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Food Safety**

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DIRECTORATE GENERAL FOR INTERNAL POLICIES
POLICY DEPARTMENT A: ECONOMIC AND SCIENTIFIC POLICIES
ENVIRONMENT, PUBLIC HEALTH AND FOOD SAFETY

Welcome Package on Food Safety

Abstract

In June 2009 a new European Parliament has been elected for a five year term, which will run from 2009 to 2014. This study, commissioned by the European Parliament, is part of a 'Welcome Package' for newly elected MEPs in the Environment, Public Health and Food Safety Committee.

This Welcome Package proposes a road map for Food Safety legislation in this mandate of the European Parliament (2009-2014). Past legislation is outlined, with a description of legislation currently in the approval process.

In addition, the report identifies challenges and priorities for the forthcoming legislation. It also indicates some policy areas in the context of the implementation process in certain Member States.

Moreover, a number of maps with upcoming legislative deadlines are set out in chapter 5. The final chapter outlines the main studies and publications related to the Food Safety topics discussed in the European Parliament during the previous mandate 2004-2009.

This document was requested by the European Parliament's Committee on Environment, Public Health and Food Safety.

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List of abbreviations

ALARA	As Low As Reasonably Achievable
BSE	Bovine spongiform encephalopathies
EC	European Community
EFSA	European Food Safety Authority
ENMs	engineered nanomaterials
ENVI	The European Parliament's Environment, Public Health and Food Safety Committee
EP	European Parliament
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FIAP	Food Improvement Agents package
FVO	Food and Veterinary Office
GFL	General Food Law
GM	Genetically-Modified
GMO	Genetically-Modified-Organism
HACCP	Hazard Analysis and Critical Control Points
MEP	Member of the European Parliament
MS	Member States
PCBs	Polychlorinated Biphenyls
RASFF	Rapid Alert System for Food and Feed
SSC	Scientific Steering Committee
TRACES	Trade Control and Expert System
TSE	Transmissible spongiform encephalopathies
VCM	Vinyl Chloride Monomer
WHO	World Health Organization

1. INTRODUCTION

European Food Safety policy aims are two-fold: on the one hand to protect human health and consumers' interests and on the other hand to foster smooth operation of the EU single market. As a result, the European Union ensures that control standards are established (and adhered to) in the areas of feed and food product hygiene, animal health and welfare, plant health and prevention of food contamination from external substances. The EU also regulates labelling for these foodstuffs and food and feed products.

1.1 Legal basis

Most of the EU food safety legislation is based on Treaties Art. 37, Art.95 and Art. 152(4):

- Art. 37 sets procedures for the development of a common agricultural policy;
- Art. 95 defines the procedure for adopting approximation measures for provisions laid down by law, Regulation or administrative action in Member States whose object is the establishment and functioning of the internal market;
- Art. 152 states that: "Community action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health". The fourth point of the same article mandates the Council's role: to adopt measures in the veterinary and phytosanitary fields with the goal of protecting public health.

In addition, [Art. 153](#) of the Treaty states that: "In order to promote the interests of consumers and to ensure a high level of consumer protection, the Community shall contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their right to information, education and to organise themselves in order to safeguard their interests.

The Community will take into account consumer protection requirements in defining and implementing other Community policies and activities. The Community shall contribute to the attainment of the objectives of a high consumer protection through:

- measures adopted in the context of the completion of the internal market;
- measures which support, supplement and monitor the policy pursued by the Member States".

1.2 Principle and objectives

In the wake of a series of human food and animal feed crises (i.e. BSE, dioxins), food safety policy underwent deep reform in the early 2000s, under the 'Farm to Fork' approach, thereby guaranteeing a high level of safety for foodstuffs and food products marketed within the EU, at all stages of the production and distribution chains, for food products produced within the European Union and those imported from third countries.

Political input was launched at the Helsinki European Council of December 1999. The European Commission White Paper on Food Safety ([COM \(1999\)719](#)) proposed a number of measures designed to organise food safety in a more coordinated and integrated manner covering all sectors of the food chain, including feed production, primary production, food processing, storage, transport and retail sale.

The principles advanced by the Commission's White Paper have shaped the body of food laws enacted and currently being developed:

- Coverage of the entire food chain, including the manufacture of animal feedstuffs;
- Primary responsibility for food safety attributed to producers, industry and suppliers of raw materials;
- Traceability of products along the food chain;

- Food safety policy to be confirmed by scientific opinions and, when appropriate, by the precautionary principle.

The core objectives of the European Union's food safety policy are to ensure a high level of protection of human health and consumers' interests taking into account diversity, including traditional products, while encouraging the efficient functioning of the EU internal market.

Legislative and non legislative actions are contributing to the implementation of these objectives, specifically:

- ⇒ Establish effective control systems and evaluate compliance with EU standards in the food safety and quality sectors within the EU and in third countries in relation to their exports to the EU;
- ⇒ Manage international relations with third countries and international organisations concerning food safety;
- ⇒ Apply safeguarding actions quickly and efficiently in order to respond quickly to health emergencies that can appear anywhere in the food chain;
- ⇒ Manage relations with the European Food Safety Authority (EFSA) and employ science-based risk management.

The General Principles of Food Law (Articles 5 to 10) entered into force on 21 February 2002 established by Framework Regulation (EC) No [178/2002](#), known as the "**General Food Law (GFL)**". This Regulation lays down the general principles and requirements of food law, establishing the [European Food Safety Authority \(EFSA\)](#) and lays down procedures in matters of food safety. The Regulation takes into account the "**precautionary principle**" and sets out general provisions for imposing **traceability of food and feed**. Furthermore, the Regulation establishes the Rapid Alert System for Food and Feed (RASFF)², expands the existing notification system to include feed.

² Article 50 of EC Regulation 178/2002 establishes the rapid alert system for food and feed as a network involving the Member States, the Commission as the manager of the system and the European Food Safety Authority (EFSA). EEA countries, Norway, Liechtenstein and Iceland, are also longstanding members of the RASFF.

The RASFF was put in place to provide food and feed control authorities with an effective tool to exchange information about measures taken responding to serious risks detected related to food or feed. This exchange of information helps Member States to act more rapidly and in a coordinated manner in response to a health threat caused by food or feed. Its effectiveness is ensured by its simple structure: it consists essentially of clearly identified contact points in the Commission and at national level in member countries, exchanging information in a clear and structured way by means of templates.

Whenever a member of the network has any information relating to the existence of a serious direct or indirect risk to human health deriving from food or feed, this information is immediately notified to the Commission under the RASFF. The Commission immediately transmits this information to the members of the network.

Without prejudice to other Community legislation, the Member States shall immediately notify the Commission under the rapid alert system of:

- any measure they adopt which is aimed at restricting the placing on the market or forcing the withdrawal from the market or the recall of food or feed in order to protect human health and requiring rapid action;
- any recommendation or agreement with professional operators which is aimed, on a voluntary or obligatory basis, at preventing, limiting or imposing specific conditions on the placing on the market or the eventual use of food or feed on account of a serious risk to human health requiring rapid action;
- any rejection, related to a direct or indirect risk to human health, of a batch, container or cargo of food or feed by a competent authority at a border post within the European Union.

RASFF annual Report provides information on the functioning of the RASFF and, in particular, on the number of notifications, the origin of the notifications, the countries involved, the products and the identified risks.

According to RASFF Report 2007, the number of notifications transmitted through the RASFF rose from 823 in 2000, to 7354 in 2007. The main reason for this upward trend lies with an increased number of additional information notifications following up on the original notifications sent. In 2007 961 alerts and 2015 information notifications were received, giving rise to 4339 additional information notifications.

It also provides the control authorities with an effective information exchange tool about the measures taken to ensure food safety.

Framework Regulation EC 178/2002 was further supported by these related acts:

- Commission Decision [2004/478/EC](#) establishing a general plan for food and feed crisis management. This Decision provides for the adoption of a general crisis-management plan that will be activated whenever a critical situation arises or where there may be a potentially serious risk;
- Commission Communication [COM\(2006\)519](#) on "Better training for safer food" assesses various options for organising staff training of national authorities responsible for verifying the implementation of Community legislation on food safety.

1.3 Institutional Bodies involved in Food policies

Directorate General for 'Health and Consumers' (DG SANCO) of the European Commission

The European Commission's Directorate General for 'Health and Consumers' (DG SANCO) is responsible for the safety of food and other products, consumers' rights and the protection of people's health. National, regional and local governments in EU countries are ultimately responsible for the application of the EU's health and consumer protection laws. The Commission is responsible for ensuring that Community legislation is properly implemented and enforced throughout the EU.

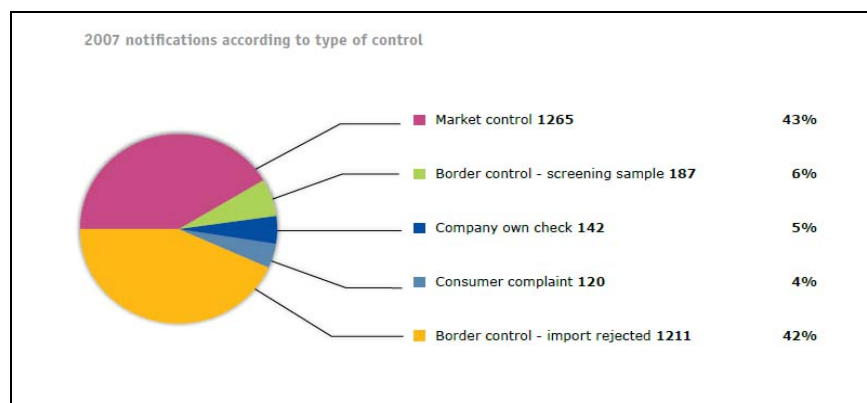
The Commission defines its annual priorities and adopts a work programme each year. This programme translates the [annual policy strategy](#) into policy objectives and an operational programme of decisions to be adopted by the Commission. It sets out major political priorities and identifies legislative initiatives, executive and other acts that the Commission intends to adopt in order to reach these goals.

European Food Safety Authority (EFSA)

The European Food Safety Authority ([EFSA](#)) is an independent European agency funded by the EU that operates separately from the European Commission, European Parliament and EU Member States. It is based in Parma (Italy). EFSA provides scientific advice as well as scientific and technical support in all areas that affect food safety.

Most notifications in 2007 concerned official controls on the internal market (43%), while 42% concerned products from non-EU countries which were blocked at the border by EU control authorities when the risks were identified. As in 2006, fish products (21%) was the product category for which the most alerts were sent.

Figure 1: RASFF notification to type of control



It constitutes an independent source of information on all matters in this field and provides a constant flow of information to the general public.

In the European food safety system, risk assessment is carried out 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 remit covers food and feed safety, nutrition, animal health and welfare, plant protection and plant health. In all these fields, EFSA most critical commitment is to provide objective and independent science-based advice and clear communication grounded in the most up-to-date scientific information and knowledge.

In 2003, Commission Regulation (EC) No 1304/2003 laid down the procedure EFSA applies when answering requests for scientific opinions. The Authority issues scientific opinions, pursuant to EU legislation, when requested to do so by the Commission, the European Parliament or a Member State, and it may also issue own-initiative opinions. It keeps a register of all requested opinions and own-initiative opinions.

Food and Veterinary Office (FVO)

The FVO is part of the Directorate-General for Health and Consumer Protection and it is based in Grange, Co. Meath, Ireland. It works to establish effective control systems and to evaluate compliance with EU standards within the EU, and in third countries for their exports to the EU. Principally, The FVO carries out inspections in Member States and in third countries exporting to the EU. Each year the FVO develops an inspection programme, identifying priority areas and countries for inspection.

The FVO makes recommendations to the countries' competent authorities to deal with any shortcomings revealed during inspections. The competent authority then presents an action plan to the FVO on how it intends to address any shortcomings.

1.4 Role of the European Parliament

The European Parliament plays a prominent role in European food safety policy. Since 1979 a series of European treaties have increased the powers of the European Parliament. Codecision is the main legislative procedure applying to matters related to food safety. It is based on the principle of parity between the European Parliament and the Council. The two institutions, acting on a proposal from the European Commission, adopt legislation jointly, having equal rights and obligations³.

An important tool for the implementation of food safety legislation is so-called Comitology-decisions⁴ to be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999. Since 2006, additional comitology decision making powers have been attributed to European Parliament through the regulatory procedure with scrutiny.

³ For a more detailed description see: http://www.consilium.europa.eu/uedocs/cmsUpload/code_EN.pdf

⁴ In accordance with Article 202 of the Treaty establishing the European Community (ECT), it is the task of the Commission to implement legislation at Community level. In practice, each legislative instrument specifies the scope of the implementing powers conferred on the Commission by the Council of the European Union. In this context, the Treaty provides for the Commission to be assisted by a committee, in line with the procedure known as "comitology". The committees are forums for discussion, consist of representatives from Member States and are chaired by the Commission. They enable the Commission to establish dialogue with national administrations before adopting implementing measures. The Commission ensures that measures reflect as far as possible the situation in each of the countries concerned.

Relations between the Commission and the committees are based on models set out in a Council Decision (the "Comitology Decision"), which gives Parliament the right to monitor the implementation of legislative instruments adopted under the codecision procedure. Parliament can object to measures proposed by the Commission or, as the case may be, the Council if it considers them to be ultra vires.

Own initiative (INI) reports are another way for the European Parliament to make its political views known to the Commission, the Council and to the public at large but are not part of a legislative process.

Oral and written Questions to the Commission and the Council are also a tool for the Parliament to get more information on specific subjects of interest from the other two Institutions.

In 1996, a temporary committee of inquiry had been set up to investigate alleged shortcomings in the implementation of Community law in relation to BSE. Likewise, on 16 January 2002, the European Parliament had established a Temporary Committee⁵ on Foot and Mouth disease which presented its findings to Parliament after one year.

⁵ Rule 175 of EP Rules of Procedures establishes that *"On a proposal from the Conference of Presidents, Parliament may at any time set up temporary committees, whose powers, composition and term of office shall be defined at the same time as the decision to set them up is taken; their term of office may not exceed twelve months, except where Parliament extends that term on its expiry. As the powers, composition and term of office of temporary committees are decided at the same time as these committees are set up, Parliament cannot subsequently decide to alter their powers either by increasing or reducing them"*.

2. THEMATIC POLICY REVIEW 2004-2009

This chapter provides an overview of the main Food Safety laws in the following areas: food hygiene and veterinary controls, food contaminants, food labelling, food additives and food flavourings, animal health, animal nutrition, animal welfare, novel foods, genetically modified organisms and nanotechnology applied to food.

The basic pieces of food safety legislation were approved during the previous legislation and in the past five years the European Parliament has been working to complete the system, addressing some very significant current issues that impact the public opinion and affect strong economic interests (i.e. nano food, animal health, labelling) and harmonizing and simplifying the EU legal system.

For each sector the relative regulations and developments in progress (i.e. Commission proposals, current legislative procedures) are illustrated with particular reference to the role of the European Parliament.

2.1 Hygiene of foodstuffs

In April 2004, within the 'Farm to Fork' approach, based on risk analysis and traceability, a new hygiene legislative framework was adopted to repeal Council Directive 93/43/EEC⁶ and to complement Council Directive 2002/99/EC⁷.

The key point in this newly introduced legislative framework is the placing of responsibility directly with the various players in the food chain. Food producers will bear responsibility for the safety of foods through a self-regulating system using the HACCP method - "Hazard Analysis and Critical Control Points".

The hygiene legislative framework, known as "hygiene package", is composed of the following acts:

- Regulation EC [852/2004](#) which seeks to ensure foodstuff hygiene at all stages of production, from primary production up to and including sale to the final customer. It does not cover issues relating to nutrition, composition or quality of foodstuffs.
- Regulation EC [853/2004](#) which lays down specific hygiene rules for food of animal origin. The provisions of this regulation apply to processed and unprocessed products of animal origin but not to foods consisting partly of products of plant origin.
- Regulation EC [854/2004](#) which activates a Community framework for official inspections on products of animal origin intended for human consumption and lays down specific laws for each section (fresh meats, bivalve molluscs, fishery products, milk and dairy products). The official checks include audits of good hygiene practice and on HACCP principles, as well as specific checks determined by the sector.

Further rules have been added on to this "legislative scaffolding" modifying and integrating the text of the various regulations, plus a series of norms contained in subsequent regulations and directives which broaden its scope of action.

The first example in chronological order to be added to the "hygiene package" is Regulation EC [882/2004](#) on official checks designed to verify compliance of feed and foods, the health and well-being on animals. This regulation sets a Community framework of national control systems which have improved and standardised the quality of controls at European Union level.

⁶ This Directive lays down the general rules of hygiene for foodstuffs and the procedures for verification of compliance with these rules.

⁷ This directive establishes norms to safeguard health regarding production, food processing, distribution and the circulation of products of animal origin for human consumption.

The regulation seeks to ensure the correctness of practices relating to trade in foods and feedstuffs and the safeguarding of consumer interests, including issues such as food and feed labeling and any other form of information aimed at consumers.

In 2004 EU Commission Regulation EC [599/2004](#) was adopted with the aim of harmonizing a model certificate and inspection report linked to intra-community trade in animals and products of animal origin.

In 2006 two Commission Decisions⁸ were taken which aim to improve the application of the rules in the hygiene package as regards trade with Third Countries in animals and products of animal origin for human consumption. These decisions establish a list of Third Countries from which it is possible to import the above-mentioned products and defines the applicable veterinary certification conditions.

In March 2007 the Commission presented a proposal for a regulation COM(2007)90⁹ amending Regulation EC 852/2004 with the aim of exempting small food businesses, which can control food hygiene by simply implementing the other requirements of regulation EC 852/2004, from the requirement to put into place, implement and maintain a permanent procedure or procedures based on the hazard analysis and critical control points HACCP principles. This exemption applies to micro-enterprises¹⁰ that are predominantly selling food directly to the final consumers. This proposal falls within the [“Action Programme for reducing administrative burdens in the European Union”](#)¹¹.

Veterinary Checks

Rules relating to veterinary checks merit a separate section due to the complementarity with the hygiene package. In December 2002 a Commission Decision 2003/24/EC was issued concerning the creation of an integrated computerised veterinary system. This decision foresaw the setting up of TRACES, the single electronic database designed to complete the functions of the previous system and integrate it in one structure.

On 19 August 2003 Commission Decision 2003/623/CE was taken which launched the creation of an integrated veterinary information system named TRACES (TRAde Control and Expert System). TRACES includes a single electronic database to control the movement of animals and some products of animal origin within the European Union and third Countries, as well as providing all the reference data relating to trade in such goods. In order to facilitate trade in animal products while ensuring a high level of food safety, the European Union has abolished veterinary checks at internal frontiers, reinforcing checks at the point of origin and arranging for checks on arrival at destination points.

Several subsequent acts¹² have established additional rules.

⁸ Commission Decision [2006/696/EC](#) of 28 August 2006 laid down a list of Non-EU Member Countries from which poultry, hatching eggs, day-old chicks, poultry meat, ratites and wild game-birds, eggs and egg products and specified pathogen-free eggs may be imported into and transit through the Community and the applicable veterinary certification conditions;

Commission Decision [2006/766/EC](#) of 6 November 2006 established the lists of Non-EU Member Countries and territories from which imports of bivalve molluscs, echinoderms, tunicates, marine gastropods and fishery products are permitted;

⁹ [COD/2007/0037B](#)

¹⁰ Companies with less than 10 employees and an annual turnover of under 2 million Euros.

¹¹ Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions - Action Programme for Reducing Administrative Burdens in the European Union COM(2007) 23

¹² Commission Regulation (EC) No 136/2004 of 22 January 2004 laying down procedures for veterinary checks at Community border inspection posts on products imported from third countries

Commission Regulation (EC) No 282/2004 of 18 February 2004 introducing a document for the declaration of, and veterinary checks on, animals from third countries entering the Community

Commission Decision of 30 March 2004 on the introduction of the TRACES system and amending Decision 92/486/EEC

An emblematic case: Chlorinated poultry

We can see an emblematic example of the application of food hygiene procedures in the so-called “Chlorinated chicken” case. In May 2008, the Commission issued proposal [COM\(2008\)0336](#) to the Committee for food and animal health. The proposal modified the definition of poultry meat in order to authorise the sale for human consumption of poultry that has undergone antimicrobial treatment with chlorine. The proposal came in the wake of the United States’ request for authorisation to export its production of poultry treated with antimicrobial or chemical substances to the European Union.

On June 19th 2008, the European Parliament approved a [Resolution](#) that denies approval to the Commission’s proposal in consideration, among other things, that the permission of antimicrobial treatment limited to importation, or even the use within the European Union would mean applying contrasting sets of Regulations to internal and external producers, when the first group has already been forced to make significant investments in order to meet the Regulations in a total food chain approach rather than the less expensive process-end procedure applied by the United States to their poultry production.

The role of the European Parliament

In the last mandate (2004-2009) the European Parliament dealt with Commission Regulation proposal on the exemption of small food businesses from the duty to implement a HACCP self-regulatory system.

In the context of the codecision procedure, during the first reading, the Parliament expressed its opinion on the following main points:

- It is important to draw the attention of Member States’ competent authorities to implement effectively the flexibility allowed by the Regulation proposal in particular in relation to smaller business.
- The exemption from the obligation to implement a self-regulatory system should in any case be dependant on a risk analysis carried out by competent authorities to evaluate whether an adequate safety level is guaranteed by the respect of general hygiene requirements.

2.2 Food Contamination

The European Union takes care to prevent and limit any contamination of foodstuffs from substances present in the environment or which can occur as a result of human activities.

Therefore the EU regulates maximum levels, safety evaluations, and the authorisation procedures for certain chemical substances, such as those used in farming, (pesticides/plant protection products, fertilizers, veterinary medicines, hormones, etc.) or in the production of certain food products. Furthermore some provisions set the maximum level of substances of biological origin such as mycotoxins. Contamination risks from food packaging materials are also monitored.

The existing regulatory framework ensures that foods placed on the market are safe and do not contain amounts of contaminants that pose a risk to health. The matter is regulated at European community level by **Council Regulation EEC [315/93](#)** of 8 February 1993. In fact according to this regulation no foodstuffs containing unacceptable quantities of contaminant substances may be marketed. The European Union considers that contaminants must be kept at the lowest level that can be reasonably achieved through the good farming and production practices and these levels are determined through studies and specific scientific opinion.

The limits currently applying to the most important contaminants are set out in **Commission Regulation EC 1881/2006**¹³ of 19 December 2006, which establishes maximum levels for those contaminants in food. It lays down maximum permitted quantities of: nitrates, mycotoxins (aflatoxins, ochratoxin A, patulin and *Fusarium* toxins), heavy metals (lead, cadmium, mercury, methyl-mercury), monochloro-propane-1, 2- diol (3-MCPD), dioxins and dioxin-type PCBs, Polycyclic Aromatic Hydrocarbons (PAH) and inorganic tin.

Official [inspection activities](#) check that existing limits are being respected and indicate indirectly the effectiveness of inspection measures that have been implemented. Important prevention measures concerning some contaminants are contained in [Recommendations](#) aimed at food sector businesses, to prevent and reduce contamination through the use of best cultivation and /or production practices.

The body of legislation regarding food contamination is completed by [numerous acts](#) which regulate sample-taking methods to be followed during official inspections on food products and raw materials.

Regulation EC 1881/2006 was amended in the previous legislation by some other regulations which have added new contaminants to the list and have modified acceptable contamination levels for some substances¹⁴.

All the maximum levels set are subject to periodic review in order to take into account progress in scientific and technical knowledge and in improvements to best farming practices.

Plant protection products – Pesticides

The EU regulates the use of plant protection products used in farming in order to prevent and limit any contamination of foodstuffs and to preserve the environment.

The European Community has developed a comprehensive regulatory framework on Plant Protection Products (PPP). Directive 91/414/EEC defines strict rules for the authorisation of plant protection products (PPPs) and requires extensive risk assessments for effects on health and environment to be carried out, before a PPP can be placed on the market and used. Community rules also exist that define maximum residue limits (MRLs) on food- and feedstuffs.

In 2006, the Commission launched a "Thematic Strategy on the sustainable use of pesticides" COM(2006) 372 to revise the current Community approach on Plant Protection Products. In particular it aims to reduce environmental and health risks while maintaining crop productivity and improving controls on the use and distribution of pesticides.

The Thematic Strategy was accompanied by a Commission proposal for a Directive COM(2006) 373 establishing a framework for Community action to achieve sustainable use of pesticides. This proposal implements those provisions of the Thematic Strategy which cannot be included in existing instruments or policies.

¹³ Commission Regulation EC [1881/2006](#) repeals Regulation EC 466/2001

¹⁴ [Commission Regulation EC 629/2008](#) - 2 July 2008 - amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs.

[Commission Regulation EC 565/2008](#) - 18 June 2008 - amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs as regards the establishment of a maximum level for dioxins and PCBs in fish liver.

[Commission Regulation EC 1126/2007](#) - 28 September 2007 - amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs as regards *Fusarium* toxins in maize and maize products.

Commission Recommendation 2006/583/EC of 17 August 2006 on the prevention and reduction of *Fusarium* toxins in cereals and cereal products

Commission Recommendation 2006/576/EC of 17 August 2006 regarding the presence of some mycotoxins in products intended for animal feeds

Therefore it contains rules on many items. The first of these, and one of the most important, concerns the creation of National Action Plans to set objectives for the reduction of hazards, risks and dependence on chemical control for plant protection (National Action Plans - NAPs), which will allow the necessary flexibility to adapt the measures to the specific situations in each Member State.

In addition the Commission adopted further proposals in order to complete the legislative rules for Plant Protection Products, in line with the goals of the Thematic Strategy:

- Proposal for a regulation [COM\(2006\) 388](#) concerning the placing of plant protection products on the market. This proposal replaces Directive 91/414/EC and repeals Directive 79/117/EEC¹⁵.
- Proposal for a Regulation [COM\(2006\) 778](#) concerning statistics on plant protection products. This proposal lays down harmonised rules for the collection and dissemination of data concerning the placing on the market and use of pesticides.
- Proposal for a directive [COM\(2008\)535](#) of the European Parliament and of the Council on machinery for pesticide application, amending Directive 2006/42/EC. The proposal introduces supplementary essential environmental protection requirements that must be fulfilled by new machinery for pesticide application, to ensure that the products do not endanger the environment unnecessarily.

In December 2008, an agreement on the revision of Directive 91/414/EEC¹⁶ and on the adoption of the above-mentioned Framework Directive¹⁷ was reached between the Council and the European Parliament.

¹⁵ Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances

¹⁶ The key points of the regulation on the production and licensing of pesticides, as now agreed, are as follows:

- A positive list of approved "active substances" (the chemical ingredients of pesticides) is to be drawn up at EU level.
- Certain highly toxic chemicals, namely those which are genotoxic, carcinogenic or toxic to reproduction, will be banned unless their effect would in practice be negligible.
- Developmental neurotoxic, immunotoxic and certain endocrine-disrupting substances will be banned if they are deemed to pose a significant risk.
- If a substance is needed to combat a serious danger to plant health, it may be approved for up to five years even if it does not meet the above safety criteria.
- Products containing certain hazardous substances ("candidates for substitution") are to be replaced if safer alternatives are shown to exist. MEPs successfully demanded a shorter deadline for their replacement, of three years rather than five.
- Member States will be able to license pesticide products at national level or through mutual recognition. The EU will be divided into three zones (north, centre and south) with compulsory mutual recognition within each zone as the basic rule. But, following pressure from MEPs, individual States will be allowed to ban a product, for example because of specific environmental or agricultural circumstances.
- The new legislation will only gradually supersede existing EU law. Pesticides which can be placed on the market under current legislation will remain available until their existing authorisation expires. There will thus be no sudden large-scale withdrawal of products from the market.

¹⁷ The main points of the directive on the sustainable use of pesticides, as agreed, are:

- Member States will adopt National Action Plans with quantitative targets, measures and timetables "to reduce risks and impacts of pesticide use" on human health and the environment, as well as measures to encourage integrated pest management and alternative pest control methods. In addition, "On the basis of indicators, timetables and targets for the reduction of use" will be established.
- Aerial crop spraying will in general be banned, with certain exceptions subject to approval by the authorities.
- Member States must ensure appropriate measures are taken to protect the aquatic environment and drinking water supplies from the impact of pesticides.

In March 2009, a compromise deal on regulation concerning statistics on plant protection products was reached between the Council and the European Parliament.

On 22 April 2009 the European Parliament adopted a legislative resolution approving the proposal for a directive on machinery for pesticide application. The resolution contains amendments to the Commission proposal that were the result of a compromise negotiated with the Council.

Maximum Residue Limits

As regards the maximum residue limits, relating to active substances acceptable in food products for human consumption or animal feed, since 1 September 2008, three Regulations¹⁸ have been adopted. These limits incorporate those stipulated in 2005 in Regulation EC [396/2005](#)¹⁹.

In addition the new 2008 Regulations define harmonized limits in a standard way throughout the Community, thus guaranteeing a high level of safeguard for European consumers and eliminating obstacles to trade both among Member Countries and between the Community and Third Countries.

Contamination caused by materials in contact with food

The definition "contact materials" refers to materials and articles which come into contact with food (kitchen and table utensils such as saucepans, cutlery, plates and glasses, containers, films and sheets such as baking paper etc.). Within the community, contact materials are regulated by Regulation EC [1935/2004](#) of 27 October 2004. It lays down the general requirements for all relevant materials and articles, while additional specific directives²⁰ contain detailed provisions for each material (plastic materials, ceramics etc).

In particular the regulation stipulates that all materials and articles must be produced in conformity with good manufacturing practices and, when used in normal or foreseeable conditions, they should not transfer to food enough components to:

- pose a danger to human health;
- cause an unacceptable modification of the composition of foodstuffs;
- cause a deterioration in the sensory characteristics.

-
- Lastly, Parliament and Council agreed to prohibit pesticide use or keep it at least to a minimum, in specific areas used by the general public or by vulnerable groups, such as parks, public gardens, sports and recreation grounds, school grounds and playgrounds and in the close vicinity of healthcare facilities.

¹⁸ Commission Regulation (EC) No 149/2008 of 29 January 2008 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council by establishing Annexes II, III and IV setting maximum residue levels for products covered by Annex I;

Commission Regulation (EC) No 260/2008 of 18 March 2008 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council by establishing Annex VII listing active substance/product combinations covered by a derogation as regards post harvest treatments with a fumigant

Commission Regulation (EC) No 839/2008 of 31 July 2008 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards Annexes II, III and IV on maximum residue levels of pesticides in or on certain products

¹⁹ Revision of the Directive 91/414/EC

²⁰ Materials which are used in manufacturing of articles which will come into contact with food are regulated by specific directives. The spirit of these regulations is based on so called "positive lists" of substances which may be used in the production of such materials as well as methods of checking their suitability. In particular we list:

- [Commission Directive 2007/42/EC](#) - 29 June 2007 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs
- Council Directive 78/142/EEC of 30 January 1978 on the approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs

As regards the above-mentioned good manufacturing practices, please refer to Commission Regulation EC [2023/2006](#), of 22 December 2006. The provision lays down that all materials and articles listed in Appendix I of Regulation n. 1935/2004 and their use in other combinations. As well as recycled materials and articles compliant with general standards and specifications on good manufacturing practices (GMP).

Considering that not all industrial sectors have determined GMP guidelines the object of the regulation in question is to guarantee uniformity among Member States.

Therefore companies which carry out activities connected with any manufacturing, processing and distribution activity of these materials and articles must adopt a quality control system.

The Position of the European Parliament

As regards contaminants, in its last mandate (2004-2009) the European Parliament focussed its attention in particular on issues linked to Pesticides and plant protection products in general.

The work dedicated to the Pesticides Package involved the European Parliament on several fronts, firstly regarding increased safety for operators and final consumers, secondly in simplifying the bureaucracy relating to the application of product approval and inspection rules and thirdly in the promotion of transparency and fair competition among businesses in the sector.

Furthermore attention was paid to animal welfare, encouraging practices which avoid the use of animals in product test phases, and in any case forbidding the use of vertebrate animals in such tests.

2.3 Food Labelling

The legal framework concerning foodstuff labelling is designed to guarantee consumer access to complete information on the content and composition of products, in order to protect their health and best interests.

The definition of "labelling" is "any words, particulars, trade marks, brand name, pictorial matter or symbol relating to a foodstuff and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such foodstuff".

The European legislation on food labelling refers to **pre-packaged** products. Member States regulate the labelling of non **pre-packaged** foods through national legislation.

Council Directive [2000/13/EC](#) includes general provisions on the labelling of foodstuffs to be delivered to the consumer and certain aspects relating to presentation and advertising. This Directive applies to foodstuffs intended for supply to restaurants, hospitals, canteens and other similar mass caterers. Furthermore, the Directive 2000/13 specifically prohibits claiming for foodstuffs any capacity of preventing, treating or curing a human disease, or reference to such properties.

The Directive has been amended several times by other Directives²¹ in order to integrate various aspects. Among those Directives, Directive [2003/89/EC](#) regulates how ingredients present in foodstuffs are to be indicated. The Directive mandates that all ingredients must be stated on the label. It specifically ensures complete information to consumers suffering from food allergies or those who wish to avoid eating certain ingredients for any other reason.

21 Commission Directive 2001/101/EC of 26 November 2001 amending Directive 2000/13/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs.

Commission Directive 2006/142/EC of 22 December 2006 amending Annex IIIa of Directive 2000/13/EC of the European Parliament and of the Council listing the ingredients which must under all circumstances appear on the labelling of foodstuffs

Commission Directive 2007/68/EC of 27 November 2007 amending Annex IIIa to Directive 2000/13/EC of the European Parliament and of the Council as regards certain food ingredients

Labelling of specific foodstuffs and ingredients

There are several "vertical" acts issued, for the most part before Directive 2000/13 that set out derogation or specification for particular products or category of products. For an exhaustive list see the EU site:

http://europa.eu/legislation_summaries/consumers/product_labelling_and_packaging/index_en.htm

Nutrition labelling

In general nutrition labelling of foodstuffs is governed by Council Directive [90/496/EC](#), amended by Commission Directive [2003/120/EC](#). Nutrition labelling means any information appearing on labelling and relating to: energy value and the presence of nutrients such as proteins, carbohydrate, fats, fibres, sodium, and vitamins and minerals listed in the Annex of the Directive and present in significant amounts as defined in that Annex.

New legislative proposals on Provision of Food Information to Consumers

In January 2008, the European Commission put forward a proposal for a Regulation on the provision of food information to consumers ([COM\(2008\)40](#)).

The proposal consolidates and updates two areas of labelling legislation, the general food and nutrition labelling respectively covered by Directives 2000/13/EC and 90/496/EEC.

Health and nutritional claims

The Health Claims Regulation (EC) [1924/2006](#) provides harmonised rules for the use of health or nutritional claims (such as "low in fat", "calcium may help improve bone density") on foodstuffs based on nutrient profiles, ensuring that any claim made on a food label in the EU is clear, accurate and substantiated. The Regulation also aims to ensure fair competition and promote and protect innovation in the area of food. Only products offering genuine health or nutritional benefits will be allowed to refer to them on their labels. Regulation entered in force on 1 July 2009.

Dietetic foods or 'foods for particular nutritional uses'

Dietetic or dietary foods, or 'foods for particular nutritional uses', are foodstuffs intended to satisfy particular nutritional requirements of specific groups of the population. The groups of dietary foods concerned are: foods for infants and young children; infant formulae and follow-on formulae; processed cereal-based foods and baby foods (weaning foods); foods intended for use in energy-restricted diets for weight reduction; foods for special medical purposes; and foods for sports people. Specific Directives have been adopted for these dietary food categories, except for 'sports food'.

Council Directive [89/398/EEC](#), as amended by Directive [96/84/EC](#) and Directive [1999/41/EC](#), sets out a framework of rules for the composition, marketing and labelling requirements of dietetic foods, including measures to ensure the appropriate use of such foods and to exclude any risk to human health.

Food and obesity

A great deal of legislation treated under other section headings of this document (and the Public Health Welcome Package) have an indirect impact on Nutrition and Obesity.

In May 2007, the Commission adopted a « White Paper on A Strategy for Europe on Nutrition, Overweight and Obesity-related health issues » ([COM\(2007\)279](#)).

The document stresses the strategies to be put in place to combat the continuing rise in obesity (food education, encouragement of physical activity, encouraging the private sector to reduce obesity by developing new and healthier products).

The role of the European Parliament

In the previous mandate (2004-2009), the EP was involved on several legislative acts concerning labelling issues and communication on food.

The most important of these are:

- Regulation EC 1924/2006 on health and nutritional claims (Co decision procedure [COD/2003/0165](#)). Some of the most important aspects of EP's position are listed below:

- Foods can bear nutrition and health claims if they comply with nutrient profile. The Commission will establish a nutrient profiling system and set nutrient profiles for foods bearing nutrition and health claims after taking scientific advice from EFSA.
- Member States are given the possibility to issue national rules on fresh food and on the use of nutrition claims referring to "low alcohol levels" or "the reduction or absence of alcohol" or "energy content" for drinks containing over 1.2% alcohol;
- By January 2010, the Commission has to draw up a "positive list" of the many well-established 'function' health claims in the EU (such as "calcium may be good for your bones") on the basis of claims submitted by the EU Member States. EFSA will provide scientific support for this process;

- Commission proposal for a Regulation [COM\(2008\)0040](#) regarding information on Provision of Food Information to Consumers (Co decision procedure [COD/2008/0028](#)). The Parliament has not adopted its own position to date. Discussion will take place in the current Parliamentary mandate 2009-2014.

2.4 Food additives and food flavourings

Food additives are substances added intentionally to foodstuffs to perform certain technological functions - for example to colour, to sweeten or to preserve - and which are not normally consumed as a food in itself and not normally used as a characteristic ingredient of food whether it has nutritional value or not.

Community Legislation on food additives is based on the principle that only those additives that are explicitly authorised may be used. Most food additives may only be used in limited quantities in certain foodstuffs.

In December 2008 a new legislative package was adopted relating to food additives, food enzymes and food flavourings. The "**Food Improvement Agents package (FIAP)**" (OJ L354, 51) introduces harmonised EU legislation on food enzymes for the first time and upgrades previous rules for flavourings and additives. For additives and flavourings, which were already covered by EU legislation, the proposals brought the rules into line with the latest scientific and technological developments and were designed to improve the clarity of the legislation. With regard to food enzymes, the draft Regulation proposed replacing divergent national legislation with new, harmonised EU rules. The regulations came into force on 20 January 2009, with most of the measures applying from 20 January 2010.

The package includes these four Regulations, dated 16 December 2008:

- Regulation EC [1331/2008](#) establishing a common authorisation procedure for food additives, food enzymes and food flavourings;
- Regulation EC [1333/2008](#) on food additives;
- Regulation EC [1332/2008](#) on food enzymes;
- Regulation EC [1334/2008](#) on flavourings and certain food ingredients with flavouring properties for use in and on foods.

Regulation EC 1331/2008 establishes a common authorisation procedure that is centralised, effective, expedient and transparent and that is based on risk assessment carried out by the European Food Safety Authority (the Authority) and a risk management system in which the Commission and the Member States take action within the framework of a regulatory committee procedure.

Regulation EC 1332/2008 harmonises EU legislation for food enzymes. It applies to enzymes which are added to food to perform a technological function in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food.

The Regulation provides for:

- a Community list of approved food enzymes;
- conditions of use of food enzymes in foods;
- rules on the labelling of food enzymes sold as such.

A food enzyme may be included in the Community list only if it meets the following conditions and, where relevant, other legitimate factors:

- it does not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer at the level of use proposed;
- there is a reasonable technological need, and
- its use does not mislead the consumer. Misleading the consumer includes, but is not limited to, issues related to the nature, freshness and quality of the ingredients used, the naturalness of a product or of the production process, or the nutritional quality of the product.

Regulation EC 1333/2008 upgrades existing EU legislation on food additives. In summary, the Regulation's provisions state that food additives used in foods, in food additives and in food enzymes would be subject to safety evaluation and approval via a Community-approved positive list. Their use in food will be evaluated according to their safety, technological need, benefit to the consumer and assurance that the consumer is not being misled.

Regulation EC 1334/2008 concerns flavourings and certain food ingredients with flavouring properties for use in and on foods.

This Regulation provides for:

- a Community list of flavourings and source materials approved for use in and on foods, set out in Annex I ('the Community list');
- conditions of use of flavourings and food ingredients with flavouring properties in and on foods;
- rules on labelling of flavourings.

The above mentioned regulations replace and repeal previous rules for additives and flavourings. Some regulations remain operative and set authorized levels for certain products.

An overview of those acts can be found in the EU web page:

http://europa.eu/legislation_summaries/consumers/product_labelling_and_packaging/index_en.htm.

Among those, Directive [2006/52/EC](#) (adopted during the last EP mandate) modifies the authorised levels of nitrates and nitrites permitted in meat and permits the use of some additives, amongst which erythritol as a sweetener in the same way as other polyols. Erythritol can be used in the preparation of fruit which is energy-reduced or has no added sugar, but not in the preparation of fruit juice beverages.

Food supplements: Food supplements are concentrated sources of nutrients or other substances with a nutritional or physiological effect whose purpose is to supplement the normal diet. They are marketed 'in dose' form i.e. as pills, tablets, capsules, liquids in measured doses etc. Directive [2002/46/EC](#) establishes harmonised rules for the labelling of food supplements and introduces specific rules on vitamins and minerals in food supplements. Annex II contains a list of permitted vitamin or mineral preparations that may be added for specific nutritional purposes in food supplements; inclusion of substances in this list is possible following a scientific safety evaluation by EFSA.

Addition of vitamins and minerals: Regulation EC [1925/2006](#) harmonises the provisions laid down in Member States for the addition to foods of vitamins, minerals and certain other substances (including trace elements, amino acids, essential fatty acids, fibre, various plants and herbal extracts, but excluding food supplements). The aim, as always, is to ensure the smooth functioning of the internal market while providing a high level of consumer protection. Inclusion of such nutrients in the list of permitted substances in the annex of the Regulation requires EFSA issue of a scientific safety assessment.

The role of the European Parliament

The European Parliament worked a great deal during the previous mandate 2004-2009 in this area specifically responding to the Commission's proposals with detailed amendments to the Directives proposed within the FIAP package. In each occasion, Parliament stressed that the common procedure must contribute to the free movement of food within the Community, a high level of protection of human health and a high level of consumer protection, including protection of consumer interest.

2.5 Animal Health

In order to prevent diseases in animals, the European Union has devised measures to limit the risks of outbreak and spread of disease and to eradicate them once they have been detected. This legislation complements the rules on veterinary checks and food hygiene.

European regulation includes general provisions on the surveillance²², notification²³ and treatment of infectious diseases and their vectors²⁴

Certain European measures have been adopted since 1992. For a comprehensive overview of specific regulation see the European Union website:

http://europa.eu/legislation_summaries/food_safety/animal_health/index_en.htm

In order to present few examples, this chapter focuses specifically on regulations dealing with:

- Bovine spongiform encephalopathy (BSE- "mad cow disease");
- Classical swine fever;
- Bluetongue.

Recent developments in European regulation on animal health

A particular turning point in regulation in the field of animal health was the spread of BSE from the mid-1990s. This phenomenon marked a genuine health emergency accompanied as it was by a rise in incidences of a human variant of the disease (Creutzfeldt-Jakob disease).

In 2001 the EU adopted Regulation EC 999/2001 outlining measures for the control of the various spongiform encephalopathies found among animals.

In the context of the crisis arising at the beginning of 2000, the Community instituted a legislative framework in order to maintain safety along the entire chain of production and distribution, "from field to fork". With this in mind, Regulation EC 1774/2002 laid down rules on animal by-products not intended for human consumption and a further proposal was adopted in 2003 to limit disease stemming from animals (e.g. Salmonella²⁵).

²² Directive [2003/99/EC](#) of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents

²³ Council Directive 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community

²⁴ Council Directive 92/119/EEC of 17 December 1992 introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease

[Council Directive 2000/75/EC](#) of 20 November 2000 laying down specific provisions for the control and eradication of bluetongue

²⁵ ([Directive 2003/99/EC](#))

In December 2004 the Commission set in motion an external assessment to examine closely the consequences of EU actions in the field of animal health and determine what course of action to take in the future. A combination of factors led to a new assessment of the current situation:

- Diseases unknown ten years previously i.e. SARS (Severe Acute Respiratory Syndrome) have emerged while others such as foot and mouth, bluetongue and avian flu have presented new challenges lately;
- Trading conditions have changed radically: the volume of trade in products of animal origin has risen notably, both within the EU and with other countries;
- Science, technology and the legislative institutions have all seen significant developments take place.

In 2007 a new European strategy for animal health was set out for the period 2007-2013, based on the idea 'Prevention is better than cure'²⁶. This lays out a basis for future policy.

The strategy identified sets out some ambitious goals aimed at improving animal health.

The objectives identified are:

- to ensure a high level of public health and food safety by minimizing the incidence of biological and chemical risks to humans;
- to promote animal health by preventing or reducing the incidence of animal diseases, and so supporting farming and the rural economy;
- to improve economic growth/cohesion/competitiveness assuring free circulation of goods and proportionate animal movements;
- to promote farming practices which prevent threats to animal health and minimize environmental impact in support of the EU Sustainable Development Strategy.

One of the first legislative procedures initiated in line with the new strategies was started in June 2008 and is connected to a proposal of the Commission stating health rules regarding by products of animal origin not intended for human consumption (regulation on by products of animal origin). An objective of this proposal is further simplification of regulation, leading to a reduction in the administrative responsibilities on the part of competent authorities (EU, national and non-EU nations) and also of operators while continuing to provide a high level of protection to public health and animal health.

Specific European regulation: regulation on spongiform encephalopathy

In 2001, in response to problems which became apparent as a result of the BSE crisis Regulation EC 999/2001 was issued. This lays down control measures regarding transmissible spongiform encephalopathies (such as Bovine Spongiform Encephalopathy or "mad cow disease", scrapie, etc.). The most important of these are controls on all animals slaughtered over a certain age (30 months for cattle, 18 for sheep, variable according to the reason for slaughter) and a complete ban on the use of animal protein in feed for ruminants. In addition, rules on the importation from non-EU countries were harmonised.

The regulation also set out temporary measures for the elimination of so-called Specified Risk Material, i.e. those parts of the animal which carry the highest probability of acting as disease vectors (head, spinal cord, intestines). These measures were applied until the adoption of a community classification system of those countries based on their BSE risk (Regulation EC 722/2007). This allows for the application of measures in each country specific to the level of risk from BSE.

²⁶ Communication [COM\(2007\) 539](#) of the Commission of the European Parliament, the Council, the Social and Economic Committee and the Committee of the Regions.

It ought to be underlined the EU has adopted a country classification system for BSE risk in line with that defined by the OIE (World organisation for animal health). As results from the OIE were pending Regulation EC 932/2005 was put in place, which prolonged the application period of the transitional measures on risk materials to 1 July 2005. While the Commission intended that the Regulation also contain a thorough revision of the rules affecting the prevention and management of BSE, Parliament has yet to consider this opportune and final regulation has thus been limited to the extension of temporary measures.

Specific European regulation: classical swine fever

Classical swine fever is a disease which has, in recent years caused significant socio-economic damage in the European Union.

The directive referring to this disease is Council Directive 2001/89/EC of 23 October 2001.

The directive outlines action to be carried out in order to prepare Member States adequately for any possible outbreak and spread of the disease.

For this, Member States must prepare emergency plans, indicate vaccine requirements for use in case of infection and areas with a high density of swine. In addition the feeding of pigs with food waste is prohibited as this can constitute a means by which the disease can spread.

The directive also outlines measures to be adopted should swine fever be found in wild animals. The directive includes a list (updated on several occasions) of national laboratories of reference for classical swine fever.

Specific European regulation: bluetongue disease

In the last decade outbreaks of this disease have occurred in various European countries. The relevant regulation is Council Directive 2000/75/EC of 20 November 2000. The directive describes courses of action to be taken in terms of vigilance and prevention in case of any outbreak.

If the disease is detected in a group of animals the official veterinary surgeon must put the affected farm under monitoring, carry out various investigations (inventory of the animals and their accommodation, epidemiological survey) and put various protective measures in place (ban on animal movement, insecticide treatment of animals, destruction and treatment of carcasses in line with Regulation EC 1774/2002).

In the event of confirmation of the presence of the disease a protection zone is set up with a radius of 100km around the affected farm. All animals present in this zone must be identified and may not leave the area, and a vaccination plan must also be implemented. The same restrictions on movement and rules on monitoring also apply to a further monitoring zone, consisting of the next 50km from the centre, but vaccination is prohibited in this zone.

Further regulations have been implemented to better specify obligations and restrictions for disease prevention and the management of centres of infection.

The role of the European Parliament

In the previous legislature 2004-2009 the European Parliament's approach on animal health was always intended to considerably simplify regulation and bureaucracy, while keeping in consideration any risks to the community.

As regards problems connected with spongiform encephalopathies and in particular with BSE, the European Parliament, during discussions on procedure [COD/2004/0270](#), delayed revision of Regulation EC 999/2001 pending availability of a community classification system of countries on the basis of BSE risk. This classification was introduced in 2007²⁷ and permits each country to apply specific measures according to the level of risk and so allows for the quicker implementation of such laws.

²⁷ Regulation EC 722/2007

With regard to products of animal origin not intended for human consumption, the European Parliament has also expressed (co decision procedure [COD/2008/0110](#)) an intention to minimise the risk of contamination to food and animal feed. A will has been expressed to increase the separation between the various sectors of production, to reach a clearer separation of responsibility for the production process and to implement control structures which guarantee safety and respect for the law.

2.6 Animal nutrition

Approximately 120 million tons of animal feed are produced annually in the EU. Previously, from 1970, the principal regulations tended to centre on aspects of production and the distribution sector while nowadays greater emphasis is given to safeguarding the health of animals and the population.

In considering animal nutrition it is again necessary to refer to Regulation EC [178/2002](#), which establishes principles and requirements for safety for both food and animal feed and outlines the responsibility of operators, traceability and the principle of precaution.

Animal feed

Regulation EC [183/2005](#) governs feed hygiene at all stages of production and distribution where there is an impact on feed and food safety, including primary production. The regulation calls for the adoption of internal monitoring procedures in feed producers and respect for basic hygiene rules.

Feed may take the form of feed materials, compound feed, feed additives, premixtures and medicated feedingstuffs. The distinction has implications for the conditions for market placement.

Council Directive [96/25/EC](#) sets out rules for the marketing and labelling of feed materials.

Council Directive [79/373/EEC](#)²⁸ refers to the circulation of compound feedingstuffs.

Feed may only be marketed if it is of "sound, genuine and of merchantable quality"; it must not present any danger to human or animal health or to the environment and must be presented or marketed in a manner that will not mislead consumers.

Compound feedstuffs must be marketed in sealed packages or containers.

Various acts state requirements for the sale of animal feed. A complete review of these acts can be found at the webpage:

http://europa.eu/legislation_summaries/food_safety/animal_nutrition/index_en.htm.

This general and complex framework relating to feed is integrated by other specific pieces of legislation, namely:

- Regulation EC [999/2001](#) which governs prevention, control and eradication of certain transmissible spongiform encephalopathies, which includes among other things, a ban on feeding ruminants with meat and bone meal or greaves;
- Regulation EC [1774/2002](#) which mandates health rules concerning animal by-products not intended for human consumption;
- Regulation EC [1829/2003](#) on genetically modified food and feed;
- Regulation EC [1830/2003](#) concerns the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive [2001/18/EC](#);
- Council Regulation EC [834/2007](#) on organic production and labelling of organic products.

In 2008 the Commission made its Proposal for a Regulation of the European Parliament and of the Council on market placement and use of feed [[COM \(2008\)124](#)] which provides for a complete overhaul of European animal feed legislation. The project is included in the Commission's rolling programme of simplification. Thus, with the prerequisite of assuring the high level of feed and food safety within the Community, the general objectives are to consolidate, revise and modernise the Directives on the circulation and labelling of feed materials and compound feed.

Feed labelling

Feed materials and compound feedstuffs in commerce must be labelled or accompanied with documentation that contains compulsory information such as the description/type, the controlling authority, net weight, date of manufacture, list of ingredients etc.

Part B of the Annex to Directive [96/25/EC](#), which was entirely replaced and updated to reflect technical and scientific progress by Directive [98/67/EC](#), and columns 2 to 4 of the Annex to Directive 82/471/EEC contain lists with designations, descriptions and labelling provisions for certain feed materials.

During the conciliation procedure concerning the adoption of Directive [2002/2/EC](#) which changed the rules on the labelling of compound feedstuffs, amending Directive 79/373 EEC, the Council and the Parliament agreed for the Commission to prepare a proposal for the establishment of a positive list of feed materials by the end of 2002 (report COM(2003)178). Commission Decision [2004/217/EC](#) adopts a list of materials whose circulation or use for animal nutrition is prohibited (negative list).

Undesirable substances

Directive [2002/32/EC](#), amended by [2003/57/EC](#) and [2003/100/EC](#), on undesirable substances in animal feed includes maximum limits for heavy metals and prohibits the dilution of contaminated feed materials.

Directive [2002/70/EC](#) establishes requirements for determining levels of dioxins and dioxin-like PCBs in feedingstuffs. In 2002, the Commission adopted a Recommendation ([2002/201/EC](#)) on the reduction of the presence of dioxins, furans and PCBs in feedingstuffs and foodstuffs.

The role of the European Parliament

The European Parliament's activities during the previous legislature 2004-2009 on animal health concentrate on several legislative procedures. In one of the most important, [COD/2008/0050](#), procedure dealing with the proposed regulation on marketing and use of feed, the Parliament approved a position in which, among other considerations, the 'opportunity was taken to protect the intellectual property of the producer'. As an example the quantitative composition of compound feed, as opposed to the names of the raw materials, can, under certain conditions, be considered protected information.

2.7 Animal welfare

Animal Welfare is one of the aspects of European food safety policy, closely related to health and nutrition of the animals.

Community legislation sets minimum requirements in order to spare animals from any unnecessary suffering in three main areas: farming, transport and slaughter. It also tackles other issues, such as animal experiments and the fur trade.

Since 1974, European legislation has been developed with a view to protecting animals and ensuring their well-being on farm holdings, during transport and at the time of slaughter. There are several legislative acts on this topic as well as legislation in the evaluation phase. This Welcome Package mentions the most significant:

- Council Directive [98/58/EC](#) of 20 July 1998 concerning the protection of animals kept for farming purposes. This Directive states that the Member States must adopt provisions to ensure that the owners or keepers of animals look after the welfare of their animals and see that they are not caused any unnecessary pain, suffering or injury.
- Council Regulation EC [1/2005](#) of 22 December 2004 on the protection of animals during transport and related operations and amending Directives [64/432/EEC](#) and [93/119/EC](#) and Regulation EC [1255/97](#). This Regulation strengthens existing legislation on animal welfare during transport by identifying the parties involved and their respective responsibilities, putting in place enhanced measures on authorisations and inspections and laying down stricter rules on transport.

On 23 January 2006, Commission Communication COM(2006)13 set up a [Community Action Plan on the Protection and Welfare of animals](#) 2006-2010. The Action Plan sets out the broad outlines for European intervention in this field, both within the EU and beyond its borders.

The Action Plan defines five main fields of interlinked action with the aim of achieving the stated objectives:

- upgrading minimum standards;
- promoting research and substitute methods for animal testing;
- introducing welfare indicators ;
- ensuring that professionals and the general public are better informed;
- supporting international initiatives for animal protection.

The Action Plan responds to the principles laid down in the protocol on animal welfare and protection annexed to the Treaty establishing the European Community (EC Treaty). This protocol recognises that animals are sentient beings and that full regard should be paid to animal welfare concerns when formulating or implementing policies relating to agriculture, transport, research and the internal market.

The impact assessment accompanying the Action Plan takes stock of the anticipated benefits of the action plan, of the existing legislation and of the research undertaken.

In 2008 the Commission set out a proposal for a Council Regulation on the protection of animals at the time of killing COM(2008)553. This proposal aims to introduce standard operating procedures for the welfare of animals at slaughter. Each operator shall be responsible for establishing and applying these operating procedures in order to spare animals for slaughter as much pain, distress or suffering as possible.

Role of the European Parliament

During last parliamentary mandate 2004-2009, the European Parliament adopted an official position in the first reading²⁹, concerning the proposal for a Council Regulation COM(2008)553 on the protection of animals at the time of killing.

Different amendments to Commission proposal are outlined in the EP position. Among the most significant are the following:

- Parliament deleted operators' obligations to ensure that animals are prevented from adverse interaction. It adds that the killing of surplus one-day chicks, by whatever means, shall no longer be permitted once appropriate alternatives to the killing of these animals are available;

²⁹ CNS/2008/0180 legislative procedure.

- EP members stipulate that bleeding shall start as soon as possible after stunning. In addition, they state that in order to take account of scientific and technical progress, the Commission may approve new stunning methods on the basis of an assessment by the European Food Safety Authority;
- Parliament states that, in the course of an inspection of slaughterhouses or establishments which have been, or are to be, approved in third countries for the purpose of being able to export to the EU in accordance with EU legislation, the Commission experts shall ensure that live animals have been slaughtered under conditions which, as far as animal welfare is concerned, are at least equivalent to those provided for in the Regulation. The health certificate accompanying meat imported from a third country shall be supplemented by a certificate certifying that the above requirement has been met.

2.8 Novel Foods

Novel foods are identified by Regulation EC 258/97 as foods and food ingredients which have not been used for human consumption to a significant degree within the Community prior to its coming into effect (15 May 1997).

This Regulation defines the framework regulation of this type of food and it is integrated by Regulation EC [1852/2001](#) which determines how certain information will be made accessible to the public.

Regulation EC [258/97](#) sets detailed rules for the authorisation of novel foods and novel food ingredients. Foods that were commercialised in at least one Member State before the Regulation on Novel Foods came into force on 15 May 1997, may remain on the EU market under the "principle of mutual recognition". As EFSA was set up in 2002, novel foods must undergo a safety assessment - carried out by EFSA - before being marketed in the EU.

Regulation EC [258/97](#) allowed the authorisation of some products derived from Genetically Modified Organisms (GMOs) in accordance with a simplified procedure, where the product was substantially equivalent to another which had already been authorised.

This simplified procedure is no longer used for the authorisation and marketing of GMOs or products derived from GMOs. Since 2003, most GMOs must be approved under Regulation EC No [1829/2003](#) concerning traceability and labelling, and establishes a single authorisation procedure.

Commission's [White Paper on Food Safety](#), set out indications to examine the application of previous Regulation of the introduction of new foodstuffs and ingredients (EC Regulation 258/97, actions 14 and 51) in accordance with EC Directive 90/220 (on GMO). In part, these objectives were met by the adoption of EC Regulation 1829/2003.

In January 2008, the Commission put forward a proposal for a new Regulation to establish harmonised rules for the placing of novel foods on the market in the Community with a view to ensuring a high level of human health and consumer protection, while ensuring the effective functioning of the internal market [COM\(2007\)872](#). It lays down rules for authorisation, supervision, labelling and use of novel foods. The new Regulation on novel foods excludes GMOs as they are now covered by Regulation (EC) No 1829/2003 on GM food and feed.

The objective of the Commission's proposal [COM \(2007\)0872](#) was to modify the current Regulation in order to:

- Streamline authorization procedure, and improve the efficiency, transparency, application of the Regulations;
- Develop guidelines for better food safety evaluation of novel foods coming from countries outside the EC;
- Clarify the definition of novel food, including the introduction of new technologies that have an impact on foods.

The Role of the European Parliament

After having examined the Commission's proposal, the EP proposed to exclude foods derived from cloned animals and their offspring from the scope of this Regulation. It introduced definitions for "cloned animals", "offspring of cloned animals" and "engineered nanomaterial", and requested that the Commission collect information from Member States regarding the classification of novel food. A new provision stipulates the prohibition of non-compliant novel foods. Finally, the EP included a broader set of conditions for: the entry of novel foods in the EC; indications for monitoring food labelling; and accompanying documentation for novel foods coming from third countries. At present the European parliament is still awaiting Council's first reading.

In addition, the EP adopted a Resolution [RSP/2008/259](#) on 3 September 2008, calling on the Commission to submit proposals prohibiting:

- the cloning of animals for food supply purposes;
- the farming of cloned animals or their offspring;
- the placing on the market of meat or dairy products derived from cloned animals or their offspring and the importing of cloned animals, their offspring, semen and embryos from cloned animals or their offspring, and meat or dairy products derived from cloned animals or their offspring.

While this resolution does not pertain specifically to "food safety", it is a significant indication of EP orientation on the subject of using cloned animals for food.

2.9 Genetically Modified Organisms

A genetically modified organism is "an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination"^{30 31}.

This definition is found in Directive 2001/18/CE of the European Parliament and the Council, of 12 March 2001, on the deliberate release into the environment of genetically modified organisms. This directive regulates the cultivation and commercialisation of genetically modified organisms and along with Regulation EC [1829/2003](#) and Regulation EC [1830/2003](#) defines the regulatory framework of the community with reference to this area.

Directive 2001/18/EC

Directive 2001/18/EC defines the procedure envisaged for authorising the deliberate release into the environment and the placing on the market of Genetically Modified Organisms (GMO). It is essentially from this directive that authorisation to grow genetically modified organisms within the EU comes.

Authorisation is limited to a period of ten years and is renewable.

The directive also envisages a common methodology for risk assessment on the release of GMO into the environment (The applicable principles for risk assessment are included in annex II of the directive).

Member States can use a safeguard clause which permits them, on the basis of documented assessment of new and further risks to health and the environment, either to ban completely or to limit partially, the cultivation and sale of previously authorised genetically modified products.

The directive furthermore introduces the obligation for public consultation and for communication on labelling of the fact that products are genetically modified.

³⁰ Directive 2001/18, article 2 - definitions

³¹ The legislation described in this paragraph does not apply to mutagenesis and cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding method

Regulation EC 1829/2003

Regulation EC 1829/2003 applies to GMOs destined for food or feed production, to food or feed containing GMOs, and to food or feed produced from or containing ingredients produced from GMOs.

The Regulation ensures that it is not possible to place into the market a GM food or feed without an authorization which must be requested following a specific procedure. Most authorisation and notification are currently presented in compliance with Regulation EC 1829/2003.

All products approved in line with this regulation are subject to mandatory labelling (the wording “genetically modified” or “genetically modified [name of organism] product” must be clearly visible on the label).

In standard products with a GMO contamination not greater than 0.9% this labelling is not mandatory provided that it can be demonstrated that this is accidental or technically unavoidable.

Member States have the duty to communicate information concerning notification, authorisation status and they are also required to institute and implement an internal system of checks and sanctions.

Regulation EC 1830/2003

In order to favour the correct application of the relevant precautions labelling of genetically modified food and feed, Regulation 1830/2003 established traceability requirements.

Traceability must be guaranteed at all stages of marketing of those products containing or consisting of GMO and food and feed obtained from GMO.

Documentation must accompany the distribution of products through the production process declaring that the product is GM, or is made from, includes or is derived from GMO and must indicate unambiguously the unique identification code of the organism.

Unique identification codes for GMO

To facilitate the traceability system and make it unambiguous, Commission Regulation [65/2004](#) establishes a system to develop and assign unequivocal identification codes to genetically modified organisms.

The Commission has instituted and manages a register of GMO (see http://ec.europa.eu/food/dyna/gm_register/index_en.cfm) in which the state of authorisation or of the procedure in course can be traced for any product.

Cross-border movements of genetically modified organisms

Regulation [EC 1946/2003](#) seeks to establish a common system of notification and information exchange on cross-border movements of GMO to non-EU countries in order to guarantee that any movements with the potential to have negative effect on the sustainable use of biological diversity or on human health are carried out respecting both the environment and human health.

GMMs – genetically modified microorganisms

Genetically modified micro-organisms can be used in various industrial processes.

Council Directive [90/219/EEC](#) establishes that Member States define and implement the requirements for a contained use of genetically modified micro-organisms in order to minimise their potential negative effects on human health and the environment.

Before starting any new installation for the use of GMM, operators must obtain specific authorisation.

The role of the European Parliament

In the previous mandate 2004-2009 the European Parliament worked on two co decision procedures concerning the application of Regulatory Procedure with scrutiny (see Chapter 1, section 1.4) respectively to Regulation EC 1829/2003 and Directive 2001/18/EC.

It dealt, in practice, with the possibility of intervening in certain regulations of these acts with a quicker legislative process. In the case of Directive 2001/18/EC, for example, this was placed under regulatory procedure with scrutiny:

- The definition of criteria and of information requirements which must be followed for notification and dossier summaries to present for placing on the market any type of genetically modified organism either as a product or constituent part thereof.
- The definition of limits on the presence of GMO in products; limits over which citation on the label becomes mandatory.
- The definition of conditions for the implementation of measures on labelling.

In the field of GMO certain problems have arisen which could be objects of work in the upcoming mandate 2009-2014:

- In the current regulatory framework there are parts requiring revision or integration to make requirements clearer or more specific;
- It is important to introduce socio-economic criteria into the risk assessment process regarding potential advantages or disadvantages for growers, consumers, society in general, European agriculture and the various sectors affected;
- The European institutions agree with giving regulatory status through comitology to the operational guidelines on environmental risk assessment being developed by EFSA on the mandate of the Commission³².

2.10 Nanotechnologies applied to foods

The term nanotechnology in the field of science and technology refers to the nanometric scale of atoms and molecules, to scientific principles and to new properties which can comprise and be controlled at this level. These properties can be seen and exploited both at microscopic and macroscopic scale, for example to develop materials with new functions and properties.

The applications of nanotechnologies are expanding and will have an effect on the lives of all citizens before long. During the last ten years the European Union has built a solid base of knowledge in the field of nanoscience. This pre-eminence is nevertheless at risk as the EU invests proportionally less than principal competitors and lacks a world class infrastructure ("centres of excellence") which would allow the necessary critical mass to be gathered. This is happening in spite of investment in national programs within the EU growing rapidly albeit autonomously.

On 12 May 2004, the European Commission issued the Communication "Towards a European Strategy for Nanotechnology"³³. This document seeks to bring the discussion on nanoscience and nanotechnology to the institutional level and proposes an integrated and responsible strategy for Europe.

³² Conclusions of the Council on genetically modified organisms (GMO)-2912th Environment Council Meeting Brussels, 4 December 2008

Draft minutes on the implementation of regulations on GMO in the EU, in particular of Directive 2001/18/EC and of Regulation EC 1829/2003 and 1830/2003 – ENVI (ref. 2008/2306(INI))

³³ [COM\(2004\)338](#).

As planned in May 2004 the European Commission then adopted, on 7 June 2005, the Action Plan "Nanoscience and Nanotechnology: An Action Plan for Europe 2005-2009"³⁴. This document defines a series of articulated and interconnected actions towards the realisation of a secure, integrated and responsible strategy for nanoscience and nanotechnology, based on priorities defined in the Communication of 2004.

On 17 June 2008 the Commission presented a further Communication [COM\(2008\)366](#) on the aspects of Regulation on nanomaterials, which defined the program for further legislative steps necessary to reach a complete legislative framework on the subject.

In February 2009 the EFSA scientific committee issued a scientific opinion on "The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety". The opinion outlines the diverse characteristics and properties of nanomaterials used in food and feed. In a further elaboration the document provides an evaluation of the possibility of carrying out effective risk analysis on nanomaterials.

The Commission is currently carrying out an enquiry into the entire EU regulatory process, analysing the frameworks which may be applicable to nanomaterials (especially chemical substances, worker protection, environmental legislation, specific regulations on products). The scope of this "inventory" is to examine and propose adaptations to EU regulations in each relevant area. Preliminary results indicate that the regulatory framework should, in principle, provide good cover. There are still, however, gaps in knowledge to be dealt with (especially toxicity thresholds, testing systems) in order to guarantee the realisation of general regulation in this area.

The role of the European Parliament

On 24 April 2009 the European Parliament adopted a resolution³⁵ on some regulatory aspects of nanomaterials, in response to the Commission Communication [COM\(2008\)366](#) on the subject. First of all, the resolution points out that the current discussion on nanomaterials is characterised by a significant lack of knowledge and information on the subject, beginning with the question of defining categorically nanomaterials.

Secondly it specifies the need to devise further regulations which guarantee the safety both of the end consumer, whether the products are food or animal feed, and of the worker who comes into contact with the nanomaterials during the production process.

With this end in mind the Parliament requires that consumers be supplied with information on the possible use of nanomaterials in consumer products: all ingredients present in the form of nanomaterials in substances, mixtures or articles must be clearly indicated on the product labelling (for example, in the list of ingredients, the name of substances should be followed with the word "nano" in brackets).

In its resolution, the European Parliament has also maintained that in the framework of new community regulation on Registration, Evaluation, Authorisation and restriction of CHEMical substances (REACH), the forms of existing nanomaterials should be treated as new substances due to their unique properties. In particular it will be necessary to know if established thresholds for the production and importation of such substances are effective also for nanoparticles.

³⁴ <http://cordis.europa.eu/nanotechnology/actionplan.htm>

³⁵ [COM\(2008\)0366](#)

3. BACKGROUND NOTES FOR NEW COMMISSIONER HEARING ON FOOD/FEED SAFETY

3.1 Introduction

The Treaty of Nice of 2001 provided for a new amendment to the appointment procedure of the European Commission. *"Thereafter the Council, meeting at the level of Heads of State or Government and acting by a qualified majority, were to nominate the President. After approval of the President nominated by the European Parliament, the Council, by common accord with the nominated President, was to adopt by qualified majority the list of the Commissioners that it intended to appoint, a list drawn up in accordance with the proposals made by each Member State. Each appointed commissioner responsible for a specific portfolio faces a public hearing in front of the respective parliamentary committee. After approval by the European Parliament, the President and the other Members of the Commission were to be formally appointed by the Council acting by a qualified majority".*

This chapter aims at providing members of the ENVI Committee with some ideas, suggestions and recommendations to prepare the new Commissioner hearing in the field of food safety, according to their normative implications. Suggested main priorities/questions could be identified as follows:

- **GMO Basic Regulation** needs to be correctly and effectively implemented by all parties;
- **Epidemic diseases linked to animal health** diseases affecting animals which can harm human health through various forms of transmission are increasingly common and it appears they may become a recurrent phenomenon to be kept under control;
- **The evolution of food preparation techniques** (i.e. new ingredients, novel foods, new methods of packaging) must be monitored in order to prevent the danger of food fraud and new possible sources of contamination;
- **Information on the products in commerce** is crucial in terms of the requirements placed on producers as well as regards to the dangers linked to incomplete or wrong communication.

3.2 Contaminants in food

3.2.1 Main priorities and challenges for the forthcoming parliamentary mandate 2009-2014

The European Union will be setting maximum levels for certain contaminants, with a view to reducing their presence in certain foodstuffs to the lowest levels reasonably achievable by means of good manufacturing or agricultural practices. The core objective is to achieve a high level of public health protection, especially for sensitive population groups, such as children, vulnerable groups (pregnant women, people who are weak or convalescent, the elderly) and/or people with allergies.

Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs, states (Article 9) that the Member States are responsible for supervising and controlling the level of nitrates in vegetables, especially green leaf vegetables. They shall communicate the results to the Commission by 30 June every year. Moreover, they shall communicate to the Commission the result of surveys carried out on the presence of contaminants in food every year. Further, several recommendations have been made by the Commission concerning the official checks on specific contaminants.

Monitoring of the presence of furan in foodstuffs³⁶ the Commission recommends that, during the years 2007 and 2008, Member States monitor the presence of furan in foodstuffs that have undergone heat treatment and regularly inform the European Food Safety Authority of the results.

Monitoring of acrylamide levels in food³⁷: in 2007, 2008 and 2009, Member States performed, in accordance with Annex 1 of Commission Recommendation³⁸, the monitoring of acrylamide levels in foodstuffs. According to the Recommendation, Member States provide EFSA by 1 June each year with the monitoring data referring to the previous year.

Concerning regulated contamination, particular attention should be paid to those violations which can arise from improper use of packaging materials or from the products employed during production processes.

The case of pesticides is particularly important because the Regulation of the pre-sales system is currently being updated using a very strict approach. The future challenge will be evaluating the application of new norms and their impacts on both product quality and agricultural production capacity to maintain current levels of efficiency using new products and techniques.

3.2.2 Recommended topics for Commissioner Hearing

On this basis, further open issues to be addressed are as follows:

- Has the Commission received the annual national control plan according to Article 9 of Regulation (EC) No 1881/2006 from all Member States?
- Are all EU Member States implementing their national control plans according to the recommendations reported above?
- What are the Commission's programs to facilitate the accomplishment and verify initiatives involving farmers in a sustainable employment of pesticides?

3.3 Food labelling

3.3.1 Main priorities and challenges for the forthcoming parliamentary mandate 2009-2014

Labelling is a significant communication tool and a key to enable consumers to make healthy choices, in order to avoid specific human health problems such as allergies and to help change unhealthy behaviour such as consuming "junk food". The labelling challenge is to enhance consumer awareness; European decision-makers main efforts are to simplifying the legislation framework, favouring implementation and harmonization.

The Commission's White Paper, titled "**A Strategy for Europe on Nutrition, Overweight and Obesity related health issues**"³⁹, of 30 May 2007, building on previous initiatives undertaken by the Commission and most significantly by the EU Platform for Action on Diet, Physical Activity⁴⁰ and a Green Paper on the same topic⁴¹, pointed out that the problem of overweight and obesity has been rising sharply over the past three decades and in 2006 it was affecting 30% of the population.

³⁶ Official Journal L 88 of 29.3.2007.

³⁷ Commission Recommendation of 3 May 2007 on the monitoring of acrylamide levels in food notified under document number COM(2007) 1873.

³⁸ Commission Recommendation of 3 May 2007 on the monitoring of acrylamide levels in food notified under document number COM(2007) 1873.

³⁹ http://ec.europa.eu/health/ph_determinants/life_style/nutrition/documents/nutrition_wp_en.pdf

⁴⁰ http://ec.europa.eu/health/ph_determinants/life_style/nutrition/platform/platform_en.htm

⁴¹ http://ec.europa.eu/health/ph_determinants/life_style/nutrition/green_paper/consultation_en.htm

While a great deal of legislation covered related issues over the period 2004-2009, only a small amount of progress has been made. The WHO Charter of 2006, that enjoys the EU's active collaboration, stated that "visible progress, especially related to children and adolescents, should be achievable in most countries in the next 4-5 years and it should be possible to reverse the trend by 2015 at the latest". The Commission will carry out a progress review in 2010.

Given its importance for human health and public health budgets, slowing the incidence of overweight and obesity will be a significant political challenge in the forthcoming parliamentary mandate.

3.3.2 Recommended topics for Commissioner Hearing

- Does the Commission intend to tackle the excessive administrative costs of the horizontal and specific labelling provision (i.e. in the wine sector)?
- What is the Commission's position toward a new Regulation for food and nutritional labelling in relation to a less prescriptive approach and alternative approaches such as deregulation, national Regulation, self-regulation, co-regulation, guidance?
- Which actions do the Commission intend to implement in order to improve consumer awareness in label reading, explaining and communicating that labelling is a communication instrument for the consumers rather than a threat?
- Will the Commission detail the principal aspects contained in the new proposal for a substantial legislative review of pre-packaged food and nutritional labelling, in order to improve clearness and harmonization in this complex legislative framework?
- What is the Commission's position on "origin labelling", a problematic issue that involves national trade policies and impacts the informed choice of consumers in the EU?

3.4 Food additives and food flavourings

3.4.1 Main priorities and challenges for the forthcoming parliamentary mandate 2009-2014

In December 2008 a new legislative package related to food additives, food enzymes and food flavourings was adopted. The package introduced harmonised EU legislation on food enzymes for the first time and upgraded previous rules for flavourings and additives. Within this package, Regulation EC 1333/2008 states that all Member States must monitor both consumption and use of food additives by means of a risk-based approach and they must communicate such data to the Commission and Authorities in due time.

3.4.2 Recommended topics for Commissioner Hearing

- When and by what means does the Commission want to set up a common methodology for gathering information from Member States on the consumptions of dietary food additives in the Community (as stated in article 27 of Regulation EC 1333/2008)?

3.5 Animal health

3.5.1 Main priorities and challenges for the forthcoming parliamentary mandate 2009-2014

According to the new objectives of "[The new Animal Health Strategy \(2007-2013\): prevention is better than cure](#)" (see section 2.5), profiling and categorization of biological and chemical risks will provide the basis for decisions on where the responsibility for action lies. Identified threats to animal health must be assessed to determine:

- their relevance to the four high level objectives of the EU strategy;
- the "acceptable level of risk" for the Community;
- Risk-reduction action priorities.

In order to avoid serious threats to human health and rural economy, it is essential to reduce the risk of a negligible level. But zero risk cannot be achieved in science. So even when dealing with high priority threats where a negligible level of risk is sought, the cost-benefit and cost-effectiveness of possible actions should be analysed to ensure the best use of limited resources, both in terms of EU funding and cost to producers.

This risk-based policy will give the following expected outcomes:

- biological and chemical risks categorisation according to level of relevance for the EU;
- agreement on the acceptable level of risk;
- setting priorities, quantifiable targets and performance indicators;
- setting the amount of resources to be allocated to identified threats.

Among the different issues concerning to animal health, the following require particular consideration:

Classical Swine Fever (CSF)

CSF is among the diseases that have caused the greatest socio-economic damage in the EU over recent decades. Although considerable progress has been made of late in the eradication and prevention of the disease, the threat for an epidemic still exists. The main reasons are that CSF virus is still present in feral pigs of some Member States and that the virus is endemic in the Balkan region.

In order to support the Commission and Member States in improving the control and eradication measures as regards classical swine fever in feral and domestic pigs, [scientific advice from EFSA](#) has been requested in this area (Article 29 of Regulation EC N° 178/2002).

Bluetongue

Council Directive 2000/75/EC as regards the control, monitoring, surveillance and restrictions on the movement of certain animals of susceptible species in relation to bluetongue, provides a regulatory framework on bluetongue. The Regulation aligns EU rules with international standards and reduces obstacles to trade that bluetongue may cause while maintaining an adequate level of guarantees.

However, during the discussions with Member States and consultation with stakeholders some gaps on scientific knowledge and scientific advice on bluetongue have been identified. In view of the disease evolution and the previous scientific opinions provided by EFSA, the current situation on bluetongue in Europe requires special consideration as regards the needs to:

- review and update previous opinions on vectors ecology (models for distribution/density), in order to identify more accurate and applicable criteria for the determination of the seasonally free period;
- review and the update previous opinions concerning over-wintering mechanisms and the length of viraemia of BT virus;
- review and update previous opinions and provide a scientific assessment of appropriateness of insecticides and repellents for Culicoides, including adequate protocols for their use;
- provide a scientific assessment on the appropriateness of a set of measures, different elements and the combinations that could be used to protect animals against attacks by vectors;
- assess the risk of transit as defined in Regulation (EC) N°1266/2007, in particular taking into account the treatment with insecticides/repellents of animals and/or the means of transport.

Avian influenza (flu)

It is expected that the EU will face further incursions of avian influenza infections in the years to come. Member States have gained practical experience in dealing with outbreaks of high and low pathogenic avian influenza. Legislation on disease control and diagnostic techniques has been updated recently.

However, new scientific information that could be of use to risk managers is available. The latest EFSA Scientific opinion on the matter was published on 5 June 2008.

During the Beijing Conference on Avian and Human Pandemic Influenza, the participants subscribed to a long-term strategic partnership among the international community and the countries affected or at risk, in which adequate and prompt financial and technical support was mobilized to complement the efforts, particularly of developing countries. The EU alone made a commitment of up to 80 million Euro financial aid.

Aquatic species susceptible to diseases listed in Directive 2006/88/EC

On 24 October 2006, the Council of the European Union adopted a new Directive on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals (2006/88/EC). The Directive lists certain diseases and the list of susceptible species to those diseases.

The Commission requested EFSA to issue a scientific opinion on [Aquatic species susceptible to diseases listed in Directive 2006/88/EC](#). The scientific opinion includes a list of non-listed species that could be considered as susceptible.

If these potentially susceptible species become infected with a listed pathogen, there would be a risk of transmission of a disease agent. This circumstance may affect disease control measures. Therefore, it is necessary to define a set of scientific criteria for the assessment of host species susceptibility.

3.5.2 Recommended topics for Commissioner Hearing

Classical swine fever

- What can be done to control and eradicate CSF in feral pig populations?
- Is fresh meat derived from vaccinated pigs safe enough to be put on the market or must it be destroyed?

Bluetongue

- When will the Commission ask for new scientific opinion and assessment on Bluetongue, to review and update old information?
- When will the Commission integrate new scientific information into the legal framework?

Avian influenza (flu)

- According to EFSA scientific opinion: what measures will be taken to tackle further incursions of avian influenza infections in the years to come?
- Does the Commission intend to promote the adoption and actuation of the Beijing commitments and what steps is it willing to take in order to comply with them?
- Will the decision to take action depend on the submission of national plans by the affected countries?
- Given the conclusion of the Conference that 'we must take measures to prepare for a possible human pandemic', would such a delay not imperil the delivery and use of the above funds promptly?

Aquatic species susceptible to diseases listed in Directive 2006/88/EC

- According to EFSA scientific opinion: when will the species listed in Part II of Annex IV to Directive 2006/88/EC be updated?

3.6 Animal nutrition

3.6.1 Main priorities and challenges for the forthcoming parliamentary mandate 2009-2014

In 2008 the Commission set out a Proposal for a Regulation "on the placing on the market and use of feed [COM\(2008\)124](#)" which provides for a complete overhaul of European animal feed legislation. The project is included in the Commission's rolling programme of simplification. Thus, with the prerequisite of assuring the high level of feed and food safety achieved in the Community, the general objectives are to consolidate, revise and modernise the Directives on the circulation and labelling of feed materials and compound feed. European Institutions have already chosen the route of a review aimed to set simpler legislation for feedstuffs. The future challenge is to define this new set of rules taking into account the interest of the various operators working along the feed chain.

3.6.2 Recommended topics for Commissioner Hearing

The label of feed materials and compound feed has a double purpose: on the one hand to enhance enforcement, traceability and control, on the other hand to transmit as much relevant information as possible to the user. At the same time, the label must not reveal sensitive industrial information to competitors. This is true for industries which produce for farms as well as for those that produce pet food destined for retail⁴².

- How does the Commission intend to satisfy both consumers' need to be informed and feed producers' need to protect their industrial secrets?

3.7 Novel Foods

3.7.1 Main priorities and challenges for the forthcoming parliamentary mandate 2009-2014

The **White Paper on Food Safety** announced, among others, Commission's intentions to examine the application of novel food legislation and to make the necessary adaptations to the existing legislation⁴³. **Novel Food Regulation now requires clarification after the removal of GM food from the category.**

⁴² [COM\(2008\)124](#)

⁴³ In accordance with the conclusions of the report on the implementation of the Regulation (EC) No 258/97 on novel foods and novel ingredients (Actions 14 and 51) and in accordance with the regulatory framework of Directive 90/220/EEC on GMO's. Partly accomplished by the adoption of the Regulation (EC) on 1829/2003 on GM food and feed.

2002 stakeholder consultations on a Commission White Paper and subsequent evaluation underlined the need to further develop a regulation on novel foods.

In accordance with these commitments the core objectives are to:

- ensure food safety;
- protect human health;
- secure the functioning of the food internal market.

In order to achieve these objectives, it aims to streamline the authorisation procedure, develop a better adjusted safety assessment system for traditional food from third countries, which is considered as novel food under the current Regulation, and **clarify the definition of novel food**, including new technologies with an impact on food, and the scope of the novel food Regulation. Further, there is a need to **improve the efficiency, transparency and application of the authorisation system**, which also contributes to better implementation of the Regulation and to empower consumers by informing them about food. In addition, **legal clarity should be achieved** by making necessary changes and updating the legislation.

3.7.2 Recommended topics for Commissioner Hearing

- Are there plans for the Adoption of a Regulation of the European Parliament and of the Council on novel foods that regulates the placing on the market of novel foods, laying down rules for authorisation, supervision, labelling and use of novel foods?
- Will the Commission repeal EC Regulation No 258/97 on novel foods and novel food ingredients laying down the general principles for authorisation of novel foods and food ingredients in the European Union?
- Will the Commission repeal EC Regulation No 1852/2001 laying down detailed rules for making certain information available to the public and for the protection of information submitted pursuant to EC Regulation No 258/97?

3.8 Genetically Modified Organisms (GMOs)

3.8.1 Main priorities and challenges for forthcoming parliamentary mandate 2009-2014

The EU is highly committed to halting the loss of biodiversity by 2010. Current policies involving the release of GMOs into the environment and their potential impacts are widely discussed among European Institutions, Member States, consumers, industry and the scientific community.

3.8.2 Recommended topics for Commissioner Hearing

Release of GMOs into the environment and their potential impacts require Commission's actions in particular on the following aspects⁴⁴:

- How will the Commission introduce economic and social risk assessment on the authorization procedure?
- How will the Commission ensure a more effective information system on GMOs among citizens?

⁴⁴ Sources:

- Council Conclusions On Genetically Modified Organisms (GMOS) 2912th Environment Council Meeting Brussels, 4 December 2008;
- Draft Report On The Implementation Of EU Legislation On GMOS, In Particular Directive 2001/18/EC And Regulations (EC) No 1829/2003 And 1830/2003 – by ENVI (rif. 2008/2306(INI));
- COM (2004) 575, COM (2007) 81, COM (2006) 626, COM (2008)560, COM (2006) 104, COM (2009) 153;
- On 22 May 2006 the Council of Agricultural Ministers adopted Conclusions on Coexistence in which it invites the Commission to come forward, as soon as possible, with Community labelling thresholds for seeds.

- How will the Commission improve communication with the Member States in the authorisation process of new products?
- How will the Commission ensure better harmonization in sampling and detecting GMOs?
- How will the Commission favour harmonization in environmental risk assessment?
- Will the Commission strengthen the role of EFSA in the exchange of information and documentation among the organizations involved in the authorization procedure, and in what way?
- Will the Commission structure the creation of GMO-free zone? And how?
- How will the Commission improve the monitoring of health risks for the population and for animals?
- What is the position of the Commission towards products such as meat, milk, eggs and other animal products produced from animals fed with GM feedstuffs in the current legislation framework?
- What is the Commission's position toward lowering the threshold for adventitious or technically unavoidable presence of GM materials in products?
- When will the Commission establish a specific labelling threshold for the adventitious or technically unavoidable presence of GM materials in seeds?

3.9 Nanotechnologies applied to foods

3.9.1 Main priorities and challenges for the forthcoming parliamentary mandate 2009-2014

EU main concern on this topic is the identification of potential risks arising from nanoscience and nanotechnologies for food and feed safety. It is claimed that nanotechnologies offer a variety of possibilities for application in the food and feed area – in production/processing technology, in food contact materials improvement, in food quality and freshness control, in traceability and product security enhance, in taste, texture, sensation, consistency and fat content modification, and in nutrient absorption enhance.

Food packaging makes up the largest share of the current and short-term nanomaterial market. Formulation at the nanosize may change the physical-chemical characteristics of materials as compared to the dissolved and micro/macro scale forms of the same substance. Their small size, high surface-to-mass ratio and surface reactivity are important properties, both for new applications and in terms of the associated potential health and environmental risks.

3.9.2 Recommended topics for Commissioner Hearing

Recommended topics are based on EP resolutions (see chapter 2, section 2.10) and EFSA scientific opinions.

- What is the current state of the risk assessment of nanotechnologies applied to food? In particular, is there sufficient data to define contamination risks or risks for human health from ingesting foods containing nanotechnologies?
- How does the Commission intend to monitor current and future commercial applications of engineered nanomaterials (ENMs) in the food and feed sectors?
- More complex ENMs are foreseeable for the future. How does the Commission intend to monitor the developments in nanotechnologies?

4. IMPLEMENTATION REVIEW

This Chapter illustrates one of the most important factors of the development of European Community (EC) law: its implementation into the national legal systems of the Member States. Relevance and effectiveness of EU policies depend on the level of implementation from the Commission to the Member States, their laws, their local authorities and administrators. The failure to implement European legislation consistently across the Member States can create severe distortions of competition, lead to loss of growth opportunities and erode public confidence in Community legislation. European Institutions have to make a greater effort to ensure the uniform implementation of Community law and the removal of bureaucratic obstacles in order to help the implementation process.

This chapter provides a qualitative overview in some EU Member States of the national legislative provisions in six food related sectors: hygiene package; animal health; animal nutrition; nutrition labelling; ingredients and GMOs.

The first chapter is a national implementation analysis focusing on the hygiene package, ranging from food hygiene standards to the management of residues of veterinary practices.

The second chapter deals with TSE animal health provisions. In this case an assessment is given on the global situation at European Union. Subsequently, an assessment of the situation on animal nutrition inspection systems has been carried out.

The fourth assessment concerns two fundamental legislative acts: Regulation EC 1924/2006 on health and nutritional indications and Directive 2003/89/CE on information on allergen labelling. The selected EU countries have been chosen for the assessment to be representative of long-standing and newly-joined Union members.

The last analysis refers to the controversial issue of products derived from Genetically Modified Organisms. Detailed information is given on the situation regarding the application of the following: Directive 2001/18/EC, Regulation EC 1829/2003 and Regulation EC 1830/2003.

4.1 Hygiene package⁴⁵ - contaminants in food

Regulations regarding the hygiene package introduce the principle of giving to operators along the food supply chain greater responsibility with regards to the hygiene and safety of their products. This seems, at worst inadequate, and at best inconsistent given the diversity of organizations operating along the food supply chain in Member States (farmers and enterprises both small and large, transport companies, distributors).

Regulations have also introduced the possibility of adapting the requirements to the structures and processes of organizations to the specific type of activity. This has led to a higher level of discretion being given to those responsible for controls within the Member States. This often fails to ensure consistency in judgment, not only between Member States but often also internally.

Hygiene procedures' manuals have often seen little use in practice, particularly in small and medium sized enterprises, specifically due to the difficulty in performing correct and extensive risk analysis.

Certain local producers, for example, operating on a small scale, encounter difficulties due to the lack of predictive microbiology models. The result of this is many producers make safe products thanks to traditional processes developed over time and thanks also to the care they take in their work. They are still not, however, in a position to formally document the requirements which guarantee the safety of their produce.

⁴⁵EC Regulations 852/2004, 853/2004 and 854/2004.

This, aside from causing difficulties for those responsible for carrying out checks, contributes to the creation of difficulties in exchanges both within the community but moreover externally. To solve this, it would be necessary to reinforce the training of those charged with making official checks and to favour communication between members on the questions of organisation and control methods. As regards operators it would be useful to create and expand, for each type of production, industrial best practice manuals.

The two main components that have been analyzed are: hygiene of foodstuffs (Hygiene Package) and residues by veterinary practices (food contaminants) which have been analyzed in more depth in the next pages.

- Hygiene of foodstuff

During the period June 2004 to October 2005 a series of missions was undertaken by FVO to all Member States with the objective of assessing systems that were in place for the official control of the hygiene of foodstuffs. Specifically the mission evaluated the implementation of the hygiene requirements set out in Council Directive 93/43/EEC⁴⁶ and the official control requirements set out in Council Directive 89/397/EEC⁴⁷. These requirements remain valid in the recast of food and feed control legislation i.e. Regulations (EC) 852/2004⁴⁸ and 882/2004⁴⁹ concerning the rules on food hygiene and the organisation of official control activities (applicable from 1 January 2006).

In respect of the hygiene requirements this mission series found that while all Member States had put in place structures for control systems there was a great variance in how these were organised, notably with regard to the frequency and effectiveness of the inspection of food establishments. In particular, certain deficiencies were found in aspects of official control (i.e. failure to meet stated sampling targets or inspect food premises at an adequate frequency). In addition, almost all Member States had failed to enforce certain aspects of the rules on hygiene, specifically the requirement that all food businesses put in place systems and procedures based on HACCP principles. This was particularly evident in the retail and catering sectors. These deficiencies were often linked by the competent authorities to shortfalls in available resources.

Council Directive 93/43/EEC required Member States to encourage the development of Guides to Good Hygiene Practice and to date over 400 national guides have been notified to the Commission services. However, it was noted that there was significant variation in the number and quality of these Guides. Article 8 of 93/43/EEC also required that inspectors give due consideration to such guides where they exist; there was, however, very little evidence of this during the inspections. Both of these provisions have been incorporated into the new Regulation (EC) No 852/2004 on the hygiene of food and feed.

The nature of deficiencies noted during this series of missions did not give rise to health concerns that would require urgent action and almost all Member States responded to the request for an action plan in response to the recommendations made in the final reports. The findings of the mission series have been reviewed and those Member States found to be weak in terms of the effectiveness of their official controls, or in their response to recommendations were the focus of inspections carried on May 2007.

During this last inspection mission, good progress was noted with regard to the implementation of the action plan and the overall compliance with the provisions of Community legislation regarding hygiene requirements in Germany and Poland. Official controls also improved and were increasingly in line with the provisions of Regulation (EC) No 882/2004 on official controls. In Finland, Hungary, Italy, Sweden and the United Kingdom some progress in both areas was noted; nevertheless deficiencies with regard to basic hygiene rules and official supervision still persisted. In comparison to the 2006 inspections no progress was noted in Greece, Malta, Portugal and Spain.

⁴⁶ Council Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs.

⁴⁷ Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs

⁴⁸ Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs

⁴⁹ 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

In Bulgaria initially the controls carried out by the competent authorities in relation to structural requirements, eligibility of raw material, traceability and identification/labelling of products were not reliable. By the end of April 2007, however, the competent authority had the capacity and capability to evaluate establishments correctly for approval for intra-Community trade. Deficiencies in the ability of the competent authorities to evaluate establishments for approval for intra-Community trade were also identified initially in Romania. In the course of 2007 good progress was made to bring the evaluation of establishments into line with EU requirements. In both Member States, problems remained with regard to official controls over compliance with raw milk criteria.

- Residues by veterinary practices

Council Directive 96/23/EC⁵⁰ lays out the requirements that each Member State must meet in relation to the planning and execution of their national residue control plans for live animals and products of animal origin. The principal objective of the legislation is to ensure that Member States:

- (a) detect the abuse of substances illegally used in animal production, the misuse of authorised veterinary medicines; and
- (b) take appropriate actions to minimise recurrence.

Council Directive 96/23/EC obliges Member States to check live animals and animal products for residues of veterinary medicinal products and contaminants. In the vast majority of Member States the primary criterion for inclusion of a certain residue in the national residue control plan is the ability of the laboratory (network) to analyse for it. The selection of analytes is sometimes also based on perception of which medicines within therapeutic categories are likely to be used in certain production sectors.

The validation of analytical methods and accreditation of laboratories remain major tasks for the majority of Member States. Progress is being made but it is slow. Few deficiencies in the authorisation of veterinary medicinal products were seen although the 'special licence' systems, established to address small internal markets for veterinary medicines, could result in consumers being exposed to residues of substances so authorised. Different approaches are also being taken with regard to medicated feedingstuffs, particularly concerning the requirements for monitoring homogeneity and stability of final product and the issue of top dressing. The issue of medicine controls, especially at the level of farm and veterinary practitioner, is one where there is particular divergence between Member States. Following each of the individual reports, Member States were requested to produce 'action plans' to address the recommendations made. Action plans have been produced by all Member States. In the case of those Member States who submitted action plans in advance of the final report being issued, their plans have been published on the Commission's website alongside the final report. Member States have, in general, responded positively.

4.2 Animal health

The main objective is to protect and raise the health status and condition of animals in the Community, in particular food-producing animals, whilst permitting intra-Community trade and imports of animals and animal products in accordance with the appropriate health standards and international obligations.

⁵⁰ Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC

This chapter focuses on two major EC measures related to animal health:

- Regulation (EC) No 999/2001⁵¹, as amended⁵², and specifically addressing both active and passive TSE epidemic-surveillance in bovine animals; control and eradication of TSE in ovine and caprine animals and, lastly, the removal and handling of Specified Risk Material (SRM);
- Council Decision 2000/766/EC⁵³, as repealed⁵⁴, and addressing the prohibition of feeding processed animal proteins (PAP) to farmed animals (the "total feed ban"), and exceptions applicable to this prohibition.

4.2.1 Assessment of Regulation (EC) No 999/2001

In most Member States, the legal and administrative frameworks were further strengthened. Nonetheless, a number of shortcomings could be summarized as:

- national legislation not always is fully in line with Community legislation;
- implementation of the programme demonstrated certain inconsistencies, which were mainly due to a lack of co-ordination between the Competent Authorities (CA) at central and regional level;
- instructions and/or records concerning the supervision and monitoring of the BSE epidemio-surveillance were not sufficient to satisfactorily demonstrate that all eligible animals were being tested. Although the central bovine databases are recognised by the Commission as being fully operational in many Member States, this tool was not always sufficiently used in monitoring the efficiency of the surveillance programmes.

All EU Member States have a system in place for the identification and registration of small ruminants. However, Council Directive 92/102/EEC⁵⁵ as repealed⁵⁶, was not sufficiently implemented or enforced in some cases.

In some EU Member States the TSE monitoring programmes in ovine and caprine animals were either delayed or in the implementation phase at the time of the mission.

The control measures and/or TSE monitoring programmes as applied in the Member States did not always fully meet the requirements laid down in Regulation (EC) 999/2001, as amended. The main deficiencies concerned the level of awareness for scrapie amongst farmers, the collection of fallen stock, the control on the eligibility of animals and the supervision of the monitoring programme.

Adequate legal and administrative measures related to Specified Risk Materials (SRM) are largely in place in the MSs. In terms of implementation measures, the Competent Authorities often did not issue specific instructions aimed at uniform application of the Decision's requirements, and/or the necessary checks on the age of the animals. Responsibility for the removal, collection and disposal of SRM was largely left to the plants, whose staff did not receive sufficient or ongoing training/instruction to ensure adequate knowledge on what and how to remove.

SRM was usually removed manually and only in some MSs additional measures were adopted aimed at preventing / minimising cross contamination; only in some MSs the official staff had been instructed to carry out a final control of the carcasses, which may lower the detection of residual spinal cord in carcasses.

⁵¹ Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies

⁵² Commission Regulation (EC) No. 357/2008 - 22 April 2008 – amending Annex V to Regulation (EC) No. 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies.

⁵³ OJ L 306, 7.12.2000, p. 32

⁵⁴ Commission Regulation (EC) No 1234/2003 of 10 July 2003 amending Annexes I, IV and XI to Regulation (EC) No 999/2001 of the European Parliament and of the Council and Regulation (EC) No 1326/2001 as regards transmissible spongiform encephalopathies and animal feeding

⁵⁵ Council Directive 92/102/EEC of 27 November 1992 on the identification and registration of animals

⁵⁶ Council Directive 2008/71/EC of 15 July 2008 on the identification and registration of pigs (Codified version)

4.2.2 Assessment of Council Decision 2000/766/EC as repealed by Commission Regulation (EC) No 1234/2003

Considerable efforts have been made by EU Member States to implement the total feed ban.

Separation requirements to avoid cross contamination of ruminant feed with derogated PAP (Processed Animal Proteins allowed under the derogation foreseen in Article 1 of Commission Decision 2001/9/EC: fishmeal, hydrolysed proteins and dicalcium phosphate) were interpreted differently among MSs, resulting in either production in dedicated plants only or production in separate lines. In the latter case, the effectiveness of this separation was not always properly verified. In addition, the potential for cross contamination through means of transport was not always adequately addressed.

MSs did set up systems of animal feed controls. However, their effectiveness was affected by weaknesses in their organization: frequent non-compliance with the sampling procedure, sometimes insufficient co-ordination between the different competent bodies, the exclusion of some stages of production and use, and a lack of verification of the performance of the laboratories approved for the animal feed controls were the most common deficiencies. In addition, delays in the production of test results – due to lack of laboratory capacity – made the adoption of adequate corrective action difficult.

4.3 Animal nutrition

An assessment of the situation on animal nutrition inspection systems has been carried out as closely interlinked with the animal health aspects.

In most EU Member States the systems in place for official inspections, approval and registration were largely satisfactory. However, there were considerable differences in some areas and some common weaknesses in the design and implementation of these systems which hampered a uniform official supervision over the feed sector. In few EU Member States, a limited control programme, lack of import controls in certain feed materials and lack of documented verification in approval and registration procedures undermined the efficacy of their official controls. In a small number of EU Member States, the approval and registration procedures were just starting or had been considerably delayed.

The official controls in the field of animal nutrition in the EU Member States were frequently organised under the administration of different Ministries/official services. Responsibilities between the services involved and their co-operation were in general established. However, in nine EU Member States, gaps in the responsibilities and insufficient cooperation for certain tasks between central, regional, local levels and/or with customs may have hampered the effectiveness of official controls.

In five EU Member States, limited financial and/or staff resources led to shortcomings in the official control system and/or delays in the approval and registration of operators. In one EU Member State, the independence of private bodies, to which some tasks in the approval and registration procedure had been delegated, was not ensured.

Official inspections in the field of animal nutrition were applied in all EU Member States on the basis of Community legislation. EU requirements as laid down in Directive 95/53/EC were largely transposed, be it with considerable delay in three EU Member States. In all EU Member States except one, annual control programmes had been drawn up largely in line with EU requirements and the annual Commission Recommendations on the coordinated inspection programmes. In general, the measures were applied accordingly and a considerable number of inspections and analyses were carried out annually. All EU Member States had established a rapid alert system for feed (RASFF) in line with EU requirements for information about serious risks to animal and/or public health identified in feedingstuffs⁵⁷.

⁵⁷ Regulation (EC) No 178/2002 of 28 January 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 safety

4.4 Nutrition labelling: implementation status of Regulation EC 1924/2006

Regulation EC 1924/2006 on nutrition and health claims made on foods sets different provisions for the management of nutrition claims and health claims.

This Regulation defines:

- "claim" any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics;
- "nutrition claim" any claim which states, suggests or implies that a food has particular beneficial nutritional properties;
- "health claim" any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health.

In addition, a nutrition claim indicates food nutritional properties related to:

- high/low calories or energy indication (i.e. low in fat);
- presence or rate of substances contained in food (like salt or fat, cholesterol free).

The Regulation establishes that foods can be eligible to bear a nutritional claim only if the overall content of substances is in line with the prescription of scientific knowledge established by EFSA.

In order not to mislead consumers in their purchase decisions EFSA should have issued nutritional profile of each category of foods by 19 January 2009. The compliance to this profile is necessary for a food to bear a nutritional claim.

A health claim is any representation in labelling or advertising that states, suggests or implies that a relationship exist between consumption of an ingredient in the food and a person's health.

In January 2009 EFSA published the list of the 4,185 main health claims received from the Commission for assessment as well as a great number of new "functional" health claims, based on newly developed scientific evidence. Some of them were rejected as misleading for the consumers and were sent to the European Parliament in order to exercise its right of scrutiny.

Different and stricter rules apply to children health claims relating to reduction of disease risk or to children's development or health, which fall under Article 14 of the Regulation, which can be registered in the "positive list" only after being assessed by EFSA and approved by the Commission and Member States.

The technical Committee has received to date 249 applications and 14 applications have been withdrawn; 52 scientific opinions have, to date, been adopted, covering 59 applications. Technical guidance for the preparation and the presentation of the application for health claim authorisation is also applicable to article 14 claims.

The Commission must submit a first report on the implementation of the Regulation to the EP and Council by January 2013. The report must include an evaluation of the impact of the new legislation framework related to nutrition and health claims on dietary choices and the potential impact on obesity and non-communicable diseases.

4.5 Ingredients: Directive 2003/89/EC

New food allergen labelling rules were introduced by Directive 2003/89/EC⁵⁸. This Directive requires food manufacturers to indicate 12 groups of potential allergens by reference to the source allergen if they are used as an ingredient at any level in pre-packed foods, including alcoholic drinks. The new rules also abolish the “25 percent rule” under which it was not mandatory to label components of compound ingredients if they made up less than 25 percent of the final food product. The new allergen labelling rules were to be fully implemented as from November 25, 2005. Products not complying with the new legislation are prohibited for sale in the EU.

The table below presents the status of implementation of this legislation in several EU countries.

Table 1: Directive 2003/89 – implementation status

Member State	Implementation notes
Czech Republic	<p>Text title: Decree on labelling of foodstuffs and tobacco products of 4 March, 2005. In force since 2005.</p> <p>Abstract: This Decree of the Ministry of Agriculture, which is composed of 15 articles, and implements more several EC Directives, sets out provisions on labelling of foodstuffs and tobacco products, including genetically modified foodstuffs. The provisions are laid down as per categories of products.</p>
France	Passed into French Law by Decree 2005-944 on August 2nd 2005. In force since August 6th 2005.
Italy	<p>Text title: Legislative Decree No. 114 implementing Directives 2003/89/EC, 2004/77/EC and 2005/63/EC as regards indication of the ingredients present in foodstuffs of 23 March 2006.</p> <p>Abstract: In implementation of Directives 2003/89/EC, 2004/77/EC and 2005/63/EC, this Legislative Decree lays down some amendments to Legislative Decree No. 109 of 1992 concerning the labelling, packaging and advertising of foodstuffs. The amendments regard the indication of the ingredients present in foodstuffs.</p>
Poland	<p>Text title: Regulation on labelling of food products. Of July 10 2007. In force since 1 August 2007.</p> <p>Abstract: The present Regulation of the Minister of Agriculture and Rural Development regulates labelling of foodstuffs serviced in packaging or foodstuffs without packaging intended directly for ultimate consumption or to mass caterers. The Regulation is composed of the following Sections: General provisions (sect. 1); Provisions concerning labelling of all foodstuffs in packaging (sect. 2); Detailed provisions concerning labelling of individual types of foodstuffs (sect. 3); Transitional and final provisions (sec. 4). The following information has to be provided on the packaging: name of foodstuff; information about components; date of minimal durability or date of usefulness for consumption; method of preparation, if required; data identifying foodstuff producer; net weight or number of pieces in the package; conditions of storage, if required; marking of production portion; class of commercial quality, if required.</p>

⁵⁸ Amending general food labelling Directive 2000/13/EC.

Member State	Implementation notes
Portugal	<p>Text title: Decree-Law No. 126/2005 implementing EC Directive No. 2003/89/CE on foodstuff ingredients. August 5th 2005. In force since 2005</p> <p>Abstract: This Decree-Law, composed of 6 articles, introduces in the national legal system, EC Directive No. 2003/89/CE ruling on foodstuff ingredients' indication. In particular, it rules on the substances not to be considered as ingredients, and on the definition of composite ingredients. Finally, it rules on labelling requirements for alcoholic beverages.</p>
UK	<p>Text title: Food Labelling (Amendment) (No. 2) Regulations 2004 (S.I. No. 2824 of 2004). 20 October 2004. In force since 26 November 2004.</p> <p>Abstract: The Regulations require that in the case of food containing any allergenic ingredient or an ingredient originating from an allergenic ingredient referred to in paragraphs 1 to 11 of the Schedule, the food be marked or labelled with a clear reference to the name of the allergenic ingredient concerned (reg. 12 and 14). There are exemptions in the case of food which is not prepacked, food which is prepacked for direct sale and fancy confectionery products (reg. 10(b) and 11). They extend the allergen labelling requirements to specified packages and bottles as a national measure (reg. 26 of the principal Regulations and reg. 4 and 12 of these Regulations refer). The Regulations remove the previous exemption from ingredient listing in the case of the ingredients of a compound ingredient which constituted less than 25 per cent of the finished product, whilst providing a limited exemption for some compound ingredients constituting less than 2 per cent of the finished product (reg. 7(b) and (c)). The Regulations make some other adjustments to the detailed rules regarding the order in which ingredients are to be listed (reg. 5) and add a further ingredient to those which do not need to be named (reg. 8(b)). The Regulations make some consequential amendments (reg. 3(b), 6, 7(a), 8(a), 9 and 15) and contain a transitional provision (reg. 13).</p>

4.6 Genetically Modified Organisms (GMOs): implementation status of the current legal framework referring to GMOs, GM foods and GM feeds

The EU, according to evaluation of the Council⁵⁹, has defined comprehensive legal framework to manage GMO and it is therefore necessary to look for improvement of the implementation of current legal framework composed of:

- **Directive 2001/18/EC** on the deliberate release into the environment of genetically modified organisms;
- **Regulation EC 1829/2003** on genetically modified food and feed and
- **Regulation EC 1830/2003** concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.

⁵⁹ Council Conclusions on Genetically Modified Organisms (GMOs), 4 December 2008

The Commission has published two reports on the implementation of Directive 2001/18/EC⁶⁰, one report on the implementation of Regulations EC 1829/2003⁶¹ and EC 1830/2003⁶² and two reports on the coexistence of genetically modified crops with conventional and organic farming⁶³.

Status of implementation of Directive 2001/18/EC.

All EU Member States have already transposed Directive 2001/18/EC into national laws. In general Member States shall:

- adopt any measure to avoid negative effects on human health and on the environment due to the deliberate release and putting on the market of GMOs and GM products;
- assure that only GMOs authorized according to the Directive may be released or put on the market in their territory;
- establish a competent national authority for receiving notification and managing the part of the authorization procedure assigned to Member States;
- conduct environmental risk assessment, if required, to complete the authorization procedure;
- establish a communication system with EFSA, the commission and the other stakeholders;
- implement a system of controls to verify the respect of the Directive requirements and an alert system for risky situations.

Every three years, Member States shall send the Commission a report based on the implementation status of the Directive and on their experience with GMOs. The Commission shall forward a summary of these reports to the European Parliament and to the Council, making it accessible to the public, and add, if suitable, appropriate proposals.

Member States, according to the Directive 2001/18/EC, can adopt restrictive measures for cultivation or trade of authorized GMOs, if there are specific environmental situations that can be compromised in case of coexistence as documented on a scientific basis. GMO-free zones can, however, be created on the basis of voluntary agreement.

Table 2: EU Member States who have a total or partial ban for GMOs

Area	Detail on the ban
Austria	Ban on cultivation of Monsanto maize MON 810, MON 863 and T25 Notified in June 1999, initially under Article 16 of Directive 90/220/EEC, and subsequently maintained in February 2004 under Article 23 of Directive 2001/18/EC
France	Ban on cultivation of Monsanto maize MON 810. Notified in February 2008, under Article 23 of Directive 2001/18/EC; and under EU Regulation 1829/2003
Greece	Ban on cultivation of Monsanto maize MON 810. Application lodged in April 2005 under Article 18 of Directive 2002/53/EC, and subsequently in January 2006 extended/maintained the measure under Article 23 of Directive 2001/18/EC
Hungary	Ban on cultivation of Monsanto maize MON 810. Notified in September 2006, under Article 23 of Directive 2001/18/EC
Italy	General ban on the cultivation of all genetically

⁶⁰ COM (2004) 575, COM (2007) 81

⁶¹ COM (2006) 626

⁶² COM (2008) 560

⁶³ COM (2006) 104, COM (2009) 153

Area	Detail on the ban
	engineered crops. Notified by ministerial circular in March 2006. This ban will stay in place until the Italian regions have regulated the “coexistence” between GM, conventional and organic crops.
Luxembourg	Ban on cultivation of Monsanto maize MON 810. Notified in March 2009, under Directive 2001/18/EC
Poland	Ban on cultivation of Monsanto maize MON 810. Application lodged in March 2005 under Article 16 of Directive 2002/53/EC (EU Seeds Directive). The ban under the Seeds Directive affects 16 out of 31 MON 810 varieties. However, in May 2006 the Polish government complemented the ban with a general prohibition –based on national law- to sell any GM seeds in Poland.

Source: www.gmo-free-regions.org

Status of implementation of Regulation EC 1829/2003 and Regulation EC 1830/2003.

Regulation EC 1829/2003 and Regulation EC 1830/2003 are directly applicable in all EU Member States. They must determine systems of penalties for the violation of any legislation and develop a monitoring system to be run by national authorities. Controls on the compliance with Regulations and Directives are conducted according to national control systems, but there is still little harmonization in sampling and detection methods. National authority control methods of the prevention system adopted by operators that do not label their traditional products due to adventitious and unavoidable presence of GMOs are set at different levels: some refer to documentation while others investigate even the production methods. The extension and the quality of controls implemented are strongly influenced by the high cost of sampling and analysis.

There are also difficulties in monitoring unauthorized GMOs and genetically stacked events because valid analytical methods have yet to be officially established. The flow of information on the presence of GMOs along the food chain does not always work well even though some resistance encountered immediately following the introduction of traceability Regulations has been overcome. Traceability requirements are applied principally in feed exchanges both national and international.

As of March 2009 there are 27 authorized GM products, 14 of which are notified as existing products whose approval is granted on the basis of pre-2003 Regulations⁶⁴. No new authorization was for cultivation after 1998; within those authorized there are 3 existing products with scope for cultivation.

The only genetically modified plant cultivated in the EU is maize MON810 (renewal of authorisation already submitted) for about 100.000 hectares (2008), representing 1,2 % of the total area of maize cultivation in the EU; interested states are Spain, Portugal, Germany, Czech Republic, Romania and Slovakia.

The most active states in presenting notification for GM foods or feeds are the United Kingdom, Germany, France, the Czech Republic and the Netherlands⁶⁵.

At the moment about 50 scientific assessments are still pending⁶⁶. Due to this there is a need to strengthen cooperation between Member States and EFSA.

⁶⁴ The Community register of GM products.

⁶⁵ EFSA – www.efsa.europa.eu

⁶⁶ EFSA - www.efsa.europa.eu

Coexistence

EU Member States have to implement a legislation framework to assure coexistence between GMO crops and GMO free crops. As of February 2009, 15 Member States have adopted specific legislation on coexistence and three have already sent drafts to the commission.

The management of coexistence presents various questions that relate to cross contamination between GM plants and conventional crops (including organic crops)

The Commission, in deciding which approach to take toward the problem of coexistence, has to take into account the international trade contest that, through the WTO, has heavily criticised the precautionary position of the European Union, initiating proceedings against it in 2003, and the fact that any eventual ban or declaration of GMO free zones depends on a peculiar territorial analysis that cannot be centralized.

In addition operators require a compensation system for damage resulting from the presence of genetically modified organisms in non-gm crops.

5. STRATEGIC OVERVIEW MAPS (SOM) OF IMPLEMENTATION AND REVIEW CLAUSE DEADLINES SET WITHIN EXISTING/AGREED LEGISLATION

This chapter is designed for new MEPs as a tool that provides easy access to the dates and deadlines of legislative procedures arising from the previous mandate and already scheduled during the upcoming legislation. In addition it identifies scheduled tasks for which a precise deadline has not yet been set. It is divided by legislative policy areas.

The symbol "→" is used to illustrate the time period for the ongoing tasks or actions.

5.1 Contaminants in food

DOCUMENT	PRE-2009	2009	2010	2011	2012	2013	2014	Post - 2014
COMMISSION REGULATION (EC) No 1881/2006 Member States shall monitor nitrate levels in vegetables and communicate the results regularly to the Commission by 30 June of each year.	30/06	30/06	30/06	30/06	30/06	30/06	30/06	30/06
COMMISSION REGULATION (EC) No 1881/2006 - Member States shall communicate each year to the Commission the results of investigations undertaken including occurrence data and the progress with regard to the application of prevention measures to avoid contamination by ochratoxin A, deoxynivalenol, zearalenone, fumonisin B1 and B2, T-2 and HT-2 toxin.	→	→	→	→	→	→	→	→

DOCUMENT	PRE-2009	2009	2010	2011	2012	2013	2014	Post - 2014
<p>COMMISSION REGULATION (EC) No 1881/2006 A review of the maximum levels for deoxynivalenol, zearalenone, fumonisin B1 and B2 as well as the appropriateness of setting a maximum level for T-2 and HT-2 toxin in cereals and cereal products, taking into account the progress in scientific and technological knowledge on these toxins in food.</p>	01/07/2008							
<p>COMMISSION REGULATION (EC) No 1881/2006 – Consideration will be given on the maximum levels for dioxins and dioxin-like PCBs.</p>	31/12/2008							
<p>COUNCIL REGULATION (EEC) No 2377/90 of 26/06/1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin</p>	Commission/Council initial legislative document COM(2007) 0194 of 17/04/2007		The Commission will present in 2010 an assessment of the problems in the application of the veterinary medicinal products Directive with a view to making, where appropriate, legal proposals.					
<p>REGULATION 852/2004: excluding micro-enterprises from the requirement to put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles</p>		The Commission shall, not later than 20/05/2009, submit a report to the European Parliament and the Council.						

5.2 Nutrition and Obesity

DOCUMENT	Pre-2009	2009	2010	2011	2012	2013	2014	Post-2014
GOAL OF REDUCING OBESITY								2015
Implement actions/suggestions for reaching white paper goals	→	→	→					
White paper Review			Within 2010					

5.3 Labelling of food and health claim

DOCUMENT	PRE-2009	2009	2010	2011	2012	2013	2014	Post-2014
REGULATION 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on foods								
REGULATION 1924/2006: Establishment of nutrient profile scheme by the commission with regulatory procedure with scrutiny		<i>19/01/2009 - expected for end 2009</i>						
REGULATION 1924/2006: <i>Issue of a "positive list" of the 'function' health claims (article 13) by the Commission</i>			<i>01/2010</i>					
REGULATION 1924/2006: Commission must submit a report on the EP and Council that must include an evaluation of the impact of the Regulation on dietary choices and the potential impact on obesity and non-communicable diseases						<i>01/2013</i>		

DOCUMENT	PRE-2009	2009	2010	2011	2012	2013	2014	Post-2014
<p>COM(2008)0040 Proposal for a Regulation of the European Parliament and of the Council on the provision of food information to consumers (repealing Directives 90/496/EEC and 2000/13/EC) Codecision procedure – Discussion on “Provision of food information to consumers (repeal. Directives 90/496/EEC and 2000/13/EC)”</p>		14/12/2009 EP plenary sitting (indicative date)						

5.4 Food additives and food flavourings

DOCUMENT	Pre-2009	2009	2010	2011	2012	2013	2014	Post-2014
<p>REGULATION (EC) No 1334/2008 After the Authority has been consulted, a common methodology for the gathering by Member States of information on the consumption and use of flavourings set out in the Community list and of the substances listed in Annex III shall be adopted in accordance with the regulatory procedure referred to in Article 21(2)</p>				20/01/211				
<p>REGULATION (EC) No 1334/2008 Member States shall establish systems to monitor the consumption and use of flavourings set out in the Community list and the consumption of the substances listed in Annex III on a risk-based approach, and shall report their findings with appropriate frequency to the Commission and to the Authority.</p> <p>No precise date has been set</p>	→	→	→	→	→	→	→	→

DOCUMENT	Pre-2009	2009	2010	2011	2012	2013	2014	Post-2014
<p>REGULATION (EC) No 1334/2008 Amendments to Annexes II to V to this Regulation to reflect scientific and technical progress which are designed to amend non-essential elements of this Regulation shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 21(3), following the opinion of the Authority, where necessary.</p> <p>No precise date has been set</p>	→	→	→	→	→	→	→	→
<p>REGULATION (EC) No 1332/2008 A producer or user of a food enzyme shall, at the request of the Commission, inform it of the actual use of the food enzyme. Such information shall be made available to Member States by the Commission.</p> <p>No precise date has been set</p>	→	→	→	→	→	→	→	→

5.5 Animal Nutrition

DOCUMENT	Pre-2009	2009	2010	2011	2012	2013	2014	Post-2014
<p>COD/2008/0050 Animal feed: placing on the market and use</p> <p>Procedure needs to be ended</p>	→	→	→	→	→	→	→	→

5.6 Animal health

DOCUMENT	Pre-2009	2009	2010	2011	2012	2013	2014	Post-2014
<p>REGULATION 932/2005 Some articles of Regulation 999/2001/EC, have to be reviewed, as written in the proposal of the Regulation 932/2005/EC, which move it to future procedures. The following articles have to be modified: 3, 5, 6, 7, 8, 9, 12, 13, 15, 16 and 21.</p> <p>No precise date has been set</p>	→	→	→	→	→	→	→	→

5.7 Novel foods

DOCUMENT	Pre-2009	2009	2010	2011	2012	2013	2014	Post-2014
			23/3/2010					
Novel Food COD/2008/0002								
EP Approval		23/3/2009						
Implementation		→	→	→	→			
Review					23/3/2012			

5.8 Genetically Modified Organisms (GMOs)

DOCUMENT	Pre-2009	2009	2010	2011	2012	2013	2014	Post-2014
DIRECTIVE 2001/18/CE Article 31(6): Report from the Commission to the Council and the European Parliament on the experience of Member States with GMOs placed on the market under Directive 2001/18/EC	COM/2004/0575 of 31/08/2004 COM/2007/0081 of 05/03/2007		10/2010					
DIRECTIVE 2001/18/CE article 26a: Commission report on the coexistence situation in Member States, based on information provided by the Member States.	COM(2006) 626 of 25/10/2006 COM/2009/0153 of 02/04/2009				2012			

6. OVERVIEW OF EXISTING STUDIES/BRIEFINGS AND WORKSHOP

This chapter outlines the main studies and publications related to the Food Safety topics discussed in the European Parliament during the previous mandate 2004-2009.

The following products have been requested by the ENVI Committee concerning *Food Safety* policy. They can also directly be accessed through the European Parliament website ("studies" section).

These documents provide further detail on the topics discussed in this Welcome Package.

<http://www.europarl.europa.eu/activities/committees/studies.do?language=EN>.

Studies	
<p>Welcome package (June 2009)</p>	<p>Study prepared in the context of a "Welcome Package" for the newly elected MEPs in the next legislature 2009-2014. This study contains an overview of existing legislation, the Thematic policy review for the period 2004-2009, background notes for new Commissioner Hearings on food safety, a strategic Overview Maps (SOM) of implementation and review clause deadlines set within existing/agreed legislation.</p>
<p>http://www.europarl.europa.eu/activities/committees/studies/download.do?file=23531</p>	
<p>Trans Fatty Acids and Health : a Review of Health Hazards and Existing Legislation (November 2008)</p>	<p>Trans fats are found in commercial baked goods, fried foods, frozen foods, margarines, red meat and dairy products. There is a considerable body of scientific evidence that associates their ingestion with cardiovascular diseases, obesity, diabetes, blindness, cancer and others. Based upon the evidence of negative health impacts of industrial trans fats and the success of the ban in various locations, this study recommends that a ban be considered at EU level.</p>
<p>http://www.europarl.europa.eu/activities/committees/studies/download.do?file=23271</p>	
<p>Workshop Food Labelling (November 2008)</p>	<p>In order to get a balanced picture of the variety of views seriously considered among professionals in this field, a workshop on Food Labelling has been organised. The workshop included presentations of 3 experts, followed by a question and answer session (Q&A).</p>
<p>http://www.europarl.europa.eu/activities/committees/studies/download.do?file=22471</p>	
<p>The benefits of strict cut-off criteria on human health in relation to the proposal for a Regulation concerning plant protection products (September 2008)</p>	<p>This study assesses the health benefits of strict 'cut-off criteria' on human health in relation to the proposal for a Regulation concerning the placing of plant protection products on the market (COM(2006) 388).</p>
<p>http://www.europarl.europa.eu/activities/committees/studies/download.do?file=22471</p>	

Workshop Novel Foods (September 2008)	The workshop tackles different elements mentioned in the Commission proposal COM (2007)872 on Novel Foods. The workshop involved experts to advice ENVI Members, giving a balanced picture of the variety of views seriously considered among professionals in this field.
http://www.europarl.europa.eu/activities/committees/studies/download.do?file=22431	
Advertising and marketing practices on child obesity (January 2008)	The briefing addresses the following causes or factors of children's food preferences: 1) exposure to advertising and marketing, 2) effectiveness of self-regulation of media providers about commercials on food and beverages1, 3) impact of production and distribution on childhood obesity.
http://www.europarl.europa.eu/activities/committees/studies/download.do?file=19988	
The Effect of Advertising and Marketing Practices on Child Obesity (January 2008)	This study, based on existing data and expertise, assesses several aspects: the problem's dimension, to what extent the exposure to advertising and marketing influences children diet behaviour; existing regulations in food and beverages marketing towards children and the impact of production and distribution on children's obesity.
http://www.europarl.europa.eu/activities/committees/studies/download.do?file=19308	
Alternative progress indicators to Gross Domestic Product (GDP) as a means towards sustainable development (October 2007)	conomic performance is generally being measured through GDP. However, GDP does not properly account for social and environmental costs and benefits. Therefore, in order to effectively measure 'progress, wealth and well-being', one must go beyond GDP. This study highlights the benefits and some of the shortcomings of GDP.
http://www.europarl.europa.eu/activities/committees/studies/download.do?language=en&file=19990	
Catering Waste Assessment of the Current State of Implementation of Regulation 1774/2002 on Catering Waste in 10 EU Member States (February 2007)	This study analyses and assesses the current state of the implementation of Regulation 1774/2002 and the specific decision of the European Commission 328/2003/EC on catering waste in 10 selected Member States in the European Union.
http://www.europarl.europa.eu/activities/committees/studies/download.do?language=en&file=16303	
On the European Commission's Green Paper "Healthy Diets and Physical Activities" (May 2006)	Commission's Green Paper on promoting Healthy Diets and Physical Activity is triggering debate on initiatives aiming at preventing obesity. It invites contributions from interested parties on a wide range of issues, including topics relating to nutrition and physical activity. The aim is to gather information with a view to giving a European dimension to the battle against obesity, in terms of support for and coordination of the existing national measures.
http://www.europarl.europa.eu/activities/committees/studies/download.do?language=en&file=12965 http://www.europarl.europa.eu/activities/committees/studies/download.do?language=en&file=12707 http://www.europarl.europa.eu/activities/committees/studies/download.do?language=en&file=12969 http://www.europarl.europa.eu/activities/committees/studies/download.do?language=en&file=12703	

<p>Nutrition and Health Claims</p> <p>(February 2006)</p>	<p>It is of importance for the promotion of public health and the creation of wealth in the European Community to promote balanced dietary choices in adults and especially in children. Therefore, it is essential to reach agreed conditions and rules for the use of nutrition and health claims in the EU. These studies explain the status quo in the European Union and other parts of the world with respect to the use of health claims in the labelling of the various food products by the industry.</p>
<p>http://www.europarl.europa.eu/activities/committees/studies/download.do?language=en&file=12888 http://www.europarl.europa.eu/activities/committees/studies/download.do?language=en&file=12883 http://www.europarl.europa.eu/activities/committees/studies/download.do?language=en&file=12893 http://www.europarl.europa.eu/activities/committees/studies/download.do?language=en&file=12881</p>	
<p>Review of COM 671 – European Commission proposal for a regulation of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to food</p> <p>(February 2004)</p>	<p>European Commission recommends a Regulation to harmonise divergent national rules on the voluntary addition of vitamins and minerals (and certain other substances) to foods.</p>
<p>http://www.europarl.europa.eu/comparl/envi/pdf/externalexpertise/easac/fortified_foods.pdf</p>	
<p>Review of COM 689 – European commission proposal for a regulation of the European Parliament and of the Council on materials and articles intended to come into contact with food</p> <p>(February 2004)</p>	<p>European Commission recommends a Regulation to cover novel packaging materials, arising from advances in science and technology, designed to maintain or improve the condition of food and prolong its shelf life.</p>
<p>http://www.europarl.europa.eu/comparl/envi/pdf/externalexpertise/easac/materials_intended_to_come_into_contact_with_food.pdf</p>	
<p>Briefing on the European Commission Proposal for a Regulation on maximum residue levels of pesticides in plant and animal products.</p> <p>(November 2003)</p>	<p>The Commission proposes a simplification of the current arrangements for securing pesticide safety within the EU. It proposes unified arrangements for setting safety levels and transfers responsibility for them from Member States to the European Food Safety Authority (EFSA).</p>
<p>http://www.europarl.europa.eu/comparl/envi/pdf/externalexpertise/easac/mrl.pdf</p>	

Briefing notes for delegations

<p>Food Safety situation in Turkey</p> <p>(October 2008)</p>	<p>Considerable efforts have been made, and significant progress has been achieved, in modifying Turkish legislation and regulation in the areas of food standards and food safety towards harmonization with EU standards. However, a large number of regulatory issues exist where current requirements differ in Turkey from those stipulated by Community legislation.</p>
<p>http://www.europarl.europa.eu/activities/committees/studies/download.do?file=22851</p>	

<p>Food safety and public health situations in the Former Yugoslav Republic of Macedonia (FYROM)</p> <p>(October 2008)</p>	<p>The FYROM Government has been given a list of short-term and mid-term priorities to be completed in the coming years, as part of the pre-Accession phase towards ultimate EU membership. This short report gives an insight into the progress being made on these priorities in the areas of Public Health and Food Safety.</p>
<p>http://www.europarl.europa.eu/activities/committees/studies/download.do?file=22771</p>	
<p>Food Safety in Turkey</p> <p>(September 2006)</p>	<p>This briefing note on the "Food safety situation in Turkey" has been prepared in relation to the Committee Delegation visit to Turkey scheduled in October 2006. Turkish food sector is characterised by a great variety and quantity of agricultural products, a large domestic market and young population, and increasing volume of foreign trade. But industry is not well structured yet, which results in a lack of cooperation with the agricultural sector.</p>
<p>http://www.europarl.europa.eu/activities/committees/studies/download.do?language=en&file=12977</p>	

DIRECTORATE-GENERAL FOR INTERNAL POLICIES

POLICY DEPARTMENT ECONOMIC AND SCIENTIFIC POLICY **A**

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