
論 説

Food Safety Regulation in Europe and Germany

Prof. Dr. Arno Scherzberg
and research assistant Irena Garbe (LLM)
Organizer Kenji Shimoyama

本論文は、2017年9月11日に一橋講堂会議室にて、執筆者であるアルノ・シェアツベック教授による「ヨーロッパとドイツにおける食品安全規制」と題した講演内容をもとにしたものである。この講演では、ヨーロッパとドイツにおける食品の安全性に関わる代表的な事件を取りあげ問題点を明確化した上で、食品安全に対する責任の所在、現行制度、食品安全に関する諸原則、近年の法制度に関するトピックに加え、法執行とその問題点、権利論、そして、改革の必要性について言及され、いくつかの提案が行われた。この講演に対する質疑応答を受けて本論文が執筆された。

シェアツベック教授は、2000年からドイツ・エアフルト大学国家学部公法・行政学講座の正教授であり、食品や化学物質、原子力などのリスク制御に関する法的研究におけるドイツの第一人者である。共同執筆者であるイレナ・ガーベ氏は、同教授の講座において2014年から助教を務めている。この講演は、科学研究費補助金基盤研究(B)「東アジア地域における食品安全法制の比較法的研究」(研究代表者：高橋滋法政大学教授。研究課題番号：16H03541)による研究成果の一部である。

I. Introduction

No matter how strict a system of food legislation may be, it cannot guarantee that food posing a health risk will never enter into the human food chain. Food legislation can only create a framework of conditions to ensure that the food supply is on the whole safe and of a high quality and that the consumer is enabled to make well informed choices. The European Union and its Member States are striving to reach this goal. Nevertheless, food safety scandals continue to occur,

sometimes on a large scale and sometimes affecting hundreds or even thousands of victims. This raises doubts as to the efficacy of the European system. Our paper is aimed at clarifying the basic features of European food safety protection and to establish how far this area is in need of reforms.

To this end we will first discuss some recent food scandals to outline the scope of the problem; we will then address the allocation of responsibilities for legislation and execution in the food sector in Europe, mention the most important pieces of legislation and introduce the principles of food safety specified therein. We will briefly mention questions of law enforcement, of the legal protection of the food operators and the rights of the consumers before towards the end we'll point out some areas where reforms are needed.

II. A Few Examples of Food Safety Scandals to begin with

1. The BSE Crisis¹⁾

The Mad Cow Disease (Bovine Spongiform Encephalopathy) first appeared in the 1980s in England and some time afterwards there was an outbreak on the European Continent. Cattle had been fed for years with meal produced from animal carcasses, even including animals that had been infected with scrapie, a fatal, degenerative disease that affects the nervous systems of sheep and goats. As a result, 180,000 cattle in England were infected with BSE, a disease caused by protein building blocks (prions) clumping together in the brain.

The British authorities first played down the full extent of BSE, mainly by disputing that there were any health risks for humans, but it became evident that the consumption of BSE-infected beef can cause a form of brain damage in humans known as the Creutzfeldt–Jakob disease (vCJD). Worldwide almost 200 people died from this disease.

It was mainly the EU wholesale ban on meat-and-bone meal as animal feed and

1) Focus Online, Vor zehn Jahren tobte der Rinderwahn, http://www.focus.de/gesundheit/ratgeber/gehirn/krankheiten/tid-20533/bse-vor-zehn-jahren-tobte-der-rinderwahn_aid_574970.html, (26.10.2017).

mass slaughter of the infected herds which ended the BSE infections. As a result of the BSE scandal, certification of origin for beef was prescribed in order to limit the risk of any future cases.

2. Meat Scandals²⁾

From 2005 – 2007 several meat scandals occurred in Germany. In 2005 some thousand metric tonnes of unsafe beef and turkey were confiscated from various butchers throughout the country. In addition, it came to light that a wholesale trader had re-labelled about 200 tonnes of meat which had been unfit for human consumption and had sold the meat to be used for doner kebabs. At the same time, the Federation of German Food and Drink Industries gave voice to their suspicion that up to 15,000 tonnes of rotten meat, which till then had not been discovered, was still in circulation.

In February 2013 there was solid evidence that, in several European countries, horse meat had been re-labelled as beef and had been used for the production of frozen lasagne and beef burgers. Rumanian horse meat labelled as beef and processed in ready-made meals was being sold to a French meat factory by a Dutch wholesale trader with a business address in Cyprus before the meat finally ended up in Austrian, German, British and French supermarkets.

However, the measures taken as a result of these findings were unsatisfactory: the EU Commission shrank back from requiring a general certificate of origin for all meat products. This allegedly would have been too cumbersome for the meat industry in the face of the convoluted system of supply chains.

Whether as a direct result of the meat scandals or due to life-style changes, meat consumption in Germany is in decline - since 2010 by five per cent. Nowadays about 10 % of the population basically eat no meat and 56 % have

2) *Sauer*, Fleischskandal bleibt folgenlos, <http://www.fr.de/wirtschaft/dossier/spezials/lebensmittel/pferdefleischskandal-fleischskandal-bleibt-folgenlos-a-656382>, (26.10.2017); *Kwasniewski*, Ein weiterer Pferdefleischskandal ist jederzeit möglich, <http://www.spiegel.de/wirtschaft/ein-jahr-nach-dem-pferdefleischskandal-ist-in-der-eu-wenig-passiert-a-951882.html>, (26.10.2017); Spiegel Online, Herkunfts-Label könnte Fleisch massiv verteuern, <http://www.spiegel.de/wirtschaft/soziales/eu-bericht-warnt-herkunfts-label-verteuert-fleisch-massiv-a-931310.html>, (26.10.2017).

made the conscious decision to eat less meat than they used to.³⁾

3. The EHEC Epidemic⁴⁾

Between May and July 2011 almost 4,000 people in Germany fell ill to an infection with a dangerous intestinal pathogen known as EHEC, 53 people died. The epidemic had also affected other European countries.

The process of reconstructing the commodity flow and delivery routes of the supposedly contaminated food proved to be difficult.⁵⁾ After some false conclusions involving warnings against the consumption of lettuce and tomatoes, there were a few weeks of uncertainty before the cause was identified as sprouts from Egypt, which had been grown and distributed by a firm in northern Germany. It came to light that the authorities had grossly underestimated the risk caused by the consumption of raw shoots. They had categorized the German sprout farm as a “horticultural business” and not as a food producer – with the result that the business was subjected to lower hygiene standards and less strict controls. As a consequence of the epidemic, there are new stipulations for imports, hygiene and traceability of seeds and sprouts.⁶⁾

4. Fipronil⁷⁾

In July 2017 Fipronil, an anti-lice insecticide, was found in eggs from chicken coops which had been treated with a certain cleaning agent. The eggs, originated

3) Vegetarierbund Deutschland, Anzahl der Vegetarier und Veganer in Deutschland, <https://vebu.de/veggie-fakten/entwicklung-in-zahlen/anzahl-veganer-und-vegetarier-in-deutschland/>, (16.11.2017).

4) Focus Online, EHEC-Darmkeim auf Sprossen, http://www.focus.de/gesundheit/ernaehrung/lebensmittelskandale/tid-11388/lebensmittelskandale-heute-antibiotika-gestern-ehec-und-morgen-ehec-darmkeim-auf-sprossen_aid_631612.html, (16.11.2017).

5) Food-monitor, EHEC-Krise 2011 völlig unzureichend aufgearbeitet, <https://www.food-monitor.de/2012/05/ehec-krise-2011-voellig-unzureichend-aufgearbeitet/>, (26.10.2017).

6) Foodwatch, EHEC-Krise 2011 ist nicht aufgeklärt, <https://www.foodwatch.org/de/informieren/ehec/mehr-zum-thema/>, (26.10.2017).

7) Frankfurter Allgemeine, Das sollten Verbraucher über den Fipronil-Skandal wissen, <http://www.faz.net/aktuell/gesellschaft/gesundheit/fipronil-eier-informationen-fuer-verbraucher-15135041.html>, (26.10.2017).

in the Netherlands, meanwhile entered the market in at least 45 countries, including the USA, South Africa and Hong Kong. Fipronil has a toxic effect on the nervous systems of vertebrates; the effect on humans is not exactly known. However, the extent of contamination in most of the eggs is regarded to be below any health risk levels. Nevertheless, more than 35 million eggs in Germany, the Netherlands and Denmark have so far been destroyed and, for several months, searches were going on in egg products such as egg salad, pasta and cakes for any sign of Fipronil contamination. The affected eggs can be relatively easily identified by their certificates of origin, but there is no comparable labelling system for processed eggs.

Apart from the criminal energy displayed by the cleaning agent producers, who applied Fipronil illegally, this case showed considerable gaps in the European food monitoring system. The Dutch authorities are believed to have known about this problem for several months, and the Belgian authorities for several weeks, before the announcement of the contamination, but they first kept back their findings from the EU authorities. They did so allegedly to ensure that the perpetrators would be prosecuted, but also possibly to protect their own food industry in the context of international competition. This is why the European Rapid Alert System for Food and Feed, which will be discussed later, completely failed.

Apart from these publicly discussed cases there are, of course, numerous everyday infringements against Food Law. According to the latest report from the German Federal Office for Consumer Protection and Food Safety, in 2015 a little more than 500,000 food operators in Germany out of 1, 2 million were inspected; there were complaints against 25% of the businesses and 12 % of the products. The complaints were mainly about infringements against hygiene regulations and labelling obligations; 16 % of the complaints however concerned microbiological contaminations.⁸⁾ These “everyday” infringements are not generally made available to the public.⁹⁾

8) Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Häufiger Mängel bei der Lebensmittelkennzeichnung, https://www.bvl.bund.de/DE/08_PresseInfothek/01_Fuer-Journalisten/01_Presse_und_Hintergrundinformationen/01_Lebensmittel/2016/2016_11_30_HI_Jahrespressekonferenz_2016.html, (26.10.2017).

9) Foodwatch, Jeder vierte Betrieb wird beanstandet, <https://www.foodwatch.org/de/>

However, food safety is a deep public concern. According to a recent survey 58 % of the Germans are afraid of food contamination, making this issue the fifth biggest fear of the German population, next to issues as terrorism and political extremism.¹⁰⁾

III. Food Safety as an Item of European and National Law

1. The responsibilities for Food Safety in the European Union

The EU Member States have basically conferred their legislative powers in food safety law to the European Union, as differing regulations for food safety would obstruct cross-border trade in the Single Market. At the moment, there are over 30 EU regulations in force, which directly apply to each Member State. 15 regulations alone are concerned with the implementation and monitoring of food hygiene. The national law of each Member State implements and enforces these stipulations; according to estimates in the relevant publications, 38 national laws and more than 100 EU regulations in food safety law are in force in Germany.¹¹⁾ The European Commission together with its subsidiary organ, the Food and Veterinary Office, monitor the implementation of the European standards by the Member States.

However, not all the areas of food safety law have been standardised throughout Europe. For example, there are no EU regulations concerning food irradiation. In such a case, the general rule of the Single Market (Article 34 – 36 Treaty on the Functioning of the European Union) is applied: products, which have been legally introduced by a Member State into the food chain, can be lawfully distributed in all the other Member States as long as there are no compelling factors endangering the public interest such as the health and safety of the consumers.¹²⁾

informieren/smiley-system/mehr-zum-thema/lebensmittelkontrollen/, (26.10.2017).

10) R+V Versicherung, R+V-Studie: Die Ängste der Deutschen 2017, <https://www.ruv.de/presse/aengste-der-deutschen/grafiken-die-aengste-der-deutschen>

11) *Zipfel/Rathke*, Lebensmittelrecht, Loseblatt-Kommentar, 2013, B. Einführung, para. 27, beck-online.

12) ECJ Case 120/78, *Cassis de Dijon*, <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:61978CJ0120&from=DE>.

The implementation of EU-food law and the monitoring of food safety is primarily the responsibility of the national authorities. In Germany, the final authority for legislation is at the Federal level whereas the 16 Federal States are almost exclusively responsible for law enforcement and for on-site food safety inspections.¹³⁾ The Federal States have set up more than 400 inspection authorities and around 35 offices for monitoring food safety. Since 2012 a cross-state agreement sets up a Common Task Force and a crisis management policy for cases where unsafe food entered the food chain in various Federal States.¹⁴⁾

2. The Legal Framework

a) The General Food Regulation (EC) No. 178/2002¹⁵⁾

The General Food Regulation of 2002 comprises the basic principles of Food Law and food safety and is applicable as long as no specific regulation governs the issue in question. It covers all the links in the food chain from farm to fork, including the production, processing and distributing stages. The 2002 Regulation also determines the functions of the European Food Safety Authority (EFSA) and has set up the Rapid Alert System for Food and Feed (RASFF).¹⁶⁾

13) With the exception of section 40 (5) LFGB: in a few cases the warning of food which is hazardous for health is carried out by the Federal Office for Consumer Protection and Food Safety.

14) *Bobbert*, Bundes- und Länderkompetenzen zwischen Konvergenz und Divergenz, in: *Möstl/Meyer* (eds.), *Lebensmittelüberwachung: was uns Krisen lehren*, 2015, P.C.O., p.5, 13.

15) 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, OJ L31/1, 01.02.2002.

16) *Hagenmeyer*, *Lebensmittelrecht*, Skript 2013/2014, Behr's, p. 7-8; *Weck*, *Lebensmittelrecht*, 3rd ed., 2017, Kohlhammer, p. 11-13; the role of EFSA is discussed by *Zielinski*, *The role of the European Food Safety Authority in shaping the safety and quality of food*, in: *Härtel/Budzinowski* (eds.), *Food Security, Food Safety, Food Quality*, 2016, Nomos, p. 49 -58.

b) Regulation (EU) No. 1169/2011¹⁷⁾

The Regulation on food information of 2011, in force since December 2014, covers the general principles, demands and responsibilities for information concerning food and its labelling. The Regulation applies to all the members of the food industry whose business involves passing on information to the consumer, mainly producers, vendors and restaurants.

c) Regulation (EU) No. 2015/2283¹⁸⁾

The recently reformed Regulation regarding novel food determines the authorisation of food and additives, which were not used for human consumption in great quantities within the European Community before the 15th May 1997.

d) Regulation (EC) No. 1829/2003¹⁹⁾ and 1830/2003²⁰⁾

These two Regulations concern genetically modified food and feed and its traceability and labelling. These kinds of food are also subject to licence.

e) Regulation (EC) No. 1331/2008

The Regulation 1331/2008 establishes a common authorization procedure for food additives, food enzymes and food flavorings. Additives are substances which are not consumed in food in their own right or used as an extra ingredient, but

17) Regulation (EU) No. 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No. 1924/2006 and (EC) No. 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No. 608/2004, OJ L 304, 22.11.2011, p.18.

18) Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001, p. 1.

19) Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, OJ L 268, 18.10.2003, p. 1.

20) Regulation (EC) No. 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning 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, OJ L 268, 18.10.2003, p.24.

which are added for technological reasons in the processes of production, processing, packaging or storage, thus becoming incorporated as part of the food. Additives can trigger off allergies and are often associated with causes of diseases such as cancer. This is why the EU admits additives to the market only if they appear in an EU positive list. In addition, certain maximum quantities can be stipulated for their use.

f) The Hygiene Regulations²¹⁾

The Regulations (EC) No. 852-854/2004 cover the hygiene requirements to be followed in the handling of food. They contain specific rules applying to the handling of food originating from animals. For example, slaughter houses, egg producers and producers of milk products from raw milk are all subject to licence.

In general, the stipulations demand a high standard of hygiene for all the stages of food production. Appropriate hygiene provisions are especially essential for combating bacteria, viruses and parasites on food such as in the well known cases of salmonella in poultry and listeria in milk and meat products. The EU was able to reduce the number of salmonella cases in the EU region by more than a half between 2007 and 2011 on account of the tightening of the hygiene requirements in 2003.²²⁾

g) EC Food Monitoring Regulation No. 882/2004²³⁾

The Monitoring Regulation addresses the monitoring authorities in order to guarantee compliance with the high standards of the EU. It defines the

21) Regulation (EC) No. 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs, OJ L 139, 30.4.2004, p. 1; Regulation (EC) No. 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin, OJ L 139, 30.4.2004, p.55; Regulation (EC) No. 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organization of official controls on products of animal origin intended for human consumption, OJ L 139, 30.4.2004, p.206-320.

22) EU-Kommission: Lebensmittelsicherheit, 2014, p. 7, https://europa.eu/european-union/file/1288/download_de?token=GETML06L, (16.11.2017).

23) 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, OJ L 191, 28.5.2004, p. 1.

competences for the various inspection agencies at both the national and European levels.

h) The EC Health Claim Regulation No. 1924/2006²⁴⁾

The Health Claim Regulation is concerned with admissible information for labelling and advertising of food destined to reach the final consumers. Examples of health information on food products include claims such as an item of food being nutritious or that it might lessen the risk for a particular disease or even that it reduces weight. This kind of information can only be made if it has been entered into an official EU list, which guarantees the reliability of the data on a scientific basis.

In addition, the foods in question should be in line with a so-called nutritional profile, which stipulates the necessary requirements for food to be classified, for example, as “low-fat” or “non-fat”. In this way, unhealthy food bearing a health claim is prevented from entering the market. However, the EU Commission has up till now still not finalised the nutritional profiles.

i) The German Food and Feed Code²⁵⁾

In Germany the Food and Feed Code (LFGB) aims not only at giving concrete form to the EU laws but also at supplementing them. The purpose of the Code is to protect the consumer by preventing and averting health risks and to protect consumers from any forms of fraud within the food chain. Alongside the regulations combating health risks and promoting precautionary measures, the Food and Feed Code also includes regulations on food additives, on the responsibilities and execution of surveillance measures, on food monitoring, on the sampling process and on penalties and fines.

j) The Objectives of European Food Law

All the acts of legislation mentioned above follow three main objectives:

24) Regulation (EC) No. 1924/2006 of the European Parliament and of the Council of 20 December on nutrition and health claims made on foods, OJ L 404, 30.12.2006, p. 9.

25) The German Food and Feed Code of 3rd June 2013, BGBl I, 1426.

- health protection
- consumer information and protection against fraud
- promotion of innovations and - implicitly - securing an adequate food supply.²⁶⁾

In order to achieve these objectives, they establish a set of principles of European Food Safety discussed below (4.).

3. The Scope of the Food Law

Food (or “foodstuff”) as defined within the general principles and requirements of EU Food Law means “any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans”. This definition also includes drinks, chewing gum and any substance - including water - intentionally incorporated into the food chain during its manufacture or treatment.²⁷⁾

The scope explicitly excludes feed, live animals not intended for placing on the market for human consumption, plants prior to harvesting, pharmaceutical products, cosmetics, tobacco and tobacco products, narcotics and drugs.²⁸⁾

The definition of food also includes food supplements, and diet food intended for specific groups of people. Differentiating foodstuffs from pharmaceuticals is often a difficult issue.²⁹⁾ The so-called “functional food” comprises foodstuffs enhanced with ingredients such as fatty acids, vitamins, mineral substances, fibre as well as bacteria or plant substances such as ginkgo, aloe vera or garlic. These

26) Surprisingly, besides in Recital 29, 30 of Regulation 2015/2283, the objective of securing an adequate food supply is not mentioned in EU food law. Obviously the EU has complete trust in the power of the market. According to Recital 1 General Food Regulation “the free exchange of goods with safe and nutritious food is an important aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests.” However, e.g. in Germany, the right to food is widely acknowledged as an unwritten basic human right; cf. *Härtel*, *The Right to Food*, in: Härtel/Budzinowki (eds), *Food Security, Food Safety, Food Quality*, 2016, Nomos, p. 15, 33.

27) *Hagenmeyer*, (supra n. 16), p. 11.

28) *Weck*, (supra n. 16), p. 10.

29) *Hagenmeyer*, (supra n. 16), p. 20.

are mainly intended to prevent illnesses, to fortify the immune system or to aid digestion. According to the stipulation, all these cases come under foodstuffs as long as the dosage is made up in such a way that the effects on the organism do not exceed the effects that would be produced by consuming a reasonable quantity of food.³⁰⁾

4. The Principles of Food Safety

a) Defence against Hazards

Food Law requires a high level of health safety as stated in Article 5 (1), Article 6 General Food Regulation and Section 1 (1) No.1 Food and Feed Code. The consumption of food cannot be allowed to have any adverse effects on the lives and health of the consumers and any possible dangers are to be prevented.

Consequently, a general ban on the production of unsafe food or food harmful to health is in force and on placing such food on the market (Article 14 (2) (a) General Food Regulation; Section 5 (1) Food and Feed Code).³¹⁾ The probable short, mid and long-term effects of any food on the health of the consumers and also on subsequent generations are to be taken into consideration when assessing health risks. The ban only applies if there is a sufficient probability of there being some negative effects on human health. If, despite the bans, health risks become apparent, then the European Rapid Alert System for Food and Feed will be activated, which will be discussed at a later point

b) Precaution against Risks

In case of scientific uncertainty the precautionary principle applies. Article 7 (1) General Food Regulation makes allowances for risk prevention with regard to any case of scientific uncertainty.³²⁾ If the possibility of any effects injurious to health has been established on a scientific basis, but with an element of uncertainty about

30) ECJ ruling of 15.11.2007, C-319/05 ZLR 2008, p. 48 ff.; German Federal Court of Justice (BGH) ruling of 26.06.2008, I ZR61/05, ZLR 2008, p. 619 ff. para.23.

31) *Hagemeyer*, (supra n. 16), p. 4.

32) Cf. *Simon*, Risikoverwaltung im neuen Lebensmittelrecht, BayVBl 2009 p. 161, 163 f.

the existence and scope of a danger, then temporary risk management procedures can be implemented until further scientific evidence for a more comprehensive evaluation is available.³³⁾ In the case of there being potentially a risk of large-scale damage, emergency measures can be deemed necessary even before a risk analysis has taken place.³⁴⁾

As temporary measures additional risk investigations, public warnings and imposing obligations to withdrawing a product or to eliminate a cause of risk can be taken into consideration³⁵⁾. The choice of the temporary measures is to be carried out in accordance with the general criterion of proportionality as discussed below.

The precautionary principle e.g. was applied in the BSE crisis when, right at the beginning, differing scientific positions were maintained about the risk of BSE being passed onto humans.³⁶⁾ It was also applied in the case of acrylamide.³⁷⁾ In 2002 Swedish scientists succeeded in proving for the first time that this substance, when heated, appears in many starchy foods such as french-fries, crisps and crispbread. How dangerous this substance is, was not clear at that time. This is why the threshold limit values for acrylamide were lowered in gradual stages. A conclusive risk evaluation of the potential danger to humans has only recently been published and it confirms the evaluation to the effect that these foods are, in fact, carcinogenic.³⁸⁾

c) The Principle of Proportionality

State intervention with regard to citizens' rights, and in particular, with regard to their basic rights, always has to remain within the limits of proportionality. The EU Charter of Fundamental Rights with regard to any policies to be applied in the

33) For a restrictive application of this rule see ECI Case T -70/99, ECR 2002, II-3495, para. 156-159- „Alpharma”.

34) ECJ case C-236/01, ECR 2003, I-8105-Monsanto/Italy; *Zipfell/Rathke*, (supra n. 11), Art. 7 Verordnung (EG) 178/2002, para. 16.

35) *Simon*, (supra n. 32), p. 164.

36) Federal Administrative Court, BVerwG NVwZ-RR 2012, p. 99.

37) Bundesinstitut für Risikobewertung, Schweden weisen Acrylamid in Lebensmitteln nach, http://www.bfr.bund.de/de/presseinformation/2002/10/schweden_weisen_acrylamid_in_lebensmitteln_nach-1008.html, (16.11.2017).

38) EFSA, Acrylamide in food 2015, http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/acrylamide150604.pdf, (16.11.2017).

field of the EU Law together with the national catalogue of fundamental rights concerning all other forms of intervention provides the basis for this demand. Accordingly, the interventionist policy has to involve the mildest possible measures to achieve the intended goal, use appropriate measures for the target and, within the overall view of the purpose of intervention, implement measures which should appear proportionate to the level of encumbrance.

The proportionality requirement with regard to state intervention does not only concern measures for combating hazard but also those concerned with risk prevention. As a result, risk prevention measures are typically less severe in their implementation than measures taken to combat hazard. Also, in situations of scientific uncertainty, only preliminary measures for the avoidance of any intrusion of irreparable damage are usually admissible and only up to the point of the whole situation being further clarified.

In cases of scientific uncertainty, however, the relevant risk evaluation is hampered by the fact that often no reliable conclusions can be made concerning the nature, the intensity and the probability of a hazardous event taking place. This is why it can be helpful to resort to a guiding principle which has been developed in a different context of uncertainty: for courts to decide over the involvement of preliminary measures within provisional legal protection. If the final outcome of the legal process with regard to the substance of the motion is uncertain, a successful application for provisional legal protection will depend on the settlement of any error costs incurred by a court decision. The consequences incurred by interim measures being refused despite being successful in the substance of the motion is to be balanced against the consequences incurred by interim measures being accepted while the substance of the action being rejected. In this way the onset of irreparable damage can be avoided.

This approach can easily be applied on precautionary measures: they are to be considered proportional, if the consequences of an - in the final analysis - unnecessary measure are less severe for the relevant legal interests than the consequences of failing to implement a precautionary measure which proved, however, in the final analysis, to have been necessary.

d) Operator Liability: the Misuse Principle

As a general rule, resulting from the principle of proportionality, foodstuffs can be freely placed on the market without any form of registration or licensing. The legislator envisages no general risk, which would need some form of official preventive licensing or monitoring. Thus the food business operators themselves carry the prime responsibility for the safety of their food and their compliance with the relevant legal provisions. This includes the obligation to carry out a risk analysis according to Article 6 General Food Regulation and to self monitor the food production and distribution processes. The essential features of self-monitoring can be found in the so called Hazard Analysis and Critical Control Point (HACCP) System³⁹⁾, which will be discussed at a later point. State authorities intervene only in order to preventing any failure or misuse in executing these responsibilities.

e) Preventive Ban with Permit Reservation

However, owing to the high priority of food safety, the legislator allowed for a few important exceptions from the misuse principle and established a preventive ban with permit reservation;⁴⁰⁾ in these cases the respective materials are allowed to enter the market only after official permission has been given.

aa. Novel Food

This applies to food within the scope of the Novel Food Regulation.⁴¹⁾ The applications for authorisation are assessed by EFSA; the Commission in collaboration with a Standing Committee, which comprises representatives of the Member States, is responsible for the authorisation of this kind of food. For authorisation it needs to be established that the food does not, on the basis of the scientific evidence available, pose a safety risk to human health (Article 7 Novel Food Regulation).⁴²⁾ Recital 20 of the Regulation refers to the precautionary

39) Article 4 Regulation (EC) No. 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs, OJ L 139, 30.4.2004, p. 1.

40) *Doepner/Hüttebräuer*, in: Dieners/Reese (eds.), *Handbuch des Pharmarechts*, 2010, Beck, section 2 para. 100.

41) The new regulation on Novel Food (supra n. 18) is discussed by *Sokolowski*, in: Härtel/Budzinowski (eds.), *Food Security, Food Safety, Food Quality*, 2016, Nomos, p. 127 -140.

42) Article 7 Novel Food Regulation.

principle in case of any scientific uncertainties. Article 15 of the Regulation contains a significantly new provision for food traditionally used in third countries, which, if a history of safe use in the relevant third country is certified, can enter the market by means of a simple registration procedure.⁴³⁾

bb. Gene Food

Likewise food and feed which either contain genetically modified organisms (GMOs), consist of GMOs or are produced from them require authorisation: the product must be certified as safe and its development - cultivation, processing, consumption - should have no harmful effects for the health of humans, animals and for the environment.⁴⁴⁾ If there were any reasonable doubts about this, then the authorisation would be withheld on account of the precautionary principle.

The safety evaluation of GMO food and feed is also carried out by EFSA. The decision for authorisation lies again with the Commission in consultation with the Standing Committee of the Member States. The authorisation is limited to a period of 10 years. At present, about 70 varieties of genetically modified plants have been authorised in the EU for commercial purposes and use as food and feed. Almost all the cases involve imports.

Genetically modified maize (MON810) is at the moment the only GMO that is allowed to be used as seed and to be cultivated within the EU.⁴⁵⁾ Nevertheless, according to the so-called opt-out directive, the Member States are allowed to limit or even completely ban its cultivation on their territory for any compelling reasons, like the need to protect other food products from contamination.

cc. Additives

Additives are also prohibited with a ban, but still subject to authorisation. According to Recital 12 of Regulation 1331/2008 the authorisation must be preceded by an independent scientific assessment, of the highest possible standard, of the risks that they pose to human health. Furthermore their use is restricted to cases of necessity: additives can only be accepted into the EU positive list if no

43) Weck, (supra n. 16), download, www.kohlhammer.de (la0ishlt), p. 33.

44) Weck, (supra n. 16), download, www.kohlhammer.de (la0ishlt), p. 4.

45) Umweltbundesamt, Zugelassene Gentechnisch Veränderte Organismen, <http://www.umweltbundesamt.at/umweltsituation/gentechnik/zulassungen/>, (26.10.2017).

other economically or technically viable methods are available. Finally, authorisation needs to offer tangible benefits for the consumer.

At present about 320 additives have been authorised, which have been added to many kinds of food such as anti-oxidation agents, colouring, flavour enhancers, preservatives or stabilisers.⁴⁶⁾ Examples include tannin as an additive for fruit juices, aspartame as a sweetener and ascorbic acid as an anti-oxidation agent.⁴⁷⁾ If a new additive is to be authorised, an application to the EU Commission has to be made. The EU Commission then assigns the European Food and Feed Authority the task of making a risk evaluation. This evaluation should assess independently and scientifically whether the additive carries hazards for human health.⁴⁸⁾ Alongside the authorisation procedures for *new additives*, even additives already authorised before the adoption of the additive Regulation in 2008 have to undergo a new risk evaluation. Consumer protection is given a high priority status in this context.

dd. Health Claims

Finally also the Health Claims Regulation establishes a preventive ban with permit reservation for voluntary information on nutritional value and health safety on food packaging or labels⁴⁹⁾.

5. Some Aspects of Food Safety in Detail

a) Shared Responsibility

As has been previously shown, the food and feed operators are obligated to carry out regular, wide-ranging checks to ensure that they are complying with all provisions of food law. According to Article 24 Novel Food Regulation they can, in the context of an authorisation process, also be required to carry out

46) A database can be found at <http://www.zusatzstoffe-online.de/zusatzstoffe/>, (26.10.2017).

47) *Weck*, (supra n.16), para. 114, 117.

48) Cf. recital 12 of regulation (EC) No. 1331/2008, OJ L 354, p. 2.

49) The Health Claim Regulation is discussed by *Olbrisch*, Health claims - challenges and chances for management decisions in food industry, in: Härtel/Budzinowski (eds.), Food Security, Food Safety, Food Quality, 2016, Nomos, p. 141-152.

surveillance checks of their foods' progress in the food chain.⁵⁰⁾

The essential features of self-monitoring are defined by the so-called HACCP principles.⁵¹⁾ Since 1993 the Hazard Analysis and Critical Control Points System, once set up as a space project to provide nutrition for astronauts, has been part of the Codex Alimentarius issued by FAO (Food and Agriculture Organisation) of the United Nations. Its aim is to ensure that risk factors and critical points in the process of food production and distribution will be identified and monitored. If the operator comes to the conclusion that his food does not meet the requirements of Food Safety or that it presents a hazard possibly affecting the health of humans, he is obliged to either to avoid or reduce the hazards or, if necessary, to withdraw his food from the market.⁵²⁾

The surveillance of the food operator's compliance with the respective provisions is the responsibility of the state authorities. The Regulation 882/2004 defines i.a. the scope of surveillance, surveillance methods, the objects for inspection, sampling and hygiene investigations as well as collaboration with the authorities of the European Union and the Member States.⁵³⁾

b) Public Warnings

If there are sufficient grounds to suspect that an item of food can cause a health hazard, then the relevant authorities are required to undertake the appropriate steps to inform the public about the nature of the health hazard, generally by issuing a public warning (Article 10 General Food Regulation). EFSA is the body responsible at the European level, whereas in Germany it is the responsibility of the Federal Office for Consumer Protection and Food Safety and of the various ministries in the Federal States.⁵⁴⁾

In addition Section 40 (1) (a) Food and Feed Code obliges the authorities to inform the public about certain other infringements of the Food Law, independent

50) *Hagenmeyer*, (supra n. 16), p. 61.

51) The monitoring procedure applies to the following aspects: hazard identification, hazard analysis of critical checkpoints, taking corrective actions, application of regular verification procedures and creating documents and records to provide evidence.

52) *Hagenmeyer*, (supra n. 16), p. 62.

53) *Meyer/Streinz*, LFGB - BasisVO, Einführung para. 66 - 84, 2nd ed. 2012, beck-online.

54) *Weck*, (supra n. 16), p. 27.

of there being a health hazard. However, the constitutionality of this provision is doubtful as I will discuss later.⁵⁵⁾

Furthermore Section 2 (1) German Consumer Information Law (VIG) grants the citizens' right to access all relevant information pertained by state authorities concerning consumer products;⁵⁶⁾ this involves i.a. access to information on infringements of the European and National Food Laws and safety hazards or risks arising from a consumer product. Section 6 (1) (3) of this law authorises the relevant authorities to provide active information to the public in such cases. It is still a matter of dispute as to whether which also refers to public warnings.⁵⁷⁾

c) Tracing

Traceability is an important instrument both for combating health hazards and for prevention. It involves being able to trace every type of food through all its stages of production, processing and distribution. The food operators have not only to document the origin and destination of each type of food, but also have to be able to certify the source of their food or its raw constituents.⁵⁸⁾

To this end each item of food packaging carries a batch number by which the producer and the food monitoring authorities can recognise from which consignment the product came - at least in theory. In the light of the problems involved in clearing up the product chain during the EHEC epidemic, foodwatch, an international NGO promoting consumer interests in the food sector⁵⁹⁾, rightly criticised deficits of traceability with regard to highly perishable food.⁶⁰⁾

d) Product Information, Protection against Fraud

Marking, advertising and presentation of food (including the packaging) are not

55) Cf. below VI 1.

56) *Zipfel/Rathke*, (supra n. 11), B. Einführung, para. 115-124, beck-online.

57) *Möstl*, Verbraucherinformation und Anprangerung als gezielte Lenkungsmittel, in: Möstl/Meyer (eds.), *Lebensmittelüberwachung: was uns Krisen lehren*, 2015, P.C.O., p. 25, 32.

58) *Weck*, (supra n. 16), p. 24-25.

59) Cf. <http://www.foodwatch.org/en/homepage/>, (27.10.2017).

60) Foodwatch, *EHEC-Krise 2011 völlig unzureichend aufgearbeitet*, <https://www.foodwatch.org/de/informieren/ehec/2-minuten-info/>, (26.10.2017).

supposed to mislead the consumers.⁶¹⁾ The mandatory labelling stipulations are aimed at enabling the consumer to make a well informed decision on the purchase and consumption of food (Article 8 General Food Regulation; Section 1 (1) No.2, Section 11 (1) Food and Feed Code).

Former EU Regulations concerning food labelling used to apply only to potentially hazardous products.⁶²⁾ Since the 2014 Regulation on Food Information⁶³⁾ is in effect, the situation has changed. The new food labelling provisions apply to all types of food that are introduced into the food chain and which are destined to be delivered to the end-consumer (Article 6 Food Information Regulation).⁶⁴⁾ The Union is guided by the understanding that the consumer decision can be “influenced by health, economic, environmental, social and ethical considerations” (Recital 3 Food Information Regulation).⁶⁵⁾

As a matter of fact, labelling is also obligatory in Germany even when the food sent to Germany fails to comply with the provisions of German Food Law because the foodstuffs were imported in accordance with the legal provisions from another EU country: they must be registered as far as this is necessary to protect the consumer (Section 53 (4) Food and Feed Code); this rule e.g. is applicable to irradiated food; in Great Britain, fish and fruit, for example, and, in Holland, chicken meat and prawns are allowed to be irradiated.⁶⁶⁾

With pre-packed food, the food operator has to display the following information on the label: the “denotation” of the food item, the nature and quantity of the ingredients, possible allergens, the total net quantity, its minimum durability or use by date, and, if relevant, the alcohol content. With meat and other foods

61) *Grube*, in: Voit/Grube, LMIV Lebensmittelinformationsverordnung VO (EU) No. 1169/11, Kommentar, 2nd ed. 2015, Behr's, Art. 7, para. 149.

62) Institute of Technology Assessment of the Austrian Academy of Sciences (ITA) (ed.), nano trust dossiers No. 31/2012, p. 5, <http://hw.oew.ac.at/0xc1aa500d-0x002c9d9a.pdf>, (17.01.2014).

63) The LMIV entered into force on 12. December 2011, however most of the regulations were to be applied only after December 2014.

64) *Weck*, (supra n. 16), p. 29; download, www.kohlhammer.de/la0ishlt, p. 15.

65) *Grube*, in: Voit/Grube, (supra n. 61), Art. 1, para. 22-23.

66) BVL, Bericht zu bestrahlten Lebensmitteln, https://www.bvl.bund.de/DE/01_Lebensmittel/01_Aufgaben/02_AmtlicheLebensmittelueberwachung/09_BestrahlteLM/lm_bestrahlung_basepage.html, (03.11.2017).

where it is necessary to avoid misleading the consumers, the labelling of the country of origin is obligatory according to Article 26 Food Information Regulation. For almost all the food types, there is a new obligation now to provide information on the food's nutritional value (calorific value, fat content, saturated fatty acids, carbohydrates, sugar, protein, salt).

With unpackaged items such as baked goods, fruit and vegetables to be bought over the counter or to be consumed in a restaurant, the consumer has to be notified, possibly on a notice board, of any allergens.⁶⁷⁾ According to Appendix II of the General Food Law, allergens are the 14 most important substances or products which can set off allergies or similar intolerances such as milk and milk products, gluten as in wheat, nuts and soya products. These have to be highlighted in the list of ingredients in such a way that they are clearly contrasted from other ingredients, e.g. by the font, style of lettering (for example, bold print) or by background colouring.

Special regulations apply to the labelling of genetically modified organisms. In the face of differing evaluations concerning the input of gene technology into foodstuffs, the consumers should be enabled to make an informed decision either to accept or reject the intake of genetically modified foods. This affects at the moment roughly 70 kinds of food and feed bearing EU import authorisations.⁶⁸⁾ However, foodstuffs produced with the aid of GMOs such as products from animals fed on genetically modified animal feed are not included in the labelling regulations.⁶⁹⁾

Thus, not every product which has come in contact with gene technology is subject to labelling strictures. This also applies to the commingling of technically unavoidable or "chance" mixtures. In the face of the close juxtaposition of genetically modified and unadulterated raw materials, this kind of commingling is nowadays unavoidable. For these cases a threshold value 0.9 percent applies to the

67) *Weck*, (supra n. 16), download, www.kohlhammer.de (la0ishlt), p. 18.

68) Bundesministerium für Ernährung und Landwirtschaft, Fragen und Antworten: Anbauverbot für gentechnisch veränderte Pflanzen, http://www.bmel.de/DE/Landwirtschaft/Pflanzenbau/Gentechnik/_Texte/NatRegelungAnbauverbote.html, (27.10.2017).

69) Cf. *Girnau*, Bio und Gentechnik, in: Leibe (ed), Lebensmittel zwischen Illusion und Wirklichkeit, 2014, P.C.O., p. 171, 175 f.

affected additives or to the food itself: but anything under this threshold is free from labelling obligations. This, however, only applies to cases where traces of GMOs have been authorised in the EU whereas any other cases of commingling are banned.⁷⁰⁾

IV. Law Enforcement and Enforcement Problems

1. The EU Level

The European Commission is, on the one hand, a legislative organ responsible for initiating legislation but, on the other hand, it has also executive powers⁷¹⁾ in areas of food law in which a uniform decision for the Single Market is required; these are:

- The authorisation of Novel Food and GMO food and
- The inclusion of new additives and of health claims in the respective EU-

lists according to Regulations No. 1333/2008 and 1924/2006.

The Member States are included in the Commission's decision making process: their authorities receive applications from the operators and state their position with regard to the effects of the authorisation on the environment and health. Furthermore their representatives sit in the respective Standing Committee, which takes part in the final decision making.⁷²⁾

The Commission is supported by EFSA, situated in Parma, Italy, which has the task of offering scientific advice and technological support both for legislation and policy creation. It advises the Commission on the making of official statements and makes recommendations based on scientific data. It is also responsible for risk evaluation whereas the Commission is responsible for risk management.⁷³⁾

The Food and Veterinary Office (VFO) in Grange, Ireland, monitors the national food surveillance authorities and to this end, it carries out regular

70) *Girnau*, (supra n. 69), p. 176 f.

71) *Meyer/Streinz*, (supra n. 53), para. 72.

72) *Meyer/Streinz*, (supra n. 53), para. 70.

73) *Meyer/Streinz*, (supra n. 53), para. 76.

inspections in the Member States. The inspectors test the monitoring systems of the Member States, but they also carry out inspections on the food producers themselves. The results of the investigations are made available to the individual Member States, to the EU and to the general public.⁷⁴⁾

If cases of acute risks to human health become known, then, the European Rapid Alert System for Food and Feed (RASFF) set up by Article 50 General Food Regulation is engaged.⁷⁵⁾ The RASFF provides - at least in theory - swift and comprehensive communication of food safety hazards within the EU. The general public is included in this flow of information - but anonymously, so that producer and product remain undisclosed.⁷⁶⁾

2. The Nation State Level⁷⁷⁾

EU Food Law is in general executed by the Member States, and the Commission has no authority to give instructions to the national administrative bodies.⁷⁸⁾

In Germany at the national level, the Federal Institute for Risk Assessment (BfR), the Federal Office for Consumer Protection and Food Safety (BVL) and the super-ordinate Ministry for Justice and Consumer Protection are the responsible authorities. The BfR evaluates risks for food safety, communicates its findings outside and gives advice to the Federal government. The BVL coordinates the exchange of information at the national level and reports to the European Commission. Furthermore, if public health is concerned, the Robert-Koch Institute, Germany's central scientific institution in the field of biomedicine, is to be involved.

74) *Meyer/Streinz*, (supra n.53), para. 69.

75) Details concerning the application of the RASFF are specified in Regulation (EC) No. 16/2011. To comply with the homogenous operation on a nationwide basis in Germany, details are specified in the general administrative regulation on the Rapid Alert System for Food and on Reports concerning Feed.

76) *Meyer/Streinz*, (supra n.53), para. 69.

77) Bundesministerium für Ernährung und Landwirtschaft, Lebensmittelsicherheit verstehen, http://www.bmel.de/SharedDocs/Downloads/Broschueren/Lebensmittelsicherheit-verstehen.pdf?__blob=publicationFile, (27.10.2017).

78) *Meyer/Streinz*, (supra n.53), para. 69.

The execution of official food monitoring is the responsibility of each Federal State and is assigned to their various authorities (ministries, regional governments and district authorities). The district and local authorities are entrusted with implementing the actual surveillance duties.⁷⁹⁾

However, the co-ordination between the Federal government and the Federal States in case of crisis has proven to be deficient as shown by the delayed reactions to the EHEC epidemic. At a time when 3,500 people had already been infected with the disease, there was only one case registered for this disease at the Robert-Koch Institute. The Central Task Force for the Federal States was deployed only at a time when the epidemic had already abated. The first public warning against the Egypt sprouts was given only 5 weeks after the outbreak of the epidemic.⁸⁰⁾

3. Section 39 Food and Feed Code as legal basis for state interventions in Germany

Two provisions refer to state inspections of and interventions in food production, distributing and marketing: on the one hand Article 54 of the Monitoring Regulation and on the other hand Section 39 German Food and Feed Code. These two provisions empower the authorities in case of infringements of Food Law amongst others:

- to impose any measures to protect the health of the consumers,
- to restrict or prohibit the placing of food on the market
- to demand withdrawals or recalls
- to close down the operations of a business either entirely or for a limited period of time as may be appropriate.

Of course the principle of proportionality needs to be observed.⁸¹⁾

The authorities responsible for food monitoring carry out the inspections and

79) *Weck*, (supra n. 16), p. 132-133.

80) Cf. Foodwatch's documentary, <https://www.foodwatch.org/de/informieren/ehec/mehr-zum-thema/>, (03.11.2017).

81) *Zipfel/Rathke*, (supra n. 11), LFGB, section 39 para. 62-65, beck-online.

the taking of samples on a continuous basis and independently of any particular suspicion. The inspections take place without prior notice and during normal business hours. The inspectors check whether the works' premises meet the hygiene requirements, whether the production processes match the hygiene demands, whether the packaged products are appropriately labelled for their destinations, and whether persons who are obligated to have health checks possess the relevant certificates of health. The businesses will then be informed about the results of the inspection and, if necessary, will be required to remove any deficiencies established by the inspection.⁸²⁾

If there is evidence that an offence has been committed, then a fine can be imposed. If there is a suspicion that a crime has been committed, then the public prosecutor's office will be involved. The relevant criminal offences here are abstract liability torts, and so a conviction requires only proof that the food has been a general threat to human health.

V. Legal Protection for Operators and Consumer Rights

1. Legal Protection for Food Operators

Businesses affected by a ban from the national authorities or other measures deleterious to their enterprise can, in accordance with national litigation law, demand legal protection to appear before the administrative courts. Generally, after preliminary administrative review, the action for rescission or the enforcement action apply. The Decisions by the EU-Commission fall under the jurisdiction of the European Court of Justice.

If a consumer makes a claim for access to information regarding a food operator or a product, the business in question has the right to defend itself against imparting the intended items of information at the administrative courts, if necessary by way of temporary legal protection.

As Criminal Law and Administrative Offence Law refer to persons, the criminal

82) *Weck*, (supra n. 16), p. 133-134.

investigations are not directed against a business which has brought a product onto the market, but rather against the person who is responsible for the concrete violation. The person affected can appeal against this decision within a period of 2 weeks (Section 67 (1) Code of Administrative Offences) and the local court is the responsible body for these appeals.

2. Consumer Rights

Aggrieved consumers have a variety of claims against producers, vendors and authorities. Contractual claims are directed against the vendor in case of a deviation of the product from the contractually agreed condition, like safety or suitability for consumption. These claims are independent of any fault on behalf of the vendor.

Above this, the purchaser can demand compensation if the deficient food caused damage to his legal assets such as costs for medical treatment for the restoration of his health or for loss of earnings owing to temporary absence from work on account of food poisoning. However, the requirement for these claims is that the vendor caused the damage either deliberately or at least by neglect.

If there is no contractual agreement, for example with the food producer, a consumer can resort to the general law of tort and to product liability law. According to tort law, the plaintiff has to prove either malicious intention or neglect on behalf of the perpetrator.

According to Product Liability Law, the operator has to take responsibility without culpability for damage caused by certain defects. This applies, in particular, to construction defects in product development, production defects and so-called instruction errors, e.g. wrong instructions for baby food.

State liability claims come into consideration when the damage to the consumer can be traced back to the infringement of an official responsibility by the relevant office holder, e.g. in the case of failure during an authorisation procedure or of false alarms in the form of a public warning.

VI. The Need for Reforms

The problems caused by the lack of co-ordination of the risk management authorities in the EHEC case and with Fipronil have already been mentioned. In this context, foodwatch rightly calls for a simplification of the lines of communication and for shorter reporting deadlines.⁸³⁾ Furthermore, reforms are necessary in the following areas:

1. Greater Transparency of Inspection Results

Regardless whether the requirements for a public alert according to Article 10 Regulation (EC) No.178/2002 and Section 40 (1) Food and Feed Code are available, Section 40 (1) (a) Food and Feed Code enjoins an obligatory publication of the name of the food operator in the following two cases

- infringements against threshold values or maximum quantities' regulations and
- not inconsiderable or repeated breaches against provisions of Food Law, which are designed for health safety or for protection of the consumer from deception.

The infringements don't need to have caused a concrete hazard or a risk for the consumer. But the imposition of a fine of at least 350 Euros⁸⁴⁾ must be expected.

This "naming and shaming" sanction is expected to ensure a closer compliance with Food Law. But various reservations based on the precept of legal certainty, the principle of proportionality and the presumption of innocence have been raised against this provision.⁸⁵⁾ In many of the German Federal States, the implementation of this norm has been suspended.⁸⁶⁾

83) Foodwatch, (supra n. 6).

84) Which at present (2017) is approximately equal to 45,000 Yen.

85) *Theis*, Transparenzgesetzgebung bei Lebensmitteln und Verbraucherprodukten, DVBl. 2013, p. 627, 633; *Möstl*, (supra n. 57), p. 25, 38 f.

86) *Elsing/Rosenow*, Mehr Transparenz bei Lebensmittelverstößen - § 40 Absatz 1a LFGB ist verfassungs- und europarechtskonform!, ZLR 2013, p. 240 ff.

Efforts for more transparency concerning the results of food inspections are still stuck at the discussion stage. Other European States have made more progress in this area; since 2001, in Denmark, hygiene Smileys have been awarded, which make the results of the food inspections immediately visible for the consumer⁸⁷⁾, and since 2017 in France the results of the national food inspections are being published.⁸⁸⁾ In the EU, discussions for a reform of the Monitoring Regulation are now taking place and are aiming at creating an EU-wide legal basis for the publication of all the inspection results including a comparative evaluation either by using a Smiley system or by hygiene traffic light symbols.⁸⁹⁾

2. Better Protection against Deceiving the Consumer in Health Claims

At present health claims are admissible even for unhealthy foods. In a recent report, foodwatch criticised cases of misleading the consumer by highlighting vitamin supplements in advertisements for food. According to the study, all the products under investigation proved to be too sweet, too fatty or too salty and failed to meet the WHO criteria for well-balanced food. “The food industry artificially adds vitamins to hundreds of products in tiny amounts in order to give ‘a healthy gloss’ to sweets, sugary drinks and other kinds of junk food …”, says foodwatch.⁹⁰⁾

The legal background to this deficit lies in the fact that the EU Commission has up till now still not worked through the nutritional profiles planned by the regulation 1924/2006 on health claims. The food industry has even tried to have this item removed from the Regulation. A resolution to this end was accepted in

87) Hygiene Ampel, Wie funktioniert der Smiley in Dänemark, <http://www.hygieneampel.de/die-hygieneampel/entwicklung/smiley/>, (27.10.2017).

88) Cf. Ministère de l’Agriculture et de l’Alimentation, Trial of Transparency of food hygiene official controls results in restaurants in Paris and Avignon, <http://agriculture.gouv.fr/trial-transparency-food-hygiene-official-controls-results-restaurants-paris-and-avignon>.

89) *MöStL*, (supra n. 57), p. 25, 42.

90) Foodwatch study, Food Industry Misleading Consumers with Vitamin-Fortified Junk Foods, p. 3 https://www.foodwatch.org/fileadmin/Themen/Health_Claims/Dokumente/2016-03-31_foodwatch_study.pdf, (16.11.2017).

Food Safety Regulation in Europe and Germany (Arno Scherzberg · Irena Garbe · Kenji Shimoyama)
the European Parliament on 12th April, 2016.⁹¹⁾

There is also a deficit in the regulations for food marketing aimed at children.⁹²⁾ 15% of children in Germany are overweight and this trend is on the increase. In 2007 a voluntary restriction on food marketing for children was agreed, according to which certain nutritional profiles for the food being advertised have to be fulfilled. But according to the findings of foodwatch, these proved to be ineffective: 90 % of the products advertised for children in Germany failed to fulfil the recommendations published by WHO for marketings for children.⁹³⁾ Foodwatch is calling for effective legal restrictions in conjunction with the German Diabetes Society and the German Adiposity Association.⁹⁴⁾

3. Better Protection against Contamination such as that from Mineral Oil in Food Packaging

It has long since been known that contamination in many foodstuffs comes, amongst other causes, from mineral oil being passed onto the food when packaged in recycled cardboard. It also affects supposedly healthy foods such as such as muesli, rice and oat flakes. A foodwatch test in three European States found some form of contamination in 43 % of the investigated foods.⁹⁵⁾ With confectionery, sample testing found that in a fifth of the foods the contamination even reached carcinogenic levels.⁹⁶⁾

An EFSA study shows that the concentration of mineral oil in the human body accumulates, can become extremely high over the years and may lead to chronic

91) Cf. Food Navigation.com: European Parliament votes to scrap Nutrition Profiles, <https://www.foodnavigator.com/Article/2016/04/12/European-Parliament-votes-to-scrap-nutrient-profiles>

92) Foodwatch, Wie die Industrie aus Kindern Junkfood-Junkies macht, <https://www.foodwatch.org/de/informieren/kinderernaehrung/2-minuten-info/>, (16.11.2017).

93) Foodwatch, (supra n.92).

94) Foodwatch, Sugar, fat and salt: when food causes disease, <https://www.foodwatch.org/en/what-we-do/topics/sugar-fat-and-salt/2-minute-info/>, (16.11.2017).

95) Foodwatch, Foodwatch Test 10/2015 Mineralöle in Lebensmitteln, https://www.foodwatch.org/fileadmin/_migrated/content_uploads/Testergebnisse_Mineraloele_in_Lebensmitteln.pdf, (16.11.2017).

96) Foodwatch, (supra n. 95).

food poisoning, cancer and genetic alterations.⁹⁷⁾ Packaging free of mineral oils is readily available and is only slightly more expensive. It is quite clear that the self-monitoring of the producers as well as the official food inspections have all failed. Thus there is an urgent demand for compulsory EU threshold values to be introduced for mineral oil contamination.

4. More Effective Criminal Food Law for Food Fraud

There are also serious deficiencies in the Criminal Law sanctions for food fraud. At present there is not even a standardised definition across Europe⁹⁸⁾, although cases of fraud are constantly occurring in the food market as has been seen in the meat scandals discussed earlier.⁹⁹⁾

National Law is the relevant body to carry out criminal sentences. According to Section 11 Food and Feed Code it is forbidden to bring food into the food chain with inadequate information or to promote such foods. A deliberate case of deception is punishable with up to a one-year prison sentence or with a fine. Cases of neglectful behaviour will only count as a misdemeanour. However, a catalogue which provides an automatic linkage of infringements and fines doesn't exist, and - as is generally the case with the law for administrative offences - the imposing of a fine is left to the discretion of the prosecuting agency.¹⁰⁰⁾ Thus the general deterrent effect of the provisions for fines is very slight.

There would be a threat of a custodial sentence of up to five years or a fine, if it were a case of fraud according to the Code of German Criminal Law; however this applies only if the food operator intendedly damaged the assets of the customer. In cases of culpable physical injury the sentence would be up to three

97) EFSA, Scientific Opinion on Mineral Oil Hydrocarbons in Food, <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2012.2704/epdf>, (16.11.2017).

98) *Wallau*, Lebensmittelstrafrecht - einige anstehende und künftige Fragestellungen, LMuR 2016, 89, beck-online.

99) *Herzog*, Ausmaß und Dimension des Lebensmittelbetrugs, in: Möstl/Meyer (eds.), Lebensmittelüberwachung: was uns Krisen lehren, 2015 P.O.C., p. 59 ff.

100) *Wallau*, Steuerung durch Sanktion - Grenzen und Potentiale des Ordnungswidrigkeitenrechts, in: Möstl/Meyer (eds.), Lebensmittelüberwachung: was uns Krisen lehren, 2015, P.O.C., p. 45, 50 f.

years. In general the reinforcement of Food Law by the criminal code is relatively weak.

Therefore the EU presses for improvements in the fight against fraud. In 2013, it was agreed by the European Council to make the exposure of organised criminal groups, involved in the intentional infringement of the Food Law regulations, a top priority in the work of the security authorities. But the implementation of new measures of investigation and prosecution is mainly up to the Member States; the Council can only call for an increase in staff and financial resources for the national authorities.

VII. Summary

The scandals and problems outlined during the course of this paper point to four essential causes for damage to the consumers, and a fifth cause needs to be added:

- a lack of knowledge about or an unwillingness to admit hazardous features of food and additives with the legislator, administration, producer or distributor, as in case of BSE
- criminal energy expended into disregarding the safety rules available in the context of the production chain and/or deficits regarding the official inspections as in the meat scandals
- the ponderous legislation in the EU, whether it be a case of insufficient insight into the necessity of some aspects of regulation or a case of indulgence towards the food lobby, which manages to prevent a quick reaction even when defects have been scientifically proven, as in the cases of mineral oil contamination, lacking rules for advertising aimed at children and the missing nutritional profiles for health claims
- the complexity of the globalised commodity chains, which hamper the monitoring of all the stages of production and processing and a rapid identification of causes in crisis situations as it happened during the EHEC epidemic.
- And as a fifth cause to be added: the consumer him- and herself. In Western societies the consumer supports a system in which the main

factor for competition in the food sector is pricing.¹⁰¹⁾ This encourages the food industry to save on staff and precaution measures and accept compromises at the expense of consumer health as in the case of mineral oil contamination caused by cheap packaging practices.

Thus, in spite of some improvements introduced as a result of the past food scandals the European food sector needs further reforms. Law makers and executive organs are on the right track, but are still a long way from effectively ensuring safety and transparency in the European food market. And they need, as in many other policy fields, a strong encouragement by the consumers and their NGO advocates.

101) *Herzog*, (supra n. 99), p. 59, 60.