI procedure is used also to improve preparedness in relation to risk assessments, raising awareness of knowledge gaps or methodological deficiencies. Overall, the objectives of the ERI procedure and in particular its relevance for strategic thinking of future food safety policies is not well defined. No methodology is in place to estimate the value of its outputs in terms of value of avoided risk or avoided losses.

**Table 3:** Evaluation of emerging risks

| Strengths   | Weaknesses   | Opportunities  | Threats  |
|---|--|--|--|
| <i>Evaluation</i>   |  |  |  |
| The scope of the ERI is set by legislation  | ERI procedure is oriented at identifying and responding to short-term risks.   | Include characterisation of medium- and long-term issues to define emerging risks, reflecting current knowledge and recommendations for follow-up actions  | ERI focus limited to detection of food safety incidents/crisis   |
| A definition and criteria for emerging risk identification were agreed and a procedure is in place supported by networks of experts | Medium- and long-term risks are not characterised<br><br>Absence of a system to track issues over a long time period to assess their development into risks  | Define EFSA's role on emerging risk governance to include emerging issue characterisation, prioritisation and long-term monitoring (i.e. knowledge management)                                   | Evaluation affected by perceived relevance and uncertainty<br><br>ERI not recognised as a way to examine the resilience food systems |
| Up-front contextual frame for strategy planning and/or means of challenging assumptions and prevailing opinions                     | Lack of a communication strategy: considering timeliness and relevance of message, traction with priorities/policies, and risk perceptions<br><br>A clear view on EFSA's role in follow-up actions | Develop a communication strategy that addresses data gaps, knowledge uncertainty, and risk perception issues<br><br>Develop a prioritisation or ranking approach involving different stakeholder | Limited visibility of output in terms of avoided risks   |

### 3. Areas for further development

A number of themes have been identified by the SWOT analysis covering both needs and opportunities and these present a foundation to build a more holistic approach for the identification of emerging risks.

Which strengths identified in the ERI procedure can be utilised in maximising the opportunities identified? What actions can EFSA take (bearing in mind strengths of the ERI procedure) to address the weaknesses and external threats identified?

The SWG-ER proposals for further development focus on the following areas:

- 1) A food system-based approach that applies resilience thinking in ERI to understand the complex interactions and dynamics that exist between actors and the drivers operating in the food system environment over different time horizons.
- 2) The application of the Data-Information-Knowledge-Intelligence hierarchy (data pyramid) to ensure the 'right' data is used in ERI. This includes a good breadth of information, effective use of available data through a collaborative approach and integration of big data and advanced data analytics.
- 3) The definition of EFSA's role in relation to the coordination of ERI procedure and communication.

#### 3.1. Food systems-based approach

Food production happens within complex and continuously evolving food systems that encompasses several components, including supply of raw materials, primary production, processing, distribution and selling on a global scale, as well as dependencies that link supply chain activities with the wider environment. A simple food supply chain as depicted in Figure 1 is an example of a food system; it consists of actors such as suppliers, farmers, processors, retailers and consumers that are connected through the production of food. In reality, food supply chains are interconnected, through global trade into what is, in effect an interconnected food 'web'. Food systems, such as supply chains, vary among countries and regions, and may be influenced by factors such as geography, demographics, socio-economics, policies, cultural traditions and anthropological structures (Kearney, 2010). Understanding the linkages and influences of these factors on the food system is fundamental in ERI (Tummala and Schoenherr, 2011).



**Figure 1:** Food supply chain

The interconnectivity of food supply chains may enhance resilience by building buffering capacities that absorb perturbations (Ge et al., 2016) but magnifies vulnerabilities (FAO, 2003; Nordic Council of Ministers, 2007; FSA, 2008). A crop failure in one part of the world may be compensated by sufficient crop production and stocks elsewhere. The contrasting effect of interconnectivity is that of increasing vulnerability through cascading, where a failure in one part of a food production system carries over to other parts of the food production systems or to other systems such as social or ecological systems. Interconnectivity is particularly relevant for food production systems where plant and animal diseases may transfer rapidly through global food supply chains. The introduction and spread of animal and plant diseases may also transfer from food production systems to ecological systems (e.g. in the case of forest pests) or regional economic systems.

Besides external factors like social, economic and environmental drivers, emerging risks are also the outcome of the behaviours (or actions) of food system actors. Figure 2 represents the food system, distinguishing actors in terms of their relation with risks, i.e. causal actors, affected actors and managing actors (Oude Lansink, 2011). Emerging risks may affect a range of affected actors such as farmers, tourists and consumers. The damage to the affected actors is an endogenous variable and is the outcome of the joint actions of causal actors and managing actors. Causal actors are actors involved in activities that, for example, increase the introduction and spread of pests and diseases in the food system or that increase the exposure of biological and chemical hazards to consumers. An example of causal actors in food supply chains are importers of plant and animal products and materials, or citizens through recreational, touristic and sports activities.

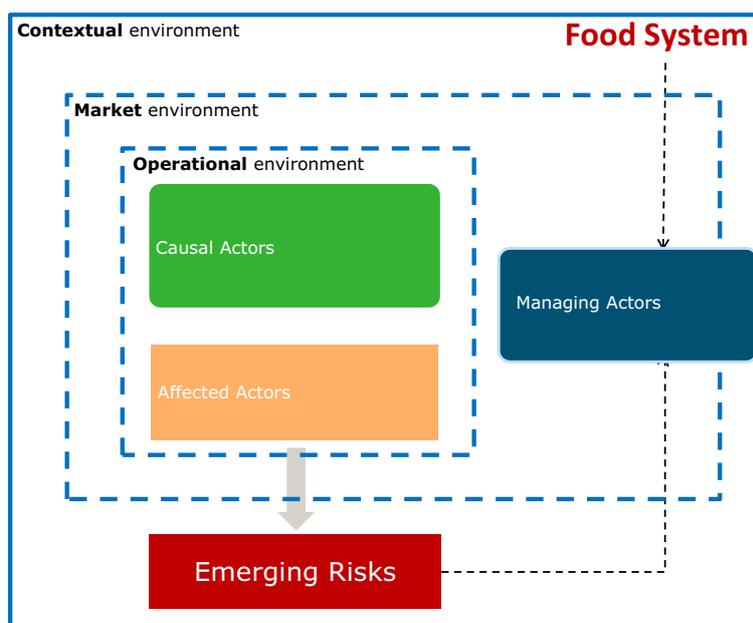
Managing actors can take actions that either directly or indirectly reduce damage to affected actors. Direct actions may take the form of, e.g. monitoring of biological and chemical hazards in the food system. Indirect actions may consist of policies and biosecurity regulations that seek to affect the behaviour of causal actors to undertake precautionary actions to reduce risks, such as mandatory certification of importers and imposing tracking and tracing systems. Actions/interventions on actors (causal and/or affected) may trigger consequences in the medium to long term.

Actor groups are generally heterogeneous entities. Within these groups, different risk perceptions may prevail (e.g. between seed potato and ware potato producing farmers). Also, the three groups of actors are not mutually exclusive. Farmers may, for example, be both managing and affected actors. Similarly, tourists can both increase risks (making them a causal actor), as well as experience the negative consequences of risks in case a cultural landscape is less attractive due to a new pest (making them an affected actor).

Identification of emerging risks in food or feed systems may consider a long-, medium- and short-term perspective (European Communities, 2001; FAO, 2015). The terms, operational, market and contextual environments, are often used in this context to pinpoint the type of 'activities and actors' in the environment that are key driving forces (Brown, 2007; Rathe et al., 2013).

- **Operational environment (short term):** trends or driving forces that are having an impact now or in the short term (i.e. 1–3 years). Issues in this time horizon are visible and well understood and are often ones that are already being responded to, or considered to be of strategic importance and require action.
- **Market environment (medium term):** emerging trends that are expected to have an impact in the near-future or medium term (i.e. 3–10 years). Issues in this time horizon are less characterised and often these are not fully understood, nor are their implications.
- **Contextual environment (long term):** less known, 'new' driving forces that may shape the food system in the long term (i.e. 10+ years). Issues in this time horizon can be difficult to characterise in detail since they are the long-term outcome of a range of exogenous factors, some of which may not be fully in play at the present time.

How these three time horizons relate to one another, is illustrated in Figure 2



**Figure 2:** Conceptual framework

### 3.1.1. Integrating horizon scanning in the ERI procedure

Various tools and approaches exist to detect emerging issues associated with food and feed safety, including data mining, scanning of the internet for information, foresight tools, citizen science and state-of-the-art monitoring technologies used to analyse trends (e.g. EFSA, 2017a–d). Such tools and approaches can be incorporated in an ERI procedure to detect signals of change, but when those signals are weak,<sup>4</sup> the detail and impact of emerging issues are usually uncertain and difficult to anticipate. This means identifying and monitoring emerging issues requires an understanding of uncertainty around the probability of occurrence and the potential consequences. A judgement about the 'knowability' of the issue offers a number of broad categories of signals<sup>5</sup>:

- (a) **short-term issues** (low levels of uncertainty) – this is where we understand a phenomenon and its likely probability, i.e. things we are aware of, and understand.

This may include known risks from food-borne microorganisms that cause infectious diseases. Other examples include yield failures in rice, causing dramatic shift in trade flows, technological changes such as 3D printing (food, bioprinting of organic tissues) or blockchain (traceability and food safety in agricultural sector) (Opperman, 2017; Ramachandran, 2017) that may lead to structural change in food patterns and product flows.

- (b) **medium-term issues** (medium levels of uncertainty) – this is where we understand a phenomenon but do not have knowledge to determine the likely probability, i.e. things we are aware of, but do not understand; and things we understand, but are not aware of.

This may include the potential for bacterial contamination of food through direct (and to some extent indirect) contamination routes. Bio-based economy encompassing the production of renewable resources and their conversion into food, feed and bioenergy may possibly impact on the safety of the food chain (European Commission, 2012). Other main issues identified in the literature are circular economy producing products for reuse (MacArthur Foundation, 2017), food authenticity and adulteration, ecological intensification of agricultural production (European Commission, 2015); all of which may pose risks to food safety.

- (c) **long-term issues** (high levels of uncertainty) – this is where we have low awareness of a phenomenon or its likely probability due to 'slow-burning' megatrends, like climate change impacts (EEA, 2017) and demographic shifts, i.e. the 'surprises'; things we have little

<sup>4</sup> <http://wiwe.iknowfutures.eu/what-is-a-weak-signal/>

<sup>5</sup> Rumsfeld (2002) cited in Science for Environment Policy. Future brief: Identifying emerging risks for environmental policies (Science for Environmental Policy, 2016).

awareness or understanding of, but can erupt into crises and spur far-reaching food safety problems.

This may also include potential allergenic risks associated with alternative protein sources (e.g. insects) or supply chain vulnerability to risk factors related to possible contamination from deliberate malicious contamination or economically motivated food fraud. Synthetic biology, Internet of Things and non fossil fuel energy sources (Alford et al., 2012; Government Office for Science UK, 2017, WEF, 2017) has multiple impacts upon the long-term structural development of firms in food supply chains, which may introduce behaviour change that is difficult to anticipate (McKinsey&Company, 2015).

Current action on short-term issues relies on the ability to produce evidence that has a high degree of rigour in order to assess the threat from, and devise measures to prevent, food safety risks. The benefit of such methods is well known (Vecchiato, 2012), but these tend to drill down into the data to get a 'single' view of *what has happened in the past*, how it has impacted on *what is happening now*, and *what is likely to happen in the future*. In a food safety context, this refers to:

- 1) **retrospective/diagnostic analysis** that allow us to learn about what has caused a food safety incident we already know about;
- 2) **predictive analysis** that allows us to derive trends or patterns from the data, which help to determine what is driving activities and behaviour in order to predict what future problems/threats are likely to emerge.

Regulatory authorities' expectations are that systems developed to identify emerging risks are capable of anticipating the next big food incident. However, examples such as Sudan I in spices and the horsemeat incident of 2015 show that although early intelligence was available authorities lacked the capability to characterise the issues and failed to make connections between different data sources.

Such failings confirm the need to develop integrated forward-looking assessments that draw on horizon scanning and other foresight approaches to generate insights regarding the dynamics of change, future challenges and options. ERI has significant potential to address such failings but there are data gaps and uncertainties in the evaluation process, which poses challenges.

### 3.1.2. Systematic identification of a wider range of issues

Horizon scanning can be integrated into the ERI process to anticipate medium to longer term issues, by analysing observable trends or patterns in obscure data that warn us about the possibility of future food safety issues. These issues often emerge from disconnected data or 'chatter' in less tangible information sources (e.g. news alerts, social media), but can form part of a larger pattern when viewed through a specified frame or connected with other data sets such as those emerging from a more targeted search of the scientific literature or via media monitoring (Palomino et al., 2013).

Horizon scanning can be applied to assess current and emerging issues in light of the dynamics, dimensions and discourses around food and feed safety (e.g. Dreyer and Stang, 2013; Cuhls et al., 2015; Bourgeois and Sette 2017). To capture a wider range of issues scanning should generally not restrict how far forward the scans will canvas, rather it should include multiple time horizons to detect a broader range of issues that may have an impact at different points in the future (Bengston, 2013).

Two, often complementary, scan functions may be adopted to gather strategic intelligence. Each scanning approach described below has its role/function in the ERI process. A balance between the two is possibly a good approach for EFSA, but relies on how the results will be used and the outputs communicated:

**Exploratory scanning** – A broad exploratory scan of the food and feed policy landscape, and the types of incidents (risk factors) and motivations involved may be adopted to highlight alternative plausible developments, their potential sector-specific consequences and cross-cutting influences that may have an impact at the meta-policy level. Exploratory scanning identifies a wide range of signals from broad searches of the literature using key words or factors of interest. It involves compiling potential emerging issues from a wide variety of information sources. Often this requires open searches that tend not to include a specified frame for scanning and are appropriate for identifying new developments across the whole food system and anticipating change at a macrolevel. Open searches are guided by the novelty or intensification of an issue, scale and timing, and implications for the future.

**Issue-focused scanning** – A food/feed issue focused scan to fill an analytical gap may be adopted to extend current trend analysis (e.g. heat mapping risks) with broader indicators (drivers) of incidents

that are likely to unfold in the medium- and/or long term, thereby supporting development of future narratives for regulation and identifying short-term responses needed. Issue-focused scanning identifies signals of relevance to a particular food and feed issue using specified searches of the literature. Current media monitoring and searches of the scientific literature that EFSA does is particularly useful here. Such searches involve identifying core information sources on the issue that describes potential future developments of that issue. Often closed searches tend to be more focused with a specified frame for scanning; for example, if there is an increase in fraud associated with certain types of food, but there are significant information gaps or if there is a need to focus on particular trends at a particular point in planning cycles. A more targeted search would require identifying why a particular trend is important, how it is developing, evidence of what is causing it, and an assessment of uncertainty and potential impact.

The challenge for EFSA may lie in integrating exploratory scanning approaches into the ERI process. There will be a need to consider how easily output from a scan is transferred through to the data evaluation stages of the ERI process. Qualitative scanning procedures including the use of software to capture data from websites (e.g. zotero, pearltree, evernote) are simple, systematic and flexible enough to be integrated (i.e. followed-up) with more automated methods such as the text-mining or manual clustering of issues. Weight of evidence frameworks (similar to those reported by Linkov et al., 2015) can establish a more systematic process for filtering vast amounts of information (typically gathered during exploratory scanning) and evaluate the evidence used to identify weak signals. Quality controlling non-scientific sources of information (typically used in exploratory scans) may be challenging, but can be overcome if quality control frameworks allow for (Millington and Schultz, 2009):

- 1) Formal consideration of the wide range of information sources in horizon scanning, beyond traditional sources of evidence (e.g. academic journals).
- 2) An evaluation of statistical or methodological rigour that applies across all sources of horizon scanning information.
- 3) Assessment scoring, which evaluates the strength of evidence for a claim, but does not implicitly discount valuable information or weak signals.

A scan of data sources can use standard frameworks to achieve a broad grouping of potential emerging issues. One example of a framework used in the food system context is STEEPLE (Societal, Technological, Environmental, Economic, Political, Legal and Ethical), which provides some metrics to navigate a vast quantity of information, thus systematising scan activities. Early grouping of issues supports the selection of high priority (or important/relevant) issues as it allows for filtering a potentially extensive list of issues.

Considering the scale and timing of an issue as well as the uncertainty and variability of the evidence supporting the issue are important factors in reviewing the quality of the information and its source as an initial filtering mechanism. A reference system can be set up to keep track of sources used, including information such as type or origin of article, author and date of publication, which can be reviewed periodically to assess quality and usefulness of sources.

Introducing a temporal dimension for emerging issues is useful for illustrating when an impact will be seen and can assist in clarifying which MS and policy-making levels could have a potential interest in the issue. A time horizon however, should not be mistaken as an indicator of when regulators need to act since an issue that creates impact in 10 years may need action now to prevent it happening.

### 3.1.3. Alignment of horizon scanning and development of strategic plans

One of the most challenging areas of ERI is bringing the outputs of horizon scanning closer to decision-making processes. Often risk assessors and risk managers contest that issues reported from horizon scanning processes are not specific to the priorities of national authorities and not timed appropriately; i.e. targeting periods where data or knowledge gaps exist or where certain information is required (solicited) at a particular stage in the strategic planning cycle. EFSA could create greater visibility and utility of ERI by aligning horizon scanning activities to strategic planning.

One way to align horizon scanning to decision-making is to produce periodic outlooks (e.g. Smith-Bingham, 2018), which illustrate how the food safety landscape is changing and the level of preparedness required. The outlook represents a key programming document enabling risk assessors and risk managers to work together in the ever-changing food system, through (i) alignment with priorities reported to have a presumptive evidence of impact (Fischer, 2001, 2004; Derry and Fischer, 2005), (ii) being a means to inform target audiences by deciphering the often confusing evidence (Duncan and Wack, 1994; Van der Heijden et al., 2002) into a language to cross disciplinary

boundaries for 'strategic conversations' (Van Notten, 2006), and (iii) integrating possible events, innovations and disruptive changes into a consistent picture of future food systems (OECD, 2017).

### 3.1.4. Prioritisation and characterisation of issues and risks

A strategy to estimate the subjective probability of each of the criteria was proposed in 2012 ERI procedure (2012a). The criteria (Table 4) in use are included in the current briefing note template for emerging risks (EFSA, 2017b) but the estimation of probabilities was assessed as difficult and not implemented (EFSA, 2012b). A streamlined assessment of emerging issues through qualitative evaluation (i.e. a structured expert evaluation based on the agreed evaluation criteria) is applied when limited time and information is available.

In the current ERI process, the author of the briefing note will provide a qualitative evaluation of each criterion that justify the reasoning why it is considered a possible emerging issue. All issues are brought for discussion and the same criteria are discussed at the EREN and StaDG-ER meetings, conclusions and recommendations are recorded in the briefing note template. EFSA is responsible for deciding on follow-up actions after assessment of the presented evidence and taking into account conclusion and recommendations from the various stakeholders involved.

**Table 4:** Evaluation criteria

|                              |   |
|------------------------------|---|
| 1. Novelty                   | Has a new hazard been identified? If so, which one and how? Hazard known, but re-emerging, either in the same or in another matrix  |
| 2. New or increased exposure | Has a possible exposure through the food/feed chain to the new hazard been identified? If so, who could be exposed to the hazard?   |
| 3. New susceptibility        | Could the possible exposure to the new hazard lead to adverse health effects in (vulnerable) subgroups of the population?   |
| 4. Soundness                 | What is the reliability of the source of information? What is the amount of existing knowledge underpinning the proposed issue?   |
| 5. Imminence                 | How soon it is estimated that the potential emerging hazard will manifest in the food and feed, environment? How soon is it estimated that this emerging health risk will manifest in the population? What is the expected time scale for development of the risk?  |
| 6. Severity                  | What could be the severity of effects on human, plant and animal health in terms of, e.g. magnitude of symptoms, morbidity, mortality, number of individuals affected and potential economic impact.  |
| 7. Scale                     | What is the rate at which it is spreading (i.e. temporal and spatial dimensions)? What is the number of people (animals, plants) and Member States (maximum geographical area) potentially exposed to this hazard (i.e. spatial scale)? What is the maximum duration and or frequency of the potential effects (i.e. temporal scale)? |
| 8. Risk management issue     | Is it already subject to risk management measures and or controls?  |

A score system or multicriteria decision analysis technique (Vos et al., 2011; Cox et al., 2013; ECDC, 2017) could be applied for prioritisation to ensure there is reproducibility and sufficient guidance for panel working in related areas (i.e. follow-up risk assessments).

Prioritisation of emerging issues requires a simple and systematic process for meaningful evaluation of issues against agreed metrics so that outputs are deemed relevant to the priorities and policies of EFSA's audience. As such, prioritisation would require collaboration with wider audience than the EFSA ER Networks (e.g. whole staff, panels, scientific committees). This can take the format of a workshop and involve those collaborators/partners EFSA needs to validate and take ownership of the outputs.

There is a number of existing prioritisation methods used in horizon scanning that can be easily adapted. This would involve assigning a high-level 'score' of importance that reflects general implications for European regulators and risk managers; i.e. a nominal (value) score to assess the 'probability' (i.e. likelihood of occurrence) or 'desirability' and impact of an emerging issue, often through expert consultation (Table 5).

**Table 5:** Examples of issues prioritisation methods<sup>(a)</sup>

| Institution/horizon scanning initiative  | Assessment method   | Pros and Cons   |
|--|---|---|
| STT Horizon Scan 2050 (Netherlands)  | A ranking system (using an online questionnaire) where experts rank a long list of about 150 'signals of change' according to: possibility, impact and desirability of the signal actually occurring. Highly ranked issues debated in a series of workshops used to build possible future scenarios of 'Grand Challenges' | Pro: Normative approach that lends to exploring creative and anticipatory actions needed through scenario analysis<br>Con: 'Value'-based scoring open to bias and misrepresentation of issues |
| Cranfield Institute for Resilient Futures (CIRF) – Defra's futures partnership (United Kingdom)                | An importance rating on a 5-point scale for three criteria (environmental, social and economic) is derived for each issue and then plotted against the expected timing of a development (short-, medium- and long term) to indicate when an emerging threat is likely to have an impact                                   | Pro: Great potential to be integrated with broader risk assessment frameworks<br>Con: 'Value'-based scoring open to bias and misrepresentation of issues                                      |
| US Environmental Protection Agency, Office for Research and Development – Foresight (United States of America) | An importance rating on a 5-point scale for seven criteria (novelty, scope, severity, visibility, timing, probability, and organisational relevance) is derived for each issue to assess its overall relevance  | Pro: Wider range of criteria included for more comprehensive review of relevance<br>Con: 'Value'-based scoring open to bias and misrepresentation of issues                                   |

(a): Sources: Cuhls et al. (2015); Garnett et al. (2016); US EPA (2005).

EFSA currently evaluates possible emerging issues against a set of criteria (Table 4), but should introduce a procedure that will allow for characterising the development of emerging issues, and exploring connections among selected issues to identify common themes that represent significant challenges for the food system.

Emerging issues should be characterised to describe and explain the cause-effect relationships between 'behaviour or actions' of food system actors and their consequences (e.g. potential risks to food and feed safety).

Characterisation is usually carried out by reviewing the most relevant and recent scientific literature to examine what is driving the actions of causal actors, what are the effects/impacts of these actions, and what are the implications (risk or opportunity) for regulation (intervention).

There are existing characterisation frameworks that may be applicable, including those used to characterise environmental issues, the DPSRI framework or the Kates framework (Parris and Kates, 2003) used in a sustainable development context to identify developmental challenges, signalling indicators (and possible critical thresholds) of change.

Introducing a procedure for emerging risk characterisation will enable EFSA and its stakeholders to examine whether an issue is expected to persist or whether an increasing trend can be established that suggests a significant risk is emerging.

The characterisation of issues should emerge from workshop discussions around: (i) the risk an issue poses, (ii) the timeline of emergence of the risk; i.e. from now to the identified time horizon, (iii) uncertainty of impact/consequences and evidence gap(s) to be considered, and (iv) who the issue (and potential risk) most concerns and who should take it forward? Increasing the capability to characterise an issue offers a clear rationale for reducing the extent of issues published by EFSA, where only those issues that present an emerging food and feed safety risk would be highlighted, and protocols established for communicating the risk to EFSA's wider audience and the public.

Adopting a more systemic approach to ERI would require EFSA to synthesise issues into clusters that reflect those trends that will have an impact at a sectoral level, and also cross-cutting issues that will have an impact on multiple actors/sectors. Clustering issues would reveal 'common themes' that can subsequently be used as metrics to evaluate the vast quantity of information produced during horizon scanning, thus focusing scan activities. There is a risk, however, that narrowing down searches to a set of pre-defined themes would limit EFSA's ability to scan the external macro environment (big picture) to detect and understand the broad, long-term issues that could influence regulation.

## 3.2. Data management, data analytics and data governance

The journey from data to evidence follows an itinerary starting from selecting and collecting to appraising and validating, and finally analysing and integrating information for evidence use in scientific assessments (PROMETHEUS) (EFSA, 2015a). Big data and big data analytics options (i.e. applying an algorithmic or mechanical process) for deriving insights about emerging issues in the domain of ERI are at an early stage of development (Marvin et al., 2017). Making it work requires a strategic big data design and thoughtful big data architecture that examines current data streams and repositories. A more data driven ERI requires data processing pipelines to seamlessly use data sets through easily access, reusability and interaction for analysis. Thereby, the full potential perhaps of data driven methodologies is only obtained when multiple data sources can be combined, mixed and contrasted for analysis. This requires interoperability standards, domain ontologies and clearly defined business rules and governance structures.

### 3.2.1. Data processing pipelines to prepare big data analytics

While there is no rigorous definition of big data, it refers to large amounts of data produced very quickly by a high number of diverse sources (European Commission, 2014a,b). Improved analytics and processing of data, generally considers three steps: (i) collecting large amounts of data, from varied sources often largely agnostic on specific structures such as email messages, social media conversations, pictures or video recordings, sensor data, etc. (Dean and Ghemawat, 2004); (ii) sense making by a high speed of analyses by use of algorithms, machine learning, and statistic correlations; and (iii) characterisation and validation resulting in a more profound understanding, predictions or profiling of emerging risks and opportunities (Klous, 2016; Marvin et al., 2017).

Big data can be seen as a sociotechnological phenomenon within the emergence of pre-emptive surveillance, offering ERI the possibility of conducting predictive analyses of large quantities of data, structured or unstructured, in different formats, in a shorter period of time leading to original new insights and knowledge (van Brakel, 2016). What generates value for ERI is the ability to accumulate signals of indicators over time and space (e.g., Verisk Maplecroft's Global Risks Forecast Alerts<sup>6</sup> or the Australian International Biosecurity Intelligence System<sup>7</sup>). It opens a path for the ERI procedure to be applied to the analysis of indicators of drivers of change over time horizons based on previous and new trends (Lloyd's 2015). Big data science, i.e. umbrella of techniques used when trying to extract insights and information from complex and large data sets (Zhu and Xiong, 2015), has potential for deriving data insights from various sources brought together without changing their original structure in so-called 'data lakes' (O'Leary, 2014), but there are many challenges and issues to be addressed.

Data management involves the development and execution of architectures, policies, practices and procedures that properly manage the full data lifecycle (Early, 2011) from the initial generation of data sets or capture of a wide range of data sources to its archive and/or deletion at the end of its useful life in the ERI procedure. Applying big data approaches as part of the ERI procedure is expected to require cutting edge storage systems (repositories) that are non-relational, open source and horizontally scalable. These are collectively referred to as NoSQL (non-structured query language) as opposed to SQL-compliant database systems (Yi et al., 2010; Marvin et al., 2017). By adopting a 'share nothing' system architecture, complexity is reduced as much as possible to reliably make data available for analytics (Chen et al., 2014). Examples are MapReduce (Dean and Ghemawat, 2004) or popular Hadoop (Apache, 2005), containing an open source implementation of the MapReduce data processing framework (Aridhi et al., 2015; Shvachko et al., 2010).

Big data is critical to achieving the ERI's objectives and, this is likely to increase in importance in the near future. Machine learning algorithms and natural language processing can discover patterns and relationships in information from millions of texts, books, online articles (Brug et al., 2014) and other sources (e.g. social media), harvesting information that could take researchers (humans) decades to discover, retrieve and digest (EFSA, 2009b; Härle et al., 2015; Lloyd's, 2015). TM, also known as Text Data Mining or Knowledge-Discovery in Text (KDT), offers the automatic extraction of previously unknown information from different written (digital) sources. EFSA has successfully explored the potentials of TM tools for the systematic identification of emerging risks and how these tools (i.e.

<sup>6</sup> <https://maplecroft.com/portfolio/new-analysis/categories/global-risks-forecast/>

<sup>7</sup> Australian International Biosecurity Intelligence System (IBIS) project. Available online: <http://www.agriculture.gov.au/SiteCollectionDocuments/biosecurity/agwhitepaper/acwbpf-communique-july-2017.pdf>, <https://ibisbiosecurity.org/welcome/>

ERIS designed to support the identification of new and unexpected hazards specifically in the food and feed chain) can be integrated in the ERI procedure (Brug et al., 2014; Lucas Luijckx et al., 2016).

In 2016, JRC (Ispra) developed a novel TM tool for monitoring innovation and technological development called Tools for Innovation Monitoring (TIM). Despite the limitation of a delayed timing of publishing technological innovations either in journals, conferences, papers or patents, TIM allows to detect trends in text corpora and to analyse time horizons assisting to detect gaps in scientific knowledge, while keywords analysis may lead to follow emerging trends (Giraldi, 2017). Moreover, knowing the innovations underway in food systems, and focussing on the vulnerabilities in supply chains is a key factor in allowing new and emerging threats to be researched as part of the information and data collection-step in the ERI (EFSA, 2012a–c).

Ongoing activities of the outsourced procurement project AQUARIUS (i.e. food supply chain analysis for emerging risks identification) and the grant agreement DEMETER (i.e. development of methodologies and collaborative approaches in the ERI procedure) (EFSA, 2017b) is expected to provide an overview of data retrieval methods as well as a comparison of platform features supporting search protocols for various data source types and data mining activities. The challenge lies in devising a methodological framework, respectively to find sets of (multilingual) sources by information retrieval (Manning et al., 2008), to extract data (facts) from heterogeneous text corpora, as the largest readily available source of knowledge and, to capture facts into an understandable data schemes or patterns (Chia-Hui et al., 2006). Search protocols can be divided into data-driven (i.e. usage of machine learning, data mining and statistics), knowledge based (i.e. exploiting existing expert knowledge) or hybrid techniques inheriting the advantages of data-driven and knowledge-driven (Hogenboom et al., 2016). To capture a wider range of emerging issues information retrieval methods should include domain dependencies (e.g. social sciences, citizen science), for instance, connecting sentiment of actors using KDT to facts as well as to fully take into account spatiotemporal aspects by exploiting the information in reasoning (Hansena et al., 2013). In general, the involvement of domain experts in the usage of TM techniques, both to define search strategies and to define data interpretation approaches for results, is crucial for the quality of ERI.

Data analytics based on integrating a growing number of internal and external data sources is of increasing relevance to the ERI procedure. Sound data governance and data preparation protocols built into ERI, can significantly improve the transformation from weak signal gathering to intelligence.

Data analysis extracts information from data and adds context; expert advice and engagement with others provides ERI with knowledge and insight from this intelligence. This capability requires processing pipelines to inspect, clean, transform and enrich the data for analysis through a self-service data integration, preparation, and management platform. Software platforms supported by a graphical user interface (GUI) should be able to process data from a wide range of sources, automate complex data synthesis and customise direct data outputs for delivery to other platforms in defined forms such as network output, file output or graphical output. AQUARIUS profiled various specialised platforms like KNIME,<sup>8</sup> WEKA,<sup>9</sup> RapidMiner<sup>10</sup> and Orange<sup>11</sup> as well as general platforms such as R<sup>12</sup> and Python.<sup>13</sup> The AQUARIUS consortium concludes that each option will not provide an 'off-the-shelf' solution.

### 3.2.1.1. FAIR data principles and metadata

A central idea for data governance is the need to reuse data in different spatiotemporal settings, as well as generating new channels of information through data sharing of data stored in widely disparate repositories. The FAIR (Findability, Accessibility, Interoperability and Reusability) data principles deserve consideration to ensure the ability of machines to automatically find and use data sets, in addition to supporting its manual reuse by users, like data scientists (Wilkinson et al., 2016).

Insights on an emerging issue cannot be unified and retrieved unless the data set is well governed. Data governance and taxonomy functionalities ensure that the 'right' data (Poppy, 2017) exists throughout the complete lifecycle in ERI, and can be retrieved by the ERI knowledge networks. Metadata (data about data) gives context to data sets and can be seen as the linkage between data

<sup>8</sup> <https://www.knime.org/>

<sup>9</sup> <http://www.cs.waikato.ac.nz/ml/weka/>

<sup>10</sup> <https://rapidminer.com/>

<sup>11</sup> <https://orange.biolab.si/>

<sup>12</sup> <https://www.r-project.org/>

<sup>13</sup> <https://www.python.org/>

strategy and data architecture. Metadata helps to provide guidance as to where to find data, its meaning, characteristics and inter-relationships between different data sets.<sup>14</sup>

### 3.2.1.2. Explore the potential of citizen science capacity for ERI

Crowdsourcing in the context of ERI calls for research and practical experience to explore associated organisational, human and sociotechnical challenges (Kosonen, 2015; Vera and Salge, 2017). The EU-funded project 'Decentralised Citizen Owned Data Ecosystem (DECODE)' researches tools that put individuals in control of whether they keep their personal data private or share it for the public good by uploading to a platform (Reynolds, 2017). A frequent communication about emerging risks and its alignment with priorities may encourage the affected actors to report presumptive evidence of impact. The project 'EUROCIGUA' (Eagle, 2016) developed communication tools principally aimed at fishermen and doctors, to make them aware of the potential health effects of exposure to ciguatoxins and, to encourage them to report suspected cases for further investigation. However, 'citizen science' may be open to bias and misrepresentation of issues (Sloman and Fernbach, 2017 because scientific facts may be seen as equally important as alternative facts and fake news (Subedar, 2017).

Considering a focus on engagement in social media by active listening (i.e. citizens science), acknowledges that the ERI system is aware of concerns and information needs (Starr, 1969; McCormack, 2016). Inspired by Unilever's SEAC activities on public-private data sharing, its Open Innovation web tool (i.e. addresses the voluntary sharing of information between parties based on trust and a desire to identify emerging risks) could offer new ways to work with the public domain in ERI to collect useful data.<sup>15</sup>

### 3.2.1.3. Information on actors behaviour

An important and developing big data source will be inputs from 'causal actors' in food systems that is, those who may have triggered the issue or hold relevant information about an emerging issue. The behaviours of these individuals, groups or authorities can have positive or negative impacts on the time horizon, severity and scale of emerging issues. These actors can not only have significant impact on the quality of information supplied but also the effectiveness of any planned corrective actions. In general, social scientists have little experience with massive data sets; however they have extensive experience with causal inference (Grimmer, 2015). Studying an awareness raising strategy, big data from social media has great potential to collect useful information on emerging issues (Kasperson, 2014).

Additionally to the use of social media as data source, other examples of data from social sciences that could provide further insight into the identification of emerging risks are:

- The data base of DANS (Data Archiving and Networked Services) contains thousands of data sets within social sciences data. Among them are many that specifically deal with food consumption. Also, there are data sets dealing with education and crime (indicator for fraud?).
- There is a wealth of scanner data across Europe with detailed information about food consumer purchases. Such data could be used to identify trends in food consumption, local products versus products imported, organic versus conventional products, purchases of products for consumers with allergies, etc..
- Census data from agriculture, providing insights into shifts in crops being produced and animals being kept (helpful for identifying long-term changes in risks). Each country in Europe has its own agricultural census. In the Netherlands this is produced by the Central Bureau of Statistics (CBS). European wide, there is of course Eurostat.
- Similarly, the Farm Accountancy Data Network (FADN) of the EU holds a wealth of socio-economic information on the farm (input use and outputs being produced) and the farm family. Again, this data set could provide interesting insights into changing production patterns.
- The plant and animal health services have information on interceptions of imported consignments of animal and plant products. This information could be put into real time data that can provide instant insight into the likelihood of pests being introduced. Bayesian modelling can be used to identify a potentially new risk, i.e. think of a clear deviation from a seasonal pattern, or a multiyear trend. This technique is used already in for example dairy farming where real time data of milk yields are used as an indicator of cow diseases.

<sup>14</sup> <https://searchcompliance.techtarget.com/VeritasInfoGovernance/Using-Metadata-Wisely-to-Mitigate-Risk-and -Uncover-Opportunities>

<sup>15</sup> <https://www.unilever.com/about/innovation/open/innovation/>

#### 3.2.1.4. Big data validation

In developing a big data-driven framework for ERI, there is the risk of the input becoming exponentially incomputable (De Laat, 2014). To mitigate the problem, it is necessary to implement a data validation system to justify a selection of data sources. The data life cycle starts with identifying which data could (potentially) contribute to ERI procedure. Following questions might help in understanding which data this might be, such as: Which data is 'nice to have' and which is absolutely required? How reliable is the data and how long to keep data? Or which auxiliary data are needed to acquire?

An important element of implementing a data validation system is the ability to produce a comprehensive view on what emergences or changes in the 'ecosystem' of food systems. The ERI procedure has an important role in screening disparate information. This kind of information needs to be filtered and validated in order to provide an added value. Adding more data, either by increasing the sample size to reduce statistical errors or by combining independent sources to reduce systemic errors and advanced statistics and modelling techniques to properly estimate the impact, may sound like a straight-forward solution (Klous, 2016); however, an insight into the reliability of data sets remains an important issue for ERI. The idea that more information always leads to better identification should be challenged, particularly in the context of fragmented sources that require a judgement whether the resulting issue has validity for food safety (Glanville et al., 2014). The quality parameters proposed by Rodgers et al. (2011) may assist to streamline the 'wealth' of data.

A parallel challenge concerns the quality and usefulness of big data gathered from unstructured digital channels such as social media, smart phone applications, public health or economic indicators. To enhance their predictive or investigative power in an ERI context, much effort is needed for information retrieval by establishing specific keywords and/or writing complex search queries to find useful data assets from articles, news messages, web pages or videos. For example, the structural complexity of complex databases or the semantic relationships between data stored in databases can be grasped by an interactive query generation through ontologies to retrieve and extract relevant information about different (weak) signals (Munir and Anjum, 2017). It is emphasised that any analytics solution implemented must be able to identify and deliver trustworthy information through the existing data governance and taxonomy funnel (Ghosh, 2017).

Retrieved big data should be represented in such a way to understand what the data means (Chen et al., 2014). Because results are highly dependent on the search string design, therefore, they should be interpreted by illustrative visualisation approaches, as non-conclusive analysis that represent a starting point for further investigations (Boelman et al., 2016). Visualisation tools, like e.g., the GUI of a software platform, analyses information efficiently via statistical graphs, plots and information graphs, or network plot functions showing, for instance, the spatial spreading of emerging hazards using R (Schumacker and Tomek, 2013) or a (mathematical) model to predict mycotoxins in grains (EFSA, 2009a; Marvin et al., 2013). The text mining tool TIM can visualise large data sets (Giraldi, 2017). While a class of probabilistic modelling originating from Bayesian statistics and decision theory combined with graph theory, so-called Bayesian Belief Network (Marvin et al., 2016), has the ability to visually model changes in variables related to each other, either through strict or undetermined dependence relationships such as drivers of change (EFSA, 2014a,b).

#### 3.2.2. Data sharing agreements to explore mutual benefits

In the constantly evolving field of data generation, developing partnerships offers the possibility to access and integrate all types of data (Healing, 2017). This is especially pertinent to iteratively reveal unknown patterns, relationships and insights on resilience in food systems and emerging issues (Poppy, 2017).

Sharing of knowledge and methodologies should avoid unnecessary duplication of efforts, and allow for learning with and from each other's experience (Council of Europe, 2013). The existing RASFF-channel would not be the appropriate online platform to share emerging issues, but a similar platform should be created, where signals of potential future risks can be shared and complemented by national strategies to collect feedback on categorised issues including data and data sources.

It is of primary importance to build a broader sharing of all information regarding emerging issues identified with MS and the whole Risk Assessment community. First, it is clear that there is a need to support the whole ERI procedure by building on the existing initiatives to reinforce and maintain an emerging risks community (EFSA, 2017c). It is proposed to move toward a European community on emerging risks where information of the EREN network is circulated also to EFSA staff, Focal Points, Advisory Forum members, national agencies, academia and scientific societies and vice versa. The project DEMETER is a first step in developing a collaborative Emerging Risk Knowledge Exchange

Platform (ERKEP). An illustrative example to do this might be the Environment Knowledge Community (EKC) – created in 2015 to optimise the generation and sharing of environmental knowledge – agreed to work jointly towards anticipating emerging issues (<http://digitalearthlab.jrc.ec.europa.eu/networks/environmental-knowledge-community-ekc-citizen-science-kip>).

The increasing interconnectivity of data delivered through, for example, social media, text mining, crowdsourcing and cloud computing (CRO Forum, 2016; OECD, 2017, Rübmann et al., 2015) constitutes a challenge (Shackelford, 2015). In applying big data analytics, identifying privacy risks is needed (Bennett and Bayley, 2016) as well as protocols to access data. Boulet and Hernanz (2013) reported possible scenarios for law enforcement bodies in the EU when accessing company data; those scenarios may contribute to developing mutual benefits for public-private collaboration in ERI.

### 3.2.2.1. Revisiting emerging issues

It is fundamental to have the same understanding within the emerging risks community of what is a concern, what is an emerging issue, what is an emerging risk and when an issue becomes a risk. As yet web coverage of EFSA's database (repository) for emerging issues is underutilised and maintains an inadequate understanding of the nature and needs of the ERI procedure. A way forward is to improve tracking by better and frequent links with risk management at DG SANTE and MS level (e.g. EFSA's Advisory Forum) (EFSA, 2011a,b; McCormack, 2016).

The current Annual Emerging Risks activity report (e.g. EFSA, 2017b) is not found effective enough in delivering in due time data and information on emerging issues identified. Possible actions to strengthen the tracking for revisiting issues may include: (i) circulation of EREN's insights on emerging issues also with, e.g. focal points to increase awareness; (ii) creation of an emerging risks newsletter, RSS feed or push e-mail to target audience; (iii) annual data workshop on emerging issues/risks and related methodologies; (iv) improve content of intelligence on emerging risks (e.g. Data Catalog Vocabulary (DCAT) designed to facilitate interoperability between data catalogues published on the Web (i.e. EFSA and Member States) and a data dictionary).

## 3.3. EFSA role on ERI

The regulatory framework (Reg. 178/2002/EC) for identification of emerging risks establishes the principles for EFSA ERI procedure, collection of information and knowledge and communication of serious risks (European Commission, 2002).

### *Art 34 - Identification of emerging risks*

- 1) *The Authority shall establish monitoring procedures for systematically searching for, collecting, collating and analysing information and data with a view to the **identification of emerging risks** in the fields within its mission.*
- 2) *Where the Authority has information leading it to suspect an **emerging serious risk**, it shall **request additional information** from the Member States, other Community agencies and the Commission. The Member States, the Community agencies concerned and the Commission shall reply as a matter of urgency and forward any relevant information in their possession.*
- 3) *The Authority shall use all the information it receives in the performance of its mission to identify an emerging risk.*
- 4) *The Authority shall **forward the evaluation and information** collected on emerging risks to the European Parliament, the Commission and the Member States.*

Based on these principles, EFSA developed its own ERI procedure (Appendix 1- EFSA, 2012a) which includes information collection and analysis and communication to risk managers.

### 3.3.1. Emerging risks identification in food and feed procedure

The difficulty of governing emerging risks compared with familiar risks (known risks evolving in familiar conditions) is that emerging risks are characterised by uncertainty regarding their potential consequences and or probabilities of occurrence and attempts to assess emerging risks within a strict risk assessment framework may be difficult or even impossible.

The governance of emerging risks needs to be performed at strategic levels of decision-making in order to cope with both underlying complexity and uncertainty (Dreyer and Renn, 2009). The IRGC (2005, 2017) developed an analytical model that serves as a guideline for emerging risks assessment and control, a circular model in five steps where measures are examined based on reviewing the risk development, as understanding of new risks unfolds, the circle is reiterated.

Risk assessors and managers tend to focus on the detection of the next big food safety incidents. Foresight work would offer the opportunity to direct ERI into more strategic systems-based approach as well as bridging the gap between ERI and policy development.

Developing studies 'outlooks' focusing on specific drivers with a food system approach (Section 3.1.3) into the areas of EFSA's remit would enable risk assessors and risk managers to work together in the ever-changing food system.

Making sense of the mid- to long-term future in this way challenges mental models and prevailing mind-sets (Wack, 1985; Schoemaker, 1995), and may involve learning from the past (i.e. root cause analysis) and investigating fundamental uncertainties (EFSA, 2014a,b). Innovative about IRGC guidelines for emerging risk governance, is that issues/risks are no longer addressed solely from a technological point of view: there is also attention for the way in which actors and stakeholders think about risks and the reasons they put forward for accepting or not accepting emerging risks.

It is important to recognise that, due to the levels of uncertainty associated with emerging issues an iterative approach is needed.

The first time the emerging issue is characterised by applying EFSA existing criteria (EFSA, 2012a,b) a profile is developed of the emerging issue: when and where it might arise in the food system, who might be affected, what knowledge and data are required in order to measure the severity and the probability that it will occur, and possible impact. By iterating steps 1–3, further information may be considered. In this way well-founded decisions can be taken about how and when action needs to be taken.

A representation of the ERI procedure is proposed by the SWG ER (Figure 3) that addresses the need for review/iteration and characterisation. The three main phases of the emerging risks identification process are shown:

- Identification of priority emerging issues;
- Information sources and data collection;
- Evaluation to identify emerging risks.

The colours used for these main phases (blue, green, orange) correspond to the more specific processes shown in the detailed description. The symbols are based on the standard ISO 9001 flowcharts. The various organisations providing input for the procedure are shown on the right (purple).

At the start of the procedure, a signal of an emerging issue is received from EFSA or an organisation that EFSA is in contact with; via the StaDG-ER or EREN. Such information may be gathered via dedicated horizon scanning processes, or other channels. These signals are assessed to determine whether they match the EFSA definition for 'emerging issue'. If this is not the case, it is not considered as an emerging issue and no further action is taken at this point.

If it matches the definition further information and data will be collected. Briefing notes are drafted by the signal/issue identifier and consultation with EFSA panels and units and other institutions is made. Revised versions of the briefing notes are distributed to EREN members/observers.

EFSA staff is responsible for coordinating the consultation process but the content of each BN is the responsibility of the author. The briefing notes are discussed at the biannual EREN meetings, and a consensus is reached about if the identified issue is indeed an emerging issue. Information on qualifying criteria (soundness, severity, imminence and scale) is recorded.

The SWG-ER proposes to characterise issues (for example, use existing frameworks, such as DPSRI, i.e. Drivers, Pressures, States, Response and Impact analysis). Characterisation can lead to recommendations such as:

- No action if the issue is deemed as not compliant with the definition of emerging issue and relevant criteria.
- Recommendation to perform additional research when data gaps are identified.
- Recommendation for future detailed risk assessment procedure.
- Recommendation to continue monitoring and collect information.
- Recommendation for specific risk management options.

The briefing notes are updated with the results of the discussion and shared with EREN members and observers, relevant EFSA panels and units. Meeting notes with a summary of the conclusions are also shared with the EFSA Advisory Forum Focal points. Briefing notes of selected issues identified by EREN are shared with the StaDG-ER and the discussion conclusions and recommendations recorded in updated briefing notes. EFSA revise all conclusions and recommendations and produce a list of issues/risks that is included in the Emerging risks Annual activity report.

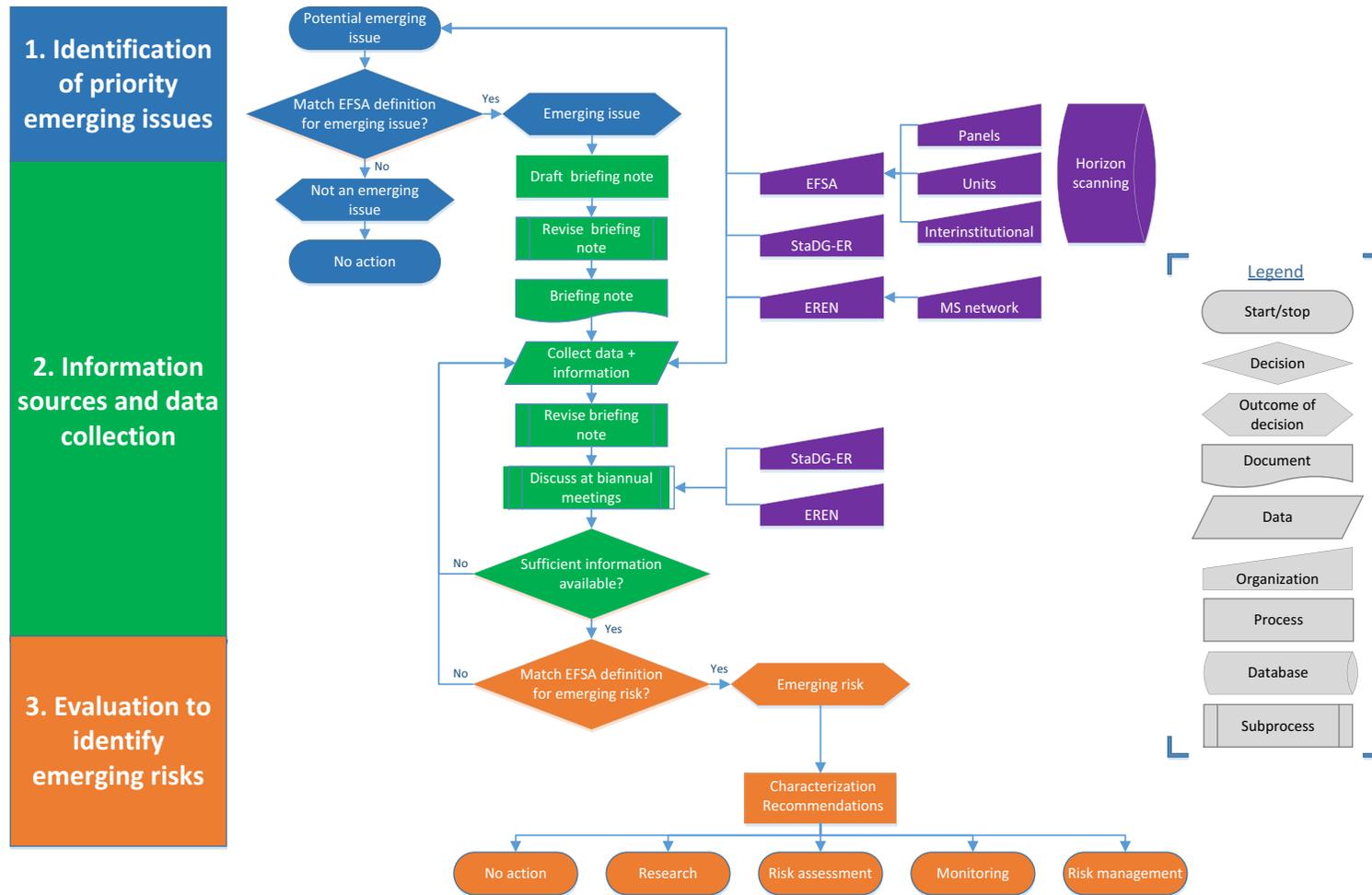


Figure 3: Proposed diagram of the ERI procedure

### 3.3.2. Communication of emerging risks

Emerging risks are characterised by high levels of uncertainty and often ambiguity, uncertain risks may be associated with potentially large benefits, these characteristics potentially make it more difficult to communicate about emerging risks than about familiar risks.

Risk communicators may be concerned about the potential unintended effects of communicating about risks that are poorly understood. These concerns may include, for example, the fear of causing unnecessary panic, and the fear of decreasing consumer trust in authorities which communicate risks (FAO/WHO, 2016).

At the same time, to proactively communicate emerging risks about a suspected (potential) risk may be preferable to staying silent until intervention (and communication) becomes urgent, since emerging risk communication can help prepare the ground for future communication and policy once the risk has become better understood. *'Early engagement is better, even if uncertainties exist rather than short notice requiring immediate action'* (EFSA, 2011a,b).

EFSA communication on emerging risks should also address the need for additional information on identified issues or even identification of weak signals on new issues and ensure that possible recommendations are addressed to the right target audience (e.g. Eagle, 2016; Sloman and Fernbach, 2017). A more proactive communication about emerging issues to scientists, stakeholders and the public at large can help to retrieve data and knowledge to better understand risks.

Communication about emerging risks can contribute to improving knowledge about the risk at stake, by encouraging consumers to report presumptive evidence of impact (ICF and GfK, 2017). Emerging risks in the food system are linked to various factors, including changes in the feeding and drinking habits of consumers, scientific discoveries and technological innovations being applied to food products, or fraudulent activities exposing consumers to new risks through the consumption of adulterated food or drink.

The regulatory purpose for communication on emerging risks is to inform the European Parliament, the Commission and the Member States about serious risks that may affect public health, as well as animal or plant health.

In the current system, information on emerging issues/risks is shared between EFSA networks (e.g. Scientific panels and scientific units, EREN members and observers, Advisory Forum, Focal points and the European Commission) in the form of briefing notes and meeting notes/minutes (EFSA, 2012a,b).

A report of the various activities related with ERI is published yearly in EFSA web site containing a summary of the issues/risks identified, characterisation and recommendations for follow up (e.g. EFSA, 2014c, 2016, 2017b). EFSA has also developed a repository of past issues accessible by registered users (Scientific panels and scientific units and EREN members and observers).

Raising awareness to possible risks can have an important role on prevention by changing behaviours of causal actors. By using an awareness raising approach, ERI may arrive at a better balanced judgment by developing a list of issues as initial output that reflects the factual evidence about the emerging issue at hand in relation to its persistence for being effective, managing uncertainty, enhancing trust in information sharing, and creating a knowledgeable and transparent assessment process (Renn, 2014; Kasperson, 2017).

The EU insight (survey) on emerging risk (ICF and GfK, 2017) contributes to building an understanding of the differences in awareness and risk perception throughout the EU Member States. The survey results suggests that respondents were more concerned about familiar risks rather than emerging risks, but they would like to be informed about emerging risks early on in the process of its identification, even if there is scientific uncertainty. Results of the survey constitute a first step for the development of a best practice to communicate about emerging risks in a two-way approach that will help ERI to implement information sharing on collecting more information of the emerging issue identified.

ERI could benefit from assessing the psychological processes of citizens, such as judgment and decision-making in the consumer domain (i.e. unconscious versus conscious), consumer information processing, motivation and self-regulation, and consumers' affective, cognitive, and behavioural responses towards fear stimuli and persuasive appeals (e.g. Starr, 1969; Hansena et al., 2013; European Commission, 2014b; McCormack, 2016). Thorough sociological insights are essential for shaping and integrating citizens' science as great potential for comprehensive information sharing. Target audiences and communication narratives adapted to ERI can also help prevent the amplification of perceived risks and unnecessary food scares or, on the contrary, in attenuation and food risks being ignored or not taken seriously enough, given high levels of scientific uncertainty. That is because the absence of official

communications on emerging risks may leave a vacuum that is filled by media speculation or rogue 'scientific' analysis.

Part of the ERI improvement should include an awareness raising approach with four steps that are of critical importance: (i) persuade audience (e.g. applying citizen science); (ii) engage stakeholders (e.g. targeted engagement platforms); (iii) create arousal (e.g. risk assessment bodies and risk management bodies) and (iv) develop networking and virtual platforms including Twitter, Facebook, blogs/vlogs, traditional media etc. (e.g. DEMETER). Dominant among these elements is 'creating arousal', which can be likened to 'throwing a stone in a still pond'; it should cause ripples by extending knowledge in ever-widening circles, including crowd sourcing for supporting evidence (Eller and Schneider, 2016).

## 4. Conclusions

Since 2006, EFSA has gained experience in developing and maintaining an ERI procedure. Annual reports on activities undertaken prove the potential usefulness of this proactive approach in emerging issues identification, but also limitations.

A systematic approach to the identification of emerging issues based on experts' networks is the major strength of the procedure but at present the procedure is mainly focused on single issues, over short to medium time horizons, no consistent weighting or ranking is applied and clear governance of emerging risks follow-up actions is missing.

To begin the identification and convergence (i.e. characterisation and prioritisation) process, an important step forward is to develop a systematic and harmonised foresight approach that can be coherently applied across food and feed safety, animal health and welfare and plant health. Efforts are required to explore the benefits of horizon scanning, addressing different time horizons and thus the various types of uncertainty, complexity and dynamism in changing food systems.

Regular intelligence updates on emerging issues, their relevance for risk assessment, and assessing options for preventive response will help to provide a proactive guidance and support to EFSA and Member States in identifying prospective issues. Further efforts are needed to develop a food system-based approach including the integration of social sciences to improve understanding of interactions and dynamics between actors and drivers.

Digitisation forces EFSA to look differently at the growing amounts of data. Big data has only value if it is used. The two main ingredients to do this in a responsible way are cooperation and trust. To support ERI in a data-driven way of working, the possibilities of an ecosystem could be explored. The ecosystem places the information demand centrally with the various data sources in perfect integration, in such a way that EFSA and its partners can work together, generating new insights on emerging issues (i.e. platform thinking).

Cloud computing can help to overcome silos and makes organisations more cohesive and automated by enabling data to be stored and accessed from a common data repository. Data management and data governance need to be expanded to include (semi-)structured and unstructured data sources. There is also a need for (legal) frameworks, sharing protocols and technologies to access data between EFSA and other European or international (public) organisations.

Thoughtful analysis and integration of target audiences and communication narratives adapted to ERI may help EFSA preventing the amplification of perceived risks and unnecessary food scares or, on the contrary, in attenuation and food risks being ignored or not taken seriously enough, given high levels of scientific uncertainty and/or ambiguity. The absence of official communications on emerging risks may leave a vacuum that is filled by media speculation or rogue 'scientific' analysis. Applying an awareness raising approach in communication offers a consultation process for more detailed characterisation of emerging issues. The SWG-ER advocates a closer interaction between the EFSA and risk managers for timeliness of messages and the need to anticipate actions or share information.

## 5. Recommendations

The SWG-ER proposes three main areas for developments and concrete actions for future consideration to further improve the efficacy of established EFSA procedures for ERI:

*A food system-based approach that applies resilience thinking in ERI to understand the complex interactions and dynamics that exist between actors and the drivers operating in the food system environment over different time horizons.*

EFSA should consider the following actions to improve their ability to capture a wider range of issues across short-, medium- and long-term time horizons:

- Develop a food system approach integrating social sciences methods to improve understanding of interactions and dynamics between actors and drivers.
- Improve horizon scanning capacity through collaboration with wider audiences than the current EFSA knowledge Networks and higher levels of international cooperation.
- Combine exploratory and issue-based scanning to identify drivers and trends by detecting different signals (including weak signals) and the emergence of issues over short, medium and long time horizons.
- Adopt standard protocols, such as weight of evidence, for scanning and filtering information sources, and utilise scanning frameworks (e.g. STEEPLE) to group relevant issues, actors and change drivers into defined subject categories (e.g. political, technological, etc.).
- Develop and disseminate 'outlooks' focusing on specific drivers and what is most relevant to EFSA by providing a list of emerging issues/risks into the areas of EFSA's remit.

EFSA could develop a procedure for the prioritisation and characterisation of emerging issues and risks, through the following actions:

- Identify clusters of issues (common themes) that illustrate how the food safety landscape is changing and the level of preparedness required. Clustered issues could reveal vulnerabilities in the food system that warrant attention, either through a more focused scan to fill evidence gaps or an exploratory scan to better understand and characterise potential emerging risks.
- Introduce a nominal scoring technique to systematise the evaluation of issues against the current criteria adopted by EFSA. Engaging stakeholders in a prioritisation exercise will also ensure issues taken forward are deemed relevant to the priorities and policies of EFSA's audience.
- Develop a transparent, open and trackable approach in prioritising the emerging risks in order to provide a stronger basis for communicating risks.

*Improve data processing pipelines to prepare big data analytics, implement a data validation system and develop data sharing agreements to explore mutual benefits;*

EFSA could provide data processing pipelines to prepare big data analytics, through the following actions:

- Improve FAIR data principles to ensure the ability of machines to automatically find and use data sets. In particular, a metadata-type reference system is needed to keep track of data and data sources used, which can be reviewed periodically.
- Apply data validation systems to assess the quality of data sources, and the origin of data.
- Implement KDT from multilingual (written) sources, as well as, online media.
- Analyse social science data to understand changes in consumer and producer behaviour or changes in sourcing, green policies, megatrends and persistent trends and their implications in the sectors of EFSA's remit.
- Explore the utility of a hosted or cloud platform provider and, pilot with advanced analytics and big data, to gain experience with consistent data definitions, metrics, and data interpretations.
- Employ illustrative data visualisation approaches in such a way to understand what the data or patterns means that services for further investigations.

EFSA could improve its data sharing agreements to explore mutual benefits, through the following actions:

- Create a data integration ecosystem using an appropriate platform that enables stakeholders to work together on ERI.
- Connect with ongoing EU Agency network for Scientific Advice (EU ANSA) WG on data quality and reliability.
- Aim for further developing a DCAT for internal and external exchange of information about data such as meaning, relationships to other data, origin, usage and format.
- Create possibilities for a broader sharing of data with the food industry using open food safety data and sharing public and private data.

*Improve the definition of EFSA's role in relation to the coordination of ERI procedure and communication.*

EFSA could further improve its role in the ERI procedure by the following actions:

- Apply a structured approach of risk governance for profiling the emerging issue: how a potential risk is composed, what scientific knowledge is still lacking, how the issue is viewed by society and what are measures to prevent or reduce undesirable and adverse effects.
- Employ the improved characterisation processes to highlight short-, medium- and long-term issues reflecting current knowledge and making recommendations for follow-up actions.
- Develop a repository for mediated access to the intelligence on emerging issues/risks that can be regularly updated and accessed for tracking emergence of issues and lessons learnt, e.g. policy changes related to foresight outputs.

EFSA could improve communication on emerging risks by the following actions.

- Ensure synergies with existing networks and collaborators are improved through the sharing of data sources and intelligence to ensure issues reflect the priorities/interest of EFSA target audience.
- Develop a communication strategy that more clearly articulates the distinction between incident response and emerging risks and that addresses the uncertainties associated with emerging issues including limited data and knowledge and the perception of such issues.
- Develop communication strategies adapted to the communication objectives (e.g. stimulate research, collect data and/or information, prevent risks and raise awareness) and the audience (risk assessors, scientists, risk managers and the public in general).
- Develop and disseminate communicative narratives at early stages of ERI by acknowledging explicitly the uncertainties concerning both the existence and significance of possible emerging risks (i.e. data sharing agreements beyond EREN).
- Establish more effective channels of communication not just across EFSA staff, scientists (experts) and risk managers, but reflecting different audiences (i.e. issues across the supply chain), and ensure consistency between the narratives (e.g. sector-specific implications) to encourage fast action on available scientific evidence, understandings including uncertainties and needs.

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## Glossary and Abbreviations

|                     |   |
|---------------------|---|
| Behavioural science | The systematic analysis and investigation of determinants and mental processes resulting in human behaviour. Behavioural science uses a range of methods, ranging from exploratory and qualitative approaches such as interviews, observations, surveying and experimentation.  |
| Big data            | Big data refers to large amounts of different types of data produced with high velocity from a high number of various types of sources <sup>16</sup>  |
| Characterisation    | A structured approach used to describe and explain the chain of causal links associated with an emerging issue. In a food system context, this is the cause-effect relationships between 'behaviour or actions' of food system actors and their consequences (i.e. potential risks or opportunities for food and feed safety, what is driving the actions of causal actors, what are the effects/impacts of these actions, and what are the implications (risk or opportunity) for policy/regulation (intervention)). |
| Citizen science     | The general public engagement in scientific research activities when citizens actively contribute to science either with their intellectual effort or surrounding knowledge or with their tools and resources. <sup>17</sup>  |
| Crowd sourcing      | Designing a certain problem or task to an undefined, large group of people in order to solicit their creative input for solving the problem or improving the situation. <sup>18</sup>   |

<sup>16</sup> EC, E. C. (2014). *Towards a thriving data-driven economy*. Brussels: Communication from the Commission to the European Parliament, the Council, the European Economic and social committee and the committee of the regions.

<sup>17</sup> EC's digital science unit, 'Green paper on Citizen Science for Europe: Towards a society of empowered citizens and enhanced research', available online at: <https://ec.europa.eu/digital-single-market/en/news/green-paper-citizen-science-europe-towards-society-empowered-citizens-and-enhanced-research>

<sup>18</sup> Miia Kosonen, 'User motivation and knowledge sharing in idea crowdsourcing', presentation held at EFSA at EFSA@EXPO on 16 October 2015. Available online at: [http://www.efsa.europa.eu/sites/default/files/160121\\_4\\_KOSONEN.pdf](http://www.efsa.europa.eu/sites/default/files/160121_4_KOSONEN.pdf)

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|----------------------|---|
| Data Analytics       | Involves applying an algorithmic or mechanical process of examining raw data with the purpose of deriving insights about that information; runs through a number of data sets to look for meaningful correlations between each other; discovery of meaningful patterns in data, usually revealed by an analytics software solution.   |
| Database             | Collection of data that is purposefully arranged for fast and convenient search and retrieval by business applications and Business Intelligence software.  |
| Data governance      | Management of the availability, usability, integrity and security of the data stored within an enterprise.  |
| Data lake            | Storage repository that holds a large amount of raw data in its native format until it is needed.   |
| Data management      | Development and execution of architectures, policies and practices to manage the data life-cycle needs of an enterprise.  |
| Data mining          | Data mining is the study of collecting, cleaning, processing, analysing, and gaining useful insights from data. <sup>19</sup>   |
| Data quality         | Refers to the contextually quality of an organisation's collection of data. The more relevant, available, complete and accurate the information, the better chance profitable ERI insights will be created.   |
| Data source          | Information of a range of types of data sources (published peer reviewed and other literature, databases, websites, newsfeeds, opinions, blogs, etc.) that provide information and intelligence that can support the identification of an emerging risk. <sup>20</sup>  |
| Data Science         | Is the combination of statistics, mathematics, programming, problem-solving, capturing data in ingenious ways, the ability to look at things differently, and the activity of cleansing, preparing and aligning the unstructured and structured data. A field of study involving the processes and systems used to extract insights from data in all of its forms.  |
| Data Visualisation   | Transforming numerical data into a visual or pictorial context in order to assist users in better understanding what the data is telling them.  |
| Driver/driving force | Generally, the energy providing impetus to a development. In futures research, drivers are frequently referred to as internal/external factors influencing developments, decisions, policies etc., helping to define possible future scenarios. Often used in parallel to, or overlapping with, the term "trend", but a driver can be observed as having a direct or indirect impact on the system while a trend reflects change within the system. Hence, a driver is more specifically used for describing the phenomena underlying trends and other developments that eventually lead to the emergence of risks.   |
| Emerging issues      | An issue that could be a food or feed safety risk that has very recently been identified and a merit further investigation, and for 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. <sup>21</sup> |
| Emerging risks       | A risk resulting from a newly identified hazard to which a significant exposure may occur, or from an unexpected new or increased significant exposure and/or susceptibility to a known hazard. <sup>22</sup>   |

<sup>19</sup> Aggarwal, C. C. (2015). An Introduction to Data Mining. In *Data Mining: The Textbook* (pp. 1–26). Cham: Springer International Publishing.

<sup>20</sup> EFSA (2011). Data collection for the identification of emerging risks related to food and feed. *EFSA journal* 9(8): EN-185.

<sup>21</sup> Costa, M. C., et al., Risk identification in food safety: Strategy and outcomes of the EFSA emerging risks exchange network (EREN), 2010e2014, *Food Control* (2016), <https://doi.org/10.1016/j.foodcont.2016.04.045>

<sup>22</sup> EFSA, 'Definition and description of "emerging risks" within the EFSA's mandate, (adopted by the Scientific Committee on 10 July 2007)'. Available online at [http://www.efsa.europa.eu/sites/default/files/scientific\\_output/files/main\\_documents/escoe\\_mriskdefinition.pdf](http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/escoe_mriskdefinition.pdf)

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|---------------------------|---|
| Foresight                 | Foresight, in the context of emerging risks identification, is generally defined as a process of systematic intelligence gathering about the future and the creation of scenarios about 'systemic developments' over the medium-to-long-term, aimed mainly at supporting decision-making.   |
| Horizon scanning          | Horizon scanning, often referred to as environmental scanning, external scanning or strategic scanning, is a systematic process for capturing and monitoring change. Horizon scanning involves the gathering of data and information across a wide range of sources and domains (e.g. Social, Technological, Economic, Environmental, and Political, Legal, Ethical, i.e. STEEPLE). The process identifies emerging issues that are on the periphery of current thinking and planning, and provides early signs of how trends and developments may lead to changes in behaviour and create new challenges (or opportunities) for relevant actors. <sup>23</sup> |
| Indicator                 | Measurement or observation (by some references referred to as 'signals'): providing information on nature of the hazard and source of the risk; reliable, sensitive and quantifiable; pointing to the risk directly or indirectly related to the food chain. Can be either qualitative or quantitative in nature (NB the latter could allow for imposing threshold levels for alerts triggering further action). <sup>24</sup>  |
| Intelligence              | Ability to learn or understand or to deal with new or trying situations; broadly defined as the capacity to acquire and apply knowledge. Epidemic intelligence refers to all activities related to early identification of potential health hazards that may represent a risk to health, and their verification, assessment and investigation so that appropriate health control measures can be recommended. <sup>25</sup>   |
| Machine learning          | A type of artificial intelligence that provides computers with the ability to learn without being specifically programmed to do so, focusing on the development of computer applications that can teach themselves to change when exposed to new data.  |
| Metadata                  | Describes other data within a database and is responsible for organisation while an end-user sifts through collected data.  |
| Scenarios                 | Scenarios refer to a wide range of approaches involving the construction and use of scenarios – more or less systematic and internally consistent visions of plausible future states of affairs. They may be produced by means of deskwork, workshops, or the use of tools such as computer modelling. <sup>23</sup>  |
| Social media              | Websites and applications that enable users to create and share content or to participate in social networking. <sup>26</sup>   |
| Structured Query Language | Accepted standard for relational database systems, covering query, data definition, data manipulation, security and additional aspects of data integrity.   |
| Text mining               | Text mining as the process of identifying novel, interesting, and understandable patterns from a collection of texts. <sup>27</sup>   |
| Threat                    | Sometimes used as a synonym of hazard.  |
| Weak signals              | These signals are defined as unclear observable trends or patterns that warn us about the possibility of future events. They illustrate potential future developments (i.e. emerging issues) for which limited and scattered evidence is currently available. Often there is ambiguous interpretations of the origin, meaning and/or implications of weak signals. <sup>4</sup>   |

<sup>23</sup> The handbook of Technology Foresight: Concepts and Practice (2008). Georghiou, L., Cassingena Harper, J., Keenan, M., Miles, I., Popper, R. (eds.) Edward Elgar Publ. Limited, Cheltenham, UK, 1–427 pp.

<sup>24</sup> EFSA Scientific Committee (2007) Definition and description of "emerging risks" within the EFSA'S mandate (EFSA/SC/415 Final). Parma: European Food Safety Authority. Available online at: [http://www.efsa.europa.eu/sites/default/files/scientific\\_output/files/main\\_documents/escoemriskdefinition.pdf](http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/escoemriskdefinition.pdf)

<sup>25</sup> ECDC (2005) Surveillance of communicable diseases in the European Union. A long-term strategy 2008–2013, available online at: [https://ecdc.europa.eu/sites/portal/files/media/en/aboutus/Key%20Documents/08-13\\_KD\\_Surveillance\\_of\\_CD.pdf](https://ecdc.europa.eu/sites/portal/files/media/en/aboutus/Key%20Documents/08-13_KD_Surveillance_of_CD.pdf)

<sup>26</sup> <https://en.oxforddictionaries.com/>

<sup>27</sup> Blake, C. (2011). Text mining. Annual Review of Information Science and Technology, 45(1), 121–155

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|--------------|--|
| Web-crawling | Web crawling is the systematic, automated navigation of a series of Internet-based references. <sup>28</sup> |
| AI           | Artificial Intelligence  |
| ANSA         | Agencies for Scientific Advice   |
| AQUARIUS     | AQUA culture Risk Identification Underpinning Safety   |
| CBS          | Central Bureau of Statistics   |
| CLEFSA       | Climate Change and Emerging Risks on Food Safety   |
| CRO          | Chief Risk Officers  |
| DACO         | Data Collection for the identification of Emerging Risks related to food and feed                            |
| DANS         | Data Archiving and Networked Services  |
| DCAT         | Data Catalogue Vocabulary  |
| DECODE       | Decentralised Citizen Owned Data Ecosystem   |
| DEMETER      | DEtermination and METrics of Emerging Risks  |
| DG ENV       | Directorate-General Environment  |
| DG SANTE     | Directorate-General for Health and Food Safety   |
| DPSRI        | Drivers, Pressures, States, Response and Impact  |
| ECDC         | European Centre for Disease Prevention and Control   |
| ECHA         | European Chemicals Agency  |
| EEA          | European Environment Agency  |
| EKE          | Expert Knowledge Elicitation   |
| EREN         | Emerging Risk Exchange network   |
| ERI          | Emerging risk identification   |
| ERIS         | Identification Support System  |
| ERKEP        | Emerging Risk Knowledge Exchange Platform  |
| ESCO         | EFSA Scientific Cooperation  |
| FADN         | Farm Accountancy Data Network  |
| FAIR         | Findability, Accessibility, Interoperability and Reusability   |
| FAO          | Food and Agriculture Organization  |
| FDA          | Food and Drug Administration   |
| FSA          | Food Standards Agency  |
| GUI          | Graphical User Interface   |
| INFOSAN      | International Food Safety Authorities Network  |
| IRGC         | International Risk Governance Council  |
| IT           | Information Technology   |
| JRC          | Joint Research Centre  |
| KDT          | Knowledge-Discovery in Text  |
| MCDA         | Multi-criteria Decision Analysis   |
| MeDYSIS      | Medical Information System   |
| MS           | Member State   |
| NoSQL        | non-structured query language  |
| OECD         | Organisation for Economic Co-operation and Development   |
| OIE          | World Organisation for Animal Health   |
| RASFF        | Rapid Alert System for Food and Feed   |
| REACH        | Registration, Evaluation, Authorisation and Restriction of Chemicals   |
| SC           | Scientific committee   |
| SCER         | Scientific Committee and Emerging Risk Unit  |
| StaDG-ER     | Stakeholder Discussion group   |
| SQL          | Structured Query Language  |
| STEEPLE      | Societal, Technological, Environmental, Economic, Political, Legal and Ethical                               |
| SWG-ER       | Standing working group on Emerging Risks   |
| SWOT         | Strengths, Weaknesses, Opportunities en Threats  |

<sup>28</sup> Massimino, B. (2016). Accessing Online Data: Web-Crawling and Information-Scraping Techniques to Automate the Assembly of Research Data. *Journal of Business Logistics*, 37(1), 34–42.

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|-----|---------------------------------|
| TM  | text mining                     |
| TIM | Tools for Innovation Monitoring |
| ToR | Terms of Reference              |
| URL | Uniform Resource Locator        |
| WEF | World Economic Forum            |
| WG  | Working group                   |
| WHO | World Health Organization       |