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# General tasks and structure of the European Food Safety Authority (EFSA) and its role on risk assessment for microbiological hazards

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**Abstract.** The European Food Safety Authority (EFSA) is the keystone of European Union (EU) risk assessment for food and feed safety. EFSA provides independent scientific advice and information about existing and emerging risks following a farm to fork approach. When a food safety question on biological hazards is to be answered, which is under the remit of the EFSA's Scientific Panel on Biological Hazards (BIOHAZ), whenever possible and as a basis for their work, the risk assessment framework developed by Codex Alimentarius is applied. BIOHAZ opinions cover different approaches ranging from quantitative risk assessments over structured qualitative risk assessment/risk ranking to opinions with short deadlines summarising existing knowledge from the scientific literature. The approach taken depends on the terms of reference as received from the requestor, the available data and resources and the timeframe for the work. This paper reviews the integrated approach followed by EFSA towards risk assessment, with a special focus on human health and the whole food chain, and on science based interventions to lower the risk to consumers. The outcomes of some of the activities developed during the last two years (July 2012 until May 2014) by the current BIOHAZ Panel were summarised.

**Keywords.** EFSA – BIOHAZ – Risk assessment – Microbiological hazards.

## ***Fonctions générales et structure de l'Autorité européenne de sécurité des aliments (EFSA) et son rôle dans l'évaluation des risques microbiologiques***

**Résumé.** L'Autorité européenne de sécurité des aliments (EFSA) est la pierre angulaire de l'Union européenne (UE) pour ce qui concerne l'évaluation des risques relatifs à la sécurité des aliments destinés à l'alimentation humaine et animale. L'EFSA fournit des avis scientifiques indépendants ainsi qu'une communication claire sur les risques existants et émergents en suivant une approche de la ferme à la fourchette. Lorsqu'une question de sécurité alimentaire est adressée, qui relève du domaine de compétence du groupe scientifique de l'EFSA sur les dangers biologiques (BIOHAZ), il est appliqué autant que possible et en tant que base pour le travail du groupe, le cadre d'évaluation des risques développé par le Codex Alimentarius. Les avis du groupe BIOHAZ couvrent différentes approches allant de l'évaluation quantitative des risques liée à une évaluation qualitative structurée de risques/classification des risques à des avis sous délai rapide résumant les connaissances existantes à partir de la littérature scientifique. L'approche retenue dépend des termes de référence formulés par le demandeur, des données et ressources disponibles, et du délai imparti à ce travail. Cet article passe en revue l'approche intégrée suivie par l'EFSA concernant l'évaluation des risques, en particulier axées sur la santé humaine et la chaîne alimentaire dans son ensemble, et les interventions fondées sur la science visant à diminuer les risques pour les consommateurs. Finalement sont résumés les résultats de certaines activités menées par l'actuel groupe BIOHAZ sur les deux dernières années (de juillet 2012 à mai 2014).

**Mots-clés.** EFSA – BIOHAZ – Évaluation des risques – Dangers microbiologiques.

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## I – Introduction

The European Food Safety Authority (EFSA) was set up in January 2002, following a series of food crises in the late 1990s (Bovine Spongiform Encephalopathy - BSE, dioxin, foot and mouth disease, etc), as part of a comprehensive programme to improve European Union (EU) food safety systems, to ensure a high level of consumer protection and to restore and maintain confidence in the EU food supply. As the risk assessor, EFSA produces scientific opinions and advice to provide a sound foundation for European policies and legislation and to support the European Commission (EC), European Parliament (EP) and EU Member States (MSs) in taking effective and timely risk management decisions. EFSA's remit covers food and feed safety, nutrition, animal health and welfare, plant protection and plant health. In all these fields, EFSA's most critical commitment is to provide objective and independent science-based advice and clear communication grounded in the most up-to-date scientific information and knowledge. In the EU, food legislation has to be based on "risk analysis" following the Founding Regulation EC No 178/2002 (EU, 2002), which establishes EFSA and the general principles governing food and feed safety. The risk analysis framework, as initially defined by FAO, WHO and the Codex Alimentarius Commission (CAC, 1999), consists of three separate but interconnected elements: risk assessment, risk management and risk communication. This paper aims to explain the mission and structure of EFSA and its role on developing risk assessments. It also describes the specific mission of the BIOHAZ Panel, the procedure of its work, the activities developed in the area of microbiological risk assessment, and its latest scientific opinions or reports related to food-borne diseases, food hygiene and BSE/TSE related issues.

## II – EFSA

### 1. Role and mission

EFSA's role is to assess and communicate on all risks associated with the food chain. Since its advice serves to inform the policies and decisions of risk managers, a large part of EFSA's work is undertaken in response to specific requests for scientific advice from the EC, EP and MSs. EFSA also undertakes scientific work on its own initiative (self-tasking). As defined in its Founding Regulation (EU, 2002), EFSA's main mission is to provide scientific advice and scientific and technical support for the Community's legislation and policies in all fields which have a direct or indirect impact on food and feed safety. The missions assigned to EFSA are: (i) issuing scientific opinions based on risk assessment, (ii) promoting and coordinating the development of risk assessment methodologies, (iii) commissioning scientific studies, (iv) collecting and analyzing scientific and technical data, (v) identifying emerging risks, (vi) establishing networks of relevant organisations, (vii) assisting the EC in crisis management, (viii) providing independent information on all matters within its mission with a high level of openness and transparency and (ix) communicate the risks. EFSA's activities are guided by a set of core values: excellence in science, independence, openness and transparency, and responsiveness.

### 2. Structure

EFSA is organised in five departments overseen by EFSA's Executive Director: Risk Assessment and Scientific Assistance (RASA), Scientific Evaluation of Regulated Products, Science Strategy and Coordination (the three science departments), Communications department and Resources and Support department. The RASA department supports EFSA's Scientific Panels to carry out risk assessments. Its Units also provide specialised support on data collection, exposure assessment and risk assessment methodologies. EFSA's Scientific Panels are responsible for EFSA's risk assessment work including delivering scientific opinions in the different areas of the food and feed chain. The Scientific Committee (SC) has the task of supporting the work of the ten Panels on cross-cutting issues and scientific matters of a horizontal nature. The SC and the Panels are

composed of independent scientific experts with a thorough knowledge of risk assessment and are supported by the above mentioned three scientific departments. EFSA is governed by an independent Management Board whose members are appointed to act in the public interest and do not represent any government, organisation or sector. EFSA's Advisory Forum connects EFSA with the national food safety authorities of all 28 MSs, Iceland and Norway, with observers from Switzerland and the EC.

### III – Risk assessment for microbiological hazards

#### 1. BIOHAZ Panel

The Panel on Biological Hazards (BIOHAZ Panel) provides independent scientific advice on biological hazards in relation to food safety and food-borne diseases, covering food-borne zoonoses, transmissible spongiform encephalopathies (BSE/TSEs), food microbiology, food hygiene and associated waste management issues (animal by products). The BIOHAZ Panel's risk assessment work is based on reviewing scientific information and data in response to requests for scientific advice (terms of reference) from risk managers (most commonly, the EC) or on its own initiative. The BIOHAZ Panel regularly sets up working groups involving external scientists with relevant expertise to focus on specific matters and help produce draft scientific opinions. The BIOHAZ Panel meets regularly in plenary sessions to discuss work in progress and to adopt finalised scientific opinions.

#### 2. Risk assessment methodologies for microbiological hazards

The risk assessments are usually provided to the risk manager in the form of scientific opinions and can be either quantitative or qualitative, depending on the scope and on the extent of data, resources and time available, or may also take the simpler form of risk profiles depending on the terms of reference provided (Romero-Barrios *et al.*, 2013). In general, the scientific opinions are structured according to the four well-established principles of microbiological risk assessment (CAC, 1999): hazard identification, exposure assessment, hazard characterization and risk characterization.

Since the appointment of the first mandate in 2003, the BIOHAZ Panel has evolved in its scientific advice to the risk managers. Until 2007, scientific opinions of the BIOHAZ Panel (with the exception of those on BSE/TSE) were mainly based on qualitative and in some cases semi-quantitative risk assessment (Hugas *et al.*, 2007). In September 2004, EFSA launched a project tender to formulate a strategy for quantitative microbiological risk assessment (QMRA) at the European level. The study commissioned to Havelaar (2005) identified many expected benefits such as: a more solid basis for common and more objective, science based criteria for food safety; support in evaluating possible risk mitigation options to be used at national level to reach common EU targets; increased transparency, enhancing risk communication between professionals and trust among stakeholders; increased sharing and optimal use of available data and resources, avoiding duplication of work between MSs, and a help to focus data collection efforts; and an useful tool to rank the relative contribution of different exposure pathways. In 2006 and 2009, respectively, EC requested to the BIOHAZ Panel to provided, for the first time, two full farm-to-fork QMRAs for the whole EU, with regard to *Salmonella* in slaughter and breeder pigs (EFSA, 2010b), and *Campylobacter* in broiler meat (EFSA, 2011a). These risk assessments, details about the models developed and other related activities are described by Romero-Barrios *et al.* (2013). Also in the field of setting targets for *Salmonella* in poultry populations (broiler flocks of *Gallus gallus* and flocks of fattening turkeys) quantitative assessments were used. More information can be retrieved in Messens *et al.* (2014).

The mandates by the EC increasingly ask for a quantitative evaluation of public health benefits and risks, which may require the development of mathematical models in order to answer to the questions in a sufficient depth. Moreover, models identify important data gaps or lacks of

knowledge thereby indicating future research priorities. In the scientific opinion "Reflecting on the experiences and lessons learnt from modelling on biological hazards" more information can be found (EFSA, 2012c).

### 3. Data collection for the risk assessment of microbiological hazards

Collection of accurate, harmonised and reliable data on hazards found in the food chain and on food consumption is a prerequisite for informed risk assessment and risk management at EU level. EFSA has an important role in collecting and analysing scientific data by working with the MSs to gather, share and analyse EU-wide data, as well as launching public consultations and calls for data to gather information from external sources.

In the area of zoonoses, data are particularly valuable for quantitatively estimating risks and/or for identifying to what extent a given control measure or intervention strategy can reduce the burden of a zoonotic disease in humans (Makela *et al.*, 2012). In the field of biological risks for human health, Directive 2003/99/EC (EU, 2003) lays down the requirement for an EU system for monitoring and reporting information, which obliges MSs to collect relevant and comparable data on zoonoses, zoonotic agents, antimicrobial resistance and foodborne outbreaks. Based on this data, every year EFSA prepares Community Summary Reports in close collaboration with the European Centre for Disease Control and Prevention (ECDC). Moreover, EFSA analyses the EU-wide baseline surveys on zoonotic agents, such as *Salmonella* and *Campylobacter*, in animal and food-populations and on antimicrobial resistance, assisted by the Task Force on Zoonoses Data Collection.

Finally, data and information for these risk assessments are also obtained through the two related scientific networks: on microbiological risk assessment (MRA) and on BSE-TSE and from the EFSA Food consumption data for exposure assessments as well from the collaboration with other EU Agencies (ECDC, European Medicines Agency (EMA), EU Joint Research Centre (EU-JRC)) and EU reference laboratories (EURLs).

### 4. Examples of scientific assessments by the BIOHAZ panel

From the beginning of the third mandate (07/2012) until now (May 2014) the BIOHAZ Panel has delivered 22 scientific outputs, of which 17 were opinions and 5 reports. Most outputs were related to food hygiene and associated waste management issues (animal by-products) (9), food-borne diseases (5), transmissible spongiform encephalopathies (BSE/TSEs) (6) and safety of microorganisms (2). In line with the farm to fork approach and looking for a high multidisciplinary component, the BIOHAZ Panel has been working in some cases in close collaboration with other agencies in the EU public health area such as the EMA and the ECDC.

#### A. Scientific assessment of food hygiene issues

##### a] Meat Inspection (EFSA, 2013 h,i,j,l)

During the referred period, four opinions dealing with meat inspection of solipeds, bovine animals, farmed game and small ruminants (EFSA, 2013 h,i,j,l) were published. EFSA was asked to identify and rank the main risks for public health that should be addressed by meat inspection at EU level, to assess the strengths and weaknesses of the current meat inspection, and to recommend new inspection or other methods fit for the purpose of meeting the overall objectives of meat inspection.

Relevant meat-borne hazards were identified and ranked based on their incidence and severity in humans, their prevalence on carcasses and the role of meat from these species as a risk factor for human disease. Following an assessment of current methods of meat inspection, alternatives or improvements were recommended, including how to address hazards not covered by current methods, both at farm level and during processing at abattoir. The hazards considered to be the most important were: verocytotoxin-producing *E. coli* (VTEC) and *Salmonella* for cattle; VTEC and *Toxoplasma* for sheep and goats; *Trichinella* for solipeds, *Toxoplasma* for farmed deer;

*Salmonella* and *Toxoplasma* for farmed wild boar. The public health related strengths identified were that the Food Chain Information (FCI) provides information on disease occurrence and veterinary treatments, enabling a focused inspection of animals with problems. On the other hand, the use of FCI for food safety purposes is today limited because the data that it contains is very general and does not address specific hazards of public health importance. Lastly, it was considered that palpation and incision techniques used during *post-mortem* inspection for some species could cause bacterial cross-contamination. It was concluded that to ensure effective control of the hazards of relevance, a comprehensive meat safety assurance, combining measures applied on-farm and at-abattoir, is necessary. A prerequisite for this system would be the setting of targets for these hazards to be achieved by food business operators at carcass level. Targets in primary production can be considered if intervention methods at the farm level exist.

#### **b] Public health risks related to mechanically separated meat (EFSA, 2013g)**

The public health risks linked to mechanically separated meat (MSM) types from pork and poultry were identified and compared with fresh meat, minced meat and meat preparations (non-MSM). Also methods to select, rank and suggest objective measurement methods and values for parameters to distinguish MSM types were assessed. Microbial hazards in MSM are expected to be similar to those in non-MSM, although the risk of microbial growth increases with the degree of muscle fibre degradation, thus with the separation pressure. For the distinction between the different types of MSM and non-MSM chemical, histological, molecular, textural and rheological parameters were considered as potential indicators. Published data suggested that calcium and, if confirmed cholesterol content, was the only appropriate chemical parameters which could be used to distinguish MSM from non-MSM products. A model was developed and it was determined that a calcium content of 100 mg/100 g, corresponds to a probability of 93.6% for a product to be classified as MSM. It was recommended that in order to improve methods for MSM identification, specifically designed studies for the collection of data obtained by standardised methods on indicators such as calcium and cholesterol should be undertaken, while studies based on combinations of different parameters could also be useful.

#### **c] Transport of meat (Part 1) (EFSA, 2014c)**

EFSA assessed whether or not it was possible to apply alternative core temperatures higher than the current requirement of 7 °C, in combination with specific transport durations for meat (carcasses) of domestic ungulates after slaughter without increasing the risk associated with the growth of pathogenic microorganisms. The growth of *Salmonella* spp., VTEC, *Listeria monocytogenes* and *Yersinia enterocolitica* during chilling was modelled. Combinations of maximum surface temperatures at carcass loading and maximum chilling and transport times that result in pathogen growth equivalent or less than that obtained when carcasses are chilled to a core temperature of 7 °C in the slaughterhouse were provided. The second part of the mandate (part 2) deals with minced meat and this activity is ongoing.

### **B. Scientific assessment of food-borne diseases**

#### **a] VTEC-seropathotype and scientific criteria regarding pathogenicity assessment (EFSA, 2013d)**

The seropathotype concept of Karmali *et al.* (2003) was reviewed. This empirical system classifies VTEC strains based on their reported frequency in human disease, their known association with outbreaks and the severity of the outcome including haemolytic uraemic syndrome (HUS) and haemorrhagic colitis (HC). This classification system utilises a gradient ranging from seropathotype A – high risk – to seropathotypes D and E – minimal risk. In addition, it was assessed whether the pathogenicity can be excluded for defined VTEC serotypes, and whether an alternative concept based on detection of verocytotoxins or genes encoding for verocytotoxins in isolates could be proposed. EFSA was also asked to assess the contribution by VTEC to diarrhoeal cases and to more severe outcomes in the EU.

During 2007-2010, 13 545 confirmed human VTEC infections were reported in the EU, including 777 HUS cases. The clinical manifestations were reported for 53% of cases; 64% of which presented with diarrhea alone and 10% with HUS. Isolates from 85 % of cases were not fully serotyped and therefore could not be classified using the Karmali seropathotype concept. It was concluded that there is no single or combination of phenotypic or genetic marker(s) that fully define 'pathogenic' VTEC. Isolates which contain the *vtx2* (verocytotoxin 2) in combination with the *eae* (intimin-encoding) gene or *aaiC* (secreted protein of enteroaggregative *E. coli*) and *aggR* (plasmid-encoded regulator) genes have been associated with a higher risk of more severe illness. A molecular approach targeting genes encoding VT and other virulence determinants is thus proposed to allow an assessment of the potential severity of disease that may be associated with a given VTEC isolate.

#### **b] Evaluation of molecular typing methods for major food-borne pathogens (Part 1) (EFSA, 2013c)**

An evaluation of molecular typing methods that can be applied to the food-borne pathogens *Salmonella*, *Campylobacter*, VTEC and *Listeria monocytogenes* was conducted. This evaluation was divided in two parts. Firstly, commonly used molecular typing methods were assessed against a set of predefined criteria relating to discriminatory capacity, reproducibility, repeatability and current or potential suitability for international harmonisation. Secondly, the methods were evaluated for their appropriateness for use in different public health-related applications. These applications included outbreak detection and investigation, attribution modelling, the potential for early identification of food-borne strains with epidemic potential and the integration of the resulting data in risk assessment. The results of these evaluations provided updated insights into the use and potential for use of molecular characterisation methods, including whole genome sequencing technologies, in microbial food safety. Recommendations were also made in order to encourage a holistic and structured approach to the use of molecular characterisation methods for food-borne pathogens. Currently, the BIOHAZ Panel is working on the follow-up of this opinion to evaluate the requirements for the design of surveillance activities for food-borne pathogens and to review the requirements for harmonised data collection, management and analysis.

#### **c] Food of non animal origin (FoNAO): a) Risk posed by pathogens in food of non-animal origin: Part 1 (EFSA, 2013b)/ b) Part 2: *Salmonella* and Norovirus in leafy greens eaten raw as salads (EFSA, 2014a)**

Food of non-animal origin (FoNAO) have the potential to be associated with large outbreaks as occurred in 2011 when sprouted fenugreek seeds were implicated in the major VTEC O104:H4 outbreaks in Germany and in France. In 2012, upon request by the EC, a comparison of the incidence of human cases linked to consumption of FoNAO and of food of animal origin (FoAO) was carried out. In order to identify and rank specific food/pathogen combinations most often linked to foodborne human cases originating from FoNAO in the EU, a model was developed using seven criteria: (i) strength of associations between food and pathogen based on the foodborne outbreak data from EU Zoonoses Monitoring (2007-11); (ii) incidence of illness; (iii) burden of disease; (iv) dose-response relationship; (v) consumption; (vi) prevalence of contamination; and (vii) pathogen growth potential during shelf life. The top five ranking food/pathogen combination found was *Salmonella* spp. and leafy greens eaten raw followed by (in equal rank), *Salmonella* spp. and tomatoes, *Salmonella* spp. and melons, *Salmonella* spp. and bulb and stem vegetables and pathogenic *Escherichia coli* and fresh pods, legumes or grain (EFSA, 2013b).

The outcome of this model in terms of specific food/pathogen combinations was used to identify the main risk factors, to recommend possible risk mitigating options and to consider microbiological criteria throughout the production chain. The first opinion out of five has been recently published and assessed the risk posed by *Salmonella* and Norovirus in leafy greens eaten raw as salads (EFSA, 2014a). It was concluded that each farm environment represents a

unique combination of numerous characteristics that can influence occurrence and persistence of pathogens in leafy greens production. It was proposed to define a *E.coli* Hygiene Criterion at primary production level. It was also concluded that a Food Safety Criterion for *Salmonella* in leafy greens could be used as a tool to communicate to producers and processors that *Salmonella* should not be present in the product. Studies on the prevalence and infectivity of Norovirus are limited, and quantitative data on viral load are scarce making establishment of microbiological criteria for Norovirus on leafy greens difficult.

It is foreseen that during 2014, additional Scientific Opinions will be adopted on the risk posed by: (i) *Salmonella* and Norovirus in berries; (ii) *Salmonella* and Norovirus in tomatoes; (iii) *Salmonella* in melons; and (iv) *Salmonella*, *Yersinia*, *Shigella* and Norovirus in bulb and stem vegetables, and carrots.

#### **d] Carbapenem resistance in food animal ecosystems (EFSA, 2013e)**

EFSA provides scientific support and advice on the possible emergence, spread and transfer to humans of antimicrobial resistance (AMR) EFSA cooperates closely with ECDC and EMA and also plays a role in the analysis of the monitoring data on AMR collected from food and animals throughout the EU.

EFSA produced a number of risk assessments in the AMR area over recent years, last one being on carbapenem resistance in food animal ecosystems This assessment reviewed the information available on the occurrence of carbapenem resistance in animals and food thereof and concluded that to date only sporadic studies have reported the occurrence of carbapenemase-producing (CP) bacteria in food-producing animals and their environment, and none in food derived from food-producing animals. The assessment proposed a methodology for the detection of CP strains of *Enterobacteriaceae* and *Acinetobacter* spp. The assessment concluded that active/passive monitoring and/or targeted surveys for CP bacteria should cover key zoonotic agents, animal pathogens and indicator organisms. The assessment also indicated that there are no data on the comparative efficacy of individual control options. It recommended continuing to prohibit the use of carbapenems in food-producing animals, and to decrease the frequency of use of antimicrobials in animal production in the EU, in accordance with prudent use guidelines.

### **C. BSE/TSE related risks**

EFSA activities in the TSE risk assessment area are mainly aimed to support the EC during the review of the TSE control measures envisaged by the TSE Roadmap 2<sup>1</sup>, an EC strategy paper for 2010-2015, listing the future policy options available for the control of TSEs. EFSA has been recently producing risk assessments in relation to: (i) the revision of the list/age limit for Specified Risk Material (SRM), EFSA provided a quantitative assessment of the BSE infectious load that might enter the food and feed chain yearly if bovine intestine and mesentery from animals born and raised in the EU would be re-allowed for consumption (EFSA, 2014d); (ii) the revision of the BSE surveillance, EFSA (2012a) provided an evaluation of the epidemiological trends of BSE in 25 EU MSs and assessed the design prevalence and the sensitivity of different BSE monitoring scenarios, EFSA has been also providing similar support to the European Free Trade Association (EFTA) Surveillance Authority, evaluating the ability of a proposed Norwegian BSE monitoring programme in detecting BSE, and the impact of the past use of fishmeal in feed for ruminants on the overall risk of BSE in Norway (EFSA 2013a); and (iii) the revision of scrapie eradication measures, EFSA provided advice on the provisional EURL results of a study on genetic resistance to scrapie in goats in Cyprus (EFSA, 2012b). An ongoing assessment is also evaluating the scrapie situation in the EU after 10 years of monitoring and control in sheep and goats. In addition, EFSA assessed the risk of transmission of classical scrapie via the transfer of in vivo derived embryo in ovines (EFSA, 2013m). This opinion confirmed that classical scrapie could be vertically transmitted in sheep. It

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<sup>1</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)



also concluded that the risk of transmitting classical scrapie due to the transfer of homozygous or heterozygous ovine ARR embryos can be considered negligible.

The relatively recent recognition of atypical forms of cattle BSE (L-type and H-type Atypical BSE), pose new challenges to the diagnosis and surveillance of the disease. In order to generate new data on the presence, distribution and infectivity level of these atypical agents in cattle, the EC recently asked EFSA to develop a protocol for further studies on samples from infected.

#### ***D. Evaluation of applications: decontamination treatments of food of animal origin and alternative treatments for disposal of ABP***

##### **a] Safety and efficacy of peroxyacids for decontamination of poultry carcasses (EFSA, 2014b)**

Article 3 (2) of Regulation (EC) No 853/2004 which lays down specific hygiene rules for food of animal origin provides a legal basis to authorise the use of substances other than potable water to remove surface contamination from products of animal origin. Before taking any risk management decisions on their approval, a risk assessment should be carried out by EFSA. In addition to the efficacy and safety of the substance, the potential emergence of reduced susceptibility to biocides and/or resistance to therapeutic antimicrobials and the impact of the substance or its by-products on the environment are also matters of concern.

Since the revision of the guidance document (EFSA, 2010a), EFSA has published five scientific opinions on decontamination treatments: recycling hot water as a decontamination technique for meat carcasses (EFSA, 2010c), lactic acid for the removal of microbial surface contamination of beef carcasses, cuts and trimmings (EFSA, 2011d), Cecure® for the removal of microbial surface contamination of raw poultry products (EFSA, 2012e), Listex™ P100 for the removal of *Listeria monocytogenes* surface contamination of raw fish (EFSA, 2012f) and peroxyacetic acid solutions for reduction of pathogens on poultry carcasses and meat (EFSA, 2014b). Commission Regulation (EU) No 101/2013 (EU, 2013) allows the use of lactic acid to reduce microbiological surface contamination on bovine carcasses. No other substances are currently authorised for this purpose within the EU.

##### **b] Bioreduction application (EFSA, 2013f)**

Regulation (EC) No 1069/2009 has introduced a procedure for the authorisation of alternative methods of use or disposal of animal by-products (ABP) or derived products. Such methods may be authorised by the EC following receipt of an opinion from the EFSA. The application procedure, including the detailed requirements for the technical dossier, is described under Article 20. ABP arise mainly during the slaughter of animals for human consumption, during the production of products of animal origin such as dairy products, and in the course of the disposal of dead animals and during disease control measures. Regardless of their source, they pose a potential risk to public and animal health and the environment.

EFSA published a statement on the format for applications for new alternative methods for animal by-products (EFSA, 2010e). Since then, EFSA published several opinions: 'Biomation' application for an alternative method for the treatment of ABP (EFSA, 2012d), on hatchery waste as animal by-products (EFSA, 2011b), capacity of oleochemical processes to minimise possible risks linked to TSE in Category 1 ABP (EFSA, 2011c) and on Neste Oil Application for a new alternative method of disposal or use of ABP (EFSA, 2010d). A method for on-farm containment of animal by-products (ABPs), called a 'Bioreduction' system, was recently assessed. The material for containment was of ovine origin and classified as a Category (Cat.) 1 ABP material. The Bioreduction system can reduce the risks related to pathogens such as non-spore forming bacteria and viruses. However, it is highly improbable that the risks related to more resistant biological hazards can be reduced. As the whole system could not be considered

as a closed system, it was not considered as a safe alternative method for on farm containment of animal by-products.

### ***E. Evaluation of the safety of microorganisms used as sources of food and feed additives, enzymes and plant protection products (QPS)***

A wide variety of microorganisms (including viruses) are intentionally added at different stages into the food chain, either directly or as a source of additives or food enzymes. EFSA is requested to assess the safety of these biological agents in the context of applications for market authorisation as sources of food and feed additives, enzymes and plant protection products received by EFSA.

In 2012 (EFSA, 2012g) the BIOHAZ Panel reviewed microorganisms previously assessed including bacteria, yeasts, filamentous fungi and viruses used for plant protection purposes and confirmed all taxonomic units and their qualifications previously recommended for the QPS list. Filamentous fungi and enterococci were not recommended for the QPS list. The 2013 update (EFSA, 2013n) reviewed previously assessed microorganisms and confirmed all taxonomic units and their qualifications previously recommended for the QPS list. Plant viruses were assessed for the first time and were recommended for the QPS list. Filamentous fungi and enterococci were not recommended for the QPS list following updating and reviewing of current scientific knowledge.

## **IV – Conclusions**

Food safety is a continuum in which each of the chronological steps in the food chain (e.g. feed production, food-producing animals, production/processing/serving of food) requires to be considered to assess the impact on human health. An integrated approach is essential for the achievement of EFSA's main objective, which is to provide independent scientific advice and clear communication on existing and emerging risks relating to food safety. When a question concerning any biological hazard which is capable of being transmitted to humans via food at any stage of its production (and processing) is being addressed, an Opinion or report is to be provided by the BIOHAZ Panel. The Panel also provides advice the best ways to collect data, the most suitable diagnostic tests and suggestions to improve the analysis of the data on zoonoses collected under Zoonoses Directive 2003/99/EC. The risk assessments done by the BIOHAZ Panel are in line with the EU strategy of one health, include a farm to fork approach and in many cases have a high multidisciplinary component. Whenever possible, the Panel applies this risk assessment framework developed by Codex Alimentarius as a basis for their work on food safety.

The outcomes of some of the activities developed by the current BIOHAZ Panel during the last years were summarised in this paper. From these it can be seen that the work covers different areas and approaches, ranging from quantitative risk assessments over structured qualitative risk assessment/risk ranking to opinions with short deadlines summarising existence knowledge from scientific literature. The approach taken depends on both the terms of reference as received from the EC, the available data and resources, and the time frame for the work following the risk managers' needs.

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