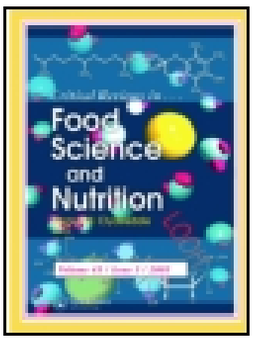


Taylor & Francis
Taylor & Francis Group

Critical Reviews in Food Science and Nutrition

ISSN: 1040-8398 (Print) 1549-7852 (Online) Journal homepage: http://www.tandfonline.com/loi/bfsn20

Food and Feed Chemical Contaminants in the European Union: Regulatory, Scientific and Technical Issues Concerning Chemical Contaminants Occurrence, Risk Assessment and Risk Management in the European Union

Marco Silano & Vittorio Silano

To cite this article: Marco Silano & Vittorio Silano (2015): Food and Feed Chemical Contaminants in the European Union: Regulatory, Scientific and Technical Issues Concerning Chemical Contaminants Occurrence, Risk Assessment and Risk Management in the European Union, Critical Reviews in Food Science and Nutrition, DOI: 10.1080/10408398.2015.1059313

To link to this article: http://dx.doi.org/10.1080/10408398.2015.1059313

Accepted online: 11 Sep 2015.

Food and feed chemical contaminants in the European union: regulatory, scientific and technical issues concerning chemical contaminants occurrence, risk assessment and risk management in the European Union

Marco Silano[1], Vittorio Silano[2]

[1]Unit of Human Nutrition and Health, Istituto Superiore di Sanità, Roma, Italy and [2]Medical School, II University of Roma Tor Vergata, Roma, Italy

Corresponding Author:

Marco Silano, MD

Unit of Human Nutrition and Health

Istituto Superiore di Sanità

Viale Regina Elena, 299

00161 Roma, Italy

e-mail: marco.silano@iss.it

phone: 0039-06-49906001

ABSTRACT

A priority of the European Union is the control of risks possibly associated with chemical contaminants in food and undesirable substances in feed. Following an initial chapter describing the main contaminants detected in food and undesirable substances in feed in the EU, their main sources and the factors wich affect their occurrence, the present review focuses on the "continous call for data" procedure that is a very effective system in place at EFSA to make possible the exposure assessment of specific contaminants and undesirable substances. Risk assessment of contaminants in food and undesirable substances in feed is carried currently in the

European Union by the CONTAM Panel of EFSA according to well defined methodologies and in collaboration with competent International Organizations and with Member States.

Keywords: Contaminants, food, undesiradable substance, feed

1.SCOPE

Although the term " chemical contaminant" is preferably used for food, whereas in the case of feed the terminology more widely used is "undesirable substance", both these terms refer to unintentionally present chemical substances characterized by a potential danger for human/animal health or for the environment (see also the following Section 2 dealing with the definitions).

The EU regulations and the risk assessment/management practices on radioactive and non radioactive chemical contaminants and on undesirable substances in products intended for human food or animal feed, fulfil two essential objectives: (i) the protection of public health, animal health and the environment; and (ii) the removal of internal/external barriers to trade.

The present paper deals with a detailed and comprehensive analysis and discussion of the past and current approaches, initiatives and policies in the European Union to assess, to manage and to control risks associated with the above mentioned radioactive and non radioactive chemical contaminants and/or undesirable substances occurring in food or in feed.

The present paper deals with the nature and effectiveness of the measures adopted within the European Union to ensure that:

- products intended for food or animal feed may enter the European Union from third countries, be put into circulation and/or used in the European Union only if they are sound, genuine and of merchantable quality and, therefore, when correctly used, do not represent any danger to human health, animal health or to the environment;

- contaminant levels in food and undesirable substances in feed are kept as low as can reasonably be achieved by following good practices at all stages of the food/feed chain;
- maximum levels for specific contaminants in food and for undesirable substances in feed are established where necessary;
- food containing a contaminant or products intended for animal feed containing an undesirable substance at an unacceptable level (e.g. exceeding the maximum permissible limit) are not placed on the Union internal market in order to protect animal and public health and the environment;
- products containing levels of contaminants/undesirable substance that exceed the established maximum levels are not mixed for dilution purposes with the same or other products; and
- the consultation of a scientific body for all provisions which may have an effect upon public human/animal health or the environmernt takes regularly place .

On the other hand, this paper does not deal with chemical contaminants associatd with migration of substances into food from contact materials, pesticide residues and residues of veterinary drugs as they are covered by separate, specific and detailed rules in the European Union neither with biological and microbiological contaminants other than mycotoxins and algal toxins.

2.DEFINITIONS

According to Regulation EC 178/2002:

- **"Food** (or '**foodstuff**') means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by

humans. 'Food' includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC. 'Food' shall not include: (a) feed; (b) live animals unless they are prepared for placing on the market for human consumption;(c) plants prior to harvesting; (d) medicinal products within the meaning of Council Directives 65/65/EEC (1) and 92/73/EEC (2); e) cosmetics within the meaning of Council Directive 76/768/EEC (3);(f) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC (4); (g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971; and(h) residues and contaminants.

- **'food law'** means the laws, regulations and administrative provisions governing food in general, and food safety in particular, whether at Community or national level; it covers any stage of production, processing and distribution of food, and also of feed produced for, or fed to, foodproducing animals;
- **'food business'** means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food;
- **'food business operator'** means the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control;

- **'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;
- **'feed business'** means any undertaking whether for profit or not and whether public or private, carrying out any operation of production, manufacture, processing, storage, transport or distribution of feed including any producer producing, processing or storing feed for feeding to animals on his own holding;
- **'feed business operator'** means the natural or legal persons responsible for ensuring that the requirements of food law are met within the feed business under their control;
- **'retail'** means the handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres and wholesale outlets;
- **'placing on the market'** means the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves;
- **'risk'** means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard;
- **'risk analysis'** means a process consisting of three interconnected components: risk assessment, risk management and risk communication;
- **'risk assessment'** means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation;

- **'risk management'** means the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options;
- **'risk communication'** means the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions;
- **'hazard'** means a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect;
- **'traceability'** means the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution;
- '**stages of production, processing and distribution**' means any stage, including import, from and including the primary production of a food, up to and including its storage, transport, sale or supply to the final consumer and, where relevant, the importation, production, manufacture, storage, transport, distribution, sale and supply of feed;
- **'primary production'** means the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing and the harvesting of wild products;
- **'final consumer'** means the ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity.

According to Directive 2002/32/EC, **products intended for animal feed,** include :

- '**feedingstuffs'** shall mean products of vegetable or animal origin, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, used singly or in mixtures, whether or not containing additives, for oral animal feeding;
- '**feed materials'** shall mean various products of vegetable or animal origin, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether or not containing additives, which are intended for use in oral animal feeding either directly as such or, after processing, in the preparation of compound feedingstuffs or as substrates for premixtures;
- **'additives'** shall mean additives as defined in Article 2(a) of Council Directive 70/524/EEC;
- '**premixtures'** shall mean mixtures of additives or mixtures of one or more additives with substances used as carriers, intended for the manufacture of feedingstuffs;
- '**compound feedingstuffs'** shall mean mixtures of feed materials, whether or not containing additives, which are intended for oral animal feeding as complete or complementary feedingstuffs;
- '**complementary feedingstuffs'** shall mean mixtures of feedingstuffs which have a high content of certain substances and which, by reason of their composition, are sufficient for a daily ration only if used in combination with other feedingstuffs;
- '**complete feedingstuffs'** shall mean mixtures of feedingstuffs which, by reason of their compo-sition, are sufficient for a daily ration;

- **“chemical food contaminant”** is any chemical substance not intentionally added to food which is present in food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food, or as a result of environmental contamination with a potential danger to human health ot to the environment (Art. 1(1) of Regulation (EEC) 315/1992). Moreover, according to Regulation EC 852/2004, "contamination" means the presence or introduction of a hazard;
- **"undesirable substance in products intended for animal feed”** (i.e. feed materials, premixtures, additives, feeding-stuffs and all other related products) means any substance or product, with the exception of pathogenic agents, which is present in and/or on the product intended for animal feed and which presents a potential danger to animal or human health or to the environment or could adversely affect livestock production (Art. 1 of Directive 2002/32/EC and subsequent modifications and integrations)..
- “**occurrence**” of a given contaminant in a specif food or product intended for animal feed refers to its presence and concentrations under a variety of different conditions which are considered of importance. Determiniing the occurrence of a given cntaminant in a specific matrix generally requires large-scale complex analytical studies, sometimes also quoted for new contaminats as “reconnaissance” studies. New contaminants are chemical substances that have not been extensively studied in the environment before, compounds where analytical methods for measuring relevant concentrations in the environment have just been developed, or newly manufactured compounds that are being introduced into

the environment. The discovery of new contaminants is, therefore, a rather common finding, although the evaluation of its significance in terms of hyman and animal health protection may be very challenging.

- **"co-occurrence"** (i.e. simultaneous presence) of different contaminants in the same food/feed is very frequent and obviously depends on the interactions of the many variables which may influence the transfer of specific chemicals into a given food/feed under specific conditions. Highly variable co-occurrence of different contaminants in specific food/feed depending on a number of different factors is one of the most worrying element in relation to public health protection, including animal health. In fact, as it will be discussed later in this paper, safety of contaminants is still largely carried out on an individual basis and the ability of assessing safety of chemical mixtures remains still rather limited.
- **"systematic co-occurrence"** makes reference to the property of some contaminants to appear systematically together in specific food or feed matrices, mainly due to the fact that they are formed simultaneously either by common metabolic processes or other transformation processes. For instance, systematic co-occurrence has been established for 3-acetyl deoxynivalenol, 15-acetyl deoxynivalenol and fumonisin B3, deoxynivalenol and fumonisin B1and B2. The same applies to nivalenol for which to a certain degree cooccurrence with deoxynivalenol can be observed. In some cases, co-occurrence in specific matrices may make possible to estimate the concentration of specific contaminants from the knowledge of the level of one or more co-occurrent contaminants. For instance, it is not necessary due to co-occurrence to consider specific measures for 3-

acetyl deoxynivalenol, 15-acetyldeoxynivalenol and fumonisin B3, as measures with regard to in particular deoxynivalenol and fumonisin B1 and B2 would also protect the human population from an unacceptable exposure from 3-acetyl deoxynivalenol, 15-acetyl deoxynivalenol and fumonisin B3. Moreover, for some time , benzo(a)pyrene has been used as a marker for the occurrence and effect of carcinogenic polycyclic aromatic hydrocarbons (PAHs), such as benz(a)anthracene, benzo(b)fluoranthene, benzo(j)fluoranthene, benzo(k)fluoranthene, benzo(g,h,i)perylene, chrysene, cyclopenta(c,d)pyrene, dibenz(a,h)anthracene, dibenzo(a,e)pyrene, dibenzo(a,h)-pyrene, dibenzo(a,i)pyrene, dibenzo(a,l)-pyrene, ndeno(1,2,3-cd)pyrene and 5-methylchrysene, contaminating foods during smoking processes and heating and drying processes that allow combustion products to come into direct contact with food in food.

According to Regulation EC 852/2004,

- **“food hygiene"**, means the measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff taking into account its intended use;
- **"primary products"** means products of primary production including products of the soil, of stock farming, of hunting and fishing;
- **"establishment"** means any unit of a food business;
- **"equivalent"** means, in respect of different systems, capable of meeting the same objectives;
- **"wrapping"** means the placing of a foodstuff in a wrapper or container in direct contact with the foodstuff concerned, and the wrapper or container itself;

- **"packaging"** means the placing of one or more wrapped foodstuffs in a second container, and the latter container itself;
- **"hermetically sealed container"** means a container that is designed and intended to be secure against the entry of hazards;
- **"processing"** means any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes;
- **"unprocessed products"** means foodstuffs that have not undergone processing, and includes products that have been divided, parted, severed, sliced, boned, minced, skinned, ground, cut, cleaned, trimmed, husked, milled, chilled, frozen, deep-frozen or thawed; and
- **"processed products"** means foodstuffs resulting from the processing of unprocessed products.

According to Regulation EC 882/2004, the following definitions also apply:

- **'official control'** means any form of control that the competent authority or the Community performs for the verification of compliance with feed and food law, animal health and animal welfare rules;
- **'verification'** means checking, by examination and the consideration of objective evidence, whether specified requirements have been fulfilled;
- **'feed law'** means the laws, regulations and administrative provisions governing feed in general and feed safety in particular, whether at Community or national level; it covers all stages of production, processing and distribution of feed and the use of feed;

- **'competent authority'** means the central authority of a Member State competent for the organisation of official controls or any other authority to which that competence has been conferred; it shall also include, where appropriate, the corresponding authority of a third country;
- **'control body'** means an independent third party to which the competent authority has delegated certain control tasks;
- **'audit'** means a systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives;
- **'inspection'** means the examination of any aspect of feed, food, animal health and animal welfare in order to verify that such aspect(s) comply with the legal requirements of feed and food law and animal health and animal welfare rules;
- **'monitoring'** means conducting a planned sequence of observations or measu-rements with a view to obtaining an overview of the state of compliance with feed or food law, animal health and animal welfare rules;
- **'surveillance'** means a careful observation of one or more feed or food busi-nesses, feed or food business operators or their activities;
- **'non-compliance'** means non-compliance with feed or food law, and with the rules for the protection of animal health and welfare;
- **'sampling for analysis'** means taking feed or food or any other substance (including from the environment) relevant to the production, processing and distribution of feed or

food or to the health of animals, in order to verify through analysis compliance with feed or food law or animal health rules;

- **'official certification'** means the procedure by which the competent authority or control bodies, authorised to act in such a capacity, provide written, electronic or equivalent assurance concerning compliance;
- **'official detention'** means the procedure by which the competent authority ensures that feed or food is not moved or tampered with pending a decision on its destination; it includes storage by feed and food business operators in accordance with instructions from the competent authority;
- **'equivalence'** means the capability of different systems or measures to meet the same objectives; and 'equivalent' means different systems or measures capable of meeting the same objectives;
- **'import'** means the release for free circulation of feed or food or the intention to release feed or food for free circulation within the meaning of Article 79 of Regulation (EEC) No 2913/92 in one of the territories referred to in Annex I;
- **"introduction'** means import as defined above, and the placing of goods under the customs procedures referred to in points (b) to (f) of Article 4(16) of Regulation (EEC) No 2913/92, as well as their entry into a free zone or free warehouse;
- **'documentary check'** means the examination of commercial documents and, where appropriate, of documents required under feed or food law that are accompanying the consignment;

- **'identity check'** means a visual inspection to ensure that certificates or other documents accompanying the consignment tally with the labelling and the content of the consignment;
- **'physical check'** means a check on the feed or food itself which may include checks on the means of transport, on the packaging, labelling and temperature, the sampling for analysis and laboratory testing and any other check necessary to verify compliance with feed or food law; and
- **'control plan'** means a description established by the competent authority containing general information on the structure and organisation of its official control systems.

3. OCCURRENCES AND CO-OCCURRENCE OF CHEMICAL CONTAMINANTS

3.1. Main sources of chemical contaminants in food and of undesirable substances in products intended for animal feed and factors affecting their occurrence

The present section deals with the main sources of chemicals likely to be associated with possible risks to human/animal/plant health under specific conditions, and factors modulating the unintentional occurrence of these chemicals in the food/feed chain.

3.1.1.Main sources

Intentionally made chemicals. The importance from a public health standpoint of intentionally produced chemicals as a source of chemicals occurring in the food/feed chain is generally recognized. The chemical industry has been growing worldwide and is economically significant in the EU. In the analysis recently compiled for 168 toxic chemicals, based on production quantities collected pursuant to the Prodcom regulation, the toxicity classes were assigned

according to the classification and labelling system ('risk phrases' or R-phrases). The production volumes of toxic chemicals (i.e. carcinogenic, mutagenic, reprotoxic, chronically toxic, very toxic, toxic and harmful) in the EU amounted to about 200 million tons per year during the last 7 years (EEA, 2011). The relative importance of the toxic substances belonging to the above mentioned different toxicity classes was as follows: carcinogenic, mutagenic and reprotoxic (CMR) chemicals (16%), chronically toxic chemicals (4%), very toxic chemicals (21%), toxic chemical (32%) and harmful chemicals (27%) (EEA, 2011).

Man-made chemical substances can be released during any stage of their lifecycle (Figure 1) from production (or import) through processing, manufacturing and use (industrial and consumer) to disposal. This can lead to gross pollution (poorly managed industries, contaminated sites, and accidents), as well as diffuse releases that may lead to long term exposure to low levels of chemicals and/or chemical mixtures. For substances used in slowly degradable products or construction materials, emissions resulting from waste disposal stage can continue several decades after production and processing of a substance or a product. This is one reason why some substances are still found in the environment or in biological systems decades after their use has ceased.

Non-intentionally produced chemicals. These figures, in addition to being partial with respect to chemicals manufactured by industry, do not include the large amounts of toxic or harmful chemicals released into the environment, but not intentionally-produced, by industrial and other activities such as those related to mining, gas and oil exploitation, energy transformation, transport, urban activities, and waste disposal. Moreover, hazardous chemical substances are also generated during the processing of food or feed (food/feed process contaminants). Processing

means: (i) changing plants or animals into what we recognize as food (e.g. harvesting, slaughtering, fractionation, fermentation and smoking); (ii) getting food from the farm or processing plant to the consumer or a food service facility like a restaurant, or hospital kitchen (e.g. distribution and storage); (iii) getting the food ready to eat (e.g. cooking). A number of examples of contamination during processing are known, although food processing employs several techniques to increase food safety. However, some of these processing measures themselves may produce chemical by-products harmful to human health. The best known processes that cause substantial changes in food include cooking (heat treatment in various ways, fermentation, acid hydrolysis, etc). Examples of process contaminants produced by cooking include acrylamide formation in fried starchy food, polyaromatic hydrocarbons (PAHs) formation in grilled meat and heterocyclic amines formation in (certain) cooked foods. Fermentation and acid hydrolysis are two commonly used methods to breakdown or convert food components into smaller fragments or individual molecules. During these processes, many reaction products may be formed. For example, ethyl carbamate may be generated during fermentation, and 3-chloropropane-1,2-diol (3-MCPD) during acid hydrolysis in soy sauce.

Natural chemicals. Natural events, such as volcanic emissions and fires, or agents as well as toxin-producing microorganisms such as certain *Aspergill*us and *Fusarium* fungi, dinoflagellates, cyanobacteria as well as certain plant species contribute to the overall hazardous chemical load in the environment and/or directly in the food/feed chain. Moreover, it should also be considered that, even for naturally occurring chemicals, human activities may increase their mobility or the amount, allowing them to enter the food/feed chain at higher levels than would otherwise occur.

3.1.2 – Main modulating factors of occurrence

Hazardous chemicals released into the environment, especially those that do not break down easily, may enter different environmental compartments and the food or feed chain, thus contributing to the likelihood of exposure of human beings, animals and/or plants through different pathways. Whether a substance can be found in the air, soil , aqueous environment or in the food/feed chain, depends on a number of factors, including how the chemical is released, the amount released, the pattern of release and, most importantly, its physico-chemical properties. The relative importance of different sources of chemical contamination ,therefore,depends on a number of factors. For instance, the major sources of contamination of the aquatic environment are treated and untreated wastewaters, run-offs, atmospheric deposition (including spray drift), and leaching. The fate of emissions in a particular water body will depend not only on the amount of the substance emitted, but also on the transport, dispersion and transformation processes (e.g. biode-gradation, hydrolysis, photolysis) in the receiving body. The preventative measures, such as (bio)degradation and sewage treatment, taken to minimize contamination are, therefore, important considerations.

As indicated by the Codes of Practice developed by the Codex Alimentarius, there are several factors which may affect levels of chemical intermediates/impurities, posing a potential risk to human, animal health or to the environment, including: (i) the local environmental and climatic conditions; (ii) the primary production conditions, including fertilization, harvesting and drying modalities; (iii) the storage and transport conditions including moisture levels, temperature and exposure to light; (iv) the processing and manufacturing techniques applied to specific products including the use of high temperatures, particular milling conditions or contaminated water; (v)

the nature of the food/feed product including those deriving from older animals or specific animal organs such as kidneys; and (vi) the properties of the hazardous chemical substance considered, including its physico-chemical properties, especially persistence.

As it is also indicatd by the codes of practice developed by the Codex, providing information on prevention and reduction of a number of contaminants covered by the legislation and available in the "Official Standards" section of the Codex website at: http://www.codexalimentarius.net/web/index_en.jsp, there are several factors that may affect levels of contamination of the food and feed supplies, including: (i) the environment; (ii) the primary production (including harvest); (iii) the storage and transport conditions; (iv) the processing and manufacturing conditions; (v) the nature of the product; and (vi) other factors (Table 3.1). This Table does not address, however, all the complexity of the issue as the presence and level of contamination of a specifid food/feed matrix by a specific chemical contaminant also depends on the physico-chemical properties of the contaminant, and especially its persistence and solubility characteristics, as well as on the nature of the food matrix/organism, and especially its ability to accumulate specific substances or to support the growth and multiplication of specific (micro) organisms able to produce toxins. It should also be considered that contaminants may be not only be of antropic origin as it is the case for lead (as in the case of use of leaded gasoline) or of nitrates (used as a fertilizer), but also of natural origin as it is the case for *Fusarium* toxins or toxic metabolites in vegetable tissues or of mixed origin.

.2. Main contaminants and undesirable substances

The high complexity of the contaminants occurrence analysis as depending on variable interactions of a number of factors is clearly highlighted by accumulated experience over the years in different cases. This experience has made possible to identify contaminantswhich are characteristic for specific food/feed matrices. The characterization of possible contaminants in specific segments/compartments of the food/feed chain is a highly complex process requiring the consideration of the relevance of a number of variable factors in each specific situation as well as is the case of the confirmation of their presence often requiring highly sofisticated chemical, chemico-physical and/or biological analytical methologies. Therefore, it is evident that the identification of the importance of particular contaminants in specific food (Table 3.2) or feed is an indication of a hi prevalence of specific contaminants in particular food and feed matrices, but connot be used as an approach to exclude the presence of a specific contaminants in specific matrices.

3.2.1. Main non radioactive contaminants in food

Non radioactive chemical contaminants in food can be divided into three main categories (see also Section 3.1.):

- *agricultural* contaminants are present mainly as the consequence of agricultural practices (e.g. nitrate and mycotoxins such as aflatoxins, ochratoxin A);
- *environmental* contaminants are present mainly as the consequence of environmental pollution or natural phenomena (e.g. heavy metals, dioxins, polychlorinated biphenyls (PCBs) and organotins);

- *industrial* contaminants are present mainly as the consequence of processing/ manufacturing of food (e.g. polycyclic aromatic hydrocarbons (PAH), acrylamide, furan, 3-mono-chloropropanediol (3-MCPD), ethylcarbamate).

3.2.2. Non radioactive undersirable substances in products intended for animal feed

Undesirable substances in feed can be divided in several groups, including:

- inorganic contaminants and nitrogenous compounds
- mycotoxins
- inherent plant toxins
- organochlorine compounds, including dioxins and PCBs
- harmful botanical impurities
- authorised feed additives in non-target feed following unavoidable carry-over.

The undesirable substances to be specifically considered in relation to safety of specific products intended for animal feed include arsenic, lead, fluprine, mercury, nitrites, cadmium, Aflatoxin B1, Hydrocianic acid , Free gossypol, Theobromine, Volatile mustard oil, Vinyl thiooxazolidone , Rye ergot , Weed seeds and unground and uncrushed fruits containing alkaloids, glucosydes or other toxic substances separately or in combination, *Datura spp,* Seeds and husks of *Ricinus communis L., Croton tiglium L. and Abrus precatorius L.*and products deriving from their transformation, separately or in combination, *Crotalaria spp,* Aldrin, Dieldrin, Camphechlorsum of indicator congeners CHB 26,50 and 62, Chlordane (sum of cis- and trans-isomers and of oxychlordane, expressed as chlordane), DDT (sum of DDT-,TDE- and DDE-isomers, expressed as DDT), Endosulfan (sum of alpha- and beta-isomers and of

endosulphansulphate expressed as endosulfan), Endrin (sum of endrin,and of delta-keto-en-drin, expressed as endrin), Heptachlor (sum of hepthachlor and of heptachlorepoxide, expressed as heptachlor), Hexachlorobenzene (alfa-,beta- and gamma-isomers), Dioxins (sum of polychlorinated dibenzo-*para*-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) expressed in WHO toxic equivalents, using the WHO-, Dioxins and dioxin-like PCBs (sum of poly-chlorinated dibenzo-*para*-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) and polychlorinated biphenyls (PCBs) expressed in WHO toxic equivalents, using the WHO-TEFs (toxic equivalency factors, 1997), Unhusked beech mast — *Fagus silvatica* L., Purghera — *Jatropha curcas* L., Indian mustard — *Brassica juncea* (L.)
Czern. And Coss. ssp. *Intergrifolia* (West.) Thell., Sareptian mustard — *Brassica juncea*
(L.) Czern. And Coss. ssp. *Juncea*, Chinese mustard — *Brassica juncea* (L.) Czern. And Coss. ssp. *juncea* var. *lutea* Batalin, Black mustard — *Brassica nigra* (L.) Koch, Ethiopian mustard — *Brassica carinata* A. Braun, Lasalocid sodium, Narasin, Salinomicine sodium, Monesin sodium, Maduramicine ammonium alpha, Deochinate, Halofuginone bromohidrate, Nicarbazine and Diclazuril (Directive 2002/32/CE and subsequent modifications and integrations).

3.2.3.Radioactive contaminants in food and feedRadioactive contamination of foodstuffs and of feedingstuffs which may be placed on the market are mainly associated with nuclear accidents or other cases of radiological emergency which is likely to lead to or has led to significant radioactive contamination. The main radioactive isotopes involved (e.g. Sr-90, I-131, Cs-134 and Cs-137) depend largely on the nature of the accident and the source of the radiological emergency.

3.3. Collection of chemical contaminants occurrence data in food and feed and evaluation of exposure

3.3.1. Commission Recommendations on occurrence monitoring

The European Commission has guided with commitment the monitoring of food contaminants through *ad hoc* recommendations in order to ensure the availability of the data needed to evaluate human exposure (see Table 3.4)

Specific monitoring recommendations have also been introduced by the Council Directive 96/23/EC, as modified by Regulation (EC) n.806/2003 and by Regulation (EC) n.882/2004, on " substances and groups of residues" listed in Annex I that includes, in addition to substances having anabolic effect and unauthorized substances, veterinary drugs and substances, also environmental contaminants (e.g. organichlorine compounds, including PCBs, organophosphorus compounds, chemical elements, mycotoxins, dyes). The production process of animals and primary products of animal origin shall be monitored for the purpose of detecting the presence of the residues and substances listed in Annex I in live animals, their excrement and body fluids and in tissue, animal products, animal feed and drinking water. Where there is evidence of residues of authorized substances or products of a level exceeding the maximum limit for residues, the competent authority shall carry **out** an investigation in the farm of origin or departure, as applicable, to determine why the above limit was exceeded. Annex III of this Directive addresses the sampling strategy, whereas Annex IV concerns levels and frequencies of samling in differrent animal species.

Setting of action levels as an early warning tool to allow authorities to proactively identify and eliminate sources of contamination is aslo a quite effective system ro produce additional useful data on the occurrence of specific contaminants (See Section 5.4).

3.3.2. Assistance to the Commission and cooperation by the Member States in the scientific examination of questions relating to food in the frame work of Council Directive 93/5/ EEC of 25 February 1993 (SCOOP)

The Council Directive 93/5/EEC of 25 February 1993 adopted a formal mechanism to ensure assistance to the Commission and cooperation by the Member States in the scientific examination of questions relating to food at the time in the competence of the Scientific Committee for Food (see Section 4.1). This Directive was adopted in view of the fact that:

- the process of achieving a satisfactory scientific base for matters relating to food safety has to be, in the interests of consumers and industry independent, transparent and effective and must reflect the situation existing in all Member States;
- in order to ensure the smooth running of the Scientific Committee for Food (see Section 4.1.) the Community needs scientific support from the Member States;
- the Commission must have access to the information and assistance available in the Member States, which must facilitate the accomplishment of its tasks;
- it is necessary to use scientific resources in member States effectively to support Communi-ty activities through cooperation.

According to this Directive:

- Member States had to take the necessary measures to enable their competent authorities and bodies to cooperate with the Commission and lend it the assistance it needs in the scientific examination of questions of public interest relating to food, particularly in the field of public health, through disciplines such as those associated with medicine, nutrition, toxicology, biology, hygiene, food technology, biotechnology, novel foods and processes, risk assessment techniques, physics and chemistry. This cooperation procedure shall apply when a Council act requires the opinion of the Scientific Committee for Food.
- Each Member State had to designate the authority or body which will be responsible for the cooperation with the Commission and for distribution of work to appropriate institutes within Member States as regards the tasks laid down in Article 3 and shall notify the Commission accordingly. Each designated authority shall send to the Commission a list of the institutes participating in the cooperation procedure in its jurisdiction, and any modifications to that list. The Commission shall circulate this information to the above authorities and other interested parties.

The principal tasks to be carried out by the institutes participating in the cooperation included : (i) drawing up protocols for the assessment of risks relating to food components and elaborating methods of nutritional evaluation; (ii) assessing the nutritional adequacy of the diet; (iii) examining test data submitted to the Community rule and the production of a monograph for assessment by the Scientific Committee for Food; (iv) carrying out food intake surveys, particularly those necessary for the determination or evaluation of the conditions of use of food additives or the laying down of limit values for other substances in food; (v) conducting investigations relating to components of diets of the various Member States or of biological or

chemical food contaminants; and (vi) helping the Commission honour the Community's international commitments by providing expertise on food safety questions. It was also foreseen that the Commission could, after consultation with the national authorities, invite institutes in third countries to participate, on a voluntary basis, in carrying out the tasks necessary for the achievement of the objectives. The Commission was also expected to report to the European Parliament and to the Council on the structures, works and efficiency of the Scientific Committee for Food within three years of the implementation of Directive 93/5/EEC and every three years thereafter.

The SCOOP procedure has been applied with good results to a number of food contaminants including te following ones.

A). Patulin

Patulin is mycotoxin produced by fungi belonging to several genera, 9ncluding *Penicillium, Aspergillus* and *Byssochylamys* species. Although patulin can occure in many mouldy fruits, grains and and other foods, the major sources of patulin contaminantion are apples and apple products. Patu7lin is relatively heat stable and is not destroyed by pasteurisation of apple juice at 90° C for 10 seconds. However, it is broken down in fruit juice and other foods in nthe presence of su7lphur dioxixw used as preservative. It does not appeasr to survive fermentation processes and is noit usually found in alcphplic drinks such as cider (Reports on tasks for scientific cooperation, Task 3.2.8. "Assessment of dietary intake of Patulin by the population of EU Member States. http://ec.europa.eu/food/food/chemicalsafety/contaminants/task3.2.8_en.pdf, carried out in the frame work of Directive 93/5/EEC, 2000)

B) Ochratoxin A

Ochratoxin A (OTA) is a mycotoxin produced by several fungal species of the genera *Penicillium* and *Aspergillus.* Contamination of food commodities, including cereals and cereal rpoducts, pulses,coffee, beer, grape juice, dry wine fruits and wine as well as cacao products,nuts ans spices,has been reported from all over the world. In addition, significant contamination of animal feeds with OTA may result in the pèresence of residues in edible offal and blood serum , but not in meat,milk and eggs. Within the EU cereals, cereal products,dried wine fruits, roasted coffee, wine, grape juice and foods for infants and young childrencontribute significantly to the general hunman exposure to OTA or to the exposure of vulnerable groups of consumers such as children (Reports on tasks for scientific cooperation. Task 3.2.7. Assessment of dietary intake of Ochratoxin A by the population of the EU Member States http://ec.europa.eu/food/food/chemical safety/contaminants/task 3.2.7._en.pdf, carried out in the frame work of Directive 93/5/EEC.

C) Dioxins and dioxin-like compounds

Exposure estimates taking into account the SCOOP-task ‘Assessment of dietary intake of dioxins and related PCBs by the population of EU Member States’ finalised in June 2000 indicate that a considerable proportion of the Community population has a dietary intake in excess of the TWI.From a toxicological point of view, any level set should apply to both dio-xins and dioxin-like PCBs, but in 2001 maximum le-vels were set on Commu-nity level only for dioxins and not for dioxin-like PCBs, given the very limi-ted data available at that time on the prevalence of dioxin-like PCBs. Since 2001, however, more data on the presence of dioxin-like PCBs have become available, therefore, maximum levels for the sum of dioxins and dioxin-like PCBs have

been set in 2006 as this is the most appropriate approach from a toxicological point of view (Reports on tasks for scientific cooperation, Task 3.2.5 ‘Assessment of dietary intake of dioxins and related PCBs by the population of EU Member States’. http://ec.europa.eu/dgs/health_consumer/library/pub/pub08_en.pdf OJ L 42, 14.2.2006, p. 26.) Environmentally persistent dioxins and dioxin-like compounds include 29 congeners of dioxins, furans and polychlorinated biphenyls (PCB) with similar toxic effects, their quantification commonly expressed as toxic equivalent units according to their varying potency. While the amount of those compounds in the environment has declined since the late 1970s, there is a continued concern because of their accumulation in the food chain, particularly in animal fat. In 2002 the European Commission prescribed a list of actions to further reduce the presence of dioxins and dioxin-like PCBs and later introduced action and maximum levels with random monitoring by Member States. A total of 7,270 samples collected in the period 1999-2008 from 19 Member States, Norway and Iceland were analysed in detail. Dioxin and furan congeners comprised between 30% and 74% of the total concentrations depending on food or feed group, while mono-*ortho* PCBs comprised between 15% and 45% of the dioxin-like PCBs. The highest mean levels of dioxins and dioxin-like PCBs in food expressed on fat basis were observed for „liver and products thereof from terrestrial animals‟ and on whole weight basis for „fish liver and products thereof‟. In feed the highest levels were found in „fish oil‟. An overall 8% of the samples exceeded different maximum levels and a further 4% exceeded some action levels. However, some of these samples clearly originated from targeted sampling during specific contamination incidences and there were large variations between groups (EFSA, 22 July 2010).

D) Arsenic

Nine Member States submitted occurrence and intake data for arsenic in fish, the main source of arsenic in the food, for the mean adult population. Very few data was provided on arsenic in other foodstuffs. An accurate estimation of the total intake was, therefore, not possible in most Member States. The results from DK and the UK, which cover all major food groups, indicate that fish and other seafood contribute more than 50% of the dietary arsenic. The mean daily intake of arsenic from fish and other seafood is below 0.35 mg. It is thus assumed that the total daily intake of arsenic by the mean adult population is below 1 mg. Consumers of fish and seafood may reach an intake of 1 mg/day from these foods alone. Data from FR and DE indicate that children have a lower intake of arsenic than adults. The burden/kg bodyweight of children may, however, be larger than for adults due to their lower bodyweight. The type of water in which the fish is caught, i.e. marine or fresh, is of major importance for the As-content, with the highest levels in marine species. No data was available on the inorganic arsenic-species, which are the most toxic species present in food. The ratio inorganic/total As in foodstuffs is thus largely unknown (European Commission Directorate-General Health and Consumer Protection-Assessment of the dietary exposure to arsenic, cadmium, lead and mercury of the population of the EU Member States. SCOOP 3.2.11, 2004).

E) Cadmium

Thirteen Member States submitted occurrence and intake data for the mean adult population. DK, FI, FR, DE and the UK had the best data to make an accurate intake estimation. IR had data for only two food categories. The mean intake in the Member States is less than 30% of the

PTWI, with the exception of the Netherlands with 38%. The PTWI is 0.49 mg for a person weighing 70 kg. In the UK the intake by mean consumers is 22% of the PTWI, whereas for high consumers is 37% of the PTWI. Cereals and vegetables are the main sources of cadmium in the diet, representing approximately 2/3 of the mean cadmium intake. Data from FR and DE indicate that children have a lower intake of cadmium than adults. However, children have a larger burden/kg body weight, due to their lower body weight. The cadmium dietary intake of children 4-6 years old is estimated to 65% of the PTWI (European Commission Directorate-General Health and Consumer Protection- Assessment of the dietary exposure to arsenic, cadmium, lead and mercury of the population of the EU Member States. SCOOP 3.2.11, 2004).

F) Lead

Twelve Member States submitted occurrence and intake data for the mean adult population. Only DK and the UK had sufficient data to make a complete intake estimation. All other Member States were lacking data from one or several food groups. The results indicate, however, that in 11 Member States the average intake of lead via food by is less than 25% of the PTWI, which is 0.025 mg/kg bodyweight/week (equal to 1.75 mg for a person weighing 70 kg). In PT the intake was in the order of 50% of the PTWI. This high intake is due to certain food groups which were reported to contain unusually high lead levels. In PT these foods, e.g. potatoes, were analysed with methods with extremely high detection limits (<1 mg/kg). Since half of that limit is used as the occurrence level for the intake calculation, intake may erroneously appear to be very high. In e.g. IR the intake is underestimated (0.4% of the PTWI) since occurrence data were available only from a few food items . The mean intake in the Member States is 14% of the PTWI. In the UK the intake by the mean population is 11% of the PTWI, whereas the intake by mean

consumers is 24% and for high level consumers 43% . Specific foodstuffs from some Member States were reported to contain very high lead levels (wine, game, fish and meat). If these high occurrence levels are confirmed, or the sampling found to be representative, consumers in these Member States may be at risk of exceeding the PTWI. Data from FR and DE indicate that children have a lower intake of lead than adults. However, children have a larger burden/kg body weight, due to their lower body weight, and may reach 35 % of the PTWI (European Commission Direc-torate-General Health and Consumer Protection- Assessment of the dietary exposure to arsenic, cadmium, lead and mercury of the population of the EU Member States. SCOOP 3.2.11, 2004).

G) Mercury

Thirteen Member States submitted occurrence and intake data for fish**.** DK, DE and the UK had the best data to make an accurate intake estimation. FI, IT and SE had data for only one food category. Fish is the main source of mercury in the food, for the mean adult population. In fish and shellfish, mercury is present mainly in the form of methylmercury, while its almost entirely inorganic mercury in other foodstuffs.Fruits and vegetables are the main source of mercury in FR, NL and DE. In FR and DE mushrooms is included in this category,which strongly affects the intake level. Dried fruit and vegetables also has an enhancing effect on the intake in DE. The mean intake for the Member States is less than 30% of the PTWI for total mercury, corresponding to 0.35 mg for a person weighing 70 kg. In the UK the intake by mean consumers is 6% of the PTWI, whereas for high consumers is 13% of the PTWI. The current PTWI (established 2003) for methylmercury is 1.6 μg/kg bodyweight, which corresponds to 0.112 mg/week for a person weighing 70 kg. Data were reported for total mercury, but as an

overestimate assuming this was all methylmercury, the mean intake of methylmercury from fish and shellfish in the Member States would be less than 30% of the PTWI for methylmercury. In the UK the methylmercury intake by mean consumers would be 13% of the PTWI, whereas for high consumers it would be 41% of the PTWI for methylmercury. In NO the methylmercury intake by mean consumers would correspond to 78% of the PTWI for methylmercury, whereas for high consumers, the PTWI for methylmercury would be exceeded.

Data from FR and DE indicate that children have a lower intake of mercury than adults. However, children have a larger burden/kg body weight due to their lower body weight. Depending upon the proportions of methylmercury present in the foods tested for total mercury, it is possible that the intake could exceed the PTWI for methylmercury . The results from the SCOOP task indicate that there is a risk that population-groups with a high consumption of fish and seafood may have intakes of methylmercury that are close or even exceed the PTWI for methylmercury of 1.6 □g/kg body weight/week. More information is needed on the relative proportions of methylmercury to total mercury in different foods (European Commission Directorate-General Health and Consumer Protection- Assessment of the dietary exposure to arsenic, cadmium, lead and mercury of the population of the EU Member States. SCOOP 3.2.11, 2004).

H) Monochloropropane-1,2-diol (3-MCPD)

This substance belongs to a group of chemicals called chloropropanols. Other chloropropanols include 2-monochloro-1,3-propandiol (2-MCPD), 1,3-dichloro-2-propanol (1,3-DCP) and 2,3-dichloro-2-propanol (2,3-DCP). These can be formed in foods as a result of processing

conditions, though the mechanism for their formation is not fully understood. In the 1980's it was found that the procedure used to manufacture acid hydrolysed vegetable protein (acid-HVP), the most widely used HVP, could generate small amounts of chloropropanols, the most common of which is 3-MCPD10,11. Since then it has been found to occur in several other foods and food ingredients as a result of processing, storage conditions or less frequently from migration from certain food contact materials. Acid-HVP is a savoury ingredient used in foods such as soups, prepared meals, savoury snacks, gravy mixes and stock cubes. Typical levels of use range from 0.1% to approximately 0.8% in these foodstuffs11. Chloropropanols have most noticeably been found in soy sauce. Therefore, chloropropanols and particularly 3-MCPD have become an international issue affecting foods worldwide. The European limit for 3-MCPD in soy sauce and acid-HVP has been set at 0.02 mg/kg based on the liquid product containing 40% dry matter5. The regulation was formally adopted on 8 March 2001, and applied from 5 April 2002. Acid-HVP is produced by treating proteins from vegetables, such as soya, with hydrochloric acid13. During this process, components of fats and oils in the starting materials may be chlorinated at high temperature (**Reports on tasks** for scientific cooperation, Task 3.2.9 'Collection and collation of data on levels of 3-monochloropropa-nediol (3- MCPD) and related substances in foodstuffs'. http://ec.europa.eu/food/food/chemicalsafety/contaminants/scoop/task 3.2.9_final_report_ chloropropanols_en.pdf)

I) Acrylamide

Acrylamide (CH2=CHCONH2) may be formed in foods, typically carbohydrate-rich and protein-low plant commodities, during cooking or other thermal processing such as frying, baking or roasting at temperatures of 120 °C or higher. The European Food Safety Authority

(EFSA) has published a report on acrylamide levels in food including an exposure assessment to estimate the intake of acrylamide for different age groups as well as the major contributors to acrylamide exposure in the diets of consumers in Europe. The report is based on data submitted by Member States between 2007 and 2009[1] and will be used by the European Commission and EU Member States to help them assess the effectiveness of voluntary measures taken by the food industry to reduce acrylamide levels. When comparing data from 2007 with those of 2009, a trend towards lower acrylamide levels could only be found in 3 out of 22 food groups (decrease of acrylamide in crackers, infant biscuits and gingerbread). Over the three-year monitoring period, acrylamide levels were shown to have increased in crisp bread and instant coffee and remained unchanged in a number of other food groups[2]. The highest average levels of acrylamide were found in such foods as potato crisps and substitute coffee, which includes coffee-like drinks derived from chicory or cereals such as barley. Exposure estimates for the different age groups were comparable with those previously reported for European countries. Acrylamide is a chemical compound that typically forms in starchy food products during high-temperature cooking, including frying, baking and roasting. An EFSA statement in 2005 noted that there may be a potential health concern with acrylamide which is known to be both carcinogenic and genotoxic (i.e. it can cause damage to the genetic material of cells). Following a recommend-dation by the European Commission in 2007, Member States are requested to perform yearly monitoring of acrylamide levels and submit the data to EFSA for assessment and compilation in an annual report. This latest report – which compares data submitted in 2009 with previous data from 2007 and 2008 – also includes an assessment estimating acrylamide exposure in different age groups in Europe. The pooled monitoring results submitted by Member States

were combined with individual dietary information from the EFSA Comprehensive European Food Consumption Database[4] to establish exposure to acrylamide through food. Fried potatoes (including French fries), roasted coffee and soft bread were identified as the major contributors to acrylamide exposure in adults; fried potatoes, potato crisps, biscuits and soft bread were identified as the major contributors to exposure in adolescents and children. The exposure estimates for these different age groups in Europe were comparable to those previously reported in scientific literature and in risk assessments carried out by the Joint FAO/WHO Expert Committee on Food Additives (JECFA)[5]. At that time, JECFA concluded that acrylamide may indicate a human health concern and that efforts should be made to reduce exposure[6]. As in previous annual acrylamide reports (EFSA 2009, 2010), it can also be concluded that the voluntary measures developed by industry to reduce acrylamide levels in foods, the so-called "toolbox" approach, have had only limited success. To lower overall exposure it would be desirable to further reduce acrylamide levels in food groups that contribute the most to acrylamide exposure. The report also recommends that sampling in future years should consistently cover the same products and contain sufficient sample numbers in each food group to make interpretation of results easier and to establish clear statistical trends. fully understood it is thought that it can be formed via a number of pathways: (i) Reactions between naturally present components of food; (ii) Reactions between component parts of food and chemicals used in the manufacture/packaging of food; (iii) Reactions resulting from the application of heat to food during processing. Acid-HVP is a frequently used ingredient of savoury foods such as soups, prepared meals, savoury snacks, gravy mixes and stock cubes. 3-MCPD has also been found to occur in a range of other foods and ingredients, most notably in soy sauce 12,15. 1,3-

DCP has also been detected in acid-HVP9,10 and soy sauce.Domestic cooking and the effects of cooking on levels of 3-MCPD have shown elevated levels in formation in toasted bread, some grilled cheeses and fried batters (Scoop,2004).

L) Fusarium toxins

Table 2.5. presents a summary of food categories most frequently contaminated with *Fusarium* mycotoxins. Cereals ranking first, among them corn and wheat showed the highest level of contamination with *Fusarium* mycotoxins. The average level intakes (mean food consumption and mean 1 occurrence data) for the entire population as well as for the group adults of deoxynivalenol. are low and do not exceed 46.1 % of the TDI of 1 μg/kg bodyweight/day. However for the group of young children the intake might approach the TDI. Especially for group of young children the TDI can be exceeded. For the group of adolescents (13-18 years) the intake might come to the TDI **(SCOOP ,2003)**. Collection of occurrence data on Fusarium toxins in food and assessment of dietary intake by the population of EU MS was performed and finalised. Based on the scientific opinions and the assessment of the dietary intake, it is appropriate to set maximum levels for deoxynivalenol, zearalenone and fumonisins. As regards fumonisins, monitoring control results of the recent harvests indicate that maize and maize proucts can be very highly contaminated by fumonisins. Intake estimates indicate that the presence of T-2 and HT-2 toxin can be of concern for public health. Therefore, the development of a reliable and sensitive method, col-lection of more occurrence data and more investigations/research in the fac-tors involved in the presence of T-2 and HT-2 toxin in cereals and cereal products, in particular in oats and oat products, is necessary and of high priority (Reports on tasks for scientific cooperation, Task 3.2.10 ‘Collection of occurrence data of

Fusarium toxins in food and assessment of dietary intake by the population of EU Member States'.

http://ec.europa.eu/food/fs/scoop/task3210.pdf, in the framework of Directive 93/5/EEC).

All intakes of nivalenol are far below the t-TDI of 0.7 μg/kg bodyweight/day (SCOOP,2003). The t-TDI of 0.06 μg/kg bodyweight/day for the sum of the two toxins (T-2 and HT-2 Toxin) is often exceeded. However, the significance of the total number of positive samples must be considered. Only 20 % of the samples tested for HT-2 toxin and 14 % of the samples tested for T-2 toxin were positive. Therefore the mean 1 (and the intake) is strongly influenced by the limit of detection of the used analytical methods. Wheat and wheat containing products (like bread and pasta) are the predominant source for DON, NIV T-2 toxin and HT-2 toxin intake (SCOOP,2003). As far as the information is available, the intakes other trichothecenes are very low (SCOOP,2003). The average daily intakes of Zearalenone ranged among adults from 0.8 to 29 ng/kg body weight. Small children had the highest average daily intakes ranging from 6 to 55 ng/kg bodyweight/day. The t-TDI value of 0.2 μg/kg of body weight per day is not exceeded. Main contributors for the intake were found to be corn, wheat and the corresponding products. (SCOOP, 2003). The average daily intakes Fumonisins. are well below the fumonisins group TDI of 2 μg/kg body weight/day. Higher intakes were noted for young children. Cereals represent the major source of intake for fumonisins. Among cereals, corn and wheat dominate as main contributors to the total intake (SCOOP, 2003).

M) Occurrence of polycyclic aromatic hydrocarbons (PAH)

In the framework of Directive 93/5/EEC, a specific SCOOP-task 'Collection of occurrence data on PAH in food' has been performed in 2004. High levels were found in dried fruits, olive

pomace oil, smoked fish, grape seed oil, smoked meat products, fresh molluscs, spices/sauces and condiments. In order to protect public health, maximum levels are necessary for benzo(a)pyrene in certain foods containing fats and oils and in foods where smoking or drying processses might cause high levels of contamination. Maximum levels are also necessary in foods where environmental pollution may cause high levels of contamination, in particular in fish and fishery products, for example resulting from oil spills caused by shipping. In some foods, such as dried fruit and food supplements, benzo(a)pyrene has been found, but available data are inconclusive on what levels are reasonably achievable (Reports on tasks for scientific co-operation, Task 3.2.12 'Collection of occurrence data on polycyclic aromatic hydrocarbons in food'. http://ec.europa.eu/food/food/chemicalsafety/contaminants/scoop_ task 3.2.12_final_report_pah_en.pdf).

PAH can be formed from a variety of combustion and pyrolysis processes. Humans can be exposed to PAHs through different routes. For nonsmokers, the major route of exposure is from food with a minor contribution from inhaled air. In cigarette smokers, the contribution from smoking and food may be of similar magnitude. Food can be contaminated from environmental sources, industrial food processing and from home food preparation. However, there are some uncertainties in relation to the accuracy of benzo[*a*]pyrene as a general indicator for overall PAH contamination and the selection of food groups specified in the regulation.The Commission thus issued recommenda-tion 2005/108/EC2 asking Member States tomonitor the level of priority PAHs in food and requested that the European Food Safety Authority collate and evaluate the information gathered. Seventeen Member States submitted useful results from testing of 9,714 food samples belonging to 95 different Codex food categories for the presence of up to 25

different PAHs,including the 16 nominated compounds. The maximum concentration recorded for any priority PAH was 1,064 μg/kg of benzo[*a*]anthracene in tinned sprats in oil, while 31.8% of samples tested negative for any PAH. Benzo[*a*]pyrene concentrations over the detection limit were found in 72 of the 95 Codex food categories or in 47% of the samples tested. Only 36 food categories or 13.4% of the samples had concentrations exceeding 1 μg/kg and 16 food categories or 2.3% of the samples had concentrations exceeding 10 μg/kg. Samples belonging to food categories covered by Regulation (EC) 1881/2006 exceeded the respective limits for benzo[*a*]pyrene in up to 7.3% of cases (processing factors for preserved fish samples could not be calculated). However, some other PAHs were present at higher or much higher concentrations. Testing of some other food categories revealed relatively high concentrations of several PAHs in cocoa butter, canned smoked fish and food supplements while dried fruit had considerably lower concentrations. There was a lack of reporting of production conditions associated with the different samples.It was possible to elucidate that smoking temperature had a significant influence on the formation of PAH in that higher temperatures were associated with higher PAH levels. The assumption that benzo[*a*]pyrene is a good indicator of any PAH contamination was proved dubious. Of the samples tested for all of the 15 SCF priority PAHs, 33% showed concentrations for one or more PAH above the limit of detection with benzo[*a*]pyrene concentrations below the limit of detection. Results varied across food categories and the different PAHs. Chrysene was the most problematic compound with 38% above the limit of detection and concentrations of up to 343 μg/kg found in samples with benzo[*a*]pyrene below the limit of detection. Benzo[*c*]fluorene, the compound highlighted by JECFA, had the second highest maximum of almost 27 μg/kg in a sample testing negative for ben-zo[*a*]pyrene. In view

of these findings, the suitability of maintaining benzo[*a*]pyrene as a marker needs to be carefully assessed, alongside with other possible risk management options. The results also poin to a problem with high levels of PAH found in cocoa butter, canned smoked fish and food supplements that might be considered for separate legislative action, while it seems possible to produce dried fruits without elevated levels of PAH .(EFSA/datex/002 (revision 1) Findings of the EFSA data collection on polycyclic aromatic hydrocarbons in food, first issued on 29 june 2007 and revised on 31 july 2008)..

N. Nitrates

The total intake of nitrate is normally well below 3,65 mg/kg bw, corresponding to the acceptable daily intake (ADI). It was recommended, however, continuation of efforts to reduce exposure to nitrate via vegetable food and water (Opinion of 22 September 1995 (Reports of the Scientific Commit-tee for Food, 38th series, Opinion of the Scientific Committee for Food on nitrates and nitrite, p. 1, http://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_38.pdf).

3.3.3 Continuous call for collection of chemical contaminants occurrence data in food and feed

In the framework of Articles 23 and 33 of Regulation (EC) No 178/2002 EFSA has received from the European Commission the mandate to collect on a continuous basis all available data on the occurrence of chemical contaminants in food and feed In particular, in mandate M-2010-0374 the Commission summarises the scope of the continuous data collection on chemical contaminants.

After consulting with the Commission and the EFSA Network on Chemical Occurrence Data, a continuous annual call for data (deadline October each year) is issued requesting data on a list of chemical contaminants. The continuous call for data includes several contaminants for which Commission Recommendations on occurrence monitoring are in place (see the previous Section 3.3.1.)

Member States, research institutions, academia and any other stakeholders are invited to submit data on the presence of these contaminants. EFSA also welcomes data on occurrence of other contaminants in food and feed that have been analysed in Member States. Data will be extracted from the EFSA data management system and used in future EFSA scientific opinions and reports.

Rules on use, disclosure and re-use of contaminant occurrence data in food and feed were agreed by the former Standing Committee on the Food Chain and Animal Health, section 'Toxicological Safety of the Food Chain' on 19 May 2010.

Call for data

National food authorities, research institutions, academia, food business operators and other stakeholders are invited to submit data on occurrence of any of the following contaminants (Tab 3.1).If data providers are willing to submit data on any other chemical contaminants not listed in the above table, a more detailed list of the data collection groups is also provided. Submitted data should be compliant with the Standard Sample Description (SSD) agreed between EFSA and the EU Member States and published in January 2010 (

http://www.efsa.europa.eu/en/efsajournal/pub/1457.htm). The nature of the food samples should be always defined according to the catalogue "FOODEX" and be reported in the variable **EFSAProdCode**. Please, note that the catalogue "MATRIX" is of specific interest in reporting Pesticide Residues and its use is optional in the context of this call for data (use the available XXXXXXA code in the variable **prodCode** when MATRIX catalogue not available or applicable).

SSD compliance of data not generated according to this standard can be obtained in the following ways: (i) through appropriate mapping in case of data existing in database form or (ii) using the provided excel sheets (simplified format) in case of manual entry. Data can be submitted in electronic format (XML) or in the simplified Microsoft Excel reporting format. Electronic transmission in XML format is strongly recommended. The XML schema to validate the XML message can be downloaded from http://www.efsa.europa.eu/en/scdocs/doc/1895ax1.zip (file: StandardSampleDescription.xsd). More details on how to submit the occurrence data can be found at http://www.efsa.europa.eu/en/datexcallsfordata/datexsubmitdata.htm and in the Guidance on Data Exchange (http://www.efsa.europa.eu/en/scdocs/doc/1895.pdf) . The "Guidance on Standard Sample Description" and the "Generic Reporting Format" are generally applicable. For some contaminant groups listed in the same web page, specific additional rules are applicable. These are reported as instruction files and specific excel formats. The specific formats are not deviating from the general SSD, they only prescribe different status (optional/mandatory) for some fields and may restrict the catalogues to only the applicable entries. Data should be transmitted using the EFSA web interface "Data Collection Framework (DCF)"

(https://dcf.efsa.europa.eu/dcf-war). In order to receive access to the DCF web interface please contact data.collection@efsa.europa.eu. In case data are compiled using the simplified excel file, they cannot be transmitted using the DCF web interface. In this case data should be sent to the e-mail address (data.collection@efsa.europa.eu).

These data are regularly utilized by EFSA for the evaluation of population groups exposure as a fundamental parte of the risk assessment associate with te occurrence of contaminants in food/feed.

4. RISK ASSESSMENT

4.1. Introduction

The presence of chemical contaminants or undesirable substances in food and feed is often unavoidable as these substances may occur ubiquitously (e.g. dioxins and dioxin-like PCBs or heavy metals such as lead and cadmium) or are of natural origin (e.g. inherent plant constituents such as alkaloids, or mycotoxins such as aflatoxins (EFSA, 2004a-d, 2005a, 2006b, 2007a, b, 2008a, 2009b, 2011c)). Therefore, human exposure to such substances is also unavoidable. The risk assessment of chemical contaminants in food relies on the integration of two components: knowledge about the human exposure to these substances via food and other routes, and their potential to cause adverse health effects (i.e. the hazard). The risk is the likelihood of the occurrence of adverse health effects at a given exposure. The assessment of animal health risks associated with the presence of undesirable chemical substances in feed follows the same principles as the human health risk assessment (see risk assessment principles). However, in the

hazard characterisation, species-specific and inter-species differences in animals need to be taken into account.

At the European level, the scientific Bodies in charge for providing scientific assessments on food/feed contaminants have been the Scientific Committee for Food (SCF) until May 2003 and the European Food Safety Authority (EFSA) since then. According to Reg. EC 178/2002, "risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner." Moreover, very active, but working at an international and not European level, has been in this sector the Joint Scientific Committee FAO/OMS (JECFA) (See Section 4.2.4) .

4.2. Main European and International Bodies competent of risk assessment

4.2.1. The Scientific Committee for Food (SCF)

The Scientific Committee for Food was originally established by Decision 74/234/EEC of 18 April 1974, replaced by Commission Decision 95/273/EC of 6 July 1995 and then by Commission Decision 97/579/EC of 23 July 1997 to advise the European Commission on scientific and technical questions concerning consumer health and food safety associated with the consumption of food products and in particular questions relating to toxicology and hygiene in the entire food production chain, nutrition, and applications of agrifood technologies, as well as those relating to materials coming into contact with foodstuffs, such as packaging. Moreover, in 1997, in order to ensure an effective coordination of the 8 Scientific Committees established by Commission Decision 97/579/EC with different mandates including the SCF, they were all transferred to the responsibility of the General Directorate of the European Commission for Consumer Protection and the so called "Scientific Steering Committee", was established

consisting of all the chairmen of the different Scientific Committees and of a small number of external experts.

This Committee remained in place, with the denomination “Scientific Committee on Food” until the year 2003 when the European Food Safety Authority entered into force. Consultation of this Committee was required, in relation to questions of public health, by a number of Directives such as those on dietetic foodstuffs, materials and articles intended to come into contact with foodstuffs, additives, flavourings and extraction solvents and, obviously, contaminants.

Members were appointed to the Scientific Committees for a term of three years, and were not allowed to remain in office for more than two consecutive terms. Members of the Scientific Committees, in their capacity as such, were expected to act independently of all external influence. Each year the members of the Scientific Committees had to inform the Commission of any interests which might have been considered prejudicial to their independence. Members of the Scientific Committees and the external experts had also to declare at each meeting any specific interests which might have been considered prejudicial to their independence. . In agreement with the Commission, the Scientific Committees and the sub-committees could invite specialized external experts to participate in their work and establish specific working parties with clearly defined tasks. Each working party had to be chaired by a member of the Committee or of the sub-committee and could include external experts. The Commission was in charge for providing the secretariat of the Scientific Committees, the sub-committees and the working parties. The agendas, minutes and opinions of the Scientific Committees were made publicly available without undue delay and with regard being had to the need for commercial

confidentiality. Minority opinions were always be included and attributed to members only at their request. Without prejudice to Article 214 of the Treaty, the members and external experts were obliged not to divulge information acquired as a result of the work of the Scientific Committees, sub-committees or one of the working parties, when they had been informed that this information was subject to a request for confidential.

4.2.2. The European Food Safety Authority (EFSA) and its CONTAM Panel

The European Food Safety Authority (EFSA) was set up in January 2002 by Reg. CE 178/2002, following a series of food crises in the late 1990s and especially the BSE crisis, as an independent source of scientific advice and communication on risks associated with the food chain. EFSA was established as part of a comprehensive programme to improve EU food safety, ensure a high level of consumer protection and restore and maintain confidence in the EU food supply. In the European food safety system, risk assessment is done independently from risk management. 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, European Parliament and EU Member States 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.

EFSA's role is to assess and communicate on all risks associated with the food chain. Since EFSA's 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. Requests for scientific assessments are received from the European Commission, the European Parliament and EU Member States. EFSA also undertakes scientific work on its own initiative, so-called "self-tasking". Accordingly, EFSA's advice frequently supports the risk management and policy-making processes. These may involve the process of adopting or revising European legislation on food or feed safety, deciding whether to approve regulated substances such as pesticides and food additives, or, developing new regulatory frameworks and policies for instance in the field of nutrition. EFSA is not involved in these management processes. Through its risk communications activities EFSA seeks to raise awareness and further explain the implications of its scientific work. EFSA aims to provide appropriate, consistent, accurate and timely communications on food safety issues to all stakeholders and the public at large, based on the Authority's risk assessments and scientific expertise.

In developing its scientific opinions, EFSA follows a workflow that runs from the moment EFSA receives a request for scientific advice or initiates its own activity to the moment it publishes and communicates its scientific findings. EFSA has developed a comprehensive body of good risk assessment practices to guide the 10 Scientific Panels. Competent in different sectors, and the Scientific Committee (Figure 4.1) to help ensure EFSA opinions respect the highest scientific standards. The Scientific Committee and each Panel consist of about 20 experts in different disciplines as required by the respective missions; these scientific experts are selected through a worldwide call for manifestation of interest mainly on the basis of the quality and relevance of their scientific productions. Moreover, working groups can be established with additional experts included in the EFSA List of External Experts or not.

Figure 4.1- Organisational Structure of EFSA on 01/01/2015 (Source: EFSA Website)

The workflow for scientific opinions runs from the moment EFSA receives a request for scientific advice or initiates its own activity to the moment it publishes and communicates its scientific findings (Figure. 3). EFSA implements a quality assurance system to continually review and strengthen the quality of its scientific work. The risk assessment and risk communication work carried out by EFSA is underpinned by strict legal criteria. EFSA has its own legal personality and while funded from the Community budget, it operates independently of the community institutions such as the European Commission and the Parliament. It is managed by an Executive Director, who in turn is answerable to an independent Management Board. Since its creation, EFSA has established key operating principles and rules which have been adopted by its Management Board. They include a commitment to openness and transparency in all of the Authority's work. In addition the Authority is bound by European Union legislation on issues such as public access to documents. In accordance with its Founding Regulation, EFSA is legally obliged to publish on its website outcomes of its scientific work as well as main management documentation such as budgets, accounts and contracts.

EFSA is organized in five departments, under the supervision of the EFSA Executive Director (see Table 4.1):

- scientific departments:
    - Risk assessment & scientific assistance (RASA)
    - Scientific evaluation of regulated products (REPRO)
    - Science strategy& coordinationt (SCISTRAT)

- non-scientific departments

  - Communications & external relations (COMMS)

.. - Resources& support (RESU)

EFSA has also access to substantial in-house scientific expertise with about 450 employes (63% female and 37% male) , most of which with a scientific background coming from many EU Member States with a budget amounting to about EUR 70 million entirely funded by the European Union .

Although EFSA does not fund research of its own, it will likely be able to access such funding as specific needs are demonstrated. It will also work closely with DG Research and will use its own funds to make possible short term studies as specific needs arise. The financial resources is used in a number of areas covering science, communications, institutional relations and administration. Networking and collaboration is also important as the Authority is committed to finding leading experts in a wide range of food-related scientific fields. Experts from all over Europe are engaged in the Authority's comprehensive work programme, with annual and multi-annual components, some of which will require the use of external scientific services.

A main recent development in the EFSA's organization has been the establishment of the Applications Helpdesk with two main roles:

- To act as a front office and support desk for applicants, Member States and other stakeholders who have questions regarding applications for the scientific evaluation of regulated products

- To centralise and process, within EFSA, the initial administrative steps of all applications (including reception, registration and verifying the completeness of the information in the submitted application).

The Applications Helpdesk is the first point of contact within EFSA for applicants; the dedicated section on EFSA's website provides extensive information regarding applications (e.g. legal framework, procedures, available guidance documents, data requirements, information on the processing and the status of their application). There is also a dedicated web form for applicants to submit more specific questions. The Application Helpdesk will either answer the question directly, liaising as needed with the scientific unit, or guide the applicant to an appropriate contact point.

Many food and feed related products require scientific risk assessment by EFSA before they can be authorised for use on the EU market: 'regulated products' include substances used in feed and food (such as additives, enzymes, flavourings, nutrient sources), food contact materials and pesticides, GMOs, food manufacturing processes and processing aids. EFSA's regulated products mandate also includes the scientific substantiation of nutrition and health claims. Within EFSA, the Scientific Evaluation of Regulated Products Directorate (REPRO) supports most of EFSA's work in the evaluation of substances, products and claims intended to be used in the food chain in order to protect public, plant and animal health as well as the environment. This work accounts for 60 % of EFSA's outputs and some 40 % of its resources. Within REPRO the Applications Helpdesk is responsible for centralising and processing the initial administrative and scientific steps of all applications before they are forwarded to the respective units for

evaluation by the experts on the relevant Scientific Panel with the support of EFSA's scientific staff. The centralisation and service-orientation of this work within the Applications Helpdesk aims to standardise the handling of applications and ensure consistent quality control of applications received.

The EFSA's CONTAM Panel consists of about 20 experts with different nationalities and expertises, assisted by a team part of the Unit on Biological Hazards and Contaminants (BIOCONTAM Unit) . The Scientific secretariat providing technical assistance and coordination to the CONTAM Panel and its working groups. The chairperson and two vice-chairs are generally elected for the three years of the mandate.

The mandate of the EFSA Panel on Contaminants in the Food Chain (CONTAM Panel) is t**o** deliver scientific opinions on contaminants in food and feed, associated areas and undesirable substances i.e. natural toxicants, mycotoxins and residues of non authorised substances not covered by another Panel. The overall objective is to assess whether exposure to a chemical contaminant in food is likely to be associated with adverse health effects in the European population or whether exposure to a contaminant in feed is likely to be associated with adverse health effects in farm animals, fish and pet in Europe ,or to represent a risk to the consumer of foods of animal origin . Therefore, tensure a high level of protection of human health but also the protection of animal health.

Within this context the CONTAM Panel, over many years since its inception, has assessed human and animal health risks related to the presence of persistent organic pollutants, natural toxins and plant toxicants, metals and metalloids, reaction products from thermal food processing, cross-contamination of feed for non-target animals with chemicals authorised for use

such as feed additives, or non-authorised substances such as hormones, and complex mixtures such as mineral hydrocarbons in food and/or feed. The majority of the requests were received from the European Commission (EC) (95 %) a smaller amount of requests came from Member States (1 %) and the European Parliament (1 %). In addition the CONTAM Panel carried out also a few self tasking activities during this period. Since its establishement ,the CONTAM Panel of EFSA has published ,in addition to other documents, 122 scientific outputs of which 67 address contaminats in food, 42 contaminants in feed and 13 consist of a combined assessment of contaminants in food and in feed. The Contam Panel has also provided several " Urgent advices**",** within its remit , on the following subjects:

- Melamine in food and feed (July 2007) (EFSA Statement in 10 days);
- Mineral oil in sunflower oil (April 2008) (Initial view in 1 day & EFSA Statement in 4 weeks);
- Melamine in food (September 2008) (EFSA Statement in 6 days);
- Dioxins in Irish pork (December 2008) (EFSA Statement in 2 days);
- Nicotine in wild mushrooms (April 2009) (EFSA Statement in 10 days);
- Icelandic volcanic ashfall (April 2010) (EFSA Statement in 3 days)
- Ammonium in water filters (October 2012) (EFSA Statement in 15 days);
- Phenylbutazone in horse meat (April 2013) (Joint EFSA and EMA Statement in 6 weeks); and

- Derogation of maximum levels of DON, ZEA and FBs in maize and maize food products (April 2014) (EFSA Statement in 6 weeks).

4.2.3. The Joint Scientific Committee FAO/OMS (JECFA) and Codex Alimentarius

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) is an international scientific expert committee that is administered jointly by the Food and Agriculture Organization of the United Nations FAO and the World Health Organization WHO. It has been meeting since 1956, to evaluate mainly the safety of food additives. Its work now also includes the evaluation of contaminants, naturally occurring toxicants and residues of veterinary drugs in food. to date, JECFA has evaluated approximately 50 contaminants and naturally occurring toxicants. The Committee also develops principles for the safety assessment of chemicals in food that are consistent with current thinking on risk assessment and take account of recent developments in toxicology and other relevant sciences.

The Codex Alimentarius Commission was estalished in 1963 by FAO and WHO to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. The main purposes of this Programme are protecting health of the consumers and ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations. Codex standards are based on scientific advice as provided by JECFA and JMPR (for the pesticide residues).

The principles and methods applied by JECFA and JMPR for the safety assessment of chemicals in food are outlined in the Monograph EHC 240 - Principles and methods for the risk assessment of chemicals in food.

Among a number of different chemicals assessed by JECFA , dioxins,furans and dioxin-like PCBs have received a special attention. During the assessment in 1997 at the WHO/IPCS expert consul-tation in Stockholm, it was agreed to re-evaluate TEF values on a regular basis, preferably at five-year intervals. Such a re-evaluation should be based on new scientific information published in the peer reviewed literature subsequent to the last expert consultation. To follow this recommen-dation and to take account of a vast amount of new scientific studies, in 2005 WHO organized an expert workshop to review and assess all new information and to recommend updated TEF values for dioxins, furans, and dioxin-like PCBs as appropriate.

During the workshop, the expert group developed and applied a systematic decision scheme to review existing TEFs, using the WHO 98 TEF values (Van den Berg et al., EHP 106, 1998) and the recently published updated database of relative potencies (REP) (Haws et al., ToxSci 89, 4-30, 2006) as a starting point. Previous decisions of the 1997 expert consultation were reviewed in light of new data and of the distribution of REP values. For each congener, the decision scheme was applied and the 2005 TEF value derived and expressed as half-log increments. The decision taken for each congener is described in detail which significantly increases the transparency of the TEF derivation and allows for easier refinement should new data become available. As a result, a number of TEF values have been changed, notably for PCBs, octachlorinated congeners and pentachlorinated furans. In addition the expert group commented in detail on the application

of the TEF concept and the possible inclusion of new compounds into this concept. Recommendations are given for future developments in this area.

The outcome of this expert consultation has been published as peer-reviewed article in the journal Toxicological Sciences (7 July 2006).

Compound	WHO 1998 TEF	WHO 2005 TEF*
chlorinated dibenzo-p-dioxins		
2,3,7,8-TCDD	1	1
1,2,3,7,8-PeCDD	1	1
1,2,3,4,7,8-HxCDD	0.1	0.1
1,2,3,6,7,8-HxCDD	0.1	0.1
1,2,3,7,8,9-HxCDD	0.1	0.1
1,2,3,4,6,7,8-HpCDD	0.01	0.01
OCDD	0.0001	0.0003
chlorinated dibenzofurans		
2,3,7,8-TCDF	0.1	0.1
1,2,3,7,8-PeCDF	0.05	0.03

Compound	WHO 1998 TEF	WHO 2005 TEF*
2,3,4,7,8-PeCDF	0.5	0.3
1,2,3,4,7,8-HxCDF	0.1	0.1
1,2,3,6,7,8-HxCDF	0.1	0.1
1,2,3,7,8,9-HxCDF	0.1	0.1
2,3,4,6,7,8-HxCDF	0.1	0.1
1,2,3,4,6,7,8-HpCDF	0.01	0.01
1,2,3,4,7,8,9-HpCDF	0.01	0.01
OCDF	0.0001	0.0003
Non-ortho substituted PCBs		
PCB 77	0.0001	0.0001
PCB 81	0.0001	0.0003
PCB 126	0.1	0.1
PCB 169	0.01	0.03
mono-ortho substituted PCBs		
105	0.0001	0.00003
114	0.0005	0.00003

Compound	WHO 1998 TEF	WHO 2005 TEF*
118	0.0001	0.00003
123	0.0001	0.00003
156	0.0005	0.00003
157	0.0005	0.00003
167	0.00001	0.00003
189	0.0001	0.00003

In 2005, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) performed also a risk assessment on PAHs, basically agreed with the SCF selection, downgraded one substance from the SCF list, and nominated one further compound for observation in food (JECFA, 2005). The combined list nominated by either SCF or JECFA would thus comprise of 16 substances. Maximum levels of benzo[*a*]pyrene, used as a marker for PAH contamination, in a range of foodstuffs are now specified in Commission Regulation (EC) 1881/20061.

4.3. Risk assessments on food contaminants and undesirable substances in products intended for animal feed

Both the SCF and EFSA have been very active in carrying out risk assessment on food contaminants, covering the all period from 1974 to today.

4.3.1. Risk assessments carried out by the SCF

Throughout about 30 years of activity, the Scientific Committee for/on Food has been extremely active, with the help of the SCOOP procedure during its 10 years of activity, in assessing risks associated with food contaminants (Table 4.2). Main opinions have been provided on nitrates, aflatoxins, ochratoxin A, patulin, Fusarium toxins, arsenic, cadmium, lead, mercury, tin, 3-monochloro-propane-1,2-diol (3-MCPD), dioxins and PCBs and polycyclic aromatic hydrocarbons. Changing the basis for calculating toxic equivalent units of Dioxins and dioxin-like PCBs to the new recommendations issued by WHO in 2005 will overall result in 14% lower values with the extent of the difference highly variable across food and feed groups.

4.3.2. Risk assessments carried out by EFSA/CONTAM Panel

The activity of EFSA in evaluating food/feed contaminants through the CONTAM Panel has been very intensive (Table 4.3) since its establishment (see also the article entitled "Risk assessment of contaminants in food and feed», published in the EFSA Journal 2012;10(10):s1004).

4.3.2.1. Methodologies adopted by EFSA

A) Data sources and data mining in risk assessment – assumptions and uncertainty

In contrast to many other Panels, the CONTAM Panel does not base its risk asses-sments on an application presented to EFSA, e.g. in the framework of a marketing authorisation procedure, but relies on scientific information that is in the public domain. That holds for data on the toxicological effects of the substances under investigation, for occurrence data in the relevant food and/or feed matrices and for food or feed consumption data. These data are usually collected from publicly available sources such as peer-reviewed papers published in scientific

journals, official national reports from EU MSs or risk assessment evaluations from international organisations such as the World Health Organization. To complement these open data sources, the Data Collection and Monitoring (DCM) Unit of EFSA regularly launches a call for data on occurrence of the substance(s) of interest and collects food consumption data.

In response to these calls, mainly competent authorities of European countries but also other stakeholders submit occurrence data in a specific format as requested by EFSA. Depending on the substance(s) for which information is requested, the number of countries providing data and the total number of submitted results may differ considerably. While for some contaminants (e.g. some marine biotoxins and mycotoxins) only a small number of results was submitted, for other substances, such as cadmium, the number of submitted results exceeded 100 000 (EFSA, 2004a; EFSA Panel on Contaminants in the Food Chain (CONTAM), 2009a, 2010a, 2012a). It should be noted that normally occurrence data submitted to EFSA do not stem from samples that were intended for risk assessment purposes, but originate from samples that were analysed within the framework of official food and feed control with the objective to check whether food and feed commodities comply with legal limits. As a consequence, the data submissions often contain a high number of left-censored data, i.e. data below the limit of detection (LOD) or the limit of quantification (LOQ). In addition, the LOD and LOQ of the analytical methods are sometimes adjusted to the legal limits and not to the actual background of the respective contaminants in food and feed. These issues may introduce considerable uncertainty in the occurrence data and the submitted data are therefore thoroughly checked by the DCM Unit to provide all relevant information and as reliable estimate as possible of the distribution of the respective substance(s) in food and feed.

Human exposure is a key element in the risk assessment of contaminants. For this purpose, occurrence levels in food are combined with consumption patterns across European populations to estimate human exposure to the respective contaminants. In addition to the general population, the risk assessments generally also consider the exposure of specific consumer groups, such as infants, children, and people following specific diets (e.g. vegetarians). Information on consumption for all these groups stems from national consumption surveys submitted to EFSA and combined in the Comprehensive European Food Consumption Database. This database includes information from more than 30 national dietary surveys from 22 European countries. In combination with the occurrence data, it forms the basis for the estimation of human exposure to contaminants from food. Depending on the nature of the toxicity of the contaminant of interest, chronic and/or acute exposure assessments are performed, using probabilistic models where possible to provide some insight into the uncertainties around the exposure estimate.

Comparable databases for feed consumption do not exist in Europe. Therefore the assessment of animal exposure is based on the submitted occurrence data and/or the data collected from the literature and from typical European feed regimes for various animal species.

Compared to the assessment of individual substances, additional uncertainties are introduced when the risk assessment concerns mixtures of substances such as polychlorinated biphenyls (PCBs) and flame retardants such as polybrominated diphenylethers (EFSA, 2005a; EFSA Panel on Contaminants in the Food Chain (CONTAM), 2011a,b). Due to their different physical-chemical properties, the different components of these mixtures vary with respect to their behaviour in the environment and their appearance in the food chain. Consequently the composition of the original technical mixture which was tested in toxicity studies generally does

not resemble the composition of the mixture of substances to which humans are exposed via food.

The evaluation of the inherent uncertainties in the assessment of exposure to contaminants is performed following the guidance of the Opinion of the Scientific Committee related to Uncertainties in Dietary Exposure Assessment (EFSA, 2006a). According to this guidance document, uncertainties in assessment objectives, exposure scenario, exposure model, and model input (parameters) are generally considered. In addition, uncertainties in the scientific basis of the hazard characterisation are qualitatively considered. In this way, the CONTAM Panel provides an overall assessment of the uncertainties inherent in the risk assessments.

B) Human risk assessment

The presence of chemical contaminants or other undesirable substances in food and feed is often unavoidable as these substances may occur ubiquitously (e.g. dioxins and dioxin-like PCBs or heavy metals such as lead and cadmium) or are of natural origin (e.g. inherent plant constituents such as alkaloids, or mycotoxins such as aflatoxins (EFSA, 2004a-d, 2005a, 2006b, 2007a,b, 2008a, 2009a; EFSA Panel on Contaminants in the Food Chain (CONTAM), 2011c)). Therefore, human exposure to such substances is also unavoidable. The risk assessment of chemical contaminants in food relies on the integration of two components: knowledge about the human exposure to these substances via food and other routes, and their potential to cause adverse health effects (i.e. the hazard). The risk is the likelihood of the occurrence of adverse health effects at a given exposure. The task of the CONTAM Panel is to assess whether or not exposure to a chemical contaminant in food is likely to be associated with adverse health effects in the European population or in certain sub-groups. Whenever possible, the CONTAM Panel

establishes an exposure level at which there is no appreciable health risk, called a health-based guidance value (HBGV) such as a tolerable daily intake. In the identification and characterisation of the hazard the Panel takes into account all toxicological information available, including studies on humans, experimental animals, cell- and other systems. In the absence of toxicity data from humans, the HBGV is usually based on data from repeated-dose studies on experimental animals, such as chronic toxicity or multigeneration studies in rats and mice. For the establishment of an HBGV, a reference point (RP) needs to be identified, based, if possible, on mathematical modelling of the dose-response relationship. The EFSA Scientific Committee recommended the use of a benchmark dose lower confidence limit (BMDL) as the RP (EFSA, 2009b). The BMDL is an estimate of the lowest dose that is 95 % certain to cause no more than a specified change in response over background. If modeling is not considered appropriate, another RP may be used such as the no-observed-adverse-effect level (NOAEL), which is the highest dose not causing a statistically significant adverse effect compared to the controls. The HBGV is established by dividing the RP by uncertainty factors to account for extrapolation from animals to humans and for variability in human sensitivity. In some cases the CONTAM Panel has been able to model human data and to incorporate information from biomarkers of exposure or of effect in the characterisation of the hazard, e.g. cadmium and lead (EFSA, 2009b,c; EFSA Panel on Contaminants in the Food Chain (CONTAM), 2010b). This allows the use of a body burden approach, where an estimate of systemic exposure (body burden), rather than external dose, is used in the risk characterisation.

As some substances the CONTAM Panel assesses could give rise to acute health effects in relation to short periods of intake (e.g. certain metals, opium alkaloids, some mycotoxins or

marine biotoxins), the Panel establishes, if possible, an acute reference dose (ARfD) as the HBGV for such substances (EFSA, 2008b-d, 2009d-h; EFSA Panel on Contaminants in the Food Chain (CONTAM), 2009a, 2011d). This is usually based on short-term toxicity data from experimental animals (e.g. acute toxicity or developmental toxicity), but also based on human data when available (e.g. pharmacological activity of opium alkaloids, outbreaks of food poisoning caused by some marine biotoxins). Conversely, when a substance shows a long biological half-life, tends to accumulate in the human body and exposure over a longer time period therefore matters, the CONTAM Panel usually establishes a tolerable weekly intake as the HBGV (e.g. for cadmium or the mycotoxin ochratoxin A (EFSA, 2006b, 2009a)). If human exposure to the substance from food and other sources is below HBGV, the CONTAM Panel usually concludes that such exposure does not pose an appreciable risk to human health.

This "classical" approach for risk assessment needs sufficient knowledge on human exposure (i.e. occurrence data in food and food consumption data), a sufficiently sound toxicological database and the absence of genotoxic potential. This is because the HBGV approach, which assumes a dose threshold for toxicity, is not considered applicable to substances that are genotoxic. In contrast to the situation for substances that are intentionally used for specific purposes in food production (e.g. food additives and plant protection products), for food contaminants there is no manufacturer to provide additional toxicological information. This is a particular challenge for the CONTAM Panel as, unfortunately, the toxicity database on contaminants is often incomplete and limited (e.g. certain marine biotoxins and many mycotoxins).

Many substances that the CONTAM Panel has to assess show genotoxic potential (e.g. aflatoxins, ethyl carbamate, pyrrolizidine alkaloids or polycyclic aromatic hydrocarbons (PAHs) (EFSA, 2004c, 2007a-c, 2008e; EFSA Panel on Contaminants in the Food Chain (CONTAM), 2009a, 2011c)). For substances that cause genotoxicity by a mechanism involving reaction with DNA, it is not possible to identify a dose threshold of effect. Until 2005, the advice given by the risk assessor to the risk manager was to reduce exposure to such substances to a level that is as low as reasonably achievable (known as the ALARA principle). However, it was long recognised that such advice does not provide risk managers with a basis for setting priorities for action, either with regard to the urgency or to the extent of measures that may be necessary. To overcome this, the EFSA Scientific Committee proposed the margin of exposure (MOE) approach4 (EFSA, 2005b) as a harmonised approach for the risk assessment of substances that are both genotoxic and carcinogenic. The MOE approach takes into account the fact that carcinogens differ in their potency, that is, they differ in their likelihood of inducing a tumor at a given dose over time. Information about potency is mostly derived from laboratory studies on rodents (e.g. acrylamide or furan (EFSA, 2004e, 2005c)), since with few exceptions (e.g. arsenic (EFSA Panel on Contaminants in the Food Chain (CONTAM), 2009b)), human data are rarely available. The MOE approach, similar to the derivation of a HBGV, uses an RP on the dose-response relationship often taken from an animal study, corresponding to a dose that causes a low, but measurable cancer incidence in animals (usually the BMDL for a 10 % extra risk). This RP is then compared with various dietary exposure estimates in humans, taking into account differences in consumption patterns. The CONTAM Panel used this approach in several of its assessments of substances that are both genotoxic and carcinogenic (e.g. ethyl carbamate,

pyrrolizidine alkaloids and PAHs (EFSA, 2007c, 2008e; EFSA Panel on Contaminants in the Food Chain (CONTAM), 2011c)). Furthermore, the benchmark dose (BMD) approach can also be applied to human data, which was done by the CONTAM Panel in its assessment of aflatoxin B1 (EFSA, 2007b).

The MOE approach is not confined to substances that are genotoxic and carcinogenic and it can also be applied to cases where the data are insufficient or otherwise considered inappropriate to establish a HBGV. As an example of this, the CONTAM Panel considered it appropriate to calculate MOEs to support the risk characterisation of lead (EFSA Panel on Contaminants in the Food Chain (CONTAM), 2010b). The CONTAM Panel identified developmental neurotoxicity in young children and cardiovascular effects and nephrotoxicity in adults as the critical effects for the risk assessment. The Panel then calculated respective BMDLs for these effects from blood lead levels, which were then extrapolated to external exposure levels for comparison to estimated dietary exposure in various human population subgroups.

There are, however, situations in which the available data on a substance occurring in food do not allow either the establishment of a HBGV or calculation of a BMDL for use as an RP in the MOE approach. This was the case when the CONTAM Panel had to assess the *Alternaria* toxins (EFSA Risk assessment on contaminants EFSA Journal 2012;10(10):s1004 6 Panel on Contaminants in the Food Chain (CONTAM), 2011e). In this case, the CONTAM Panel explored the use of the "threshold of toxicological concern (TTC) approach", which is a screening tool that has been developed in order to assess substances with known structures of unknown toxicity present at very low levels in the diet (EFSA Scientific Committee (SC), 2012).

Application of the TTC approach requires only knowledge of the chemical structure of the substance concerned and information on human exposure, for which there is confidence that it is not an underestimate. It utilises generic human exposure threshold values (also called TTC values) that have been established for substances grouped according to their chemical structure and likelihood of toxicity. The human exposure threshold values developed are based on data from extensive toxicological testing in animals. There are a number of different threshold values and these can be used for substances either with or without a structural alert for genotoxicity, respectively. At exposures below the generic human exposure threshold values, the probability of adverse effects on human health is considered to be very low. For *Alternaria* toxins there are few or no relevant toxicity data, but the chemical structure of several of them is known and in addition dietary exposure data exist for some of them. In using the TTC approach, the CONTAM Panel was able to assess the relative level of concern for dietary exposure of humans to these mycotoxins (EFSA Panel on Contaminants in the Food Chain (CONTAM), 2011e).

C) Animal risk assessment

A general principle of the EU food safety policy is the integrated "farm to fork approach" which includes the protection of human as well as animal health (Regulation (EC) No 178/2002). Within this context the EC tasked EFSA to provide the scientific bases for the revision of the European Directive 2002/32/EC(5 Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed. OJ L 140, 30.5.2002, p.10–22.) which regulates undesirable substances in feed. Subsequently, the CONTAM Panel has addressed over the twelve years of its existence the risks to animal health due to the presence of many substances, including toxic plant secondary metabolites (EFSA 2008a,f-i, 2009i; EFSA

Panel on Contaminants in the Food Chain (CONTAM), 2011c, 2012b), mycotoxins (EFSA, 2004c,d,f, 2005d,e; EFSA Panel on Contaminants in the Food Chain (CONTAM), 2011e,f, 2012a,c), persistent organic pollutants (EFSA, 2005a,f-j, 2006c,d, 2007d,e), toxic metals (EFSA, 2004a,b, 2005k, 2008j) and other substances, e.g. melamine and nitrite in feedstuffs (EFSA, 2009h; EFSA Panel on Contaminants in the Food Chain (CONTAM), 2010c). Moreover, hazards related to feed production technologies (cross-contamination of feed) for non-target animals from coccidiostats authorised in Europe (EFSA, 2007f, 2008k-t) and by-products of biofuel production (EFSA Panel on Contaminants in the Food Chain (CONTAM), 2010d) for farmed animals (ruminants, poultry, pigs and rabbits), fish, and companion animals such as cats, dogs and horses were assessed. Within this mandate, the CONTAM Panel also determined the possible impact on human health from the carry-over of undesirable substances or contaminants into food of animal origin such as meat, milk, eggs and honey.

The assessment of animal health risks associated with the presence of undesirable chemical substances in feed follows the same principles as the human health risk assessment (see Risk assessment principles). However, in the hazard characterisation, species-specific and inter-species differences in animals need to be taken into account. The exposure assessment and risk characterisation are based on the respective animal species and their specific diets. The hazard characterisation aims to identify the most relevant toxicological endpoint for the respective animal species to derive a safe intake level. Most often a NOAEL/lowest-observed-adverse-effect level is identified, at least for major farm animal species, but a BMDL can also be used (EFSA Panel on Contaminants in the Food Chain (CONTAM), 2011f) as an RP. Physiological differences such as the microbiological flora in the forestomach of ruminants and the species-

specific rate of absorption and biotransformation have to be taken into account when assessing the toxicokinetics of a chemical substance in target animal species. However, such data are frequently not available and the available information is confined to case reports of intoxications lacking information about the actual dose and time of exposure. The physiological differences referred to above also influence the potential carry-over of toxic substances and/or their metabolites into food of animal origin. Therefore, the CONTAM Panel flags such uncertainties when evaluating the effects of contaminants on animal species and, via animal-derived products, in humans.

Exposure estimates for animals take into account the amount of feedstuffs consumed by the respective species, as well as the concentration of the particular contaminant in animal feed. Geographic origin, climatic conditions and plant stress influence the level of many undesirable substances in animal feeds. Analytical data on contaminants in feed are often made available by MSs and/or are taken from the open literature (e.g. *Alternaria* toxins and citrinin in feed (EFSA Panel on Contaminants in the Food Chain (CONTAM), 2011e, 2012a)). In Europe, different husbandry and farming systems for animals exist and consequently the composition of animal diets varies considerably. This constitutes a challenge in risk assessment. In order to address this, the CONTAM Panel has recently developed an exposure assessment approach for animals taking into account common standards in animal nutrition. In practice this means that for individual animal species and production stage (i.e. the age of the animal) a standard consumption pattern per feed category has been defined that is combined with the measured concentrations of the specific contaminant in feedstuffs. Where appropriate, decontamination procedures are taken into

account. The CONTAM Panel applied this approach for the first time in the opinion on T-2 and HT-2 toxins in feed (EFSA Panel on Contaminants in the Food Chain (CONTAM), 2011f).

The risk characterisation relates the estimate of animal exposure to the hazard characterisation and concludes on potential animal health risks. However, due to a paucity of data on the shape of the dose-response curve, there is usually considerable uncertainty in the assessment of possible health risks for individual farm animal species, particularly minor species. As a result, animal health risk assessment is still accompanied by a high degree of uncertainty and needs further development.

D) Reference points for action for non-allowed pharmacologically active substances in food of animal origin

EFSA was asked by the European Commission to deliver a Scientific Opinion on guidance on methodological principles and scientific methods to be taken into account when establishing **Reference Points for Action (RPAs)** for non-allowed pharmacologically active substances in food of animal origin. The guidance document adopted by the CONTAM Panel (EFSA Journal 2013;11(4):3195) presents a simple and pragmatic approach which takes into account both analytical and toxicological considerations. The aim is to define an analytical concentration for a non-allowed pharmacologically active substance that can be determined by official control laboratories and is low enough to adequately protect the consumers of food commodities that contain that substance. The proposed step-wise approach considers factors such as analytical capability, toxic potential and pharmacological activity of the substance in question, and includes

the identification of the Reasonably Achievable Lowest Limit of Quantification (RALLOQ), the establishment of a Toxicological Screening Value (TSV) and the derivation of a Toxicologically Based Limit of Quantification (TBLOQ). The TBLOQ is compared with the RALLOQ for the respective substance. If the TBLOQ is equal to or higher than the RALLOQ, then the latter can be accepted as the RPA. If the TBLOQ is lower than the RALLOQ, then the sensitivity of the analytical method needs to be improved. In the case where no further analytical improvements are feasible, a substance-specific risk assessment should be considered. The CONTAM Panel concluded that RPAs should be matrix independent. The CONTAM Panel noted that sometimes non-edible matrices are monitored to identify the administration of non-allowed pharmacologically active substances. In these cases, RPAs cannot be applied. The CONTAM Panel also proposed several criteria where the European Commission might consider it appropriate to consult EFSA for a substance-specific risk assessment.

4.3.2.2. Main results obtained

Table 4.4. summarizes the main subjects of the opinions adopted by EFSA , through the Contam Panel, on food, feed and both food and feed.

A) Selected food contaminants

More than 50% of the requests reaching the CONTAM Panel have been dealing with the assessment of contaminants in food. In general these requests have dealth with metals, mycotoxins,plant toxicants, marine biotoxins , persistent organic pollutants and food processing agents. The assessment of health risks associated with the presence of contaminants in food follows the principles as the human health risk assessment (see the previous Section on risk assessment principles). Representative examples are reported in Table 4.5.

B) Selected undesirable substances and other contaminants in products intended for animal feed

The European Commission tasked EFSA to provide the scientific bases for the revision of the European Directive 2002/32[1] which regulates undesirable substances in feed. Subsequently, the CONTAM Panel has addressed over the twelve years of its existence the risks to animal health due to the presence of many substances including toxic plant secondary metabolites (EFSA 2008a, f-i, 2009k, 2011c, 2012b), mycotoxins (EFSA, 2004c, d, f, 2005d, e, 2011e, f, 2012a, c), persistent organic pollutants (EFSA, 2005a, f-j, 2006c, d, 2007d, e), toxic metals (EFSA, 2004a, b, 2005k, 2008j) and other substances e.g. melamine and nitrite in feedstuffs (EFSA, 2009j, 2010c). Moreover, hazards related to feed production technologies (cross-contamination of feed) for non-target animals with coccidiostats authorised in Europe (EFSA, 2007f, 2008k-t) and by-products of biofuel production (EFSA, 2010d) for farmed animals (ruminants, poultry, pigs and rabbits), fish, and companion animals such as cats, dogs and horses were assessed. Within this mandate, the CONTAM Panel also determined the possible impact on human health from the carry-over of undesirable substances or contaminants into food of animal origin such as meat, milk, eggs and honey.

The assessment of animal health risks associated with the presence of undesirable chemical substances in feed follows the same principles as the human health risk assessment (see risk assessment principles). However, in the hazard characterisation, species-specific and inter-

[1] Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed. OJ L 140, 30.5.2002, p.10.

species differences in animals need to be taken into account. The exposure assessment and risk characterisation are based on the respective animal species and their specific diets. The hazard characterisation aims to identify the most relevant toxicological endpoint for the respective farm animal species to derive a safe intake level. Most often a NOAEL/lowest-observed-adverse-effect-level is identified, at least for major farm animal species, but a BMDL can also be used (EFSA, 2011f) as a RP. Physiological differences such as the microbiological flora in the forestomach of ruminants and the species-specific rate of absorption and biotransformation have to be taken into account when assessing the toxicokinetics of a chemical substance in target animal species. However, such data are frequently not available and the available information is confined to case reports of intoxications lacking information about the actual dose and time of exposure. The physiological differences referred to above also influence the potential carry-over of toxic substances and/or their metabolites into food of animal origin. Therefore, the CONTAM Panel flags such uncertainties when evaluating the effects of contaminants on animal species and animal-derived products

Exposure estimates for animals take into account the amount of feedstuffs consumed by the respective animal species, as well as the concentration of a particular substance in animal feed. Geographic origin, climatic conditions and plant stress influence the level of many undesirable substances in animal feeds. Analytical data on contaminants in feed are often made available by MSs and/or are taken from the open literature (e.g. *Alternaria* toxins and citrinin in feed (EFSA, 2011e, 2012a)). In Europe different husbandry and farming systems for animals exist and consequently the composition of the animal diets varies considerably. This constitutes a challenge in risk assessment. In order to address this, the CONTAM Panel has recently

developed an exposure assessment for animals taking into account common standards in animal nutrition. In practice this means that for individual animal species and production stage (i.e. the age of the animal) a standard consumption pattern per feed category has been defined which is combined with the measured concentrations of a particular undesirable substance in feedstuffs. Where appropriate, decontamination procedures are taken into account. The CONTAM Panel applied this approach for the first time in the opinion on T-2 and HT-2 toxins in feed (EFSA, 2011f)

The risk characterisation relates the outcome of the animal exposure to the hazard characterisation and concludes on potential animal health risks. However, due to a paucity of data on the shape of the dose-response curve, there is usually a considerable level of uncertainty in the assessment of possible health risks for individual farm animal species, particularly minor species. As a result, animal health risk assessment is still compromised by a high degree of uncertainties and needs further development. It is worth noting that the number of requests to the CONTAM Panel concerning dossiers dealing with undesirable substances and other contaminants evaluated by EFSA in products intended for animal feed has considerably decreased during more recent years.

A) Selected contaminants in food and feed

Only a rather small percentage (i.e. about 10%) of the requests reaching the CONTAM Panel has been dealing with the assessment of contaminants in both food and feed and their number is considerably increasing in more recent years. In general these requests have dealth with

mycotoxins,plant toxicants and persistent organic pollutants. Representative examples are reported in Table 4.7.

5. RISK MANAGEMENT

5.1. Introduction

EC food and feed law is based on the principle that food and feed business operators at all stages of production, processing and distribution within the businesses under their control are responsible for ensuring that food and feed satisfy the requirements which are relevant to their activities. Regula-tion (EC) 178/2002 of the European Parliament and of the Council of 28 january2002 lays down the general principles and requirements of food law, establishes the European Food Safety Autho-rity (also competent for feed safety) and the procedures in matters of food and feed safety . The principle aim of the Regulation is to protect human health and consumers' interests in relation to food. Risk management shall take into account the results of risk assessment, and in particular, the opinions of EFSA, other factors legitimate to the matter under consideration and the precaution-nary principle, where relevant.

Articles 14 and 15 of Reg. 178/2002 lay down, respectively, the food and feed safety requirements and provides that food and feed shall not be placed (and used) on the market if it is unsafe. The Articles state that food shall be deemed unsafe if it is considered to be: (i) a) injurious to health; and b) unfit for human consumption, whereas feed shall be deemed to be unsafe for its intended use if it

is considered to: (i) have an adverse effect on human or animal health; (ii) make the food derived from food-producing animals unsafe for human consumption. The main criterion to establish that a food/feed is safe consistes in its conformity with the existing Community and (in absence)

national legislation. Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food/feed law which are relevant to their activities and shall verify that such requirements are met.

Member States shall enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by food and feed business operators at all stages of production, processing and distribution. For that purpose, they shall maintain a system of official controls and other activities as appropriate to the circumstances, including public communication on food and feed safety and risk, food and feed safety surveillance and other monitoring activities covering all stages of production, processing and distribution. Member States shall also lay down the rules on measures and penalties applicable to infringements of food and feed law. The measures and penalties provided for shall be effective, proportionate and dissuasive (as it is well known ,this component of the Communiuty legislation is not yet harmonized) .

In the case of contaminants/undesirable substances, it is fundamental that the food/feed business ta-kes all initiatives to ensure that the batches imported or manufactured are in full compliance with the relevant Community rules. A specific guidance document on certain key questions related to import requirements and the new rules on food hygiene and on official food controls has also been made available in June 2005 (see http://europa.eu.int/comm/food/food/foodlaw/guidance/index_en.htm).

5.2. Obligations of food/feed business operators in relation to hygiene requi-rements and prevention of food/feed contamination

Community Regulations EC 852/2004 and 853/2004 in the case of food and EC 183/2005 in the case of feed prescribe with very detailed approaches the hygiene requirements within the European Union in relation to all stages of production, processing , distribution, export and import under the control of food/feed business operators. In particular, food businesses that handle food of animal origin must, in addition to Regulation (EC) No 852/2004, also implement the appropriate require-ments of Regulation (EC) No 853/2004.

The key obligations of the food and/or feed business operators are set out in the Commission docu-ment available at **http://europa.eu.int/ comm/dgs/health_consumer/foodsafety.htm**. Food business operators should ensure that they are familiar with the provisions, requirements and obligations set out in this Regulation. Section 4 of Regulation (EC) 178/2002 sets out the general requirements of food law. In view of the importance of these regulations, the European Commission- Health and Consumers Directorate-General issued on 16 February 2009 a non official "Guidance document" on the implementation of certain provisions of Regulation 852/2004 on the hygiene of foodstuffs, mainly directed at food businesses and competent authorities, to give clarification and guidance, in responses to specific clarification requests, on the implementation of these rules. To produce this document, the Commission's Health and Consumers Directorate General has held a series of meetings with experts from the Member States in order to examine and reach consensus on a number of issues concerning the implementation of this regulation. In the interest of transparency, the Commission has also promoted discussion with stakeholders so as to allow different socio-economic interests to express an opinion. This document highlights also that for a complete understanding of the different aspects of Reg. 852/2004, it is essential to be also familiar with other parts of

Community legislation, and in particular with the principles and definitions of regulations listed in Table 5.1.

In spite of many obvious, expected and unavoidable differences, the food and feed hygiene regulations are characterized by some common features such as:

- The obligation of food/feed business operators to ensure that all stages of production, processing and distribution under their control are carried out in accordance with Community legislation, national law compatible therewith, and good practice;
- The obligation for a food or feed business operator who considers or has reason to believe that a food or a feed which he/she has imported, produced, processed, manufactured or distributed is not in compliance with the food or feed safety requirements, to immediately initiate procedures to withdraw the food or feed in question from the market where the food/feed has left the immediate control of that initial food/feed business operator, to inform and collaborate with the competent authorities thereof and , where necessary, to inform the users.
- The availability for both food and feed of specific hygiene provisions mainly applicable to primary production and general hygiene requirements (e.g. premises , equipments, person-nel qualification and training, waste disposal systems and water supply) and the following associated operations (e.g. transport, storage and handling of primary products at the place of production);
- The obligation for both the food and feed business operators, with the main exception of those involved in the primary production , to put in place, implement and maintain per-manent procedures based on the HACCP principles (see Table 5.1).

The HACCP system is a dynamic instrument to be adapted to each company and to its evolution (Table 5.2). Through its adoption the food/feed business operator should be able to keep uner control the strategic phases of the industrial processes in order to control any risk factor for the safety of products. Food and feed risk factors may be of physical nature (e,g. stones, metallic particles, packaging particles), of chemical nature (e.g.. contaminants/undesirable substances exceeding permissible limits, residues of active principles and additives due to cross-contamination and carry over) and of biological nature (e,g. presence of pathogenic microrganisms and their products).The food/feed business operator has to carry out an analysis of the risk factors in order to identify those more significant in relation to their products and processes.

The Critical Control Points (CCPs) are strategic phases of the process whose control is important to assure safety of products. When deciding on HACCP procedure, it is important to provide evidence of criteria used by the business operator for chosing CCPs, through decision tree or other valid instruments. Some critical limits are established by the regulations, but this is not always the case and, in any case, the operator may choose more conservative limits, as long as the criteria are clear. The monitoring is aiming at showing that the CCPs are maintaimed under control. Ideally, monitoring of a CCP should be able to show a "tendency" to a loss of control before that this may cause a safety problem for the product. Therefore, monitoring should be carried out through observations/measurements providing immediate (on time) or at least rapid (e.g. visual obsservations, rapid analytical kits) results. The operator should establish which actions have to be adopted on the process in case the monitoring indicates a loss of control of the CCP. Each loss of control of a CCP as well as each corrective action adopted on the process

must be registered and documented. Such a verification is aimed at ensuring that the CCPs and, in general, the all HACCP system is adequate for the specific company and is properly working . The HACCP procedure in place must be documented to show the system in place and its reliability under the specific conditions of use. Intentional modifications of the manufacturing process or of storage and distribution of the product has to imply a revision of the HACCP approach and to make it visible. The food business operators must provide to the competent Authorities the procedures based on the HACCP together with the relative documents:

a) providing the evidence of their conformity with the system HACCP as requested by the competent Authority;

b) ensuring the permanent updating of the documentation concerning the procedures developed.

The competent Authority considers the nature and the dimension of the industrial activity when deciding on the specific requirements to be satisfied.

It is also quite important to stress that the food/feed business operators have to cooperate with the competent authorities in accordance with applicable Community legislation or, if it does not exist, with national law, also by notifying the appropriate competent authority, in the manner that the latter requires, of each establishment under its control that carries out any of the stages of production, processing and distribution of food, with a view to the registration of each such establishment. Food business operators should also ensure that the competent authority always has up-to-date information on establishments, including by notifying any significant change in activities and any closure of an existing establishment.

The possibility, in the absence of regulatory indications about specific sampling or analysis methods, food/feed business operators may use appropriate methods laid down in other

Community or national legislation or, in the absence of such methods, methods that offer equivalent results to those obtained using the reference method, if they are scientifically validated in accordance with internationally recognised rules or protocols.

The food/feed business operators importing food/feed from third countries are obliged to ensure that importation takes place only in accordance with the following conditions:

(a) the third country of dispatch appears on a list, drawn up in accordance with Article 48 of

Regulation (EC) No 882/2004, of third countries from which imports are permitted;

(b) the establishment of dispatch appears on a list, drawn up and kept updated by the third country in accordance with Article 48 of Regulation (EC) No 882/2004, of establishments

from which imports of feed are permitted;

(c) the food/feed was produced by the establishment of dispatch or by another establishment

appearing on the list referred to in the previous point (b) or in the Community;

and

(d) the feed satisfies: (i) the requirements laid down in any Community legislation laying down rules for feed; or(ii) those conditions recognised by the Community to be at least equivalent thereto; or (iii) where a specific agreement between the Community and the exporting country exists, the requirements contained therein.

The obligation of food/feed business operators exporting food/feed to third countries to ensure that food/feed which is produced in the Community for placing on the market in third countries, satisfies the provisions of Article 12 of Regulation (EC) No 178/2002.

The obligation to apply *mutatis mutandis* article 50 of Regulation (EC) No 178/2002 (rapid alert system) in case a specific food/feed presents a serious risk to human or animal health or to the environment also applies.

.

5.3.Maximum levels of contaminants in food and feed

5.3.1. Radioactive contaminants

The EU regulations concerning radioactive contaminants in food and feed has been developed essentially in reference to the possibility of nuclear accidents.

The Council Regulation (Euratom) No 3954/87 laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs following a nuclear accident or any other case of radiological emergency was first adopted on 22 December 1987. The EU Regulations set out the procedure to be followed for determining the maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs which may be placed on the market following a nuclear accident or any other case of radiological emergency. Where the Commission has received information about the existence of an accident or any other case of radiological emergency during which the maximum permitted levels are likely to be reached or have been reached, it shall adopt a Regulation rendering applicable those maximum levels. The period of validity of such a Regulation shall be as short as possible and shall not exceed three

months. The Commission shall submit to the Council a proposal for a Regulation to adapt or confirm the provisions of the abovementioned regulation.

Regulation within one month of its adoption. When so doing it shall take account of the opinion of experts, the basic standards laid down in accordance with the Treaty and the principle that all expo-sures shall be kept as low as reasonably achievable in order to protect public health. The period of validity of this second Regulation is also limited; the period may be revised at the request of a Member State or on the initiative of the Commission. The maximum permitted levels laid down in the Regulations may be revised or supplemented in the light of expert opinion. Foodstuffs and feedingstuffs not in compliance with the maximum permitted levels shall not be placed on the market.

Moreover, Regulation (Euratom) No **944/89** laying down maximum permitted levels of radioactive contamination in minor foodstuffs following a nuclear accident or any other case of radiological emergency was adopeted on 12 April 1989.This Regulation established the list of minor foodstuffs, i.e. those which are consumed least. For these foodstuffs the maximum permitted levels are. in general, ten times higher.

Maximum permitted levels of radioactive contamination of feedingstuffs following a nuclear accidents or any other case of radiological were adopeted by Reg. EURATOM n. 770/90 on 29 March 1990 (Table 5.4).

Following the Chernobyl accident, arrangements for agricultural imports were adopetd on 15 July 2008, for the time period 19.8.2008 – 31.3.2020, with the Regulation (EC) No 733/2008

laying down conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station and amended with the Regulation (EC) No 1048/2009 on 7.11.2009 . It promotes trade between the European Union (EU) and countries in the rest of the world whilst ensuring that consumers' health is protected. This Regulation applied to agricultural products from third countries covered by: (i)Annex I to the Treaty on the Functioning of the European Union; (ii) Regulation (EC) No 1667/2006 on glucose and lactose;(iii) Regulation (EC) No 614/2009 on ovalbumin and lactalbumin; and (iv) Regulation (EC) No 1216/2009 applica-ble to certain goods resulting from the processing of agricultural products.

This Regulation lays down the maximum permitted radioactive contamination levels to be complied with in order for agricultural products from third countries to be offered for sale on the European Union (EU) market. The accumulated maximum radioactive level in terms of caesium-134 and -137 was prescribed to be 600 Bq/kg. For milk and foodstuffs intended for infants, the maximum radioactive level was much lower, namely 370 Bq/kg. The level applicable to concentrated or dried products was expected to be calculated on the basis of the reconstituted product as ready for consumption. Member States were attributed the responsibility of checking compliance with these maximum permitted levels**,** taking into account contamination levels in the country of origin. Depending on the results of the checks carried out, Member States shall take the necessary measures and inform the Commission without delay. In cases of repeated non-compliance with the maximum permitted levels, these measures may take the form of a prohibition of the import of products originating in the third country concerned.

Following the accident at the Fukushima nuclear power station, the Commission implementing regulation (EU) No 297/2011 was adopted on 25 March 2011 imposing special conditions governing the import of feed and food originating in or consi-gned from Japan . This Regulation in essence confirmed the above mentioned- maximum levels in foodstuffs and feeding-stuffs and prescribed that, in oder to facilitate identification, pre-notyification and official control, each consignment of the products referred to in Article 1 shall be accompanied by a declaration (model attached in the Annex) , attesting that

— the product has been harvested and/or processed before 11 March 2011, or

— the product is originating from a prefecture other than Fukushima, Gunma, Ibaraki, Tochigi, Tiyagi, Yamagata, Niigata, Nagano, Yamanashi, Saitama, Tokyo and Chiba, or

— in case the product is originating from the prefectures Fukushima, Gunma, Ibaraki, Tochigi, Miyagi, Yamagata, Niigata, Nagano, Yamanashi, Saitama, Tokyo and Chiba, the product does not contain levels of the radionuclides iodine-131, caesium-134 and caesium-137 above the maximum levels provided for in Council Regulation (Euratom) No 3954/87 of 22 December 1987, Commission Regulation (Euratom) No 944/89 of 12 April 1989 and Commission Regulation (Euratom) No 770/90 of 29 March 1990.

However, on 17 March 2011 the Commission was informed of lower action levels adopted in Japan these action levels were as provisional regulation values. The authorities from Japan also informed the Commission that products that are not allowed to be placed on the Japanese market, are also not allowed to be exported. It becomes now evident that these action levels will be applied in Japan for a longer term. It is therefore appropriate in order to provide consistency between the pre-export controls performed by the Japanese authorities and the controls on the

level of radionuclides performed on feed and food originating in or consigned from Japan at the entry into the EU, to apply on a provisional basis the same maximum levels in the EU for radionuclides in feed and food from Japan as the action levels applicable in Japan as long as these are lower than the EU values. Therefore, Commission implementing regulation (EU) No 351/2011 amending Regulation (EU) No 297/2011 was adopted on 11 April 2011 imposing special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station. Therefore, the maximum levels of radioactive contaminants were as reported in Tables 5.4. and 5.5. .

The level applicable to concentrated or dried products is calculated on the basis of the reconstituted product as ready for consumption. Each maximum level is relative to a feed with a moisture content of 12 %.

Lastly, it should be noted that a new Euratom Council Regulation has been proposed (COM(2010)184 definitivo 2010/0098 (CNS)) to establish maximun permissible levels of radioactivity for food and feed following nuclear accidents or in case of other radioactive emergencies.

5.3.2. Non radioactive contaminants

Specific food and feed laws cover contaminants in food or feed. Copies of the relevant European legislation are available from the Commission website at **http://eur-lex.europa.eu/en/index.htm**.

5.3.2.1. Food contaminants

EC legislation on contaminants in food is made under the framework regulation for food contaminants, **Council Regulation 315/93/EEC** of 8 February 1993, which lays down Community procedures for contaminants in food and applies to those contaminants which are not covered by other specific Community legislation. Article 2 of this Regulation provides that:

i) food containing a contaminant in an amount that is unacceptable from the public health viewpoint, and in particular at a toxicological level, shall not be placed on the market (a definition of placing on the market can be found at Article 3.8 to Commission Regulation 178/2002); and

ii) in order to protect public health, where necessary, maximum levels shall be set for specific contaminants by the European Commission and that these levels shall be adopted in the form of a non-exhaustive Community list and may include:

— limits for the same contaminant in different foods;

— analytical detection limits;

— a reference to the sampling and analysis methods to be used.

iii) furthermore, in addition to keeping contaminants at levels which do not cause health concerns, contaminant levels shall be kept as low as can reasonably be achieved by following good practices at all the stages.

As it appears from the Table 5.6, the Regulation 1881/2006 has been mofified frequently to provide consumers with an increased measure of protection by setting EC maximum levels for specific contaminats. Community measures have been introduced under Council Regulation 315/93/EEC through Commission Regulation (EC) 1881/2006 of 19 December 2006) which

repeals and expands Commission Regulation (EC) 466/2001, This Regulation aims to keep these contaminants at levels that are toxicologically acceptable and to exclude grossly contaminated food from entering the food chain. They also harmonise Member States' existing measures, thereby facilitating trade. Maximum levels for lead, cadmium, mercury, dioxins, and nitrate (environmental chemical conta-minants), 3- monochloropropane-1,2-diol (3-MCPD) (a process contaminant), aflatoxins, ochra-toxin A, patulin, Fusarium toxins (deoxynivalenol, zearalenone and fumonisins) (mycotoxins), polycyclic aromatic hydrocarbons (environmental and processing contaminant) and inorganic tin (in canned foodstuffs) are covered by this legislation. Regulation !881/2006 has been amended by Commission Regulation (EC) No 1126/2007 of 28 September 2007 as regards *Fusarium* toxins (i.e. deoxynivalenol, zearalenone, and fumonisins in maize, maize products and other products as well as by Commission Regulation (EC) No 629/2008 of 2 July 2008 as regards certain contaminants in foodstuffs (i.e. lead, cadmium and mercury.).
The Appendix I provides an integrated summary of the food commodities to which maximum levels of specific contaminants apply and links to the relevant EC legislation.

According to Council Regulation 315/93/EEC, in view of the requirement to protect public health by keeping contaminants at levels that are toxicologically acceptable, as an ongoing task, the European Commission in cooperation with Member States investigates whether limits should be set for additional contaminants and also reviews the maximum levels of those contaminants currently covered by the legislation. Should a Member State deem it necessary to adopt new legislation, it shall communicate to the Commission and the other Member States the measures envisaged and give the reasons justifying them. The Commission shall consult the Member

States within the Standing Committee on Foodstuffs if it considers such consultation to be useful or if a Member State so requests. Member States may take such envisaged measures only three months after such communication and provided that the Commission's opinion is not negative. In the latter event, before the expiry of the period referred to in the second paragraph, the Commission shall initiate the procedure provided for in order to determine whether the envisaged measures may be implemented subject, if necessary, to the appropriate amendments.

5.3.2.2. Feed contaminants

Following the dioxin crisis in the late 1990s, the EU made many changes to European undesirable substances in order to improve food security and to better protect human and animal health and the environment. Directive 2002/32/CE of the European Parliament and of the Council of the 7 May 2002 deals with undesirable substances in animal feed, as modified by Directive 2001/102/CE of the Council of 27 November 2001, that repealed Directive 1999/29/CE of the Council , has been amended and integrated by number of subsequent Directives and Regulations (Table 5.7.)

This Directive sets maximum levels to limit as far as possible the presence of undesirable substances and products in animal feed put into circulation within the European Union. According to Directive 2002/32/CE, "*products intended for animal feed may enter for use in the Community from third countries, be put into circulation and/or used in the Community onnly if they are sound, genuine and of merchantable quality and, therefore, when correctly used, do not represent any danger to human health, animal health or to the environment and could not adversely affect livestock production*. This prescription shall be deemed not satisfied if the level

of undesirable substances they contain does not comply with maximum levels laid down in the Annex I of Directive 2002/32/CE and subsequent modifications and integrations (see Appendix II). Moreover, to prevent fraud,products intended for animal feed that contain undesirable substances at a level exceeding the maximun levels established in the above-mentioned Annex I cannot be mixed, for dilution purposes, with the same product or with othet products intended for animal feed. The range of substances covered by the Directive, that applies to all products intended for animal feed, including raw materials for feed, additives and complementary feedingstuffs , is very wide. The list of undesirable substances has been regularly updated in the light of technical progress. There can be no derogations from the Directive. However, where a danger to human or animal health or to the environment becomes apparent, Member States may provisionally take more stringent measures, reducing the maximum level set in the Directive, while informing at the same time the European Commission and providing the evidence behind their decision.

Maximum levels have been established in different products intended for animal feed (e.g. feed materials, additives, premixtures, complementary feedingstuffs, complete feedingstuffs, oils and fats, and protein hydrolysates) according to the Annex I to Directive 2002/32/EC and subsequent modifications and integrations, expressed as mg of contaminats/kg of feed (humidity level 12%) for as many as about 50 contaminants and contaminant groups . Taking into account the proportion prescribed for their use in the daily ration, the complementary feedingstuffs may not contain levels of the undesirable substances listed in the Annex I that exceed those fixed for complete feedingstuffs.

5.4. Official control

Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 april 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules and its corrigendum lay down general rules for the performance of official controls to verify compliance with Community rules aiming, in particular, at: (a) preventing, eliminating or reducing to acceptable levels risks to humans and animals, either directly or through the environment; and (b) guaranteeing fair practices in feed and food trade and protecting consumer interests, including feed and food labelling and other forms of consumer information. The offical control of food/feed within the EU has two main targets: (a) the establishments where food/feed are manufactured, sold and administered in the EU; and (b) the food/feed present on the internal market either produced within the EU or imported from thied countries.

Food business operators must ensure that all the requirements of Regulation 882/2004 are properly implemented in order to ensure food safety.

According to art.3 of this regulation, Member States shall ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency, so as to achieve the intended object-tives taking account of:

(a) identified risks associated with animals, feed or food, feed or food businesses, the use of feed or food or any process, material, substance, activity or operation that may influence feed or food safe-ty, animal health or animal welfare;

(b) feed or food business operators' past record as regards compliance with feed or food law or with animal health and animal elfare rules;

(c) the reliability of any own checks that have already been carried out; and

(d) any information that might indicate non-compliance.

Official controls should be carried out without prior warning, except in cases such as audits where prior notification of the feed or food business operator is necessary and may also be carried out ran-domly or on an ad hoc basis due to specific suspicions or to other motivations. Official controls should be carried out at any of the stages of production, processing and distribution of feed or food and of animals and animal products. They should include controls on (i) feed and food businesses; (ii) the use of feed and food; (iii) the storage of feed and food; (iv) any process, material, substance, activity or operation including transport applied to feed or food; and (v) on live animals. Official controls shall be applied, with the same care, to exports outside the Community, to the placing on the market within the Community and to introductions from third countries into the Community.

5.4.1.Designation of competent authorities and operational criteria

According to art.4 of Reg.882/2004, Member States shall designate the competent authorities responsible for the purposes and official controls. They will ensure:

(a) effectiveness, appropriateness, impartiality, quality and consistency of official controls on live animals, feed and food at all stages of production, processing and distribution, and on the use of feed;

(b) adequate competence and proper training of the staff carrying out official controls, free from any conflict of interest;

(c) access to, adequate laboratory capacities for testing and a sufficient number of suitably qualified and experienced staff so that official controls and control duties can be carried out efficiently and effectively;

(d) appropriate and properly maintained facilities and equipment to ensure that staff can perform official controls efficiently and effectively;

(e) the legal powers to carry out official controls and to take the measures needed; and

(f) availability of contingency plans .

When a Member State confers the competence to carry out official controls on an authority or authorities other than a central competent authority, in particular those at regional or local level, efficient and effective coordination should be ensured between all the competent authorities involved, including where appropriate in the field of environmental and health protection. Competent authorities in Member States should carry out internal audits or may have external audits carried out by Commission's inspectors, and should take appropriate measures in the light of their results, to ensure that they are achieving the expected objectives.

5.4.2. Control and verification procedures

Competent authorities are expected to carry out official controls in accordance with documented procedures that contain information and instructions for the staff performing the official controls by addressing : (a) approaches to verify the effectiveness of official controls that they carry out; and (b) to ensure that corrective action is taken when needed; and methodologues for appropriate repor-ting about the control activities performed. Member States shall ensure that they have legal proce-dures in place in order to ensure that staff of the competent authorities have access to premises of and documentation kept by feed and food business operators so as to be able to accomplish their tasks properly.

5.4.2.1. Establishment authorization

All food and feed establishments are subject to control procedures, but only some of them are also subject to a preliminary authorization.

As far as food products are concerned, according to art. 2 of Reg. 853/2004 establishments handling those products of animal origin for which Annex III to this Regulation lays down requirements shall not operate unless the competent authority has approved them, with the exception of establishments carrying out only:

(a) primary production;

(b) transport operations;

(c) the storage of products not requiring temperature-controlled storage conditions; or

(d) specific retail operations.

An establishment subject to approval in accordance with the previous regulation will not operate unless the competent authority has :

(a) granted the establishment approval to operate following an on-site visit; or

(b) provided the establishment with conditional approval.

Food business operators shall cooperate with the competent authorities and shall ensure that an establishment ceases to operate if the competent authority withdraws its approval or, in the case of conditional approval, fails to prolong it or to grant full approval.

On the other hand, feed business operators have to ensure that establishments under their control are authorized by the competent authority, where such establishments carry out one of the following activities:

(a)feed additives covered by Regulation (EC) No 1831/2003 or products covered by Directive 82/471/EEC and referred to in Chapter 1 of Annex IV of Regulation 183/2005;

(b) manufacturing and/or placing on the market of premixtures prepared using feed additives referred to in Chapter 2 of Annex IV Regulation 183/2005;

(c) manufacturing for placing on the market, or producing for the exclusive requirements of their holdings, compound feedingstuffs using feed additives or premixtures containing feed additives and referred to in Chapter 3 of Annex IV Regulation 183/2005;

(d) handling animal by-products registered or approved under Regulation (EC) No 1069/2009)

5.4.2.2. Inspections and audits

The main difference in the official control of establishments subject in the EU to authorization and those that are not subject, is in the prescription for the first ones concerning formal approval by the competent authority in each Member State, following at least one on-site official control before the activation of the establishment, based on inspections and audits and periodic controls of the approved establishments following the same approach plus sampling at different stages during the working flow and/or on the final food/feed, to be carried out by the officials in charge of the con-trol and analyses to be carried out by qualified laboratories in each Member State. In the case of food/feed establishments not subjecr to a preliinary aithorization procedure, inspections, including audits and sampling, are carried out on eisting establishments according to national/local plans developed mainly on statistical basis and risk analysis. These procedures aim at ensuring that :

- premises, facilities, equipments, personnel and standard working and cleaning procedures are adequate in each establishment;

- intermediate and final food/feed are in compliance with Community regulations concerning contaminants;

Tasks related to official controls shall, in general, be carried out using appropriate control methods and techniques such as monitoring, surveillance, verification, audit, inspection, sampling and analysis. Inspections to be carried out in feed and food manufacturing and transformation establishments may be:

a) **planned inspections** : they are generally planned on a yearly basis and regularly carried out with a frequency bases on risk analysis in the different food/feed sectors. In case samples are taken during the inspection, no provision exists for an administrative sequestro of the sampled batches;

b) **inspections based on suspect:** they are generally **un**planned, but carried out on the basis of :

 funded suspicions of irregularity;

 ad hoc investigations;

 informations provided by control bodies and other subjects;

 epidemiological break outs;

 toxicologival emergencies ; and /or

 extraordinary events .

In this cases, samped batches are put under administratuve sequestro until the results of the analy-sis have shown the conformity of the batches to the relevant EU regulations .

c) **extraplan inspections :** they may be cartied out on the basis of

 epidemiological needs;

 research needs.

In case during an inspection extrapaln samples are taken for future analyses , there is no need for a preventive sequestaration of the stock sampled.

Regardless of whether they are planned, on suspecion or extraplan, inspections have to include, *inter alia,* the following activities:

(a) examination of any control systems that feed and food business operators have put in place and the results obtained;

(b) checks on : (i) primary producers' installations, feed and food businesses, including their surroundings, premises, offices, equipment, installations and machinery, transport, as well as of feed and food; (ii) raw materials, ingredients, processing aids and other products used for the preparation and production of feed and food; (iii) semi-finished products; (iv) materials and articles intended to come into contact with food; (v) cleaning and maintenance products and processes, and pesticides; (vi) labelling, presentation and advertising;

(c) checks on the hygiene conditions in feed and food businesses;

(d) assessment of procedures on good manufacturing practices (GMP), good hygiene practices (GHP), good farming practices and HACCP, taking into account the use of guides established in accordance with Community legislation;

(e) examination of written material and other records which may be relevant to the assessment of compliance with feed or food law;

(f) interviews with feed and food business operators and with their staff (generally referred to as "audits"(see the European Commissin Decision 2006/677/CE concernig the guidelines to define execution criteria of audits in conformity with Reg. 882/2004);

(g) the reading of values recorded by feed or food business measuring instruments;

(h) controls carried out with the competent authority's own instruments to verify measurements taken by feed and food usiness operators; and

(i) any other activity required to ensure that the objectives of this Regulation are met.

An important element in structuring the official control strategy for each establihment is its deep connection with the internal control procedure used by the food/feed business operator responsible for the very estalishment addressed. In fact, official control procedures should preferibly start from an analysis of the HACCP approach and be modulated according to its quality and efficacy.

Reports have to be prepared on the results of each inspection by the inspectors. In case of evidence for a lack of compliance with relevant regulations, which may imply risks for human or animal health or the envirinment, the inspection report must be transfered immediately to the competent officials for imposing remedial action and/or sanctions. Moreover, the official control competent service has the responsibility of controlling through an ad hoc inspections whether prescriptions provideed were implemented.

5.4.2.3. Lists of authorized establishments

The results of the control actvities carried out in each Member States and the list of authorized establishments are regularly transferred to the European Commission for the development of of European lists of authorized establishment such as the:

Lists of European food establishments approved under Regulation (EC) No 853/2004).

Lists of European plants handling animal by-products registered or approved under Regulation (EC) No 1069/2009)

Lists of Third Country establishments approved to export food of animal origin to EU Member States.

List of Third Country establishments approved to export of frozen food of vegetable origin to EU Member States.

5.4.2.4. Health and identification marking

An additional control tool, dealing with health and identification marking, is provided for food animal origin by Article 5 of Reg.853/2004. In fact, food business operators shall not place on the market a product of animal origin handled in an establishment subject to approval in accordance with Article 4(2) of this regulation unless it has either: (a) a health mark applied in accordance with Regulation 882/2004 ; or (b) when that Regulation does not provide for the application of a health mark, an identification mark applied in accordance with Annex II, Section I, of Reg.853/2004.Food business operators may apply an identification mark to a product of animal origin only if the product has been manufactured in accordance with Reg. 853/2004 in previously authorized establishments. Food business operators may not remove a health mark from meat unless they cut or process it or work upon it in another manner.

5.4.3.Methods of food/feed sampling and analysis

Sampling and analytical methods used in the context of official controls of food/feed shall comply with relevant Community rules or, (a) if no such rules exist, with internationally recognised rules or protocols, for example those accepted by the European Committee for Standardisation (CEN) or agreed upon in national legislation; or, (b) in the absence of the

above, with other methods fit for the intended purpose or developed in accordance with scientific protocols.

Food/feed sampling approaches should ensure representativeness of the samples taken for the different food/feed batches as well as coverage of the all productive food/feed chain including distribution, transport and administration and whole products, additives, specific ingredients and intermediate products.

Food/feed sampling may be carried in compliance with different criteria, such as:

- **casual o not pre-determined:** these are offficial sampling approaches planned with "**monitoring purposes**" to evaluate the time-evolution of a specific contamination phenomenon . In such a case, in general, non preventive administrative sequestro of the sampled batch is forseen.
- **planned:** these are official samples in the absence od suspicion planned within ad hoc "**surveillance plans",** taking into account risks for human and animal health or for the environment and previous data concerning lack of conformity. No preventive official detention of the sampled batch is foreseen.
- **on suspicion:** these are ofiial sampling based on:
  - irregularity suspicions deriving from ad hoc investigations or information deriving from other control Bodies;
  - epidemiological emergencies.;
  - toxicological emergencies;
  - extraordinary events.

In all these cases an official preventive detention of the sampled batch is foreseen togetherr with, other measures aiming at clarifying , the implementation of all measures aiming at tracing back the activities needed for the identification of food/feed stocks positive or suspect and the evaluation of preventative measures to be adopted. Specific sampling forms, developed at Euroen level should be used.

Wherever possible, methods of analysis shall be characterised by the appropriate criteria set out in Table 5.8.

In particular, it is important to ensure that feed and food business operators can obtain sufficient numbers of samples for a supplementary expert opinion, unless impossible in case of highly perishable products or very low quantity of available substrate. Samples must be handled and labelled in such a way as to guarantee both their legal and analytical validity. The Regulation 1881/2006 also specifies the methods of sampling and analysis that are required to be used for the official control of levels of the substances specified in the legislation. These methods are set out in a number of allied Commission Regulations, details of which are given in the Table 5.9. Specific rules on sampling and analysis have been established also for feed and animal feeding (Table 5.10)

For each sample only one substance or substance family has to be analysed. Moreover, when an official sampling programme is carried out with reference to a family (or group) of substances, it should be understood that the analyis has to cover all the substances belonging to the family and that the *ad hoc* sampling has to be used. All the samples, including those concerning monitoring and surveillance programmes, have to be obrtained in at least 4 replicates for the laboratory.

5.4.4.Member State official laboratories and Community and National reference laboratories

The competent authority in each Member State shall designate laboratories that may carry out the analysis of samples taken during official controls ("***Member State official laboratories"***). Competent authorities may only designate laboratories that operate and are assessed and accredited in accordance with the following European standards:

(a) EN ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories';

(b) EN 45002 on 'General criteria for the assessment of testing laboratories';

(c) EN 45003 on 'Calibration and testing laboratory accreditation system — General requirements for operation and recognition', taking into account criteria for different testing methods laid down in Community feed and food law.

The ***"Community reference laboratories"*** for feed and food listed in Table 5.11are those responsible for: (a) providing national reference laboratories with details of analytical methods, including reference methods; (b) coordinating application by the national reference laboratories of the mentioned methods , in particular by organising comparative testing and by ensuring an appropriate follow-up of such comparative testing in accordance with internationally accepted protocols, when available;

(c) coordinating, within their area of competence, practical arrangements needed to apply new analytical methods and informing national reference laboratories of advances in this field; (d) conducting initial and further training courses for the benefit of staff from national reference laboratories and of experts from developing countries; (e) providing scientific and technical assistance to the Commission, especially in cases where Member States contest the results of

analyses; (f) collaborating with laboratories responsible for analysing feed and food in third countries.

Community reference laboratories have also been established in the animal health sector for coordinating the methods employed in the Member States for diagnosing diseases and may be established in other sectors in accordance with the procedure referred to in Article 62(3) of reg.882/2004. Community reference laboratories may be subject to Community controls to verify compliance with the requirements of this Regulation. If these controls find that a laboratory is not complying with those requirements or tasks for which they have been designated.

- Member States are expected to arrange for the designation of one or more "***national reference laboratories"*** for each Community reference laboratory. A Member State may also designate a laboratory situated in another Member State or European Free Trade Association (EFTA) Member and a single laboratory may be the national reference laboratory for more than one Member State. These national reference laboratories shall: (a) collaborate with the Community reference laboratory in their area of competence; (b) coordinate, for their area of competence, the activities of official laboratories responsible for the analysis of samples ; (c) where appropriate, organise comparative tests between the official national laboratories and ensure an appropriate follow-up of such comparative testing; (d) ensure the dissemination to the competent authority and official national laboratories of information that the Community reference laboratory supplies; and (e) provide scientific and technical assistance to the competent authority for the

implementation of coordinated control plans. Additional responsibilities and tasks for national reference laboratories may be laid down .

5.4.5. Official controls on the import of food and feed from third countries and safeguard measures

The Commission shall be responsible for requesting third countries intending to export goods to the Community to provide the following accurate and up-to-date information on the general organisation and management of sanitary control systems: (a) any sanitary or phytosanitary regulations adopted or proposed within its territory; (b) any control and inspection procedures, production and quarantine treatment, pesticide tolerance and food additive approval procedures operated within its territory; (c) risk-assessment procedures, factors taken into consideration, as well as the determination of the appropriate level of sanitary or phytosanitary protection; (d) where appropriate, the follow-up given to the recommendations made pursuant to controls. The above- information shall be proportionate to the nature of the goods and may take account of the specific situation and structure of the third country and the nature of the products exported to the Community.

To the extent that the conditions and detailed procedures to be respected when importing goods from third countries or their regions are not provided for by Community law and in particular by Regulation (EC) No 854/2004, they may, if necessary, be laid down, in accordance with the procedure referred to in Article 62(3) of Reg. 882/ 2004 on;

- the establishment of a list of third countries from which specific products may be imported ;
- the establishment of models of certificates accompanying consignments;

- special import conditions, depending on the type of product or animal and the possible risks associated therewith.

The requirements for veterinary checks on feed and food of animal origin provided for in Directive 97/78/EC apply. However, the competent authority designated in accordance with Directive 97/78/EC should, in addition, carry out official controls to verify compliance with aspects of feed or food law that that Directive does not cover, as appropriate, including those aspects referred to in Title VI, Chapter II of Reg. EC 882/2004. Moreover, the general rules of Articles 18 to 25 of Reg. 882/ 2004 also apply to official controls on all feed and food, including feed and food of animal origin. The competent authority shall carry out regular official controls also for imported feed and food of non-animal origin. *Ad hoc* controls wil be organized on the basis of the multi-annual national control plan drawn up in accordance with Articles 41 to 43 of Reg. 882/2004 and in the light of potential risks, covering all aspects of feed and food law. These controls shall be carried out at an appropriate points of entry identified by Member States for the organisation of the official controls . The official controls on foods and feed of non animal origin will include at least a syste-matic documentary check, a random identity check and, as appropriate, a physical check.

The competent authority shall place under official detention feed or food from third countries that does not comply with feed or food law to prevent its access to the interrnal market.Specific pre-export checks that a third country carries out on feed and food imme-diately prior to export to the Community with a view to verifying that the exported products satisfy Community requirements may be approved in accordance with the procedure referred to in Article 62(3) of Reg. 882/2004. As shown by the COMMISSION REGULATION (EC) No 669/2009 of 24

July 2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC, already amended four times with : Commission Regolation (UE) 212/2010 of 12 marzo 2010: (i) commission regulation (EU) No 878/2010 of 6 October 2010 ; (ii) Commission Regulation (UE) n. 1099/2010 of 26 November 2010 (iii) Commission Regulation (UE) n. 187/2011 of 25 february 2011 (iv) Commission Regulation (UE) n. 433/2011 of 4 maggio 2011;(v) it is evident that the European Commission has given a high priority to the definition of the criteria that Member States have to follow in performing the official control.

In response to frequent findings of non-compliance of certain contaminants in some products originating from some third countries, A number of safeguard measures have been introduced, imposing special conditions on the import of the affected products form the concerned countries:

- melamine in products from China (Regulation (EC) No 1135/2009)
- mineral oil in sunflower oil from Ukraine (Regulation (EC) No 1151/2009)
- aflatoxins in certain products from certain third countries (Regulation (EC) 1152/2009)
- pentachlorophenol and dioxins in guar gum from India (Regulation (EU) 258/2010).
- Imposing special conditions governing the import of certain foodstuffs from certain third countries s has been an approach chosen to deal with contamination risk by aflatoxins (see Commission regulation (EC) No 1152/2009 of 27 November 2009) Approval of pre-export controls on wheat and wheat flour from Canada on ochratoxin A (Regulation (UE) n. 844/2011 of 23 August 2011

5.4.6.Administrative assistance and cooperation in the areas of feed and food

Reg. 882/2004 provides also clear guidance on how competent authorities in the Member States concerned will provide each other with administrative assistance , when the outcome of official controls on feed and food requires action in more than one Member State. To this end each Member State shall designate one or more liaison bodies to liaise as appropriate with other Member States' liaison bodies with the role of assistinng and coordinating communication between competent autho-rities and, in particular, the transmission and reception of requests for assistance. Upon receiving a reasoned request by another Member State, the requested competent authority will ensure that the requesting competent authority is provided with all necessary information and documents enabling the latter to verify compliance with feed and food law within its jurisdiction. For that purpose, the requested competent authority shall arrange for the conduct of any administrative enquiries necessary to obtain such information and documents. Assistance may be provided even without request, when a competent authority beco-mes aware of noncompliance and if such non-compliance may have implications for another Member State or States, by passing such information to the other Member State(s) without prior request and without delay.

5.4.7. Multi-annual national control plans and integrated national plans

In order to ensure the effective implementation of Article 17(2) of Reg.178/2002, of animal health and animal welfare rules and of Article 45 of this Reg. 882/2004, each Member State has to prepare a single integrated multi-annual national control plan. Each multi-annual national

control plan shall contain general information on the structure and organisation of the systems of feed and food control, and of animal health and animal welfare control in the Member State concerned, in particular on: (a) the strategic objectives of the plan and on how the prioritisation of controls and allocation of resources reflect these objectives; (b) the risk categorisation of the activities concerned; (c) the designation of competent authorities and their tasks at central, regional and local level, and on resources available to these authorities; (d) the general organisation and management of official controls at national, regional and local level, including official controls in individual establishments; (e) control systems applied to different sectors and coordination between the different services of competent authorities responsible for official controls in these sectors; (f) where appropriate, the delegation of tasks to control bodies; (g) methods to ensure compliance with the operational criteria; (h) the training of staff performing official controls ; (i) the documented procedures; (j) the organisation and operation of contingency plans for animal or food-borne disease emergencies, feed and food contamination incidents and other human health risks; (k) the organisation of cooperation and mutual assistance. Multi-annual national control plans, that will also take account of guidelines to be drawn up by the Commission in accordance with the procedure referred to in Article 62(2) of Reg. 882/2004, may be adjusted during their implementation to take into account the evolution of the regulatory situation or the emergence of new data.

An interesting example of a multi-annual national control plan is offered by the 2012-2014 plan of the Italian Ministry of Health in relation to animal feeding. Main objectives of such a plan have been :

a) to ensure the homogeneous and co-ordinated performance of feed controls throughout the different steps of production, trasformation and distribution,taking into account the primary responsibility of feed business operators in relation to feed safety.

b) to establish a rational and easy to use monitoring and surveillance data gathering system to ensure fast communications among all the competent control organisms in Italu and at Community level;

c) to verify structural and functional requirements of feed companies, especially in relation to :

• manufacturing, transformation, stoccaggio,transport, distribution and administration of feed to animals;

• procedures and tools aiming at avoiding contaminations;

• traceability" of products, ingredients and intermediate products;

• interal control systems and good laboratory practice

d) compliance with relevant feed safety regulations,

Specific priority objective for the years 2012-2014 included:

- updating of the register of companies working in the feed sector according to Reg. (EC) 183/2005;
- official control on the implementation of restrictions concerning the prohibition of the use of transformed animal proteins (TAP) ;
- official controls on: (i) mycotoxins (aflatoxin B1, ocratoxin A, zearalenone, Zeossinivalenol, fumonisine, toxins T-2 e HT-2); (ii) inorganic contaminants and nitrogen-containing substances, organochlorinated compounds, and radionuclides; (iii)

forbidden additives and pharmacologically- active substances; (iv) Dioxins and PCBs ; (v) *Salmonella* spp; and (vi) OGMs;

The 2012-2014 plan consisted of three main parts:the first part is descriptive of the general inspections and sampling activities; the second part is technical and applicative and deals with specific official control programmes; and the third part includes the relevant modules and the information on practical indications necessary for carrying out the controls. There were several novelties in the 2012-2014 Italian Plan, including:

 the use of the terminology of Reg. EC 882/2004 concerning monitoring and surveillance, with the adoption of the same sampling protocol for both the official programmes;

 Adjustment of the samples number according to the results of the risk analysis, also taking into account the results of previous years;

 Exclusive attribution to the monitoring activity of samples on: (i) nutritional addditives (oligoelements); (ii) inorganic contaminants; (iii) nitrogen-containing substances; (iv) organochlorinated compunds; and (v) radionuclides;

 Amendment of the format to report on inspections, according to OIE requests ,

 Amendment of the format to report on sampling to include more information on the country of origin and on treatments on feeds sampled for the search of Dioxins.

Another important planning tool at a national level is the “Integrated National Plan” (INP) aiming at coordinating the official controls on food/feed safety with those on frauds along the entire food/feed productive chain , according to the risks to be controlled. To such an end , the control activities on food production are integrated with those on related fields such as on

animal health and safety, zootecnical feeding, plant health and environmental protection. The INP 2015-2018, Produced from the Italian Ministry of Health in collaboration with the other competent national Italian Administrations**,** in compliance with Regulation (EC) n.882/2004 and with Decision 2007/363/CE, has been approved on 18 December 2014.

5.4.8. Commission recommendations about monitoring of specific contaminants in selected food products

The European Commission has also exerted a clear role in orientating specific monitoring programs on dangerous contaminants (see Table 5.12).

In addition to identifying specific contaminats on which additional monitoring work is needed, **in** some cases the European Commission has also produced guidance documents to help competent Authorities in their actions for the control of compliance with EU legislation on specific subjects.

This has been the case for aflatoxins (Guidance document for competent authorities for the control of compliance with eu legislation on aflatoxins- november 2010-). This guidance document focuses mainly on the official control of aflatoxin contamination in food products which are subject to Commission Regulation (EC) No 1152/2009 of 27 November 2009 imposing special conditions governing the import of certain foodstuffs from certain third countries due to contamination risk by aflatoxins and repealing Decision 2006/504/EC. Nevertheless, the provisions in this guidance document are also applicable, where relevant, to the control of aflatoxins in food products not subject to Commission Regulation (EC) 1152/2009

This kind of document is generally an evolving document and will be updated to take account of the experience of the competent authorities or of information provided . Moreover, these

documents are "recommendations" which have, in general, no formal legal status and, in the event of a dispute, ultimate responsibility for the interpretation of the law lies with the Court of Justice.

5.4.9. Community controls in Member States and in third countries

Commission experts will carry out general and specific audits systems in Member States, by appointing, when needed, experts from Member States to assist its own experts and organizing on a regular basis general and specific audits in cooperation with Member States'competent authorities to verify that official controls take place in Member States in accordance with the multi-annual national control plans and in compliance with Community law. Specific audits and inspections in one or more specific areas may supplement general audits. These specific audits and inspections shall in particular serve to: (a) verify the implementation of the multi-annual national control plan, feed and food law and animal health and animal welfare legislation and may include, as appropriate, on-thespot inspections of official services and of facili-ties associated with the sector being audited; (b) verify the functioning and organisa-tion of competent authorities; (c) investigate important or recurring problems in Member States; (d) investigate emergency situations, emerging problems or new developments in Member States. The Commission shall report on the findings of each control carried out. Its report shall, if appropriate, contain recommendations for Member States on the improvement of compliance with feed and food law and animal health and animal welfare rules. The Commission shall make its reports publicly available.

Commission experts may carry out official controls also in third countries in order to verify the compliance or equivalence of third-country legislation and systems with Community feed and food law and Community animal health legislation. Such official controls shall have particular regard to: (a) the legislation of the third country; (b) the organisation of the third country's competent authorities, their powers and independence, the supervision to which they are subject and the authority they have to enforce the applicable legislation effectively; (c) the training of staff in the performance of official controls; (d) the resources including diagnostic facilities available to competent authorities;(e) the existence and operation of documented control procedures and control systems based on priorities; (f) where applicable, the situation regarding animal health, zoonoses and plant health, and procedures for notifying the Commission and relevant international bodies of outbreaks of animal and plant diseases; (g) the extent and operation of official controls on imports of animals, plants and their products; (h) the assurances which the third country can give regarding compliance with, or equivalence to, Community requirements.

The Commission may organise training courses for the staff of the competent autho-rities of Member States responsible for the official controls to promote a harmonised approach to official controls in Member States. They may include in particular training on: (a) Community feed and food law and animal health and animal welfare rules ; (b) control methods and techniques, such as the auditing of systems that operators design to comply with feed and food law, animal health and animal welfare rules; (c) controls to be carried out on goods imported into the Community;

(d) feed and food production, processing and marketing methods and techniques.The training courses may be open to participants from third countries, in particular developing countries.

5.5. Crisis management

For the implementation of the general plan for crisis management referred to in Article 55 of Regulation (EC) No 178/2002, Member States shall draw up operational contingency lans setting out measures to be implemented without delay when feed or food is found to pose a serious risk to humans or animals either directly or through the environment. Contingency plans will specify: (a) the administrative authorities to be engaged; (b) their powers and responsibilities; and (c) channels and procedures for sharing information between the relevant parties; and (d) the role of stakeholders in the establishment and operation of contingency plans. Regulation (EC) n. 178/2002 has attributed to the European Commission specific competences to manage emergency cases . In case a specific food or feed (of commuunity origin or coming from a third Country) is characterized by a risk for human or animal health (or for the environment) that cannot be properly manged individually by the interested Member States, the European Commission, with the assisstance of the Committee for the food chain and animal welfare, may act on own initiative or upon request of a Member State, adopting the measures specified by art. 53 (1) of Reg. 178/ 2002, depending on the origin of the product under consideration. For instance, for products of Community origin, the Commission is authorized to suspend the use and/or marketing and impose other temporary measures needed. For risky products deriving from a third country, the Commission may suspend the import of the product from all the third country or from a part of it and to establish specific temporary conditions for its use .

To better coordinate the efforts and find out more effective measures based on reliable scientific data, Reg. 178/2002 prescribes the preparation of a general plan for crisis management (art. 55, Reg. 178/2002) and the establishment of a "crisis unit" (art. 56, Reg. 178/2002). The crisis management plan is elaborated by the Commission in close collaboration with the European Food Saffety Agency and Member States (art. 55(1), Reg.. 178/2002); it defines the situations implying direct or indirect risks associated with food or feed as well as the measures needed to manage the crisis. The crisis unit is established by the European Commission in case a situation is identified involving a serious direct or indirect risk for human health and in case it would not be possible to prevent, eliminate or control the risk through current measures or only through emergency measures (art. 56, Reg. 178/2002). To such an unit it also froseen the participation of EFSA with the task off providing the needed scintific and technical assistance .The crisis unit task is , in particular, to gather and evalkuate all available data and to suggest measures to prevent, eliminate or reduce the risk in a rapid and effecrive manner.

5.6. Rapid alert system (RASFF)

Regulations relevant for the "rapid alert system include art.50 of Reg. (CE) n.178/2002 for food and art.29 of Reg. (CE) n.183/2005 for feed. Ad hoc guidelines have been published on 13 November 2008, The Food Standards Agency in the UK and other relevante Food Safety Agencies in EU member States have established online forms or other communication tools through which food and feed businesses can notify the relevant local and national food safety authorities if they are withdrawing any products from the market not being compliant with the food or feed safety requirements of Regulation 178/2002 and subsequent regulations. For the UK ,this can be found at **http://www.food.gov.uk/food industry/regulation/foodfeedform**.

The Reg. (UE) 16/2011 of the Commission, of 10 January 2011, concerns the implementation of the rapid alert system for food and feed **(RASFF)**, by codifying the rules of art. 50 of Reg. 178/2002 on the basis of about 25 years of experience achieved, at an European level, since the adoption in 1984 of Decision (CEE) n. 84/1334. However, it should be noted that the rapid alert procedure of Reg.CE 178/2002, did not cover feed and was only dealing with food or industrial products, intended for the final consumer. The system introduced by Reg.178/2002 showed its limitations in relation to the BSE and Dioxin crises associated, as it is well known with feedstuff intended for zootechnical animals. Therefore, the extension of the alert system to feed took place, since 1st January 2006, with art. 29 of Reg. 183/2005.

Art. 1 of Reg. 16/2011 provides the specific definitions, concerning the rapid alert system; they are adde to those already in cluded in art. 50 of Reg. 178/2002 and in Reg. 882/2004. Procedures to be followed are described in art. 2; all the network contact points , consisting of Member States, of the European Commission and of EFSA (and , currently, ESA(Vigilance Authority of EFTA), Island, Liechtenstein, Norvey and Switzerland) must communicare trough *ad hoc* designated officials and by making use of specific predefined information modules. According to art. 2(6) of Reg. 16/2011, all the contact points should be accessible 24 hours around the clock every day of the week. According to art. 3 of this regula-tion , each point of the network is expected to send out the alert notifi-cation to the Commission's contact point as early as possible and, in any case, within 48 hours from the receival of the information on risk . The Commission contact point has to send the notification received to all other contact points of the network within 24 hours from its receival, after having checked, in compliance with art. 8 of Reg. (EU) 16/2011, the:

- completeness and understandability of each information with respect to the technical terminology referred to in art. 7 of Reg.16/2011 and of indications provided through the specific formulari;
- correctness of juridical basis referred to document the lack of conformity of the product with respect to relevant rules;
- compliance with the rules contained in art. 50 of Reg. 178/2002;
- understendability for all the contact points of the network of the language used for the notification ;
- efficacy in underlining in each notification whether it deals with an identical operator,or risk or country of origin of other previous notifications in order to draw attention of competent authorities on repetitive events which may need special approaches.

In case of "notification of *respingimento alle frontiere»,*'art. 5, par. 2, of Reg.16/2011 requires the Commission contact point to transfer the notifi-cations to *"posti di ispezione frontaliera" of Member States* specified in Directive (EC) 97/78 as well as to entry points mentioned in Reg. 882/ 2004. According to art. 10 of Reg.16/2011, if the notified product origi-nates from a Third Country, the Commission will contact the competent authorithy in that Country to negotiate needed actions. According to art. 9 of Reg. 16/2011, the notification is withdrawn or modified in case it will become clear that iy has been based on wrong data.

Since the adoption date of Reg. 178/2002, notified cases through the RASFF system have been yearly more than 3000. Of the 3291 notifica-tions in 2010, the great majority (2873) has been related to products intended for human consumption , whereas 190 notifications have been related to animal feeding and 229 food contact materials. Among chemical contaminants, in

addition to residues of plant protection products and to some food packaging substances, e.g. benzophenone, those more frequently notified are mycotoxins, and heavy metals (especially chromium, nickel, cadmium and lead).

«Criteria to notify risks» include the presence of products containing:

- forbidden substances according to current regulations;
- pesticides residues at levels exceeding prescribed limits;
- genotoxic or carcinogenic substances at livels exceeding prescribed limits;
- yeasts, toxins, bacteria or viruses at levels able to «*induce with high probability the emergence of human diseases*»;
- non auhtorized new products and OGM;
- allergens not mentioned in the allergen list.

5.7. European Union strategies for the reduction and prevention of specific contaminants

.

Improving the exchange of data and information on contaminat levels detected in food and feed. Is permanent priority within the EU. As extensively described in the present paper, many different attempts and procedure are being tested to ensure a more systematic information:

(i) of the European Commission from Member States about the results of investigations undertaken and the progresses with regard to the application of prevention measures to avoid specific contaminations (e.g. by ochratoxin A, deoxynivalenol, zearalenone, fumonisin B1 and B2, T-2 and HT-2 toxin) as well as to the findings of specific control programmes dealing with contaminants (e.g. aflatoxins). The Commission shall make the results available to the Member States.

(ii) of the European Food Safety Authority from member States in relation to relevant contaminant occurrence data and to findings on ad hoc contaminant monitoring programmes (e.g. those on furan, ethylcarbamate, perfluoroalkylated substances, acrylamide and ergot alkaloids).

The key issue in terms of human and animal health protection is that when there evidence that the maximum contaminat levels foreseen by current Regulations are exceeded , Member States, in cooperation with the concerned economic operators, must carry out *ad hoc* investigations to identify the source of the problem. The European Commission will have to be informed on the outcome of the investigations and on the measures implemented to reduce the contaminant level. When needed, the European Commission has specific powers to intervene in the interest of human and animal health. The main tools generally utilized by the European Commission are : (i) Contaminants action levels ; (ii) Codes of good practice; and (iii) Targeted consumer advice.

5.7.1. Contaminants action levels

The "action levels" are a tool for competent authorities and operators to highlight those cases where it is appropriate to perform a more active monitoring to identify the source of contamination and to be able to take measures to reduce or eliminate it. This type of proactive approach to active-ly reduce the levels of contaminants requires that the maximum levels of contaminants applicable are reviewed within a defined period of time with the objective to set lower levels, when necessary. It should be pointed that the "action levels" approach is not only important as it makes possible to gather additionnal data on the occurrence of specific high risk contaminants, but it is also a true and effective risk management tool to prevent adverse effects of specific contaminants on human and animal health.

As an example it can be mentioned that Directive 2002/32/CE established action thresholds to trigger such investigations for :

- Dioxins (sum of polychlorinated dibenzo-*para*-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) expressed in WHO toxic equivalents, using the WHO-TEFs (toxic equivalency factors, 1997;
- Dioxins and dioxin-like PCBs (sum of polychlorinated dibenzo-*para*-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) and polychlorinated biphenyls (PCBs) expressed in WHO toxic equivalents, using the WHO-TEFs (toxic equivalency factors, 1997).

These action thresholds together with specific comments and additional information (e.g. nature of investigations to be undertaken were updated by the Commission Recommendation 2004/704/EC of 11 October 2004 and by the Commission Recommendation 2006/88/EC of 6 February 2006 on the reduction of the presence of dioxins, furans and PCBs in feedingstuffs and foodstuffs On 23 August 2011 , a new Commission Recommendation (2011/516/EU) was adopted on the reduction of the presence of dioxins, furans and PCBs in food and to repeal the Commission Recommendation 2006/88/EC. The approach adopted in this Recommendation to determine the action levels for dioxins, furans and PCBs was quite different from that previosuly used as the World Health Organisation (WHO) had organized an expert workshop on 28 to 30 June 2005 concerning the re- evaluation of the values of the toxic equivalency factors (TEFs) established by WHO in 1998. Considering that a number of TEF values were changed, notably for PCBs, octachlorinated congeners and pentachlorinated furans and that the data on the effect of the new TEF values and the recent occurrence were compiled in the European Food Safety Authority's (EFSA) scientific report 'Results of the monitoring of dioxin levels in food and feed'

(EFSA Journal 2010; 8(3):1385, http://www.efsa.europa.eu/en/ efsajournal/doc/1385.pdf), it was concluded that it was appropriate to review the action levels taking into account the new TEF values, taking also into account the cases where the exceedence of the action level is not related to a specific source of contamination that can be reduced or eliminated, but to the overall environmental pollution. Member States were invited to perform, proportionate to their production, use and consumption of feed and food, random monitoring of the presence of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in feed and food. In cases of non-compliance with the provisions of Directive 2002/32/EC and Regulation (EC) No 1881/2006, and in cases where levels of dioxins and/or dioxin-like PCBs were in excess of the action levels specified in Table 5.13 as regards food and in Annex II to Directive 2002/32/EC as regards feed are found, Member States should, in cooperation with operators, : (a) initiate investigations to identify the source of contamination; and (b) take measures to reduce or eliminate the source of contamination. Member States should inform the Commission and the other Member States of their findings, the results of their investigations and the measures taken to reduce or eliminate the source of contamination.

A similar approach has been adopted by the European Commission also to deal with on the presence of deoxynivalenol, zearalenone, ochratoxin A, T-2 and HT-2 and fumonisins in products intended for animal feeding (Commission Recommendation 2006/576/EC of 17 August 2006).

5.7.2. Codes og good hygiene practice and Commission's recommendations for prevention and reduction of specific contaminants

The development of Community or national guides to good practice (so called "manuals of good practice") in the food and feed sectors and for the application of HACCP principles is clearly addressed for the food sector by Regulation 852/2004 and for the feed sector by Regulation EC 183/2005. Where Community guides are prepared, the Commission shall ensure that they are developed and disseminated: (a) by or in consultation with appropriate representatives of European food/feed business sectors and other interested parties, such as consumer groups; (b) in collaboration with parties whose interests may be substantially affected, including competent authorities. Obviously, the opportunity to participate in developing and/or making use of Community and National "guides of good practice" or "codes of practice" is an important help to improve the implementation of the HACCP also for the control of specific contaminants .

Although being voluntary, the use of guides of good practice/ codes of practice is generally very helpful for an optimal identification of the relevant hazards and of the critical control points. This approach has been used for the reduction of the presence of dioxins, furans and PCBs in feedingstuffs and foodstuffs (Commission Recommendation 2006/88/CE of 6 february 2006 **,** for several contaminants among which: (i) patulin (see the Commission Recommendation 2003/598/EC of 11 August 2003 on the prevention and reduction of patulin contamination in apple juice and apple juice ingredients in other beverages) ; (ii) *Fusarium*-toxins (Commission Recommendation 2006/583/EC of 17 August 2006 on the prevention and reduction of *Fusarium* toxins in cereals and cereal products , including maize and maize products contains general principles for the prevention and reduction of *Fusarium* toxin contamination (zearalenone, fumonisins and trichothecenes) in cereals to be implemented by the development of national codes of practice based on these principles)) and (iii) , ethylcarbamate Member Staes were

invited to take the necessary measures to ensure that the Code of Practice on the prevention and reduction of contamination in stone fruit spirits and stone fruit marc spirits is implemented by all operators involved in the production, packaging, transport, holding and storage of stone fruit spirits and stone fruit marc spirits . The analysis of these three Appendices shows clearly how complicate and problematic the control of specific contaminants in food and feed may be.

In addition to several information notes, guidance documents for control and enforcement (e.g. aflatoxins, dioxins, sampling) and toolbox and information brochures (e,g, acrylamide) have also been issued at EU level.

5.7.3. Targeted consumer advice.

This has been an appropriate approach in the case of methyl-mercury for protecting vulnerable groups of the population. An information note on methylmercury in fish and fishery products responding to this need has, therefore, been made available on the website of the Health and Consumer Protection Directorate-General of the European Commission (http://ec.europa.eu/food/food/chemicalsafety/contaminants/information_note_mercury-fish_12-05-04.pdf). Several Member States have also issued advice on this issue that is relevant to their population.

6. THE IDENTIFICATION OF CHEMICAL EMERGING RISKS

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

Where the Authority has information leading it to suspect an emerging serious risk, it shall request additional information from the Member States, other Community Agencies and the Commission. The Member States, the Community Agencies concerned and the Commission shall reply as a matter of urgency and forward any relevant information at their disposal. The Authority shall use all the information it receives in the performance of its mission to identify an emerging risk. The Authority shall forward the evaluation and information collected on emerging risks to the European Parliament, the Commission and the Member States.

For the correct understanding and implementation of the above legislation, it is very important to stress that it requires a two-step procedure. The first step is based on the "suspicion of emerging serious risks" and request of 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 to human/animal/plant health associated with the 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, the Authority 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 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 competent EFSA Panels, to check for additional data requirements, before reporting to the European Parliament, Commission and Member States. These considerations highlight that a formal declaration of an emerging risk by EFSA would imply a careful consideration by European and Member States responsible for deciding on research financing.

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 a harm (i.e. injury or damage or adverse response) 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[2]. Therefore, the identification of an emerging risk can be stated as:

[2] 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 sensitivity 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 of human beings, animals and/or plants is discovered to an agent of unknown (but possible) toxicity/pathogenicity or a new toxicity/pathogenicity is discovered for a hazard with unknown (but possible) 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 getting more toxicity/pathogenicity or exposure data, respectively, which could lead to the identification 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.

EFSA has developed a framework for the identification of emerging chemical risks as defined by Regulation (EC) 178/2002 occurring in the food and feed chain with a likely direct or indirect impact on human beings, animals, plants or any other organisms under the EFSA's competence mainly associated with intentionally and non-intentionally manufactured industrial

chemicals as well as with natural contaminants transferred to the food/feed chain through the environment. (EFSA,2014).

The proposed procedure uses in a structured manner: (i) a variety of data sources that have recently become available on industrial chemicals produced in the European Union, or on environmental occurrence of chemical contaminants; and (ii) software models for the prediction of the environmental behaviour, biological and toxic activity of specific chemicals from molecular structures and physico-chemical properties.

In general, the framework consists of a multi-step selection procedure that starts from a list of chemical substances (referred to as "entry point") to which a sequence of selection (inclusion/exclusion) criteria is applied to identify the chemicals of potential concern in the present context. The selection criteria take into account volumes of production or import, persistence in the environment, bioaccumulation, dispersive uses, toxicity, and any available risk assessments.

The procedure is discussed in terms of: (i) main entry points in the selection procedure (e.g. lists of chemicals to be screened, such as industrial chemicals registered under REACH regulation or chemical contaminants consistently found in the environment) with a subset of more specific entry points depending on particular objectives characterizing the application of the procedure and relevant data availability; (ii) several selection (inclusion/exclusion) criteria, including production volume, dispersive use, persistence, bioaccumulation, toxicity, evidence from existing regulations or previous risk assessments; and (iii) selection process for the chemicals: multi-step procedure with a varying number of steps in which the outcome of each step becomes the entry point for the next step, and the last leads to the identification of emerging risks.

Some selection criteria are better applied through a deterministic approach (i.e. yes/no or an exclusion threshold), whereas for others a probabilistic approach (i.e. inclusion/exclusion range) can be applied. The proposed procedure may also be applied in an iterative manner in order to evaluate the impact of different threshold values adopted for specific selection criteria on the outcome of the procedure or to test different combinations of specific selection criteria.

The proposed procedure includes two main entry points - industrial chemicals registered under the REACH regulation, and the non-intentionally produced or natural chemicals detected in different environmental compartments (e.g. water, soil and biota).

The first main entry point is the REACH Registered Substances Information of industrial chemicals produced or imported in the European Union. The first two main procedural steps aim at selecting those chemicals which are produced in high volumes (first step) and used with dispersive modalities (second step). The third step of the procedure consists of parallel selection of: (i) high volume industrial chemicals characterized by highly dispersive use modalities, high persistence and tendency to bioaccumulate; and (ii) high volume industrial chemicals characterized by highly dispersive use modalities and high toxicity. The fourth step consists of a probabilistic combination of these two criteria and results in the selection of industrial chemicals characterised by highly dispersive use modalities, high persistence and tendency to bioaccumulation or high toxicity. The fifth procedural step is intended to exclude from the selected chemicals those that are already regulated as food contaminants, as undesirable substances in feed, or authorized or prohibited for specific uses in the food chain. The sixth procedural step, aiming at the exclusion of chemicals already assessed by EFSA and other scientific bodies, identifies chemicals classified as emerging issues (i.e. unregulated toxic

chemicals likely to occur in the food chain). The seventh, and last, procedural step, consists of the selection of chemicals classified as constituting emerging risks according to the EFSA operational definition (i.e. toxic chemicals likely to occur in the food chain that have not been regulated in food/feed and have neither been evaluated by the European Commission or EFSA, nor authorized for use in food/feed).

The second main entry point aims at identifying chemicals, not included in the REACH register, using several different databases, including the Norman Network. This entry point includes, for example, chemicals of natural origin (e.g. mycotoxins, phytotoxins), or substances detected in specific environmental compartments (e.g. water, soil, sediments, biota or wildlife) which may be contaminants of the food/feed chain. After the exclusion of industrial chemicals included in the REACH Registered Substances Information, the previously-described procedure from step three to step seven applies.

In the two examples described, the exclusion criteria are applied in a deterministic manner, whereas some inclusion criteria (i.e. persistence/bioaccumulation and toxicity) are applied probabilistically and others (i.e. production volume and dispersive use) deterministically. Moreover, it is important to stress that the sequence of the selection criteria is intended to be flexible. Namely, to save time and resources, criteria that can be easily and quickly applied to large numbers of chemicals in the relevant context should be always used as soon as possible in the selection procedure.

The procedure proposed in this report needs to be tested and further developed, preferably through a pilot project. Testing this procedure starting from a specific list of chemicals will show whether the procedure works effectively, and it may also provide additional inputs for

improvement and refinement. It is expected that a software program will be needed to manage efficiently the large amount of data in the different selection steps to test the procedure. Further specific suggestions are provided on how to streamline the pilot phase to refine the proposed approach, and to test it with specific examples. The results of the proposed pilot project should then be used to decide on additional activities for the further refinement of the proposed approach.

As a follow-up to this proposal a project has been recently outsourced to test and validate this procedure, focising initially on some industrial chemicals drawn from the rEACH registration database. The final report of the project is expected by the end of 2016.

7. CONCLUSIONS

The present paper clearly shows the priority that has been attributed in the European Union to the control of risks possibly associated with chemical contaminants in food and undesirable substances in feed.

Following an initial chapter describing the main contaminants detected in food and undesirable substances in feed in the EU, their main sources and the factors wich affect their occurrence, the present review focusses on the "continous call for data" procedure that is a very effective system in place at EFSA to make possible the exposure assessment of specific contaminants and undesirable substances. Risk assessment of contaminants in food and undesirable substances in feed is carried currently in the European Union by the CONTAM Panel of EFSA according to well defined methodologies and in collaboration with competent International Organizations and with Member States, following an accurate planning throughout the years. The workplan for

2015 is already focussed, in addition to the completion of the on going work on "Risks to human health related to the presence of **acrylamide** in food" , requested from the European Commission following an initial proposal received from Denmark, France, Germany and Sweden**, on :**

- Risks for animal and public health related to the presence of deoxynivalenol, metabolites of deoxynivalenol and masked deoxynivalenol in food and feed
- Risks for animal and public health and the environment related to the presence of nickel in feed
- Risks for public health related to the presence of tetrahydrocannabinol (THC) in milk and other foods of animal origin
- Risks for public health related to the presence of 2- and 3-MCPD, their esters and glycidyl esters in food
- Risks for animal and human health related to the presence of phorbol esters in *Jatropha* kernel meal
- Risk assessment on the presence of nitrofurans in food of animal origin and non-animal origin
- Risks for public health related to the presence of on chlorate in food
- Risk assessment on the presence of malachite green in food of animal origin and non-animal origin
- Risks for animal and public health related to the presence of erucic acid in vegetable oils and fats in feed
- Assessment on toxicity of dioxins and re-evaluation of the health-based-guidance-value

In addition, requests expected on ”Risks to public health related to the presence of dioxins in food” and ”Risks to public health related to the presence of non-allowed pharmacological substances in food (and feed) ”, some items of the workplan for the year 2016 have also been already identified as follows:

- Risks to animal and public health related to the presence of moniliformin in food and feed; and
- Risks to animal and public health related to the presence of diacetoxyscirpenol in food and feed

The last part of this paper is focussed on the highly sophisticated approach that the European Institutions (i.e. Parliament, Commission and Member States have developed to manage the risks associated with contaminants in food and undesirable substances in feed. Risk management is based on clear obligations of food/feed business operators in relation to hygiene requirements of and maximum permitted levels of chemical contaminants in food and undesirable substances in feed. The safety of food and feed with respect to chemical contaminants and undesirable substances is built in the general structure of the ”official control” carried out jointly by the European Commission and competent authorities in Member States, described through its main components including: (i) the designation of competent authorities and operational criteria; (ii) the control and verification procedures; (iii) the methods of food/feed sampling and analysis; (iv) the Member State official laboratories and Community and National reference laboratories; (v) the Official controls on the import of food and feed from third countries and safeguard measures; (vi) the adminis-trative assistance and cooperation in the areas of feed and food; (vii)

the multi-annual national control plans and integrated national plans; (viii) Commission recommendations about monitoring of specific contaminants in selected food products ; and (ix) Community controls in Member States and in third countries. Moreover, strategies developed in the European Union for the reduction and prevention of specific contaminants or to deal with crisis management and rapid alert system have been specifically addresses in the present review.

REFERENCES

Alexander J et al. (2012) Risk assessment of contaminants in food and feed. The EFSA Journal; **10**: s1004

Robinson T. et al (2012) EFSA's approach to identifying emerging risks in food and feed: taking stock and looking forward. EFSA Journal, **10**: s1015

For the other references (CE directives and regulationts), please refer to the tables

TABLE 3.1. FACTORS THAT MAY AFFECT LEVELS OF CONTAMINATION OF FOOD AND FEED SUPPLIES

(i) Environment

Local environmental conditions may lead to the contamination of a product. The impact of various environmental factors should be considered including:

 Air quality e.g. crops or livestock grown or reared in close proximity to significant sources of chemical emissions to air.

 Water quality e.g. fish and shellfish should not be harvested from polluted waters

 Land quality and land history e.g. the proximity of land used for growing or rearing of crops or livestock to an industrial site or a site which has previously been used for industrial purposes

 Climatic variations e.g. the implications of a drought or excessive rain upon a raw material

(ii) Primary production (including harvest)

Primary producers should be aware of and utilise Good Agricultural Practices (GAPs). Primary producers should consider intervention and controls to minimise contamination of a product during its growth and harvest, e.g.:

 Damp harvesting conditions are likely to increase mycotoxins in certain crops

 Crops may be contaminated during ‘drying’ processes

 Possibility of contamination from contaminated feed or fertiliser

 The control of nitrate level in fresh lettuce and fresh spinach may be difficult due to climatic conditions in some Member States, since climatic conditions have a major influence on the levels of nitrate in certain vegetables such as lettuce and spinach andd nitrate levels depend on the

season. A better control of nitrate levels in these vegetable species can be achieved by progressively modifying farming methods by applying the good agricultural practices at national level.

 Climatic conditions during the growth, in particular at flowering, have a major influence on the *Fusarium* toxin content. However, good agricultural practices, whereby the risk factors are reduced to a minimum, can prevent to a certain degree the contamination by *Fusarium* fungi.

(iii) Storage and transport conditions

Following both the harvesting and processing/manufacturing of a product it is important to maintain appropriate controls to ensure that the possibility of contamination is minimised:

 Suitable storage and transport conditions should be maintained taking into account the nature of the product. Considerations should include appropriate moisture levels, temperature and exposure to light, e.g. damp storage conditions are likely to increase mycotoxin levels in certain crops

 Measures should be considered to prevent or control possible infestation or taint, e.g. cross contamination from contaminated storage facilities or transport .

(IV) Processing and manufacturing conditions

Processing and manufacturing techniques, which are applied to specific products, may concentrate or dilute contaminant levels. Processors and manufacturers should utilise existing Good Manufac-turing Practices (GMPs) as these can assist in identifying potential areas of contamination or dilution through use of specific production techniques and may also help to control cross contamination, e.g.:

 The formation of some PAHs in products can be related to specific heating conditions

 The use of contaminated water could lead to increased levels of tin, lead or cadmium in a product

 The use of appropriate manufacturing processes can control the formation of 3-MPCD in a product

 Good manufacturing processes can assist in reducing mycotoxin levels, e.g. patulin in apple juice. and sorting or other physical treatments make it possible to reduce the aflatoxin content of consignments of groundnuts, nuts, dried fruit and maize.

 The dry milling process results in milling fractions with different particle size from the same batch of unprocessed maize. The milling fractions with smaller particle size are known to contain a higher level of *Fusarium* toxins than the milling fractions with a larger particle size. Regardless the levels of *Fusarium* toxins present in unprocessed maize, *Fusarium* toxins were not detected or detected only at very low levels in starch produced from maize. Moreover, the degree to which *Fusarium* toxins in unprocessed cereals are removed by cleaning and processing may vary.

(v) The nature of the product

Some products are known to naturally accumulate certain contaminants eg:

 Older animals and fish are likely to have accumulated higher levels of certain contaminants than younger ones; moreover, certain fish species originating from the Baltic region may contain high levels of dioxins and dioxin-like PCBs due to significant bioaccumulation of these contaminats in these fish species located at the top of the acquatic food chain.

 Certain animal organs can selectively accumulate certain contaminants (e.g. kidney tends to concentrate cadmium)

 Some varieties of vegetables and fruits naturally absorb and accumulate higher levels of certain contaminants during growth

Source: (UK, 2007- modified)

TABLE 3.2. MAIN FOOD COMMODITIES AND RELATIVE POSSIBLE CHEMICAL CONTAMINANTS IN THE EU

COMMODITY	CONTAMINANT
Apple juice and solid apple products intended for direct human consumption	Patulin, lead, cadmium
Baby foods and processed cereal based foods for infants and young children Infant formulae and follow-on formulae, including infant milk and follow-on milk Dietary foods for special medical purposes intended specifically for infants Apple juice and solid apple products for infants and young children	Aflatoxin B1, ochratoxin A, patulin (not cereal-based products), deoxynivalenol, zearalenone, nitrate, lead,cadmium, PAHs Aflatoxin M1, lead, cadmium, PAHs Aflatoxin B1, ochratoxin A, lead, cadmium, PAHs Patulin, lead, cadmium, PAHs
Barley, Buckwheat (*Fagopyrum* spp.), Corn, Maize, Oats, Rye, Sorghum, Wheat ,Bran, Germ Processed products including bread, pastries, biscuits and cereal snacks Rice	Aflatoxin B1, aflatoxins (B1+B2+G1+G2), Ochratoxin A, deoxynivalenol, zearalenone, lead, cadmium Aflatoxins B1, aflatoxins (B1+B2+G1+G2), ochratoxin A, lead, cadmium

Roasted coffee beans, ground roasted coffee and soluble coffee	Ochratoxin A
Butter Butter fat Cheese Infant formulae/follow-on formulae Milk Milk fat Milk powder/dried milk Yoghurt	Aflatoxin M1, lead, dioxins Lead, dioxins Aflatoxin M1, lead, dioxins Aflatoxin M1, lead, dioxins Aflatoxin M1, lead, dioxins Lead, dioxins Aflatoxin M1, lead, dioxins Aflatoxin M1, lead, dioxins
Eggs and egg products	Dioxins
Fats, including milk fat	Lead, dioxins, PAHs
Fish and fishery products (including Bivalve molluscs Cephalopods Crustaceans)	Lead, cadmium, dioxins, mercury and PAHs
Fruit – dried Apples, Avocados, Bananas ,Bilberries, Blackberries,Cherries, Cranberries, Currants (red, black or white), Dewberries Apricots, Dates Currants (dried grapes), Dried vine fruit (currants, raisins, sultanas), Raisins, Sultanas	 Lead, cadmium Aflatoxin B1, aflatoxins (B1+B2+G1+G2), lead, cadmium Ochratoxin A, lead, cadmium
Figs, Grapes, Plums, Prunes	Aflatoxin B1, aflatoxins (B1+B2+G1+G2),

Gooseberries, Grapefruit, Kiwi fruit, Kumquats, Lemons, Limes, Loganberries, Lychees, Manda-rins (including clementines & other hybrids), Mangoes,Olives,Oranges, Passion fruit, Pea-ches, Pears, Pinneapples, Pomegranates , Pome-los, Quinces, Raspberries, Strawberries, Wild berries, Others	lead, cadmium Lead, cadmium
Fruit – fresh or uncooked, frozen Apples, Apricots, Avocados, Bananas, Bilberries Blackberries, Cherries, Cranberries, Currants (red, black or white), Dates, Dewberrie, Figs, Gooseberries, Grapefruit ,Grapes, Kiwi fruit , Kumquats, Lemons,Limes, Loganberries, Lychees,Mandarins (including clementines & other hybrids), Mangoes, Olives, Oranges Passion fruit , Peaches, Pears ,Pineapples , Plums,Pomegranates,Pomelos, Quinces Raspberries, Strawberries, Wild berries Others	Lead, cadmium
Fruit juices and Concentrated fruit juices (for	Patulin, lead

direct consumption) Grape juice and grape must	Ochratoxin A , Patulin, lead
Fruit nectars (unfermented product obtained by addition of water and sugar to fruit juice or fruit purée)	Patulin, lead, cadmium
Fungi (cultivated)	Lead, cadmium
Fresh herbs Chervil Chives,Parsley, Celery leaves, Others Cadmium	Cadmium
Hydrolysed vegetable protein	3-MCPD
Legumes Beans,Peas, Soybeans Groundnuts (Peanuts)	Lead, cadmium Aflatoxin B1, aflatoxins (B1+B2+G1+G2),
Beef, kidney, liver, lamb, mutton, offal, pork, poultry meat and Farmed game Horsemeat	Lead, cadmium, dioxins, PAHs Cadmium, PAHs
Mushrooms (cultivated)	Lead, cadmium
Almonds, Apricot kernels, Areca nuts, Brazil nuts , Cashew nuts, Chestnuts, Cobnuts, Coco-nuts, Cola nuts, Filberts, Groundnuts, Hazelnuts , Macadamia nuts, Pecans, Pine nuts,	Aflatoxin B1, aflatoxins (B1+B2+G1+G2)

Pistachios and Walnuts 2)	
Horse offal , Kidney (cattle, sheep, pig, poultry), Liver (cattle, sheep, pig, poultry)	Lead, cadmium, dioxins, PAHs
Oils	Lead, cadmium, dioxins, PAHs
Beans, Lentils, Peas, Others	Lead, cadmium
Soy sauce	3-MCPD, lead, cadmium
Black pepper2), Cayenne pepper,Chillies,Chilli powder, Dried fruits of Capsicum spp. - whole or ground, Fruits of Piper spp. , Ginger, Nutmeg, Paprika , Pepper, Turmeric, White pepper, Mixed spices containing above spices , Spice products e.g. curry powder containing above spices)	Aflatoxin B1, aflatoxins (B1+B2+G1+G2)
Wines and other alcoholic drinks Wines (including sparkling wine but excluding liqueur wines), Aromatised wine, Aromatised wine-based drinks, Aromatised wine-product cocktails Cider Fruit wines and Perry	Lead, cadmium, ochratoxin A Patulin, lead, cadmium Lead, cadmium

Vegetables – fresh or uncooked, frozen or dried Artichokes, Asparagus , Aubergines , Beans, Beetroot, Broccoli , Brussels sprout, Cabbage , Carrots, Cardoons, Cauliflower, Celeriac ,Celery, Celery, Chard, Chinese cabbage, Courgettes, Cress, Cucumbers , Fennel , Garlic, Gherkins, Horseradish , Kale, Kohlrabi, Lamb's lettuce , Leeks , Lettuce, Melons , Onions, Parsley root , Parsnips ,Peas,Peppers ,Potatoes , Radishes , Rhubarb , Salsify, Scarole, Shallots, Spinach Spring onions , Squashes , Sweetcorn ,Sweet potatoes, Swedes , Tomatoes, Turnips Lead, Watercress, Watermelons , Witloof, Yam	Lead, cadmium
Fresh, preserved,deep-frozen and frozen spinach; Fresh (protected and oen grown) lettuce and icebergype lettuce; and processed cereal-based foods and baby foods for infants and young children	Nitrate

Source: UK (2007)

TABLE 3.4 - EUROPEAN COMMISSION RECOMMENDATIONS ON CONTAMINANTS OCCURRENCE MONITORING

Recommendation 2003/598/EC on patulin: The Commission hereby recommends Member States to make all necessary steps to ensure that the "Code of Practice for the prevention and reduction of patulin contamination in apple juice and apple juice ingredients in other beverages" described in the Annex attached is implemented by all operators engaged in the apple processing industry. The aim pursued is to further reduce the presence of patulin in apple juice. The recommendations for reducing patulin contamination in apple juice are divided into two parts, as follows: (I) Recommended practices based on Good Agricultural Practices (GAP); (II) Recommended practices based on Good Manufacturing Practices (GMP). GAP applies to (i) preharvest, (ii) harvesting and transportation of fruit, (iii) post-harvest handling and storage practices of fruit for the fresh fruit market, and (iv) post-storage grading of fruit for the fresh market or juice manufacture. GMP concern (i) transportation, checking and pressing of fruit, (ii) packaging and final processing of fruit, as well as (iii) quality assessment of fruit.

Recommendation 2005/108/EC on polycyclic aromatic hydrocarbons . Commission Recommendation 2005/108/EC makes the point that a number of uncertainties remain over the levels of PAHs in certain foods and that Regulation 466/2001, as amended by 208/2005, requires a review of these measures by 1 April 2007, in line with the recommendation made by the SCF in the Annex (195 pages) to its report in December 2002. Food oils and fats which are produced under conditions which are likely to lead to high levels of PAHs are to be scrutinised and methods which would give lower levels are to be optimised. This also applies to methods for

producing smoked and dried foods. The recommendation also requires that the outcome of investigations into the presence and prevention of PAHs in cocoa butter should be reported to the Commission by 31 October 2006.

Recommendation 2007/196/ EC on furan: Member States were invited to perform during the years 2007 and 2008 amonitoring on the presence of furan in foodstuffs that have undergone heat treatment by including commercial foodstuffs as purchased disregarding any further preparation and commercial foodstuffs analysed as consumed after further preparation in the laboratory and to provide on a regular basis to EFSA the monitoring data with the information and in the format as set out by EFSA

Recommendation 2007/331/EC of 3 May 2007; Recommendation 2010/307/EU and Recommendation of 8 November 2013 on acrylamide in food: The new Commission **Recommendation** of 8 November 2013 on investigations into the levels of **acrylamide** in food sets new levels for acrylamide, based on the EFSA monitoring data from 2007-12, to be monitored by European Union Member States, in collabo-ration with food business operators. Member States should report the findings to the Commission by 31 October 2014 and by 30 April 2015. Acrylamide level of acrylamide should be assessed without considering the analytical measurement uncertainty. Food business operator shall identify in their **HACCP** system the relevant processing steps which may lead to the formation of acrylamide and appropriate mitigation measures should be taken. Currently known options for the minimisation of acrylamide levels, e.g. those mentioned in the Code of Practice for acrylamide adopted by the

Codex Alimentarius Commission and the acrylamide 'toolbox' FoodDrinkEurope, should be implemented by the food business operators.

Recommendation 2010/133/EU on ethyl carbamate: It has been shown to be a genotoxic carcinogen in animals and is considered to be a potential carcinogen in humans. In fact, the International Agency for Research on Cancer (IARC) has classifed ethyl carbamate as a Group 2B, possibly carcinogenic to humans. When consumed in food or drink, most ethyl carbamate is degraded in the body within 24 hours, to carbon dioxide, water and ammonia, with the intermediate formation of ethanol and other metabolites. The majority of the remainder is excreted in urine as unchanged ethyl carbamate. Concern first arose in 1985 when a survey of alcoholic beverages sold in Canada found elevated levels of ethyl carbamate in certain brands. As a result the Canadian Health Protection Board introduced a guideline limit of 150 microgram/l for ethyl carbamate in distilled drinks. There is no similar guideline limit in the EU.Earlier studies in 1990 - 92 by the Ministry of Agriculture, Fisheries and Food (UK) had analysed spirit drinks, fruit brandies, beer, wine, bread and yoghurt for ethyl carbamate. Using data from these studies and data on consumption of these products, it was possible to calculate which products were the major sources of dietary exposure to ethyl carbamate. The largest mean intakes arose from whisky.In 1992, expert committees recommended that ethyl carbamate in foods should be reduced to the lowest possible levels and supported the need for further surveys.

Recommendation 2010/161/EU on perfluoroalkylated substances (PFOS): Member States were invited to monitor during 2010 and 2011 the presence of perfluoroalkylated substances in food by including a wide variety of foodstuffs reflecting consumption habits including food of

animal origin such as fish, meat, eggs, milk and derived products and food of plant origin in order to enable an accurate estimation of exposure, by keeping EFSA regularly informed of the results.. It was also recommended that the Member States carry out the analysis of perfluoroalkylated substances in order to detect the presence of the compounds PFOS and PFOA and, if possible, their precursors such as perfluorooctane sulphonamide (PFOSA), N-ethyl perfluorooctane sulfonamidoethanol (NEtFOSE) and 8:2 fluorotelomer alcohol . Member States were invited to perform, in accordance with the Appendix , the monitoring of acrylamide levels in the foodstuffs referred to in the Annex of Commission Recommendation 2010/307/EU and to provide to the EFSA by 1 June of each year the data for the previous year in the format as set out by EFSA for compilation into one database

Recommendation 2012/154/EU on ergot alkaloids. Member States were invited to perform with the active involvement of the feed and food business operators monitoring on the presence of ergot alkaloids in cereals and cereal products intended for human consumption or intended for animal feeding, in pasture/forage grasses for animal feeding and in compound feed and food. Member States should analyse the samples for at least the following ergot alkaloids: (i) ergocristine/ ergocristinine ; (ii) ergotamine/ergotaminine ; (iii) ergocryptine/ergocryptinine ; (iv) ergometrine/ ergometrinine ; (v) ergosine/ergosinine ; and (vi) ergocornine/ergocorninine. . Member States should determine, whenever possible, simultaneously the sclerotia content in the sample in order to be able to improve the knowledge on the relation between the content of sclerotia and the level of individual ergot alkaloids. The analytical results should be provided on a regular basis to EFSA for compilation into a database

Recommendation 2014/193/EU on cadmium: On 4 April 2014, the European commission published a recommendation 2014/193/EU on the reduction of the presence of cadmium in food stuffs, which involves the decrease of cadmium input during the growing of crops and vegetables for human consumption on land. To achieve the reduction of cadmium levels in food, the Member States have to implement the already available mitigation method to farmers and food business operators. The progress of the implementation should be regularly monitored and reported to the Commission. Meanwhile, the occurrence data of cadmium should be collected and reported to European Food Safety Authority (EFSA) to reassess the situation by 31 December 2018

TABLE 3.5.: SUMMARY OF FOOD GROUPS MOST FREQUENTLY CONTAMINATED WITH *FUSARIUM* MYCOTOXINS

Fusarium toxin	**Main food items/food groups contaminated (percentage of positive samples)**
Type B trichothecenes	
Deoxynivalenol	corn (89 %), wheat* (61 %)
Nivalenol	corn (35 %), oats (21 %), wheat*(14 %)
3-Acetyldeoxynivalenol	corn (27 %), wheat*(8%)
Type A trichothecenes	
T-2 Toxin	corn (28 %), wheat (21 %), oats (21 %)
HT-2 Toxin	oats (41 %), corn (24 %), rye** (17 %)
Zearalenone	corn (79 %), corn milling fractions (51 %), corn based products (53%); wheat (30 %), wheat milling fraction (24 %), wheat based products (11 %); baby food (23 %)
Fumonisins	
Fumonisin B1	corn (66 %), corn flour (79 %), corn based pro-
Fumonisin B2	ducts (31%), corn flakes (46 %); wheat (79 %) corn (51 %)

Source; SCOOP (2003) ***** Wheat and wheat flour ** Rye and rye flour

Table 3.6

Data collection	*Occurrence group name for data submission*
Process Contaminants	OCC_GROUP2
• Furan[1]	
• Acrylamide[2]	
• PAHs	
• 3-MCPD esters	
• Ethyl Carbamate[3]	
Organic contaminants	OCC_GROUP1
• Dioxins and DL PCBs	
• Non dioxin-like PCBs	
• Brominated Flame Retardants	
• PFAS[4]	

• Mineral oil hydrocarbons	
• Melamine and analogues	
Inorganic	
• Nitrates in vegetables and other food commodities	
• Cadmium	
• Lead	OCC_GROUP4
• Arsenic (inorganic and total)	
• Mercury (methyl mercury and total mercury)	
• Fluorine in feed	
• Nitrite in feed	
Mycotoxins	
• Aflatoxins (B1 in feed and B1 and Total in food, M1 in dairy)	OCC_GROUP3
• Ochratoxin A	
• Deoxynivalenol (and acetylated derivatives)	

• Zearalenone	
• Fumonisins	
• Patulin	
• T-2 and HT-2	
• Nivalenol	
• Ergot alkaloids[5]	
Inherent plant toxins	OCC_GROUP3
• Opium alkaloids in poppyseeds	
• Pyrrolizidine alkaloids	
• Glucosinolates in feed	
• Tropane alkaloids	
• Inherent plant toxins in feed regulated by 2002/32/EC[6] or not yet regulated o Free Gossypol o Hydrocyanic acid (feed and food) o Theobromine	

○ Ricin ○ Abrin ○ Crotin I	
Organochlorine compounds	
• Organochlorine compounds in feed regulated by Directive 2002/32/EC[6] ○ Aldrin ○ Dieldrin ○ Camphechlor ○ Chlordane ○ DDT ○ Endosulfan ○ Endrin ○ Heptachlor ○ Hexachlorobenzene (HCB) ○ Hexachlorocyclohexane (HCH-alpha, beta and gamma isomers)	OCC_GROUP1

TABLE 4.1. – THE FIVE EFSA's DIRECTORATES

Name of the Directorate	Tasks of the Directorate	PANELS and Units
Risk assessment and scientific advive (RASA)	Risk assessment in priority sectors such as biological hazards, chemical contaminants, plant health, and nimal health and wefare.	AHAW Panel BIOHAZ Panel; Biological Monitoring CONTAM Panel; Dietetic and chemical Monitoring PLH Panel Support to scientific evaluation
Scientific evaluation of regulated products (REPRO)	Scientific evaluation of substances, products and claims intended to be used in the food chain to protect public, animal and plant health as well as the environment.	FEEDAP Panel ANS Panel CEF Panel GMO Panel NDA Panel PPR Panel Re-evaluation of active substances used in pesticides-
Scientific strategy and coordinaton (SCISTRAT)	Strategic leadership and science strategy of EFSA.Organization of	ADVISORY FORUM Scientific Cooperation

	the work of the Scientific Committee and of the Advisory Forum. Promotion of the cooperation with Member States and at international level.	Emerging risk SCIENTIFIC COMMITTEE
Communication (COMMS)	Comunication with risk managers, national authorities, interested parties and public in general, communication channels on-line and off-line and instruments such as the sito web, publications and information materials for the media.	Editorials Communication channels
Resources and support (RESU)	Administrative and support services. Strategic approaches to human resources and management of knowledge, efficient IT systems, finance management and other services.	Accounting Finance Services Human resources and knowledge management IT systems Legal and regulatory affairs

TABLE 4.2- OPINIONS OF THE SCIENTIFIC COMMITTEE FOR FOOD AND EVALUATIONS CARRIED OUT THROUGH SCIENTIFIC COOPERATION (SCOOP) ON FOOD CONTAMINANTS

CONTAMINANT	OPINION OF THE SCIENTIFIC COMMIT-TEE FOR FOOD/SCOOP EVALUATION	SOURCE
Nitrates	An ADI of 3,65 mg/kg bw was accepted.	The Scientific Committee for Food in 1990 (Commission of the European Communities, 1992)
Patulin	The provisional maximum tolerable daily intake (PMTDI) of 0,4 μg/kg bw was established	Minutes of the 120th Meeting of the Scientific Committee on Food held on 8 and 9 March 2000 in Brussels, Minute statement on patulin. http://ec.europa.eu/food/fs/sc/scf/out55_en.pdf
Fusarium toxins	In December 1999 (a) a tolerable	(a) Opinion of the Scientific Committee

	daily intake (TDI) of 1 μg/kg bw was established for deoxy-nivalenol; In June 2000 (b) a temporary TDI of 0,2 μg/kg bw for zearalenone; In October 2000 (c) (up-dated in April 2003) (d) a TDI of 2 μg/kg bw for fu-monisins; In October 2000 (e) a temporary TDI of 0,7 μg/kg bw was established for nivalenol; In May 2001 (f) a temporary TDI of 0,06 μg/kg bw was established for T-2 and HT-2 toxin and a combined temporary ADI and thetrichothecenes as group in February 2002(g).	on Food on Fusarium-toxins Part 1: Deoxynivalenol (DON), (expressed on 2 December 1999) http://ec.europa.eu/food/fs/sc/scf/out44_en.pdf (b) Opinion of the Scientific Committee on Food on Fusarium-toxins. Part 2: Zearalenone (ZEA), (expressed on 22 June 2000) http://ec.europa.eu/food/fs/sc/scf/out65_en.pdf (c) Opinion of the Scientific Committee on Food on Fusarium-toxins Part 3: Fumonisin B1 (FB1) (expressed on 17 October 2000) http://ec.europa.eu/food/fs/sc/scf/out73_en.pdf (d) Updated opinion of the Scientific Committee on Food on Fumonisin B1, B2 and B3 (expressed on 4 April 2003) http://ec.europa.eu/food/fs/sc/scf/out185_e

		n.pdf (e) Opinion of the Scientific Committee on Food on Fusarium-toxins Part 4: Nivalenol (expressed on 19 October 2000) http://ec.europa.eu/food/fs/sc/scf/out74_en.pdf (f) Opinion of the Scientific Committee on Food on Fusarium-toxins Part 5: T-2 toxin and HT-2 toxin (adopted on 30 May 2001) http://ec.europa.eu/food/fs/sc/scf/out88_en.pdf (g) Opinion of the Scientific Committee on Food on Fusarium-toxins Part 6: Group evaluation of T-2 toxin, HT-2toxin, nivalenol and deoxynivalenol. (adopted on 26 February 2002) http://ec.europa.eu/food/fs/sc/scf/out123_en.pdf
Lead	Endorsment of the provisional	As regards, the SCF adopted an opinion

	tolerable weekly intake (PTWI) of 25 μg/kg bw proposed by the WHO n 1986. The SCF concluded in its opinion that the mean level in foodstuffs does not seem to be a cause of immediate concern.	on 19 June 1992 (Reports of the Scientific Comttee for Food, 32nd series, Opinion of the Scientific Commit-tee for Food on 'The potential risk to health presented by lead in food and drink', p. 7, http://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_32.pdf
Arsenic, cadmium, lead and mercury	Assessment of the dietary exposure to arsenic, cad-mium, lead and mercury of the population of the EU Member States. In view of this assessment and the opinion delivered by the SCF, it is appropriate to take measures to reduce the presence of lead in food as much as possible	
Cadmium	The SCF endorsed in its the PTWI of 7 μg/kg bw and recommended greater efforts to reduce dietary exposure to	Opinion of 2 June 1995. Reports of the Scientific Committee for Food, 36th series, Opinion of the Scientific Committee for Food on cadmium, p. 67,

	cadmium since foodstuffs are the main source of human intake of cadmium. A dietary expo-sure assessment was per- formed in the SCOOP-task 3.2.11. In view of this assessment and the opi-nion delivered by the SCF, it is appropriate to take measures to reduce the presence of cadmium in food as much as possible	http://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_36.pdf. A dietary exposure assessment was performed in the SCOOP-task 3.2.11.
Inorganic tin	The SCF concluded that levels of inorganic tin of 150 mg/kg in canned beverages and 250 mg/kg in other canned foods may cause gastric irritation in some individuals.To pro-tect public health from this health risk it is necessary to set maximum levels for inorganic tin in canned foods and canned bevera-ges. Until data become available on the	Opinion of the Scientific Commit-tee on Food on acute risks posed by tin in canned foods (adopted on 12 December 2001) http://ec.europa.eu/food/fs/sc/scf/out110_en.pdf

	sensitivity of infants and young chil-dren to inorganic tin in foods, it is necessary on a precautionary basis to protect the health of this vulne-rable population group and to establish lower maximum levels.	
3-monochloro-propane-1,2-diol (3-MCPD)	The SCF on the basis of new scientific information and established a tolerable daily intake (TDI) of 2 μg/kg bw for 3-MCPD. Taking into account the lack of genotoxicity and the likely secondary mechanisms of the tumorigenic effects seen in the chronic toxicity/carcinogenicity studyin the rats, the Committee considered that a threshold-based approach for deriving a Tolerable Daily Intake (TDI) would be appropriate. The	Opinion of the Scientific Committee on Food on 3-monochloro-propane1,2-diol (3-MCPD) updating the SCF opinion of 1994 (adopted on 30 May 2001) http://ec.europa.eu/food/fs/sc/scf/out91_en.pdf Reports of the Scientific Committee for Food, 36th series, Opinion of the Scientific Committee for Food on 3-mono-chloro-propane- 1,2-diol 3-MCPD), p. 31, http://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_36.pdf

	Committee noted that at the lowest dose (1.1 mg/kg bw/day) in the above-mentioned rat study there are some indications of adverse effects in several organs, which attain statistical significance at higher doses. Despite of the lack of statistical significance at the lowest dose, the Committee considered this to be a LOAEL, being close to a NOAEL. Taking also into account other limitations in the database (e.g. lack of reproduction/develop-mental toxicity studies) an overall uncertainty factor of 500 was used by the Committee to derive a TDI of 2 μg/kg bw.	
3-monochloro-propane-1,2-diol (3-MCPD)	The main contributors of 3-MCPD to dietary intake were soy sauce and soy-sauce based	In the framework of Directive 93/5/EEC the SCOOP-task ‘Collection and colla-tion of data on levels of 3-MCPD and related

	products. Some other foods eaten in large quan-tities, such as bread and noodles, also contributed significantly to intake in some countries because of high consumption rather than high levels of 3-MCPD present in these foods. Accordingly maximum levels should be set for 3-MCPD in hydrolysed vegetable protein (HVP) and soy sauce taking into account the risk related to the consumption of these foods. Member States are requested to examine other foodstuffs for the occurrence of 3-MCPD in order to consider the need to set maximum levels for additional foodstuffs.	sub-stances in foodstuffs' was performed and finalised in June 2004.
Dioxins and PCBs	As regards, the SCF adop-ted on 30 May 2001 an opinion on dioxins and dioxin-like PCBs in	Opinion of the Scientific Committee on Food on the riskassessment of dioxins and dioxin-like PCBs in food. Update based on

	food, updating its opinion of 22 November 2000 fixing a tolerable weekly intake (TWI) of 14 pg World Health Organisation toxic equivalent (WHOTEQ)/ kg bw for dioxins and dioxin-like PCBs. Dioxins as referred to in this Regulation cover a group of 75 polychlorina-ted dibenzo-p-dioxin (PCDD) congeners and 135 polychlorinated dibenzofu-ran (PCDF) congeners, of which 17 are of toxicological concern. Polychlorinated biphenyls (PCBs) are a group of 209 different congeners which can be divided into two groups according to their toxicological properties: 12 congeners exhibit toxicolo-gical properties similar to dioxins and are thereof-re	new scientific information available since the adoption of the SCF opinion of 22nd November 2000 (adopted on 30 May 2001) http://ec.europa.eu/food/fs/sc/scf/out90_en.pdf Opinion of the Scientific Committee on Food on the risk assessment of dioxins and dioxin-like PCBs in food. (adopted on 22 November 2000) http://ec.europa.eu/food/fs/sc/scf/out78_en.pdf

	often termed dioxin-like PCBs. The other PCBs do not exhibit dioxin-like toxi-city but have a differrent toxicological profile. Each congener of dioxins or dioxin-like PCBs exhibits a different level of toxicity. In order to be able to sum up the toxicity of these different congeners, the concept of toxic equivalency factors (TEFs) has been introduced to faci-litate risk assessment and regulatory control. This means that the analytical results relating to all the individual dioxin and dioxin-like PCB congeners of toxicological concern are expressed in terms of a quantifiable unit, namely the TCDD toxic equivalent (TEQ).	
		.

Polycyclic aromatic hydrocarbons	The SCF concluded that a number of polycyclic aro-matic hydrocarbons (PAH) are geno-toxic carcinogens. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) performed in 2005 a risk assessment on PAHs and estimated margins of exposure (MOE) for PAH as a basis for advice on compounds that are both genotoxic and carcinogenic.	Opinion of the Scientific Com-mittee on Food on the risks to human health of Polycyclic Aromatic Hydrocarbons in food (expressed on 4 December 2002) http://ec.europa.eu/food/fs/sc/scf/out153_en.pdf Evaluation of certain food contaminants — Report of the Joint FAO/WHO Expert Com-mittee on Food Additives), 64th meeting, Rome, 8 to 17 February 2005, p. 1 and p. 61. WHO Technical Report Series, No. 930, 2006 — http://whqlibdoc.who.int/trs/WHO_TRS_930_eng.pdf

TABLE 4.3- LIST OF EFSA CONTAM PANEL SCIENTIFIC OPINIONS, STATEMENTS AND OTHER SCIENTIFIC REPORTS ON FOOD/FEED CONTAMINANTS SINCE EFSA INCEPTION (2003-2014)

- Modified mycotoxins in food and feed (11 December 2014 Scientific Opinion of the CONTAM Panel)
- Chloramphenicol in food and feed (26 November 2014 Scientific Opinion of the CONTAM Panel)
- *In vivo* genotoxicity of nivalenol and deoxynivalenol (25 November 2014 External Scientific Report)
- Toxicokinetics and genotoxicity of Alternariol (7 November 2014 External Scientific Report)
- Perchlorate in food, in particular fruits and vegetables (17 October 2014 Scientific Opinion of the CONTAM Panel)
- Beauvericin and enniatins in food and feed (7 August 2014 Scientific Opinion of the CONTAM Panel)
- Residues in live animals and animal products – Results 2012 (13 June 2014 Technical report)
- Maximum levels deoxynivalenol, fumonisins, zearalenone (22 May 2014 Statement of EFSA)
- Oral toxicity of PFASs (10 April 2014 External Scientific Report)

- Chromium in food and drinking water (13 March 2014 Scientific Opinion of the CONTAM Panel)
- Maximum levels of deoxynivalenol in certain cereal products (17 December 2013 Statement of the CONTAM Panel
- Study on the influence of food processing on nitrate levels in vegetables (5 December 2013 External Scientific Report)
- Tropane alkaloids in food and feed (15 October 2013 Scientific Opinion of the CONTAM Panel)
- Nivalenol in food and feed (19 June 2013 Scientific Opinion of the CONTAM Panel)
- Sterigmatocystin in food and feed (7 June 2013 Scientific Opinion of the CONTAM Panel)
- Phenylbutazone in horse meat (15 April 2013 Statement of EFSA)
- Mercury and methylmercury in food (20 December 2012 Scientific Opinion of the CONTAM Panel)
- Mercury toxicity in experimental animals and humans (2002-2011) (20 December 2012 External Scientific Report)
- Re-evaluation of acceptable previous cargoes for edible fats and oils – Part III of III (18 December 2012 Scientific Opinion of the CONTAM Panel)
- Reports on toxicokinetics, toxicity and allergenicity data (18 December 2012 External Scientific Report)
- Dioxins and DL-PCBs in foods for infants and young children (13 December 2012 Scientific Opinion of the CONTAM Panel)

- Clarifications on technical issues about smoked skin-on sheep meat (26 October 2012 Scientific Report of EFSA)
- Emerging and Novel BFRs in Food (19 October 2012 Scientific Opinion of the CONTAM Panel)
- Ammonium released from water filters (19 October 2012 Statement of EFSA)
- Ergot alkaloids in food and feed (19 July 2012 Scientific Opinion of the CONTAM Panel)
- Meat inspection of poultry (29 June 2012 Opinion of the Scientific Committee/Scientific Panel)
- Mineral oil hydrocarbons in food (6 June 2012 Scientific Opinion of the CONTAM Panel)
- Re-evaluation of acceptable previous cargoes for edible fats and oils – Part II of III (30 May 2012 Scientific Opinion of the CONTAM Panel)
- Experimental study: uptake of coccidiostats in vegetables (25 April 2012 External Scientific Report)
- Brominated phenols and their derivatives in food (16 April 2012 Scientific Opinion of the CONTAM Panel)
- *In vitro* metabolic study on alkanes in hepatic microsomes from humans and rats (4 April 2012 External Scientific Report)
- Hygiene criteria to be applied to clean seawater (29 March 2012 Opinion of the Scientific Committee/Scientific Panel)
- Citrinin in food and feed (23 March 2012 Scientific Opinion of the CONTAM Panel)

- Phomopsins in feed and food (23 February 2012 Scientific Opinion of the CONTAM Panel)
- T-2 and HT-2 toxins in food and feed (19 December 2011 Scientific Opinion of the CONTAM Panel)
- TBBPA and its derivatives in food (19 December 2011 Scientific Opinion of the CONTAM Panel)
- Re-evaluation of acceptable previous cargoes for edible fats and oils – Part I of III (19 December 2011 Scientific Opinion of the CONTAM Panel)
- Survey on ergot alkaloids in cereals intended for human consumption and animal feeding (8 December 2011 External Scientific Report)
- Pyrrolizidine alkaloids in food and feed (8 November 2011 Scientific Opinion of the CONTAM Panel)
- Opium alkaloids in poppy seeds (8 November 2011 Scientific Opinion of the CONTAM Panel)
- *Alternaria* toxins in feed and food (26 October 2011 Scientific Opinion of the CONTAM Panel)
- Meat inspection of swine (3 October 2011 Opinion of the Scientific Committee/Scientific Panel)
- 90-day toxicological study of 3-MCPD and its dipalmitate (6 September 2011 External Scientific Report)
- HBCDDs in Food (26 July 2011 Scientific Opinion of the CONTAM Panel)

- Dioxins and dioxin-like PCBs in liver from sheep and deer (19 July 2011 Scientific Opinion of the CONTAM Panel)
- Zearalenone in food (21 June 2011 Scientific Opinion of the CONTAM Panel)
- Proposed production method for smoked "skin-on" sheep meat (15 June 2011 Opinion of the Scientific Committee/Scientific Panel)
- PBDEs in Food (30 May 2011 Scientific Opinion of the CONTAM Panel)
- Toxicity of endosulfan in fish (12 April 2011 Statement of the CONTAM Panel)
- Tolerable weekly intake for cadmium (3 February 2011 Statement of the CONTAM Panel)
- Abiotic risks of glycerine from biodiesel production process (16 December 2010 Scientific Opinion of the CONTAM Panel)
- Nitrate in vegetables - children (9 December 2010 Statement of the CONTAM Panel)
- PBBs in Food (13 October 2010 Scientific Opinion of the CONTAM Panel)
- Safety and efficacy of hot water decontamination (30 September 2010 Opinion of the Scientific Committee/Scientific Panel)
- Marine Biotoxins in Shellfish – Further elaboration of the consumption figure of 400 g shellfish meat on the basis of new consumption data (11 August 2010 Statement of the CONTAM Panel)
- Marine Biotoxins in Shellfish – Emerging toxins: Brevetoxin group (26 July 2010 Scientific Opinion of the CONTAM Panel)
- Occurrence of T-2 and HT-2 in Europe (13 July 2010 External Scientific Report)
- Toxicity of HT-2 and T-2 toxins (1 July 2010 External Scientific Report)

- Seeds of Ambrosia spp. in Feed (10 June 2010 Opinion of the Scientific Committee/Scientific Panel)
- Marine Biotoxins in Shellfish – Cyclic imines (spirolides, gymnodimines, pinnatoxins and pteriatoxins) (7 June 2010 Scientific Opinion of the CONTAM Panel)
- Marine Biotoxins in Shellfish – Emerging toxins: ciguatoxin group 87 June 2010 Scientific Opinion of the CONTAM Panel)
- Recent scientific information on the toxicity of Ochratoxin A (4 June 2010 Statement of the CONTAM Panel)
- Statement of EFSA on the possible risks for public and animal health from the contamination of the feed and food chain due to possible ash-fall following the eruption of the Eyjafjallajökull volcano in Iceland. (26 April 2010 Statement of EFSA)
- Lead in Food (20 April 2010 Scientific Opinion of the CONTAM Panel)
- A benchmark dose analysis for lead exposure in children (20 April 2010 External Scientific Report)
- Melamine in Food (13 April 2010 Opinion of the Scientific Committee/Scientific Panel)
- Marine Biotoxins in Shellfish – Palytoxin group (15 December 2009 Scientific Opinion of the CONTAM Panel)
- Scientific information on mycotoxins and natural plant toxicants (3 December 2009 External Scientific Report)
- Survey on use of veterinary medicinal products in third countries (3 December 2009 External Scientific Report)

- Evaluation of previous cargoes (1 December 2009 Scientific Opinion of the CONTAM Panel)
- Arsenic in Food (22 October 2009 Scientific Opinion of the CONTAM Panel)
- Marine biotoxins in shellfish – Summary on regulated marine biotoxins (26 August 2009 Scientific Opinion of the CONTAM Panel)
- Marine biotoxins in shellfish – Domoic acid (24 July 2009 Scientific Opinion of the CONTAM Panel)
- Effects on public health of an increase of the levels for aflatoxin total from 4 µg/kg to 10 µg/kg for tree nuts other than almonds, hazelnuts and pistachios - Statement of the Panel on Contaminants in the Food Chain (30 June 2009 Statement of the CONTAM Panel)
- Marine biotoxins in shellfish – Pectenotoxin group (19 June 2009 Scientific Opinion of the CONTAM Panel)
- Review of the criteria for acceptable previous cargoes for edible fats and oils (29 May 2009 Scientific Opinion of the CONTAM Panel)
- Uranium in Food (28 April 2009 Scientific Opinion of the CONTAM Panel)
- Marine biotoxins in shellfish – Saxitoxin group (17 April 2009 Scientific Opinion of the CONTAM Panel)
- Nitrite as undesirable substances in animal feed[1] - Scientific Opinion of the Panel on Contaminants in the Food Chain (15 April 2009 Scientific Opinion of the CONTAM Panel)
- Influence of processing on the levels of lipophilic marine biotoxins in bivalve molluscs (31 March 2009 Statement of the CONTAM Panel)

- Cadmium in food - Scientific opinion of the Panel on Contaminants in the Food Chain (20 March 2009 Scientific Opinion of the CONTAM Panel)
- Saponins in Madhuca Longifolia as undesirable substances in animal feed (23 February 2009 Scientific Opinion of the CONTAM Panel)
- Marine biotoxins in shellfish – Yessotoxin group[1] - Scientific Opinion of the Panel on Contaminants in the Food chain (3 February 2009 Scientific Opinion of the CONTAM Panel)
- Gossypol as undesirable substance in animal feed - Scientific Opinion of the Panel on Contaminants in the Food Chain (28 January 2009 Scientific Opinion of the CONTAM Panel)
- Statement of EFSA on the risks for public health due to the presence of dioxins in pork from Ireland (10 December 2008 Statement of EFSA)
- Marine biotoxins in shellfish – Azaspiracid group[1] - Scientific Opinion of the Panel on Contaminants in the Food chain (8 October 2008 Scientific Opinion of the CONTAM Panel)
- Statement of EFSA on risks for public health due to the presences of melamine in infant milk and other milk products in China (25 September 2008 Statement of EFSA)
- Ricin (from Ricinus communis) as undesirable substances in animal feed [1] - Scientific Opinion of the Panel on Contaminants in the Food Chain (12 September 2008 Scientific Opinion of the CONTAM Panel)

- Theobromine as undesirable substances in animal feed [1] - Scientific opinion of the Panel on Contaminants in the Food Chain (9 September 2008 Scientific Opinion of the CONTAM Panel)
- Tropane alkaloids (from Datura sp.) as undesirable substances in animal feed[1] - Scientific Opinion of the Panel on Contaminants in the Food Chain (5 August 2008 Scientific Opinion of the CONTAM Panel)
- Polycyclic Aromatic Hydrocarbons in Food [1] - Scientific Opinion of the Panel on Contaminants in the Food Chain (4 August 2008 Scientific Opinion of the CONTAM Panel
- Perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA) and their salts Scientific Opinion of the Panel on Contaminants in the Food chain [1] (21 July 2008 Scientific Opinion of the CONTAM Panel)
- Nitrate in vegetables - Scientific Opinion of the Panel on Contaminants in the Food chain (5 June 2008 Scientific Opinion of the CONTAM Panel)
- Cross-contamination of non-target feedingstuffs by diclazuril authorised for use as a feed additive - Scientific opinion of the Panel on Contaminants in the Food Chain (30 May 2008 Scientific Opinion of the CONTAM Panel)
- EFSA statement on the contamination of sunflower oil with mineral oil exported from Ukraine (27 May 2008 Statement of EFSA)
- Cross-contamination of non-target feedingstuffs by nicarbazin authorised for use as a feed additive[1] - Scientific opinion of the Panel on Contaminants in the Food Chain (30 April 2008 Scientific Opinion of the CONTAM Panel)

- Cross-contamination of non-target feedingstuffs by decoquinate authorised for use as a feed additive [1] - Scientific opinion of the Panel on Contaminants in the Food Chain (21 April 2008 Scientific Opinion of the CONTAM Panel)
- Cross-contamination of non-target feedingstuffs by robenidine authorised for use as a feed additive [1] - Scientific opinion of the Panel on Contaminants in the Food Chain (21 April 2008 Scientific Opinion of the CONTAM Panel)
- Cross-contamination of non-target feedingstuffs by halofuginone hydrobromide authorised for use as a feed additive [1] - Scientific opinion of the Panel on Contaminants in the Food Chain (21 April 2008 Scientific Opinion of the CONTAM Panel)
- Mercury as undesirable substance in animal feed [1] - Scientific opinion of the Panel on Contaminants in the Food Chain (9 April 2008 Scientific Opinion of the CONTAM Panel)
- Statement of the Scientific Panel on Contaminants in the Food chain (CONTAM) on a request from the European Commission related to 3-MCPD esters (31 March 2008 Statement of the CONTAM Panel)
- Marine biotoxins in shellfish - okadaic acid and analogues - Scientific Opinion of the Panel on Contaminants in the Food chain (31 January 2008 Scientific Opinion of the CONTAM Panel)
- Cross-contamination of non-target feedingstuffs by monensin authorised for use as a feed additive [1] Scientific Opinion of the Panel on Contaminants in the Food Chain (28 January 2008 Scientific Opinion of the CONTAM Panel)

- Cross-contamination of non-target feedingstuffs by maduramicin authorised for use as a feed additive - Scientific opinion of the Panel on Contaminants in the Food Chain (25 January 2008 Scientific Opinion of the CONTAM Panel)
- Cross-contamination of non-target feedingstuffs by semduramicin authorised for use as a feed additive - Scientific opinion of the Panel on Contaminants in the Food Chain (25 January 2008 Scientific Opinion of the CONTAM Panel)
- Cross-contamination of non-target feedingstuffs by salinomycin authorised for use as a feed additive - Scientific Opinion of the Panel on Contaminants in the Food Chain (25 January 2008 Scientific Opinion of the CONTAM Panel)
- Glucosinolates as undesirable substances in animal feed - Scientific Opinion of the Panel on Contaminants in the Food Chain (15 January 2008 Scientific Opinion of the CONTAM Panel)
- Chlordane as undesirable substance in animal feed[1] - Scientific Opinion of the Panel on Contaminants in the Food Chain (23 November 2007 Scientific Opinion of the CONTAM Panel)
- Ethyl carbamate and hydrocyanic acid in food and beverages[1] - Scientific Opinion of the Panel on Contaminants (24 October 2007 Scientific Opinion of the CONTAM Panel)
- Cross-contamination of non-target feedingstuffs by narasin authorised for use as a feed additive[1] - Scientific Opinion of the Panel on Contaminants in the Food Chain (12 October 2007 Scientific Opinion of the CONTAM Panel)

- Cross-contamination of non-target feedingstuffs by lasalocid authorised for use as a feed additive[1] - Scientific Opinion of the Panel on Contaminants in the food Chain (12 October 2007 Scientific Opinion of the CONTAM Panel)
- Opinion of the Scientific Panel on contaminants in the food chain (CONTAM) related to hormone residues in bovine meat and meat products (18 July 2007 Scientific Opinion of the CONTAM Panel)
- EFSA provisional statement on a request form the European Commission related to melamine and structurally related to compounds such as cyanuric acid in protein-rich ingredients used for food and feed (8 June 2007 Statement of EFSA)
- Opinion of the Scientific Panel on contaminants in the food chain [CONTAM] related heptachlor as an undesirable substance in animal feed (5 June 2007 Scientific Opinion of the CONTAM Panel)
- Opinion of the Panel on contaminants in the food chain [CONTAM] related to pyrrolizidine alkaloids as undesirable substances in animal feed (22 May 2007 Scientific Opinion of the CONTAM Panel)
- Opinion of the scientific panel on contaminants in the food chain [CONTAM] related to the potential increase of consumer health risk by a possible increase of the existing maximum levels for aflatoxins in almonds, hazelnuts and pistachios and derived products (1 March 2007 Scientific Opinion of the CONTAM Panel)
- Opinion of the Scientific Panel on contaminants in the food chain [CONTAM] related to cyanogenic compounds as undesirable substances in animal feed (13 February 2007 Scientific Opinion of the CONTAM Panel)

- Opinion of the Scientific Panel on contaminants in the food chain [CONTAM] related to DDT as an undesirable substance in animal feed (21 December 2006 Scientific Opinion of the CONTAM Panel)
- Opinion of the Scientific Panel on contaminants in the food chain [CONTAM] related to Hexachlorobenzene as undesirable substance in animal feed (26 October 2006 Scientific Opinion of the CONTAM Panel)
- Statement on a request from the commission related to iodine in seaweed (13 October 2006 Statement of the CONTAM Panel)
- Opinion of the Scientific Panel on contaminants in the food chain [CONTAM] related to ochratoxin A in food (9 June 2006 Scientific Opinion of the CONTAM Panel)
- Advice of the Scientific Panel CONTAM related to relevant chemical compounds in the group of brominated flame retardants for monitoring in feed and food (6 March 2006 Statement of the CONTAM Panel)
- Opinion of the Scientific Panel on contaminants in the food chain [CONTAM] related to endrin as undesirable substance in animal feed (7 December 2005 Scientific Opinion of the CONTAM Panel)
- Opinion of the Scientific Panel on contaminants in the food chain [CONTAM] related to aldrin and dieldrin as undesirable substance in animal feed (7 December 2005 Scientific Opinion of the CONTAM Panel)
- Opinion of the Scientific Panel on contaminants in the food chain [CONTAM] related to the presence of non dioxin-like polychlorinated biphenyls (PCB) in feed and food (30 November 2005 Scientific Opinion of the CONTAM Panel)

- Opinion of the Scientific Panel on contaminants in the food chain [CONTAM] related to gamma-HCH and other hexachlorocyclohexanes as undesirable substances in animal feed (14 July 2005 Scientific Opinion of the CONTAM Panel)
- Opinion of the Scientific Panel on contaminants in the food chain [CONTAM] related to fumonisins as undesirable substances in animal feed (13 July 2005 Scientific Opinion of the CONTAM Panel)
- Opinion of the Scientific Panel on contaminants in the food chain [CONTAM] related to concentration limits for boron and fluoride in natural mineral waters (13 July 2005 Scientific Opinion of the CONTAM Panel)
- Opinion of the Scientific Panel on contaminants in the food chain [CONTAM] related to Endosulfan as undesirable substance in animal feed (7 July 2005 Scientific Opinion of the CONTAM Panel)
- Opinion of the Scientific Panel on contaminants in the food chain [CONTAM] related to the safety assessment of wild and farmed fish (1 July 2005 Scientific Opinion of the CONTAM Panel)
- Opinion of the Scientific Panel on contaminants in the food chain [CONTAM] related to ergot as undesirable substance in animal feed (31 May 2005 Scientific Opinion of the CONTAM Panel)
- Statement on summary report on Acrylamide in food of the 64th meeting of the joint FAO/WHO expert committee on food additives by the Scientific Panel on contaminants in the food chain (CONTAM) (26 April 2005 Statement of the CONTAM Panel)

- Opinion of the Scientific Panel on contaminants in the food chain [CONTAM] related to Arsenic as undesirable substance in animal feed. (2 March 2005 Scientific Opinion of the CONTAM Panel)
- Opinion of the Scientific Panel on contaminants in the food chain [CONTAM] related to camphechlor as undesirable substance in animal feed. (16 February 2005 Scientific Opinion of the CONTAM Panel)
- Report of the CONTAM Panel on provisional findings on furan in food (22 December 2004 Scientific Report of EFSA)
- The EFSA's 1st Scientific Colloquium Report - Dioxins (1 December 2004 Event Report)
- Opinion of the Scientific Panel on contaminants in the food chain [CONTAM] to assess the health risks to consumers associated with exposure to organotins in foodstuffs (26 October 2004 Scientific Opinion of the CONTAM Panel)
- Opinion of the Scientific Panel on contaminants in the food chain [CONTAM] related to ochratoxin A (OTA) as undesirable substance in animal feed. (14 October 2004 Scientific Opinion of the CONTAM Panel)
- Opinion of the Scientific Panel on contaminants in the food chain [CONTAM] related to Fluorine as undesirable substance in animal feed (14 October 2004 Scientific Opinion of the CONTAM Panel)
- Opinion of the Scientific Panel on contaminants in the food chain [CONTAM] related to the toxicity of fishery products belonging to the family of Gempylidae. (15 September 2004 Scientific Opinion of the CONTAM Panel)

- Opinion of the Scientific Panel on contaminants in the food chain [CONTAM]related to Zearalenone as undesirable substance in animal feed. (9 August 2004 Scientific Opinion of the CONTAM Panel)
- Opinion of the Scientific Panel on contaminants in the food chain [CONTAM] related to Deoxynivalenol (DON) as undesirable substance in animal feed. (17 June 2004 Scientific Opinion of the CONTAM Panel)
- Opinion of the Scientific Panel on contaminants in the food chain [CONTAM] related to cadmium as undesirable substance in animal feed. (16 June 2004 Scientific Opinion of the CONTAM Panel)
- Opinion of the Scientific Panel on contaminants in the food chain [CONTAM] related to lead as undesirable substance in animal feed. (16 June 2004 Scientific Opinion of the CONTAM Panel)
- Opinion of the Scientific Panel on contaminants in the food chain [CONTAM] related to Aflatoxin B1 as undesirable substance in animal feed (19 March 2004 Scientific Opinion of the CONTAM Panel)
- Opinion of the Scientific Panel on contaminants in the food chain [CONTAM] related to mercury and methylmercury in food (17 March 2004 Scientific Opinion of the CONTAM Panel)
- EFSA's 11th Scientific Colloquium - Acrylamide carcinogenicity - New evidence in relation to dietary exposure (17 March 2004 Event Report)

Source: EFSA Journal

TABLE 4.4.- MAIN SUBJECTS OF OPINIONS ADOPTED BY EFSA ON FOOD CONTAMINANTS, FEED CONTAMINANTS AND CONTAMINANTS IN FOOD AND FEED

FOOD	**67**
Metals	8
Mycotoxins	6
Persistent organic pollutants	11
Plant toxicants	1
Marine biotoxins	13
Food processing	4
Other	24
FEED	**42**
Metals	4
Mycotoxins	6
Persistent organic pollutants	10
Plant toxicants	8

Coccidiostats	11
Others	3
FOOD&FEED	**13**
Mycotoxins	8
Plant toxicants	2
Other	2
Persistent organic pollutants	1

TABLE 4.5.- SELECTED FOOOD CONTAMINANTS EVALUATED BY EFSA

Furan	Furan occurs in a variety of foods such as coffee, canned and jarred foods including baby food containing meat, and various vegetables, which suggests that there are probably multiple routes of formation rather than a single mechanism which was postulated for flavour volatiles. Fresh vegetables do not contain furan. Only a limited set of data on occurrence of furan in various food categories as well as consumption data are available For baby food 273 analyses show furan concentrations ranging from non detectable to 112 µg/kg. Assuming an exclusive intake of commercial baby food in glass jars, corresponding to 234 g food per day, this would lead to exposures ranging from <0.2 - 26 µg furan per day. Furan can easily pass through biological membranes and is readily absorbed from the lung or intestine. It is rapidly metabolised by P-450 enzymes and cis-2-butene-1,4-dial has been identified as a key metabolite. Furan is clearly carcinogenic to rats and mice, showing a dose-dependent increase in hepato-cellular adenomas and carcinomas in both sexes. In rats, also a dose-dependent increase in mononuclear leukaemia was seen in both sexes. A very high incidence of cholangiocar-cinomas of the liver	EFSA (European Food Safety Authority), 2004e. Report of the Scientific Panel on Contaminants in the Food Chain on provisional findings on furan in food. The EFSA Journal, 137, 1-20.

	was present in both sexes, even at the lowest dose tested. Furan-induced carcinogenicity is probably attributable to a genotoxic mechanism. It appears that there is a relative small difference between possible human exposures and the doses in experimental animals that produce carcinogenic effects, probably by a genotoxic mechanism. However, a reliable risk assessment would need further data on both toxicity and exposure.	
Acrylamide	The critical effects of acrylamide are its neurotoxicity and carcinogeni-city. Acrylamide is considered to be both geno-toxic and carcinogenic in laboratory animals. In its recent evaluation, the JECFA applied a margin of exposure (MOE) approach for the risk assessment of acrylamide (FAO /WHO, 2005). This approach is also currently proposed by the EFSA Scientific Committee for compounds that have both genotoxic and carcinogenic properties (EFSA, 2005). JECFA noted that the calculated MOEs were low for a compound that is genotoxic and carcinogenic . Furthermore, JECFA cautioned that there are uncertainties in its conclusion as the toxicological database is incomplete and recommended that (FAO/WHO, 2005): □acrylamide be re-evaluated when results of ongoing	EFSA (European Food Safety Authority), 2005c. Statement of the Scientific Panel on Contaminants in the Food Chain to a summary report on Acrylamide in food of the 64th meeting of the joint FAO/WHO Expert Committee on food additives.

	carcinogenicity and long-term neurotoxicity studies become available. □work should be continued on using physiologically based pharma-cokinetic (PBPK) modelling to better link human biomarker data with exposure assessments and toxicological effects in experimental animals. □appropriate efforts to reduce acrylamide concentrations in food should continue. The CONTAM Panel agreed with the principal conclusions and recommendations of the JECFA .	The EFSA Journal, 619, 1-2.
Ochra-toxin A in food	OTA has been found to be a potent renal toxin in all of the animal species tested. It induces a typical karyomegaly and a progressive nephropathy. The extent of renal injury is dose-dependent, but also associated with the duration of exposure, as OTA accumulates in renal tissue. OTA can also induce renal tumors in rodents at high dosages. Recent scientific evidence indicates that the site-specific renal toxicity as well as the DNA damage and genotoxic effects of OTA, measured in various *in vivo* and *in vitro* studies, are most likely attributable to cel-lular oxidative damage. On the basis of the lowest observed ad-verse effect level (LOAEL) of 8 μg/kg body weight (b.w.) per day for early	EFSA (European Food Safety Authority), 2006b. Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the Commission related to ochratoxin A in food. The EFSA

	markers of renal toxicity in pigs (the most sensitive animal spe-cies), and applying a composite uncertainty factor of 450 for the uncer-tainties in the extrapolation of experimental data derived from animals to humans as well as for intra-species variability, a Tolerable Weekly Intake (TWI) of 120 ng/kg b.w. was derived for OTA. The dietary exposure of adult European consumers to OTA revealed that at present the weekly exposure ranges from 15 to 60 ng OTA per kg body weight per week, including high consumers of foods containing OTA.	Journal, 365, 1-56.
Ochratoxin A in food	Five publications, most of which were from one research group, were submitted to EFSA . Four of these publications addressed the possible co-exposure to ochratoxin A and aristolochic acid of the human population in areas previously identified as having a higher prevalence of Balkan Endemic Nephropathy, the etiology of which has not yet been established, and the pathologies related to these two substances. In addition, a new method of analysis for multiple mycotoxins was presented in one of the papers, including data from breakfast cereals from the French retail market The Panel concluded that the nature of the information provided by these papers was not relevant to the	EFSA (European Food Safety Authority), 2010 Statement on recent scientific information on the toxicity of Ochratoxin A EFSA Journal ; 8(6):1626, 7pp

	overall assessment of the risks related to food contamination with the mycotoxin ochratoxin A.	
Tolerable weekly intake for cadmium	The European Commission asked to confirm whether the current tolerable weekly intake (TWI) of 2.5 μg/kg b. w. for cadmium is still considered appropriate or whether any modifications are needed in view of the provisional tolerable monthly intake (PTMI) of 25 μg/kg b.w. established by the JECFA in 2010. Both assessments used the same epidemiological dataset and have two primary components, a concen-tration-effect model that relates the concen-tration of cadmium in urine to that of beta-2-microglobulin (B2M), a biomarker of renal tubular effects, and a toxicokinetic model that relates urinary cadmium con-centration to dietary cadmium intake. Following an evaluation of the two approaches, the CONTAM Panel concluded that the current TWI for cadmium of 2.5 μg/kg b.w. was correct.	EFSA (European Food Safety Authority), 2011. Statement on tolerable weekly intake for cadmium. EFSA Journal 2011,4 (2):1975, 19pp.
Marine biotoxins in shell-fish	The CONTAM Panel has prepared a series of opinions sin-ce 2007 on various marine biotoxins, including emerging toxins, to assess the current European Union (EU) limits with regard to human health and methods of analysis as established in the EU legislation. In order to protect high consumers against acute effects of marine biotoxins, the	EFSA Panel on Contaminants in the Food Chain (CONTAM), 2010 Statement on further

	CONTAM Panel identified 400 g of shellfish meat as an appropriate estimate of a large portion size consumed in Europe to be used in the risk assessments. This portion size was then applied to all the scientific opinions on marine biotoxins. Recently EFSA has received new data from Belgium, France, Portugal and Spain on the shellfish portion sizes consumed. In addition, new consumption data have been submitted to EFSA for inclusion in the Comprehensive European food consumption database (Comprehensive Database). Based on the assessment of the new data provided to EFSA and the information included in the EFSA Comprehensive Database, the CONTAM Panel concluded that the earlier established estimate of the consumption figure of 400 g shellfish meat is appropriate for protecting high consumers against acute effects of marine biotoxins.	elaboration of the consumption figure of 400 g shellfish meat on the basis of new consumption data EFSA Journal 2010; 8(8):1706 ,20 pp..
Brevetoxin group in shell-fish and fish	Brevetoxin-(BTX) group toxins in shellfish and fish are marine biotoxins which can accumulate in shellfish and fish. BTX-group toxins are primarily produced by the dinoflagellate *Karenia brevis* and cause neurologic shellfish poisoning (NSP). Symptoms and signs of NSP include e.g. nausea,vomiting, diarrhoea, parasthesia, cramps, bronchoconstriction, paralysis, seizures and coma. To date BTX-group toxins ha-	EFSA Panel on Contaminants in the Food Chain (CONTAM), 2010 Scientific Opinion on marine biotoxins in

	ve not been reported in shellfish or fish from Europe and currently there are no regulatory limits for BTX-group toxins in shellfish or fish in Europe. The toxicological database for BTX-group toxins is limited, comprising mostly acute toxicity studies,but no acute reference dose (ARfD) could be established. As there is some evidence that BTX-2 forms DNA adducts, some concern was raised about its potential carcinogenicity and consequential long term effects. Due to the lack of data on shellfish or fish in Europe, the limited data on acute toxicity and the lack of data on chronic toxicity, the CONTAM Panel could not comment on the risk associated with the BTX-group toxins in shellfish and fish that could reach the European market.	shellfish – Emerging toxins: Brevetoxin group EFSA Journal 2010; 8(7):1677,29 pp.
Lead in food	Lead occurs primarily in the inorganic form in the environment. Human exposure is mainly via food and water, with some via air, dust and soil. In average adult consumers, lead dietary exposure ranges from 0.36 to 1.24, up to 2.43 µg/kg body weight (b.w.) per day in high consumers in Europe. Exposure of infants ranges from 0.21 to 0.94 µg/kg b.w. per day and in children from 0.80 to 3.10 (average consumers), up to 5.51 (high consumers) µg/kg b.w. per day. Cereal products contribute most to dietary lead	EFSA Panel on Contaminants in the Food Chain (CONTAM), 2010b. Scientific Opinion on Lead in Food. EFSA Journal, 8(4):1570, 147 pp

	exposure, while dust and soil can be important non-dietary sources in children. Lead is absorbed more in children than in adults and accumulates in soft tissues and, over time, in bones. The Panel on Contaminants in the Food Chain (CONTAM Panel) identified developmental neurotoxicity in young children and cardiovascular effects and nephrotoxicity in adults as the critical effects for the risk assessment. The CONTAM Panel concluded that the current PTWI of 25 μg/kg b.w. is no longer appropriate as there is no evidence for a threshold for critical lead-induced effects. In adults, children and infants the margins of exposures were such that the possibility of an effect from lead in some consumers, particularly in children from 1-7 years of age, cannot be excluded. Protection of children against the potential risk of neurodevelopmental effects would be protective for all other adverse effects of lead, in all populations.	
Nitrates in vegetables children	Nitrate is a naturally occurring compound present in vegetables, the consumption of which can contribute signifycantly to nitrate dietary exposure (see the opinion on 'Nitrate in vegetables' of 2008) . For infants, cooked spinach is more likely to be a component of the diet than	EFSA Panel on Contaminants in the Food Chain (CONTAM), 2010 Statement on possible

	lettuce. Nitrate exposure at the current or proposed maximum levels for nitrate in spinach cooked from fresh is unlikely to be a health concern, although a risk for some infants eating more than one spinach meal in a day cannot be excluded. For children, the CONTAM Panel concluded that levels of nitrate in lettuce are not a health concern. However the concentrations of nitrate in spinach have the potential to increase dietary nitrate exposure to levels at which a health concern can not be excluded for some young children. Enforcing the current maximum levels for nitrate in lettuce and spinach, or proposed maximum levels at 500 mg/kg higher than the current maximum levels, would have a minor impact compared to the situation of local derogations from the maximum levels, because only about 1 % of lettuce samples and 5 % of spinach samples exceeded the respective current maximum levels. Inappropriate storage of cooked vegetables can result in *in situ* conversion of nitrate to nitrite, resulting in an increased potential for causing methaemoglobinaemia.	public health risks for infants and young children from the presence of nitrates in leafy vegetables . EFSA Journal 2010;8(12):1935**,**42 pp.
Polybromi-nated Bi-phenyls	PBBs are additive flame retardants which were applied in synthetic fibres and polymers. PBBs are present in the environment at low concentrations and likewise in biota and	EFSA Panel on Contaminants in the Food Chain (CONTAM), 2010

(PBBs) in food	in food and feed. Data from the analysis of 16 PBB congeners in 794 food samples were provided to EFSA by 6 Member States, covering the period from 2003 to 2009. Toxicity studies were carried out with technical PBB mixtures of which the exact congener composition is not known. Main targets were the liver, thyroid hormone homeostasis and the reproductive, nervous and immune systems. PBBs are not directly genotoxic. The hepatic carcinogenic effects are the critical effect, with a no-observed-effect level (NOEL) of 0.15 mg/kg body weight (b.w.). Since this NOEL was obtained in a study with a technical PBB mixture, the congener profile of which differs from that currently found in food, this NOEL was considered to be not appropriate to derive a health based guidance value. The intake of PBBs by high and frequent consumers of fatty fish, the subgroup with the highest dietary exposure, was approximately 6 orders of magnitude less than this NOEL. Exposure for high consuming breast-fed infants is 5 orders of magnitude less than this NOEL.	Scientific Opinion on Polybrominated Biphenyls (PBBs) in Food .EFSA Journal 2010; 8(10):1789 ,151 pp..
Dioxins and dioxin-like PCBs	Results from 332 sheep liver, 175 sheep meat and 9 deer liver samples submitted by eight European countries were evaluated to estimate the exposure through consumption of	EFSA Panel on Contaminants in the Food Chain

in liver from sheep and deer.	sheep liver for adults (consumers only) and children. Regular consumption of sheep liver would result on average in an approximate 20 % increase of the median background exposure to dioxins and dioxin-like PCBs (DL-PCBs) for adults. On individual occasions, consumption of sheep liver could result in high intakes exceeding the tolerable weekly intake (TWI). It was concluded that the frequent consumption of sheep liver, particularly by women of child-bearing age and children, may be a potential health concern. Additional intake of non dioxin-like PCBs (NDL-PCBs) from consumption of sheep liver does not add substantially to the total dietary intake. The range of fat content in sheep liver is considerably narrower than for a number of other food categories regulated in Regulation (EC) No 1881/2006. Therefore, no need was identified to change the basis for expression of results and maximum levels solely for liver from fat weight to fresh weight basis. A lower activity of CYP1A enzymes in sheep than in cattle was identified as a possible reason for higher dioxin and DL-PCB levels in sheep liver.	(CONTAM), 2011a. Scientific Opinion on the risk to public health related to the presence of high levels of dioxins and dioxin-like PCBs in liver from sheep and deer. EFSA Journal, 9(7):2297, 71 pp.
Hexabromocyclododecanes	HBCDDs are additive flame retardants primarily used in expanded and extruded polystyrene applied as construction and packing materials, and in textiles. The Panel on	EFSA Panel on Contaminants in the Food Chain

(HBCDDs) in food.	Contaminants in the Food Chain (CONTAM Panel) selected α-, β- and γ-HBCDD to be of primary interest. Since all toxicity studies were carried out with technical HBCDD, a risk assessment of individual stereoisomers was not possible. Main targets were the liver, thyroid hormone homeostasis and the reproductive, nervous and immune systems. HBCDDs are not genotoxic. Neurodevelopmental effects on behaviour as the critical endpoint, and derived a benchmark dose lower confidence limit for a benchmark response of 10 % (BMDL10) of 0.79 mg/kg body weight. Due to the limitations and uncertainties in the current data base, it was concluded that it was inappropriate to use this BMDL to establish a health based guidance value, and instead used a margin of exposure (MOE) approach for the health risk assessment of HBCDDs. Current dietary exposure to HBCDDs in the European Union was considered not to raise a health concern. Also additional exposure, particularly of young children, to HBCDDs from house dust is unlikely to raise a health concern.	CONTAM); Scientific Opinion on Hexabromocyclodo-decanes HBCDDs) in Food. EFSA Journal 2011;9(7):2296. [118 pp.]
Polybromi-nated Diphenyl	TBBPA is primarily used as reactive flame retardant covalently bound to epoxy and polycarbonate resins. Data from the analysis of TBBPA in 344 food samples were	EFSA Panel on Contaminants in the Food Chain

Ethers (PBDEs) in food	submitted to EFSA by two European countries (Norway and Spain), covering the period from 2007 to 2010. All samples were in the food group "Fish and other seafood", and all analytical results were reported as less than the limit of quantification (LOQ) (about 1 ng/g wet weight). Toxicological studies with TBBPA have been carried out using different experimental designs with single or repeated administration during gestation, postnatally or in adulthood. The main target is thyroid hormone homeostasis. TBBPA is not genotoxic. There are no indications that TBBPA might be carcinogenic. It was identified a lower confidence limit for a benchmark response of 10 % ($BMDL_{10}$) of 16 mg/kg b.w. reported for changes in thyroid hormones as the critical reference point. Due to the limitations and uncertainties in the database, the CONTAM Panel used a margin of exposure (MOE) approach for the health risk assessment of TBBPA. In view of the large MOEs, the CONTAM Panel concluded that current dietary exposure to TBBPA in the European Union does not raise a health concern. Similar conclusions apply to exposure of infants via human milk and to exposure, particularly of young children, to TBBPA from house dust.	(CONTAM), 2011b. Scientific Opinion on Polybrominated Diphenyl Ethers (PBDEs) in Food. EFSA Journal, 9(5):2156, 274 pp

Opium alkaloids in poppy seeds in food	Poppy seeds are obtained from the opium poppy (*Papaver somniferum* L.). They are used in bakery products, on top of dishes, in fillings of cakes and in desserts and to produce edible oil. The opium poppy plant contains narcotic alkaloids such as morphine and codeine. Poppy seeds do not contain the opium alkaloids, but can become contaminated with alkaloids as a result of insect damage, or through poor harvesting practices. Based on the relative prevalence of the alkaloids present in poppy seed and food samples analysed, and on their pharmacological potency, the CONTAM Panel concluded that the risk assessment could be based on dietary exposure to morphine alone. The CONTAM Panel applied an uncertainty factor of 3 to establish from the lowest known single oral therapeutic dose of 30 µg morphine/kg body weight (b.w.) an acute reference dose (ARfD) of 10 µg morphine/kg b.w. Estimates of dietary exposure to morphine from foods containing poppy seed demonstrate that the ARfD can be exceeded during a single serving by some consumers, particularly children, across the EU. This risk assessment relates to poppy seed samples with an alkaloid profile comparable to that of the submitted data and should not be extrapolated to poppy seed samples with a	EFSA Panel on Contaminants in the Food Chain (CONTAM), 2011d. Scientific Opinion on the risks for public health related to the presence of opium alkaloids in poppy seeds. EFSA Journal, 9(11):2405, 150 pp.

	qualitatively different alkaloid profile.	
Zearale-none in food	Zearalenone is a mycotoxin produced by several *Fusarium* species. It is commonly found in maize but can be found also in other crops such as wheat, barley, sorghum and rye. ains and grain-based foods, in particular grains and grain milling products, bread and fine bakery wares, made the largest contribution to the estimated zearalenone exposures. Vegetable oils also made an important contribution to the zearalenone exposure. The critical effects of zearalenone result from its oestrogenic activity. Based on recent data in the most sensitive animal species, the pig, and taking into account comparisons between pigs and humans, a tolerable daily intake (TDI) was established for zearalenone of 0.25 µg/kg b.w. Estimates of chronic dietary exposure to zearalenone based on the available occurrence data are below or in the region of the TDI for all age groups and not a health concern. A potential increase for zeara-lenone in breakfast cereals from 50 µg/kg to 75, 100, 125 or 150 µg/kg is unlikely to result in a chronic dietary exposure exceeding the TDI. In a worst case scenario, it is possible that an individual could consume the same batch of breakfast cereal containing zearalenone every day for 2 to 4	EFSA Panel on Contaminants in the Food Chain Scientific Opinion on the risks for public health related to the presence of Zearale-none in food EFSA Journal 2011;9(6): 2197. 124 pp.

	weeks, in which case exposures may exceed the TDI.	
Bromina-ted Flame Retardants (BFRs) in Food: Bro-minated phenols and their derivatives in food..	A call for data was issued by EFSA in December 2009,but no data on brominated phenols or their derivatives were submitted to EFSA. A limited number of occurrence data, covering the food group "Fish and other seafood", was identified in the literature. Data from European sampling showed that 2,4,6-tribromophenol (2,4,6-TBP) predominates over the other brominated phenols. Toxicity studies are scarce and mostly relates to 2,4,6-TBP. The main targets are liver and kidneys. In a limited repeated dose oral toxicity study a no-observed-adverse-effect level (NOAEL) for 2,4,6-TBP of 100 mg/kg b.w. per day was iden-tified. 2,4,6-TBP was not genotoxic in bacterial tests *in vitro*, and not *in vivo*, but induced chromosomal aberrations in mammalian cells *in vitro*. No long-term toxicity or carcinogenicity studies with 2,4,6-TBP were identified. It was concluded that due to the limitations and uncertainties in the current database, the establishment of a health based guidance value for 2,4,6-TBP was not appropriate. Therefore, the Panel derived a margin of exposure to assess the level of possible health concern for high consumers of fish, molluscs and crustaceans. The CONTAM Panel concluded that it is	EFSA Panel on Contaminants in the Food Chain (CONTAM), 2012b Scientific Opinion on Bromi-nated Flame Retar-dants (BFRs) in Food: Brominated Phenols and their Derivatives. EFSA Journal 2012;10 (4): 2634 [42 pp.].

	unlikely that current dietary exposure to 2,4,6-TBP in the European Union would raise a health concern. Also exposure of infants to 2,4,6-TBP via breast feeding is unlikely to raise a health concern.	

Source: EFSA Journal

TABLE 4.6.- SELECTED UNDESIRABLE SUBSTANCES AND OTHER CONTAMINANTS EVALUATED BY EFSA IN PRODUCTS INTENDED FOR ANIMAL FEED

Cadmium as undesirable substance in animal ffed	Current statutory maximum levels for feedstuffs successfully prevent toxic effects in farm animals. Dietary cadmium exposure affects the absorption of trace elements, particularly that of copper resulting in an apparent copper deficiency in ruminants. In turn, high copper supplementation of feeds for pigs was considered to comprise the risk of an undesirable cadmium accumulation in the liver and kidneys, whereas zinc supplementation of feed reduces cadmium bioavailability. Within the EU maximum levels have been set for trace elements in animal diets, including copper and zinc (Commission Regulation (EC) 1334/2003). If these permissible levels are not exceeded, the overall tissue burden of cadmium is unlikely to exceed the maximum levels set for foods from animal origin under the	EFSA (European Food Safety Authority), 2004a. Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the Commission related to cadmium as undesirable substance in animal feed. The EFSA Journal, 72, 1-24.

	conditions of current agricultural practice. Ruminants and horses, however, may be exposed during their entire lifespan to cadmium present in pastures. In distinct regions, this may result in an undesirable cadmium accumulation particularly in kidneys of older animals and wildlife animals thus contributing significantly to the overall human exposure.	
Ochratoxin A (OTA) as undesirable substance in animal feed	In animal feed materials the toxin is found most commonly in cereals (rye, barley, maize, and wheat) and to a lesser degree in peanuts and soybean. Toxin production usually occurs during storage. The distribution of ochratoxin A in stored grains is very heterogeneous, making analysis and dietary exposure assessment of farm animals difficult . Ochratoxin A is a potent renal toxin in all animal species investigated as of yet and has been causally associated with nephropathy in pigs and poultry. Exposure to nephrotoxic doses is associated with renal	EFSA (European Food Safety Authority), 2004d. Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the Commission related to ochratoxin A (OTA) as

	tumours in laboratory rodents but no data on carcinogenicity are available in other animal species. Ochratoxin A is also immunotoxic and teratogenic but usually at higher than nephrotoxic doses. Pigs, dogs and poultry are particularly sensitive to the nephrotoxicity and a no-observed-adverse-effect level has not been established in pigs or dogs; ruminants are less sensitive due to degradation of ochratoxin A to the less toxic ochratoxin α by the rumen microflora. Upon absorption from the gastro-intestinal tract, ochratoxin A binds to serum proteins resulting in considerable variation in elimination half-lives across species depending on the affinity and degree of protein binding. Accumulation occurs in blood, liver and kidney, and significant lower residue concentrations are found in muscle tissue, fat and milk. Carry-over into eggs has been demonstrated under experimental conditions using high toxin concentrations.	undesirable substance in animal feed. The EFSA Journal, 101, 1-36.

Aldrin and dieldrin as undesirable substance in animal feed.	Aldrin and dieldrin (a metabolite of aldrin as well as a marketed pesticide) are both fat soluble persistent and bio-accumulating organochlorine insecticides. There are still residues of dieldrin in the environment and in human tissues, but the levels have been declining during the last 30 years. In both animals and humans, aldrin and dieldrin are readily absorbed via the gastrointestinal tract. The conversion of aldrin to dieldrin occurs much more rapidly than the subsequent biotransformation and elimination of dieldrin, resulting in the accumulation of dieldrin in lipid rich tissues. The dominant toxic effects are in the nervous system and the liver, the latter mainly following chronic exposure. Aldrin and dieldrin are approximately equally toxic. They are not genotoxic or teratogenic. The transfer rates from feed to milk, eggs and adipose tissue are among the highest found for chlorinated	EFSA (European Food Safety Authority), 2005j. Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the Commission related to aldrin and dieldrin as undesirable substance in animal feed. The EFSA Journal, 285, 1-43.

	pesticides, making aldrin, and especially dieldrin, highly accumulative compounds. Dieldrin rather than aldrin predominates in feed materials of animal origin. The daily intake from food for adults and children seems to be in the range of 1 to 10 ng/kg b.w. Thus, the dietary intake is substantially below the provisional tolerable daily intake (PTDI) of 100 ng/kg b.w. established by the JMPR (FAO/WHO Joint Meeting on Pesticide Residues).	
Hexachlorobenzene as undesirable substance in animal feed.	Hexachlorobenzene (HCB was banned in 1981 for agricultural use in the European Community. Nevertheless, it is still used to some extent as an industrial chemical and is still released to the environment during incineration. HCB is quite volatile, highly lipophilic and among the more persistent environmental pollutants. In its evaluation of this contaminant, the CONTAM Panel examined occurrence data to assess the levels that are currently found in the environment	EFSA (European Food Safety Authority), 2006c. Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the Commission related to

	and in food and feed. Fish derived products, particularly fish oils, were generally found to contain the highest levels of HCB. But high levels were also occasionally found in plant products such as pumpkin seeds as well as in vegetable oils from contaminated areas.HCB is readily absorbed in humans and animals. It has low acute toxicity. The liver is the predominant organ to be affected resulting in enzyme induction and porphyria. HCB is immunotoxic and causes ovarian toxicity in monkeys at a very low dose. Mink and Japanese quail seem to be among the most susceptible animal species. HCB is classified by IARC as a possible human carcinogen based on tumourigenic effects observed in experimental animals. HCB in some tests exhibits weak mutagenic activity and therefore a genotoxic mode of action could not be completely excluded. Recent dietary HCB intake for adults and children (breastfed infants excluded) ranges up to a few ng/kg body weight (b.w.) per day which is far below the suggested	hexachlorobenzene as undesirable substance in animal feed. The EFSA Journal, 402, 1-49.

	health based guidance value of 170 ng/kg b.w. per day.	
DDT as undesirable substance in animal feed	The main insecticidal activity can be attributed to *p,p'*-DDT. Moreover, DDT is used as an intermediate in the production of the pesticide dicofol and may occur as a major impurity in the final product. DDT was banned in many European countries for most uses in the early 1970s. The use of DDT as a pesticide has been very restrictive since 1981 and banned since 1986 in the EU. However, DDT is still used for vector control especially in areas with endemic malaria, and extended use was recently recommended by WHO for indoor residual spraying to control malaria. Because of the lipophilic properties and persistence in the environment, DDT and related compounds are bioaccumulated and biomagnified along the food chain. DDT is readily absorbed in humans and animals; the half-life for DDT varies from one month in rats to four years in humans. DDT has	EFSA (European Food Safety Authority), 2006d. Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the Commission related to DDT as undesirable substance in animal feed. The EFSA Journal, 433, 1-69.

	low acute toxicity to mammals and most bird species. The main target organs are the nervous system and the liver. It also affects hormonal tissues, reproduction, fetal development and the immune system. DDT including *p,p*'-DDE and DDD cause tumours mainly in the liver of experimental animals and are mostly negative in genotoxicity studies. DDT is classified by IARC as possibly carcinogenic to humans (group 2B). The Joint FAO/WHO Meeting on Pesticide Residues (JMPR) derived a provisional tolerable daily intake (PTDI) for DDT of 0.01 mg/kg b.w. In feed samples of animal origin the metabolite *p,p'*-DDE normally represents more than 50 % of sum of DDT. Samples of plant origin are generally dominated by the parent compound *p,p'*-DDT. Feed commodities including fish derived products generally contain levels in the low mg/kg range and thus are far below those that have been found to cause adverse effects in fish and domestic animals. Despite its presence in the environment, many foodstuffs and animal	

	feed, the data show a considerable decline of up to 90 % in human exposure to DDT and related compounds over the past three decades. Food of animal origin is the major source of human exposure and recent studies performed in some EU Member States indicate a mean dietary intake for adults and children of 5 - 30 ng/kg b.w. per day. This exposure level is more than two orders of magnitude below the PTDI of 0.01 mg/kg b.w.	
Saponins in *Madhuca Longifolia* L. as undesirable substances in animal feed.	Saponins can form stable foam in aqueous solutions, hence the name "saponin" from the Latin word for soap (*sapo*). Traditionally, they have been used as detergents, piscicides and molluscicides in addition to industrial applications as foaming and surface active agents.*Madhuca longifolia* and other *Madhuca* species are large evergreen or semi-evergreen trees with a dense spreading crown extensively cultivated in warm climates for their oil-containing seeds. The present opinion deals with saponins in *Madhuca longifolia* and other	EFSA (European Food Safety Authority), 2009k. Scientific Opinion of the Panel on Contaminants in the Food Chain on a request from the European Commission on Saponins in *Madhuca*

	Madhuca species as potentially undesirable compounds in feed. In food and feed, saponins can have an "anti-nutritional" effect and cause toxic effects, but have also been claimed to cause beneficial health effects. Many saponins have a general action on lipid membranes and cause haemolysis *in vitro* or when injected intravenously. In general, saponins, as glycosides, have low oral bioavailability, but may be hydrolysed in the intestinal tract and cause systemic toxicity dependent on the structure and absorption of the aglycone. Toxicity studies and observations of toxic effects in feeding studies have been reported using crude total saponins or defatted seed meal from various *Madhuca* species. The oral LD50 in mice of crude *Madhuca* saponins (exact botanical source not given) was about 1.0 g/kg body weight. In mice and rats *Madhuca* saponins caused local gastro-intestinal toxicity as well as liver and kidney toxicity. At lower doses, *Madhuca* saponins can cause feed refusal and starvation	*Longifolia* L. as undesirable substances in animal feed. The EFSA Journal, 979, 1-36.

	with reduced body weight gain and increased mortality. The Panel confirmed that although Mahua oil (oil from *Madhuca longifolia*) caused bilateral testicular atrophy with degenerative changes in the seminiferous tubules in rats; saponins are the substances mainly responsible for the toxicity of *Madhuca longifolia* in animal feed. Because of the limited data available, no health-based guidance value (ADI, TDI) can be established for *Madhuca* saponins. Toxicity studies of *Madhuca* seeds on monogastric target animals are scarce. *Madhuca* seed cake in chick mash at approximately 12% level was lethal. Except for piscicidal effect of *Madhuca* saponins by water exposure in guppy fish, no toxicity studies after dietary exposure were identified in fish. The CONTAM Panel concludes that human dietary exposure to *Madhuca* saponins in the EU can be considered as negligible.	

TABLE 4.7.-REPRESENTATIVE CONTAMINANTS EVALUATED BY EFSA IN FOOD/FEED

***Ambrosia* seeds and human or animal health**	The genus *Ambrosia* (Asteraceae family) is distributed worldwide. *Ambrosia artemisiifolia* (common ragweed) has heavily colonised several areas of South -East Europe. *Ambrosia* spp., both in their native range and in invaded areas, are of public health concern due to the allergenic properties of their pollen. The NDA Panel concluded that inhalation of the plant pollen causes rhino-conjunctivitis and asthma, with skin allergies and food allergy playing minor roles. *Ambrosia* may cross-sensitize patients to other allergens, including food allergens. There is some evidence for allergenicity of *Ambrosia* pollen in animals. With regard to the effects on the environment of the further distribution of *Ambrosia* spp. in the European Union, the PLH Panel concluded	EFSA (European Food Safety Authority), 2010. Scientific Opinion on the effect on public or animal health or on the environment on the presence of seeds of Ambrosia spp. in animal feed EFSA Journal 2010; 8(6):1566, 37 pp.

	that there is no direct evidence that *Ambrosia* spp. cause extinction of plant species. However, there are some indications that *A. artemisiifolia* could become highly invasive in certain environmentally-valuable habitats and might be linked to an impoverishment of species richness, therefore further ecological studies are needed. *Ambrosia* seeds may contaminate feed. However, animal feed materials compounded for use in livestock are extensively processed. This processsing destroys *Ambrosia* seeds and hence the contribution of compounded feed to the dis-persion of *Ambrosia* is considered to be negligible. Bird feed often contains significant quantities of *Ambrosia* seeds and remains unprocessed. Therefore, bird feed seems to play an important role in introducing *Ambrosia* to new, previously not infested areas.	
Pyrrolizidine alkaloids in	Pyrrolizidine alkaloids are toxins exclusively biosynthesised by plants. Although there might	EFSA Panel on Contaminants in the

food and feed.	be other sources of exposure, due to lack of data the CONTAM Panel performed estimates of both acute and chronic exposure to Pas only through honey for three different age groups. A number of PAs were identified as being of particular importance for food and feed. Based on the present knowledge of metabolism, activation, DNA adduct-formation, genotoxicity and carcinogenicity, 1,2-unsaturated PAs may act as genotoxic carcinogens in humans. Therefore, it was decided to apply the Margin of Exposure (MOE) approach. A benchmark dose lower confidence limit for a 10 % excess cancer risk ($BMDL_{10}$) of 70 µg/kg b.w. per day for induction of liver haemangiosarcomas by lasiocarpine in male rats was calculated as the reference point for comparison with the estimated dietary exposure. There is a possible health concern for those toddlers and children who are high consumers of honey. There is generally a low risk of PA poisoning in	Food Chain (CONTAM), 2011c. Scientific Opinion on Pyrrolizidine alkaloids in food and feed. EFSA Journal, 9(11):2406, 134 pp.

	livestock and companion animals in the EU as most PA poisonings reported recently are due to accidental exposure.	
***Alternaria* toxins in food and feed**	In addition to causing plant diseases on many crops such as cereals, oilseeds, tomatoes, apples and olives, some of these toxins are genotoxic *in vitro* and/or fetotoxic in rats. This opinion deals with alternariol, alternariol monomethyl ether, tenuazonic acid, iso-tenuazonic acid, altertoxins, tentoxin, altenuene and AAL-toxins (*Alternaria alternata* f. sp. *lycopersici* toxins). Generally these toxins were found in grains and grain-based products, tomato and tomato products, sunflower seeds and sunflower oil, fruits and fruit products, and beer and wine. . The knowledge on toxic effects of *Alternaria* toxins on farm and companion animals and occurrence data in feed were insufficient to assess the health risk for different species. For chicken there are indications that alternariol	EFSA Panel on Contaminants in the Food Chain (CONTAM), 2011e. Scientific Opinion on the risks for animal and public health related to the presence of *Alternaria* toxins in feed and food. EFSA Journal, 9(10):2407, 97 pp.

	represents a health risk but it cannot be excluded that tenuazonic acid could also be of concern. Considering: (1) there are few or no relevant toxicity data on *Alternaria* toxins, (2) the chemical structure of several of them is known, (3) dietary exposure data exist for some of them, the Panel on Contaminants in the food chain used the threshold of toxicological concern (TTC) approach to assess the relative level of concern for dietary exposure of humans to these mycotoxins. For the genotoxic *Alternaria* toxins, alternariol and alternariol monomethyl ether, the estimated chronic dietary exposure exceeded the relevant TTC value indicating a need for additional toxicity data. The dietary exposure estimates for non-genotoxic tentoxin and tenuazonic acid are lower than the relevant TTC value and are considered unlikely to be a human health concern.	
T-2 and HT-2	T-2 toxin and HT-2 toxin are mycotoxins	EFSA Panel on

toxins in food and feed	produced by various *Fusarium* species. The European Commission asked EFSA for a scientific opinion on the risk to human and animal health related to the presence of T-2 and HT-2 toxin in food and feed. . The highest mean concentrations for the sum of T-2 and HT-2 toxins were observed in grains and grain milling products, notably in oats and oat products. Grains and grain-based foods, in particular bread, fine bakery wares, grain milling products to the sum of T-2 and HT-2 toxin exposure for humans. T-2 toxin is rapidly metabolised to a large number of products, HT-2 toxin being a major metabolite. Pigs are amongst the most sensitive animals towards the effects of T-2 toxin, the most sensitive endpoints being immunological or haematological effects. Using these data and a benchmark dose analysis, a group tolerable daily intake (TDI) of 100 ng/kg b.w. for the sum of T-2 and HT-2 toxins was established. Estimates of chronic human dietary expo-sure	Contaminants in the Food Chain (CONTAM), 2011f. Scientific Opinion on the risks for public health related to the presence of T-2 and HT-2 toxin in food and feed. EFSA Journal, 9(12):2481, 187 pp.

	to the sum of T-2 and HT-2 toxins based on the available occurrence data are below the TDI for populations of all age groups, and thus not a health concern. For ruminants, rabbits and farmed fish the estimated exposures to the sum of these toxins based on the available occurrence data are considered unlikely to be a health concern, while for pigs, poultry, dogs and horses the risk of adverse health effects is low. For cats the health risk from the exposure to T-2 and HT-2 toxins cannot be assessed.	
Ergot alkaloids in food and feed	Ergot alkaloids (EAs) in food and feed are produced by se-veral members within the fungal orders of Hypocreales and Eurotiales. In Europe, *Claviceps purpurea* is the most wide-spread *Claviceps* species within the Hypocreales. Based on the EAs identified in sclerotia of *C. purpurea*, and recent literature data, the EFSA Panel based its risk assessment on the main *C. purpurea* EAs, namely ergometrine, ergotamine, ergosine, ergocristine, ergocryptine (which is a mixture	EFSA Panel on Contami-nants in the Food Chain (CONTAM), 2012 c Scientific Opinion on Ergot alkaloids in food and feed .. EFSA Journal 2012c; 10(7):2798 [158 pp.].

	of α- and β- isomers), ergocornine, and the corresponding –inine epimers. Estimates of both chronic and acute exposure were performed for various age groups. A $BMDL_{10}$ of 0.33 mg/kg b.w. per day was calculated for the incidence of tail muscular atrophy in a 13-week rat feeding study of ergotamine. This effect was considered representtative of the vasoconstrictive effects of EAs and provided a suitable reference point for establishment of a group acute reference dose of 1 μg/kg body weight (b.w.) and a group tolerable daily intake of 0.6 μg/kg b.w. per day. The Panel concluded that whilst the available data do not indicate a concern for any population subgroup, the dietary exposure estimates relate to a limited number of food groups and a possible unknown contribution from other foods cannot be discounted. Estimates of exposure for livestock based on example diets and levels of EAs in cereal grains suggest that under normal conditions the risk of toxicosis is	

	low.	
Modified forms of certain mycotoxins in food and feed	Modified (often called "masked") mycotoxins are metabolites of the parent mycotoxin formed in the plant or fungus, e.g. by conjugation with polar compounds. Fumonisins, which are difficult to extract from the plant matrix, are also termed modified mycotoxins For modified forms of zearalenone, nivalenol, T-2 and HT-2 toxins and fumonisins, 100 %, 30 %, 10 % and 60 % were added, respectively, based on reports on the relative contribution of modified forms. The same factors were used for animal exposure from feed. In the absence of specific toxicity data, toxicity equal to the parent compounds was assumed for modified mycotoxins. Risk characterization was done by comparing exposure scenarios with reference doses of the parent compounds. In humans, all lower bound (LB) and upper bound (UB) mean and 95th percentile exposures to the sum of modified and parent toxins were below the	Scientific Opinion on the risks for human and animal health related to the presence of modified forms of certain mycotoxins in food and feed EFSA Journal 2014;12(12):3916

	respective provisional maximum tolerable daily intakes (PMTDIs) and tolerable daily intakes (TDIs), with two exceptions: for zearalenone and modified zearalenone the UB 95th percentile exposure was up to 2.2-fold the TDI. For fumonisins and modified fumonisins the exposure of toddlers and other children exceeded the PMTDI at both the LB and the UB estimates, which could be of concern. For farm animal species and pets the exposure to the sum of modified and parent toxins was in general not of concern. The risk in fish could not be addressed. The CONTAM Panel identified several uncertainties and data gaps for modified mycotoxins.	

Source: EFSA Journal

TABLE 5.1 – MAIN FOOD/FEED SAFETY COMMUNITY REGULATIONS

1) Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety2.(also referred to as the General Food Law),

2) Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare3,

3) Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs, and

4) Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No853/2004 and for the organisation of official controls under Regulations (EC) No 854/2004 and No 882/2004, derogating from Regulation (EC) No 852/2004 and amending Regulations (EC) No 853/2004 and No 854/20045.

TABLE 5. 2-PRINCIPLES OF THE HACCP PROCEDURE

(a) identify any hazards that must be prevented, eliminated or reduced to acceptable levels;

(b) identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;

(c) establish critical limits at critical control points which separate acceptability from unacceptability, for the prevention, elimination or reduction of identified hazards;

(d) establish and implement effective monitoring procedures at critical control points;

(e) establishing corrective action when monitoring indicates that a critical control point is not under control;

(f) establishing procedures to verify that the measures outlined in points (a) to (e) are complete and working effectively. Verification procedures shall be carried out regularly;

(g) establish documents and records commensurate with the nature and size of the feed businesses to demonstrate the effective application of the measures set out in points (a) to (f).

—

TABLE 5.3 MAXIMUN PERMITTED LEVELS OF RADIOACTIVE CONTAMINANTS IN FOODSTUFFS AND FEEDINGSTUFFS (Bq/kg or Bq/l)

	Baby foods(1)	*Dairy products (2)(3)*	*Other foodstuffs except minor foodstuffs(4)*	*Liquid foodstuffs(5)*	*Feedingstuffs(6)*
Isotopes of strontium, notably Sr-90		*125*	*750*		
Isotopes of iodine, notably I-131		*500*	*2000*		
Alpha-emitting isotopes of plutonium and transplutonium elements, notably Pu-239, Am-241		*20*	*80*		
All other nuclides of		*1000*	*1250*		

half-life greater than 10 days, notably Cs-134 and Cs-137					

(1) Baby foods are defined as those foodstuffs intended for the feeding of infants during the first four to six months of life, which meet, in themselves, the nutritional requirements of this category of person and are put up for retail sale in packages which are clearly identified and labelled 'food preparation for infants'. Values to be established.

(2) Dairy produce is defined as milk falling within headings Nos 04.01 and 04.02 of the Common Customs Tariff, and the corresponding headings of the combined nomenclature as from 1 January 1988.

(3) The level applicable to concentrated or dried products shall be calculated on the basis of the reconstituted product as ready for consumption.

(4) Minor foodstuffs and the corresponding levels to be applied to them will be as defined in accordance with Article 7.

(5) Liquid foodstuffs as defined by Chapters 20 and 22 of the Common Customs Tariff and by the corresponding Chapter of the combined nomenclature as from 1 January 1988. Values are calculated taking into account consumption of tap-water and the same values should be applied

to drinking water supplies at the discretion of competent authorities in Member States. Values for liquid foodstuffs to be established.

(6) Values to be established.

(7) Carbon 14 and tritium are not included in this group.

TABLE 5.4. - MAXIMUM PERMITTED LEVELS OF RADIOACTIVE CONTAMINATION (CAESIUM-134 AND CAESIUM-137) OF FEEDINGSTUFFS (Reg. EURATOM 770/90)

–

Animal	Radioactivity (Bq/kg (1)(2)
Pigs	1250
Poultry,lamss, calves	2500
Other	5000

(1) These levels are intended to contribute to the observance of the maximum permitted levels for foodstuffs; they do not alone guarantee such obser-vance in all circumstances and do not lessen the requirement for monitoring contamination levels in animal products destined for human consumption.

(2) These levels apply to feedingstuffs as ready for consumption

TABLE 5.5.MAXIMUM LEVELS OF RADIOACTIVE CONTAMINANTS FOR FEEDINGSTUFFS (2) **(Bq/kg)**

	Feedingstuffs
Sum of Cs-134 and Cs-137	500 (1)
Sum of Isotopes of iodine, notably I-131	2 000 (2)

(1) In order to ensure consistency with action levels currently applied in Japan, this value replaces on a provisional basis the value laid down in Commission Regulation (Euratom) No 770/90. (2) This value is laid down on a provisional basis and taken to be the same as for foodstuffs, pending an assessment of transfer factors of iodine from feedingstuffs to food products.

TABLE 5.6.- COMMUNITY REGULATIONS ESTABLISHING MAXIMUM LEVELS OF CONTAMINANTS IN SELECTED FOOD CATEGORIES

Framework Regulation

Council Regulation 315/93/EEC of 8 February 1993, which lays down Community procedures for contaminants in food

Regulations establishing maximun contaminant levels in specific food categories

COMMISSION REGULATION (EC) No 565/2008 of 18 June 2008

COMMISSION REGULATION (EC) No 629/2008 of 2 July 2008

COMMISSION REGULATION (EU) No 105/2010 of 5 February 2010

COMMISSION REGULATION (EU) No 165/2010 of 26 February 2010

COMMISSION REGULATION (EU) No 420/2011 of 29 April 2011

COMMISSION REGULATION (EU) No 835/2011 of 19 August 2011

COMMISSION REGULATION (EU) No 1258/2011 of 2 December 2011

COMMISSION REGULATION (EU) No 1259/2011 of 2 December 2011

COMMISSION REGULATION (EU) No 219/2012 of 14 March 2012

COMMISSION REGULATION (EU) No 594/2012 of 5 July 2012

COMMISSION REGULATION (EU) No 1058/2012 of 12 November 2012

COMMISSION REGULATION (EU) No 1067/2013 of 30 October 2013

COMMISSION REGULATION (EU) No 212/2014 of 6 March 2014

COMMISSION REGULATION (EU) No 362/2014 of 9 April 2014

COMMISSION REGULATION (EU) No 488/2014 of 12 May 2014

COMMISSION REGULATION (EU) No 696/2014 of 24 June 2014

TABLE 5.7- .- COMMUNITY REGULATIONS ESTABLISHING MAXIMUM LEVELS OF UNDESIRABLE SUBSTANCES IN ANIMAL FEED

Framework Regulation

Directive 2002/32/CE of the European Parliament and of the Council of the 7 May 2002 dealing with undesirable substances in animal feed

Regulations establishing maximun levels of undesirable substances in specific feed categories

COMMISSION DIRECTIVE 2003/57/EC Text with EEA relevance of 17 June 2003

COMMISSION DIRECTIVE 2003/100/EC Text with EEA relevance of 31 October 2003

COMMISSION DIRECTIVE 2005/8/EC Text with EEA relevance of 27 January 2005

COMMISSION DIRECTIVE 2005/86/EC Text with EEA relevance of 5 December 2005

COMMISSION DIRECTIVE 2005/87/EC Text with EEA relevance of 5 December 2005

COMMISSION DIRECTIVE 2006/13/EC Text with EEA relevance of 3 February 2006

COMMISSION DIRECTIVE 2006/77/EC Text with EEA relevance of 29 September 2006

COMMISSION DIRECTIVE 2008/76/EC Text with EEA relevance of 25 July 2008

COMMISSION DIRECTIVE 2009/8/EC Text with EEA relevance of 10 February 2009

REGULATION (EC) No 219/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 March 2009

COMMISSION DIRECTIVE 2009/124/EC Text with EEA relevance of 25 September 2009

COMMISSION DIRECTIVE 2009/141/EC Text with EEA relevance of 23 November 2009

COMMISSION DIRECTIVE 2010/6/EU Text with EEA relevance of 9 February 2010

COMMISSION REGULATION (EU) No 574/2011 of 16 June 2011

COMMISSION REGULATION (EU) No 277/2012 of 28 March 2012

COMMISSION REGULATION (EU) No 744/2012 of 16 August 2012

COMMISSION REGULATION (EU) No 107/2013 of 5 February 2013

COMMISSION REGULATION (EU) No 1275/2013 of 6 December 2013

TABLE 5. 8 -CHARACTERISATION OF METHODS OF ANALYSIS

1. Methods of analysis should be characterised by the following criteria:

(a) accuracy; (b) applicability (matrix and concentration range); (c) limit of detection;

(d) limit of determination; (e) precision; (f) repeatability; (g) reproducibility; (h) reco-very; (i) selectivity; (j) sensitivity; (k) linearity; (l) measurement uncertainty; (m) other criteria that may be selected as required.

2. The precision values referred to in 1(e) shall either be obtained from a collabora-tive trial which has been conducted in accordance with an internationally recognised protocol on collaborative trials (e.g. ISO 5725:1994 or the IUPAC International Harmonised Protocol) or, where performance criteria for analytical methods have been established, be based on criteria compliance tests. The repeatability and repro-ducibility values shall be expressed in an internationally recognised form (e.g. the 95 % confidence intervals as defined by ISO 5725:1994 or IUPAC). The results from the collaborative trial shall be published or freely available.

3. Methods of analysis which are applicable uniformly to various groups of commodities should be given preference over methods which apply only to individual commodities.

4. In situations where methods of analysis can only be validated within a single laboratory then they should be validated in accordance with e.g. IUPAC Harmonised Guidelines, or where performance criteria for analytical methods have been established, be based on criteria compliance tests.

5. Methods of analysis adopted under Regulation EC 882/2002 should be edited in the standard layout for methods of analysis recommended by the ISO.

Source : Annex III, Reg. ECC 882/2004

TABLE 5.9 METHODS OF SAMPLING AND ANALYSIS FOR THE OFFICIAL CONTROL OF CONTAMINANTS IN FOOD

COMMISSION REGULATION (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs ;

COMMISSION REGULATION (EC) NO. 1882/2006, lays down methods of sampling and analysis for the official control of levels of nitrate in certain foodstuffs. The Regulation replaces Commission Directive 2002/63/EC

COMMISSION REGULATION (EC) NO. 1883/2006, lays down methods of sampling and analysis for the official control of levels of dioxins and dioxin-like PCBs. The Regulation replaces and revokes Commission Directive 202/69/EC, as amended.

COMMISSION REGULATION (EC) NO. 401/2006 lays down methods of sampling and analysis for the official control of levels of aflatoxins, ochratoxin A, patulin and Fusarium toxins in foodstuffs. The Regulation replaces and revokes Commission Directives 98/53/EC, 2002/26/EC, 2003/78/EC and 2005/38/EC.

COMMISSION REGULATION (EC) NO. 333/2007, lays down methods of sampling and analysis for the official control of levels of lead, cadmium, mercury, inorganic tin, 3- MCPD and benzo(a)pyrene in certain foodstuffs. The Regulation replaces and revokes Commission Directive 2001/22/EC, Commission Directive 2004/16/EC and Commission Directive

2005/10/EC. To ensure that the samples are representative for the sampled lot, Member States should follow the sampling procedures laid down in part B of the Annex to this Regulation.

COMMISSION REGULATION (EU) No 178/2010 of 2 March 2010 amending Regulation (EC) No 401/2006 as regards groundnuts (peanuts), other oilseeds, tree nuts, apricot kernels, liquorice and vegetable oil

COMMISSION REGULATION (EU) No 836/2011 of 19 August 2011 amending Regulation (EC) No 333/2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs as rectified

COMMISSION REGULATION (EU) No 252/2012 of 21 March 2012 laying down methods of sampling and analysis for the official control of levels of dioxins, dioxin- like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EC) No 1883/2006

TABLE 5.10 METHODS OF SAMPLING AND ANALYSIS FOR THE OFFICIAL CONTROL OF CONTAMINANTS IN FEED

- **DIRECTIVES 2000/77/CE AND 2001/46/CE** on the organization of official controls in the sector of anoimal nutrition
- **COMMISSION RECOMMENDATION of 4 October 2004** on technical guidance for sampling and detection of genetically modified organisms and material produced from

genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003

- **RECOMMENDATION (CE) 91/2003** of 10 February 2003, on the coordinated inspection program in the sector of animal nutrition for the year 2003, in compliance with the Council Directive 95/53/CE
- **RECOMMENDATION (CE) 925/2005** of 14 December 2005 on the coordinated control program in the sector of animal nutrition for the year 2006 in compliance with the Council Directive 95/53/CE
- **COMMISSION REGULATION (EC) No 152/2009 of 27 January 2009** laying down the methods of sampling and analysis for the official control of feed and Guidance Document for Feed Sampling
- **COMMISSION REGULATION (EU) No 619/2011 of 24 June 2011** laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorisation procedure is pending or the authorisation of which has expired.

_____.

TABLE 5 .11 -COMMUNITY REFERENCE LABORATORIES

- Community reference laboratory for milk and milk products -Afssa-Lerhqa F-94700 Maisons- Alfort
- Community reference laboratories for the analysis and testing of zoonoses (salmonella) - Rijksinstituut voor Volksgezondheid en Milieu (RIVM) 3720 BA Bilthoven The Netherlands
- Community reference laboratory for the monitoring of marine biotoxins-Ministerio de Sanidad y Consumo Vigo Spain
- Community reference laboratory for monitoring the viral and bacteriological contamination of bivalve molluscs -The laboratory of the Centre for Environment, Fisheries and Aquaculture Science, Weymouth, United Kingdom.
- Community reference laboratories for residues (a) For the residues listed in Annex I, Group A 1, 2, 3, 4, Group B 2 (d) and Group B 3 (d) to Council Directive 96/23/EC- Rijksinstituut voor Volksgezondheid en Milieu (RIVM) 3720 BA Bithoven The Netherlands (b) For the residues listed in Annex I, Group B 1 and B 3 (e) to Council Directive 96/23/EC and carbadox and olaquidonx- Laboratoires d'études et de recherches sur les médicaments vétérinaires et les désinfectants .AFSSA - Site de Fougères BP 90203.France. (c) For the residues listed in Annex I, Group A 5 and Group B 2 (a), (b), (e) to Council Directive 96/23/EC- Bundesamt für Verbraucherschutz und Lebensmit-telsicherheit (BVL) Postfach 140162. D-53056 Bonn . (d) For the residues listed in Annex I, Group B 2 (c) and Group B 3 (a), (b), (c) to Council Directive 96/23/EC. Instituto Superiore di Sanità -00161 -Roma

- Community reference laboratory for transmissible spongiform encephalopathies (TSEs) The laboratory referred to in Annex X, Chapter B of Regulation (EC) No 999/2001Community reference laboratory for additives for use in animal nutrition The laboratory referred to in Annex II of Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition.
- Community reference laboratory for genetically modified organisms (GMOs) The laboratory referred to in the Annex to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (2).
- Community reference laboratory for material intended to come into contact with foodstuffs. The Joint Research Centre of the Commission

Souurce: Annex III, Reg.882/2004

TABLE 5.12. RECOMMENDATIONS OF THE EUROPEAN COMMISSION CONCERNING THE MONITORING OF DIFFERENT CONTAMINANTS IN SELECTED FOOD PRODUCTS

- COMMISSION RECOMMENDATION 2012/154/UE of 15 March 2012 on the monitoring of the presence of ergot alkaloids in feed and food
- COMMISSION RECOMMENDATION 2011/516 of 23 August 2011 on the reduction of the presence of dioxins, furans and PCBs in feed and food
- COMMISSION RECOMMENDATION 2013/647/EU of 2 June 2010 on investigations into the levels of acrylamide in food
- COMMISSION RECOMMENDATION 2010/161 of 17 March 2010 on the monitoring of perfluoroalkylated substances in food
- COMMISSION RECOMMENDATION 2007/331 of 3 May 2007 on the monitoring of acrylamide levels in food
- COMMISSION RECOMMENDATION 2007/196 of 28 March 2007 on the monitoring of the presence of furan in foodstuffs
- COMMISSION RECOMMENDATION 2006/794 of 16 November 2006 on the monitoring of background levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in foodstuffs

- COMMISSION RECOMMENDATION 2005/108 of 4 February 2005 on the further investigation into the levels of polycyclic aromatic hydrocarbons in certain foods

---

TABLE 5.13 ACTION LEVELS FOR DIOXINS AND FURANS AND FOR DIOXIN-LIKE PCBS IN FOOD

—

Dioxins (sum of polychlorinated dibenzo-para-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs), expressed as World Health Organisation (WHO) toxic equivalent using the WHO-toxic equivalency factors (WHO-TEFs)) and dioxin- like polychlorinated biphenyls (PCBs), expressed as WHO toxic equivalent using the WHO-TEFs. WHO-TEFs for human risk assessment based on the conclusions of the World Health Organisation (WHO) – International Programme on Chemical Safety (IPCS) expert meeting which was held in Geneva in June 2005 (Martin van den Berg et al., The 2005 World Health Organisation Re-evaluation of Human and Mammalian Toxic Equivalency Factors for Dioxins and Dioxin-like Compounds. Toxicological Sciences 93(2), 223–241 (2006)) Food

Food	**Action level for dioxins + furans (WHO-TEQ) (1)**	**Action level for dioxin-like PCBS (WHO-TEQ) (1)**
Meat and meat products (excluding edible offal) (2) of the following animals: — bovine animals and sheep,	1,75 pg/g fat (3) 1,25 pg/g fat (3)	1,75 pg/g fat (3) 0,75 pg/g fat (3)

— poultry, — pigs. Mixed fats	0,75 pg/g fat (3) 1,00 pg/g fat (3)	0,5 pg/g fat (3) 0,75 pg/g fat (3)
Muscle meat of farmed fish and farmed fishery products	1,5 pg/g wet weight	2,5 pg/g wet weight
Raw milk (2) and dairy products (2), including butter fat	1,75 pg/g fat (3)	2,0 pg/g fat (3)

(1) Upperbound concentrations: upperbound concentrations are calculated assuming that all the values of the different congeners less than the limit of quantification are equal to the limit of quantification. (2) Foodstuffs listed in this category as defined in Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55). (3) The action levels are not applicable for food products containing < 2 % fat.

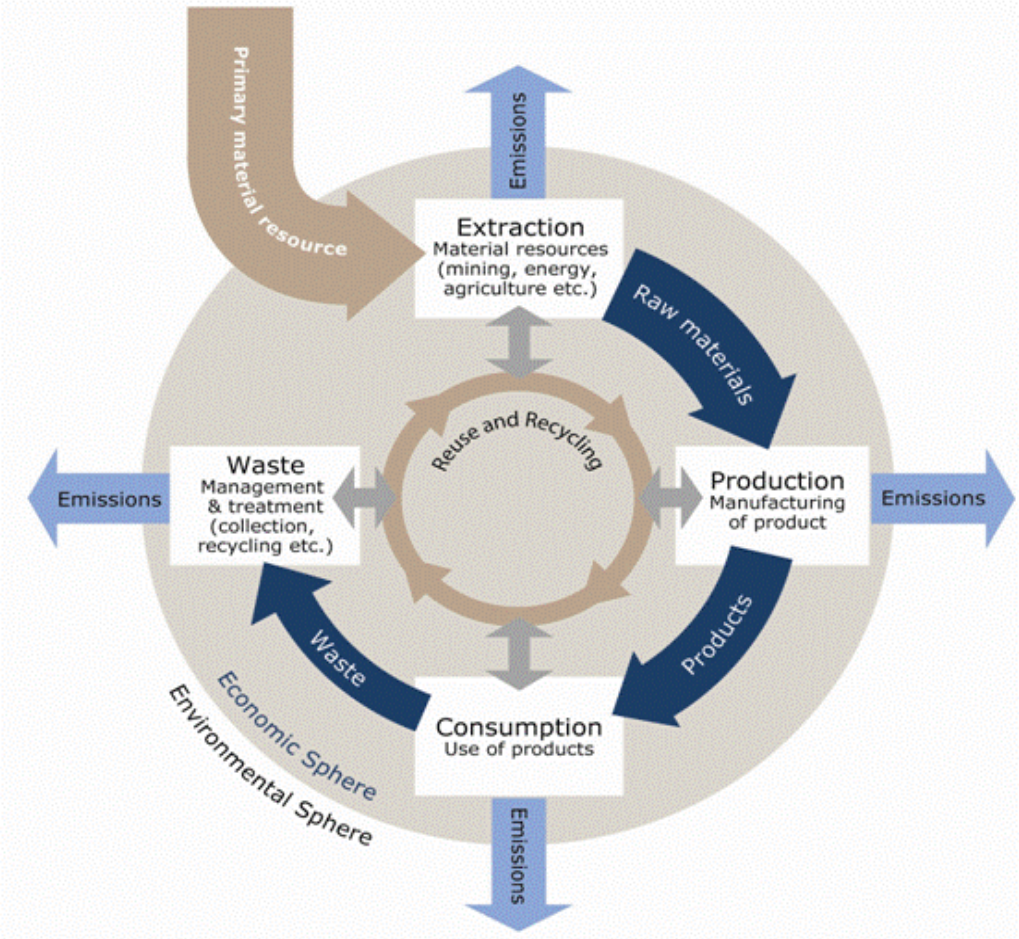


Figure 1-Life cycle of chemical products (Source: European Environment Agency)

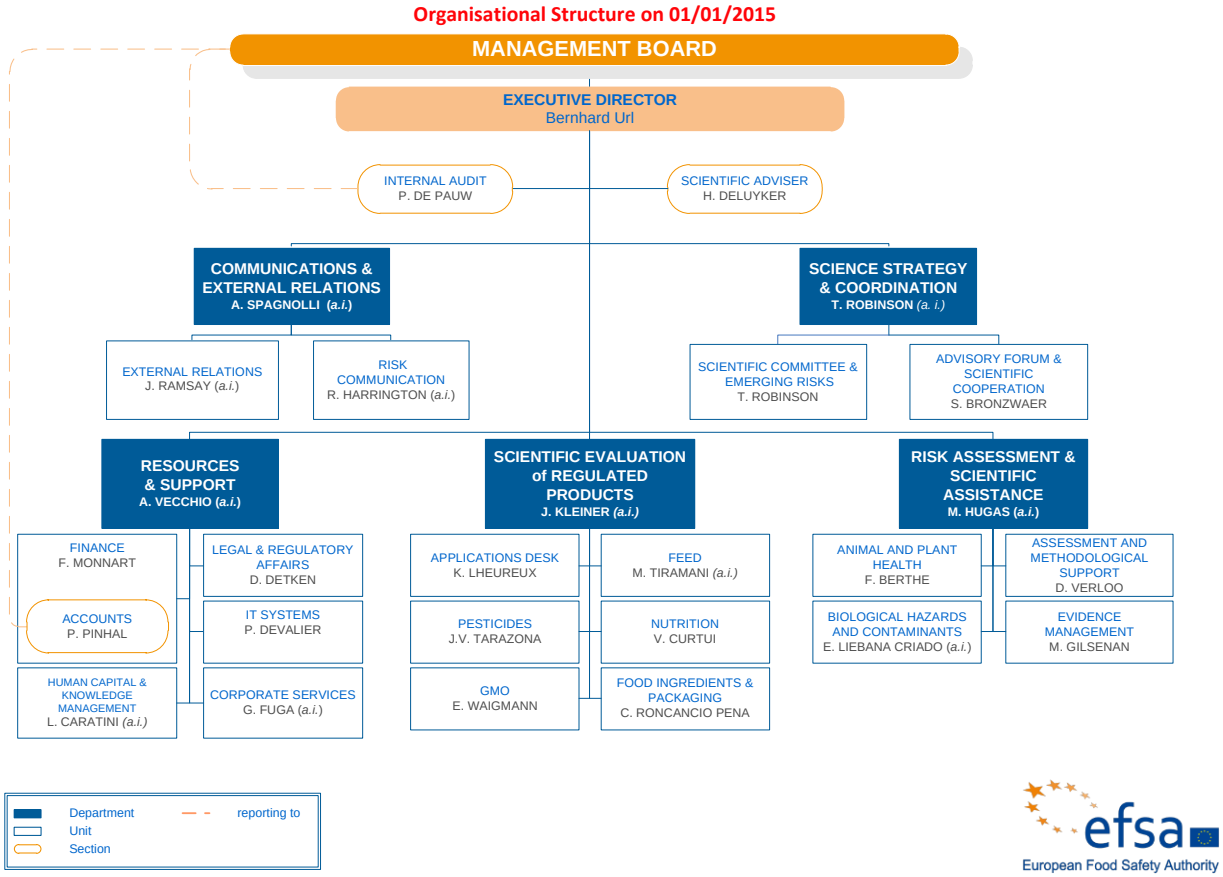
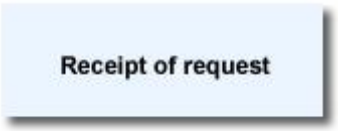


Figure 2-EFSA organization (from EFSA website)

Figure 3. Workflow of EFSA's scientific opinions (from EFSA website)

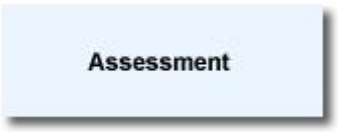
Receipt of request

EFSA's advice informs the policies of risk managers - so EFSA carries out much of its work in response to requests from the European Commission, European Parliament and EU Member States, as well as initiating its own scientific activities.



Assessment

EFSA's main task is to carry out scientific risk assessments. The evaluation stage is the main part of the risk assessment workflow. It is carried out by scientific experts tasked to deliver opinions on specific issues.



Adoption and Communication

Risk communication is part of EFSA's mandate. EFSA makes all of its scientific advice publicly available through its website and seeks to raise awareness and explain its findings to all interested parties.