

Millefeuille

The emergence of a multi-layered controls system in the European food sector

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1. Introduction

1.1. A rather ordinary case

In October 2004 a routine inspection of milk at a farm near Lelystad in the Netherlands showed high levels of dioxin. An analysis performed by the RIKILT Institute for Food Safety¹ at the request of the Dutch Consumer Products Safety Authority² demonstrated that the statutory maximum was exceeded six times.³ Initially, it was suspected that the high levels of dioxin were caused by a malfunction in a combustion furnace. However, further investigation led to the conclusion that the contamination of milk was brought about by dioxin in potato peels that had been processed to animal feed. The potato peels turned out to originate from a factory producing French fries and other snacks for the international food market. The processed potatoes were not contaminated, but in the sorting process to separate high quality potatoes from lower quality ones, separator clay had been used.⁴ The clay in question was obtained from a marl quarry in Germany with a high level of natural dioxin. After this puzzle was unravelled, the cause of the problem could be eliminated and all the contaminated products that had not been identified until that moment could be tracked down and taken off the market. In this process all relocation of animals from 162 farms in the Netherlands, 8 in Belgium and 3 in Germany, which received the animal feed, was blocked by the competent national authorities. After it was established that the incident was not limited to the Netherlands, the Dutch competent authorities had also notified the European Commission to coordinate further action within the so-called rapid alert system.⁵ The course of this incident shows the spreading of a source of contamination through the food industry where it was used as a processing aid. From there it moved on as a part of the by-products used as animal feed for milk-producing cattle. Finally the dioxin surfaced in the dairy industry. Thus, several links in the food and feed chain were involved as well as consumers who had bought contaminated milk. This is therefore a striking example of the interdependence within

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1 See: <http://www.rikilt.wur.nl/UK/>.

2 *Voedsel en Waren Autoriteit* (VWA), see: <http://www.vwa.nl>.

3 The risks of dioxin have become vivid in the public imagination after an attempt was made to assassinate the presidential candidate (now president of Ukraine) Viktor Yushchenko. The attempt failed but resulted in a severe disfigurement of his skin and face.

4 The clay is used to manipulate the specific gravity in water in such a way that potatoes depending on their quality either float or sink.

5 See: European Commission, Dioxin contamination: EU traceability and alert notifications systems work well, press release IP/04/1343, Brussels, 5 November 2004. On the rapid alert system see below Section 5.5.

the feed and/or food production chain. Furthermore, this makes it clear that in case an incident occurs, the industry and competent authorities in one or more Member State(s) as well as the Commission are involved in a situation in which the competent authorities are confronted with an incident they cannot redress by control measures on a national level.

This dioxin crisis is just a random example of a food safety incident. It occurred in the midst of major developments on a European level in the field of food safety. These developments started about ten years ago when both Community and Member State food safety systems were under unprecedented pressure as a result of several feed and food emergencies. In order to re-establish public confidence in food supply, food science, food law and food controls, the European Commission initiated a major regulatory reform. In this article we will focus on the restructuring of European food legislation as far as this affects food controls. First of all, we will elaborate on the background of the regulatory reform and the most important regulatory issues concerning the responsibilities of the food industry and government authorities will be addressed. Subsequently, it will be shown that a multi-layered controls system has arisen from this reform, in which food and feed business operators,⁶ competent authorities of the Member States as well as the European Commission and the Commission's inspection agency are involved. Finally, we will address the question what is to be expected of this multi-layered controls system.

2. Developments in the food and feed sector

2.1. Food chain complexity

Although quite a few parties in the production chain were involved in the aforementioned dioxin crisis it was nevertheless quite straightforward in the sense that it was mainly local in nature and the effects were limited to parts of the Netherlands, Germany and Belgium. However, more and more substances used in (the processing of) food as well as food products travel world wide and as a result the food production chain is becoming increasingly complex. In every European supermarket products can be found originating from for example North and South America (like soy, maize and beef), Asia (like rice and shrimp), Africa (like cocoa and sugar peas) and New Zealand (like kiwis). As a consequence of the free movement of goods, substances and food products – apart from live animals and products from animal origin – originating from EU Member States may circulate freely (without specific control measures) and the same goes for substances and products that are imported from third countries after these goods have entered the EU. It goes without saying that within a free market, the safety of products that reach the consumer at the end of the production chain depends entirely on the safety and control measures that are taken in all stages of the production process. During this process different types of problems may occur that originate for example in the natural environment (viruses, bacteria and moulds) or in local production methods like the use of pesticides or antibiotics. These food safety issues travel along with products all over the world or all over Europe. The dioxin incident shows that a problem at the beginning of the food or feed chain may have serious consequences in the following links. Apart from safety measures within individual businesses, food and feed chain integration⁷ is therefore of the utmost importance.

6 The addressees of EU food law are 'food (and feed) business operators. They are defined as: 'any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food' (Art. 3(2) Regulation 178/2002). On this concept see Thomas Mettke, 'Lebensmittelsicherheit vor Menschlichkeit. Zur Rückverfolgbarkeit von Lebensmittelspenden', 2005 *Zeitschrift für das gesamte Lebensmittelrecht*, no. 1, pp. 1-3.

7 E.g. the structural cooperation of businesses in different stages of the feed and food production and distribution chain aimed at ensuring the quality and safety of the end product as it is provided to the consumer.

2.2. Food safety crises

Food crises that have brought to light serious shortcomings in safety assurance have made regulatory reform an important issue. Although several food crises have taken place in the last decades, it is most certainly the BSE crisis that has been a catalyst for the recent developments in the field of EU food legislation. The BSE crisis occurred in the later half of the 1990s. Public awareness of the epidemic, and of the time it took British and European authorities to address it, presented a major challenge to European co-operation in the area of food safety. When the extent of the crisis became public, the European Union issued a blanket ban on British beef exports. In response, Great Britain adopted a policy of non-cooperation with the European institutions, and sought to deny the extent and seriousness of the BSE problem.⁸

The European Parliament played a crucial role in defusing this crisis. Although often accused of being a debating society of little consequence, during the BSE crisis the Parliament proved itself capable of political decisiveness and effective democratic control. A temporary Enquiry Committee was instituted to investigate the actions of the national and European agencies involved in the crisis.⁹ The Enquiry Committee presented its report in early 1997.¹⁰ The report strongly criticized the British government as well as the European Commission. The Commission was accused of wrongly putting industry interests before public health and consumer safety. The Enquiry Committee did not confine itself to an analysis and critical comments. The report went on to make concrete recommendations for the improvement of the structure of European food law. Paradoxically, this reproachful report provided the Commission with the impetus it had hitherto lacked to take the initiative for restructuring European food legislation in a way that considerably strengthened its own powers. The Commission's President at that moment, Jacques Santer, undertook a far-reaching commitment to implement the Committee's recommendations.

As early as May 1997, the Commission published a Green Paper on the general principles of food law in the European Union.¹¹ Consumer protection was made the first and foremost priority. The Commission committed to strengthening its food safety control function. This led directly to the setting up of the Food and Veterinary Office (FVO) in Dublin in 1997, charged to carry out the Commission's control responsibilities in for instance the food safety sector.¹² Furthermore the establishment of an independent food safety authority was announced. At the European summit in Luxemburg at the end of the same year, the European Council adopted a statement on food safety.¹³ The Commission kept the pressure on beyond 1997, eventually gaining the support of the European Court of Justice for the measures that had been taken against Great Britain at the climax of the crisis.¹⁴ Meanwhile, public attention had turned to a new food safety scare: the Belgian dioxin crisis.¹⁵ The Commission proved it had learnt a valuable lesson from its experi-

8 To convince the population that there was nothing wrong with British beef the responsible Minister, John Gummer, had his young daughter, Cordelia, eat a hamburger on TV (on 16 May 1990). The pictures are all over the Internet, for instance: <http://news.bbc.co.uk/1/hi/health/1482140.stm>.

9 *OJ* 1996 C 261/132.

10 Report of the Temporary Committee of Inquiry into BSE, set up by the Parliament in July 1996, on the alleged contraventions or maladministration in the implementation of Community law in relation to BSE, without prejudice to the jurisdiction of the Community and the national courts of 7 February 1997, A4-0020/97/A, PE 220.544/fin/A. See <http://www2.europarl.eu.int/omk/sipade2?PUBREF=//EP//NONSGML+REPORT+A4-1997-0020+0+DOC+PDF+V0//EN&L=EN&LEVEL=2&NAV=S&LSTDOC=Y>.

11 Commission Green Paper COM(97) 176, The general principles of food law in the European Union. See: <http://www.foodlaw.rdg.ac.uk/eu/green-97.doc>.

12 See Section 5.6.

13 Conclusions of Luxembourg summit 1997; Luxembourg European Council 12 and 13 December 1997; Presidency Conclusions on Environment/Health and Annex 2 'Declaration by the European Council on Food Safety': See: http://www.vm.ee/eng/euro/aken_prindi/2799.html

14 See judgments of 5 May 1998, Cases C-157/96, [1998] *ECR* I-2211, and C-180/96, [1998] *ECR* I-2265, and judgment of 1 October 1998, Case C-209/96, *ECR* I-5655.

15 The notorious dioxin crisis, not to be confused with the more recent one described in the introduction.

ence with BSE, and moved quickly and efficiently to protect consumers from the dioxin crisis. Nonetheless, this crisis brought to light further shortcomings in European food law.¹⁶

Despite the resignation of Santer's Commission (which was succeeded by the Commission led by Romano Prodi), food safety remained a priority issue. On 12 January 2000 the Commission published its White Paper on Food Safety.¹⁷

2.3. White Paper on Food Safety; shared responsibilities

The main goal of the White Paper was the reinstatement of consumer trust in food supply, food science, food law and food controls. Nevertheless there is also an economic aspect to the White Paper. The agro-food sector is of major importance for the European economy. The European food and drink industry covers about 15% of European industrial production. Given the economic importance of food and the essential role of food for human existence, in the opinion of the Commission food safety is a matter of the utmost importance for society as a whole and for government authorities and food producers in particular.

The White Paper called for a wide range of measures to improve and bring coherence to the corpus of legislation covering all aspects of food products 'from farm to fork'. The reconstruction was necessary due to wide variations in the manner in which Community legislation has been implemented and enforced in Member States. As a result consumers could not be sure of receiving the same level of protection across the Community, which also made it difficult for the effectiveness of national authority measures to be evaluated. The Commission therefore identified a wide range of measures necessary to improve food safety standards. Considering the developments described above, it is clear that, in a number of areas, existing European legislation had to be brought up to date. A new legal framework was proposed to cover the whole of the food chain, including animal feed production, in order to establish a high level of consumer health protection. Within the context of this article it is important to refer to the fact that the White Paper provides for a shared responsibility for safe food production between food business operators, national authorities and the European Commission.

Operators have the responsibility to comply with legislative provisions, and to provide for adequate risk management. The ability to trace products through the whole food chain is considered a key issue. Scientific advice must underpin food safety policy, whilst the precautionary principle shall be used where appropriate. The ability to take rapid, effective, safeguard measures in response to health emergencies throughout the food chain is recognized as an important element. Proposals for the animal feed sector had to ensure that only suitable materials could be used in its manufacture.

In the White Paper national authorities are held responsible for ensuring that food safety standards are respected by food and feed business operators. They need to establish control systems to ensure that Community rules are being respected and, where necessary, enforced. In the opinion of the Commission these systems should be developed at Community level, so that a harmonized approach is followed. To ensure that national control systems are effective, the Commission, through the FVO, would carry out a programme of audits and inspections to evaluate the performance of national authorities against their ability to deliver and operate effective control systems, which would be supported by visits to individual premises to verify

¹⁶ On the development of EU food law see: B.M.J. van der Meulen, *The Right to Adequate Food. Food Law between the Market and Human Rights*, The Hague 2004, and Bernd van der Meulen and Menno van der Velde, *Food Safety Law in the European Union*, Wageningen 2006.

¹⁷ COM(1999) 719 final.

that acceptable standards are actually being met. The Commission envisioned a Community framework consisting of three core elements:

1. **Operational criteria set up at Community level**, which national authorities would be expected to meet. These criteria would form the key reference points against which the competent authorities would be audited by the FVO, thereby allowing it to develop a consistent and complete approach to the audit of national systems.
2. **The development of Community control guidelines**. These would promote coherent national strategies, and identify risk-based priorities and the most effective control procedures. A Community strategy would take a comprehensive, integrated, approach to the operation of controls. These guidelines would also provide advice on the development of systems to record the performance and results of control actions, as well as setting Community indicators of performance.
3. The enhancement of **administrative cooperation** in the development and operation of control systems. There would be a reinforced Community dimension to the exchange of best practice between national authorities. This would also include promoting mutual assistance between the Member States by integrating and completing the existing legal framework.

Furthermore, this would cover issues such as training, information exchange and longer term strategic thinking at Community level.¹⁸

3. Legislative intervention

3.1. General Food Law; general remarks

Annexed to the aforementioned White Paper is the Action Plan on Food Safety, a list of 84 legislative steps that the Commission deemed necessary to create a regulatory framework capable of ensuring a high level of protection of consumers and public health. The first new regulation took effect in 2002 and in the few years that have since passed most of the 84 steps have been taken.¹⁹ The new regulatory framework is based on regulations rather than directives.

The first step in the realization of the reform of food law as planned in the White Paper, was the passage of 'Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety'.²⁰ The popular name of this regulation is: the General Food Law (GFL).²¹ To avoid confusion it should be noted that the GFL is not a code encompassing all food legislation. It is the fundament to a general part of food law. Next to it many (hundreds) of other European and national rules and regulations continue to play their role. The GFL provides the basis for the assurance of a high level of protection of human health and the consumers' interests in relation to food, taking into account in particular the diversity in the supply of food including traditional products, whilst ensuring the effective functioning of the internal market. It establishes common principles and responsibilities, the means to provide a strong science base, efficient organizational arrangements

18 White Paper, *supra* note 17, p. 30.

19 See: Klaus Knipschild, *Lebensmittelsicherheit als Aufgabe des Veterinär- und Lebensmittelrechts*, Baden-Baden 2003; Ulrich Nöhle, 'Risikokommunikation und Risikomanagement in der erweiterten EU', 2005 *Zeitschrift für das gesamte Lebensmittelrecht*, no. 3, pp. 297-305, and Gijs Berends and Ignacio Carreno, 'Safeguards in food law – ensuring food scares are scarce', 2005 *E.L.rev.*, no. 30, pp. 386-405.

20 *OJ/L* 31/1, 1.2.2002. For guidelines for its interpretation see: Guidance on the Implementation of Articles 11, 12, 16, 17, 18, 19 and 20 of Regulation (EC) no. 178/2002 on General Food Law, Conclusions of the Standing Committee on the Food Chain and Animal Health, 20 December 2004; http://www.europa.eu.int/comm/food/food/foodlaw/guidance/index_en.htm

21 See for a commentary: D. Gorny, *Grundlagen des europäischen Lebensmittelrecht. Kommentar zur Verordnung (EG) Nr. 178/2002*, Hamburg 2003.

and procedures to underpin decision making in matters of food and feed safety (Art. 1(1) GFL). The GFL is of major significance for the subject of this article because it sets standards for the division of tasks in the area of food safety controls.

3.2. The concept of food safety

Pursuant to Article 14 GFL it is forbidden to place unsafe feed and food on the market. Food is considered to be unsafe if it is injurious to health or unfit for human consumption.²² In determining whether food is unsafe, regard shall be had to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods. In answering the question whether food is injurious to health, regard shall be had not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations, to the probable cumulative toxic effects and to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers. In determining whether food is unfit for human consumption, regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay. Feed shall be deemed to be unsafe for its intended use if it is considered to have an adverse effect on human or animal health and/or make the food derived from food-producing animals unsafe for human consumption.

Food and feed that comply with specific Community provisions governing food safety are regarded safe insofar as the aspects covered by the specific Community provisions are concerned. Where there are no specific Community provisions, food shall be deemed to be safe when it conforms to the specific provisions of national food law of the Member State in whose territory the food is marketed. However, conformity of a food with specific provisions applicable to that food shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the food is unsafe.

3.3. Food safety: a duty of care

The GFL by principle imposes on food and feed business operators the responsibility for the safety of the food they bring to the market. This principle is laid down in Article 17 (1) ('Responsibilities'):

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

22 While the notion of injurious to health is rather straightforward, the latter – unfit for human consumption – is not a very clear concept. For this reason the risk of differing interpretations in the Member States is apparent. In the Netherlands for instance the VWA has published an interpretation stating that food is unfit for human consumption in case of a deviation unacceptable for consumers such as the presence of a chemical or micro-organism, deviations in taste or smell or mistakes in labelling with possible health consequences. See: http://www2.vwa.nl/CDL/files/8/1004/10385%20Infoblad_69_melden_traceren_levensmiddelen-2.pdf.

Food and feed business operators are not only held responsible for adherence to the law – which is to be considered more or less obvious – but they must also *verify* whether the requirements are actually met. In other words, they must have systems of self control. We will come to these systems later on in this article.

3.4. Taking care of food safety

Food and feed business operators are obliged to take action if they consider or have reason to believe that a feed or food which they have imported, produced, processed, manufactured or distributed is not in compliance with the food and feed safety requirements (see Arts. 19 and 20 GFL). They shall immediately initiate procedures to withdraw the feed and food in question from the market where the food has left the immediate control of that initial food business operator and inform the competent authorities thereof. In case the product may have reached the consumer of food products or the users of feed, the operator shall effectively and accurately inform the consumers of the reason for its withdrawal, and if necessary, recall from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection. With respect to animal feed the GFL requires in these circumstances that the feed shall be destroyed, unless the competent authority is satisfied otherwise.

A food or feed business operator, responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the food or feed shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the food-safety requirements and shall participate in contributing to the safety of the food by passing on relevant information necessary to trace a food, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities. A food or feed business operator shall immediately inform the competent authorities if it considers or has reason to believe that a food which it has placed on the market may be injurious to human health. Operators shall inform the competent authorities of the action taken to prevent risks to the final consumer and shall not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a food or feed. Finally, food and feed business operators shall collaborate with the competent authorities on action taken to avoid or reduce risks posed by a product which they supply or have supplied.

In order to be able to act adequately in a situation where food or feed problems arise, it is necessary that the product can be tracked down as soon as possible. For this reason Article 18 GFL contains a traceability requirement. This requirement forms an important aspect for food chain integration and will therefore be discussed in Section 4.2.²³

3.5. Official controls and enforcement

Article 17 GFL also establishes the responsibility of the Member States for official controls and enforcement of food law, and to monitor and verify that the relevant requirements of food law are fulfilled by food and feed business operators at all stages of production, processing and distribution. For that purpose, they have to maintain a system of official controls and other activities appropriate to the circumstances, including public communication on food and feed safety and risks, food and feed safety surveillance and other monitoring activities covering all stages of production, processing and distribution (Art. 17(2)). The GFL does not elaborate on

²³ On the subject of this paragraph see also: Harald Hohmann, 'Rückverfolgbarkeit, Krisen- und Risicomangement', 2005 *Zeitschrift für Stoffrecht*, 2/6, pp. 273-278.

further requirements that have to be met by the Member States in the establishment of an official controls system. However, at a later stage two Regulations were adopted that set specific standards for national controls systems (see below). With regard to sanctions Article 17(2) GFL requires Member States to lay down the rules on measures and penalties applicable to infringements of food and feed law. The measures and penalties provided for shall be effective, proportionate and dissuasive.

3.6. Multi-layered controls system

Although the provisions of the GFL are restricted to individual parties in the food production chain on the one hand and Member States on the other hand, it is considered to have an important impact on the relations between parties in the food chain, as well as on the relationship between parties in the food chain and national authorities. It is fair to say that all the developments that have led to the GFL have resulted in a multi-layered controls system, in which all parties involved play their own role. In the next sections we will explore the multi-layered system in more detail.

4. Self controls

4.1. Self controls in food businesses

Space-age experience has shown that the testing of food products does not provide sufficient certainty that similar products in the same lot are safe. To ensure that astronauts will not suffer from diarrhoea or food poisoning during their stay in space, in 1959 the US space agency NASA developed a method of food production aimed at eliminating all possible hazards from the production process. This is known as the HACCP system (Hazard Analysis and Critical Control Points).²⁴ Within this system the production process is analyzed to establish what kind of hazards may enter the product in which part of the process. Procedures have been developed to prevent hazards or to deal with the consequences. Meticulous application of such a system in combination with testing of products achieves the highest possible level of food safety. The World Health Organization (WHO) and the Food and Agricultural Organization (FOA) have recommended the world-wide use of HACCP-based systems to ensure safe production of food (also known as: food hygiene).²⁵ This recommendation has been implemented in EU legislation.²⁶ The application of HACCP is obligatory for virtually²⁷ all food businesses in the EU. As a consequence food businesses have to analyze their processes, to establish procedures to ensure hygiene and to exercise self control on the functioning of these systems. In other words: the businesses have to formulate and uphold the rules that apply to their processes.

Regulation 853/2004 on the hygiene of foodstuffs,²⁸ gives the general requirements on the hygienic production of food. In addition Regulation (EC) no. 853/2004 laying down specific

24 See on HACCP and other quality assurance systems: G. Temmerman et al., *Toevoegsels, Hygiëne en HACCP*, Brugge 1995; M. Fogden, 'Hygiene', in: Kaarin Goodburn (ed.) *EU food law*, Cambridge 2001; P.A. Luning, W.J. Marcelis and W.M.F. Jongen, *Food quality management, a techno-managerial approach*, Wageningen 2002; and Marjolein van der Spiegel, *Measuring effectiveness of food quality management* (Ph.D. thesis at Wageningen University, the Netherlands), 2004.

25 See: for instance *CAC/RCP 1-1969, rev. 4 (2003)* Recommended International Code of Practice General Principles of Food Hygiene; *CAC/GL 21 – 1997*; Principles for the Establishment and Application of Microbiological Criteria for Foods; *CAC/GL-30 (1999)* Principles and Guidelines for the Conduct of Microbiological Risk Assessment. These texts have been published in: ftp://ftp.fao.org/codex/Publications/Booklets/Hygiene/FoodHygiene_2003e.pdf.

26 First in directives, like Directive 93/43/EEC and Directive 95/2/EC. On 1 January 2006 there were 17 directives on hygiene in force. These have been replaced by the regulations discussed in the text.

27 There are some exceptions. *E.g.* to primary production a somewhat less stringent regime of food hygiene applies.

28 *OJ L 226/3*, 25.6.2004, effective as from 1 January 2006.

hygiene rules for food of animal origin lays down the hygiene requirements to be respected by food businesses handling food of animal origin at all stages of the food chain. The word 'hygiene' is taken in a broad sense. It means measures and conditions necessary to control hazards and ensure fitness for human consumption of a foodstuff taking into account its intended use. On the basis of Regulation 1831/2003/EC HACCP also applies to feed business operators. Regulation 853/2004/EC sets out the general requirements of a HACCP system:²⁹

Article 5 of Regulation 853/2004

Hazard analysis and critical control points

1. Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.

2. The HACCP principles referred to in paragraph 1 consist of the following:

- (a) identifying any hazards that must be prevented, eliminated or reduced to acceptable levels;
- (b) identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;
- (c) establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;
- (d) establishing and implementing effective monitoring procedures at critical control points;
- (e) establishing corrective actions when monitoring indicates that a critical control point is not under control;
- (f) establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively; and
- (g) establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).

When any modification is made in the product, process, or any step, food business operators shall review the procedure and make the necessary changes to it.

3. Paragraph 1 shall apply only to food business operators carrying out any stage of production, processing and distribution of food after primary production [...].

4. Food business operators shall:

- (a) provide the competent authority with evidence of their compliance with paragraph 1 in the manner that the competent authority requires, taking account of the nature and size of the food business;
- (b) ensure that any documents describing the procedures developed in accordance with this Article are up-to-date at all times;
- (c) retain any other documents and records for an appropriate period.

5. [...].

The general obligation enshrined in Article 17 GFL to verify that food satisfies the requirements of food safety law has thus been elaborated in a rather detailed system of imposed self controls in food businesses. The HACCP principles have been further developed in various food producing industries. It must be borne in mind that in addition to food hygiene requirements, other sanitary measures may apply such as animal health and plant health requirements.

²⁹ See also Guidance document on the implementation of procedures based on the HACCP principles, and on the facilitation of the implementation of the HACCP principles in certain food businesses, Brussels, 16 November 2005.

4.2. Self-controls in the food chain

4.2.1. Civil law

The HACCP system applies to the handling of products within the business(es) under the responsibility of the operator. Hazards may however originate earlier on in the food chain. For the quality and safety of their products businesses largely depend on the reliability of the processes that have been applied upstream.³⁰ The processes upstream may or may not fall within the scope of EU food safety law. Of course all EU-based food businesses fall within the scope of EU law, but as far as import from third countries is concerned, it is a matter of contractual arrangements in which the quality standards of imported products should be defined. In principle all imported food products should conform to EU food safety law,³¹ but in particular the production of food of animal origin is subject to strict regulations. For these products controls by the FVO (see below) are mandatory before third countries can export their products to the EU. All other food products are not subject to preceding controls in third countries. Importers of food products from third countries should therefore arrange for quality standards in private contracts. And even if EU law is applicable, the legal requirements may or may not have been thoroughly adhered to. To ensure a high quality level in all links in the food chain, systems have been set up on the basis of civil law that apply certification and third-party audits. In particular the big retail chains have elaborated quality and safety standards which they impose on the whole chain upstream. Well known are the BRC (British Retail Consortium),³² IFS (International Food Standard)³³ and EurepGap³⁴ standards. The audits under these systems form a second layer of controls on top of the self-controls within the businesses required by HACCP.³⁵

4.2.2. Public law

The holistic approach ‘from farm to fork’ of the new EU regulatory system strongly furthers the tendency to food chain integration. The requirements that have to be met by individual food businesses form an impulse for a coherent approach within the production chain in order to ensure that the production of food is safe throughout the production chain. Apart from the fact that every food business operator has to comply with specific requirements in the field of food law, the GFL requires that food, food ingredients and food-producing animals be traceable. The intention of this traceability system is to enable food safety problems to be identified at the source, and across the food chain. To this end food business operators must keep comprehensive records of exactly where their food material originated and where they went. The relevant provision is laid down in Article 18 GFL.³⁶

30 See: Karola Krell, *Haftungsverteilung im Lebensmittelrecht. Geltung und Anwendbarkeit der Modelle Kettenverantwortung und Stufenverantwortung im Lichte aktueller europäischer und nationaler Rechtssetzung*, Bayreuth 2005.

31 Art. 11 GFL.

32 See: http://www.brc.org.uk/standards/about_food.htm.

33 See: www.food-care.info.

34 See: http://www.eurepgap.org/Languages/English/index_html.

35 See on the chain perspective to food safety: P. A. Luning, F. Devlieghere and R. Verh  (eds.), *Safety in the agri-food chain*, Wageningen 2006. See more in general on chain- en networks sciences: Theo Camps et al., *The Emerging World of Chains & Networks. Bridging Theory and Practice*, The Hague 2004.

36 See: Anneke van de Kamp, Floor Verdenius and Ria Westendorp, *Traceerbaarheid. De uitwerking van de Algemene Levensmiddelen Verordening*, The Hague 2005.

Article 18 of Regulation 178/2002

Traceability

1. The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution.
2. Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed.
To this end, such operators shall have in place systems and procedures which allow for this information to be made available to the competent authorities on demand.
3. Food and feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the competent authorities on demand.
4. Food or feed which is placed on the market or is likely to be placed on the market in the Community shall be adequately labelled or identified to facilitate its traceability, through relevant documentation or information in accordance with the relevant requirements of more specific provisions.
5. [...].

Article 18 does not require an intact paper trail to accompany each individual food ingredient from the farm to the fork.³⁷ The general traceability requirements go only one step up and one step down the food chain. Food and feed business operators must be able to identify their own sources and customers (except for the final consumer).³⁸ The burden to reconstruct the whole food chain is on the authorities and to that end traceability information has to be made available to those authorities on demand.

5. Developments in official controls

5.1. Institutional autonomy

Within the EU what is known as the principle of institutional autonomy applies. In principle the EU respects the institutional organization of the Member States. This means that – unless secondary Community law explicitly states otherwise – the Member States decide in what way to fulfil their obligations under Community law, which organs are responsible and what procedures apply.³⁹ At first sight EU food law seems to respect this principle of institutional autonomy. However, a closer look reveals otherwise.

5.2. Enforcement of food law

Although Article 17 of the General Food Law holds the Member States responsible for the enforcement of food law, European food law increasingly sets standards for national enforcement and provides for supervision. On 30 April 2004 two Regulations were published in the Official

37 Such requirements do however exist for genetically modified foods. See Regulation 1830/2003/EC, *OJL* 268/24, 18.10.2003. See on this subject: B.M.J. van der Meulen, 'The new EU regulatory framework for GM food (Part I) Traceability, labelling & enforcement', 2005 *Journal of International Biotechnology Law*, no. 2, pp. 158-162, and Margaret Rosso Grossman, 'Traceability and Labeling of Genetically Modified Crops', 2005 *Journal of Food Law & Policy*, no. 1, pp. 43-85.

38 Communication with the consumer on matters of food safety mainly goes through the media.

39 Case 8/88, *Commission/Germany*, [1990] *ECR* I-2321. On this subject see further: J.H. Jans et al., *Inleiding tot het Europees Bestuursrecht*, Nijmegen 2002, pp. 39-53 (English language version forthcoming).

Journal of the European Union: ‘Regulation (EC) no. 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules’ and Regulation (EC) no. 854/2004 of the European Parliament and of the Council laying down specific rules for the organization of official controls on products of animal origin intended for human consumption.⁴⁰

These Regulations have become effective as from 1 January 2006.⁴¹

Generally speaking, enforcement encompasses both verification of adherence to legal obligations and sanctions in case of infringements. The new Regulations include obligations for verification by the Member States, measures to be taken in case of infringements, a framework for co-operation between national authorities and the European Commission, and for the Commission to monitor the performance of national authorities in the Member States and even in third countries. In this respect it is interesting to examine the background of the Official Controls Regulation especially as far as the type of sanctions are concerned.

In recent years the scope of institutional autonomy of the Member States has been under discussion in several fields of European law. In this discussion the question was addressed whether specific sanctions, *i.e.* criminal penalties, could be required on the basis of the European Treaties. Although the European Court of Justice (ECJ) ruled in several cases that criminal law in principle belongs to the sphere of competence of the Member States,⁴² in 1999 the European Council held in Tampere called for efforts to agree on common definitions, incriminations and sanctions to be focused on a limited number of sectors of particular relevance.⁴³ This has resulted in several council framework decisions and directives on the enforcement of serious offences of European legislation through criminal law. Although the Commission was opposed to the instrument of a framework decision to be used in this respect, the Council persevered in its opinion that this was the correct instrument to impose on Member States the obligation to provide for criminal sanctions. Based upon this opinion the Council in 2003 adopted the Framework Decision on the protection of the environment through criminal law.⁴⁴ The Commission challenged the Framework Decision before the ECJ, and in its ruling of 13 September 2005 the Court annulled the Framework Decision for being based upon the third pillar that does not provide a legal basis.⁴⁵ More important for our account of controls in the field of food law are the considerations of the ECJ concerning the general question whether criminal law or the rules of criminal procedure can under certain circumstances fall within the Community’s competence. The Court held that although criminal law belongs in principle to the sphere of competence of the Member States, this does not prevent the Community legislature, when the application of effective, proportionate and dissuasive criminal penalties by the competent national authorities is an essential measure for combating serious environmental offences, from taking measures which relate to the criminal law of the Member States which it considers necessary in order to ensure that the rules which it lays down on environmental protection are fully effective. The judgment

40 OJ L 139/206, 30.4.2004, corrigendum OJ L 226/83, 25.6.2004. See on these Regulations: Lars O. Fuchs, *Lebensmittelsicherheit in der Mehrebenenverwaltung der Europäischen Gemeinschaft*, Bayreuth 2004, chapter 1.IV ‘Inhaltliche Anforderungen an die Lebensmittelüberwachung’; Axel Preuss, ‘Vertrauen ist gut – risikobasierte Kontrolle ist besser. Amtliche Lebensmittelkontrolle mit der Verordnung (EG) 882/2004’, 2005 *Zeitschrift für das gesamte Lebensmittelrecht* no. 2, pp. 225-240; M.J. Lugt, et al. *Hoofdlijnen levensmiddelenrecht*, The Hague 2003, chapter 8: ‘Handhaving van levensmiddelenrecht’.

41 See on the previous situation: Marieke Lugt, *Enforcing European and National Food Law in the Netherlands and England*, Lelystad 1999; Raymond O’Rourke, *European Food Law*, Bembidge 2001, chapter 12; Debra Holland and Helen pope, *EU Food Law and policy*, The Hague/London/New York 2004, chapter 18.

42 See for references: Simone White, ‘Harmonisation of criminal law under the first pillar’, 2006 *E.L.Rev.*, no. 31, p. 81.

43 See: Simone White, ‘Harmonisation of criminal law under the first pillar’, 2006 *E.L.Rev.*, no. 31, p. 82.

44 Council Framework Decision 2003/80/JHA on the protection of the environment through criminal law, OJ L 29/55, 5.2.2003.

45 Case C-176/03, *Commission/Council*.

lays down principles going far beyond the case in question. In reaction to the ECJ ruling the Commission adopted a Communication on the implications of the Court's judgment.⁴⁶ In this Communication the Commission elaborates that the arguments on which the Court's ruling is based can be applied in their entirety to the other common policies and to the four freedoms (freedom of movement of persons, goods, services and capital). The Commission will have to determine, when submitting proposals, whether this test of necessity, is met on a case-by-case basis. The Commission then formulates several points of interest that have to be taken into account. The bottom line of all this is that in principle the EC legislator is considered competent to impose an obligation upon Member States to apply criminal law in the enforcement of EC legislation.

With respect to European food law it is interesting to note that in the proposed Regulation on official controls the Commission emphasized the importance of criminal penalties stating that special attention is paid to enforcement measures and in particular to the imposition of sanctions at national and Community level. For that purpose, the proposal contained minimum requirements on criminal sanctions to be imposed by the Member States with regard to serious offences that are committed intentionally or through serious negligence. The proposal also provided for new tools for the Commission to enforce the implementation of Community feed and food law by the Member States. In Article 55 it was stated that:⁴⁷

- '1. Member States shall lay down the rules on penalties applicable to infringements of feed and food law and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions and any subsequent amendment to the Commission without delay.
2. For the purpose of paragraph 1, the activities referred to in Annex VI shall be criminal offences when committed intentionally or through serious negligence, insofar as they breach rules of Community feed and food law or rules adopted by the Member States in order to comply with such Community law.
3. The offences referred to in paragraph 2 and the instigation to or participation in such offences shall, as for natural persons, be punishable by sanctions of a criminal nature, including as appropriate deprivation of liberty, and, as for legal persons, by penalties which shall include criminal or non-criminal fines and may include other penalties such as exclusion from entitlement to public benefits or aid, temporary or permanent disqualification from engaging in business activities, placing under judicial supervision or a judicial winding-up order'.

Thus, on the basis of this proposal, Member States would be under the obligation to enforce certain offences of European feed and food law by criminal law. Somewhat by contrast, in the recitals to the proposal the Commission stated that the nature of the sanctions can only be determined under national law by the Member States. Precisely for this reason the Commission has this time been overruled in the legislative process. In its final version, the Regulation does not regulate questions of criminal investigation and prosecution, nor questions of criminal procedure. It is up to the authorities in the Member States to decide whether the offences listed

⁴⁶ Communication from the Commission to the European Parliament and the Council on the implications of the Court's judgment of 13 September 2005 (Case C-176/03, *Commission/Council*), Brussels, 24 November 2005, COM(2005) 583 final/2.

⁴⁷ Proposal for a Regulation of the European Parliament and of the Council on official feed and food controls COM(2003) 52 final.

in the Regulation must be prosecuted in any case or whether the competent authority may refrain from providing for criminal penalties in minor cases where the impact on feed and food safety is insignificant.⁴⁸ This time the institutional autonomy has been upheld. However after the case law discussed above, the core argument that the EC legislator is lacking in competence is no longer valid. The Commission has clearly stated its intentions in the draft for the Official Controls Regulation. It seems to be only a matter of time before the Commission makes a new attempt.

According to Article 17 GFL it is the responsibility of the Member States to enforce food law, and to monitor and verify that the relevant requirements of the law are fulfilled by food and feed business operators at all stages of production, processing and distribution. For that purpose, they have to maintain a system of official controls and other activities appropriate to the circumstances, including public communication on food and feed safety and risks, safety surveillance and other monitoring activities covering all stages of production, processing and distribution. Compared to the proposal of the GFL the European legislator has opted for a general requirement concerning the enforcement by the Member States.

5.3. First line inspections

National inspectors supervise the application of the requirements of feed and food law. In several Member States these inspectors work in the context of food safety authorities, which are often more or less autonomous agencies. The national inspectors have powers under national law to inspect premises where animals are kept or where food is handled and to report on irregularities. Such irregularities may result in sanctions.

Two EU Directives concern controls of intra-Community trade in live animals and products of animal origin.⁴⁹ The Member States are under the obligation to ensure that products are accompanied by health certificates or other documents that European Community rules provide for. Products may only be intended for trade when they have been obtained, checked, marked and labelled in accordance with Community rules. Checks can be carried out on the place of dispatch and at the place of destination. The Directives require notification to other Member States in case an animal disease occurs, and adequate measure must be taken.

Regulation 882/2004/EC is concerned with food-related controls in general. It distinguishes a great variety of inspection types: ‘official control’, ‘verification’, ‘audit’, ‘inspection’, ‘monitoring’, ‘surveillance’, ‘sampling for analysis’, ‘official certification’, ‘official detention’, ‘documentary check’, ‘identity check’ and ‘physical check’. These distinctions seem rather subtle for a framework that is intended to be applied in all the Member States. Member States are responsible for ensuring that official controls are carried out regularly, with appropriate frequency proportionate to the risk for food safety posed by the business operator where the official controls take place. What frequency is appropriate depends amongst other things on identified risks and past performance. Good past performance by a food business operator may lead to a reduced frequency in inspections.

Official controls must cover the whole food chain ‘from farm to fork’. As a rule they must be carried out without prior warning. Nevertheless, the national competent authority must ensure

48 See: Gerard Dannecker (ed.), *Criminal Law on Food Processing and Distribution, and Administrative Sanctions in the European Union*, Köln 1994.

49 Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market, *OJ L* 224, 18.8.1990, and Council Directive 89/662/EEC concerning veterinary checks in intra-Community trade with a view to the completion of the European market, *OJ L* 395, 30.12.1989, corrigendum *OJ L* 151, 15.6.1990.

that they carry out their activities with a high level of transparency. National legislation must ensure that the staffs of the competent authorities have access to the premises of and documentation kept by food business operators. Food business operators are obliged to undergo any inspection and to assist the staff of the competent national authority in the accomplishment of their tasks.

The Member States may collect fees or charges to cover the costs occasioned by official controls. For some activities they are even under an obligation to do so in order to avoid a distortion of intra-Community trade by different practices. If non-compliance leads to extra official controls, then the operators responsible will be charged. The Regulation requires Member States to prepare integrated multi-annual national control plans, to report on the results yearly and also to prepare contingency plans for dealing with emergency situations. Regulation 882/2004/EC does not bring any changes in specific rules on controls in the field of animal health and animal welfare. In addition Regulation 854/2004/EC holds specific measures to control compliance with Regulation 853/2004/EC (on hygiene of food of animal origin). The Regulation lays down requirements as regards for instance the approval of establishments, assistance in carrying out controls, presentation of documents, etc. The controls include audits of HACCP and good hygiene practices.

5.4. Official controls versus self-controls

Now that systems of self-control have become mandatory in all food businesses, official controls shift their focus from the quality of the final product to the quality of these control systems. Where these systems on the basis of private law arrangements are subject to third-party audits, this focus may shift even further.

Within Member States and also on a European level there is a growing interest in the consequences of food chain integration for the performance of official controls. In the Netherlands the Ministry of Agriculture, Nature and Food Quality (LNV)⁵⁰ has issued a proposal for restricted official controls in case food chain integration leads to adequate controls within a food production chain.⁵¹ The general idea is to perform controls on the functioning of the private system rather than in individual food businesses. The Dutch Minister put these developments on the agenda at the informal European Agricultural Council that took place from 5 to 7 September 2004. A poll amongst the EU Member States has shown that three-quarter of the Member States is of the opinion that the balance between industry and national authorities in the field of control measures should be reconsidered. Two thirds of the Member States subscribes to the idea of further developing private control systems, within a European framework that has to be devised by the European Commission. It should be noted though that the Member States agree that food safety is also a public responsibility that cannot be left entirely to the food and feed industry, and Member States will have responsibility to set standards and to enforce these standards.⁵² Although the GFL does not coerce food chain integration, it can be concluded that these developments show that food chain integration may, in the longer run, have consequences as regards the performance of official controls.

50 Landbouw, Natuur en Voedselkwaliteit.

51 Beleidskader Toezicht op Controle (Toezicht op Toezicht): http://www9.minlnv.nl/pls/portal30/docs/FOLDER/MINLNV/LNV/STAF/STAF_DV/DOSSIERS/MLV_VVBK/MLV_REGELS/TOEZICHTOPCONTROLE.PDF.

52 N. Bondt, S.D.N. Deneux, J. van der Roest, G.M. Splinter, S.O. Tromp, J.J. de Vlieger, *Nederlandse levensmiddelenketens*, LEI, rapport 5.02.02, The Hague April 2005.

5.5. RAS

Results of inspections are not only used for enforcement measures within the jurisdiction of the inspection agency concerned, but must in particular be made available for risk management in the whole area that may be affected by a food safety problem. The GFL establishes a rapid alert system for the notification of a direct or indirect risk to human health deriving from food or feed (RAS or RASFF).⁵³ It involves the Member States, the Commission and the European Food Safety Authority (EFSA).⁵⁴ The Member States, the Commission and the EFSA have each designated a contact point, which is a member of the network. The Commission is responsible for managing the network. Where 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 shall be immediately notified to the Commission under the rapid alert system. The Commission shall transmit this information immediately to the members of the network. The EFSA may supplement the notification with any scientific or technical information, which will facilitate rapid, appropriate risk management action by the Member States. The Member States shall immediately notify the Commission under the rapid alert system of:

- a) 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;
- b) 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;
- c) 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.

The notification shall be accompanied by a detailed explanation of the reasons for the action taken by the competent authorities of the Member State in which the notification was issued. It shall be followed, in good time, by supplementary information, in particular where the measures on which the notification is based are modified or withdrawn. The Commission shall immediately transmit to members of the network the notification and supplementary information received under the first and second subparagraphs. Where a batch, container or cargo is rejected by a competent authority at a border post within the European Union, the Commission shall immediately notify all the border posts within the European Union, as well as the third country of origin. Where a food or feed which has been the subject of a notification under the rapid alert system has been dispatched to a third country, the Commission shall provide the latter with the appropriate information. The Member States shall immediately inform the Commission of the action implemented or measures taken following receipt of the notifications and supplementary information transmitted under the rapid alert system. The Commission shall immediately transmit this information to the members of the network. Participation in the rapid alert system may be opened up to applicant countries, third countries or international organizations, on the basis of agreements between the Community and those countries or international organizations, in accordance with the procedures defined in those agreements. The latter shall be based on

⁵³ Arts. 50-52 GFL. See for information of RAS and for weekly overviews of alerts: http://ec.europa.eu/comm/food/food/rapidalert/index_en.htm.

⁵⁴ As has been indicated in Section 3.1, the EFSA has been instituted by the GFL. It is an independent agency responsible for scientific risk assessment and risk communication. Risk management through law making and enforcement is the responsibility of the European Institutions, the Commission in particular, and the Member States.

reciprocity and shall include confidentiality measures equivalent to those applicable in the Community.

Alert notifications are sent when the food or feed presenting the risk is on the market and when immediate action is required. Alerts are triggered by the Member State that detects the problem and has initiated the relevant measures, such as withdrawal/recall. The notification aims at giving all the members of the network the information to verify whether the concerned product is on their market, so that they can take the necessary measures. Information notifications concern a food and feed for which a risk has been identified, but for which the other members of the network do not have to take immediate action, because the product has not reached their market. These notifications mostly concern food and feed consignments that have been tested and rejected at the external borders of the EU. They avoid attempts to import them through another point of entry, thus preventing the placing on the market of a food or feed which presents a risk to the consumer.

5.6. Second line inspections

As we have mentioned before, in 1997, the FVO was instituted.⁵⁵ It is not an independent agency (like the EFSA) but a part of the Directorate General Health and Consumer protection (known by its French acronym as DG Sanco) that in turn is a part of the European Commission's civil service apparatus. It has its headquarters in Ireland, however, at a distance from the other parts of DG Sanco in Brussels.⁵⁶

The Commission, in its role as guardian of the Treaties, is responsible for making sure food safety law is implemented and enforced. This is the foundation for the work of the FVO. The main role of FVO inspectors is to check how national authorities implement and enforce relevant EU legislation. Inspections are primarily targeted towards evaluating the nature and effectiveness of the national control systems in place and whether they are capable of delivering the required standards. At the same time, FVO inspectors also carry out on-the-spot checks on farms, markets, food-processing establishments, and other places where food is prepared or handled, to make sure that the reality matches what should be implemented. This is essential if the inspectors are to have a full picture, and be able to give a true, complete, description of the real situation.⁵⁷ The Member States must give all necessary assistance and provide all documentation that the Commission experts – the FVO – request. Each year, the FVO prepares a programme of inspections that is published on the website of DG Sanco.⁵⁸ Inspections can be carried out in response to requests from (third) countries looking for approval to export to the EU (see below).

Following an inspection, the FVO produces a report of its findings and conclusions, making recommendations for actions to be taken by the national authorities to correct any shortcomings that may have been identified. The authorities have to frame an action plan, showing how to deal with problems, and including deadlines for corrective action. The final report of the inspection is published on the DG's website, together with any comments from national authorities. Should

55 The former Community Office for Veterinary and Phytosanitary Inspection and Control which had been set up in 1991 and was attached to the Directorate-General for Agriculture was transformed into a Food and Veterinary Office attached to the Directorate-General for Consumer Policy and Consumer Health Protection.

56 See: http://europa.eu.int/comm/food/fvo/index_en.htm. See also: http://europa.eu.int/comm/dgs/health_consumer/newsletter/200209/consumervoices_en.pdf

57 FVO inspectors have no competence to carry out national enforcement measures against companies, farms, etc.; they can only report findings and conclusion towards national competent authorities.

58 See: http://ec.europa.eu/comm/food/fvo/index_en.htm. For the 2006 programme of inspections, see: http://ec.europa.eu/comm/food/fvo/inspectprog/2006-year_en.pdf. FVO plans to perform 270 inspections in 2006, 172 of which concern food safety. 160 inspections are to take place within the EU and 110 outside.

a serious, general health risk be identified, the Commission can impose a safeguard clause on the Member State or third country concerned. This allows for a wide range of additional controls, varying from systematic testing of imports to the imposition of a total ban on trade in certain animals or products. Where a specific problem is identified – for example where a food-processing establishment in a third country is found to be operating in an unsafe manner – the Commission can remove it from the list of establishments approved for export to the EU.

Non-compliance by Member States may result in infringement proceedings.⁵⁹ The Commission's civil servants in the FVO carry out an important task in the context of the role of the Commission as guardian of the Treaties. In most other areas of substantive EU law active inspection of the Member States' performance by EU officials is unheard of. Although the FVO is not mentioned as such, the new Regulation 882/2004 provides a further legal basis for its activities in the first paragraph of Article 45.

Article 45(1) of Regulation 882/2004/EC

Commission experts shall carry out general and specific audits in Member States. The Commission may appoint experts from Member States to assist its own experts. General and specific audits shall be organized in cooperation with Member States' competent authorities. Audits shall be carried out on a regular basis. Their main purpose shall be to verify that, overall, official controls take place in Member States in accordance with the multi-annual national control plans referred to in Article 41 and in compliance with Community law. For this purpose, and in order to facilitate the efficiency and effectiveness of the audits, the Commission may, in advance of carrying out such audits, request that the Member States provide, as soon as possible, up-to-date copies of national control plans.

5.7. Controls in third countries

Although the FVO formally has no jurisdiction outside the EU, Regulation 882/2004/EC provides for official controls in third countries in Article 46.

Article 46 of Regulation 882/2004/EC

Commission experts may carry out official controls in third countries in order to verify [...] the compliance or equivalence of third-country legislation and systems with Community feed and food law and Community animal health legislation. The Commission may appoint experts from Member States to assist its own experts.

These controls in third countries may only be executed if the authorities in those countries agree to them. However, as such controls may be a condition for export to the EU, these authorities have little alternative.⁶⁰ Imports of animal products from third countries are only allowed if the exporting state and the specific establishment appear on a list of approved countries/establishments. The FVO performs controls in third countries in order to establish whether or not the approval can be given and maintained. Both Regulation 882/2004/EC and 854/2004/EC elaborate on the criteria that have to be met by third countries.

⁵⁹ Art. 226 EC Treaty.

⁶⁰ The inverse situation also exists, third countries carrying out inspections in the EU, and the Regulation provides that the Commission has to assist Member States in dealing with such situations.

6. Cooperation between sector and authorities

6.1. Back to the case

The case described in the introduction provides an example where HACCP failed in the sense that a major hazard was not eliminated, but traceability contributed to solving the ensuing problem. Apparently the use of clay for separating potatoes was not identified as a critical step where contamination had to be prevented. Apparently the dioxin escaped other detection points as well. However, because the dairy farms could provide information on the origin of the animal feed they had used, the cause of the contamination could be identified by the Dutch authorities and the affected products could be taken off the market.

6.2. Interaction

It seems very likely that the developments within the food chain and the emergence of voluntary and imposed systems of self-control will have an effect on official controls by the Member States. Some effects are spontaneous, some imposed on the national level and some on the European level.

A recurring feature in EU food law is the obligation for food business operators to keep records and to provide the information on request to the authorities. We find this in the provisions on HACCP and traceability cited above and also in provisions on risk management like the obligation to withdraw unsafe products from the market and to recall them from consumers.⁶¹

6.3. Rights of defence?

A loose end in EU food safety law is the balance between risk management and enforcement. Risk management calls for cooperation and an obligation for food business operators to provide information on food safety problems, while enforcement goes hand in hand with the rights of defence provided for in the European Convention on the Protection of Human Rights and Fundamental Freedoms (Art. 6), in particular the right to remain silent and not to incriminate oneself. EU legislation shows little concern for the rights of defence at this point. One may wonder whether the emphasis that EU law puts on enforcement and deterring sanctions may not discourage food business operators from promptly reporting on problems they may have caused. It is likely that a considerable amount of discussion will arise as to what extent the information that business operators are obliged to provide, may be used by the authorities when imposing sanctions on the operator. As long as discussion on matters of human rights and criminal law rage, food business operators may be tempted to protect themselves first and food safety second. The German legislator has taken a clear position in this regard. The German application of the EU requirements to cooperate; § 44 second indent of the *Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch* (LFBG; Food, Food Contact Materials and Feed Code),⁶² explicitly states that the information provided by the food business operator may not be used against him/her in criminal or punitive proceedings.

61 Art. 19 GFL.

62 See: <http://bundesrecht.juris.de/lfgb/BJNR261810005.html> or http://www.sadaba.de/GSBT_LFGB_01_16.html. See on this subject: Peter M. Huber, 'Meldepflichten, Information und Warnung – zwischen Art. 19 BasisVO, § 40a LMBG, § 8 ProdSG und dem Glykol-Beschluss des Bundesverfassungsgerichts', 2004 *Zeitschrift für das gesamte Lebensmittelrecht*, no. 3, pp. 241-264.

Protection of the rights of defence in Germany

LBF § 44 (2)

Übermittlung nach Absatz 3 Satz 1 oder nach Artikel 18 Abs. 3 Satz 2 der Verordnung (EG) Nr. 178/2002 darf nicht zur strafrechtlichen Verfolgung des Unterrichtenden oder Übermittelnden oder für ein Verfahren nach dem Gesetz über Ordnungswidrigkeiten gegen den Unterrichtenden oder Übermittelnden verwendet werden. Die durch eine Unterrichtung nach Artikel 19 Abs. 1 oder 3 Satz 1 oder Artikel 20 Abs. 1 oder 3 Satz 1 der Verordnung (EG) Nr. 178/2002 erlangten Informationen dürfen von der für die Überwachung zuständigen Behörde nur für Maßnahmen zur Erfüllung der in § 1 Abs. 1 Nr. 1 oder 4 Buchstabe a Doppelbuchstabe aa genannten Zwecke verwendet werden.

This provision gives priority to risk management over enforcement. It will undoubtedly stimulate operators to come forward with problems they discover within their organization. However, there is also the risk that this provision will be misused to escape punishment for intentional neglect. EU-wide harmonization on this issue is called for. It seems worth considering shifting the emphasis in food safety law from enforcement to cooperation in risk management.

7. Conclusion

The case presented in the introduction shows how in modern EU food safety law the different layers of controls interrelate. A coincidence of lapses in the HACCP systems applied in the consecutive stages of the food and feed chain had allowed dioxin to enter the production process and spread through the interrelated chains undetected. This illustrates the interdependence of the links in the chain. The international nature of the chains concerned required the cooperation of the national authorities in three countries and of the European Commission. Thanks to a better functioning system of traceability the source of the problem could finally be identified and eliminated. The multi-layered system of food safety controls may not be perfect, at least in this specific case it proved more or less to be up to its task to eliminate a food-borne threat to public health within reasonable time. Nevertheless we have doubts whether the intensive regulations on controls will be the most effective way to safeguard food safety.

In this respect, first of all, we refer to the title of this article. Millefeuille is a pastry made of two layers of puff pastry – in itself a layered product – with a layer of custard in between. It is notoriously difficult eating. If you bite it or apply a fork to it, the custard is likely to spray all over the place. It has sometimes been used in interviews with job applicants to test their ability to deal with the dilemma of insulting by refusing the kind offer and losing dignity by being unable to eat it in a decent way. Similarly the food sector is faced with the challenge not to be squeezed between the layers of self-controls and third-party controls from below and the layers of national official controls and EU interference from above.

We agree with the reconstruction of EU food law in reaction to food safety crises in principle. However, the new regulatory system takes refuge in command and control: it stacks layer upon layer of controls. Food and feed business operators are responsible for food and feed safety. They are required to execute self-controls within their businesses. These self-controls are supplemented by controls within the food chain. From a public law point of view, the latter controls are voluntary. They are regulated by private law, and therefore in theory formal relations based on mutual agreement. Nevertheless the power concentration at the end of the food chain (retail) is such that the obligation to adhere to civil law systems weighs on business operators in a similar

way that public law requirements do. These obligations based upon private law may turn out to be more effective than strictly regulated official controls.

In reaction to the emergence of self-controls the approach of official controls shifts from product inspections to process inspections and further to system inspections. National food safety controls are not only heavily regulated by EU legislation, but also put under supervision by the Food and Veterinary Office. These controls even go beyond the external borders of the European Union. It is only natural that a regulatory system that was created in response to crises shows some martial characteristics. Nevertheless squeezing the food sector between four layers of controls seems a little overdone. It is to be hoped that a fair balance will be found between what is necessary from a risk management point of view and what is reasonable from an administrative burdens point of view. In this respect the authors appreciate the envisaged lessening of intensity of official controls in situations where private law arrangements prove effective.

It is a good thing that the Commission's desire to impose upon the Member States the use of criminal law has so far been countered. Nevertheless a fair balance has not yet been struck between the requirements of enforcing against food business operators on the one hand and encouraging food business operators to cooperate in risk management on the other hand. It is the authors' view that such a balance is more likely to be found in administrative law than in criminal law.