

## TECHNICAL REPORT

# Drivers of emerging risks and their interactions in the domain of biological risks to animal, plant and public health: a pilot study<sup>1</sup>

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### ABSTRACT

This technical report describes the outcomes of a pilot study for the identification of drivers of emerging risks and their interactions in the domain of biological risks to animal, plant and public health. Steps were taken towards a structured approach for identification of drivers of emerging biological risks and their interactions. The pilot study was based on three steps. Step 1 involved a consultation of the Animal health and welfare (AHAW) and Biological hazards (BIOHAZ) Panels through an adapted Delphi approach with the overall objective of identifying drivers and emerging issues. Step 2 involved a workshop using General Morphological Analysis (GMA) to structure the complex domain of drivers of emerging risk and their interaction. Step 3 involved discussion of the results of step 1 and 2 with the EFSA AHAW, BIOHAZ and Plant health (PLH) Panels and the EFSA Scientific Committee by discussion of the outcomes in their plenary meetings and by written consultation. The outcomes of this pilot study provide conclusions on the applicability of the approach proposed as a tool to achieve a proactive assessment of emerging risks in the domain of biological risks to animal, plant and public health. The technical report also provides recommendations on steps to be taken to further develop the approach outlined in this report and to continue to explore further tools to identify emerging biological risk.

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### KEY WORDS

Emerging risks, Delphi process, expert elicitation, general morphological analysis, forecasting, scenario building.

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## SUMMARY

In order to improve the ability of competent Authorities to control risks associated with new or developing hazardous agents, the European Food Safety Authority (EFSA) is required by Regulation (EC) 178/2002 (art. 34), to establish “monitoring procedures for systematically searching for, collecting, collating and analyzing information and data with a view to the identification of emerging risks in the fields within its mission” (i.e. human, animal and plant health as related to the food and feed chain). Following the activity undertaken by EFSA since its inception in 2003 to develop a methodological approach to identify emerging risks, a Standing WG on Emerging Risks was established in 2013 to support EFSA in the identification of Emerging Risks.

The identification and prioritization of emerging risks is a complex process involving the gathering and evaluation of large amounts of information from different sources. The EFSA definition of emerging risks can be made more applicable to emerging biological risks by considering any risk as new if it has not yet been observed in the EU territory and may require attention by EU risk managers, and by further differentiating the category of new exposures to include species jumps/host shift and geographic jumps.

This report describes the outcomes of a pilot study for the identification of drivers of emerging risks and their interactions in the domain of biological risks to animal, plant and public health. Steps were taken towards a structured approach for identification of drivers of emerging biological risks and their interactions. The results described in this report are to be considered as preliminary, more steps are needed before consolidated results are available.

Step 1 involved a consultation of the Animal health and welfare (AHAW) and Biological hazards (BIOHAZ) Panels through an adapted Delphi approach. The overall objective of the Delphi process was to identify drivers and emerging issues. It was found that the identified drivers are highly connected, but may show effects on different timescales. Several identified drivers are in areas outside EFSA’s existing expertise.

Step 2 involved a workshop using General Morphological Analysis (GMA) to structure the complex domain of drivers of emerging risk and their interaction. A prototype GMA model was developed, which needs to be further developed in order to be a practical working tool to identify and prioritize drivers of emerging risks. The GMA was found to be a promising tool for evaluating the complex interaction between drivers. The prototype GMA model needs further refinement in order to consider whether one generic model could be applicable or whether several specific models should be used.

Step 3 involved discussion of the results of steps 1 and 2 with the EFSA AHAW, BIOHAZ and Plant health (PLH) Panels and the EFSA Scientific Committee by discussion of a draft of this report in their plenary meetings and by written consultation. It was recommended that EFSA should further develop the GMA approach outlined in this report as a tool to achieve a proactive assessment of emerging biological risks and to consider broadening the approach to all of EFSA’s remit. Next steps should include expertise on food systems, trade, economics, social sciences, etc., in the identification of drivers and their inclusion in the GMA approach. Furthermore, EFSA should continue to explore other tools to identify emerging biological risk (horizon scanning, scenario building techniques, etc.).

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## **BACKGROUND AS PROVIDED BY EFSA**

According to the European Food Safety Authority (EFSA)'s Founding Regulation, the Authority is required to “undertake action to identify and characterise emerging risks” in the field of food and feed safety. The Scientific Committee and Emerging Risks Unit (SCER) contributes to this mission by supporting the establishment of structures for the screening and analysis of information sources with a view to identifying emerging risks in the fields of food and feed safety, and animal and plant health. To achieve this objective, EFSA carried out, over recent years, extensive expert consultations and a testing phase to develop a transparent and practicable framework approach to emerging risks identification (ERI). Following the adoption of an operational definition of “emerging risk” by EFSA in 2007, ad hoc Working Groups (WG) were created (i.e. the Emerging Risks Internal Collaboration group (ERIC) the Stakeholder Consultative Group on Emerging Risks (StaCG-ER) and the WG on Data Collection for the identification of emerging risks (DACO-WG)) along with a Network of Member States, to start discussing and testing data collection and evaluation approaches in such a framework.

In 2011 the WG on Methodology for ERI, established to support EFSA in the further development of a transparent framework, assessed the performance of the EFSA procedure in place and provided recommendations for improvement. The WG proposed a revised simplified framework for ERI including three main steps: 1) identification of emerging issues, 2) identification of appropriate data sources and data collection, 3) final evaluation and identification of emerging risks (EFSA, 2012). Emerging issues should be identified at the beginning of the process preferably through expert consultations and access to specialized databases. The WG on Methodology recognised that ERI requires a high level of expertise, as it is typically based on scattered information and major data gaps, which are difficult to interpret without a solid knowledge of the entire food chain. One of the major constraints identified in the efficiency of the procedure piloted by EFSA was the direct accessibility to experts from the SC and Panels. This was deemed to be crucial for an efficient identification of specific issues for focussed monitoring and a meaningful expert evaluation of the issues identified. Thus, it was recommended that the entire ERI process should be coordinated by the SCER Unit with the support of the SC, who will be responsible for the endorsement of the final report on emerging risks.

Thus, the SCER Unit was requested to establish a Standing WG of the SC on Emerging Risks, to provide scientific support to EFSA throughout the entire ERI process: from the identification of emerging issues that merit further consideration to the final identification of emerging risks. Furthermore, experience in operating the pilot phase of the ERI process at EFSA has shown a need to improve the decision and priority making process for attributing resources to follow up on identified emerging risks. To this end, the WG of the SC on Emerging Risks reports directly to the SC, that provides recommendations for potential follow up actions.

## TERMS OF REFERENCE AS PROVIDED BY EFSA

The objective(s) of the Standing Working Group on Emerging Risks is to collaborate with the SCER Unit on the ERI process, i.e. from the identification of priority emerging issues that merit further consideration for the final identification of emerging risks. The outcome of this work will be submitted to the SC for consideration. The specific tasks of the WG are to:

### 1) Assist in the identification of emerging issues

- Through the systematic application of the scientific criteria adopted, prioritize the emerging issues identified, indicating those for which specific reports should be further developed;
- 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;
- Develop draft conclusions and recommendations on the emerging issues identified and present them to the SC for endorsement and confirmation or not of an emerging risk.
- Contribute to the EFSA's work on the identification of research priorities.

### 2) Assist in the review of the ERI process

Following experience gained in the operation of the process, and for March 2014:

- Review the data sources already identified for the identification of emerging issues and, if needed, suggest additional ones;
- Review the scientific criteria already identified to screen data sources to identify the emerging issues and, if needed, suggest additional ones;
- Review the scientific criteria to analyse the emerging issues deserving further consideration and, if needed suggest additional ones;
- Recommend further modifications to the process to take it forward.

Part of the present mandate was completed by the sub-WG dealing with emerging risks of chemical nature which delivered a technical report on a systematic procedure for the identification of emerging chemical risks in the food and feed chain (EFSA, 2014). The present report describes the work carried out by the sub-WG dealing with emerging risks of biological nature. The activities of the sub-WG focused primarily on elements of the second of the terms of reference of the Standing WG on Emerging Risks. In particular the sub-WG elaborated a strategy to address the specific issues posed by the risks of biological nature.

## 1. Introduction

### 1.1. The EFSA's mission and activities on the identification of emerging risks

According to Art. 34 of Regulation (EC) 178/2002<sup>4</sup>, the European Food Safety Authority (EFSA) shall establish “monitoring procedures for systematically searching for, collecting, collating and analyzing information and data with a view to the identification of emerging risks in the fields within its mission” (i.e. human, animal and plant health as related to the food and feed chain).

Where EFSA 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. The EFSA shall use all the information it receives in the performance of its mission to identify an emerging risk. The EFSA shall forward the evaluation and information collected on emerging risks to the European Parliament, the Commission and the Member States.

The first step is based on the suspicion of emerging serious risks and the request for additional information by EFSA to the Member States, other Community Agencies and the Commission that would make it possible to move from a simple suspicion to a more scientifically-based conclusion about the identification of the emerging risk. The second step is based on the identification of emerging risks, i.e. scientifically-based possibility/likelihood of harmful effects for human/animal/plant health associated with exposure to specific hazards, although there may remain a need for additional scientific information to carry out a full risk assessment.

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

EFSA has worked intensively to develop a methodological approach to identify emerging risks since its inception in 2003 (Robinson et al., 2012). According to EFSA's operational definition of emerging risk adopted in 2007, an emerging risk is understood to be associated with the probability of harm to human, animal and/or plant health, resulting from a newly identified hazard which may be an agent of physical, chemical or biological nature to which a significant exposure of the target organism may occur, or from an unexpected new or increased significant exposure and/or susceptibility to a known hazard through the food chain for humans, through the feed chain for animals and through the environment for plants<sup>5</sup>. Therefore, the identification of an emerging risk can be stated as:

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<sup>4</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

<sup>5</sup> Food as defined in this report is any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans with the exemptions mentioned in art.2 of Regulation (EC) 178/2002 and covers all types of foods including food supplements and fortified foods. ‘Feed’ (or ‘feedingstuff’) means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to Animals (art.3(4), Reg (EC) 178/2002).

- A new hazard, to which a significant exposure of humans, animals and/or plants is possible/likely;
- A new/increased exposure of humans, animals/or plants to a known hazard as possible/likely;
- Increased susceptibility of humans, animals and/or plants to a known hazard, e.g. as a consequence of immune depression in persons exposed.

A preliminary important step in such a process is identified when a new exposure to human beings, animals and/or plants is discovered to an agent of unknown toxicity/pathogenicity or a new toxicity/pathogenicity is discovered for a hazard with unknown human, animal and/or plant exposure. Such a condition is operationally defined in the present context as an “emerging issue” that conceptually corresponds to the suspicion of serious emerging risk mentioned in the second paragraph of Art. 34 of Reg. (EC) 178/2002. In fact, it clearly points to the need for more data on toxicity/pathogenicity or exposure, which could lead to the identification of an emerging risk. Emerging risks or issues can be identified in association with a variety of biological, chemical and/or physical hazards of natural or industrial origin, as well as for a variety of target organisms, including human beings, animals and/or plants. In view of EFSA’s status as a European Agency, the mandate provided by Regulation (EC) 178/2002 in terms of emerging risks identification applies to the European Union and to its food and feed chain.

Following the recommendations of the working group on methodology for ER identification (EFSA, 2012), a standing WG was established in 2013. The WG proposed to have a survey of experts from the Panels and the SC to ask their views on what they see as potential areas of concern in the next five years. Such a survey could be expanded to a Delphi process with two or three rounds. This approach would make use of the expertise available to EFSA and could direct the search activities of EFSA. The time needed to design, conduct and deliver this type of survey will strongly depend on the breadth of the exercise and the resources and expertise deployed, *e.g.* the number of experts included, the number and type of questions, and the support of an external contractor. Additionally, EFSA could perform more in-depth analysis through an expert workshop process with a more limited number of experts (either from its database, or from its relevant committees). The identified drivers for emerging risks could also serve as the basis for focused data searches by EFSA.

The ultimate goal of this exercise is to support decisions and to identify priority areas for EFSA including areas for self tasking. This exercise aims at keeping track of what is happening now, what could plausibly happen in the future, and most importantly what could be done by EFSA order to be more prepared. The strategic time horizon considered should be 5-10 years. The practical outputs will be a list of priority areas for EFSA, with specific drivers and emerging issues/risks and their interactions. This activity is also linked to the Horizon 2020 activity for future research priorities of DG-Research. Some of the inputs given could also impact the work of the Scientific Committee and the Panels, who could trigger self tasking mandates. This report describes a pilot study that was carried out to explore possible approaches and to decide on the way forward. It should be noted that predictions on outbreaks or emerging agents are beyond the scope of this exercise.

It is worth noting that various activities related to emerging risks identification are, or have been recently, carried out in EFSA at Panel or Unit level. The working group has taken stock of that work and implemented some of those aspects into its proposed strategy. Examples of such EFSA activities include the following:

- The AHAW Panel is focused on risk assessments of animal health and welfare in the primary production area as well as at slaughter. The framework used is based on the World Organisation for

Animal Health (OIE) risk analysis and assessment outline and often focuses on animal diseases having emerged in the EU such as Bluetongue (EFSA AHAW Panel, 2011). Another task is assessing the risks of an animal disease emerging in the EU such as Rift Valley Fever (EFSA AHAW Panel, 2013a). When assessing the risk of introduction of bee parasites into the EU the outline from the international plant health protection commission was used (EFSA AHAW Panel, 2013 b). Moreover, tools to assess risks to animal welfare have been developed (EFSA AHAW Panel, 2012a) and in this process the use of animal based indicators are crucial. This is exemplified by the guidance for risk assessment of animal welfare of genetically modified animals (EFSA GMO and AHAW Panels, 2012)

- The BIOHAZ Panel produced a series of scientific opinions addressing emerging risks in a wider sense. Issues addressed in these opinions include: carbapenem resistance in food animal ecosystems (EFSA BIOHAZ Panel, 2013a); VTEC-seropathotype and scientific criteria regarding pathogenicity assessment (EFSA BIOHAZ Panel, 2013b); Monitoring and assessment of the public health risk of ‘*Salmonella* Typhimurium-like’ strains (EFSA BIOHAZ Panel, 2010); the risk posed by Shiga toxin-producing *Escherichia coli* (STEC) and other pathogenic bacteria in seeds and sprouted seeds (EFSA BIOHAZ Panel, 2011a) and the risk posed by pathogens in food of non-animal origin (EFSA BIOHAZ Panel, 2013c).

- Recent examples of scientific opinions developed by the PLH Panel dealing with emerging risks have addressed the following issues: citrus black spot (CBS) and its potential introduction in the EU (EFSA PLH Panel, EFSA 2014a); Citrus canker and its potential introduction in the EU (EFSA PLH Panel, 2014b) and the presence of the plant pathogenic bacterium *Xylella fastidiosa* in olive trees (EFSA, 2013). In June 2011, EFSA organised a scientific colloquium on emerging risks in Plant Health (EFSA, 2011a) with the objective to provide inputs for the development of EFSA’s methodological framework for emerging risk identification in plant health, including systems and methodologies for data monitoring, data filtering and risk assessment of emerging plant health risks. In that context, EFSA is currently conducting a study for development and testing of the media monitoring tool MedISys for the monitoring, early identification and reporting of existing and emerging plant health threats. This project is using the MedISys software developed for public health monitoring, intending to evaluate its ability of capturing signals from the media in the field of plant health.

## 1.2. Definition of emerging risks

The WG has discussed EFSA’s definition of emerging risks in the context of biological hazards, and has compared it with a recent paper by Engering et al. (2013). In the paper the authors developed a general framework for emergence of infectious diseases in animal reservoirs, based on pathogen-host-environment interactions for existing diseases from which new disease may emerge by:

- Acquisition of new traits;
- Spill-over to new hosts;
- Spreading to new areas.

EFSA	Engering <i>et al.</i> (2013)
<ul style="list-style-type: none"> <li>• A new hazard, to which a significant exposure of humans, animals and/or plants is possible/likely;</li> </ul>	<ul style="list-style-type: none"> <li>• Acquisition of new traits;</li> </ul>
<ul style="list-style-type: none"> <li>• A new/increased exposure of humans, animals/or plants to a known hazard as possible/likely;</li> </ul>	<ul style="list-style-type: none"> <li>• Spreading to new areas</li> </ul>
<ul style="list-style-type: none"> <li>• Increased susceptibility of humans, animals and/or plants to a known hazard, e.g. as a consequence of immune depression in persons exposed.</li> </ul>	<ul style="list-style-type: none"> <li>• Spillover to new hosts;</li> </ul>



These definitions are related to each other, but do not completely overlap. A key element in Engering et al.'s framework is the existing pool of pathogens from which pathogens may emerge. This is a key concept as human activities do not (yet) directly lead to the generation of new pathogens, but may create conditions under which natural processes can result in their appearance.

The elements on new hazards in the EFSA definition and pathogens displaying new traits in Engering et al.'s framework appear to be closely related. The element of significant exposure from EFSA's definition is also included in Engering et al.'s framework as only pathogens that "bring sudden disease flare-up and/or that become dominant in a host community are truly emerging". Factors influencing the appearance of new hazards (e.g. virulence jumps) are related to the nature of the pathogen (rates of mutation, recombination, re-assortment or acquisition of new genetic material). In particular, RNA viruses are prone to species jumps. Furthermore, intensification of agriculture (including the domestication of new species), globalization and selective pressure by antimicrobials and vaccines may represent new selection pressures favouring opportunities for new pathogens to spread.

The element on new exposure in the EFSA definition is related to both the new host and the new areas elements in Engering et al.'s definition. As these two elements are under the influence of different drivers, a subdivision of the EFSA definition may be useful. Successful establishment of a pathogen in a new host (species jump) is influenced primarily by contact structures between or within host species, which are influenced by changing ecology causing increased mixing of previously separated host populations. These new contact structures include wildlife incursion into farming areas as well as population growth of animals and humans. Establishment of pathogens in new areas involves either geographic expansion or geographic jump. Geographic expansion is primarily influenced by changing landscapes caused by climate change or changes in land use. Geographic jumps are related to globalisation, but may also involve natural processes such as bird migration. Also in the domain of plant health, species jump/host shift are a similar concept.

The third element in the EFSA definition is not included in Engering et al.'s framework but appears to be an important element of disease emergence as well. Relevant aspects that may modify the outcomes of exposure of human, animal or plant populations to biological hazards include for example chronic immunosuppression / lifelong drug treatments (HIV, cancer, and transplant patients), increasing use of proton-pump inhibitors in humans, medication or diets leading to dysbacteriosis and rapid gastric emptying and selective pressure by breeding on production results in animals, changes in cultivation techniques, changes in environmental conditions linked to climate changes ( $T^{\circ}$  fluctuations, changes in precipitation patterns drought) and landscape remodelling for plants.

In conclusion, the two definitions are not contradictory. The EFSA definition for emerging risks could be made more operational when appropriate by considering the elements present in Engering's framework. In particular the concepts of species jump and geographic jump are relevant for biological hazards.

The concept "new" also needs further definition in the domain of evaluation of emerging biological risks. In many cases, a relevant hazard already exists somewhere in the world, in one or more species. For the purpose of evaluation by EFSA, it is advisable to consider any risk as new if it has not yet been observed in the EU territory and may require attention by EU risk managers. This would include truly new hazards, originating by mutation or recombination or hazards causing major diseases/outbreaks somewhere else in the world.

### **1.3. The identification of emerging biological risks**

For the purpose of this pilot study, targeted at human, plant and animal health, a biological risk was defined as "Micro-organisms, pests, parasites and prions having a direct or indirect impact on the safety of the food and feed supply chains, animal health and welfare, and plant health". According to the definition above, examples of emerging biological risks include Norovirus (since 1968),

thermophilic *Campylobacter* spp. (since 1972), Shiga-toxin producing *Escherichia coli* in beef, mutton and vegetables (since 1980s), BSE and vCJD (since 1987), infectious salmon anaemia (ISA) (late 1980s), outbreaks of *Trichinella* spp. in horse meat (late 1980ties), pandemic of *Salmonella enteritidis* in eggs (since 1990s), foot and mouth disease and classical swine fever outbreaks (1990s and 2000-2010), Asian Longhorned Beetle, *Anoplophora glabripennis* (starting in the EU in 2001), *Tuta absoluta* in tomato (2006), bluetongue spreading from the Mediterranean to northern Europe (2010), and enterohaemorrhagic *E. coli* in sprouts (2011). This is not an exhaustive list; some examples will be presented in more detail later in this report.

Biological risks are an outcome of natural processes which may be influenced by human activities or autonomous developments. The (long term) anticipation of emerging risks should therefore be based on the identification of drivers. One does not have to be able to identify a specific hazard in order to be able to anticipate that a certain action or change in conditions may well give rise to the emergence of a risk. A useful conceptualisation of this approach was provided by the UK Foresight Infectious Disease project (Tait, 2006). In that project, the following concepts were defined:

- Drivers:  
Social, economic or physical factors that affect disease outcome by changing the behaviour of disease sources or pathways.
- Sources  
Phenomena or biological events that:
  - Give rise to potential new diseases;
  - Enable existing diseases to become more harmful;
  - Enable existing diseases to infect new hosts;
  - Enable existing diseases to spread to new areas
- Pathways  
Mechanisms or routes by which a disease organism can transfer from one host to another, within or between species
- Outcomes  
Diseases of plants and animals at the individual, community and ecosystem or farming system level, and diseases of humans at individual and societal levels.

The UK framework was used as a starting point for the discussion in the WG as it is related to the EFSA definition of Emerging Risks. However, because of the complexities involved the WG decided to explore further structured approaches.

Emerging biological risk identification is a complex process requiring a high level of expertise and thorough knowledge of the food chain. In fact, emerging risks identification is typically based on limited and scattered information, characterised by significant data gaps and uncertainties. A high level of expertise is necessary to scrutinise and discriminate relevant emerging issues among the large amount of information available. Structured expert advice is a method often used to cope with these kinds of uncertainty (Armstrong 2001).

As indicated in (EFSA, 2011a), drivers have been defined as issues shaping the development of a society, organisation, industry, research area, technology, etc. Drivers can be classified in categories such as STEEP (i.e. Social, Technological, Economic, Environmental, Political). One important characteristic of drivers is that they may act as modifiers of effect on the onset of emerging risks, namely they can either amplify or attenuate the magnitude or frequency of risks arising from various sources. A large body of literature is available on drivers in different fields, including economy, social sciences, technology, health and environmental sciences.

EFSA has access to a large number of experts through its Panels and its many Networks (EFSA, 2011b). Involving experts already working with EFSA (*e.g.* Panels, SC members and EFSA's Networks) in the selection of priority emerging issues could be a particularly efficient approach, as it would tap into a vast reservoir of scientific knowledge. Thus, it was recommended that resources should be specifically allocated to facilitate the inclusion of views of these experts at the beginning of the ERI process to identify selected priority issues meriting further evaluation.

## 2. Methods

A number of validated methods are available for integrating expert advice into an emerging risk identification process (Armstrong, 2001). Expert judgment approaches essentially divide into those that utilise many experts, and those that utilise a relatively smaller number of experts (*e.g.* workshops with up to 20 participants)(Armstrong, 2001; Rowe, 2007). The former generally involves the use of questionnaires, and is typified by the Delphi approach, in which a survey is reiterated over a number of 'rounds', during which feedback from prior rounds is provided and at which experts are encouraged to rethink the problem and revise their estimates if they deem this appropriate. The latter approach generally involve the use of highly structured small group methods, which require experts to be present at one place/time, and which may take place (in the first instance) over a couple of days. 'Structure' is important, because unstructured group meetings are well-known to suffer from a variety of problems, such as over-dominance by dogmatic individuals, political game playing, premature closure of discussions, the tendency of individuals in groups to discuss common knowledge at the expense of unusual or uniquely held ideas and so on (Armstrong, 2001; Rowe, 2007).

Most of these methods involve: the use of experienced facilitators who are adept at pre-empting some of the typical group process problems; brainstorming-like approaches, to ensure that problems are not too-narrowly framed; open or secret voting, to ensure that all participants have a say and use of materials (*e.g.* post-its) to explicitly display ideas/concepts and the relationships between these. Empirical evidence of the relative validity of such approaches (*e.g.* scenario workshops versus horizon scanning events) is scant, with professional consultants tending to advocate the specific approach with which they are most familiar (Armstrong, 2001).

Thus, the WG decided to combine the two approaches: including several experts in a simple survey/consultation process with BIOHAZ and AHAW Panels, and fewer experts in a dedicated follow up workshop. The consultation with the Panels provided data on drivers and emerging issues, while the expert workshop was useful to provide more in-depth and contextual information on the likely nature of particularly interesting or important emerging issues (*e.g.* their drivers, potential timelines, likelihood, health impact on the population) or possible likely scenarios.

The overall objective of the consultations was to identify and prioritise drivers for emerging risk monitoring and identification in the domain of biological hazards. This would inform strategies to monitor factors leading to disease emergence and risk based disease surveillance. The process involved experts from the EFSA Scientific Committee and the EFSA BIOHAZ and AHAW Panels.

### 2.1. Consultation with AHAW and BIOHAZ Panels

The expert consultation was inspired by the Delphi approach. The process was explained at the plenary preceding the consultation, clarifying the objective and the procedure of the exercise. The brainstorming sessions with the Panels lasted about 2 hours. The experts were provided with a briefing note with background information on the objectives of the exercise. For each Panel consultation, the experts were divided in 4 breakout groups and they were asked to identify drivers and emerging biological risks to animal and public health in the next 5-10 years.

This consultation took place during the Panel plenary of the BIOHAZ and the AHAW Panels in separate sessions. In total about 40 experts participated. The participants were confronted with two main questions:

- a) What factors (or drivers) do you think are most likely to lead to emerging food risks in the next 5-10 years? [‘When thinking about factors, think about Political, Economic, Social, Technological, Legal and Environmental ones.’]
- b) Thinking about these factors, what emerging food risks do you think are most likely to consequently emerge over the next 5-10 years?

In order not to repeat previous exercises and to avoid collecting information we are already aware of, a table with main drivers already identified in the literature was distributed (e.g. climate change, globalisation, increase in price), as the WG was interested only in new information. The session was moderated by the EFSA secretariat and two Panel members, who were also WG members. Following the analysis of the results of the consultation with the Panels, an evaluation and consolidation of a list of drivers and emerging issues was prepared (Table 1 and 2).

### **2.1.1. Follow up activities of the AHAW Panel**

The outcome of the consultation with the AHAW and BIOHAZ Panels described in section 2.1 was a list of priority drivers of disease emergence in animal and public health for the next 5 – 10 years. The results from the AHAW Panel consultation were disseminated to the Panel and discussed in a series of events organised by the AHAW secretariat.

The first took place at a scientific event on preparedness in animal health "Risk assessment - thinking out of the box" and a Satellite Symposium: “Assessing risks in animal health requires preparedness” at the 31st World Veterinary Congress in Prague. The EFSA scientific event in Prague aimed at looking at the interactions of the drivers identified by the AHAW Panel and at how they could be integrated into risk assessment.

At the 7th EPIZONE annual meeting in Brussels a further AHAW contribution was organised with a satellite meeting on preparedness in animal health: "Emerging animal diseases in the EU: what have we learned?" The objective of this satellite meeting was to re-think emerging animal diseases, reflecting on their origins and - more importantly - on the level of preparedness. The workshop also contributed to identifying critical issues to be addressed in the coming years by EFSA and the scientific community in general.

Additional discussion took place at the annual meeting of the EFSA Scientific Network for Risk Assessment in Animal Health and Welfare in October 2013 in Parma, and in the framework of an EFSA Taskforce for the development of collaboration between EFSA and ECDC on non-foodborne zoonotic and emerging diseases at the animal-human interface.

## **2.2. General Morphological Analysis workshop**

A second workshop was organised with the aim to analyse and integrate the results of the consultation with the Panels. The workshop was structured around the use of General Morphological Analysis, a procedure based on morphological modelling for the development of scenarios (Ritchey, 2006).

This workshop focused on one specific area identified by the WG as being of particular concern:

- What are the most important parameters (factors/variables) concerning viral agents associated with the food chain relevant for human and animal health, and how they interact?

This exercise took place over 2 days and involved 7 experts, i.e. 5 members of the biological subgroup of the standing WG on Emerging Risks, and two additional experts with expertise in the specific topic of the workshop (viral agents and emerging risks) and was facilitated by an external contractor. The aim was to develop a number of plausible future scenarios for the risks of concern (identifying key drivers; causal chains; key uncertainties; likely impacts and timelines; and their interactions).

Based on the outcome of the consultation with the Panels the WG decided to focus the test modelling on the following eight parameters that were found to be the most relevant to answer the question of the workshop:

1. Climate change
2. Agriculture and animal production
3. Innovation
4. Globalization
5. Consumer behaviour
6. Demographic changes
7. Legislation and policies
8. Biological processes (Proximate causes for potential emerging risks)

In order to measure and visualise how these parameters interact, and thus influence the total system of parameters, the experts went through two steps of analysis.

### **Step 1: Parameter influence analysis**

During the first step the experts were guided through the use of Weighted Influence Diagrams (WIDs) in order to analyse the cross-impact or cross-influence relationships between the different parameters. The analysis allows making a relative determination of which parameters are: *drivers* (strongly influencing but not strongly influenced), *passive* (strongly influenced but not strongly influencing), *critical* (both strongly influenced and strongly influencing) or *buffers* (neither strongly influenced nor strongly influencing). The purpose of this analysis is to identify the most important parameters to be considered in developing the scenario modelling framework and thus the final scenarios.

With the support of the dedicated software provided by the external contractor the relative influence scores attributed to the different pairs of parameters were used to calculate *influence indices* based on the methodology described in (Cole, 2006).

### **Step 2: Scenario modelling framework**

For the development of the prototype scenario modelling framework, limited time was available. Therefore, it was decided to focus only on those parameters shown to be “critical” in the parameter influence analysis: i.e. which are both highly influencing other parameters, and highly influenced by other parameters. During a brainstorming session the experts defined the possible states for each of the parameters found to be critical. The parameters considered and their respective spectrum of states defines the morphological field of analysis.

Based on the total number of possible (formal) configurations in the morphological field the experts went through a cross-consistency assessment of the possible configurations, i.e. a pairwise comparison of all possible combinations of parameter states. For each pair, an evaluation to what extent the pair can coexist was made and qualitative codes were assigned. Through this exercise of eliminating configurations that were not plausible, the morphological field was reduced to a solution space composed of only internally consistent configurations. Based on this solution space, the experts worked on the definition of testbed scenarios relevant for the analysis.

In order to have a better understanding of the applicability of the methodology, it was decided to work on historical cases to evaluate the applicability of the GMA approach.

### **2.3. Follow-up**

The draft report was discussed in the plenary meetings of the EFSA AHAW, BIOHAZ Panels and the EFSA Scientific Committee in March and April 2014, and circulated for written comments to the PLH Panel in April 2014. The feedback from the Panels was incorporated in the final version.

### 3. Results

The Standing Working Group of the Scientific Committee on Emerging Risks and the SCER Unit organised two expert consultations on emerging biological risks. One with the AHAW Panel that took place on the 26<sup>th</sup> of June 2013, and one with the BIOHAZ Panel on the 11<sup>th</sup> of July 2013.

#### 3.1. Consultation with AHAW and BIOHAZ Panels

The results of the consultation with the AHAW and BIOHAZ Panels, further elaborated by the WG, are summarised in Table 1 and Table 2. Table 1 lists the drivers of emerging risks that were identified during the workshop. Table 2 reports the emerging issues and the primary drivers associated with their emergence that were identified.

The main drivers reported in these two consultations include: different aspects of climate change, environmental contamination, biological processes, agriculture and animal production, innovation, scientific discoveries, globalisation, price fluctuations, consumer behaviour, demographic changes, legislation and policies. For each driver, relevant sub-drivers were identified.

**Table 1.** Identified drivers of emerging risks (after BIOHAZ and AHAW consultation).

Driver	Subdriver
<b>Environment</b>	
<b>Climate change</b>	<ul style="list-style-type: none"> <li>- Rising and more fluctuating temperatures</li> <li>- Changing precipitation patterns (drought / flooding)</li> <li>- Increase in natural disasters related to climate change</li> </ul>
<b>Environmental contamination</b>	<ul style="list-style-type: none"> <li>- Increasing release of industrial (chemical) contaminants in the environment and in the food chain</li> <li>- Pressure for increased recycling and less waste all along the food chain</li> <li>- Water treatment and waste disposal treatment</li> <li>- Indirect impact of pharmaceuticals and industrial chemicals on foodborne diseases and organism susceptibility to evolution</li> </ul>
<b>Biological processes</b>	<ul style="list-style-type: none"> <li>- Spread of diseases from humans to animals</li> <li>- Unintended changes in ecology of microorganisms. Creation of ecological niches</li> <li>- Appearance of new niches, due to disease eradication</li> <li>- More wild life density</li> <li>- Spontaneous genetic mutation of and gene transfer between micro-organisms</li> <li>- Evolution of intermediate hosts for vector borne diseases</li> <li>- Appearance of organisms with increased potential for biofilm formation and environmental persistence</li> <li>- New selective pressures leading to new adapted phenotypes, invasion, migration, replacement</li> <li>- Mix of species with an unpredictable outcome (e.g. influenza)</li> <li>- Reduced immunity due to reduced environmental exposure to microorganisms</li> <li>- Diminishing biodiversity and ecosystem services</li> </ul>
<b>Agriculture and Animal production</b>	<ul style="list-style-type: none"> <li>- Increasing/changing antimicrobial use/resistance.</li> <li>- Changes in land use/ migration of main production areas</li> <li>- New agri-food chain structures</li> <li>- Reduction in the agricultural labour force</li> <li>- Increase in organic farming</li> <li>- Increasing importance of regional, local and alternative food chains</li> <li>- Micro-agriculture, leisure, non-trained people, lack of knowledge</li> <li>- Increasing pressure on fresh water resources</li> <li>- Changing agricultural productivity according to species and regions</li> <li>- Water scarcity for animal production and agriculture</li> <li>- Reduction of the number of available crop protection products</li> </ul>

	<ul style="list-style-type: none"> <li>- Reduced availability and/or effectiveness of biocides and rodenticides</li> <li>- Increased use of pesticides</li> <li>- Food crops being used for other purposes than consumption only</li> <li>- Increasing shortage of phosphorus for fertilisation</li> <li>- Harvesting from the natural environment</li> <li>- Possible changes to arable crop yields</li> <li>- Animal welfare</li> <li>- Increasing scale in animal farming</li> <li>- Inbreeding</li> <li>- Insufficient vet structure to cope with intensified farming</li> <li>- Lack of awareness of exotic diseases with vets/human doctors</li> <li>- Aquaculture, fresh and marine intensification</li> <li>- Increased consumption of animal proteins, strong increase in animal population</li> <li>- Pressure on breeding on production resulting in draw backs for health and welfare</li> <li>- Migration seasonal changes and movements of avian species</li> <li>- Changes in feed and feed strategies, new GI microbial niches</li> <li>- Insufficient storage and distribution of feed grain/fodder.</li> <li>- Low quality of feed and bedding</li> <li>- Mixing of species</li> <li>- Domestication of species</li> <li>- Intensification of production</li> <li>- Vertically integrated production pyramids</li> </ul>
<b>Science and Technology</b>	
<b>Innovation</b>	<ul style="list-style-type: none"> <li>- New food chain technologies</li> <li>- Selection of strains with extreme physiological properties during tech or production</li> <li>- New analytical methods</li> <li>- New crop production systems</li> <li>- New (green) energy sources</li> <li>- New generations of plant-applied products</li> <li>- Expected increase in use of biotechnology</li> <li>- Animal cloning, GMO animals</li> <li>- Expected increase in the use of nanotechnology</li> <li>- Increased use of information and communication technologies (ICTs)</li> <li>- Cyber-terrorism and failure of IT systems, problems in QC</li> <li>- Decreased interest of pharmaceutical industry in developing new drugs for animals and humans</li> <li>- Intervention with normal physiology of animals (breeding, etc.)</li> <li>- Microorganisms intentionally added to food</li> <li>- New products without history of safe use (e.g. GMO and novel foods)</li> <li>- Science curiosity</li> <li>- Very focussed monitoring, loose sight of bigger picture</li> <li>- Lack of incentive or genetic material for breeding improvements in the selection for resistance to colonization and excretion of pathogens</li> <li>- New evidence on unknown hazard</li> <li>- Unintended new hazards as consequences of new technologies</li> </ul>
<b>Economy</b>	
<b>Globalisation</b>	<ul style="list-style-type: none"> <li>- Increase in the globalisation of trade in food and feed</li> <li>- Increasing scale of food operations</li> <li>- Divergent-approaches/regulations concerning food safety among world areas</li> <li>- Increasing global demand for meat</li> <li>- Spread of animal and plant diseases through people and goods travelling across the world</li> <li>- Illegal trade of wild and farmed plants and animals</li> <li>- Introduction of ethnic foods in the EU diet</li> <li>- Internet based trade in food products between regions with different safety standards and/or less regulated</li> </ul>
<b>Price fluctuations</b>	<ul style="list-style-type: none"> <li>- Persisting volatility or increase in food and energy prices</li> </ul>



	<ul style="list-style-type: none"> <li>- Cheaper food and pressure to produce at lower costs can lead to less animal welfare and reduced hygiene control</li> <li>- Change in hygiene standards led by the economic crisis</li> <li>- Change in consumption patterns led by the economic crisis</li> <li>- Increasing health care costs</li> <li>- Retailers power and drive for cheap food instead of safe food</li> </ul>
<b>Society</b>	
<b>Consumer behaviour</b>	<ul style="list-style-type: none"> <li>- Food choice/consumer demands, increased demand for minimally processed/raw/undercooked food, exotic food, ready to eat foods, undercooked products, bush meat</li> <li>- Increasing demand for non-seasonal food of non animal origin</li> <li>- Increased use of food supplements/herbal medicines, interaction of medical treatments with health claim products</li> <li>- Food handling technologies, attitudes/education</li> <li>- Diversification and polarisation of diets and lifestyles</li> <li>- New food preferences leading to introduction of alien species</li> <li>- New sources of proteins</li> <li>- Non conventional food sourcing</li> <li>- Animal welfare and environmental awareness leading to changes in farming practices</li> <li>- Bioterrorism and deliberate release</li> <li>- Lack of consumer education</li> <li>- Sustainability of the food production process creating new pathways of exposures.</li> <li>- Shift in consumer perception and media attention on food safety issues</li> <li>- Increased total food consumption</li> </ul>
<b>Demographic changes</b>	<ul style="list-style-type: none"> <li>- Increasing prevalence of vulnerable groups (immune suppression, drugs, ...)</li> <li>- Population growth</li> <li>- Global competition for resources (e.g. energy, water, land) linked to population explosion</li> <li>- Urbanisation</li> <li>- Migration</li> <li>- Changed behaviours and consumption</li> <li>- Hygiene and poverty</li> <li>- Role of religion, ethnicity, dualisation of society</li> <li>- Political and religious stability of society</li> <li>- Breakdown of public and animal health infrastructures as consequence of civil unrest or war</li> </ul>
<b>Legislation and Policies</b>	<ul style="list-style-type: none"> <li>- New policies in toxicological risk assessment</li> <li>- Further EU enlargement, potentially coupled with further market integration</li> <li>- Lack of harmonisation in the use of veterinary medicine, prescriptions and vaccinations</li> <li>- Lack of data sharing between organisations related to newly diagnosed animals and detected contaminants</li> <li>- Societal resistance to disease control principles</li> <li>- Changes in the legislation on animal by products</li> <li>- Reduced regulation of Food Business Operators, less official sampling, more responsibility for FBO</li> <li>- Less budgetary resources into disease surveillance, public health and research</li> <li>- More biosecurity, less welfare</li> <li>- Changes in storage time of food, linked to the economic crisis</li> <li>- Breakdown of animal and public health infrastructures</li> <li>- Lack of effective control</li> <li>- Reluctance to control wild animal vectors</li> <li>- Fraudulent disease status or product certifications</li> </ul>

Specific emerging biological issues were listed in Table 2 in terms of new pathogens introduced in the EU (e.g. viruses, bacteria and parasites), possible increased exposure of known agents, and change in susceptibility.

**Table 2.** Emerging issues identified during the consultation with the Panels.

<b>New pathogens (re-)introduced in the EU</b>
<i>Viruses</i>
Rift Valley Fever
New Bluetongue Virus
African Swine Fever
virulent Porcine epidemic diarrhoea
Bovine Viral Diarrhoea
Enzootic Bovine Leukosis
Middle East Respiratory Syndrome Coronavirus (MERS-CoV)
New orbivirus
African Horse Sickness virus
Crimean Congo Haemorrhagic Virus
New Foot and Mouth Disease Virus
Highly virulent avian influenza virus
Simian viruses in bushmeat
Existing viruses becoming foodborne
Infectious salmon anaemia
Koi herpesvirus disease
Infectious pancreatic necrosis (in fish)
Newly constructed viruses
<i>Bacteria</i>
Increased antimicrobial resistance
VTEC serotypes with new virulence arsenal
Monophasic Salmonella
Caseous lymphadenitis ( <i>Corynebacterium pseudotuberculosis</i> )
<i>Parasites</i>
Highly virulent <i>Toxoplasma gondii</i> from Latin America
Drug resistance
<b>Possible increased exposure</b>
Hepatitis-E virus in pigs
Viruses (Norovirus, hepatitis-A virus) and protozoa in produce
Leishmaniasis
<i>Anisakis</i> spp. induced allergies
Increased vectorborne disease
Bovine tuberculosis
<i>Vibrio</i> spp.
<i>Brucella</i> spp.
Spore-forming bacteria in processed foods
Mycotoxin-producing fungi
Atypical TSEs
Listeriosis
<b>Changed susceptibility</b>
Decreased immunity (e.g. to hepatitis-A virus)
Listeriosis

The tables reflect the input given by the Panels and still need further interpretation after development of a framework to evaluate the interaction of different drivers.

### 3.2. General Morphological Analysis workshop

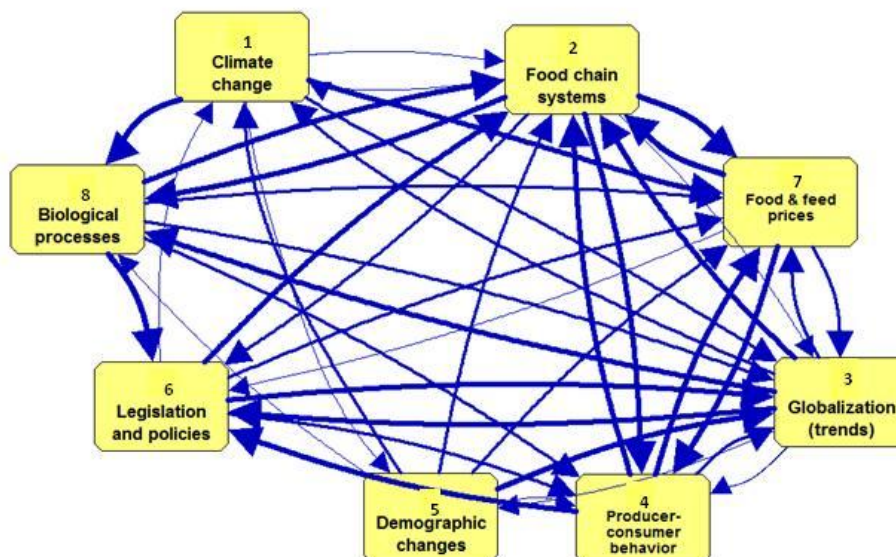
#### Step 1: Parameter influence analysis

Through the use of Weighted Influence Diagrams (WIDs,) the eight parameters as mentioned in section 2.2, were compared pairwise to analyse the cross-impact or cross-influence relationships between them. The graphical outcome of this comparison is shown in Figure 1 in the form of an influence matrix.

Wirkung VON / AUF	1	2	3	4	5	6	7	8	Su.E
1. Climate change		1	2		1		3	3	10
2. Food chain systems	1		1	3		2	3	3	13
3. Globalisation trends	2	3		1	1	3	2	3	15
4. Producer-consumer behaviour		2	2			3	3		10
5. Demographic changes	2	2	3	1			2	1	11
6. Legislations_policies	1	3	3	2			2		11
7. Food_feed proces		3	2	3		1			9
8. Biological processes		3	2	2		3	2		12
Summe Beeinflussung	6	17	15	12	2	12	17	10	

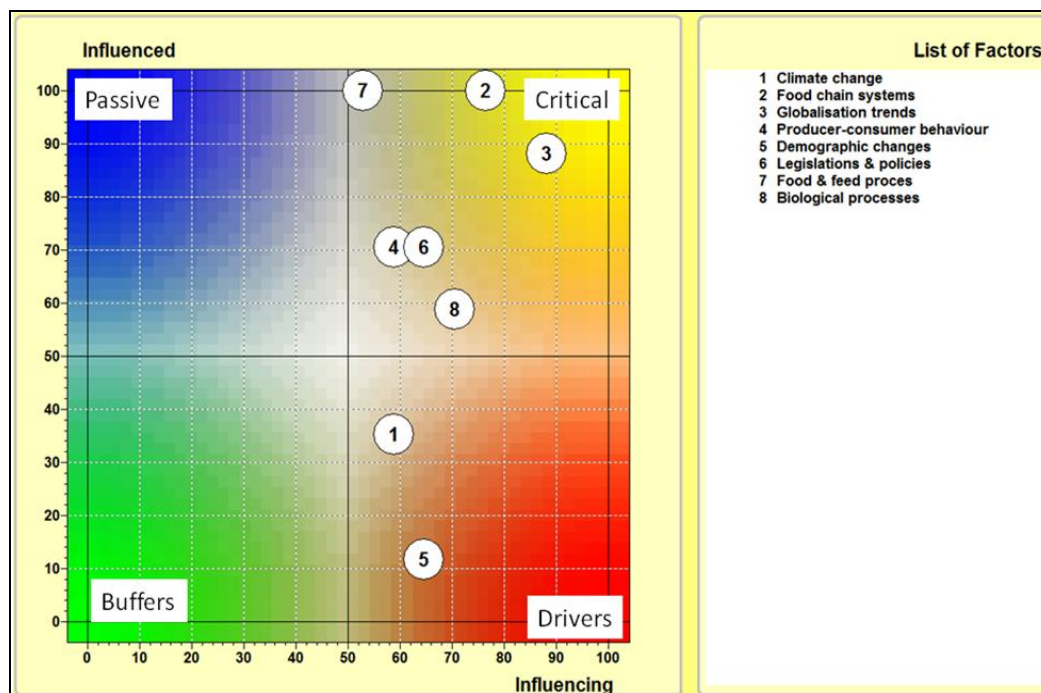
**Figure 1.** Relative influence of the eight parameters considered during the workshop. The scale used is: Blank = no direct influence; 1 = some direct influence; 2 = significant direct influence; 3 = critical/crucial direct influence.

Based on the classification described above an influence diagram visualising the relative influence of the parameters was developed (Figure 2)



**Figure 2.** Graphical representation of the relative influence of the eight parameters considered during the workshop. Thickness of the lines is proportional to the influence of the parameter considered.

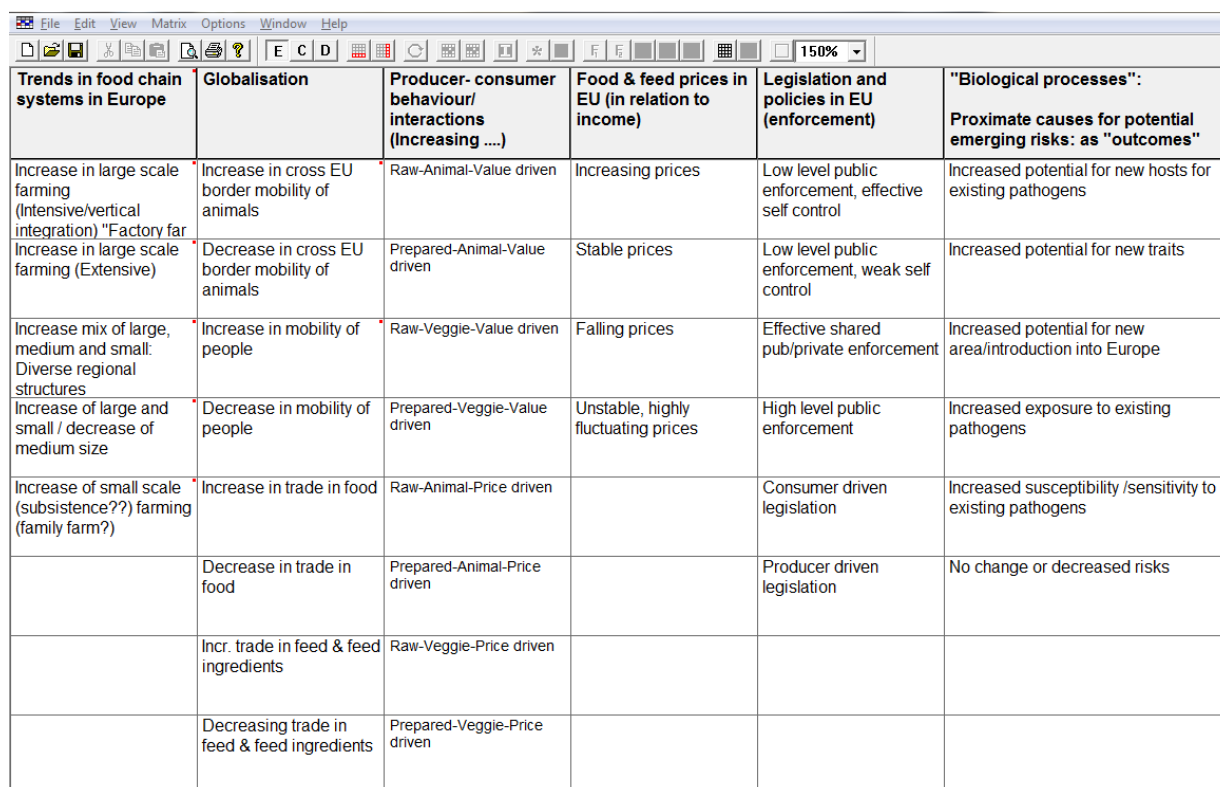
With the support of the dedicated software the relative influence scores attributed to the different pairs of parameters were used to calculate *influence indices*. The results of this parameter influence analysis are summarised in Figure 3.



**Figure 3.** Parameters influence analysis of the eight parameters considered during the workshop. The analysis is based on the methodology described in (Cole, 2006).

## Step 2: Scenario modelling framework – preliminary results

The parameters “climate change” and “demographic changes” were excluded from further analysis since they did not appear to be critical in the parameters influence analysis. For each of the six remaining parameters different possible states were defined by the experts, and formed into a morphological field (Figure 4).



Trends in food chain systems in Europe	Globalisation	Producer- consumer behaviour/ interactions (Increasing ....)	Food & feed prices in EU (in relation to income)	Legislation and policies in EU (enforcement)	"Biological processes": Proximate causes for potential emerging risks: as "outcomes"
Increase in large scale farming (Intensive/vertical integration) "Factory far"	Increase in cross EU border mobility of animals	Raw-Animal-Value driven	Increasing prices	Low level public enforcement, effective self control	Increased potential for new hosts for existing pathogens
Increase in large scale farming (Extensive)	Decrease in cross EU border mobility of animals	Prepared-Animal-Value driven	Stable prices	Low level public enforcement, weak self control	Increased potential for new traits
Increase mix of large, medium and small: Diverse regional structures	Increase in mobility of people	Raw-Veggie-Value driven	Falling prices	Effective shared pub/private enforcement	Increased potential for new area/introduction into Europe
Increase of large and small / decrease of medium size	Decrease in mobility of people	Prepared-Veggie-Value driven	Unstable, highly fluctuating prices	High level public enforcement	Increased exposure to existing pathogens
Increase of small scale (subsistence??) farming (family farm?)	Increase in trade in food	Raw-Animal-Price driven		Consumer driven legislation	Increased susceptibility /sensitivity to existing pathogens
	Decrease in trade in food	Prepared-Animal-Price driven		Producer driven legislation	No change or decreased risks
	Incr. trade in feed & feed ingredients	Raw-Veggie-Price driven			
	Decreasing trade in feed & feed ingredients	Prepared-Veggie-Price driven			

**Figure 4:** Morphological field defined by the six parameters considered and their respective states.

The total number of possible (formal) configurations in the morphological field described in Figure 4 (combination of one state for each parameter considered) is 46,080. Through a cross-consistency assessment of the possible configurations, i.e. a pairwise comparison of all possible combinations of parameter states, the experts reduced the morphological field to a solution space of 878 internally consistent configurations.

On the basis of this solution space the experts worked on the definition of five testbed scenarios. These scenarios included: i) present trends, ii) collapse of EU, iii) small scale farming, iv) large scale farming, v) positive development: good mix of parameter states leading to decreased risks (Appendix A).

Based on this same solution space the experts were able to develop plausible scenarios focusing on the different states of the parameter "biological processes" which was the parameter of major interest for the question of the workshop. Figures B.1 to B.6 in Appendix B show the possible scenarios leading to the different states of the parameter "biological processes".

It is stressed that these scenarios are preliminary, and merely serve to illustrate the potential of the GMA method. Further work is needed to arrive at scenarios which can inform EFSA's strategy for emerging risk identification.

### 3.3. Evaluation of the GMA model using historical cases

#### 3.3.1. Norovirus

##### 3.3.1.1. Case description

Norovirus (NoV) infection is the most common cause of infectious human gastro-enteritis. NoV is shed in huge quantities in the stool and vomit of infected persons, and oral exposure to only a few particles is sufficient to cause disease. Foodborne infections caused by NoV are limited to the recycling of human viruses back to humans.

NoV can be divided into distinct genogroups, based on phylogenetic analyses of the capsid protein. To date, five NoV genogroups (G) have been recognized (GI-GV). Viruses of GI, GII and GIV are known to infect humans. GII viruses have additionally been detected in pigs, and GIV viruses have been detected in a lion cub and a dog. GIII viruses infect cattle and sheep and GV viruses infect mice. Recombination between viruses from different genogroups is rare suggesting that this constitutes a species level in taxonomy (EFSA BIOHAZ, 2011b). Within genogroups, they are further categorized into clusters, and within clusters, the individual Norovirus assigned to an outbreak is referred to as a strain (Zheng et al, 2006). GII.4 cluster strains are the most common genogroup and cluster found in outbreaks (Mattison, 2011).

In the EU, the major mode of transmission for NoV remains person-to-person but it is unknown how much disease caused by NoV can be attributed to foodborne spread. Studies in some countries suggest that this can be significant. Foodborne introduction of NoV in a population often results in secondary person-to-person transmission, which makes it difficult to trace back which transmission route was responsible for the outbreak.

Information about foodborne outbreaks caused by viruses (NoV and Hepatitis A) can be found in the EU Community Summary Reports published by EFSA. The reporting of outbreaks to EFSA was initiated in 2007. In the EU Community Summary Report 2012 (EFSA and ECDC, 2014) the number of foodborne outbreaks caused by viruses from 2008-2012 can be seen. The number of outbreaks per year ranges from between approx. 500-1000 with the highest number found in 2009.

Notifications from countries about possible food-related incidents in which NoV are involved can also be seen through the rapid alert system for food and feed called RASFF<sup>6</sup>. RASFF notifications are not representative and are not based on common notification criteria. Incident notifications may follow illness reporting or detection of a virus in a food product, or both and therefore should be interpreted with care.

The number of notifications for suspected viral contamination of food products through RASFF from 2000 until March 2010, based on illness reports or virus detection in products, show that bivalve molluscs and berries are the most frequently recognized food commodities involved in foodborne NoV outbreaks. Thus among 33 outbreaks notified, 21 were caused by bivalve molluscs, 11 were caused by berries and only one outbreak was caused by another ready-to-eat food product (EFSA BIOHAZ Panel, 2011b). The increase in RASFF notifications for suspected viral contamination from 2005 to 2010 is remarkable, possibly reflecting increasing awareness (EFSA BIOHAZ Panel, 2011b).

Bitler et al (2013) has reviewed commonly implicated transmission routes and vehicles for NoV outbreaks and found a significant association between genogroup and food vehicles. Thus a greater ratio of GII only was found for outbreaks caused by produce and ready-to-eat foods compared to shellfish outbreaks, which were most frequently GI and GII. In addition they found a significant association between GII.4 outbreak strain and setting, with a greater ratio of GII.4 to non-GII.4 strain outbreaks in healthcare than in food-service setting outbreaks.

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<sup>6</sup> [http://ec.europa.eu/food/food/rapidalert/index\\_en.htm](http://ec.europa.eu/food/food/rapidalert/index_en.htm)

In conclusion, notifications from countries about possible food-related incidents in which NoV are involved have increased from 2005 till now. Increased awareness and improved analytical methods may explain part of this increase. Bivalve shellfish and berries are those food commodities that are most often notified as the cause of foodborne NoV outbreaks. Possible increased availability and consumption of raw berries (out of season i.e. imported frozen berries) and possible increased consumption of raw shellfish could also have contributed to the increase in notified outbreaks but data to support this have not been sought.

#### 3.3.1.2. Evaluation of GMA framework

The current model has focused on animal production in column 1 (*Trends in food chain systems in Europe*) and column 4 (*Food & feed prices*). These two columns are therefore less relevant for foodborne Norovirus. Also the cells in column 2 (*Globalisation*) dealing with animal mobility and trade in feed ingredients are not relevant. If the model should be relevant and useful for foodborne NoV infections, it should have been more specific. For example Column 3 (*Producer-consumer behaviour interactions*) could be improved by making it more specific on the consumption of “risky food groups” such as raw shellfish, fresh produce (berries and leafy greens) and handled ready-to-eat food. Column 5 (*Legislation and policies*) could also be improved to be more specific and focused on hygiene legislation. Column 6 (*Biological processes*) is equally relevant for Norovirus and other microorganisms. A column could be added on need for (climate change) and availability of clean water (irrigation water).

### 3.3.2. Thermophilic *Campylobacter* spp.

#### 3.3.2.1. Case description

*Campylobacter* spp. may first have been observed in stools from infants with diarrhoea in Germany by Theodor Escherich in 1881 (Escherich, 1886) but its significance as a human pathogen was not recognised until the 1970s, when routine culturing methods for this fastidious pathogen became available (Dekeyser et al., 1972; Skirrow, 1977; Butzler, 1979) and were progressively applied in routine diagnostic laboratories in the 1980s (Skirrow et al., 1993). A steady increase in reported cases was observed in all countries with established surveillance systems, originally due to culturing for *Campylobacter* becoming progressively widespread. Further increases in reported disease incidence were observed in the 1990s in many industrialised countries, and these have primarily been associated with increasing consumption of fresh poultry meat (WHO, 2001). In the 2000s, countries around the world experienced different evolutions of *Campylobacter* epidemiology. Strong increases in incidence have particularly been observed in Iceland and New Zealand, followed by decreases associated with a regulatory response; a decreasing trend was also observed in the USA.

In the EU, *Campylobacter* continued to be the most commonly reported gastrointestinal bacterial pathogen in humans in the EU since 2005 and the reported rate has increased annually. No explanation for this trend at Community level is available. Partly, it may be due to increased diagnosis as in several Member States, underreporting factors are still very high. Overall, the EU average underreporting factor was estimated at 46.7, but ranging from less than 1 to more than 39,000 in different MSs. Nevertheless, in individual MSs, statistically significant increasing trends in campylobacteriosis were observed in 13 MSs including those with low underreporting rates: Belgium, Cyprus, Denmark, Estonia, France, Germany, Hungary, Ireland, Italy, Lithuania, Luxemburg, Malta and the Netherlands. A significant decreasing trend was observed in only one country, Austria.

Different approaches have been applied to understand the sources of human exposure to *Campylobacter* including case-control studies, microbial subtyping and time-series analyses. Case-control studies have revealed the complex and multifactorial nature of campylobacteriosis. Many studies have identified consumption of poultry, or more specifically broiler, meat as a key risk factor, but have also revealed a plethora of other risk factors. Exposure associated factors include untreated

water, other (raw) meats, raw or recontaminated milk, foods of non-animal origin and animal & environmental contacts (Olson et al., 2008). Host associated factors include the use of proton-pump inhibitors (PPI) and having a chronic intestinal illness (Doorduyn et al., 2010).

Microbiological subtyping, primarily using MLST, has demonstrated that most isolates from human infections are genetically related to those from poultry reservoirs with an additional important contribution from ruminant reservoirs (Wilson et al., 2008). Recently, Mughini Gras et al. (2012) have combined the case-control and microbial subtyping approach and demonstrated that risk factors for human disease vary according to the primary reservoir of the *Campylobacter* strains. Notably, eating chicken was only a risk factor for poultry-related strains, whereas direct animal contact and environmental exposures were more important for strains from other reservoirs. Host-associated factors contributed significantly to the risk for strains from all reservoirs.

Time series analyses have initially focussed on interpreting the summer peak that is observed in human incidence, notable in Northern countries. The incidence of *Campylobacter* colonization in broiler flocks and incidence of campylobacteriosis in humans showed a concordant seasonality for six European countries between 1997-2007. There was a strong association between the incidence in both broilers and humans in a given month and the mean temperature of the northern hemisphere in the same month, as well as the preceding month. De-seasonalised trends differed between countries, and could not be explained further (Jore et al., 2010). A detailed time series analysis has been conducted for the incidence of campylobacteriosis in the Grampian region of Scotland (Strachan et al., 2013a). An epidemic rise from 1990-1999 was mainly observed in adults and was associated with increased availability of poultry meat, increasing international travel and use of proton pump inhibitors. Foodborne exposures dominated the sources of infection in the peak period from 2000 and 2001. A decline and trough were observed from 2001-2006, in particular in children < 5 years in urban regions and attributed to an (unexplained) drop in foodborne cases. The ratio of rural to urban cases increased in this period, because of direct and environmental exposure to ruminant sources. In contrast, the incidence in the elderly increased due to further increasing consumption of PPI. Resurgence was observed from 2007-2011 in all age groups, but particularly in the elderly. Explanatory factors included high prevalence of *Campylobacter* in chicken, light cooking and still further increases in PPI use. By combining time-series analysis with microbial subtyping, Strachan et al. (2013b) could attribute an increase in disease incidence in young children in rural regions of the Grampian region to strains of ruminant and environmental origin, whereas adults experienced an extended summer peak associated with chicken strains, acquired domestically as well as internationally.

In Iceland, the incidence of campylobacteriosis peaked in 1999, and was associated with increasing sales of broiler meat and an increasing proportion of fresh rather than frozen meat. A regulatory response was initiated in 2000, aiming at interventions at all levels of the food chain. In particular implementation of a *Campylobacter* surveillance program in poultry and a freezing policy for meat from *Campylobacter*-positive poultry flocks are considered to have contributed to a decrease in human incidence to pre-epidemic levels (Tustin et al., 2011). In New Zealand, reported rates of campylobacteriosis and hospitalisations have increased steadily since campylobacteriosis first became notifiable 1980 and peaked at a level of > 380 per 100,000 population in 2006 (approx. 10 times higher than in the EU in the same time period). Poultry consumption, and in particular an increase in the consumption of fresh poultry, was associated with the steady increase and was estimated to contribute more than 50% of all human cases. Authorities in New Zealand established mandatory performance targets for *Campylobacter* levels on poultry carcasses after processing, and their introduction coincided with a sharp decrease in reported campylobacteriosis as well as hospitalisations (Sears et al., 2011) as well as Guillain-Barré syndrome, which is triggered a.o. by *Campylobacter* infection (Baker et al., 2012). In the USA, the incidence of campylobacteriosis in the FoodNet active surveillance system has decreased by approx. 30% from 1996-2005 with most of the decline occurring before 2005. This decline corresponds in time with the introduction of new meat and poultry safety regulations in the USA, although further evidence for a causal relationship is not available (Olson et al., 2008).



Thus, the epidemiology of campylobacteriosis is complex. Key factors associated with emergence and (in some countries) declining incidence are listed below.

Factors contributing to the emergence of human campylobacteriosis in industrialised countries

- Routine culture methods available and widely applied in diagnostic laboratories
- Increased consumption of fresh poultry meat
- Increased prevalence of *Campylobacter* in poultry flocks
- Increasing use of proton-pump inhibitors
- International travel
- Exposure to ruminant sources in rural regions
- Light cooking

Factors contributing to a decrease in human campylobacteriosis in selected countries

- Regulatory responses to reduce contamination of fresh poultry meat

### 3.3.2.2. Evaluation of GMA framework

#### *Trends in food chain production systems*

This parameter (column) is relevant because an increase in large scale intensive farming has led to a greater availability of broiler chicken meat. Once a flock is infected with *Campylobacter*, the infection spreads to virtually all animals within a week, hence any breach in biosecurity is associated with increased risks.

#### *Globalisation*

The fresh broiler meat market is mainly regional, but increasing trade in food may have contributed to the emergence of *Campylobacter*.

#### *Producer consumer behaviour*

The underlying factors can best be summarized by the state raw-animal-price driven, even though broiler meat is usually consumed well-cooked. However, the increasing demand for fresh rather than frozen broiler meat did contribute to an increase the consumer exposure to *Campylobacter*.

#### *Food & feed prices (in relation to income)*

Broiler meat is relatively inexpensive, and the increasing efficiency of primary production has greatly contributed to these low prices. Falling prices have contributed to the increase in consumption. The price aspect is also included in the variable producer-consumer behaviour.

#### *Legislation and policies in EU (enforcement)*

Even though the public health relevance of the problem is recognized, there are currently no effective control methods or standards implemented in the EU.

#### *Biological processes (proximate causes for emerging risks)*

Overall, the increasing consumption of broiler meat and fresh meat, and the high frequency of contamination with *Campylobacter*, has led to increased exposure to an existing pathogen.

### 3.3.3. Bovine spongiform encephalopathy

#### 3.3.3.1. Case description

This review is based on the TSE reports of the DG SANCO Scientific Steering Committee (SSC)<sup>7</sup>, the scientific opinions of the EFSA BIOHAZ Panel on TSE and the references therein<sup>8</sup>, and on the DG SANCO 2005<sup>9</sup> and 2010<sup>10</sup> TSE road maps.

Transmissible Spongiform Encephalopathies (TSEs) are a family of diseases occurring in man and animals and are characterised by a degeneration of brain tissue giving a sponge-like appearance leading to death. The family includes diseases such as (variant) Creutzfeldt Jakob Disease ((v)CJD) and Kuru in humans, Bovine Spongiform Encephalopathy (BSE) in cattle, Scrapie in small ruminants (sheep and goats), Chronic Wasting Disease (CWD) in cervids and Transmissible Mink Encephalopathy (TME) in mink. The commonly accepted cause of the TSE diseases is a transmissible agent called prion (PrPres), which is an abnormal form of a normal host protein. In BSE the main route of exposure was the contaminated meat and bone meal used as protein supplement in animal feeds.

The history of meat and bone meal in animal feed started over a hundred years ago when it was recommended to exploit meat and bone meal (MBM) in animal feed for pigs and cattle. During World War II there was a significant protein deficiency for animal feeds in the UK, with the consequence that offal and carcasses were converted into protein feed on a large scale.

During 1970-1980, there were large fires in rendering plants and together with increased energy costs, this led to changes in the rendering process. The major changes were the removal of ether used for fat extraction and reduced rendering temperatures and pressure to save energy. The requirements for temperature and pressure were based on the need to inactivate *Salmonella* bacteria in the offal, animal waste and fallen stock sent for rendering.

As a consequence of these changes, BSE prions were no longer sufficiently inactivated by the rendering process. One BSE infected cow could infect 10-20 new cows through the contaminated meat and bone meal in cattle feed pathway.

In addition, the whole issue of the *illegal* international trade in SRM and MBM was a very real problem for some time after the introduction of the UK ruminant meat and bone meal ban, leading to the process of dyeing all prohibited material blue in the abattoirs.

Mad cow disease (BSE) has come in waves.

- The first wave of 1985 until the present time in the UK, peaking in 1992-1993 and now likely to fade out within a few years (2020).
- The second wave in EU including Switzerland came around 10 years after the wave in the UK (due to the exports of contaminated meat and bone meal inappropriately used for cattle feeding stuffs and export of live cattle and calves). This BSE wave should also fade out in a few years in EU and Switzerland.
- A possible 3rd wave for countries outside the EU has not been detected as of yet.

From 1985 there were observations of cows with nervous signs (sound sensitivity, walking problems, changed behaviour, emaciation) that did not respond to treatment and the cows died 1-6 months after clinical onset. During 1985-86, there were several similar cases in Southern England in dairy herds. Findings such as spongiform encephalopathy at necropsy (Wells et al., 1987) of cattle were similar to

<sup>7</sup> [http://ec.europa.eu/food/fs/bse/scientific\\_advice08\\_en.html](http://ec.europa.eu/food/fs/bse/scientific_advice08_en.html)

<sup>8</sup> <http://www.efsa.europa.eu/en/topics/topic/transmissiblespongiformencephalopathies.htm>

<sup>9</sup> [http://ec.europa.eu/food/food/biosafety/tse\\_bse/docs/roadmap1\\_en.pdf](http://ec.europa.eu/food/food/biosafety/tse_bse/docs/roadmap1_en.pdf)

<sup>10</sup> [http://ec.europa.eu/food/food/biosafety/tse\\_bse/docs/roadmap\\_2\\_en.pdf](http://ec.europa.eu/food/food/biosafety/tse_bse/docs/roadmap_2_en.pdf)

findings in scrapie-infected sheep.

At this stage (1987) BSE was defined as a combination of clinical signs and neuropathological findings. Based on descriptive epidemiology (propagating epidemic, even distribution, higher risk in dairy herds), natural experiments (difference between Jersey and Guernsey, linked to meat and bone meal supply), case studies (all cases had been exposed to MBM) and a case control study, a hypothesis of exposure through contaminated meat and bone meal used as protein supplement for cattle feed was arrived at.

The ruminant meat and bone meal ban in ruminant feedstuffs in 1988, was the start of a progressive tightening during the next 15 years to a total ban of meat and bone meal in all animal feeds, rules on processed animal proteins (PAP), the SRM bans, and in UK the OTMS scheme (dairy and beef cows over 30 months were not allowed as food) and compulsory testing of all cows in the EU both at slaughter and for fallen stock. A negative result was required for the carcass to enter the food and feed chain.

A major difficulty was the average 5 year incubation period, meaning that identified cases had been exposed in the region of 5 years ago, while any control measures only had a measurable impact 3-5 years post-implementation. A major reason for the increasing control efforts in the EU was that BSE was originally (1988-1996) considered a UK only, animal health problem, while after 1996 it was considered an EU and to some extent also a global zoonotic threat as well as an animal health problem. Major issues were the uncertainties involved in assessing the risks and impact of mitigation measures, working in risks per million created a challenge for all involved. The geographical risk assessment where risks of introduction and risk of circulation of the agent was assessed, was a cornerstone in the evidence and risk based control approaches.

In 2005 the EU Commission's (DG SANCO) road map noted in conclusion

*We have come a long way and the Commission has introduced a comprehensive set of stringent Community measures. In the last 10 years, the Commission has generated 70 primary and implementing acts which set stringent measures at Community level. The key piece of legislation to protect human and animal health from the risk of BSE and other TSEs was adopted on 22 May 2001. This Regulation (EC) No 999/2001 of the European Parliament and of the Council lays down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies, and is commonly known as the "TSE Regulation". This Regulation was applicable, within a very short time frame, as of 1 July 2001.*

In 2010 progress made, enable the Commission to conclude in its TSE road map 2 : *In setting our future strategy it is also important not to lose sight of other threats to animal and public health which have emerged in recent years, such as Salmonella and antimicrobial resistance. The balance of evidence is increasingly pointing towards the need to better prioritise actions towards diseases which may have a bigger impact than TSEs in terms of public health and to set out EU funding accordingly. The encouraging trends in relation to BSE merit a considered review of the opportunities to focus on these other threats.*

The progress made is evidenced by the monitoring reports for BSE in the EU <sup>11,12</sup> which in 2012 noted: *In 2012, a total of 4,795,332 bovine animals were tested in the EU 28 in the framework of the BSE monitoring programmes. 18 bovine animals turned out positive of which 7 were atypical BSE and 11 were classical BSE cases. In 2012 1-3 typical BSE cases were found in UK, Poland, Spain, Portugal and Ireland.*

### 3.3.3.2. Evaluation of GMA framework

#### *Trends in food chain production systems*

<sup>11</sup> [http://ec.europa.eu/food/food/biosafety/tse\\_bse/docs/annual\\_report\\_tse2012\\_en.pdf](http://ec.europa.eu/food/food/biosafety/tse_bse/docs/annual_report_tse2012_en.pdf)

<sup>12</sup> [http://ec.europa.eu/food/food/biosafety/tse\\_bse/monitoring\\_annual\\_reports\\_en.htm](http://ec.europa.eu/food/food/biosafety/tse_bse/monitoring_annual_reports_en.htm)

This parameter (column) condition intensive large scale industrial farming seems to fit. Change of production processes to be included to explain the emergence first in UK. An extra state would be needed to account for the less energy demanding processing methods.

#### *Globalisation*

The emergence in the EU fits with a large cross-border mobility of animals (calves and live cattle from UK) within the EU and large and possibly increased global trade in food and feed ingredients during the last 50 years.

#### *Producer consumer behaviour*

This parameter (column) does not fit well. Additional states would be needed, and it may be necessary to consider producer and consumer behaviours separately. Possibly, prepared animal price driven fits best. The quest for cheaper foods, with the consequence that food quality and safety were subordinated priorities, meant the cheaper ingredients were sourced as protein supplements in animal feeds where hazards and pathogens were less well known and controlled.

#### *Food and feed prices (in relation to income)*

Both fluctuating and falling prices conditions fit. The downwards pressure on prices of both beef and dairy products as well as for protein ingredients in feed encouraged extensive sourcing of new protein and energy ingredients. The dioxin and BSE food safety crises are examples thereof. Demand for cheap beef meat to be included.

#### *Legislation and policies in EU (enforcement)*

During the initial phase (before 1988 in UK, mid 1990s in EU) of low public enforcement and weak self control all due to lack of knowledge about infectious agent, its true prevalence and transmission paths. The long incubation period (4-6 years) meant one was observing what happened 5 years ago which made up-to-date legislation and self control difficult. During the later phases (last 15 years) effective public/private enforcement emerged – with a comprehensive evidence based approach aimed at protecting public health (SRM bans, PAP bans, testing with negative results) and breaking the infectious cycle of cattle rendering feed for cattle (meat and bone meal bans, SRM, monitoring).

#### *Biological processes (proximate causes for emerging risks)*

The changes in rendering opened the infectious cycle of cattle - rendering - meat and bone meal - animal feeds - cattle, thereby increasing the exposure of susceptible cattle rapidly.

### **3.3.4. Infectious Salmon Anaemia**

#### **3.3.4.1. Case description**

This review is based on the AHAW Panel opinion on infectious salmon anaemia (EFSA AHAW Panel, 2012b) and references therein (fuller text in Appendix). Furthermore, it is informed by the experiences (by the author) during the outbreak phase 1989-1994, when no diagnostic test was available for the virus. From the ISA opinion some points:

Since the first detection of infectious salmon anaemia (ISA) in Norway in mid-1980s, ISA has been causing great mortalities in salmon producing countries (Canada, Chile, USA, Norway, Faroe Islands). ISA is a fish disease caused by infectious salmon anaemia virus (ISAV), an orthomyxovirus, affecting Atlantic salmon (*Salmo salar*) by inducing a systemic and lethal condition characterised by severe anaemia and variable haemorrhages and necrosis in several organs (Rimstad et al., 2011).

The ISA story was also about species domestication (of Atlantic salmon), lack of biosecurity in fish farms and lack of disease control infrastructure (diagnostics tests). This included several possibilities for e.g., horizontal transmission of the ISA virus – transports of infected salmon (boats with special tanks, return of fish from the abattoirs), no treatment of effluents from fish farms or abattoirs. No

indemnity was present for compulsory slaughter of infected fish. No diagnostic tests for the presence of virus were available.

#### 3.3.4.2. Evaluation of GMA framework

##### *Trends in food chain production systems*

This parameter (column) needs a new condition domestication of new species. Domestication increases the number of contacts between animals where diseases can be transmitted, and also domestication is stressful for animals increasing the susceptibility of the animals. The higher density of salmon with viruses might also enable more virulent pathogens to survive in a salmon population – easier to infect next fish before the current host dies.

##### *Globalisation*

The global emergence fits well with increased cross-border mobility of animals (salmon) both nationally and regionally. In the ISA case one controversy is the mobility of breeding animals (roe, smolt) exported worldwide as transmission path. Within Norway during the first 10 years of domestication of salmon the movements of salmon was essentially free flow; e.g., between sea water farms and sites, sharing transport when salmon were sent to slaughter, not accepted salmon were returned to the farm from the slaughterhouse shared transports (boats with sea-water tanks filled with salmon from several farms, and some salmon remained in the tanks when offloading, and extensive interregional movements and trade of salmon already introduced at sea (i.e. after smoltification).

##### *Producer consumer behaviour*

This parameter (column) does not fit. Possibly, the demand for vegetarian diets could also be extended to demand for fish. It is suggested to split into consumer and producer columns. With new variables (conditions) demand for healthy food, vegetarian diet including fish, eggs, milk, vegan diet, raw food diet with additives (E-substances), demand cold stored ready to eat foods, demand lower prices for food, demand ecological food. Perhaps also have producer/processor/retailer as a separate parameter with following variables (conditions): longer shelf life, cost pressures, transparency of food chain, lower risks, etc.

##### *Food and feed prices (in relation to income)*

The salmon started with very high prices, being a luxury food item and the prices have been fluctuating but falling thereafter. Hence both fluctuating and falling prices conditions fit.

##### *Legislation and policies in EU (enforcement)*

During the initial phase of low public enforcement and weak self control. This is somewhat generic to new production/domestication of species - lack of knowledge, lack of diagnostic tools, lack of biosecurity infrastructure, change of culture from deep sea fishing to aquaculture and also of high risk acceptance. No integration from farm to fork meant sub-optimization of the whole food chain was a problem. Ownership problems (bankruptcies), insurance companies not willing to consider externalities (transmission of disease from infected fish not yet slaughtered) were also a problem magnifying the risk. During the later phases (last 20 years) effective public/private enforcement emerged – lower risk acceptance and vertical integration, better disease control knowledge, veterinary infrastructure and diagnostic tools available resulting in better biosecurity. Knowledge driven biosecurity and rules implemented, e.g., stop for movements of salmon introduced at sea to other sites.

##### *Biological processes (proximate causes for emerging risks)*

The domestication of salmon increased the potential for new virulent traits of the ISA virus to emerge and also increased the exposure of susceptible salmon to the virulent ISA virus. As domestication of salmon is stressful the salmon would also be more susceptible than the wild salmon.

### 3.3.5. The Asian Longhorned Beetle, *Anoplophora glabripennis*

#### 3.3.5.1. Case description

The Asian longhorned beetle (ALB) is a Cerambycid beetle that oviposits in the bark of a range of broadleaved trees (Haack et al., 2010). The larvae feed on the phloem, and dense populations result in tree death. ALB is spread mainly by wood packaging material and originates in China, Korea and Japan. ALB outbreaks and range expansion in China were linked to widespread afforestation and reforestation programs that began in eastern China in the 1960s, using mostly native *Populus dakuanensis*, a species later found to be highly susceptible to ALB. The largest of the tree-planting programs was the Three-North Shelterbelt Forest Program, initiated in the arid regions of northern China in 1978 with the goal of establishing forests on more than 35 million ha by 2050. The main goal of the Three-North Program was to increase forest cover and thereby slow desertification and reduce soil erosion. A secondary goal was to increase lumber production. Initially, *Populus*, *Salix*, and *Ulmus* were the principal genera planted, including several exotic *Populus* species. Single clones were used in some plantings, and mixed species or clones were used in others. As of 2003, over 22 million ha had been planted in the Three-North Program. Widespread tree mortality has been reported in several provinces, especially where ALB-susceptible *Populus* species were planted. For example, more than 80 million infested trees were cut in Ningxia and 11 million in Inner Mongolia, Heilongjiang, Jilin, Tibet, and Xinjiang. The first reported ALB interception was in 1992 in both Canada and the United States. In the EU, it was first observed in Austria in 2001, but is now present in several member states (FR, DE, GB, ...). It mainly attacks urban trees, but has been observed to develop in forested areas in the US.

#### 3.3.5.2. Evaluation of GMA framework

##### *Trends in food chain systems in Europe*

As trees do not belong to the food chain, the parameter should be broadened to agricultural and forestry production.

##### *Globalisation*

ALB mostly travels in wood packaging material (crates, pallets, dunnage) used to transport a wide range of goods. The beetles have for example often been intercepted with stone shipments or machinery from Asia. The increasing commercial exchanges favour these movements. (MacLeod et al. 2002; Van Der Gaaget al. 2008)

##### *Producer-consumer behaviour/interactions*

A taste for exotic building materials and products manufactured in Asia might favour the introduction of this pest via infested wood packaging.

##### *Food & feed prices in EU (in relation to income)*

Food and feed are not relevant, but prices in EU are. The lower cost of stone or machinery from Asia is a strong incentive to import them.

##### *Legislation and policies in EU (enforcement)*

The International Standards for Phytosanitary Measures No. 15 (FAO, 2009) is an International Phytosanitary Measure developed by the International Plant Protection Convention (IPPC) that directly addresses the need to treat wood materials of a thickness greater than 6mm, used to ship products between countries. Its main purpose is to prevent the international transport and spread of disease and insects that could negatively affect plants or ecosystems. ISPM 15 affects all wood packaging material (pallets, crates, dunnages, etc.) requiring that they be debarked and then heat treated or fumigated with methyl bromide and stamped or branded with a mark of compliance. The EU has adopted ISPM 15 in 2005, along with many other countries.

##### *Biological processes (proximate causes for emerging risks)*

Rather, perhaps, "ultimate vs. proximate biological processes".

- Ultimate: reforestation in Asia under inappropriate conditions (e.g. the "Green Wall", or "Three-North Shelterbelt Program" in China (started in 1978), designed to stop the extension of the Gobi desert. A huge proportion of the millions of poplars planted in arid or semi-arid areas died rapidly (Cao, 2008; Gao et al, 1993; Taketani, 2001). This provided cheap wood for packaging. The dying trees were extremely vulnerable to xylophagous insects such as cerambycids.
- Proximate: the polyphagy of the pest; the existence of many suitable host trees; urban trees made vulnerable because of their growing conditions.

### 3.3.6. The tomato leafminer, *Tuta absoluta*

#### 3.3.6.1. Case Description

*Tuta absoluta* (tomato borer, South American tomato moth, tomato leafminer) was first introduced from South America into Spain in 2006 (Desneux et al, 2010). In the past few years *T. absoluta* has spread rapidly through countries in the Mediterranean Basin and Near East. It has also threatened glasshouse production in Northern Europe. With its high reproductive capacity, *T. absoluta* is considered to be one of the most important lepidopterous pests on tomato. It also occurs on other plants of the Solanaceous family (aubergine, potato, weed species e.g. *Solanum nigrum*).

Until the early nineties tomatoes in North Western Europe (in particular the Netherlands) were mass produced and marketed as single fruits (as opposed to vine tomatoes), without a cultivar or brand name. However, consumers developed a demand for more tasty tomatoes and required a choice from different types of tomatoes, e.g. vine tomatoes, beefsteak tomatoes and cherry tomatoes, which were supplied by Spain, Morocco and Italy. Northern European producers responded by developing more attractive varieties and different production techniques allowing for marketing of, for example, vine tomatoes under brand names (Huets and Mol, 2013). In the following years a strong demand for vine tomatoes developed, which were supplied not only from European production, but also from import from third countries (e.g. Central and South America). Tomatoes from third countries were imported before, but these were mainly single fruits, in bulk, without green parts (stems and leaves), which were repacked for retail at locations where there was no tomato production. Pests and diseases could be readily detected by inspections of these fruits and introduction of exotic pests did not occur. With the change in consumer demand a change of import occurred and vine tomatoes were introduced from third countries. The green stems and leaves could carry pests and diseases not occurring on or in the fruits, but there was no change in plant health inspection requirements to accommodate to this new product. Moreover, repacking of bulk vine tomatoes for retail required special equipment in use by European tomato producers (they had changed to production systems for producing vine tomatoes) and repacking of exotic vine tomatoes was performed at tomato production places in Europe.

These factors combined (changed consumer demand, infestation by new pests and diseases, and handling of infested product at places of production) allowed for the unnoticed introduction of *T. absoluta* with consignments of vine tomato imported from Central or South America in 2006, the subsequent establishment on tomato production places, and the rapid spread via trade of tomatoes over Europe and the Near East.

#### 3.3.6.2. Evaluation of GMA framework

##### *Trends in food chain systems in Europe*

For addressing plant health risks the food chain system should identify the production segments as well as the trade segments of the food chain and their interactions. With respect to plant health, producers and traders have different and conflicting interests, but they depend on each other. In plant health many risks emerged due to the interaction between trade activities and production activities, allowing pests to move from traded commodities to growing plants.

### *Globalization*

If instead of ‘animals’ ‘plants’ are read, the driver fits the case rather well. For plant health ‘plants for planting’ and ‘plants and products for end use’ should be distinguished because of the difference in associated risk. A similar approach would be relevant for animal health, e.g. animals for breeding and animals for slaughter. Perhaps it could be better focused, e.g. include an awareness of quality and safety.

### *Producer-consumer behaviour/interactions*

The driver is relevant but the states of this driver do not fit for plant health. The market changes may be supply driven (marketing of modified plants, new varieties) or demand driven. If demand driven, plant health risks are associated with novelty food plants (exotic cucumbers, peppers) but also ornamental plants (palms and flowers seen in holiday resorts). Plant health risks are associated only with living plants. The interactions are complicated because consumer demands are noticed by traders rather than producers; traders give signals to producers or put pressure on producers. So response of producers to consumers is often modified by the trade segment of the supply chain.

### *Food and feed prices in EU (in relation to income)*

This driver fits, but in an indirect way; affecting the other driver ‘producer-consumer interactions’. These price effects would determine the ‘space’ on the market for exotic commodities.

### *Legislation and policies in EU (enforcement)*

This is a very important driver for plant health risks. Just as important is the observance by producers (and every citizen) of the legislation. Increase of awareness and responsibility towards the targets of the legislation are more important than enforcement, because there are too many transactions in plant trade and too many movements of plants for control.

### *Biological processes (proximate causes for emerging risks)*

This driver and its states fit well for plant health risks.

### *Need for additional columns*

The supply chain for plants with its varying purposes (food; indoor ornamentals and flowers; garden, forest and park plants) and complex interactions between producers (specialized for different stages of plants), traders, and ‘consumers’ is too vast to fit in one column. Moreover, the risks depend on the interactions.



### 3.4. Concluding remarks on GMA

GMA was piloted as a potential tool for evaluating the impact of drivers for emerging risks affecting animal, plant and public health. GMA was found to be a promising tool, but further development of the current prototype is needed. In particular the parameters need to be adjusted taking into consideration the following:

- The parameter ‘trends in food chain systems’ needs an extra state related to change in processing methods
- The parameter ‘trends in food chain systems’ needs an extra state on domestication of new species
- Globalisation primarily affects possibilities of horizontal transmission across national or regional borders.
- The parameter producer/consumer behaviour is too aggregated and should be split into producer behaviour and consumer behaviour including risk acceptance.
- States of the new parameter consumer behaviour should be more specific (e.g. animal derived diet is too unspecific and should be replaced by consumption of meat from specific animal species).
- Even though the framework was developed for human and animal viruses, it was also found to be applicable for plant health (i.e. pests) and other hazard to human and animal health (i.e. bacteria, prions).
- A narrative/story is needed for each parameter and what the different states are meant to capture in terms of risk for emerging diseases.

## 4. Next steps

Further development of the GMA framework is suggested, balancing the need for a generic framework with the details needed to come to specific conclusions. In addition, other methodologies for scenario building and horizon scanning should be explored.

For the GMA approach to be useful it may be considered to have several different frameworks/columns and cells appropriate for different categories of hazards (i.e. bacterial zoonotic pathogens, animal viruses (zoonotic and non-zoonotic), foodborne non-zoonotic pathogens (Norovirus, Shigella etc.), parasites, etc.)

The current GMA model is not evidence based. To arrive at an evidence-based GMA model, inclusion of wider expertise is needed (e.g. experts with knowledge on food systems, trade, economics, social sciences, systems analysis, legislation, political sciences). Such knowledge could come from academia, governments or industry.

As the main drivers in the preliminary GMA framework are also relevant for other domains of EFSA’s work (e.g. chemical risk, nutrition, etc.) broadening the scope of future activities to all of EFSA’s remit should be considered to aim for an overarching approach to Emerging Risks identification.

The ability of the GMA to predict areas of concern without false positives and false negatives in relation to emerging risks, should be assessed.

## CONCLUSIONS AND RECOMMENDATIONS

### CONCLUSIONS

- The present work aims at identifying and prioritising drivers of emerging risks and their interactions in the domain of biological risks to animal, plant and public health. This would inform strategies to monitor factors leading to disease emergence and risk based disease surveillance.
- The identification and prioritization of emerging risks is a complex process involving the gathering and evaluation of large amounts of information from different sources.
- The EFSA definition of emerging risks can be made more applicable to emerging biological risks by considering any risk as new if it has not yet been observed in the EU territory and may require attention by EU risk managers, and by further differentiating the category of new exposures to include species jumps and geographic jumps.
- Steps were taken towards a structured approach for identification of drivers of emerging biological risks and their interactions.
- An expert consultation involving the EFSA BIOHAZ and AHAW Panels identified a list of drivers that are considered to influence the emergence of biological risks.
- The identified drivers are highly connected, but may show effects on different timescales.
- Several identified drivers are in areas outside EFSA's existing expertise.
- The General Morphological Analysis (GMA) seems to be a promising tool for evaluating the complex interaction between drivers.
- A prototype GMA model was developed, which needs to be further developed in order to be a practical working tool to identify and prioritize drivers of emerging risks.
- The prototype GMA model was meant as a pilot study.
- The GMA approach needs further refinement in order to consider whether one generic model could be applicable or whether several specific models should be used.
- The ability of the GMA to predict areas of concern without false positives and false negatives in relation to emerging risks, should be assessed.

### RECOMMENDATIONS

- EFSA should further develop the GMA approach outlined in this report as a tool to achieve a proactive assessment of emerging biological risks and consider broadening the approach to all of EFSA's remit.
- It is necessary to include expertise on food systems, trade, economics, social sciences, etc., in the identification of drivers and their inclusion in the GMA approach.
- EFSA's activities on drivers of emerging risks should focus on gathering further information in the areas where the lack of expertise was identified.

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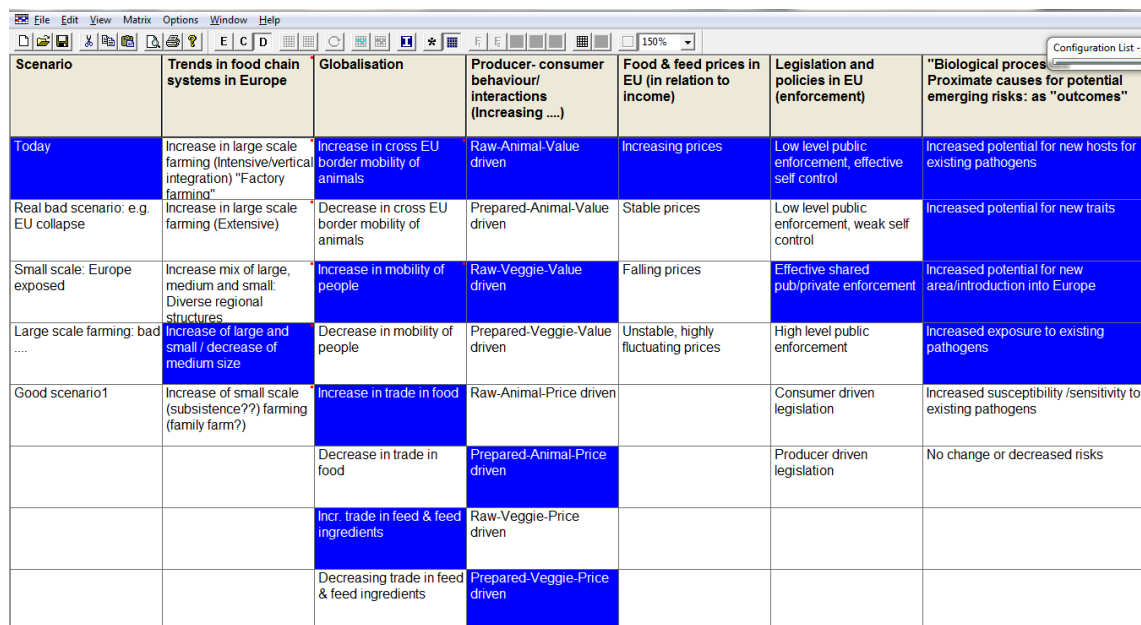
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## APPENDICES

### Appendix A. GMA: TESTBED SCENARIOS



Scenario	Trends in food chain systems in Europe	Globalisation	Producer- consumer behaviour/ interactions (Increasing ....)	Food & feed prices in EU (in relation to income)	Legislation and policies in EU (enforcement)	"Biological processes" Proximate causes for potential emerging risks: as "outcomes"
Today	Increase in large scale farming (Intensive/vertical integration) "Factory farming"	Increase in cross EU border mobility of animals	Raw-Animal-Value driven	Increasing prices	Low level public enforcement, effective self control	Increased potential for new hosts for existing pathogens
Real bad scenario: e.g. EU collapse	Increase in large scale farming (Extensive)	Decrease in cross EU border mobility of animals	Prepared-Animal-Value driven	Stable prices	Low level public enforcement, weak self control	Increased potential for new traits
Small scale: Europe exposed	Increase mix of large, medium and small. Diverse regional structures	Increase in mobility of people	Raw-Veggie-Value driven	Falling prices	Effective shared pub/private enforcement	Increased potential for new area/introduction into Europe
Large scale farming: bad ....	Increase of large and small / decrease of medium size	Decrease in mobility of people	Prepared-Veggie-Value driven	Unstable, highly fluctuating prices	High level public enforcement	Increased exposure to existing pathogens
Good scenario1	Increase of small scale (subsistence??) farming (family farm?)	Increase in trade in food	Raw-Animal-Price driven		Consumer driven legislation	Increased susceptibility /sensitivity to existing pathogens
		Decrease in trade in food	Prepared-Animal-Price driven		Producer driven legislation	No change or decreased risks
		Incr. trade in feed & feed ingredients	Raw-Veggie-Price driven			
		Decreasing trade in feed & feed ingredients	Prepared-Veggie-Price driven			

Figure A.1. Scenario based on present day trends.

Scenario	Trends in food chain systems in Europe	Globalisation	Producer- consumer behaviour/ interactions (Increasing ....)	Food & feed prices in EU (in relation to income)	Legislation and policies in EU (enforcement)	"Biological processes" Proximate causes for potential emerging risks: as "outcomes"
Today	Increase in large scale farming (Intensive/vertical integration) "Factory farming"	Increase in cross EU border mobility of animals	Raw-Animal-Value driven	Increasing prices	Low level public enforcement, effective self control	Increased potential for new hosts for existing pathogens
<b>Collapse of EU</b>	Increase in large scale farming (Extensive)	Decrease in cross EU border mobility of animals	Prepared-Animal-Value driven	Stable prices	Low level public enforcement, weak self control	Increased potential for new traits
Small scale: Europe exposed	Increase mix of large, medium and small. Diverse regional structures	Increase in mobility of people	Raw-Veggie-Value driven	Falling prices	Effective shared pub/private enforcement	Increased potential for new area/introduction into Europe
Large scale farming	Increase of large and small / decrease of medium size	Decrease in mobility of people	Prepared-Veggie-Value driven	Unstable, highly fluctuating prices	High level public enforcement	Increased exposure to existing pathogens
Positive development: good mix	Increase of small scale (subsistence??) farming (family farm?)	Increase in trade in food	Raw-Animal-Price driven		Consumer driven legislation	Increased susceptibility /sensitivity to existing pathogens
		Decrease in trade in food	Prepared-Animal-Price driven		Producer driven legislation	No change or decreased risks
		Incr. trade in feed & feed ingredients	Raw-Veggie-Price driven			
		Decreasing trade in feed & feed ingredients	Prepared-Veggie-Price driven			

Figure A.2. Scenario based on possible collapse of EU.

Scenario	Trends in food chain systems in Europe	Globalisation	Producer- consumer behaviour/ interactions (Increasing ....)	Food & feed prices in EU (in relation to income)	Legislation and policies in EU (enforcement)	"Biological processes" Proximate causes for potential emerging risks: as "outcomes"
Today	Increase in large scale farming (Intensive/vertical integration) "Factory farming"	Increase in cross EU border mobility of animals	Raw-Animal-Value driven	Increasing prices	Low level public enforcement, effective self control	Increased potential for new hosts for existing pathogens
Collapse of EU	Increase in large scale farming (Extensive)	Decrease in cross EU border mobility of animals	Prepared-Animal-Value driven	Stable prices	Low level public enforcement, weak self control	Increased potential for new traits
Small scale: Europe exposed	Increase mix of large, medium and small: Diverse regional structures	Increase in mobility of people	Raw-Veggie-Value driven	Falling prices	Effective shared pub/private enforcement	Increased potential for new area/introduction into Europe
Large scale farming	Increase of large and small / decrease of medium size	Decrease in mobility of people	Prepared-Veggie-Value driven	Unstable, highly fluctuating prices	High level public enforcement	Increased exposure to existing pathogens
Positive development: good mix	Increase of small scale (subsistence??) farming (family farm?)	Increase in trade in food	Raw-Animal-Price driven		Consumer driven legislation	Increased susceptibility /sensitivity to existing pathogens
		Decrease in trade in food	Prepared-Animal-Price driven		Producer driven legislation	No change or decreased risks
		Incr. trade in feed & feed ingredients	Raw-Veggie-Price driven			
		Decreasing trade in feed & feed ingredients	Prepared-Veggie-Price driven			

Figure A.3. Scenario based on small scale farming in the EU.

Scenario	Trends in food chain systems in Europe	Globalisation	Producer- consumer behaviour/ interactions (Increasing ....)	Food & feed prices in EU (in relation to income)	Legislation and policies in EU (enforcement)	"Biological processes" Proximate causes for potential emerging risks: as "outcomes"
Today	Increase in large scale farming (Intensive/vertical integration) "Factory farming"	Increase in cross EU border mobility of animals	Raw-Animal-Value driven	Increasing prices	Low level public enforcement, effective self control	Increased potential for new hosts for existing pathogens
Collapse of EU	Increase in large scale farming (Extensive)	Decrease in cross EU border mobility of animals	Prepared-Animal-Value driven	Stable prices	Low level public enforcement, weak self control	Increased potential for new traits
Small scale: Europe exposed	Increase mix of large, medium and small: Diverse regional structures	Increase in mobility of people	Raw-Veggie-Value driven	Falling prices	Effective shared pub/private enforcement	Increased potential for new area/introduction into Europe
Large scale farming	Increase of large and small / decrease of medium size	Decrease in mobility of people	Prepared-Veggie-Value driven	Unstable, highly fluctuating prices	High level public enforcement	Increased exposure to existing pathogens
Positive development: good mix	Increase of small scale (subsistence??) farming (family farm?)	Increase in trade in food	Raw-Animal-Price driven		Consumer driven legislation	Increased susceptibility /sensitivity to existing pathogens
		Decrease in trade in food	Prepared-Animal-Price driven		Producer driven legislation	No change or decreased risks
		Incr. trade in feed & feed ingredients	Raw-Veggie-Price driven			
		Decreasing trade in feed & feed ingredients	Prepared-Veggie-Price driven			

Figure A.4. Scenario based on large scale farming in the EU.



Scenario	Trends in food chain systems in Europe	Globalisation	Producer- consumer behaviour/ interactions (Increasing ....)	Food & feed prices in EU (in relation to income)	Legislation and policies in EU (enforcement)	"Biological processes" Proximate causes for potential emerging risks: as "outcomes"
Today	Increase in large scale farming (Intensive/vertical integration) "Factory farming"	Increase in cross EU border mobility of animals	Raw-Animal-Value driven	Increasing prices	Low level public enforcement, effective self control	Increased potential for new hosts for existing pathogens
Collapse of EU	Increase in large scale farming (Extensive)	Decrease in cross EU border mobility of animals	Prepared-Animal-Value driven	Stable prices	Low level public enforcement, weak self control	Increased potential for new traits
Small scale: Europe exposed	Increase mix of large, medium and small. Diverse regional structures	Increase in mobility of people	Raw-Veggie-Value driven	Falling prices	Effective shared pub/private enforcement	Increased potential for new area/introduction into Europe
Large scale farming	Increase of large and small / decrease of medium size	Decrease in mobility of people	Prepared-Veggie-Value driven	Unstable, highly fluctuating prices	High level public enforcement	Increased exposure to existing pathogens
Positive development: good mix	Increase of small scale (subsistence??) farming (family farm?)	Increase in trade in food	Raw-Animal-Price driven		Consumer driven legislation	Increased susceptibility /sensitivity to existing pathogens
		Decrease in trade in food	Prepared-Animal-Price driven		Producer driven legislation	No change or decreased risks
		Incr. trade in feed & feed ingredients	Raw-Veggie-Price driven			
		Decreasing trade in feed & feed ingredients	Prepared-Veggie-Price driven			

Figure A.5. Scenario based on good mix of small and large scale farming in the EU.

## Appendix B. GMA: PROXIMATE CAUSES FOR POTENTIAL EMERGING RISKS AS OUTCOMES

Scenario	Trends in food chain systems in Europe	Globalisation	Producer- consumer behaviour/ interactions (Increasing ....)	Food & feed prices in EU (in relation to income)	Legislation and policies in EU (enforcement)	"Biological processes" Proximate causes for potential emerging risks: as "outcomes"
Today	Increase in large scale farming (Intensive/vertical integration) "Factory farming"	Increase in cross EU border mobility of animals	Raw-Animal-Value driven	Increasing prices	Low level public enforcement, effective self control	Increased potential for new hosts for existing pathogens
Collapse of EU	Increase in large scale farming (Extensive)	Decrease in cross EU border mobility of animals	Prepared-Animal-Value driven	Stable prices	Low level public enforcement, weak self control	Increased potential for new traits
Small scale: Europe exposed	Increase mix of large, medium and small: Diverse regional structures	Increase in mobility of people	Raw-Veggie-Value driven	Falling prices	Effective shared pub/private enforcement	Increased potential for new area/introduction into Europe
Large scale farming	Increase of large and small / decrease of medium size	Decrease in mobility of people	Prepared-Veggie-Value driven	Unstable, highly fluctuating prices	High level public enforcement	Increased exposure to existing pathogens
Positive development: good mix	Increase of small scale (subsistence??) farming (family farm?)	Increase in trade in food	Raw-Animal-Price driven		Consumer driven legislation	Increased susceptibility /sensitivity to existing pathogens
		Decrease in trade in food	Prepared-Animal-Price driven		Producer driven legislation	No change or decreased risks
		Incr. trade in feed & feed ingredients	Raw-Veggie-Price driven			
		Decreasing trade in feed & feed ingredients	Prepared-Veggie-Price driven			

**Figure B.1.** Scenario leading to increased potential for new hosts for existing pathogens.

Scenario	Trends in food chain systems in Europe	Globalisation	Producer- consumer behaviour/ interactions (Increasing ....)	Food & feed prices in EU (in relation to income)	Legislation and policies in EU (enforcement)	"Biological processes" Proximate causes for potential emerging risks: as "outcomes"
Today	Increase in large scale farming (Intensive/vertical integration) "Factory farming"	Increase in cross EU border mobility of animals	Raw-Animal-Value driven	Increasing prices	Low level public enforcement, effective self control	Increased potential for new hosts for existing pathogens
Collapse of EU	Increase in large scale farming (Extensive)	Decrease in cross EU border mobility of animals	Prepared-Animal-Value driven	Stable prices	Low level public enforcement, weak self control	Increased potential for new traits
Small scale: Europe exposed	Increase mix of large, medium and small: Diverse regional structures	Increase in mobility of people	Raw-Veggie-Value driven	Falling prices	Effective shared pub/private enforcement	Increased potential for new area/introduction into Europe
Large scale farming	Increase of large and small / decrease of medium size	Decrease in mobility of people	Prepared-Veggie-Value driven	Unstable, highly fluctuating prices	High level public enforcement	Increased exposure to existing pathogens
Positive development: good mix	Increase of small scale (subsistence??) farming (family farm?)	Increase in trade in food	Raw-Animal-Price driven		Consumer driven legislation	Increased susceptibility /sensitivity to existing pathogens
		Decrease in trade in food	Prepared-Animal-Price driven		Producer driven legislation	No change or decreased risks
		Incr. trade in feed & feed ingredients	Raw-Veggie-Price driven			
		Decreasing trade in feed & feed ingredients	Prepared-Veggie-Price driven			

**Figure B.2.** Scenario leading to increased potential for new traits.

Scenario	Trends in food chain systems in Europe	Globalisation	Producer- consumer behaviour/ interactions (Increasing ....)	Food & feed prices in EU (in relation to income)	Legislation and policies in EU (enforcement)	"Biological processes" Proximate causes for potential emerging risks: as "outcomes"
Today	Increase in large scale farming (Intensive/vertical integration) "Factory farming"	Increase in cross EU border mobility of animals	Raw-Animal-Value driven	Increasing prices	Low level public enforcement, effective self control	Increased potential for new hosts for existing pathogens
Collapse of EU	Increase in large scale farming (Extensive)	Decrease in cross EU border mobility of animals	Prepared-Animal-Value driven	Stable prices	Low level public enforcement, weak self control	Increased potential for new traits
Small scale: Europe exposed	Increase mix of large, medium and small: Diverse regional structures	Increase in mobility of people	Raw-Veggie-Value driven	Falling prices	Effective shared pub/private enforcement	Increased potential for new area/introduction into Europe
Large scale farming	Increase of large and small / decrease of medium size	Decrease in mobility of people	Prepared-Veggie-Value driven	Unstable, highly fluctuating prices	High level public enforcement	Increased exposure to existing pathogens
Positive development: good mix	Increase of small scale (subsistence??) farming (family farm?)	Increase in trade in food	Raw-Animal-Price driven		Consumer driven legislation	Increased susceptibility /sensitivity to existing pathogens
		Decrease in trade in food	Prepared-Animal-Price driven		Producer driven legislation	No change or decreased risks
		Incr. trade in feed & feed ingredients	Raw-Veggie-Price driven			
		Decreasing trade in feed & feed ingredients	Prepared-Veggie-Price driven			

**Figure B.3.** Scenario leading to increased potential for new area/introduction into Europe.

Scenario	Trends in food chain systems in Europe	Globalisation	Producer- consumer behaviour/ interactions (Increasing ....)	Food & feed prices in EU (in relation to income)	Legislation and policies in EU (enforcement)	"Biological processes" Proximate causes for potential emerging risks: as "outcomes"
Today	Increase in large scale farming (Intensive/vertical integration) "Factory farming"	Increase in cross EU border mobility of animals	Raw-Animal-Value driven	Increasing prices	Low level public enforcement, effective self control	Increased potential for new hosts for existing pathogens
Collapse of EU	Increase in large scale farming (Extensive)	Decrease in cross EU border mobility of animals	Prepared-Animal-Value driven	Stable prices	Low level public enforcement, weak self control	Increased potential for new traits
Small scale: Europe exposed	Increase mix of large, medium and small: Diverse regional structures	Increase in mobility of people	Raw-Veggie-Value driven	Falling prices	Effective shared pub/private enforcement	Increased potential for new area/introduction into Europe
Large scale farming	Increase of large and small / decrease of medium size	Decrease in mobility of people	Prepared-Veggie-Value driven	Unstable, highly fluctuating prices	High level public enforcement	Increased exposure to existing pathogens
Positive development: good mix	Increase of small scale (subsistence??) farming (family farm?)	Increase in trade in food	Raw-Animal-Price driven		Consumer driven legislation	Increased susceptibility /sensitivity to existing pathogens
		Decrease in trade in food	Prepared-Animal-Price driven		Producer driven legislation	No change or decreased risks
		Incr. trade in feed & feed ingredients	Raw-Veggie-Price driven			
		Decreasing trade in feed & feed ingredients	Prepared-Veggie-Price driven			

**Figure B.4** Scenario leading to increased exposure to existing pathogens.

Scenario	Trends in food chain systems in Europe	Globalisation	Producer- consumer behaviour/ interactions (Increasing ....)	Food & feed prices in EU (in relation to income)	Legislation and policies in EU (enforcement)	"Biological process" Proximate causes for potential emerging risks: as "outcomes"
Today	Increase in large scale farming (Intensive/vertical integration) "Factory farming"	Increase in cross EU border mobility of animals	Raw-Animal-Value driven	Increasing prices	Low level public enforcement, effective self control	Increased potential for new hosts for existing pathogens
Collapse of EU	Increase in large scale farming (Extensive)	Decrease in cross EU border mobility of animals	Prepared-Animal-Value driven	Stable prices	Low level public enforcement, weak self control	Increased potential for new traits
Small scale: Europe exposed	Increase mix of large, medium and small: Diverse regional structures	Increase in mobility of people	Raw-Veggie-Value driven	Falling prices	Effective shared pub/private enforcement	Increased potential for new area/introduction into Europe
Large scale farming	Increase of large and small / decrease of medium size	Decrease in mobility of people	Prepared-Veggie-Value driven	Unstable, highly fluctuating prices	High level public enforcement	Increased exposure to existing pathogens
Positive development: good mix	Increase of small scale (subsistence??) farming (family farm?)	Increase in trade in food	Raw-Animal-Price driven		Consumer driven legislation	Increased susceptibility /sensitivity to existing pathogens
		Decrease in trade in food	Prepared-Animal-Price driven		Producer driven legislation	No change or decreased risks
		Incr. trade in feed & feed ingredients	Raw-Veggie-Price driven			
		Decreasing trade in feed & feed ingredients	Prepared-Veggie-Price driven			

Figure B.5. Scenario leading to increased susceptibility /sensitivity to existing pathogens.

Scenario	Trends in food chain systems in Europe	Globalisation	Producer- consumer behaviour/ interactions (Increasing ....)	Food & feed prices in EU (in relation to income)	Legislation and policies in EU (enforcement)	"Biological process" Proximate causes for potential emerging risks: as "outcomes"
Today	Increase in large scale farming (Intensive/vertical integration) "Factory farming"	Increase in cross EU border mobility of animals	Raw-Animal-Value driven	Increasing prices	Low level public enforcement, effective self control	Increased potential for new hosts for existing pathogens
Collapse of EU	Increase in large scale farming (Extensive)	Decrease in cross EU border mobility of animals	Prepared-Animal-Value driven	Stable prices	Low level public enforcement, weak self control	Increased potential for new traits
Small scale: Europe exposed	Increase mix of large, medium and small: Diverse regional structures	Increase in mobility of people	Raw-Veggie-Value driven	Falling prices	Effective shared pub/private enforcement	Increased potential for new area/introduction into Europe
Large scale farming	Increase of large and small / decrease of medium size	Decrease in mobility of people	Prepared-Veggie-Value driven	Unstable, highly fluctuating prices	High level public enforcement	Increased exposure to existing pathogens
Positive development: good mix	Increase of small scale (subsistence??) farming (family farm?)	Increase in trade in food	Raw-Animal-Price driven		Consumer driven legislation	Increased susceptibility /sensitivity to existing pathogens
		Decrease in trade in food	Prepared-Animal-Price driven		Producer driven legislation	No change or decreased risks
		Incr. trade in feed & feed ingredients	Raw-Veggie-Price driven			
		Decreasing trade in feed & feed ingredients	Prepared-Veggie-Price driven			

Figure B.6. Scenario leading to no change or decreased risks.