Transforming the European Community's Regulation of Food Safety

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PREFACE

In the year 2000, the European Commission launched its White Paper on Food Safety. Following the conclusions in this paper, the Community made an impressive overhaul of its regulation of food safety. It put into place a completely new scheme, covering all stages in the food chain and all types of foodstuffs.

The present report describe the new scheme and assesses to what extent the Community's policy on food safety has changed. The objective is to provide a legal examination in order to answer the following three research questions:

(1) To what extent does the present regulation of food safety constitute a new regime?

(2) What legal factors have been decisive for the EU's regulation of food safety before and after year 2000?

(3) What are the most important legal principles of the European Community's regulation of food safety today?

According to the author, there has been an important change in the European Community's policy on food safety. Whilst before the millennial change food safety was only a side issue of other policies (common agricultural policy and creation of a common market), today food safety constitutes a policy in its own right; a policy which is given high priority in the Community.

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Jörgen Hettne
Acting Director, SIEPS

ABOUT THE AUTHOR

Morten P. Broberg is associate professor in European Union law in the Faculty of Law of the University of Copenhagen and senior project researcher at the Danish Institute for International Studies (DIIS). His present research is primarily focussed upon the European Union's regulation within the field of food safety.

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SUMMARY AND CONCLUSIONS

The objective of this report is to provide a legal examination of the European Community's regulation in the field of food safety in order to answer the following three research questions:

(1) To what extent does the present regulation of food safety constitute a new regime?

(2) What legal factors have been decisive for the EU's regulation of food safety before and after year 2000?

(3) What are the most important legal principles of the European Community's regulation of food safety today?

The examination provides some fairly clear answers to the three questions:

In the first many years following the inception of the European Community, food safety was a matter rarely dealt with under Community law. When dealt with, it would generally be as part of the legislation on the common agricultural policy. Food safety legislation at this stage was rather sparse, patchy and incoherent.

The situation changed in the 1970s and 1980s, when a growing body of legislation and case-law was formed. This legislation and case-law grew out of the view that food safety constituted a barrier to the free movement of foodstuffs and that such barriers should be eliminated. However, the legislation continued to be only patchy and did not provide any coherent scheme.

Following the food scandals of the 1990s and the White Paper on Food Safety in 2000, the Community made an impressive overhaul of its regulation of food safety. Whilst a number of legal measures focusing upon the elimination of barriers to trade remain in force until this day, the Community put into place a completely new scheme, covering all stages in the food chain and all types of foodstuffs. The first steps towards this new scheme were taken in the mid-1990s, but the decisive step was only taken with the adoption of Regulation 178/2002. This regulation introduced a number of important general principles that now apply to all Community legislation on food safety. In this respect it is of particular importance that today public health constitutes the principal objective within the field of European food safety

In other words, whilst before the millennial change food safety was only a side issue of other policies (common agricultural policy and creation of a common market), today food safety constitutes a policy in its own right; a policy which is given high priority in the Community.

In the opinion of the present author there can be no doubt that the present regulation of food safety constitutes a new legal regime *vis-à-vis* the regulatory scheme that applied before 2000. Or rather, whereas today the Community undoubtedly has a legal regime on food safety, it may be questioned whether the regulatory measures that applied before 2000 could properly be called a regime.

Lastly, the most important legal principles of the European Community's regulation of food safety applying today may be summed up as follows:

- *Coherence* (covering all types of foodstuffs)
- *Comprehensiveness* (covering the whole food chain)
- *Transparency* (public consultation and right to information)
- *Risk-based* (based on independent scientific advice)
- *Precautionary principle* (protection of public health is given priority, even where scientific uncertainty exists)
- *Free movement of goods* (all Member State measures must be weighed against the objective of creating a common market)

1 FOOD SAFETY IN A EUROPEAN CONTEXT

1.1 Objectives and research questions

These years public health is high on the agenda in European Community politics.[1] This has not always been the case. Until the 1980s the protection of public health primarily was a task left to the Member States, whereas the primary focus of the Community was upon first the securing of sufficient food supplies and later the creation of a common market with free movement of goods etc. Since the 1990s, however, the European Community increasingly has included protection of public health as part of its policies.[2]

To a considerable extent this change was occasioned by a number of food scandals that were tormenting the European public during the latter half of the 1990s. The scandals caused the European Community to take action in a number of ways. Thus, on 12 January 2000, the European Commission published its "White Paper on Food Safety"[3] which, in the opinion of many observers, marked the introduction of a completely new approach to the

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[1] A note on the use of references in this report: The terms "European Community", "Community" and "EU" are used interchangeably. References to EU thus do not imply the exclusion of legal measures enacted under the so-called first pillar. The terms Court, Court of Justice and European Court of Justice are all used to denote the Court of Justice of the European Community. The term Court of First Instance is used to denote the Court of First Instance of the European Community. This report contains numerous references to legislation of the European Community. In order to ease the reading, the Treaty of Rome with later amendments is named "EC Treaty" or "Treaty" and I refer to provisions of this treaty according to the numbering presently in place. Where a reference is made to a directive or a regulation, this reference will include the number, the title and the place of publication in the Official Journal of the European Union (abbreviated OJ). However, the suffixes EC and EEC have been eliminated as have the indications "Council", "European Parliament and Council" and "Commission" in the titles of the legislative pieces. Where references are made to communications, decisions etc., indications of the issuing institution(s) have been retained. References are frequently made to the "common market", the "single market" or the "internal market". For the purposes of the present report no distinction is intended between the three designations.

[2] According to Vogel, D., *The New Politics of Risk Regulation in Europe* (Centre for Analysis of Risk and Regulation (LSE), Discussion Paper No. 3, 2001) p. 1, the change of the European Community's risk regulation in general began in the mid 1980s. Initially the change appeared in the field of environmental protection and was caused by factors such as the Chernobyl disaster in 1986 and the enactment of the Single European Act in 1987.

[3] White Paper of 12 january 2000: Food Safety (COM (1999) 719 final).

regulation of food safety.[4] Often this perceived new approach is referred to as a "regime change".[5]

The present report examines the claim that with the White Paper on Food Safety, the European Community introduced a completely new regime in the field of food safety.

Changing from one regime to another rarely happens overnight. At least in the wisdom of hindsight we will normally be able to see that there were signs pointing to the change before it unfolded and, likewise, traces of he old system are likely to remain afterwards. Nonetheless, for reasons of clarity the above-mentioned White Paper will constitute the dividing line.[6] The objective of this report thus is to identify and map out how the European Community has regulated the field of food safety before, respectively after, the asserted new regime was introduced with the White Book on Food Safety of January 2000. The central research question of this examination therefore is:

> (1) To what extent does the present regulation of food safety constitute a new regime?

In order to answer this question, a central objective will be to map out the decisive legal factors in the field of EU food safety regulation before and after year 2000. This research question may be worded as follows:

> (2) What legal factors have been decisive for the EU's regulation of food safety before and after year 2000?

Moreover, I will consider the most important legal principles of the European Community's contemporary regulation of food safety. This research question may be summed up as follows:

> (3) What are the most important legal principles of the European Community's regulation of food safety today?

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[4] See for example Holland, D. and Pope, H., *EU Food Law and Policy* (Kluwer Law International, 2003) chapters 1, 3 and 20, van der Meulen, B. and van der Velde, M., *Food Safety Law in the European Union – An Introduction* (Wageningen Academic Publishers, 2004), p. 25 and 227, and Flowerdew, D. W., Additives, in Goodburn, K. (ed.), *EU food law* (Woodhead Publishing Ltd., 2001), p. 69. The Commission equally took this view as is for example apparent from the address of David Byrne, Commissioner for Health and Consumer Protection to the Scientific Steering Committee on the White Paper on Food Safety, Brussels 14 April 2000 (http://ec.europa.eu/dgs/health_consumer/library/speeches/speech47_en.-print.html).

[5] In this context regime means a totality of rules, measures, and norms aimed at achieving a certain goal. A regime change is a change that affects the nature of the system as a whole.

[6] As will be shown below, a number of changes were initiated at an earlier – or sometimes at a later – point in time. For example a number of institutional changes were made in 1997.

1.2 Terminology

Food makes up an important part of the life of most European citizens and, today, a great many Europeans are concerned about food safety. Terms like "food", "food safety" and "risk" thus are part of our everyday vocabulary, but are not always used uniformly. Moreover, the field of food safety is rife with a number of technical terms such as HACCP, additives and contaminants. Where necessary I will endeavour to explain such terms before using them. However, a limited number of terms are so essential to the analysis that brief explanations are appropriate at this point. The explanations have primarily been taken from Regulation 178/2002 which forms the cornerstone of the European Community's contemporary regulatory scheme on food safety.[7]

1.2.1 Food safety

"Food safety" runs like a red thread through this report. It refers to the question whether the consumption of a foodstuff by a human may cause a risk to his/her health.[8]

1.2.2 Food

Regulation 178/2002 defines "food" or "foodstuff" as (1) any substance or product, whether processed, partially processed or unprocessed, (2) intended to be, or reasonably expected to be, ingested by (3) humans.[9] "Food" is thus a very wide concept encompassing potentially harmful products such as for example those containing transfats[10] and alcoholic beverages.

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[7] See Articles 2 and 3 in Regulation 178/2002 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 2002 L 31/1) (hereinafter referred to as Regulation 178/2002). The precision of the definitions in Regulation 178/2002 leaves something to be desired, however. For the purposes of this report exact definitions are not required and so those found in Regulation 178/2002 will be used as explanations to aid the reader without it being necessary to go into a discussion of their precise delimitation.

[8] The terms "food"/"foodstuff", "risk" and "health" are all explained below in this Section.

[9] Regulation 178/2002, Article 2. The provision moreover includes a list of products that are not food. This list includes tobacco, medicinal products, cosmetics, residues and contaminants. The judgment in Joined Cases C-211/03, C-299/03 and C-316/03 - C-318/03, *HLH Warenvertriebs*, [2005] ECR I-5141, provides guidance on the distinction between *a medicinal product* and *a foodstuff*.

[10] Transfats are presumed to produce health problems. In the United States it has been estimated that between 30,000 and 100,000 cardiac deaths per year are attributable to the consumption of these fats, cf. Mozaffarian, D., Katan, M. B., Ascherio, A., Stampfer, M. J. and Willett, W. C., Trans Fatty Acids and Cardiovascular Disease, *New England Journal of Medicine,* 354, 15 (2006), 1601-1613.

1.2.3 Food law

The term "food law", when used in this report, means the laws, regulations and administrative provisions governing aspects of food safety, whether at Community or national level; it covers any stage of production, processing and distribution of food, and also of feed produced for, or fed to, food-producing animals.[11]

1.2.4 Food business

Regulation 178/2002 defines "food business" 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.[12]

1.2.5 Risk

Regulation 178/2002 defines "risk" as a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard.[13] This definition is constituted of three elements, namely (1) the likelihood and (2) the severity of (3) a possible future negative occurrence. The definition, when used in the field of food safety, is based on the condition that the negative occurrence is upon the health of one or more human beings.

A number of observations are relevant. *Firstly,* there is no requirement that the risk manifests itself within a short period of time. For example, high levels of heavy metals, such as lead, whose adverse effect on health may only manifest itself following a long period of time may also qualify as a risk. *Secondly*, there is no requirement that the adverse health effect must be produced independently of other factors. Thus, if a given food ingredient only produces negative effects in combination with another specific ingredient, it may still qualify as a risk. The same must be true where the other factor is not found in the food product itself; for example where certain ingredients may only produce negative effects in combination with an inactive lifestyle. *Thirdly,* it is important to emphasise that where EU food law refers to "risk" this implies a scientific approach since the first step in a risk analysis is to carry out a scientific risk assessment.

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[11] Slightly adapted from Article 3(1) of Regulation 178/2002. See also the regulation's recital 11.

[12] Art. 3(1) of Regulation 178/2002.

[13] Art. 3(10). Regulation 178/2002 defines "hazard" as a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect, cf. Art. 3(14).

1.2.6 Health

Community law frequently refers to "health", but does not provide a definition thereof. In the first recital of the preamble to the Constitution of the World Health Organization (WHO), health is defined as "a state of complete physical, mental, and social well-being and not merely the absence of disease, or infirmity".[14] In this report, this rather broad understanding is used when references are made to "health".

1.3 Food and culture in European society

Obviously, food meets a physiological need and it also plays an important role in the European economy. However, within a European context it is important to observe that food also occupies an important cultural position. Thus there is a great difference between the worker's quick breakfast on the way to the factory, the young sweethearts' romantic dinner served on exclusive china and consumed in the light from chandeliers, and old friends eating crayfish with good schnapps and *a capella* singing somewhere in the Swedish skerries. What we eat – and how we eat – is closely related to our identity and thus also to our national background. Take the Italians. To them pasta must be made from durum wheat – Italian durum wheat, that is. And mozarella cheese must be made from buffalo's milk. In contrast, Scandinavians happily eat pasta made from common wheat and mozzarella made from cow milk. And if you go to a Scandinavian pizzeria, you may find pineapple on the pizza. In Italy this would be true sacrilege.

In other words: To create a common market in the field of foodstuffs is a daring challenge. More than once the European Community has faced strong resistance from the Member States when it tried to abolish national requirements that worked as trade barriers between the Member States. Several of these conflicts ended up in the European Court of Justice.[15]

A telling example is the *3 Glocken* case concerning the question whether the Italian authorities could prevent the marketing in Italy of pasta made from common wheat flour rather than from durum wheat. Federico Mancini, the then Italian Advocate General of the European Court of Justice, in an emotionally drafted opinion vehemently argued in favour of not setting aside an Italian law that required all pasta to be made from durum wheat. Mancini based his opinion upon a number of arguments and observations,

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[14] Available at www.who.int/governance/eb/who_constitution_en.pdf

[15] See for example Case 120/78 *Rewe-Zental AG v Bundesmonopolverwaltung für Branntwein (Cassis de Dijon)* [1979] ECR 649, Case 261/81 *Walter Rau Lebensmittelwerke v De Smedt* [1982] ECR 3961, Case 178/84 *Commission v Germany (Reinheitsgebot)* [1987] ECR 1227 and Case 407/85 *3 Glocken* [1988] ECR 4233.

including that ”only pasta made with durum wheat does not become sticky during cooking and arrives on the plate as the Italians like it to be: “al dente” (and therefore, as André Gide put it in his Journal, on 22 June 1942, “glissant des deux côtés de la fourchette”).” The Court of Justice took a less emotional approach to the question and found that the Italian law was incompatible with the EC Treaty.[16]

In other words, whilst foodstuffs in a Community law context undoubtedly are covered by a number of Community rules, it is important not to forget that food is more than a product – it is also an essential part of our culture.

1.4 Methodology and structure

The core of this report is a “mapping out” of how food safety has been regulated before, respectively after, the publication of the White Paper on Food Safety in January 2000. Fixing the decisive dividing line in this way necessarily holds a great deal of arbitrariness but simultaneously provides a fine instrument for testing the hypothesis that a new regime has been introduced.[17] Focus will be upon

1. How is food safety regulated (as a coherent scheme or as patchy regulation having its principal focus upon other issues but food safety)?
2. In what form is it regulated (Treaty, regulations, directives, case-law)?
3. What are the objectives of the regulation of food safety (free movement of goods, public health, or something else)?

The report is divided into three main sections. Following this introduction, in Section 2, I turn towards the Community’s approach to food safety during the four decades following the adoption of the Treaty of Rome in 1957. Thereupon, in Section 3, I examine the Community’s approach to food safety following the publication of the White Paper on Food Safety in 2000. On the basis of this examination I draw my conclusions. These conclusions have been set out at the very beginning of the report.

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[16] Joined Opinion of Advocate General Mancini in Case 407/85 *3 Glocken,* see above note 15, and Case 90/86, *Criminal proceedings against Zoni* [1988] ECR 4285 – particularly para. 4. This Opinion may be compared with Mancini’s Opinion in Case 202/82 *Commission v French Republic* [1984] ECR 933, where the French rules on pasta were under attack by the Commission. The emotional involvement of the Italian Advocate General was markedly less pronounced in the latter case.

[17] The dividing line is adhered to fairly strictly. At times, however, it is not clear whether a given legal measure must be classified as falling within the earlier or the later period. or example, if a judgment concerning the interpretation of an old directive is only rendered after January 2000 (but perhaps the case has been introduced before this date), it is arguable that it should be considered as part of the period from before 2000.

2 FOOD SAFETY AS A DEFENCE – THE FIRST 40 YEARS

2.1 National regulations in a common market

Admittedly, food safety was not really an issue of the European Community in the first years following its inception. Food was primarily dealt with under the common agricultural policy (CAP), where the main focus was upon producing enough food to a poulation still suffering from the after-effects of World War II. Hence, food safety was primarily regulated by the Member States. The consequence of this was that questions of food safety primarily arose where the Member State rules fell foul of the Community rules. The *German Beer* case is a fine illustration of this.[18]

> In 1516, in the Duchy of Bavaria, the first Reinheitsgebot (German purity law) was formally introduced. According to this Reinheitsgebot, the only ingredients which could be used for the brewing of beer were barley, hops and water.[19] The Reinheitsgebot since spread to other parts of Germany, and in 1952 – i.e. before the creation of the European Economic Community – was incorporated into the German Biersteuergesetz (beer taxation law) and the vorläufiges Biergesetz (provisional beer law). In other Member States, however, beer was produced on the basis of a number of other ingredients – including for example wheat. According to the Biersteuergesetz such beverages could not be marketed under the designation "beer" in Germany, meaning that the non-conforming foreign beers had difficulty in accessing the German beer market. The European Commission demanded the German government to give up the purity requirements with regard to non-German beers, but the government refused to do so. It argued that the Reinheitsgebot was vital in order to safeguard public health: If beer were manufactured using only the raw materials listed in the Biersteuergesetz the use of additives could be avoided, it said. And these additives constituted a risk to public health. In other words, the Commission wanted to see the measure abolished as it hindered the free movement of goods within the common market, whereas the German authorities insisted that the measure should remain in order to protect public health against potential risks.[20]

As is illustrated in the *German Beer* case, during the first four decades following the inception of the European Community, food safety would often be used as an argument put forward by one or more Member States to justify rules that to a higher or lesser extent hindered the free movement of certain food products. Food safety was, in other words, an objective that was primarily pursued by the Member States, albeit, in a limited number of instances, the Community also pursued the objective of food safety

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[18] Cf. Case 178/84 *Commission v Germany (Reinheitsgebot),* see above note 15.

[19] When the Reinheitsgebot was adopted, it was not known that a fourth ingredient – yeast – was needed to produce beer. At this time fermentation happened due to the presence of wild yeast.

[20] See in particular the report for the hearing at pp. 1231-1232 and 1240-1242.

through legislation. For this reason, in what follows, I first examine how EC law treated food safety where it was invoked by the Member States before the European Court of Justice (Sections 2.2 – 2.8). This part of the analysis essentially is an examination of the case-law of the Court of Justice. Following this I examine the treatment of food safety in secondary EC legislation (Section 2.9). Here the analysis will focus on the legal foundation and the purpose of the relevant EC legislation as well as on how this legislation has been construed by the Court of Justice. This part of the examination therefore is based on secondary Community law (i.e. regulations and directives) and case-law of the Court of Justice. On the basis of these examinations I draw up the overall picture to show the place that food safety originally occupied in Community law (Section 2.10).

2.2 The three types of relevant Treaty provisions

The EC Treaty contains three different sets of provisions that prohibit restrictions on the free movement of goods within the Community.

(i) Article 25 prohibits the imposition of customs duties and all charges having equivalent effect on the import and export of goods between Member States.

(ii) Article 90 prohibits the imposition by Member States of discriminatory internal taxes.

(iii) Articles 28-30 prohibit Member States from imposing quantitative restrictions on imports or exports as well as measures having an equivalent effect.

Together the three sets of provisions constitute an effective tool for the European Community to combat Member State measures that may hinder the free movement of goods within the Community. The protection offered by the provisions extends not only to goods originating in the Member States, but also to third country goods that have been put into free circulation within the Community.

Articles 25 and 90 are mutually exclusive, as are Articles 90 and 28. Where a given fiscal measure is challenged as hindering free movement of goods, it is appropriate to first consider whether it qualifies as a customs duty or a charge having equivalent effect so that it is caught by Article 25. If the fiscal measure is not so caught, it should be considered whether it constitutes an internal tax caught by Article 90. If the fiscal measure is neither caught by Article 25 nor Article 90, it will normally not be considered to infringe the Treaty provisions protecting the free movement of goods. The Court of Justice has, however, shown that in some particular

instances the measure may still be caught by Article 28.[21] If the contested measure is of a non-fiscal nature, it falls outside the ambit of Articles 25 and 90 and shall be examined under Article 28 only.

For the purposes of the present report the question is how Articles 25, 90 and 28 respectively apply where the purpose of the Member State measure in question is one of food safety. This matter is examined in the following Sections.

2.3 Customs duties and charges having equivalent effect

Article 25 of the EC Treaty provides:

> Customs duties on imports and exports and charges having equivalent effect shall be prohibited between Member States. This prohibition shall also apply to customs duties of a fiscal nature.[22]

The prohibition in Article 25 covers not only customs duties, i.e. a charge that is determined on the basis of a tariff specifying the rate to be paid by the importer to the host state in connection with the importation, but every kind of fiscal measure which is imposed as a result of crossing a border within the Community.[23] The provision is intended to establish free movement of goods within the Community.[24] It is thus not aimed at duties and charges of equivalent effect imposed on products imported directly from a third country.[25] The prohibition is absolute; it is thus irrelevant whether the measure does in fact restrict the free movement of goods and, in principle,

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[21] Thus, the Court of Justice has considered the legality of tax measures in relation to Article 28 of the EC treaty in Case 18/84 *Commission v France* [1985] ECR 1339 and Case C-189/95 *Franzén* [1997] I-5909. Moreover, the Court of Justice has held that an internal tax, which was permitted under Article 90, could nevertheless be contrary to Article 28, cf. Case C-47/88 *Commission v Denmark* [1990] ECR I-4509 paras. 12 and 13, and Case C-383/01 *Danske Bilimportører v Skatteministeriet* [2003] ECR I-6065. For a discussion of the last-mentioned cases, see Broberg, M. and Holst-Christensen, N., *Free Movement in the European Union*, 2nd ed. (DJØF Publishing, 2007), p. 246-249. An examination of these deviations from the general system falls outside the scope of the present report.

[22] Article 25 contains an absolute prohibition which was introduced with the Treaty of Amsterdam. Before this time, its predecessor – then Article 12 – contained a stand still clause.

[23] The provision covers both imports and exports and it also applies where the charge is applied to goods that are moved from one part of a Member State to another part of the same Member State, cf. Joined Cases C-485/93 and C-486/93 *Maria Simitzi v Dimos Kos* [1995] ECR I-2655 paras. 17 and 21 and Case C-72/03 *Carbonati Apuani v Comune di Carrara* [2004] ECR I-8027 paras. 22-25.

[24] Cf. Case 24/68 *Commission v Italian Republic* [1969] ECR193 paras. 7-8.

[25] The approach with regard to customs duties and charges having equivalent effect imposed on goods coming from within the Community is substantially different from the approach taken with regard to goods imported from outside the Community as is apparent from a number of judgments of the Court of Justice. See for example Case 70/77 *Simmenthal* [1978] ECR 1453.

there is no possibility of justifying taxes which are covered by the Article 25 prohibition.

At first glance, the connection between Article 25 and food safety may appear rather remote. The provision has nevertheless come into play where a Member State has made the marketing of imported food products conditional upon a prior food safety inspection and has required the importer to pay for this inspection. In a consistent line of rulings the European Court of Justice has held that where the charges do not constitute payment for a service of direct benefit to the food business, the payment requirement is prohibited under Article 25.

> Moulds in food products may produce aflatoxin which is one of the most virulent carcinogenic substances. For this reason, the Danish government, in what has become known as the *Peanut* case, identified a group of products which was defined by the risk of the products being contaminated by aflatoxin. The 'group' thus identified contained solely groundnuts and so Denmark, in 1971, prohibited the sale of foodstuffs containing groundnuts and groundnut products in which aflatoxins were detectable. At the same time the government introduced an administrative authorisation under which the products could only be sold in Denmark on production of a certificate which had been issued by a Danish laboratory on the basis of systematic health inspections intended to establish that the goods did not contain aflatoxin in discernible quantities. Denmark is not a producer of groundnuts and since the costs of analysis and sampling were to be borne by the undertaking concerned, in reality only importers were subject to this charge. The Commission challenged the Danish scheme, arguing among other things that the charge had to be regarded as a charge having an effect equivalent to a customs duty and therefore contravened Article 25.[26] Moreover, the Commission argued that the charge could not escape the prohibition on the basis that it formed part of a system of internal taxation. Against this the Danish government argued that the charge was payment for laboratory analyses, the costs of which were determined by the laboratory itself. In the course of the proceedings the Danish government conceded that the charge at issue was not in the nature of payment for a service rendered to the importer. It maintained, however, that it was a charge forming part of a general system of taxation. The Court of Justice did not accept the Danish argument and thus found that the charge in question infringed the Treaty provisions prohibiting customs duties and charges of equivalent effect between Member States.[27]

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[26] At the material time of the case Article 12.

[27] Case 158/82 *Commission v Denmark* [1983] ECR 3573 with brief comments by Hjalte Rasmussen, Current Survey – Member States of the European Communities – Denmark, *European Law Review* 1984, p. 66 at pp. 68-69. Other examples of Member States charging the costs of health inspections include Case C-347/95 *Fazenda Pública v UCAL* [1997] ECR I-4911 and Case C-28/96 *Fazenda Pública v Fricarnes* [1997] ECR I-4939 concerning Portuguese meat marketing charges.

In other words, if the authorities of a Member State, in order to protect public health, require imported food products to undergo inspection when entering the country, the authorities should think twice before imposing the inspection costs on the food businesses.

Whereas it is not surprising that the imposition of a duty that only burdens imported products contravenes the very idea of a common market, it is less obvious that this is also so where domestic products are subject to a similar duty so that the import duty simply balances the conditions under which domestic and imported products are sold.

> The *Bresciani* case concerned an Italian requirement that importers of products of animal origin had to pay a charge to offset the costs of a compulsory public health inspection of such products. Similar products of domestic origin were not subject to the same charge, but when animals were slaughtered in Italy there were veterinary inspections for which local authorities charged duties and the main purpose of which were to establish whether the meat was fit for consumption. The European Court of Justice found that it contravened the Treaty provisions prohibiting customs duties and charges of equivalent effect between Member States that imported products of animal origin had to bear the costs of the health inspection. In particular the Court noted that "[t]he obligation progressively to abolish customs duties is supplemented by the obligation to abolish charges having equivalent effect in order to prevent the fundamental principle of the free movement of goods within the common market from being circumvented by the imposition of pecuniary charges of various kinds by a Member State." It concluded that "any pecuniary charge, whatever its designation and mode of application, which is unilaterally imposed on goods imported from another Member State by reason of the fact that they cross a frontier, constitutes a charge having an effect equivalent to a customs duty." Therefore, it did not matter whether the duty was proportionate to the costs of the compulsory public health inspection carried out on the entry of the goods since the inspection was carried out in the interest of the general public; not in the interest of the importer. Moreover, "[t]he fact that the domestic production is, through other charges, subjected to a similar burden matters little". Only if it were possible to regard the charges as falling within a general system of internal taxation applying systematically and in the same way to domestic and imported products would the charge not infringe the said Treaty provisions.[28]

As is apparent, a charge that is imposed as a result of crossing a border contravenes Article 25, unless it forms part of a general system of internal taxation that applies systematically and uniformly to domestic as well as to imported products.

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[28] Case 87/75 *Conceria Daniele Bresciani v Amministrazione Italiana delle Finanze* [1976] ECR 129 paras. 8-11.

Where a charge is levied on the food businesses to cover the costs of veterinary inspections required by Community law, this does not necessarily conflict with Article 25.

> In *Commission v Germany* the German authorities had introduced a fee to cover the costs of veterinary inspections carried out under Directive 81/389.[29] The Commission challenged this, arguing that the fee constituted a charge having an effect equivalent to a customs duty and as such was prohibited under – *inter alia* – Article 25 of the Treaty. The European Court of Justice rejected this argument. It held that since the contested fee was charged in connection with inspections carried out pursuant to a Community provision, such fees may not be classified as charges having an effect equivalent to a customs duty if four conditions are satisfied. Namely (i) they do not exceed the actual costs of the inspections in connection with which they are charged; (ii) the inspections in question are obligatory and uniform for all the products concerned in the Community; (iii) they are prescribed by Community law in the general interest of the Community; and (iv) they promote the free movement of goods, in particular by neutralising obstacles which could arise from unilateral measures of inspection adopted in accordance with Article 30 of the Treaty. In the actual case the Court of Justice found that all four conditions were satisfied by the contested fee so that it was justified.[30]

The main difference between a charge required by Community law and one required under national law is that harmonisation of inspection requirements by Community law furthers free movement of goods since it removes a divergence between the national systems.[31] In contrast, a charge required purely under national law increases the costs of selling into that Member State and therefore constitutes a barrier to the free movement of goods.

The above brief examination clearly shows that Article 25's overriding purpose is to secure the free movement of goods within the Community. In this regard the fact that a charge is intended to cover the costs of an

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[29] Directive 81/389 of 12 May 1981 establishing measures necessary for the implementation of Directive 77/489 on the protection of animals during international transport (OJ 1981 L150/1).

[30] Case 18/87 *Commission v Germany* [1988] ECR 5427 paras. 8-9. See also Case 233/81 *Denkavit Futtermittel v Germany* [1982] ECR 2933 paras. 8-10 and Case C-426/92 *Bundesrepublik Deutschland v Deutsches Milch-Kontor* [1994] ECR I-2757 paras. 52-54.

[31] For example, in Case 138/77 *Firma Hermann Ludwig v Free and Hanseatic City of Hamburg* [1978] ECR 1645 para. 8, the Court of Justice, with regard to Directive 72/462 of 12 December 1972 on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat from third countries (OJ 1972 L302/8 – English Special Edition L302/7), observed that "the purpose of the directive is not to reinforce the arrangements for the protection of public health in the Member States, but to ensure the uniformity of the inspection systems with a view to preventing distortions of competition and deflections of trade within the common market". See also Case 1/83 *IFG Intercontinentale Fleischgesellschaft* [1984] ECR 349 para. 9, with further references.

inspection to protect public health is not attributed any weight. From this one cannot deduce that Article 25 places greater weight upon free movement than on public health, however. Article 25 only prohibits the imposition of the charge to cover the costs of the inspection; it does not prohibit the inspection as such.

In other words, whilst in practice Article 25 does make it less attractive for the Member States to introduce inspections – as they shall finance these inspections themselves – formally speaking Article 25 does not interfere with the inspection as such, but is only concerned with how it is financed.

2.4 Internal taxation

Whereas Article 25 addresses fiscal measures that are levied at the crossing of a border within the Community, Article 90 is concerned with fiscal rules that apply within a Member State. The provision only applies to indirect taxation.

Article 90(1) provides:

> "No Member State shall impose, directly or indirectly, on the products of other Member States any internal taxation of any kind in excess of that imposed directly or indirectly on similar domestic products".

The provision prohibits the imposition of higher taxes on imported products as compared with domestic products that may be considered to be "similar". If the taxation expressly distinguishes the products on the ground of their origin, this constitutes direct discrimination. In contrast, if the taxation does not expressly distinguish on the ground of origin but instead on the ground of some other criteria, which in practice means that the taxation is particularly burdensome to the imported products, this will constitute indirect discrimination. For example in one of the many cases on Member State alcohol taxation, Danish tax rules were more favourable to fruit wines than to wines made from grapes. Since fruit wines were primarily produced in Denmark, whereas wines made from grapes were imported and since the European Court of Justice considered the two products to be "similar" within the meaning of Article 90(1), the Danish taxation was declared to be in breach of Article 90(1).[32]

Whereas direct discrimination cannot be justified, a Member State may be able to justify an indirect discrimination if it is able to show both that

[32] Case 106/84 *Commission v Denmark* [1986] ECR 833. There is a considerable body of case-law on whether certain products may be considered to be "similar". See for example Case 193/85 *Cooperativa Co-Frutta* [1987] ECR 2085.

the taxation pursues an objective which the Court of Justice considers legitimate and that the taxation is proportionate to this objective.

> For example a foodstuff ingredient may be produced according to two different methods; X and Y. However, if it is produced according to the X-method, it may constitute a threat to public health when the final product is consumed. Therefore Member State A imposes a heavy tax on products produced according to the X-method to encourage the use of the ingredient produced according to the Y-method. The tax applies irrespective of the country of production of the ingredient, but it causes producers in Member State A to abandon the ingredient where it is produced according to the X-method. This taxation is likely to be compatible with Article 90.[33]

If the imported and the domestic products are not similar, the Member State taxation may be considered under Article 90(2) which provides:

> Furthermore, no Member State shall impose on the products of other Member States any internal taxation of such a nature as to afford indirect protection to other products.

Article 90(2) basically prohibits taxation that protects domestic products against competing products from other Member States. The British *Wine and Beer* case illustrates this. Wine and beer are not similar, but, nevertheless, to some extent they may be substitutable. For this reason the British government was required to change its taxation rules so that they did not afford protection to beer against the competition from wine.[34]

Situations covered by Article 90(1) or (2), where internal taxation as such is directly related to food safety, may arise where the tax is charged as part of a scheme that covers both domestic and foreign products and is intended to cover the State's costs of controlling that a given food safety standard is met.[35]

> Consider for example a situation where a Member State introduces a 'salmonellae tax' on all poultry meat sold in the country. The revenue is earmarked the fight against salmonellae in poultry. This fight may be fought through an information campaign that does not advantage domestic products *vis-à-vis* imported products. However, it may also be that the revenue is spent in a way that primarily or exclusively benefits domestic producers – for example by creating a training programme aimed at the breeders in that Member State. Such a con-

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[33] See in this regard Case 46/80 *SpA Vinal v SpA Orbat* [1981] ECR 90 para. 13, Case C-213/96 *Outokumpu* [1998] ECR I-1777 para. 30, and para. 44 of the Opinion of Advocate General Sharpston in Case C-221/06 *Stadtgemeinde Frohnleiten,* judgment of 8 November 2007 (Opinion delivered on 21 June 2007).

[34] Case 170/78 *Commission v United Kingdom (Wine and Beer)* [1980] ECR 417 and [1983] ECR 2265

[35] See for example Case 29/87 *Dansk Denkavit v Danish Ministry of Agriculture* [1988] ECR 2965 paras. 31-36.

> struction necessarily means that the tax places a heavier burden on imported than on domestic products. Indeed, if the construction means that the advantages fully offset the burden borne by the domestic product when it is placed on the market, then, in reality, it constitutes a charge having an effect equivalent to a customs duty and will be caught by Article 25. If the advantages accruing to the taxed domestic products from the use of the revenue generated by the charge only partly offset the burden borne by those products, then the charge constitutes a breach of the prohibition of discrimination laid down by Article 90. Only if the imported products also benefit from the revenue – and if proportionally they obtain at least the same advantage as do domestic products – will the construction comply with Articles 25 or 90.[36]

Like in the case of Article 25, Article 90's overriding purpose is to secure the free movement of goods within the Community. In principle an objective justification such as food safety may mean that the imposition of an internal tax falls outside the scope of Article 90. Based on the case-law of the Court of Justice it is, however, clear that if the internal tax places a heavier burden on products imported from other Member States, then the free movement objective will override the food safety objective.

Nevertheless, it is important to emphasise that Article 90 as such does not prohibit veterinary inspections and other food safety initiatives. The provision is only concerned with the taxation – i.e. the funding of such initiatives.

2.5 Articles 28-30 of the EC Treaty

As noted above in Section 2.2, the EC Treaty contains three different sets of provisions that prohibit restrictions on the free movement of goods within the Community. While Articles 25 and 90 are aimed at fiscal measures, Articles 28-30 are (primarily) aimed at measures of a non-fiscal nature. Today the last-mentioned provisions play a much more important role than do Articles 25 and 90.

Article 28 prohibits quantitative restrictions on imports and measures of equivalent effect. It is thus aimed at barriers to import.[37] Article 29 prohibits quantitative restrictions on exports and measures of equivalent effect and is thus aimed at export restrictions. Even though it does happen that a Member State introduces restrictions on its exports, this is not a common

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[36] Cf. Case C-347/95 *Fazenda Pública v UCAL,* see above note 27, paras. 21-23 and 26, and C-234/99 *Nygård v Svineafgiftsfonden* [2002] ECR I-3657 paras. 21-23.

[37] A Member State measure that burdens domestic production but not imports is not covered by Article 28, cf. Case 98/86 *Criminal proceedings against Arthur Mathot* [1987] ECR 809 para. 7.

occurrence.[38] In contrast, it surprisingly often happens that Member States introduce restrictions on imports – and a large part of these restrictions are based on food safety.[39] Below the focus will therefore be upon the former.

It is hardly possible to overstate the importance that Article 28 has had for the European Community in general and for the creation of the single market in particular. It may therefore be a surprise how succinctly the provision has been composed:

> "Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States."

The provision prohibits two types of Member State measures: (i) quantitative restrictions on imports and (ii) measures having equivalent effect to quantitative restrictions (MEEs).

In what follows, in Section 2.6, I first explain the two types of Member State measures covered by Article 28 as well as a notification scheme that has been introduced to enforce this provision. Thereupon, in Section 2.7, I examine to what extent Member States may invoke food safety as a defence. On this basis, in Section 2.8, I conclude whether Article 28 gives priority to food safety or to free movement of goods.

2.6 Quantitative restrictions and measures of equivalent effect

2.6.1 Quantitative restrictions

A quantitative restriction is a quota or a ban on the imports of a given product. For example, if a Member State prohibits the import of foodstuffs containing an additive suspected of being carcinogenic, this constitutes a quantitative restriction.

The distinction between a quantitative restriction in the form of a ban and a measure of equal effect is not clearcut. Thus, if a Member State bans the sale of a specific product, this may be qualified as a quantitative restriction (no imports accepted). However, it may also qualify as an MEE under the *Cassis de Dijon* doctrine.[40] For example, in case a Member State prohibits the sale of pasta containing additives, this may be considered a ban on the

[38] For an example of the application of Article 29, see Case C-272/95 *Bundesanstalt für Landwirtschaft und Ernährung v Deutsches Milch-Kontor* [1997] ECR I-1905.
[39] Moreover, the case-law on Article 28 is considerably more developed than the corresponding case-law on Article 29.
[40] The *Cassis de Dijon* doctrine is explained in Section 2.6.2 below.

import and sale of pasta containing additives. However, it may equally be viewed as a measure that permits the sale of pasta provided that the pasta complies with the national requirements.[41]

To sum up: Where Member States, on the plea of food safety, introduce quantitative limitations on the imports of certain food products, it will be fairly straightforward that the cases are caught by Article 28. As we shall see in Section 2.7 below, in order to be lawful, the measures will have to come within the scope of Article 30 that provides an exception to the prohibition laid down in Article 28.

2.6.2 Measures of equivalent effect (MEE)

Whereas it is often apparent whether a Member State measure constitutes a quantitative restriction, it is much less obvious whether a measure qualifies as an MEE. The Court of Justice in its judgment in *Dassonville* defined an MEE as:

> All trading rules enacted by Member States which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade are to be considered as measures having an effect equivalent to quantitative restrictions.[42]

The breadth of this so-called *Dassonville* formula is impressive.

Firstly it covers all *measures* attributable to a Member State.[43] This goes much further than just to cover legislation by the Member State. Thus an administrative practice may constitute a measure caught by Article 28, if it shows a certain degree of consistency and generality.[44] In *Buy Irish* the Court of Justice found that "the establishment of a national practice, introduced by the Irish government and prosecuted with its assistance" had potential effects on imports from other Member States comparable to that

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[41] In Case 178/84 *Commission v Germany (Reinheitsgebot),* see above note 15, Germany operated an absolute ban on the marketing of beers containing additives. In reality the ban formed a quantitative restriction, but formally speaking there was no prohibition against the imports – only against the marketing. The Court of Justice, in para. 40 of the judgment, restricted itself to observing that the measure constituted "a barrier to the importation from other Member States …". In contrast, in Case 274/87 *Commission v Germany* [1989] ECR 229 para. 5, concerning a ban on the marketing of meat products that did not comply with the German Fleisch-Verordnung, the Court of Justice qualified the measure as an MEE because it applied without distinction. In the field of food safety the qualification of a measure as a quantitative restriction or as an MEE will rarely have a material impact on the outcome of a case.

[42] Case 8/74 *Procureur du Roi v Dassonville* [1974] ECR 837 para. 5.

[43] If a measure must be regarded as a transposition of a Community provision, it will not qualify as an MEE, cf. Case C-123/00 *Criminal proceedings against Christina Bellamy and English Shop Wholesale* [2001] ECR I-2795, para. 17.

[44] Cf. Case 21/84 *Commission v France* [1985] ECR 1355 para. 13.

resulting from government measures of a binding nature.[45] The practice was thus caught by Article 30. The fact that a measure is administered by a private body does not exempt it from the scope of Article 28, if in some way the acts of this body may be attributed to the Member State.[46]

> If a Member State has managed to virtually eradicate salmonellae in poultry for human consumption, the breeders might base an advertising campaign on this fact to convince the consumers to buy the domestic salmonellae-free product. The Member State is also likely to have a strong interest in having the public to turn away from the imported products and towards the domestic salmonellae-free products *inter alia* as this is likely to lead to a decrease in the sickliness among the public caused by salmonellae. Nevertheless, the Member State should be careful not to engage itself in the campaign since it could then easily qualify as an MEE.[47]

Secondly, the *Dassonville* formula's *notion of Member State* is very wide. It covers not only bodies, of the central administration (government bodies) but also decentralised bodies such as local councils. Likewise, private bodies that in reality are either acting on behalf of the State[48] or have been given the power that may otherwise be attributable to the State to issue rules (typically professional bodies on which national legislation has conferred powers concerning professional obligations)[49] are also covered. Moreover, a Member State's failure to act may also constitute a measure attributable to that State. Thus, if a consumer organisation believes that a food product endangers public health and therefore decides to block the import of that product, the Member State may be obliged to take

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[45] Case 249/81 *Commission v Ireland* [1982] ECR 4005 para. 27.

[46] Case 249/81 *Commission v Ireland*, see above note 45, paras. 21-23. See also paras. 19-20 of this judgment.

[47] In Case 222/82 *Apple and Pear Development Council v K.J. Lewis* [1983] ECR 4083 paras 17-18, the Court of Justice observed that "a body … which is set up by the government of a Member State and is financed by a charge imposed on growers, cannot under Community law enjoy the same freedom as regards the methods of advertising used as that enjoyed by producers themselves or producers' associations of a voluntary character. In particular, such a body is under a duty not to engage in any advertising intended to discourage the purchase of products of other Member States or to disparage those products in the eyes of consumers. Nor must it advise consumers to purchase domestic products solely by reason of their national origin." In para. 19 the Court, however, continued by noting that Article 28 "does not prevent such a body from drawing attention, in its publicity, to the specific qualities of fruit grown in the Member State in question or from organizing campaigns to promote the sale of certain varieties, mentioning their particular properties, even if those varieties are typical of national production." Following the judgment in *Apple and Pear Development* the Commission asked ten Member States whether they were involved in promotional campaigns. Nine of these Member States answered in the affirmative. The Commission therefore issued Commission communication concerning State involvement in the promotion of agricultural and fisheries products (OJ 1986 C 272/3).

[48] Case 249/81 *Commission v Ireland,* see above note 45, para. 15.

[49] Case C-292/92 *Hünermund* [1993] ECR I-6787 paras. 14-15.

measures to bring the blockade to an end. Failure to do so may constitute an MEE.

Thirdly, the *Dassonville* formula covers national measures that *actually or potentially hinder intra-Community trade*. Thus it is not required that the contested measure actually hinders intra-Community trade. Suffice it that potentially it may do so.[50]

> In *Ligur Carni* fresh meat that was brought into a municipality had to be submitted to a public health inspection, even where the meat was accompanied by a health certificate issued by an official veterinary of the exporting country. Moreover, the traders importing fresh meat into the municipality were obliged to go through the municipal slaughterhouse to entrust the transport and delivery of their goods to their final destination to a local undertaking. The rules applied to both domestic and foreign meat. The Court of Justice held that these requirements constituted a barrier to imports, irrespective of the fact that the measure was limited to the territory of a municipality of a Member State. The effect of the measure was to make importation of goods from other Member State more burdensome and more difficult. In other words, even rules that only apply to a limited part of a Member State's territory will be caught, provided the measure potentially may hinder intra-Community trade.[51]

Fourthly, the *Dassonville* formula applies to Member State measures that either *directly or indirectly hinder intra-Community trade*.[52] A measure that distinguishes between domestic and imported products directly hinders intra-Community trade.

> In *Commission v United Kingdom (UHT milk)* the Commission brought legal proceedings against the United Kingdom for breach of Article 28, *inter alia* because the British government required that UHT milk could only be imported into the United Kingdom with the authorisation of the competent authority evidenced by an import licence. The British government argued that there was

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[50] In Case 53/80 *Officier van Justitie v Koninklije Kaasfabriek Eyssen* [1981] ECR 409 para. 11, the Court of Justice observed that the contested measure was "of such a nature as to affect imports of that product from other Member States, … and that it for that reason constitutes a measure having an effect equivalent to a quantitative restriction." In Joined Cases 177/82 &178/82 *Criminal proceedings against Jan van de Haar and Kaveka de Meern* [1984] ECR 1797 para. 13, the Court explained that Article 28 "does not distinguish between measures having an effect equivalent to quantitative restrictions according to the degree to which trade between Member States is affected. If a national measure is capable of hindering imports it must be regarded as a measure having an effect equivalent to a quantitative restriction, even though the hindrance is slight and even though it is possible for imported products to be marketed in other ways."

[51] Joined Cases C-277/91, C-318/91 and C-319/91 *Ligur Carni and Genova Carni v Unità Sanitaria Locale n. XV di Genova and Ponente v Unità Sanitaria Locale n. XIX di La Spezia and CO:GE:SE:MA Coop* [1993] ECR I-6621, paras. 36-37. See also Case C-67/97 *Bluhme* [1998] ECR I-8033 paras. 9 and 20.

[52] The reference to "directly or indirectly, actually or potentially" was borrowed from EC competition law. However, whereas EC competition law exempts measures of minor importance from its scope *(de minimis),* Article 28 does not operate a similar exemption.

much flexibility in the grant of these licenses. The Court of Justice simply held that even if the import licence was a pure formality – and thus did not directly hinder intra-Community trade – this would contravene Article 28.[53]

In *United Foods* Belgian legislation required that the importer of fish had to submit the product to a compulsory health inspection and at least 24 hours before the importation had to notify the Belgian authorities in writing of *inter alia* the nature, quantity and origin of the consignment. The Court of Justice held that the Belgian notification requirement had the effect of hindering imports of fish. The requirement thus constituted an indirect restriction to intra-Community trade.[54]

However, even if a measure does not formally distinguish between domestic and imported products, it may nevertheless impose a heavier burden upon the imported products and thereby hinder intra-Community trade. Such measures are referred to as indirect barriers or indistinctly applicable measures. Indirect barriers have been the object of a large number of judgments of the Court of Justice. The most famous of these was rendered in the *Cassis de Dijon* case.

The *Cassis de Dijon* case concerned the German authorities' refusal to allow Cassis de Dijon – a French liqueur made from blackcurrants – to be sold in Germany. The reason was that the French liqueur only held an alcohol content of 15 – 20%, whereas German law required an alcohol content of minimum 25%. This requirement applied equally to domestic and imported products and was, said the German government, intended to protect public health. The Court of Justice held that it was for the Member States to regulate all matters relating to the production and marketing of alcohol and alcoholic beverages on their own territory. However, to the extent the disparities between the national laws relating to the marketing of the products created obstacles to the free movement of goods within the Community, these obstacles would only be lawful in so far as they were necessary to satisfy mandatory requirements.[55]

The *Cassis de Dijon* ruling, in other words, established that if a product is lawfully produced or marketed in one Member State, as a general rule, it is lawfully marketable in all other Member States. Thereby the Court of Justice imposed upon the Member States a system of mutual recognition.[56] Illustrating examples of this are provided by the *French Milk Substitutes* Case and the *Van der Veldt* Case.

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[53] Case 124/81 *Commission v United Kingdom (UHT milk)* [1983] ECR 203 para. 9.

[54] Case 132/80 *United Foods and PVBA Aug. Van den Abeele v Belgian State* [1981] ECR 995 para. 28.

[55] Case 120/78 *Rewe-Zental AG v Bundesmonopolverwaltung für Branntwein (Cassis de Dijon),* see above note 15, para. 8.

[56] See in this respect Commission interpretative communication on facilitating the access of products to the markets of other Member States: the practical application of mutual recognition, (OJ 2003 C 265/2), and Communication from the Commission to the European Parliament and the Council – Mutual recognition in the context of the follow-up to the Action Plan for the Single Market (COM (1999) 299 final))

In the *French Milk Substitutes* Case, according to a French law dating back to 1934, there was an absolute prohibition on the marketing and importation into France of any product intended to replace milk powder or concentrated milk if this milk substitute was composed of products other than milk. The French government argued that, amongst other things, this prohibition was justified because milk substitutes could have harmful effects on particular groups of the population. The Court of Justice observed that the application of the measure to products imported from other Member States was lawful only if it could be justified under Article 30 of the EC Treaty or if it were necessary to satisfy mandatory requirements.[57] In the actual case, the Court did not find the measure justified.[58]

In the *Van der Veldt* case Belgian legislation prohibited the sale of bread and other bakery products whose salt content exceeded 2% – irrespective of the products' origin. Mr. Van der Veldt managed a shop in Belgium which imported practically all its products – including bakery products – from the Netherlands, where they were lawfully produced and marketed. In checks carried out by Belgian food inspectors it was disclosed that Mr. Van der Veldt's bread contained between 2.11 and 2.17% salt and thus exceeded the 2% limit. Since the Belgian legislation indirectly hindered intra-Community trade, the Court of Justice held that the prohibition was caught by Article 28.[59]

The Court of Justice's case-law in *Dassonville* and *Cassis de Dijon* gave Article 28 such a broad scope that it was hard to imagine a Member State measure that could not somehow be caught by the provision. To some extent at least, this problem was remedied through the Court's judgment in *Keck*. Here the Court of Justice held that while *Cassis de Dijon* remains good law, "the application to products from other Member States of national provisions restricting or prohibiting certain selling arrangements is not such as to hinder directly or indirectly, actually or potentially, trade between Member States within the meaning of the *Dassonville* judgment …, so long as those provisions apply to all relevant traders operating within the national territory and so long as they affect in the same manner, in law and in fact, the marketing of domestic products and of those from other Member States."[60] Where these conditions are fulfilled, the Member State measure falls outside the scope of Article 28.[61]

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[57] On the possibility of justifying a measure caught by Article 28 of the EC Treaty, see Section 2.7 below.

[58] Case 216/84 *Commission v French Republic* [1988] ECR 793.

[59] Case C-17/93 *Criminal proceedings against J.J.J. Van der Veldt* [1994] ECR I-3537.

[60] Cf. Joined Cases C-267/91 and 268/91 *Keck & Mithouard* [1993] ECR I-6097 para. 16. In Case C-497/03 *Kommission gegen Österreich* unpublished judgment of 28 October 2004, Austria had prohibited the sale at distance of certain foodstuffs, *inter alia* due to health reasons. This prohibition was likely to affect foreign sellers more severely than their Austrian counterparts and so the prohibition was not covered by the *Keck* doctrine. See also Case C-405/98 *Gourmet International Products* [2001] ECR I-1795 para. 25.

[61] Cf. Joined Cases C-267/91 and 268/91 *Keck & Mithouard,* see above note 60, para. 17.

> In the *Infant Milk Formula* case, Greece required that milk for infants could only be sold through pharmacies. According to the Greek government this was "necessary and appropriate in order to protect the health and life of infants during the critical first five months of life". The Commission challenged this under Article 28, but the Court of Justice found that the Greek measure complied with the requirements set out in *Keck* and therefore fell outside the scope of that provision.[62]

In the *Infant Milk Formula* case, the Commission pointed out that Greece did not itself produce processed milk for infants. However, the Court of Justice held that the applicability of Article 28 "to a national measure for the general regulation of commerce, which concerns all the products concerned without distinction according to their origin, cannot depend on such a purely fortuitous factual circumstance, which may, moreover, change with the passage of time."[63] Subsequently, the Court of Justice appears to have abandoned this construction of the *Keck* doctrine. Hence, if a Member State measure applies without distinction, but disadvantages imported products only because there is no domestic manufacture, then the measure will not be treated like an indistinctly applicable measure. This, in other words, means that the measure will be caught by the prohibition in Article 28, unless it could be justified by a public-interest objective which takes precedence over the requirement for the free movement of goods.[64]

As is apparent from the preceding examination, Article 28 has been given a very wide coverage so that if a Member State introduces food safety measures that also apply to imported products, these measures are likely to be caught by the provision. Where the measure is so caught, it will only be lawful under Community law, if the Member State is able to adduce adequate justifications. This issue is considered in Section 2.7 below.

2.6.3 Notification requirements

A major challenge to the creation of a common market has been the introduction by the Member States of new national technical regulations. The consequence of such new regulations normally is that a product may only be marketed in the Member State in question if it conforms to the technical requirements laid down in the regulation. Such requirements obviously run counter to the objective of free movement of goods and they may well be caught by Article 28. Often, however, the Member State regulations

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[62] Case C-391/92 *Commission v Greece* [1995] ECR I-1621 paras. 4 and 13-21.
[63] Case C-391/92 *Commission v Greece,* see above note 62, para. 17.
[64] Cf. Case C-416/00 *Tommaso Morellato v Comune di Padova* (*Prebaked bread)* [2003] ECR I-9343 para. 37.

pursue clearly legitimate objectives. In order to better handle this schism, the Technical Regulations and Standards Directive was introduced in 1983.[65]

The directive requires the Member States to notify to the Commission "any draft technical regulation, except where such technical regulation merely transposes the full text of an international or European standard …"[66] The draft technical regulation may only be adopted following a stand-still period of normally six months from the date of notification. Following receipt of the draft regulation, the Commission immediately distributes it to all the other Member States in order that, during the stand-still period, they and the Commission may make comments. These comments may cause the notifying Member State to amend its original draft regulation.

If a Member State fails to notify, the consequence is that the technical regulation becomes unenforceable.[67] Indeed the same is the case if the

[65] Directive 83/189 of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations (OJ 1983 L 109/8), today replaced by Directive 98/34 of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations (OJ 1998 L 204/37). The notification requirement in the Technical Regulations and Standards Directive finds parallel requirements in several other pieces of secondary Community legislation. See for example Directive 94/62 of 20 December 1994 on packaging and packaging waste (OJ 1994 L 365/10), which in Article 16 requires notification of certain measures regarding packaging, and Decision no. 3052/95 of the European Parliament and of the Council of 13 December 1995 establishing a procedure for the exchange of information on national measures derogating from the principle of the free movement of goods within the Community (OJ 1995 L 321/1), which in Article 1 lays down an obligation on the Member States to notify the Commission where they take steps to prevent the free movement or placing on the market of a particular type of product lawfully produced or marketed in another Member State. See also Jans, J. H., National Legislative Autonomy? The Procedural Constraints of European Law, *Legal Issues of European Integration,* 1 (1998), p. 25, particularly pp. 36-40.

[66] For an example of a technical regulation, in the field of food safety, which merely was honouring obligations under a Community directive, see Joined Cases C-425/97 and C-427/97 *Criminal proceedings against Adrianus Albers* [1999] ECR I-2947. Whether a certain requirement qualifies as a technical regulation or standard is not always clear. ee for example Case C-37/99 *Donkersteeg* [2000] ECR I-10223 concerning a Dutch requirement that there was a disinfectant bath for rubber boots outside a farmer's pigsty.

[67] Cf. Case C-194/94 *CIA Security International v Signalson and Securitel* [1996] ECR I-2201 para. 54. The consequences of this judgment for the national authorities were very far-reaching. Thus, in the Netherlands the Dutch government drew up a list of 400 existing national regulations which should, perhaps, have been notified before they were put into effect. Of these 400 dossiers the government, after consultations with the European Commission, decided to notify 227, cf. Report from the Commission to the Council, the European Parliament and the Economic and Social Committee – The Operation of Directive 98/34/EC from 1995 to 1998 (COM (2000) 429) p. 35, para. 97.

Member State puts into effect the technical regulation before expiry of the stand-still period.[68]

Originally, agricultural products and foodstuffs were not covered by the Technical Regulations and Standards Directive.[69] However, as from 1988 the directive's scope was broadened so as to also comprise these types of products.[70] The consequence is that a Member State, intending to introduce regulations or standards to improve national food safety, must first notify the Commission in accordance with the directive. Indeed, in these cases particular notification requirements apply.[71]

> Notification 2005/324/S provides an example concerning food safety requirements. Here the Swedish Livsmedelsverket (The National Food Administration) notified some administrative provisions on hygiene and handling of foodstuffs. According to the notified Swedish regulations it would only be lawful to place milk or cream on the market for direct consumption, if at least the process criteria set out in Codex Alimentarius Recommended International Code of Hygiene Practice for Milk and Milk Products for either pasteurisation or other treatment having an equivalent effect had been met. In the manufacture of fresh cheese in Sweden, the milk and cream used would have to comply with the requirements for pasteurisation in the Code of Hygiene Practice for Milk and Milk Products.[72]

If the technical regulation is a matter of urgency, a Member State may introduce food safety requirements without awaiting the expiry of the stand-still period.[73] The requirement must, however, still be notified under the directive and must comply with Articles 28-30.

> In 1996 the number of measures notified under the emergency procedure temporarily increased significantly. The reason was that out of a total of 40 emergency measures that year 24 were notified by the United Kingdom due to the BSE crisis.[74]

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[68] Cf. Case C-443/98 *Unilever Italia v Central Food* [2000] ECR I-7535 para. 44, commented upon by Weatherill, S., Breach of Directives and Breach of Contract, [2001] *European Law Review* 177.

[69] Article 1(7) of the directive.

[70] Cf. Directive 88/182 of 22 March 1988 amending Directive 83/189/EEC laying down a procedure for the provision of information in the field of technical standards and regulations (OJ 1988 L 81/75).

[71] Cf. Article 8(1)(4) of the directive.

[72] The notification is available at http://ec.europa.eu/enterprise/tris/pisa/app/search/index.cfm?fuseaction=pisa_notif_overview&iYear=2005&inum=324&lang=EN&sNLang=EN.

[73] Cf. Article 9(7) of the directive.

[74] European Commission, Report from the Commission to the Council, the European Parliament and the Economic and Social Committee – the Operation of Directive 98/34/EC from 1995 to 1998, see above note 67, p. 24, para. 55.

2.7 Food safety as a defence of quantitative barriers and MEEs

2.7.1 Introduction

If a Member State measure is caught by Article 28 (or 29) of the Treaty, the Member State may look to Article 30 in order to justify the measure.[75] With regard to public health, the provision is worded as follows:

> "The provisions of Articles 28 and 29 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of … the protection of health and life of humans, animals or plants … Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States."

Below I first examine the Member States' latitude to protect public health (Section 2.7.2). Thereupon I identify and analyse two tests that the European Court of Justice frequently apply as part of its examination of Member State food safety legislation (Section 2.7.3). Finally, I consider the Court of Justice's approach to the requirements that Member State measures may not constitute "arbitrary discrimination" and must be proportionate (Section 2.7.4).

2.7.2 Member States' latitude to protect public health

The public health justification is the one most frequently invoked by the Member States before the Court of Justice. Hence there is a considerable case-law to draw from. Where the level of protection has been harmonised at Community level, the Member States are normally precluded from maintaining a higher level of protection.[76]

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[75] Case 120/78 *Rewe-Zental AG v Bundesmonopolverwaltung für Branntwein (Cassis de Dijon),* see above note 15, introduced the notion of mandatory requirements so that if an indistinctly applicable Member State measure is covered by such requirement, the measure will be exempt from the scope of Article 28. Therefore (strictly speaking), only if a measure is caught by Article 28 will it be necessary to turn to the limited list of justifications provided in Article 30 to see whether the measure may nevertheless be lawful. In practice, however, indistinctly applicable Member State measures are treated as if they are also caught by Article 28, so that the mandatory requirements work as an "extra set" of justifications that apply only to these measures. Food safety both comes within the public health justification in Article 30 and is a mandatory requirement recognised under the *Cassis de Dijon* doctrine. In this report I will treat food safety as a justification that is applied following a finding that the Member State measure is caught by Article 28 without considering whether, formally speaking, food safety acts as a "mandatory requirement" or as a "justification".

[76] Indeed, the Member States may not even systematically check that food products imported from another Member State comply with the Community requirements since this would mean that the imported products will be subject to a dual control (control in country of origin and control in importing country), cf. Case 190/87 *Oberkreisdirektor des Kreises, Borken* [1988] ECR 4689 paras. 16-17 and Case C-228/91 *Commission v Italy* [1993] ECR I-2701 para. 24.

The importance of Community harmonisation was illustrated in *Skov Æg*. The case concerned some consumers who had bought salmonellae-infected eggs in a Danish supermarket causing the consumers to fall ill. Subsequently they brought legal proceedings against the supermarket to obtain compensation. The district court hearing the case in the first instance found that the eggs had been defective, that there was a causal link between the defect and the damage suffered, and that no fault had been shown on the part of the injured parties. Therefore, in accordance with Danish law, the district court ordered the supermarket to pay compensation. This judgment the supermarket appealed, arguing that the Community's Product Liability Directive[77] precluded a Member State from regulating the liability of the intermediary (the supermarket) by laying down that it was to be answerable for the liability of the producer. The European Court of Justice observed that the directive sought to achieve a complete harmonisation of product liability in the Community in order to eliminate divergences between the Member States that may distort competition and affect the free movement of goods within the common market. Since the Product Liability Directive did not allow the Member States to extend the product liability to intermediaries, the supermarket could not be held liable for the problems caused by the salmonellae-infected eggs. As regards the Danish Government's argument that that interpretation of the Product Liability Directive was likely to lower the level of consumer protection in Denmark, the Court of Justice simply noted that any extension of the liability established by the directive fell within the competence of the Community legislature. In other words, Denmark was precluded from maintaining a higher level of protection in the field of product liability.[78]

Where there is no harmonisation, the Court of Justice has often reiterated that it is for the Member States to determine the level at which they wish to ensure that human life and health are protected with due regard to the requirements of the free movement of goods.[79] The fact that the Court of Justice acknowledges the Member States' right to determine their respective level of health protection does not mean that they have completely free hands to introduce whatever measures they like, however. Hence, excep-

[77] Directive 85/374 of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (OJ 1985 L 210/29).

[78] Case C-402/03 *Skov Æg* [2006] ECR I-199. Note that the case concerned consumer protection in a wide sense. Both the Product Liability Directive and the ruling in *Skov Æg* have been the subject of a number of commentaries in the legal literature. See for example Weatherill, S., *EU Consumer Law and Policy*, (Edward Elgar Publishing Ltd. 2005), chapter 6, for an examination of the directive.

[79] Case 27/80 *Criminal proceedings against Anton Adriaan Fietje* [1980] 3839 para. 7, Case 174/82 *Sandoz* [1983] ECR 2445 para. 16, Case 97/83 *Criminal proceedings against Melkunie* [1984] ECR 2367 para. 18, Case 53/80 *Officier van Justitie v Koninklije Kaasfabriek Eyssen,* see above note 50, para. 15, Case 54/85 *Ministère public v Mirepoix* [1986] 1067 para. 13 and Case C-293/94 *Criminal proceedings against Jacqueline Brandsma* [1996] I-3159, para. 11.

tions to the rule of free movement of goods within the Community must be interpreted strictly.[80] Moreover, if a Member State measure is caught by Article 28, it is for the Member State to adduce evidence substantiating the need for this measure.

> In the *French Nutrients* Case, France had prohibited the marketing of foodstuffs fortified with nutrients. The Commission brought the case to the Court of Justice which held that, in the absence of harmonisation and to the extent that there is still uncertainty in the current state of scientific research, it is for the Member States to decide on the level of protection of human health and life that they wish to ensure and whether to require prior authorisation for the marketing of foodstuffs, taking into account the requirement of the free movement of goods within the Community. However, since Article 30 of the Treaty provides for an exception, to be interpreted strictly, to the rule of free movement of goods within the Community, it is for the national authorities, which invoke it, to show in each case that their rules are necessary to give effect to the interests referred to in that provision.[81]

That the public health exception is given a narrow interpretation is also reflected in the terminology applied by the Court of Justice. Thus, as pointed out by Advocate General Slynn,[82] the Court will normally require the Member State to show not only that there is a "risk", a "danger" etc., but rather that the risk, the danger, the harm or the hazard is "real"[83] or "serious"[84].

2.7.3 The scientific research test and the consistency test

In particular in cases where the Court of Justice is not convinced that the national measure is objectively justified, it has shown itself willing to undertake a close scrutiny of the evidence put forward by the Member

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[80] See for example Case C-205/89 *Commission v Hellenic Republic* [1991] ECR I-1361 para. 9 and Case C-24/00 *Commission v French Republic* [2004] ECR I-1277 para. 53. Case C-180/96 *United Kingdom v Commission (BSE)* [1998] ECR I-2265, does not fit into the pattern set out here. Firstly the roles were reversed so that it was a Member State that invoked the rules on free movement, whereas it was the Commission that invoked public health. Secondly the Court of Justice accepted that the Commission could adopt a decision aimed at the protection of public health, irrespective of the fact that this decision was founded on directives whose primary purpose was the completion of the internal market.

[81] Case C-24/00 *Commission v French Republic,* see above note 80, paras. 49 and 53.

[82] Cf. his Opinion in Case 178/84 *Commission v Germany (Reinheitsgebot),* see above note 15, at p. 1256.

[83] See for example Case 97/83 *Criminal proceedings against Melkunie,* see above note 79, para. 15

[84] See for example Case 97/83 *Criminal proceedings against Melkunie,* see above note 79, para. 16, Joined Cases C-13/91 and C-113/91 *Criminal proceedings against Michel Debus* [1992] ECR I-3617, para. 24, Case C-477/98 *Eurostock Meat Marketing* [2000] ECR I-10695, paras. 59, 75 and 78.

State. This scrutiny may include both a test based on international scientific research[85] as well as a test of consistency[86] concerning the Member State's legislation.

> In *Reinheitsgebot,* a German ban on the marketing of beers containing additives failed both these tests. Thus, the Court of Justice, in its scrutiny of the German ban, referred to "the findings of international scientific research, and in particular of the works of the Community's scientific Committee for Food, the Codex Alimentarius Committee of the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization". The Court also observed that "it appears from the tables of additives authorized for use in the various foodstuffs submitted by the German government itself that some of the additives authorized in other Member States for use in the manufacture of beer are also authorized under the German rules, in particular the regulation on additives, for use in the manufacture of all, or virtually all, beverages." It went on to dryly observe that "[m]ere reference to the potential risks of the ingestion of additives in general and to the fact that beer is a foodstuff consumed in large quantities does not suffice to justify the imposition of stricter rules in the case of beer." The Court thus found that the German ban was not scientifically

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[85] Case 53/80 *Officier van Justitie v Koninklije Kaasfabriek Eyssen,* see above note 50, para. 13 and Case 42/90 *Criminal proceedings against Jean-Claude Bellon* [1990] ECR I-4863 para. 14. In Case C-95/89 *Commission v Italy* [1992] ECR I-4585 para. 11, concerning the addition of nitrate to cheese, the Court of Justice held that in making the evaluation account must not only be taken of the findings of international scientific research, but also of "the assessment made by the authorities of the other Member States." See likewise Case C-344/90 *Commission v France* [1992] ECR I-4719 para. 11. In Case 247/84 *Criminal proceedings against Léon Motte* [1985] ECR 3887 para. 20, concerning a Belgian prohibition against an additive, the Court of Justice explained that "Member States must take into account the results of international scientific research and, in particular, the work of the Community's Scientific Committee for Food …" The Community's Scientific Committee for Food has since been transferred to the European Food Safety Authority (EFSA), cf. Regulation 178/2002, Article 62(1).

[86] In Case C-416/00 *Tommaso Morellato v Comune di Padova* (*Prebaked bread),* see above note 64, para. 4, concerning an Italian packaging requirement for prebaked bread, the consistency test was surprisingly straight forward. During the procedure the Italian Government, in an answer to a question put by the Court of Justice, admitted that, in reality, the packaging requirement was not based on food safety, but rather was intended to balance the competitive advantage of prebaked bread against that of bread produced according to artisanal methods. In those circumstances, the Court of Justice held, the measure could not be justified for reasons relating to the protection of the health and life of humans within the meaning of Article 30. See likewise Case 130/80 *Criminal proceedings against Fabriek voor Hoogwaardige Voedingsprodukten Kelderman* [1981] ECR 527 para.10.

> founded and that it was inconsistent with the fact that some of the additives could be lawfully used in other types of beverages.[87]

The burden of proof is firmly on the shoulders of the Member State invoking Article 30.[88] Only if the Member State is able to adduce sufficiently convincing evidence to show that the food safety requirement is objectively justified, will the Court of Justice accept it.[89]

A particular problem arises where a Member State is able to put forward scientific evidence in support of its measures, but this evidence is uncertain. Where the Court of Justice is faced with a situation like this, it will first consider whether the measure is intended to protect the public against what is claimed to constitute a "serious health risk"[90] and that it does not constitute a disguised barrier to trade.[91]

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[87] Case 178/84 *Commission v Germany (Reinheitsgebot),* see above note 15, paras. 44, 47 and 49. Advocate General Slynn, in his Opinion in the same case at pp. 1258-1259, observed that of the 27 specific additives authorised for beer in other Member States, but totally banned in Germany, all but seven were authorised for use in some foodstuffs in Germany. These foodstuffs included certain dairy products such as cheese, powdered milk, puddings, sweets, fruit juices, jams and wines. In the subsequent ruling in Case 216/84 *Commission v French Republic,* see above note 58, para. 16, the French government argued that a prohibition against the importation and sale of substitutes for milk powder and concentrated milk was justified because they could have harmful effects on certain groups of the population. The Court of Justice rejected this argument observing that not only milk substitutes could have harmful effects on certain groups of people, but also that milk products could pose a risk to people suffering from certain diseases. In the present author's view the Court's reasoning regarding the French prohibition is not persuasive on this point.

[88] The Court of Justice in Case 251/78 *Firma Denkavit Futtermittel v Minister für Ernährung* [1979] ECR 3369 para. 24 observed that it must always be the duty of a national authority relying on Article 30 to prove that the measures which the authority enforces satisfy the criteria of this provision. See likewise Case 51/83 *Commission v Italian Republic* [1984] ECR 2793 para. 17.

[89] Thus Advocate General Slynn in Case 178/84 *Commission v Germany (Reinheitsgebot),* see above note 15, at p. 1252, concerning the German ban on additives in beer, observed that "[t]he onus is on the Federal Republic to show that the ban on each item used is justified rather than on the Commission to prove that each beer made in other Member States is totally harmless, or that the additives which they contain are indispensable for technological reasons." If the Member State adduces evidence that may justify the measure restricting intra-Community trade, the burden of proof changes to fall on the Member State's opponent, cf. Case C-24/00 *Commission v French Republic,* see above note 80, paras. 69-70. See also Case 174/82 *Sandoz,* see above note 79, para. 24.

[90] In this regard the Court of Justice will consider the scientific evidence and will have particular regard to the views taken by the Community's own experts as well as the ones taken by international organisations such as WHO and FAO. See for example Case 178/84 *Commission v Germany (Reinheitsgebot),* see above note 15, para. 44, Case 176/84 *Commission v Hellenic Republic* [1987] ECR 1193 para. 38, and Joined Cases C-13/91 and C-113/91 *Criminal proceedings against Michel Debus,* see above note 84, paras. 17 and 29.

[91] If the Court of Justice considers that the measure in reality is intended to protect domestic products, it will declare it unlawful. See for example Case 35/76 *Simmenthal SpA v Ministero delle Finanze italiano* [1976] ECR 1871 para. 20 and, in general, Case 42/82 *Commission v French Republic* [1983] ECR 1013.

It is for the Member State invoking the uncertain scientific evidence in support of a prohibition against importation and marketing to demonstrate that such a prohibition is justified.[92] However, it seems that the Court of Justice has reversed the onus of proving in those cases where the alleged health risk emanates from a food additive.[93] In this situation a Member State, prohibiting a foodstuff containing an additive that has been authorised in another Member State, has only been obliged to accept the sale of this foodstuff if the Court of Justice has been satisfied that the additive does not represent a danger to public health. Moreover, the Court of Justice also seems to have required that the use of the additive meets a genuine need, in particular a technological or economic one. In deciding on such a case, the Court would take into account both the findings of international scientific research and the eating habits in the importing Member State.

Whether or not the Member State prohibition concerned a perceived risk associated with an additive or with another cause, the Court of Justice appears to have allowed the Member States an appreciable margin of discretion, provided that the Court was satisfied that the prohibition was not simply a disguised barrier against imported food products.

Some examples may illustrate the above:

> In *Melkunie,* the Dutch authorities had initiated proceedings against a milk-importer, because the imported milk had been found not to comply with the Dutch rules on the maximum level of coliform bacteria and micro-organisms in milk. The milk-importer – supported by the Commission – argued that, under the then prevailing state of scientific knowledge, it was not possible to establish the maximum quantity of such micro-organisms that man may absorb every day without serious risk. They added, however, that only if the concentration was "much higher" than the level fixed by the Dutch authorities would there possibly be a risk to human health. The Court of Justice refuted this. It held that "the data available at the present stage of scientific research do not make it possible to determine with certainty the precise number of non-pathogenic micro-organisms above which a pasteurized milk product becomes a source of danger to human health. In the absence of harmonization in this field, it is for the Member States to determine, with due regard to the requirements of the free movement of goods, the level at which they wish to ensure that human life and

[92] The case-law of the Court of Justice does not appear to be fully consistent with regard to who is to bear the burden of proof. For example in Case C-375/90 *Commission v Greece* [1993] ECR I-2055 para. 25, the burden of proof regarding whether the food safety measure was proportionate apparently was placed on the Commission. In contrast, it is not clear which of the two parties had to bear the burden of proof regarding the scientific justification of the measure in the first place.

[93] Cf. Advocate General Slynn in Case 178/84 *Commission v Germany (Reinheitsgebot),* ee above note 15, at p. 1253.

health are protected. In those circumstances, national legislation seeking to ensure that at the time of consumption the milk product in question does not contain micro-organisms in a quantity which may constitute a risk merely to the health of some, particularly sensitive consumers, must be considered compatible with the requirements of Article [30]." The Court in other words accepted the Dutch rules, even though there was no scientific certainty about their justification.[94]

In the *French Milk Substitutes* Case, in relation to an argument put forward by the French government that certain milk substitutes could cause harmful effects on particular groups of the population, the Court of Justice confined itself to remark that there was "manifestly disagreement between specialists as to the actual and potential dangers to human health of animal and vegetable fats."[95] The French ban on milk substitutes was held to contravene Article 28.

In *Sandoz,* under Dutch legislation, vitamins could not be added to food and beverages without an authorisation granted by the Dutch authorities. Sandoz wanted to sell muesli bars and certain other foodstuffs that were lawfully sold in other Member States. The products, however, contained added vitamins, so the company applied for authorisation. The Dutch authorities rejected the application on the ground that the added vitamins in the products in question represented a danger to public health. Sandoz nevertheless sold the products, causing the authorities to initiate criminal proceedings. Through a preliminary reference the case ended up before the Court of Justice in Luxembourg. The Court found that, on the one hand, in view of scientific uncertainties and, on the other, of the fact that the harmfulness of vitamins depends on the quantity absorbed with the whole nutrition of a person, it was not possible to say with certainty whether any food to which vitamins had been added was harmful or not. The Court also observed that whilst vitamins were not in themselves harmful substances, but on the contrary were recognised by modern science as necessary for the human organism, excessive consumption of them over a prolonged period might nevertheless have harmful effects. According to the observations submitted to the Court, however, scientific research did not appear to be sufficiently advanced to be able to determine with certainty the critical quantities and the precise effects. The Court therefore concluded that "in so far as there are uncertainties at the present state of scientific research it is for the Member States, in the absence of harmonization, to decide what degree of protection of the health and life of humans they intend to assure, having regard however for the requirements of the free movement of goods within the Community." [96]

In *Koninklijke Kaasfabriek Eyssen,* the Dutch authorities had prohibited the use of the additive nisin in cheese. The Court of Justice observed that it was "indeed accepted that the increasingly widespread use of that substance … has revealed the need, both at national level in certain countries and at international

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[94] Case 97/83 *Criminal proceedings against Melkunie*, see above note 79, paras. 16 and 18. In para. 17 of the judgment the Court observed that the other Member States that had also laid down a maximum limit had arrived at a level similar to the Dutch one.

[95] Case 216/84 *Commission v French Republic,* see above note 58, para. 16.

[96] Case 174/82 *Sandoz,* see above note 79, paras. 10, 11 and 16.

level, to study the problem of the risk which the consumption of products containing the substance presents, or may present, to human health". The Court also observed that international organisations, such as FAO and WHO, were undertaking research into the critical threshold for the intake of nisin. It continued that "[a]lthough those studies have not as yet enabled absolutely certain conclusions to be drawn regarding the maximum quantity of nisin which a person may consume daily without serious risk to his health, this is essentially due to the fact that the assessment of the risk connected with the consumption of the additive depends upon several factors of a variable nature …" Under these circumstances the Court found that the Dutch authorities had been justified in prohibiting the use of nisin in cheese.[97]

Mirepoix concerned the importation into France of Dutch onions that had been treated with a pesticide. This pesticide had been banned in France, however, so the sale of the treated onions was illegal there. In its judgment the Court of Justice did not consider whether banning the particular pesticide was justified. Instead it observed that, generally speaking, pesticides constituted a major risk to human and animal health and to the environment. It went on to conclude that in these circumstances, in the absence of harmonisation, it was for the Member States to determine the level of protection which should be given to human health and life. In doing so, the Member States would, however, have to take account of the EC Treaty's requirements on the free movement of goods, and, in this regard, the Member States were obliged to re-evaluate the measure for example where new information became available through scientific research.[98]

National Farmers Union (BSE) concerned measures introduced by the European Commission to safeguard the public against the Creutzfeldt-Jakob disease. The case gave rise to a number of problems including the fact that at the time of the adoption of the Commission decision there was great uncertainty as to the risks posed by the food products covered by the Commission measure. The Court of Justice held that where there is uncertainty as to the existence or extent of risks to human health, the Commission could take protective measures without having to wait until the reality and seriousness of those risks had become fully apparent.[99]

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[97] Case 53/80 *Officier van Justitie v Koninklije Kaasfabriek Eyssen,* see above note 50, para. 13.

[98] Case 54/85 *Ministère public v Mirepoix,* see above note 79, paras. 13-16. It is worth of note that the Court of Justice appears to take the view that there was no scientific uncertainty, albeit it also did note that new information could appear that called into doubt the basis on which the original decision to ban the pesticide was taken. On the obligation to review the Member State measure, see also Case 94/83 *Criminal proceedings against Albert Heijn* [1984] ECR 3263 para. 18.

[99] Case C-157/96 *R. v Ministry of Agriculture, Fisheries and Food (MAFF), ex p. NFU* [1998] ECR I-2211 paras. 62-63. See also Case C-180/96 *United Kingdom v Commission (BSE),* see above note 80, para. 61 and Case T-13/99 *Pfizer Animal Health SA v Council* [2002] ECR II-3305 paras. 113-125. With regard to Member States taking precautionary measures where there is scientific uncertainty, see Case C-192/01 *Commission v Denmark (vitamins)* [2003] ECR I-9693 para. 49, Case C-236/01 *Monsanto Agricoltura Italia and Others* [2003] ECR I-8105 paras. 106-107, and Case C-24/00 *Commission v French Republic,* see above note 80, para. 56. The three last-mentioned cases were introduced at the European Court of Justice in 2000 and 2001.

The above examination has shown that if a Member State has invoked food safety as a defence of some trade restricting measure, the European Court of Justice has been prepared to try this defence by applying a consistency test as well as a scientific test. Where the consistency test has been applied it appears that the Court has undertaken a meticulous verification. In contrast, it appears that the Court has been significantly more hesitant when it comes to testing the scientific evidence invoked by a Member State. Indeed, the Court of Justice has recognised the precautionary principle in the field of food safety, albeit the first such cases[100] did not concern Member State measures but rather measures enacted by the Community.

In other words, the Court of Justice has been ready to set aside food safety measures where these measures restrict trade between Member States.

2.7.4 Arbitrary discrimination and proportionality

Article 30, second sentence, lays down that a Member State measure will not be justifiable if it constitutes "a means of arbitrary discrimination or a disguised restriction on trade between Member States". This requirement essentially means that if the measure is exclusively aimed at imported products, whereas domestic products are not covered, the Court of Justice requires that a particularly convincing justification is put forward.

> The *French Wine-War* Case concerned a situation that took place in the early 1980s. The wine market in France was then characterised by a large increase in imports of table wine of Italian origin. That increase had the effect of reducing prices on the French market causing violent demonstrations among the French wine growers. This led the French authorities to intensify the control measures on the imports of Italian table wine. Not least did they systematically subject the Italian wine to health checks by means of analysis before releasing the consignments in question for consumption. The consequence was that considerable quantities of table wines were held up at the frontier, ultimately causing the Commission to bring legal proceedings against France for failure to fulfil its obligations under the Treaty. The French practice clearly constituted a hindrance to intra-Community trade, whilst it pretended to pursue a lawful purpose. However, where the French authorities took samples of Italian wine, this would entail the automatic detention of the wine in question until the results of the analyses were known, whereas the same did not apply to French wine. The practice therefore constituted arbitrary discrimination.[101]

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[100] Case C-157/96 *R. v Ministry of Agriculture, Fisheries and Food (MAFF), ex p. NFU,* see above note 99, paras. 62-63, Case C-180/96 *United Kingdom v Commission (BSE),* see above note 80, para. 61, Case C-507/99 *Denkavit Nederland v Minister van Landbouw, Natuurbeheer en Visserij et Voedselvoorzieningsin* [2002] ECR I-169 para. 36 and Case T-13/99 *Pfizer Animal Health SA v Council,* see above note 99, paras. 113-125.

[101] Case 42/82 *Commission v France,* see above note 91, paras. 60-61. See also Case 4/75 *Rewe-Zentralfinanz v Landwirtschaftskammer* [1975] ECR 843 para. 8, concerning phytosanitary inspection of apples imported into Germany.

In contrast to the above, the Court of Justice has accepted that a prohibition founded on public health, that only applies to domestic sales but not to exports, does not constitute arbitrary discrimination.[102]

Even if the Court of Justice is satisfied that a Member State measure pursues a lawful objective, the Member State still has one more – important – barrier to overcome. The measure must be proportionate. Under Community law the proportionality examination is comprised of three steps:

- A suitability test
- A necessity test
- A proportionality test *stricto sensu*

The *suitability test* essentially requires that the measures chosen by the Member State constitute suitable means for achieving the asserted lawful purpose.

> In *United Foods,* the Court of Justice was asked to consider a Belgian rule that fish products could only be lawfully imported if they complied with a number of technical requirements intended to protect human health. The Court held that there would have to be a "reasonable connexion" between, on the one hand, the technical requirement and, on the other hand, the control the products were going through. Failing such connection, the requirements would not constitute a suitable means for achieving the stated purpose.[103]
>
> In the *Belgian labelling requirement* case, under Belgian law the placing on the market of foodstuffs to which nutrients had been added required prior notification with the Belgian Ministry of Public Health and the Environment. Moreover, Belgian law also required that the notification number was indicated on the labelling of the foodstuff in question. The Court of Justice observed that such information, even if it provided consumers with an assurance that a file had been notified to the competent authorities, was not capable of enabling them to decide whether or not they should consume the product and, if they did consume it, in what quantities. Hence, the Court concluded that it was not "sufficiently useful to them for its inclusion to be fully justified on grounds of the protection of public health."[104]

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[102] Case 53/80 *Officier van Justitie v Koninklije Kaasfabriek Eyssen,* see above note 50, para. 16.

[103] Case 132/80 *United Foods and PVB Aug van den Abeele v Belgium,* see above note 54, para. 28.

[104] Case C-217/99 *Commission v Belgium* [2000] ECR I-10251 para. 26. In Case C-67/88 *Commission v Italy (colour-reactive sesame oil)* [1990] ECR I-4285 paras. 6-8, an Italian requirement that the marketing of certain edible oils was conditional upon the addition of colour-reactive sesame oil to combat fraudulent practices was found to be "not such as to achieve effectively the aim pursued". Hence, the Italian requirement was not a suitable means of achieving the stated objective.

Under the *necessity test* the Court of Justice examines whether the asserted lawful purpose may have been obtained through measures that restrict intra-Community trade less. In a large number of cases the Court has found that labelling or other forms of providing information to the consumer may achieve the stated purpose and for this reason has set aside more radical measures such as bans.[105]

> In *Commission v United Kingdom (UHT)* in order to protect human health, the British authorities required the importers of non-British UHT milk to pack the milk on premises within the UK. To do this, the importers would have to open the packs and then repack the milk. This procedure was very costly and constituted the equivalent of a total prohibition on imports. The British authorities argued that the disputed procedure was the only effective means of protecting the health of consumers. The Court of Justice disagreed. It found that the British authorities could ensure satisfactory safeguards by using less restrictive measures and so the British measures were not "necessary".[106]
>
> In *Firma Denkavit Futtermittel v Minister für Ernährung,* German legislation required that when certain feeding stuffs were imported into Germany, the importer should produce a certificate from the competent authority in the exporting country showing that the feeding stuffs had undergone a process to destroy salmonellae and, in addition, the German authorities should establish by bacteriological examination that the goods contained no salmonellae. The Court of Justice held that to the extent that this double check went beyond what was needed to protect the health and life of humans and animals it would exceed what Article 30 permitted. In this regard the German authorities were obliged to consider whether co-operation between the authorities of the Member States would make it possible to achieve the stated objective in a less restrictive way.[107]
>
> In *Heimdienst,* Austrian legislation required that bakers, butchers and grocers could make sales on rounds in a given administrative district, such as an Austrian Verwaltungsbezirk, only if they also traded from a permanent establishment in that administrative district or an adjacent municipality, where they offered for sale the same goods as they did on rounds. One consequence of this requirement was that a baker, a butcher or a grocer established in another Member

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[105] See for example Case 120/78 *Rewe-Zental AG v Bundesmonopolverwaltung für Branntwein (Cassis de Dijon),* see above note 15, para. 13, Case 130/80 *Criminal proceedings against Fabriek voor Hoogwaardige Voedingsprodukten Kelderman,* see above note 86, para.12 and Communication from the Commission concerning the consequences of the judgment given by the Court of Justice on 20 February 1979 in case 120/78 ('Cassis de Dijon') (OJ 1980 C 256/2). See also Case 118/86 *Openbaar Miniserie v Nertsvoederfabriek Nederland* [1987] ECR 3883 paras. 13, 16 and 17, Case 407/85 *3 Glocken,* see above note 15, para. 16, Case 178/84 *Commission v Germany (Reinheitsgebot),* see above note 15, paras. 44, 47 and 53, Case C-24/00 *Commission v French Republic,* see above note 80, para. 75, and Case 216/84 *Commission v French Republic,* see above note 58, para. 16. In the last-mentioned case the Court of Justice found that "appropriate labelling" would be an adequate measure so that a total prohibition was disproportionate.

[106] Case 124/81 *Commission v United Kingdom (UHT milk),* see above note 53, paras. 20-28.

[107] Case 251/78 *Firma Denkavit Futtermittel v Minister für Ernährung,* see above note 88, para. 23.

State was precluded from making sales on rounds in Austria. The Court of Justice thus found that the requirement constituted an MEE. The Austrian government however argued that – amongst others – the requirement was justified in hygienic considerations. The Court of Justice accepted that whilst, in principle, public health could provide a justification, that objective could be attained by measures that had effects less restrictive of intra-Community trade, such as by rules on refrigerating equipment in the vehicles used. The Austrian legislation thus failed the proportionality test.[108]

Finally, even if the measure is suitable for achieving its stated lawful purpose and even if there is no less radical measure available, the Court of Justice will still consider whether the measure has an excessive effect on intra-Community trade, i.e. a *proportionality test stricto sensu*.

Advocate General Slynn in a well-known statement in his Opinion in *Reinheitsgebot* found that the German ban on additives in beer was clearly disproportionate *stricto sensu*. He said that "the factors which the Federal Republic points to are largely legitimate factors – the need to avoid excessive use of additives, the risk of the interaction of one additive with others and with alcohol, the cumulative effect, the risk of allergy. I say "largely" because at times the argument goes too far. It seems to me disproportionate to seek to justify rules which exclude the whole of society from beer other than nationally produced beer because some additives may constitute a risk for a person who drinks in excess of 1,000 litres of beer a year or for an alcoholic already suffering from cirrhosis of the liver."[109]

To sum up, the requirement that a measure does not constitute arbitrary discrimination will often catch those measures where food safety is nothing but a cloak for an intended restriction on trade. In contrast, the proportionality principle basically requires that the Member State's choice of measure to achieve a legitimate objective is tested – and frequently the Member State's choice is rejected.

2.8 Do Articles 28-30 give priority to food safety or to free movement?

The examination provided in Sections 2.1 – 2.7 shows that the main focus of Article 28 clearly is upon free movement of goods between the Member States. Thus, whilst food safety is accepted as an objective which the Member States may legitimately pursue, in relation to Article 28 it is nevertheless clear that food safety is only an exception to the protection of free movement of goods and so must be given a narrow construction. Irrespective of the fact that, during the period under scrutiny, there was no

[108] Case C-254/98 *Schutzverband gegen unlauteren Wettbewerb v TK-Heimdienst Sass* [2000] ECR I-151 para. 36.
[109] Case 178/84 *Commission v Germany (Reinheitsgebot),* see above note 15, p. 1257.

coherent system of food safety legislation allowing the common market to work, the objective of creating such market – so-to-say – tramps food safety measures that the Court of Justice considers to be disproportionate. Therefore, where a Member State intends to introduce a food safety measure that may affect the free movement, the State must be able to adduce evidence showing that the measure is objectively founded and that it is proportionate (as defined under Community law).

In other words, Articles 28-30 give priority to free movement over food safety.

2.9 Community legislation imposing food safety as an obligation – the first 40 years

2.9.1 Introduction

During the first four decades of the European Community's existence, Community legislation in the field of food law in general was surprisingly scarce and patchy and it was far from forming a coherent whole. As MacMaoláin has put it: "One thing was very clear from the body of legislation that was devised, if it can be called a body: it would never have the desired effect of creating a single market for foodstuffs. The various pieces of secondary legislation were largely unrelated to each other, dealing with diverse, usually very specific, aspects of the food production process."[110] This observation is not least true when it comes to Community legislation in the field of food safety. Thus, food safety was primarily an objective pursued by the Member States, and the matter would only be covered by Community law where the Member State measures came into conflict with the EC Treaty. Often these conflicts would end up before the European Court of Justice, and so the Community's approach to food safety before 2000 to a considerable extent developed through the Court's case-law. Nevertheless, during this period the Community also issued a number of secondary legislation (directives and regulations). In order to provide an adequate picture of the regulation of food safety under Community law this legislation must be covered as well.

As will be apparent from the following examination, sometimes Community legislation on the Common Agricultural Policy would consider food safety. More frequently, however, the matter would be dealt with as part of the Community's drive to dismantle internal barriers to trade. Thus, more than once, the Commission pointed out that differences in national public health

[110] MacMaoláin, C., *EU Food Law – Protecting Consumers and Health in a Common Market* (Hart Publishing, 2007), p. 67.

standards were likely to constitute barriers to the free movement of food products. Community harmonisation measures were an important means to remedy this.[111]

Below I examine the different pieces of the body of secondary Community legislation that most directly affected food safety in the period up until the millennial change. The analysis will focus on the legal foundation and on the purpose of the relevant EC legislation as well as on how this legislation has been construed by the Court of Justice. In Community law the so-called *teleological* interpretation, i.e. an interpretation that emphasises the objective of the legal measure in question, plays a particularly important role. Therefore, in order to identify what factors have been decisive for the introduction of the legislative measures under scrutiny, particular emphasis will be placed upon the objective pursued by these measures.

2.9.2 Legislation on hygiene

Food hygiene refers to the measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff taking into account its intended use.[112] The first Community measures on food hygiene saw the light of day not long after the European Community had been created. Thus, for example, in 1964 the Council adopted Directive 64/433 on health problems affecting intra-Community trade in fresh meat laying down hygiene requirements concerning the handling of fresh meat.[113] The legal bases of the directive were Article 37 concerning the Community's common agricultural policy together with Article 94 concerning the establishing of a common market. That the creation of the common market was an important objective is also clear from the preamble, which refers to the elimination of hindrances to intra-Community trade.[114] Over the following years the Community developed a considerable body of legislation aimed at harmonising the control of food hygiene, so that the food products could travel more freely within the Community. This body

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[111] Cf. White Paper from the Commission to the European Council, 28-29 June 1985. Commission of the European Communities, Completing the Internal Market (COM (1985) 310 final) paras. 39-43 and Commission of the European Communities, Communication from the Commission to the Council and to the European Parliament of 8 November 1985, Completion of the Internal Market: Community Legislation on Foodstuffs (COM (1985) 603 final).

[112] Cf. Article 2(1)(a) of Regulation 852/2004 of 29 April 2004 on the hygiene of foodstuffs (OJ 2004 L 139/1).

[113] Directive 64/433 of 26 June 1964 on health problems affecting intra-Community trade in fresh meat, (OJ 1964 121) (English special edition: Series I, Chapter 1963-1964 p. 185).

[114] See also Case C-105/95 *Paul Daut GmbH & Co. KG v Oberkreisdirektor des Kreises Gütersloh* [1997] ECR I-1877 para. 19.

of legislation did not form a coherent whole, but rather each piece of legislation covered a limited range of products. Moreover, the legislation would often be very detailed and cover hygiene as well as other aspects. It has been held that inconsistencies between the different pieces of legislation were numerous.[115]

In 1993, in connection with the creation of the internal market and the consequent elimination of border controls, the Community adopted Directive 93/43 on the hygiene of foodstuffs (the Hygiene Directive).[116] Whilst the earlier hygiene legislation covered only a limited range of food products, the Hygiene Directive basically covered all food products – it was so to say horizontal in nature. Article 95 of the EC Treaty provided the legal basis of the Hygiene Directive, which meant that the directive's objective necessarily had to be the establishment and functioning of the internal market.[117]

Before the millennial change Community legislation on food hygiene was made up of a number of product specific (vertical) legislative measures together with the (horizontal) Hygiene Directive. The legal measures covered the following eleven groups of food products of animal origin:

- Fresh meat[118]
- Poultry meat[119]
- Meat products[120]

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[115] Fogden, M., Hygiene, in Goodburn, K. (ed.), *EU food law* (Woodhead Publishing Ltd., 2001) at p. 30, and Holland and Pope, *EU Food Law and Policy*, see above note 4, p. 155.

[116] Directive 93/43 of 14 June 1993 on the hygiene of foodstuffs (OJ 1993 L 175/1).

[117] The preamble's first recital is worded in the following terms: "Whereas the free movement of foodstuffs is an essential pre-condition for the completion of the internal market; whereas this principle implies confidence in the standard of safety of foodstuffs for human consumption in free circulation, and in particular their standard of hygiene, throughout all stages of preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling and offering for sale or supply to the consumer".

[118] See Directive 77/96 of 21 December 1976 on the examination for trichinae (trichinella spiralis) upon importation from third countries of fresh meat derived from domestic swine (OJ 1977 L 26/67), Directive 72/461 of 12 December 1972 on health problems affecting intra-Community trade in fresh meat (OJ 1972 L 302/24), and Directive 64/433, see above note 113.

[119] See Directive 71/118 of 15 February 1971 on health problems affecting trade in fresh poultrymeat, (OJ 1971 L 55/23) (English Special Edition, Series I, Chapter 1971(I), p. 106) and Directive 91/494 of 26 June 1991 on animal health conditions governing intra-Community trade in and imports from third countries of fresh poultrymeat (OJ 1991 L 268/35).

[120] See Directive 96/23 of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358 and 86/469 and Decisions 89/187 and 91/664 (OJ 1996 L 125/10), and Directive 80/215 of 22 January 1980 on animal health problems affecting intra-Community trade in meat products (OJ 1980 L 47/4).

- Minced meat and meat preparations[121]
- Rabbit and farmed game[122]
- Wild game[123]
- Fish[124]
- Live bivalve molluscs[125]
- Eggs and egg products[126]
- Milk and milk products[127]
- Other products[128]

The main objective of this considerable body of legislation was the elimination of hindrances to intra-Community trade.

In other words, until the millennial change, the Community had a considerable but incoherent body of legislation in the field of food hygiene, primarily covering products of animal origin. The above examination clearly

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[121] See Directive 94/65 of 14 December 1994 laying down the requirements for the production and placing on the market of minced meat and meat preparations (OJ 1994 L 368/10) and Commission Decision 97/29 of 17 December 1996 establishing health conditions and public health certification for the importation of minced meat and meat preparations from third countries (OJ 1997 L 12/33).

[122] See Directive 91/495 of 27 November 1990 concerning public health and animal health problems affecting the production and placing on the market of rabbit meat and farmed game meat (OJ 1991 L 268/41).

[123] See Directive 92/45 of 16 June 1992 on public health and animal health problems relating to the killing of wild game and the placing on the market of wild-game meat (OJ 1992 L 268/35).

[124] See Directive 92/48 of 16 June 1992 laying down the minimum hygiene rules applicable to fishery products caught on board certain vessels in accordance with Article 3(1)(a)(i) of Directive 91/493 (OJ 1992 L 187/41) and Directive 91/493 of 22 July 1991 laying down he health conditions for the production and the placing on the market of fishery products (OJ 1991 L 268/15).

[125] See Directive 91/492 of 15 July 1991 laying down the health conditions for the production and the placing on the market of live bivalve molluscs (OJ 1991 L 268/1).

[126] See Directive 89/437 of 20 June 1989 on hygiene and health problems affecting the production and the placing on the market of egg products (OJ 1989 L 212/87).

[127] See Directive 89/362 of 26 May 1989 on general conditions of hygiene in milk production holdings (OJ 1989 L 156/30), Directive 89/384 of 20 June 1989 establishing the detailed procedures for carrying out checks to ensure that the freezing-point of untreated milk laid down in Annex A to Directive 89/397 is complied with (OJ 1989 L 181/50), Council Decision 92/608 of 14 November 1992 laying down methods for the analysis and testing of heat-treated milk for direct human consumption (OJ 1992 L 407/29), and Directive 92/46 of 16 June 1992 laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products (OJ 1992 L 268/1).

[128] See Directive 92/118 of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662 and, as regards pathogens, to Directive 90/425 (OJ 1993 L 62/49).

shows that the primary objective of this legislation was the furthering of the free movement of goods within the Community. Thus, the regulation of food safety was not an objective in its own right, but rather it was a means in the creation of the common market.

2.9.3 Legislation on additives

Additives are substances that are added to a foodstuff so that it obtains a given quality.[129] Examples include preservatives, colours and sweeteners. From a very early time the Community began legislating in the area. or example, Council Directive 64/54 set out to harmonise the laws on preservatives to be used in foodstuffs for human consumption.[130]

Ten years after the adoption of Directive 64/54, on 18 June 1974, the Council adopted Directive 74/329 on the approximation of the laws of the Member States relating to emulsifiers, stabilizers, thickeners and gelling agents for use in foodstuffs.[131] In this directive's preamble it is observed that differences between national laws relating to additives "hinder the free movement of foodstuffs and may create conditions of unfair competition, thereby directly affecting the establishment or functioning of the common market".[132] It is for this reason that "the approximation of those laws is necessary for the free movement of foodstuffs".[133] The directive continues by stating that all laws relating to the additives covered by the directive must give priority to the protection of public health.[134]

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[129] Directive 89/107 of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption (OJ 1989 L 40/27), Article 1(2) defines an additive in the following terms: "'food additive' means any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods."
For a critique of this definition, see Verbruggen, R., in van der Meulen, B. and van der Velde, M., *Food Safety Law in the European Union – An introduction,* see above note 4, p. 173.

[130] Directive 64/54 of 5 November 1963 on the approximation of the laws of the Member States concerning the preservatives authorized for use in foodstuffs intended for human consumption (OJ 1964 161) (English Special Edition, series I, Chapter 1963-1964, p. 99). The directive remained in force until 1995.

[131] Directive 74/329 of 18 June 1974 on the approximation of the laws of the Member States relating to emulsifiers, stabilizers, thickeners and gelling agents for use in foodstuffs (OJ 1974 L 189/1).

[132] Recital 1 of Directive 74/329, see above note 131.

[133] Recital 2 of Directive 74/329, see above note 131.

[134] See also Case 304/84 *Criminal proceedings against Claude Muller and others* [1986] ECR 1511 para. 22.

In late 1988 the Council adopted "Directive 89/107 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption" (the Additives Framework Directive),[135] providing the framework for the Community legislation on additives and remaining in force to this day.[136] Article 95 of the EC Treaty forms the legal basis of the Additives Framework Directive, as well as the three additives directives supplementing it, and all three directives explicitly point to the elimination of the barriers to the free movement of foodstuffs that differences between the national laws may create. In other words, the primary objective is to harmonise the rules in order to further the objective of creating a common market.[137]

The conflict between, on the one hand, the Member States' intention of protecting public health by prohibiting certain additives and, on the other, the Community's objective of creating a common market with no barriers, is clearly illustrated by the judgment in the *Nitrate* case.

> In *Commission v Italy (Nitrate),* the Court of Justice had to consider an Italian prohibition on imports of cheese to which nitrate had been added. The Court observed that national rules making the use of additives subject to authorisation must fulfil two conditions. First, the rules must make provision for a readily accessible procedure enabling traders to have the additive included on the national list of authorised additives. Secondly, an application to have an additive included on the list in question may be rejected by the competent administrative authorities only if the additive does not meet any genuine need, in particular a technological need, or presents a danger to public health. In this regard the Court added that for the purpose of showing that an additive does not meet a genuine need it is not sufficient to rely on the fact that a product could be manufactured using another substance.[138]

The above examination has shown that the Community's legislation in the field of additives applying until 2000 attached greatest importance to the

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[135] Directive 89/107, see above note 129.

[136] The directive has been supplemented by Directive 94/35 of 30 June 1994 on sweeteners for use in foodstuffs (OJ 1994 L 237/3), Directive 94/36 of 30 June 1994 on colours for use in foodstuffs (OJ 1994 L 247/13), and Directive 95/2 of 20 February 1995 on food additives other than colours and sweeteners (OJ 1995 L 61/1). See also, concerning flavourings not covered by these three additives directives, Directive 88/388 of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production (OJ 1988 L 184/61).

[137] See in this respect Commission communication on the free movement of foodstuffs within the Community (OJ 1989 C 271/3).

[138] Case C-95/89 *Commission v Italy,* see above note 85, paras. 9-12. Likewise, in Joined Cases C-13/91 and C-113/91 *Criminal proceedings against Michel Debus,* see above note 84, paras. 26-28, the Court of Justice observed that the Italian authorities could not rely on "reference to another manufacturing method of the product used by national manufacturers" to justify a ban on the use of a specific additive in beer.

objective of creating a common market. In contrast, food safety did not play a prominent role in this legislation. Hence, even if a food product may be produced without the use of a given additive, and even if a Member State considers the use of that additive harmful to public health, this, in itself, is not enough to justify a prohibition that will hinder the free movement of goods.

2.9.4 Legislation on contaminants and residues

Contaminants are substances that unintentionally are present in a food product, such as heavy metals, nitrate and various toxins, such as aflatoxins and dioxin.[139] Residues are remains of substances which intentionally have been included in the production process, but which are not wanted in the final product, such as residues from veterinary medicines, from additives in feeding stuffs and from pesticides. Since different rules in the field of contaminants and residues were likely to "hinder the functioning of the common market", the Council in 1993, on the basis of Article 95 of the EC Treaty, adopted Regulation 315/93 laying down Community procedures for contaminants in food (Framework Regulation on Contaminants).[140] On the basis of the Framework Regulation on Contaminants the Commission, in 1997, adopted Regulation 194/97 setting maximum levels for certain contaminants in foodstuffs.[141]

The Framework Regulation on Contaminants did not apply to contaminants which were the subject of more specific Community rules.[142] Such more specific rules included Directive 76/895 on pesticides in fruit and vegetables,[143] Directive 86/362 on pesticides in cereals,[144] Directive 86/363 on pesticides in foodstuffs of animal origin,[145] Directive 90/642 on pesticides

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[139] "Contaminants" are defined in Article 1(1) of Regulation 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ 1993 L 37/1) as: "any substance not intentionally added to food which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food, or as a result of environmental contamination. Extraneous matter, such as, for example, insect fragments, animal hair, etc, is not covered by this definition."

[140] Regulation 315/93, see above note 139.

[141] Regulation 194/97 of 31 January 1997 setting maximum levels for certain contaminants in foodstuffs (OJ 1997 L 31/48).

[142] Cf. Article 1(2)(1) of the Framework Regulation on Contaminants.

[143] Directive 76/895 of 23 November 1976 relating to the fixing of maximum levels for pesticide residues in and on fruit and vegetables (OJ 1976 L 340/26).

[144] Directive 86/362 of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals (OJ 1986 L 221/37).

[145] Directive 86/363 of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on foodstuffs of animal origin (OJ 1986 L 221/43).

in plant products[146] and Directive 91/493 on histamine in fishery products.[147] These harmonisation measures were adopted on the basis of Article 37 concerning the Community's common agricultural policy in combination with Article 94 concerning the establishing of a common market.[148]

Like in the previous sections on secondary Community legislation, also the Community's legislation on contaminants and residues was characterised by having the dismantling of internal barriers as the primary objective. In contrast, protection of public health did not appear to be an important objective in its own right.

2.9.5 Legislation on food contact materials

When food products are transported etc. they may come into contact with other materials. Sometimes these materials could contain unwanted substances that would be able to migrate to the food product. To prevent this from happening, the Member State authorities may want to introduce legislation in the field of food contact materials. Where this legislation is non-uniform, it will create obstacles in the free movement of food products, and so the European Community has an interest in harmonising the field. Originally this was done through Directive 76/893 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs,[149] which applied to "materials and articles which in their finished state are intended to come into contact with foodstuffs or which are in contact with foodstuffs and are intended for that purpose".[150] Directive 76/893 was subsequently replaced by Directive 89/109,[151] which in Article 3(1) required that ten groups of materials

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[146] Directive 90/642 of 27 November 1990 on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables OJ 1990 L 350/71).

[147] Directive 91/493, see above note 124. See also Commission decision 93/351 of 19 May 1993 determining analysis methods, sampling plans and maximum limits for mercury in fishery products (OJ 1993 L 144/23).

[148] Directives 90/642, see above note 146, and 91/493, see above note 124, were adopted solely on the basis of Article 37 of the EC Treaty.

[149] Directive 76/893 of 23 November 1976 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs (OJ 1976 L 340/19).

[150] Cf. Article 1(1) of Directive 76/893, see above note 149. The directive also covered materials and articles which were in contact with water intended for human consumption, whereas it did not include within its scope "covering or coating substances, such as the substances covering cheese rinds, prepared meat products or fruit, which form part of foodstuffs and may be consumed together with the food".

[151] Directive 89/109 of 21 December 1988 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs (OJ 1989 L 40/38).

and articles should be subject to specific directives.[152] On the basis of these two directives some more specific directives were adopted, such as for example Directive 78/142 on the approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs.[153]

Whereas Directive 76/893 found its legal basis in Article 94 of the EC Treaty,[154] Directive 89/109 was adopted on the basis of Article 95 of the Treaty. In other words, the primary reason for regulating food safety through these legal measures was not the protection of public health, but the elimination of barriers to the free movement of goods in the Community.

2.9.6 Legislation on labelling requirements *vis-à-vis* the consumer

Whereas legislation on hygiene, additives and contaminants have a direct impact on food safety, labelling requirements only indirectly impact food safety; such food safety through labelling may be brought about, for example, by providing information about ingredients that may cause allergic reactions or by requiring a "best before" date on the food product. Until 2000 labelling requirements regarding foodstuffs were primarily regulated by the so-called Labelling Directive.[155] This directive was based on Article 94 of the EC Treaty[156] and, in its preamble, it was made clear that the harmonisation was aimed at contributing "to the smooth functioning of the common market".[157] Only once did the Labelling Directive make explicit

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[152] These ten groups were (1) plastics, including varnish and coatings, (2) regenerated cellulose, (3) elastomers and rubber, (4) paper and board, (5) ceramics, (6) glass, (7) metals and alloys, (8) wood, including cork, (9) textile products, and (10) paraffin waxes and micro-cystalline waxes.

[153] Directive 78/142 of 30 January 1978 on the approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs (OJ 1978 L 44/15). See also Directive 90/128 of 23 February 1990 relating to plastic materials and articles intended to come into contact with foodstuffs (OJ 1990 L 75/19).

[154] Together with Article 299 of the EC Treaty, which is not relevant in the present context.

[155] Directive 79/112 of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer (OJ 1979 L 33/1). The Labelling Directive applied to all types of foodstuffs and was thus horizontal in nature. It was supplemented by labelling requirements in a number of other Community measures, including Directive 90/446 of 24 September 1990 on nutrition labelling for foodstuffs (OJ 1990 L 276/40), and Regulation 258/97 of 27 January 1997 concerning novel foods and novel food ingredients (OJ 1997 L 43/1).

[156] Together with Article 299 of the EC Treaty, which is not relevant in the present context.

[157] Cf. the Labelling Directive's second recital.

reference to public health, namely in Article 15(1) where it was established that, exceptionally, Member States may forbid trade in foodstuffs, even though they complied with the rules laid down in the directive where this prohibition was justified on grounds of the protection of public health.

That food safety as such was not an objective of the Labelling Directive was equally apparent from the fact that the Court of Justice seemed to take a somewhat legalistic approach when called to interpret it.

> In *Pfanni Werke,* the Court of Justice was asked to rule on whether the Labelling Directive required that an additive used during the production process and remaining in the finished product had to be mentioned in the labelling, where the additive did not serve a technical purpose in the final product. The Court of Justice held that in this situation the additive would not have to be included in the list of ingredients.[158]

As the above examination shows, food safety has not been an objective of the Community's secondary legislation on labelling in the period until 2000. Indeed, it seems somewhat doubtful whether food safety as such was given any real consideration in the process leading to the adoption of this legislation.

2.9.7 Legislation on foodstuffs for particular nutritional uses – PARNUTS

Some foods have been designed to fulfil particular nutritional functions (so-called "PARNUTS"). To regulate these, the European Community in 1976 adopted Directive 77/94 on the approximation of the laws of the Member States relating to foodstuffs for particular nutritional uses.[159] In 1989 the original directive was replaced by Directive 89/398 on the

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[158] Case C-144/93 *Pfanni Werke Otto Eckart KG v Landeshauptstadt München* [1994] ECR I-4605 paras. 12-19. It should be observed that some argue that strengthening the labelling requirements does not necessarily improve the protection of public health, since it may reduce clarity and thereby be counterproductive in the protection of the consumers, cf. MacMaoláin, *EU Food Law – Protecting Consumers and Health in a Common Market*, see above note 110, pp. 75-76 with further references.

[159] Directive 77/94 of 21 December 1976 on the approximation of the laws of the Member States relating to foodstuffs for particular nutritional uses (OJ 1977 L 26/55).

approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses.[160]

A foodstuff for particular nutritional uses is defined as "foodstuffs which, owing to their special composition or manufacturing process, are clearly distinguishable from foodstuffs for normal consumption, which are suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability".[161] This definition covers, *inter alia,* food products that are suitable for diabetics and for persons who are allergic to gluten. It also covers food aimed at infants and young children. In order for a PARNUTS food product to be healthy, it must therefore fulfil not only the requirements applicable to foodstuffs for normal consumption, but in addition it must be appropriate for the particular nutritional use for which it is intended. Some PARNUTS foodstuffs thus, by definition, are intended to protect the health of certain groups among the population. Moreover, in particular Directive 89/398 explicitly vests in the Member States the possibility of taking specific safeguard measures where the Member State authorities have reason to believe that a PARNUTS food product may endanger human health.[162]

Whilst Directive 77/94 was based on Article 94 of the EC Treaty, Directive 89/398 found its legal basis in Article 95. This means that a primary objective of both directives was the elimination of barriers to the free movement of goods in the European Community.[163] On the other hand, the very pur-

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[160] Directive 89/398 of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses (OJ 1989 L 186/27). This directive in Annex I required provisions to be laid down by specific directives with respect to nine groups of foods, namely (1) infant formulae, (2) follow-up milk and other follow-up foods, (3) baby foods, (4) low-energy and energy-reduced foods intended for weight control, (5) dietary foods for special medical purposes, (6) low-sodium foods, including low-sodium or sodium-free dietary salts, (7) gluten-free foods, (8) foods intended to meet the expenditure of intense muscular effort, especially for sportsmen, and (9) foods for persons suffering from carbohydrate-metabolism disorders (diabetes). The work to produce these directives proved very difficult, and so in 1999 the list was shortened to cover only five categories, namely (1) infant formulae and follow-up formulae, (2) processed cereal-based foods and baby foods for infants and young children, (3) food intended for use in energy-restricted diets for weight reduction, (4) dietary foods for special medical purposes, and (5) foods intended to meet the expenditure of intense muscular effort, especially for sportsmen, cf. Directive 99/41 of 7 June 1999 amending Directive 89/398/EEC on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses (OJ 1999 L 172/38).

[161] Cf. Article 1(2)(a) of Directive 89/398, see above note 160.

[162] Cf. Articles 11 and 12 of Directive 89/398, see above note 157. See also Article 7(2) of Directive 77/94, see above note 160.

[163] See also Case C-107/97 *Criminal proceedings against Max Rombi and Arkopharma* [2000] ECR I-3367 para. 46.

pose of some PARNUTS foodstuffs is to protect certain consumer groups against substances that may endanger their health. At least with regard to these foodstuffs the protection of public health equally is a primary objective.

2.9.8 Legislation on novel foods, GMO food products and hormones

Food in Europe has developed tremendously in several respects. Numerous new types of food coming from outside the Community's borders have entered the market, and new ways of production have seen the light of day. A number of these novelties are covered by the different pieces of legislation examined above (e.g. new additives and new contact materials). Moreover, the European Community has issued legislation in the field of so-called novel foods.

Regulation 258/97 concerning novel foods and novel food ingredients (Novel Foods Regulation)[164] defines novel foods as "foods and food ingredients which have not hitherto been used for human consumption to a significant degree within the Community" and which falls within one of six categories specified in the regulation.[165] One of the six categories covers "foods and food ingredients containing or consisting of genetically modified organisms".[166] The Novel Foods Regulation is founded on Article 95 of the EC Treaty and is thus aimed at eliminating barriers to the free movement of foodstuffs in the European Community. It sets up a safety assessment procedure where one of the main objectives is to ensure that novel foodstuffs do not present a danger for the consumer.

Whereas the Novel Foods Regulation is rather new, the European Community already in 1981 took steps to restrict the presence of hormones in foodstuffs. Thus with Directive 81/602 concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action,[167] the use of substances having a hormonal action for growth promotion in farm animals was prohibited. Whilst the directive's

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[164] Regulation 258/97, see above note 155.

[165] Cf. Article 1(2) of the Novel Foods Regulation.

[166] Cf. Article 1(2)(a), of the Novel Foods Regulation with reference to Directive 90/220 of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (OJ 1990 L 117/15).

[167] Directive 81/602 of 31 July 1981 concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action (OJ 1981 L 222/32). See also Directive 85/358 of 16 July 1985 supplementing Directive 81/602 concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action (OJ 1985 L 191/46).

legal bases were Articles 37 and 94 of the Treaty (referring to common agricultural policy and creation of the common market), the directive is primarily justified by a reference to the need to protect customers. As a subsidiary justification it is observed that the hormones may affect the quality of the meat, but nowhere does it refer to the need to remove hindrances to the free movement of goods.[168]

> In the *van der Tas* Case, Mr. van der Tas, a livestock dealer, was charged with an infringement of a Dutch regulation on the ground that he had held in stock two or more bovine animals that had been given certain hormone substances. Before the national judge the question was raised whether the national regulation went beyond the limits laid down by Directive 81/602 with later supplements. The national court therefore asked the European Court of Justice for a ruling on the interpretation of that directive. In its answer the Court of Justice made it clear that the prohibition laid down in Directive 81/602 first of all was "in the interests of consumers". Only thereafter did the Court of Justice consider whether the Dutch rule was in conflict "with any of the fundamental principles of the Community, in particular that of the free movement of goods". Since this was not the case and since the prohibition moreover kept within the actual provisions of the directive, the Dutch rule was in conformity with the directive.[169]

The ruling in the *van der Tas* Case seems to confirm that protection of the consumer took precedence over other objectives of Directive 81/602. In 1996 Directive 81/602 was replaced by Directive 96/22 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of ß-agonists.[170] This directive was exclusively based upon Article 37 of the EC Treaty, concerning the common agricultural policy, and was primarily focussed upon "consumer sensitivity" and the consequences this could have upon the consumption of meat.[171] In other words, protection of the consumer in its own right was more prominent in the 1981-directive.

The Community's secondary legislation on novel foods (including GMO food products) and, in particular, its secondary legislation on hormonal growth promoters differ markedly from almost all the other pieces of secondary legislation that have been examined above in that a primary objective is the protection of public and not (only) the dismantling of bar-

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[168] See also Directive 88/146 of 7 March 1988 prohibiting the use in livestock farming of certain substances having a hormonal action (OJ 1988 L 70/16).

[169] Case C-143/91 *Criminal proceedings against Leendert van der Tas* [1992] ECR I-5045 paras. 17-20.

[170] Cf. Directive 96/22 of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of ß-agonists, and repealing Directives 81/602, 88/146 and 88/299 (OJ 1996 L 125/3).

[171] See particularly recital 8.

riers to trade within the common market. These pieces of legislation therefore do not support the working hypothesis of the present report.

2.9.9 Rapid Alert System

In 1992 the Council adopted Directive 92/59 on general product safety[172] with the purpose of ensuring that products placed on the market are safe. With this directive the Community established a so-called "rapid alert system" whereby a system for rapid exchange of information was set up. The system was to cater for situations where a Member State for reasons of public health considered it necessary to "restrict the placing of a product or a product batch on the market or require its withdrawal from the market".[173] A Member State that were to take such measures would be obliged to notify the Commission, which in turn would notify the other Member States through a pre-established network of contact points. One such network was organised for food products and another was organised for non-food products.[174]

Whilst the directive in Article 1 states that its purpose is to ensure the safety of products placed on the market in the Community, it is apparent from the directive's preamble that its primary objective was not the safety of the public in its own right, but rather the harmonisation of safety levels in order to eliminate the disparities in the level of protection afforded to persons in the different Member States, since they are liable "to create barriers to trade and distortions of competition within the internal market".[175] Moreover, the directive was adopted on the basis of Article 95 of the EC Treaty, which confirms that its objective was the elimination of barriers to trade in the internal market.[176]

To sum up, the above examination shows that the primary objective of the rapid alert system in the period before 2000 was not the protection of public health as such, but the harmonisation of divergent levels of protection in the common market and the barriers to free trade which such divergences could cause.

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[172] Directive 92/59 of 29 June 1992 on general product safety (OJ 1992 L 228/24).
[173] Cf. Article 7(1) of Directive 92/59, see above note 172.
[174] Cf. point 14 of the annex to Directive 92/59, see above note 172.
[175] Cf. Recital 2 of Directive 92/59, see above note 172.
[176] On the question of the directive's legal basis, see also Case C-359/92 *Commission v Germany* [1994] ECR I-3681.

2.10 What legal factors were decisive before 2000?

The examination of the decisive legal factors before 2000 is made up of several part analyses which is likely to make it difficult to see the wood for all the trees. On closer examination a surprisingly clear picture emerges however. Below I first sum up the main findings of the above examination, whereupon I identify the decisive legal factors before 2000.

In the first many years following the inception of the European Community, food safety was a matter rarely dealt with under Community law. When dealt with, it would generally be as part of the legislation on the common agricultural policy. Food safety legislation at this stage was rather sparse, patchy and incoherent.

In a number of instances Member States would, however, invoke food safety as a defence in cases concerning the application of Articles 25 (prohibiting customs duties and charges having equivalent effect) and 90 (prohibiting internal taxation that discriminates against foreign products) of the EC Treaty. The preceding examination nevertheless shows that these provisions were of only limited relevance *vis-à-vis* the Community's regulation of food safety. On the one hand, the two provisions do not allow for exceptions where the objective of a disputed Member State measure is that of food safety. On the other hand, the provisions do not prevent the Member States from introducing such measures; they only restrict the ways in which the Member States may fund these measures.

Turning to the Community's regulation of quantitative barriers to trade, the situation becomes more complex. Thus, in 1989 the European Commission in its "Communication on the free movement of foodstuffs within the Community" observed that its strategy for eliminating obstacles to trade between Member States essentially consisted of combining at the Community level the adoption of harmonised rules applicable to all foodstuffs marketed in the Community with the principle of mutual recognition of national regulations and standards for matters that do not require the adoption of Community legislative measures.[177]

To be more specific, the case-law developed by the Court of Justice on mutual recognition generally led to an opening of the markets to products from other Member States. Being an exception to the primary objective of establishing a common market, national food safety rules were only allowed a limited application, but nevertheless frequently posed a problem,

[177] Communication on the free movement of foodstuffs within the Community, see above note 137, p. 3.

when products crossed the internal borders. To counter this, the Community would adopt measures aimed at harmonising food safety in selected fields. The first such measures were primarily vertical in nature (i.e. aimed at a specific sector) and were part of the Community's common agricultural policy. Later a number of horizontal measures (i.e. applying across the various sectors) were adopted, which would normally be based upon Article 94 (and later Article 95) of the EC Treaty; both of which concern the creation of the common market. The choice of legal basis is important, particularly since the Court of Justice attaches considerable importance thereto, when called upon to interpret a legal measure. Hence, if a legal measure is founded upon Article 94 or 95, there is a strong presumption that its objective is the creation of the common market. In such case the Court of Justice will give high priority to the protection of free movement when balanced against, *inter alia,* protection of public health.[178]

Another important observation is that before 2000 the Community's regulation of food safety was highly fragmented and that even at the millennial change this regulation did not form anything remotely close to a coherent body of law. Community legislation thus rarely covered the complete food chain from farm to fork, neither did it cover the full spectra of products.

Lastly, the Court of Justice's case-law clearly shows that public health arguments should be based on scientific information. As part of this scientific approach, the Court of Justice recognised the precautionary principle within the field of food safety, albeit this only happened towards the end of the period up until 2000.

[178] The original prohibition against the use of hormones in farm animals (Directive 81/602, see above note 167) provides the exception that proves the rule. To some extent the regulation of novel foods (Regulation 258/97, see above note 155) and of PARNUTS (Directives 77/94, see above note 159, and 89/398, see above note 160) may also be counted as exceptions. See further above Sections 2.9.7 and 2.9.8.

3 FOOD SAFETY: AN OBJECTIVE IN ITS OWN RIGHT?

3.1 Food safety crisis and the White Paper on Food Safety

On 20 March 1996 the British government acknowledged that a variant of Creutzfeldt - Jakob disease (vCJD) had emerged and that this disease was almost certainly attributable to human consumption of food that had been contaminated by bovine spongiform encephalopathy (BSE).[179] BSE is a transmissible, neurodegenerative, fatal brain disease of cattle. It has a long incubation period of four to five years, but ultimately is fatal for cattle within weeks to months of its onset. BSE is one of several transmissible spongiform encephalopathies (TSE); i.e. transmissible brain diseases characterised by a spongy degeneration of the brain. Creutzfeldt - Jakob disease (CJD) is the prototype human TSE which normally affects elderly persons with a rather short duration of illness. When vCJD was discovered in Britain, it was observed that it primarily affected young people and that the duration of the illness was somewhat longer than the duration of CJD. Both CJD and vCJD are incurable disorders that are ultimately fatal.[180] By December 2007 a total of 166 persons in the United Kingdom had been infected by vCJD – 163 of whom had died.[181] This figure might appear substantial, but is nevertheless fairly moderate when compared with other death causes; for example, the 3,336 persons who were killed in road accidents in the United Kingdom in 2005.[182] The government's acknowledgement, nonetheless, caused a shock in Britain and throughout Europe, in no small measure due to the revelation that, in all probability, the disease was transmitted through the consumption of ordinary food combined with the fact that for a substantial period the British government had

[179] Cf. van Zwanenberg, P. and Millstone E., *BSE: risk, science and governance* (Oxford University Press, 2005) p. 4.

[180] For a general and accessible account of prion diseases see Ridley, R. M. and Baker, H. F. *Fatal Protein – The Story of CJD, BSE and Other Prion Diseases* (Oxford University Press, 1998).

[181] Cf. http://www.cjd.ed.ac.uk/vcjdworld.htm (visited 18 December 2007).

[182] Cf. EuroStat, People killed in road accidents – persons, available at http://epp.eurostat.ec.europa.eu/tgm/table.do?tab=table&init=1&plugin=0&language=en&pcode=sdi_tr1410 (visited 18 December 2007). The number has been fairly stable over the last decade. Hence, in 1996 3,740 were killed in road accidents in United Kingdom.

chosen to minimise the availability of scientific information of the potential risks of BSE to public health.[183]

The importance of the BSE crisis to food safety in Europe can hardly be overstated.[184] It was not the only food scandal that hit Europe, however. Dioxin contamination of Belgian poultry, contamination of Coca Cola bottled in Belgium and France, benzopyrene in Spanish pomace oil and the carcinogenic dye Sudan red 1 that ended up in more than 500 food products in close to 20 countries are some of the more famous food scares that Europe witnessed in the time following the BSE crisis.[185] To cut a long story short; a feeling of distrust regarding both food and public authorities rapidly grew among the European population.

Thus, it was on a background of popular fear and distrust that, in 1997, the European Commission published its green paper on "The General Principles of Food Law in the European Union"[186] followed, in 2000, by its "White Paper on Food Safety".[187] In the White Paper the Commission explains that

> "The European Union needs to re-establish public confidence in its food supply, its food science, its food law and its food controls. This White Paper on Food Safety outlines a comprehensive range of actions needed to complement and modernise existing EU food legislation, to make it more coherent, understandable and flexible, to promote better enforcement of that legislation, and to provide greater transparency to consumers. …"[188]

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[183] Cf. Grist, E.P.M., vCJD and the Unbounded Legacy of BSE in Stonebrook, M.J., ed. *Creutzfeldt-Jakob Disease: New Research* (Nova Science Publishers, 2006), pp. 127 at p. 141, Nova Science Publishers, New York and van Zwanenberg and Millstone, *BSE: risk, science and governance*, see above note 179, p. 229. See also Report on alleged contraventions or maladministration in the implementation of Community Law in relation to BSE by the European Parliament's Temporary committee of inquiry into BSE (bovine spongiform encephalopathy), PE 220.544/DEF – A4-0020/1997, available at www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+REPORT+A4-1997-0020+0+DOC+XML+V0//EN&language=EN.

[184] The BSE crisis has been called "the worst failure of UK public policy since the Suez adventure of 1956 when measured in terms of the economic, political and diplomatic harm it caused", cf. van Zwanenberg and Millstone, *BSE: risk, science and governance*, see above note 179, p. 4.

[185] Examples taken from O'Rourke, R., *European Food Law*, 3rd edition (Sweet & Maxwell 2005) pp. 6-9 and from BBC, *Business: The Company File European Warning over Coca-Cola* available at http://news.bbc.co.uk/2/hi/business/369684.stm. See also MacMaoláin, *EU Food Law – Protecting Consumers and Health in a Common Market*, see above note 110, p.1.

[186] Commission of the European Communities, The General Principles of Food Law in the European Union – Commission Green Paper (COM (1997)176 final), Brussels 30 April 1997.

[187] White Paper on Food Safety, see above note 3.

[188] White Paper on Food Safety, see above note 3, para. 7.

In the White Paper the Commission proposed what it termed "a new legal framework" in the field of food safety legislation. The White Paper proposed the creation of a European Food Safety Authority[189] together with over 80 separate actions aimed at improving food safety standards.

According to the White Paper food safety was to become the primary objective of EU food law,[190] and this food safety was to be based upon a number of "principles",[191] namely:

- A comprehensive, integrated approach ("farm to fork").
- A coherent and transparent regulation (abandoning the former sectoral approach).
- Appraisal founded on risk analysis based on scientific advice (scientifically-based approach).
- Application of the precautionary principle.
- Clear definition of the roles of all stakeholders in the food chain (primary responsibility for food safety to be placed with the private operators).
- Procedures to facilitate the traceability of feed and food and their ingredients.

The Commission committed itself to putting forward a proposal for a "General Food Law", which would both embody the above principles and "provide the general frame for those areas not covered by specific harmonised rules but where the functioning of the Internal Market is ensured by mutual recognition, as developed by the European Court of Justice in its 'Cassis de Dijon' jurisprudence."[192]

Above in Section 2 of this report, the examination of the regime that applied before 2000 was to a considerable extent based upon case-law rendered by the Court of Justice. In contrast, the examination provided below is only to a limited extent founded on such case-law. The reason for this is that there is a natural time-lag from the adoption of a piece of secondary Community legislation and until this legislation becomes subject to interpretation by the Court of Justice. Since the below examination is primarily concerned with certain rather new pieces of legislation – including in particular Regulation 178/2002 – there simply is only very limited case-law to draw on.

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[189] Referred to as "European Food Authority" in the White Paper on food Safety, see above note 3.
[190] White Paper on Food Safety, see above note 3, para. 66.
[191] White Paper on Food Safety, see above note 3, chapter 2.
[192] White Paper on Food Safety, see above note 3, para. 68.

In what follows I will examine the legislative developments following the White Paper on Food Safety and in particular I will consider the above-mentioned "principles" identified in the White Paper.

3.2 Establishing general principles – Regulation 178/2002

3.2.1 Purpose and structure

On 28 January 2002 – almost exactly two years after the publication of the White Paper on Food Safety – the European Parliament and the Council adopted Regulation 178/2002,[193] often referred to as the "framework regulation on food safety" or the "umbrella regulation" or sometimes even the "General Food Law". This regulation is of paramount importance for the European Community's regulation of food safety following the millennial change.

Regulation 178/2002's legal bases are Articles 37 (common agricultural policy), 95 (creation of an Internal Market) and 152 (protection of public health). In this connection Article 152 of the EC Treaty is of particular relevance. The provision as such concerns the protection of public health, and its section 4, subsection b, provides the Community with a basis for introducing "measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health".[194]

According to Regulation 178/2002, Article 1(1)(1):

> "This Regulation provides the basis for the assurance of a high level of protection of human health and consumers' interest 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."

Thus, by establishing a high, uniform level of food safety throughout the European Community, the regulation seeks to eliminate the barriers to trade in foodstuffs within the Community.

Regulation 178/2002 is made up of three constituents: (1) laying down general principles and requirements of food law, (2) establishing the European Food Safety Authority (EFSA) and (3) establishing a rapid alert system together with procedures for crisis management and emergencies. In Sections 3.2.3 – 3.2.7 I examine the most important of the principles laid down in Regulation 178/2002, in Section 3.4.9 I deal with the rapid alert system, and in Section 3.6 I consider the institutional developments

[193] Regulation 178/2002, see above note 7.

[194] As we shall see below, Article 152(4)(b) has formed the legal basis for a number of other legal measures in the field of food safety.

including the creation of EFSA. Immediately below I will, however, consider to what extent Regulation 178/2002 may direct the interpretation of other pieces of Community legislation.

3.2.2 Regulation 178/2002 *vis-à-vis* other Community measures

Regulation 178/2002 in its Chapter II lays down a number of "general principles of food law" whose scope is defined in Article 4 as follows:

> "1. This Chapter relates to all stages of the production, processing and distribution of food, and also of feed produced for, or fed to, food-producing animals.
>
> 2. The principles laid down in Articles 5-10 shall form a general framework of a horizontal nature to be followed when measures are taken.
>
> 3. Existing food law principles and procedures shall be adapted as soon as possible and by 1 January 2007 at the latest in order to comply with Articles 5 to 10.
>
> 4. Until then, and by way of derogation from paragraph 2, existing legislation shall be implemented taking account of the principles laid down in Articles 5 to 10."

This provision, together with the fact that "food law" has been given a very broad definition,[195] lead to the conclusion that the principles laid down in Regulation 178/2002 are to have general application from the primary producer until the sale to the final consumer, and that they are to apply at the Community as well as at the national level. These general principles thus form a framework for the interpretation of all food law.

Article 4(3) provides that existing food law principles and procedures must be adapted by 1 January 2007 at the latest in order to comply with the general principles laid down in Regulation 178/2002.

In what follows I give brief presentations of the general principles that are relevant for the purposes of this report.

3.2.3 The general objectives

Among the general principles of food law, the very first one, laid down in Article 5(1), establishes that "[f]ood law shall pursue one or more of the general objectives of a high level of protection of human life and health and the protection of consumers' interests …" Only in the second paragraph is it established that "[f]ood law shall aim to achieve the free movement in the Community of food and feed …" The protection of public

[195] Regulation 178/2002 defines "food law" in Article 3(1). See also above Section 1.2.3.

health has thus been given a slightly more prominent position than the one occupied by the creation of an internal market.[196]

3.2.4 Farm-to-fork approach

The general principles relate to all stages of the production, processing and distribution of food as well as of feed produced for, or fed to, food-producing animals.[197] In other words, it is the complete food chain that must be regulated to provide protection of public health.[198]

3.2.5 Transparency

Transparency is established as a general principle in its own right. This transparency covers both public consultation with regard to the drafting or revision of food law[199] and a requirement that the general public must be informed about possible risks to health stemming from food.[200]

3.2.6 Risk analysis

Where appropriate, food law shall be based on risk analysis.[201] As part of this risk analysis a risk assessment must be carried out based on the available scientific evidence and undertaken in an independent, objective and transparent manner.[202] In general, food law must therefore be founded on scientific evidence.

3.2.7 The precautionary principle

Where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures may be adopted, pending further scientific information for a more comprehensive risk assessment. This approach is generally referred to as the "precautionary principle".[203]

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[196] In addition, Article 5(3) requires that normally international standards must also be taken into consideration in the development or adaptation of food law.
[197] Article 4(1) of Regulation 178/2002. See also Article 1(3).
[198] See also recital 12 of Regulation 178/2002.
[199] Article 9 of Regulation 178/2002.
[200] Article 10 of Regulation 178/2002.
[201] Article 6(1) of Regulation 178/2002.
[202] Article 6(2) of Regulation 178/2002.
[203] Article 7(1) of Regulation 178/2002. Article 7(2) goes on to provide details on the application of the precautionary principle. The principle has been developed in the case-law of the Court of Justice, cf. above Section 2.7.3. See for more recent examples Case T-70/99 *Alpharma v Council* [2002] ECR II-3495 para. 152, Case T-177/02 *Malagutti-Vezinhet v Commission* [2004] ECR III-827 para. 54 and Case C-504/04 *Agrarproduktion Staebelow v Landrat des Landkreises Bad Doberan* [2006] ECR I-679 paras. 38-40.

3.3 General requirements of food law – according to Regulation 178/2002

3.3.1 Introduction

As part of the "General Food Law" established by Regulation 178/2002 a number of general requirements of food law are laid down in Articles 14-21 of the Regulation. For the purposes of this report three of these requirements are particularly relevant and should therefore be briefly recounted.

3.3.2 Safety requirements

Articles 14-15 establish the general requirement that if food or feed is unsafe, it should not be placed on the market – or, in the case of feed, be fed to food-producing animals.[204] In deciding whether food or feed may be considered unsafe, focus is upon human health.[205] Moreover, it is explicitly provided that regard may be had to the probable immediate effects, the probable short-term effects and the probable long-term effects as well as to the probable effects on subsequent generations.[206] Also the probable cumulative toxic effects must be taken into account.[207] If a specific category of consumers has particular health sensitivities (eg. babies), these must also be taken into account where the food is intended for that category of consumers.[208]

Where it has been found that some food is unsafe, there is a presumption that all food belonging to the same consignment equally is unsafe.[209] On the other hand, if some food complies with specific Community provisions governing food safety, there is a presumption that this food is safe with regard to the aspects covered by these specific Community provisions.[210]

3.3.3 Responsibilities

Primary legal responsibility for ensuring that food and feed satisfy the requirements of food law throughout the food chain lies with the food and

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[204] Cf. Article 14(1) and (2) and 15(1) and (2) of Regulation 178/2002.
[205] Cf. Articles 14(2) and 15(2) of Regulation 178/2002.
[206] Cf. Article 14(4)(a) of Regulation 178/2002.
[207] Cf. Article 14(4)(b) of Regulation 178/2002.
[208] Cf. Article 14(4)(c) of Regulation 178/2002.
[209] Cf. Articles 14(7) and – regarding feed – 15(4) of Regulation 178/2002.
[210] Cf. Articles 14(8) and – regarding feed – 15(5) of Regulation 178/2002 and Joined Cases C-211/03, C-299/03, C-316/03 – C-318/03 *HLH Warenvertriebs,* see above note 9, paras. 33-39. If no Community provision applies, but the food conforms to specific provisions of the national food law of a Member State in whose territory the food is marketed, the food is equally presumed to be safe, cf. Articles 14(9) and – regarding feed – 15(6).

feed business operators being in control.[211] Moreover, it is the duty of these business operators to verify that they have met these requirements.[212]

If a food (or feed) business operator considers – or has reason to believe – that a food (or feed), of which it is responsible, is not in compliance with the food (or feed) safety requirements, it shall immediately initiate procedures to withdraw that food (or feed) from the market and inform the competent authorities thereof.[213]

It befalls the Member States to enforce the food laws and to control that the food (or feed) business operators have fulfilled the food law requirements.[214]

3.3.4 Traceability

Whenever it is found that a foodstuff poses a danger to the public, it must be withdrawn from the market. In order to be able to make such withdrawal it is necessary to track down all the products. To this end, Regulation 178/2002 requires the traceability at all stages of production, processing and distribution of food, feed, food-producing animals and any other substance intended to be, or expected to be, incorporated into a food or feed.[215] In practice, food and feed business operators shall be able to identify any person from whom they have been supplied with any substance that is to be incorporated into a food or feed.[216] Likewise, the food and feed business operators must be able to identify any business to which their products have been supplied.[217] This system is generally referred to as "one step up – one step down".[218]

3.4 Food Legislation – developments

3.4.1 Overview

Above in Section 2.9 I have examined the Community's food legislation in the period until the millennial change. Below I will examine the legislation

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[211] Cf. Article 17(1) and Recital 30 of Regulation 178/2002. See in this respect Case 315/05 *Lidl Italia Srl v Comune di Arcole (VR)* [2006] ECR I-11181 para. 53

[212] Cf. Article 17(1) of Regulation 178/2002.

[213] Cf. Articles 19(1) and 20(1) of Regulation 178/2002.

[214] Cf. Article 17(2) of Regulation 178/2002.

[215] Cf. Article 18(1) of Regulation 178/2002.

[216] Cf. Article 18(2) of Regulation 178/2002.

[217] Cf. Article 18(3) of Regulation 178/2002.

[218] With regard to GMO food products it is required that the product can be traced all the way back to the first placing on the market of the GMO product, cf. Article 4(2) of Regulation 1830/2003 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 (OJ 2003 L 268/24).

as it appears today. In Section 3.2.2 I argue that the general principles laid down in Regulation 178/2002 are to have general application from the primary producer until the sale to the final consumer, and that these principles apply to the Community as well as to the national level. This means that all Community food law must be interpreted in the light of these general principles. In order to verify whether the present regulatory measures on food safety constitute a new regime *vis-à-vis* the regulatory measures previously in force, it is necessary first to examine the various pieces of contemporary food safety legislation in their own right. Thereafter, in Section 3.5, I will consider to what extent the Court of Justice today is interpreting this legislation in the light of the principles established by Regulation 178/2002.

3.4.2 Hygiene

On 29 April 2004 the Community adopted three regulations, which together lay down a new, comprehensive regulatory scheme in the field of food hygiene, the so-called "hygiene package".[219] The principal objective of the hygiene package "is to ensure a high level of consumer protection with regard to food safety".[220] To a large extent the package has replaced the sectoral Community legislation on food hygiene.[221]

The hygiene package is unmistakably modelled on the White Paper on Food Safety. Thus, in addition to focusing on public health rather than free movement of goods, the package also sets out to be comprehensive and

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[219] Regulation 852/2004, see above note 112. Regulation 853/2004 of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ 2004 L 139/55) and Regulation 854/2004 of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (OJ 2004 L 139/206). Corrigenda of the three regulations were published in (OJ 2004 L 226). See also Regulation 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ 2005 L 338/1), Regulation 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004 (OJ 2005 L 338/60), and Regulation 2075/2005 of 5 December 2005 laying down specific rules on official controls for Trichinella in meat (OJ 2005 L 338/60).

[220] Cf. recital 7 of Regulation 852/2004, see above note 112.

[221] Cf. the three regulations together with Directive 2004/41 of 21 April 2004 repealing certain directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Directives 89/662 and 92/118 and Council Decision 95/408/EC (OJ 2004 L 157/33).

coherent, covering all types of food as well as the whole food chain,[222] to be based on a risk approach,[223] and to leave primary responsibility to the food business operator.[224] Moreover, the package makes explicit reference to the precautionary principle.[225]

As is apparent from this brief overview, the hygiene package marks a considerable change *vis-à-vis* prior Community legislation in the field. Whereas the regime prior to 2000 was characterised by being patchy and primarily focused upon free movement of goods, the hygiene package is comprehensive, coherent and focuses upon the health of the consumer.

3.4.3 Additives

In the field of additives, the Additives Framework Directive[226] continues to be the decisive regulating measure.[227] Whereas a proposal for a new Community regulation of additives has been tabled, this proposal – perhaps somewhat surprisingly – exclusively finds its legal basis in Article 95 of the EC Treaty concerning the establishment and functioning of the internal market.[228]

Thus in the field of additives, free movement of goods continues to be the main objective underlying the Community regulation. This obviously weighs against the assumption that there has been a regime change.

3.4.4 Contaminants and residues

In the field of contaminants and residues, the Framework Regulation on Contaminants remains in force without amendments.[229] This framework regulation is, however, supplemented by a number of more specific Community rules, several of which have been replaced by Regulation 396/2005, which fixes maximum residue levels of pesticides in or on food and

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[222] Cf. Article 1(1)(b) and (1) *in fine,* of Regulation 852/2004, see above note 112.
[223] Cf. Articles 1(1)(d) and (f) and 5 of Regulation 852/2004, see above note 112, Article 10(1)(d) of Regulation 853/2004, see above note 219, and recital 6 of Regulation 854/2004, see above note 219.
[224] Cf. Article 1(1)(a) and chapter II of Regulation 852/2004, see above note 112.
[225] Cf. recital 17 of Regulation 852/2004, see above note 112.
[226] Directive 89/107, see above note 129.
[227] See further Section 2.9.3 above.
[228] Proposal for a Regulation of the European Parliament and of the Council on food additives of 28 July 2006 (COM(2006)428 final).
[229] Regulation 315/93, see above note 139, cf. Section 2.9.4 above. Regulation 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs (OJ 2001 L 77/1), has replaced Regulation 194/97, see above note 141. This replacement is not relevant for the purposes of the examination of this report, however.

feed.[230] Whereas the directives, that have now been replaced, were adopted on the basis of Article 37 concerning the Community's common agricultural policy in combination with Article 94 concerning the establishing of a common market, Regulation 396/2005 has been adopted on the basis of Article 37 in combination with Article 152(4)(b), which provides the Community with a basis for introducing measures in the veterinary and phytosanitary fields in order to protect public health. That the objective of Regulation 396/2005 is the protection of public health is also reflected in its very first Article, which provides that "[t]his Regulation establishes, in accordance with the general principles laid down in Regulation (EC) No 178/2002, in particular the need to ensure a high level of consumer protection and harmonised Community provisions relating to maximum levels of pesticide residues in or on food and feed of plant and animal origin."

In other words, the Community's regulation in the field of contaminants and residues has to a very considerable extent been changed from aiming at protecting the free movement of goods towards the protection of public health. This therefore supports the view that there has been a change of regime in the area of food safety.

3.4.5 Food contact materials

In the field of food contact materials, Directive 89/109[231] on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs was in 2004 replaced by Regulation 1935/2004 on materials and articles intended to come into contact with food.[232] This new regulation is founded upon Article 95 of the EC Treaty concerning the establishing of a common market. Moreover, the regulation in Article 1(1) provides that "[t]he purpose of this Regulation is to ensure the effective functioning of the internal market in relation to the placing on the market in the Community of materials and articles intended to come into contact directly or indirectly with food, whilst providing the basis for securing a high level of protection of human health and the interests of consumers."

It is thus clear that free movement of goods and not protection of public health is the principal objective of the primary legislative Community

[230] Regulation 396/2005 of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Directive 91/414 (OJ 2005 L 70/1).

[231] Directive 89/109, see above note 151.

[232] Regulation 1935/2004 of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ 2004 L 338/4).

measure in the field of food contact materials; indeed, this legislative measure was adopted as recently as in October 2004. This obviously does not support the assumption that there has been a change of regime.

3.4.6 Labelling requirements *vis-à-vis* the consumer

The Labelling Directive[233] remained in force until 25 March 2000. It was replaced by Directive 2000/13 of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs.[234] This new directive finds its legal basis in Article 95 of the EC Treaty and the objective, in the preamble, is explained as being to contribute "to the smooth functioning of the internal market".[235] A subsequent amendment directive, based on Article 95 of the EC Treaty, has included protection of consumers as an objective, however.[236]

The principal objective of the Community's labelling requirements in the field of foodstuffs thus continues to be the protection of the free movement of goods. Again, this goes against the assumption that the field of food safety has witnessed a change of regime.

3.4.7 Foodstuffs for particular nutritional uses – PARNUTS

In the field of foodstuffs for particular nutritional uses – so-called PARNUTS – Directive 89/398 from 1989 continues to be in force.[237] This directive is based on Article 95 and thus aimed at eliminating barriers to the free movement of goods in the Community. A number of "specific directives" have been issued on the basis of Directive 89/398.[238] Their principal purpose is to eliminate the trade barriers between the Member States.[239]

Thus, the primary objective of Community legislation on PARNUTS continues to be assisting in establishing the internal market. This clearly does not support the hypothesis of a regime change.

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[233] Directive 79/112, see above note 155, cf. Section 2.9.6 above.

[234] Directive 2000/13 of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (OJ 2000 L 109/29).

[235] Cf. recital 3 of the directive.

[236] Cf. recital 1 of Directive 2003/89 of 10 November 2003 amending Directive 2000/13/EC as regards indication of the ingredients present in foodstuffs (OJ 2003 L 308/15).

[237] Directive 89/398, see above note 160.

[238] See for example Directive 2006/141 of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC (OJ 2006 L 401/1) and Regulation 1609/2006 of 27 October 2006 authorising the placing on the market of infant formulae based on hydrolysates of whey protein derived from cows' milk protein for a two-year period (OJ 2006 299/9).

[239] See for example recital 8 of Directive 2006/125 of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children (OJ 2006 L 339/16).

3.4.8 Novel foods, GMO food products and hormones in food

The Novel Foods Regulation from 1997, based upon Article 95 of the EC Treaty, continues to be in force.[240] Originally the Novel Foods Regulation also covered GMO food products, but in 2003 the Community adopted Regulation 1829/2003 on genetically modified food and feed.[241] This GMO Regulation was based upon Article 37 (common agricultural policy), Article 95 (creation of an internal market) and Article 152 (protection of public health). Moreover, the recitals and Article 1(a) unequivocally make it clear that a primary objective of the GMO Regulation is to "provide the basis for ensuring a high level of protection of human life and health …"

With regard to Community regulation of hormones in foodstuffs, Directive 96/22 remains in force.[242] This directive was exclusively based upon Article 37 concerning the common agricultural policy. However, in 2003 it was amended by Directive 2003/74.[243] Very interestingly, this directive is exclusively based upon Article 152(4)(b) concerning the protection of public health in the veterinary and phytosanitary fields.

Novel foods, GMO foods and foods produced under the use of hormones are generally perceived to concern new – and untested – technologies where the consequences on humans that consume the products are yet to be established.[244] Whilst legal measures in respect of these "novel technologies" introduced before the publication of the White Paper on Food Safety, primarily were focussed on eliminating barriers to the free movement of food products, those measures that have been adopted subsequently to the White Paper appear to focus primarily upon the protection of public health.[245] This development therefore supports the assumption that there has been a change towards a regime focussing upon public health.

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[240] Regulation 258/97, see above note 155.

[241] Regulation 1829/2003 of 22 September 2003 on genetically modified food and feed (OJ 2003 L 268/1).

[242] Directive 96/22, see above note 170, cf. Section 2.9.8 above.

[243] Directive 2003/74 of 22 September 2003 amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists (OJ 2003 L 262/17).

[244] This general perception is not necessarily correct. In particular it may be noted that foods that have been consumed for centuries outside the EU may qualify as a "novel food" in the EU.

[245] Note, however, that Amended Proposal for a Regulation of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings (COM (2007) 672 final), is based upon Article 95, albeit in recitals 2 and 3 it refers to the protection of public health.

3.4.9 Rapid Alert System

In 1992 a rapid alert system was introduced providing for a system of rapid exchange of information and of taking preventive steps where a product (including food products) may be presumed to present a serious and immediate risk to the public.[246] In 2002 the rapid alert system was changed with respect to food products.[247] Firstly, the system has been tightened and, secondly, it has been expanded to cover also feed. In addition, the Commission has been given the power to adopt emergency measures. The original rapid alert system was introduced to harmonise safety levels in the Community so as to eliminate disparities in the protection afforded to the public in the different Member States, but in practice protection of public health was given considerable importance. Elimination of trade barriers necessarily continues to be an important objective of the new rapid alert system for food and feed, but it is equally clear that the new system is intended to protect public health – and this objective is not least an important cause to the strengthening of the system. Thus, whereas the development with regard to the rapid alert system might not be taken as a support for a change of regime, it neither contradicts that such change has occurred.

3.4.10 Control and enforcement

The White Paper on Food Safety pointed out that the legislation on official controls of food law then in force was inadequate, so that there was a need to clarify and update the existing legislation and to ensure that it would cover all steps in the production.[248] On this background the Community adopted Regulation 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.[249] The regulation, which is based on Article 37 (common agricultural policy), Article 95 (creation of an internal market) and Article 152 (protection of public health), is intended to secure the enforcement of the Community's food laws and thereby ensure that feed and food are safe and wholesome. The primary objective thus is the protection of public health, although the regulation also has the elimination of barriers to trade as an implicit objective. This therefore lends support to the assumption that a new regime has been introduced.

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[246] Directive 92/59, see above note 172.

[247] Regulation 178/2002, Chapter IV.

[248] See in particular para. 85 of the White Paper on Food Safety, see above note 3.

[249] Regulation 882/2004 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 2004 L 191/1).

3.5 The Court of Justice – new approach?

A court ruling is based on the fundamental idea that the judges do not develop the law, but rather like the Delphic Oracle they are simply "instruments" who only clarify the law on a completely objective basis. If a court ruling produces an inappropriate result, this is just the unavoidable outcome of the legislation that the judges have been called upon to apply. Avoiding such outcome is a task for the legislator, not for the courts. Of course, this fundamental idea is an illusion, but it makes it very difficult for a court expressly to adopt an interpretation that differs markedly from its own earlier interpretation, as this very likely will be construed as a reversal of its earlier case-law. From the perspective of the judges, a more preferable approach will be – case by case – to adapt the former interpretation, while they maintain that there is no change of interpretation. Only when the court consistently has applied the "adapted" interpretation will it be possible to conclude that a new approach has been adopted.

With a few notable exceptions, the European Court of Justice has never reversed its own earlier case-law. Thus, in order to conclude that the Court of Justice has adopted a new interpretation, it is often necessary to await that a sufficiently large body of case-law has been established. Moreover, the time from a case arises until proceedings have been initiated before the Court of Justice in Luxembourg may be considerable. And even when proceedings have been initiated, it may easily last a couple of years before the Court of Justice delivers judgment.

On the basis of the above it may come as no surprise that it is difficult to establish to what extent the Court of Justice has changed its approach in the field of food safety following the millennial change. Thus, it is telling that today there are no judgments directly focussed upon Regulation 178/2002 and only a limited number of judgments and orders that – while not focussing on the regulation – in one way or another are concerned with it.[250] With respect to the three regulations that make up the so-called hygiene package there are no judgments whatsoever on their interpretation.[251]

In Section 2.7.2 above I conclude that before the millennial change, the Court of Justice allowed the Member States a fair degree of latitude in

[250] Regulation 178/2002 only entered into force in February 2002, cf. its Article 65.

[251] The three regulations all entered into force in May 2004, but were not to apply until after 1 January 2006, cf. Article 18 of Regulation 852/2004, see above note 112, Article 15 of Regulation 853/2004, see above note 219, and Article 22 of Regulation 854/2004, see above note 219.

the protection of public health, where the Member State measure did not conflict with Community harmonisation and where the Court was satisfied that the measure was not simply a disguised barrier to trade. It appears that, following the millennial change, the Court has continued along this line.

> In the *Schwarz* Case that originated in Austria, Mr. Schwarz had been charged with marketing various types of non-packaged chewing gum from vending machines. This contravened the Austrian "Regulation on Hygiene in relation to Confectionary from Vending Machines". It was apparent from the case that the Austrian packaging requirement did pursue a hygienic purpose. The Court of Justice also observed that in the past non-packaged goods had been impaired by moisture or insects within vending machine containers. Moreover pathogenic germs could be transmitted via the delivery tray, but the risk of this happening would be minimised if the chewing gum was wrapped up. On this basis the Court considered the packaging requirement to be a suitable measure for the protection of public health.[252]

Likewise, the more recent case-law also confirms that public health arguments must be based on scientific information. In this respect the Court has reiterated its willingness to apply the precautionary principle, and it has accepted that Member States may invoke this principle in defence of a measure that obstructs the free movement of foodstuffs.[253] Moreover, the Court has been ready to accept Member State measures based on a zero-tolerance approach.[254]

Whilst the above shows that the Court of Justice has been sympathetic to arguments founded on public health, it is important to observe that the Court continues to vigorously enforce both the principle of mutual recognition established in the *Cassis de Dijon* Case as well as harmonisation measures adopted by the Community in order to eliminate barriers to trade.[255] The Court also normally continues to require that a risk, hazard, danger or harm invoked by a Member State in support of a food safety

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[252] Case C-366/04 *Schwarz v Bürgermeister der Landeshauptstadt Salzburg* [2006] ECR I-10139 paras. 34-36.

[253] Cf. Case C-192/01 *Commission v Denmark (vitamins)*, see above note 99, para. 49, Case C-236/01 *Monsanto Agricoltura Italia and Others,* see above note 99, paras. 106-107, and Case C-24/00 *Commission v French Republic,* see above note 80, para. 56.

[254] Cf. Case C-121/00 *Criminal proceedings against Walter Hahn* [2002] ECR I-9193. It seems that the approach applied by the Court of Justice in this case bears strong reminiscence of the precautionary principle, cf. para. 45 of the ruling. The *Hahn* ruling may be contrasted with the order of the Court of First Instance (judge hearing the application for interim measures) of 28 September 2007, in Case T-257/07 R, *French Republic v Commission* para. 38.

[255] See for example Case C-420/01 *Commission v Italy (caffeine in energy drinks)* [2003] ECR I-6445.

measure is "real" or "serious".[256] It remains to be seen to what extent the general principles in the field of food safety established by Regulation 178/2002 will lead the Court of Justice to change its approach with regard to mutual recognition and to Community harmonisation measures.[257]

3.6 Institutional developments

The present report is about the question whether a new legal regime has evolved, and thus is not concerned with the institutional developments in the field. Nonetheless, it is expedient to also briefly consider the institutional developments in the field of European food safety, as these developments may substantiate or weaken the report's overall findings.

As an immediate reaction to the food crises that hit Europe in the 1990s, in an address to the European Parliament on 18 February 1997, then Commission President Santer announced a new approach to food safety.[258] He outlined three general principles that should form the basis for a new political departure:

- Responsibility for legislation should be separate from that for scientific consultation.
- Responsibility for legislation should be separate from that of inspection.
- There should be greater transparency and more widely-available information throughout the decision-making process and inspection measures.

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[256] See for example Case C-41/02 *Commission v Netherlands* [2004] ECR I-11375 paras. 47, 49, 54, 58 and 59, Case C-192/01 *Commission v Denmark (vitamins),* see above note 99, paras. 48, 49, 52 and 56, Case C-24/00 *Commission v French Republic,* see above note 80, paras. 53 and 55-57, Case C-95/01 *Criminal proceedings against John Greenham and Léonard Abel* [2004] ECR I-1333 paras. 40, 42, 43, 47 and 48, Case C-387/99 *Commission v Germany* [2004] ECR I-3751 paras. 72, 79 and 80, and Case C-270/02 *Commission v Italy* [2004] ECR I-1559 para. 22. Contrast, however, with Case C-366/04 *Schwarz v Bürgermeister der Landeshauptstadt Salzburg,* see above note 252, para. 35, where the Court simply observed that the risk of contamination was "by no means merely theoretical".

[257] Only a very limited number of references to the general principles may be found in the presently existing case-law. See in particular Joined Cases C-154/04 and C-155/04 *Alliance for Natural Health and Nutri-Link Ltd v Secretary of State for Health* [2005] ECR I-6451 para. 69. In order of the Court of First Instance (judge hearing the application for interim measures) in Case T-257/07 R *French Republic v Commission,* see above note 254, para. 37, the judge (at the instigation of the Commission) observes that the precautionary principle has been laid down in Regulation 178/2002. However, when it comes to the conditions for the application of this principle, the judge simply refers to the Court of First Instance's judgment in Case T-13/99 *Pfizer Animal Health SA v Council,* see above note 99.

[258] Speech by Jacques Santer, President of the European Commission, to Parliament on 18 February 1997, Bulletin EU 1/2 -1997, available at http://europa.eu/bulletin/en/9701/p203001.htm.

Following President Santer's speech, the Community's Office of Veterinary and Phytosanitary Inspection, which was part of the Commission's Directorate General for Agriculture, was reformed into a new unit, namely the Food and Veterinary Office (FVO) which was transferred from the Directorate General for Agriculture to the Directorate General for Consumer Policy and Consumer Health Protection (now: DG SANCO).[259] The FVO is responsible for monitoring Member States' and third countries' compliance with Community veterinary, phytosanitary and food hygiene legislation. This monitoring the FVO performs through audits, controls and inspections to check whether the European Community's safety and food hygiene regulations are being observed along the entire production chain, either in the Member States themselves or in countries exporting to the EU.[260]

Moreover, the previously dispersed food units merged to form part of DG SANCO, whereby the tasks between those responsible for ensuring food safety, animal health and welfare and plant health were separated from those in charge of agriculture and food markets.[261] The consequence was that DG SANCO more than doubled its number of employees and came to occupy a much more prominent position with regard to profile, staff and financial resources.[262]

The creation of the European Food Safety Authority (EFSA) in January 2002 was another important development.[263] EFSA is an independent agency that carries out risk assessment in the field of food safety and thus produces scientific opinions and advice to be used as a basis when the Commission, the Parliament and the Member States take risk management decisions.[264]

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[259] Cf. Ugland, T. and Veggeland, F., Towards an Integrated Approach? Food Inspection Reforms in Canada and the European Union, *Policy and Society*, no. 4 (2004) pp. 104-124 at pp. 114-115.

[260] Cf. Europa, Summaries of legislation, "Veterinary and phytosanitary inspections" (accessible at http://europa.eu/scadplus/leg/en/lvb/l32038.htm). Since 1997 the FVO has grown significantly in size and has steadily expanded the scope of its activities, cf. Ugland and Veggeland, Towards an Integrated Approach? Food Inspection Reforms in Canada and the European Union, see above note 259. The FVO is based in Grange, Co. Meath in Ireland.

[261] European Commission, 50 Years of Food Safety in the European Union, Office for Official Publications of the European Communities, Luxembourg 2007, p. 33.

[262] Cf. Ugland and Veggeland, Towards an Integrated Approach? Food Inspection Reforms in Canada and the European Union, see above note 259, at pp. 116.

[263] Cf. Regulation 178/2002, Chapter III. The EFSA is based in Parma in Italy.

[264] On EFSA see for example van der Meulen and van der Velde, *Food Safety in the European Union – An Introduction*, see above note 4, pp. 161-169.

As is clear from this brief overview, there has been a clear development towards an institutional strengthening of European food safety. This development thus lends support to the hypothesis that post-2000 regulation of food safety constitutes a new regime.

3.7 What legal factors are decisive after 2000?

Admittedly, the above examination of the Community regulation of food safety after 2000 leaves a somewhat incomplete picture. Thus, several pieces of Community legislation in the field of food safety were adopted before 2000 and remain in force today. Many of these older pieces of legislation – together with certain adopted after 2000 – maintain the establishing of the common market as the dominant objective.[265] Moreover, where no secondary legislation has been introduced, the EC Treaty's provisions on free movement of goods continue to apply *vis-à-vis* Member State measures that, according to the Member State in question, are introduced to protect public health.[266]

Nevertheless, the above examination also makes it possible to identify three decisive changes to the Community's regulatory framework on food safety:

Firstly, a new comprehensive and coherent scheme has been put in place, covering the whole food chain and the full width of foodstuffs.

Secondly, public health has become the principal objective of many – though not all – legal measures in the field of food safety.

Thirdly, Regulation 178/2002 has introduced a number of general principles that are to apply from the primary producer until the sale to the final consumer and to apply to the Community as well as to the national level. In this respect the requirement that food safety shall be based on risk analysis and the explicit acknowledgement that the precautionary principle applies in the field of food safety are likely to be of particular importance. It remains to be seen whether the European Court of Justice will construe these general principles in such a way that the protection of public health is given priority in all fields of food safety regulation.

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[265] The best examples of this are Directive 89/107, see above note 129, and Directive 2000/13, see above note 234.

[266] See for example Case C-270/02 *Commission v Italy*, see above note 256.

SAMMANFATTNING OCH SLUTSATSER

Syftet med denna rapport är att undersöka och analysera EU:s lagstiftning på livsmedelsområdet. Följande tre frågor besvaras i rapporten:

1. I vilken utsträckning utgör den nuvarande livsmedelslagstiftningen en ny ordning i förhållande till den tidigare ordningen?
2. Vilka rättsliga faktorer har påverkat EU:s reglering på livsmedelsområdet före och efter år 2000?
3. Vilka är de viktigaste principerna för EU:s livsmedelsreglering idag?

I rapporten konstateras följande:

Under 1950- och 1960-talet var livsmedelsområdet tämligen oreglerat inom EU. De regler som förekom hade främst utfärdats inom ramen för den gemensamma jordbrukspolitiken. Under denna tidsperiod var lagstiftningen rörande livsmedelssäkerhet därför mycket begränsad och föga sammanhängande. Situationen ändrades något under 1970- och 1980-talet, då en omfattande lagstiftning och rättspraxis växte fram med anknytning till den gemensamma marknaden. Medlemsstaternas livsmedelslagstiftning utgjorde ett hinder för den fria rörligheten och blev därför föremål för harmoniseringsåtgärder för att underlätta handeln. Lagstiftningen var dock fortfarande inte särskilt sammanhängande och definitivt inte heltäckande.

Efter matskandalerna på 1990-talet och kommissionens vitbok om livsmedelssäkerhet år 2000 blev emellertid livsmedelslagstiftningen föremål för en omfattande reform. Ett antal rättsakter som har till syfte att eliminera handelshinder är fortfarande ikraft, men det infördes ett övergripande regelverk som avser alla led i livsmedelskedjan och som omfattar alla livsmedel. Ett första steg mot denna ordning togs redan i mitten av 1990-talet, men det avgörande steget togs först genom förordning 178/2000. Denna förordning innehåller en rad viktiga principer som nu är tillämpliga på all livsmedelslagstiftning. Det är särskilt viktigt att påpeka att människors hälsa numera är det överordnade syftet med EU:s livsmedelspolitik.

Det kan alltså konstateras att livsmedelssäkerhet, som före millenniumskiftet enbart var en bieffekt av annan EU-politik (jordbrukspolitik och inrättandet av en gemensam marknad), numera utgör ett eget och högt prioriterat politikområde inom EU. Det kan därmed också fastställas att den nuvarande regleringen verkligen utgör en ny ordning i förhållande till den som gällde före år 2000.

Avslutningsvis kan konstateras att de principer som den nuvarande livsmedelsregleringen inom EU bygger på är följande:

- Bred och sammanhängande lagstiftning (omfattar alla livsmedel)
- Övergripande (omfattar hela livsmedelskedjan)
- Öppenhet och insyn (offentliga konsultationer och rätt till information)
- Riskrelaterad (grundas på oberoende vetenskapliga bedömningar)
- Försiktighet (människors hälsa prioriteras även när vetenskapliga bevis inte är entydiga)
- Fri rörlighet för varor (skyddsåtgärder som medlemsstaterna vidtar måste vägas mot syftet att inrätta en inre marknad).

POSTSCRIPT

It is not the purpose of this report to identify and analyse the consequences that may flow from the European Community's new regime on food safety. Nevertheless, it does appear fitting to briefly outline four important adverse consequences that deserve further examination in the future.

(I) It may be questioned whether the costs of the new regime are justifiable relative to the benefits it produces. There are clear indications that at least parts of the present regime are very costly while leading to only limited tangible results in the form of safer food products.

> Perhaps the best example is the Community's surveillance of BSE. According to the Commission's "TSE Road Road Map", the average price of each detected animal suffering from BSE in the period from January 2001 until December 2004 was € 1.56 million.[267] Taking into account all those precautionary measures that (in addition to the BSE surveillance) must be taken to avoid the transfer of the disease to humans, this price appears very high. The Commission explains that "although active BSE monitoring is not a public health protection measure, it has contributed to increased consumer confidence and has played a role in the communication strategy of certain Member States."[268] It might be that restoring consumer confidence may justify a substantial contribution, but the question remains whether the funds could not be used in a more beneficial way.[269]

The costs of the Community's new food safety regime are so significant that it would seem justifiable to regularly review the benefits it produces – and to adapt the regime where the review so prescribes.

(II) Secondly, it is likely that the food safety regime has important consequences for the European food business sector. The new regime imposes very considerable obligations on the food business operators in many different ways. One example is the requirement that the food business operator must be able to trace all ingredients "one step up" and trace all its products "one step down".[270] Large food producers may have the resources to satisfactorily deal with this regulatory burden, but the question is whether

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[267] Cf. European Commission, The TSE Road Map, (COM (2005) 322 final), Brussels 15 July 2005, table 2 at p. 21. The costs are also shown according to age group. In the group covering animals between 30 and 35 months, the price was an exorbitant 302 million.

[268] Cf. European Commission, The TSE Road Map, see above note 267, p. 8.

[269] O'Rourke, R., European Food Law, see above note 185, p. 14, observes that the objective is not only about protecting consumer health, but also to safeguard the proper functioning of the internal market.

[270] An assessment of certain aspects of this burden has been made in Wijnands, J.H.M,. van der Meulen, B.M.J and Poppe, K.J. (eds.), Competitiveness of the European Food Industry – An economic and legal assessment 2007, (Office for Official Publications of the European Communities, 2007).

the same is true with respect to the small and medium-sized producers. The burden imposed by food safety requirements may therefore act as an incentive to concentration of the food business sector. I therefore find that there is reason to consider whether this is a desirable "side-effect" – and if not, how we could try to minimise this effect.

(III) Thirdly, the consequences of the new regime on developing countries deserve further examination. Many food businesses in developing countries are depending on access to the European market, but often the new regime acts as an insurmountable technical barrier. The matter has already been the subject of a number of social science studies. Solutions that are legally tenable should be developed. To this end, a legal examination of the developing countries' aspects of the European Community's new food safety regime is clearly needed.

(IV) Fourthly, the European Community often reiterates that its new food safety regime is founded on risk analysis based on scientific assessment. The strong emphasis on risk as the basic foundation is used to show that the regime is truly objective. The food safety regime's concept of "risk" is, however, open to challenge. "Risk" is not an unambiguous concept, and the choice of definition may have appreciable repercussions upon the final outcome of any examination of whether a foodstuff is safe. Claiming hat the use of a risk-based analysis will lead to an objective outcome, necessarily ducks the fact that as part of any risk analysis a number of (subjective) choices must be made. A legal examination of the European Community's concept of "risk" therefore appears desirable.

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