

EC food law – At the heart of the Single Market

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Introduction and background	3
The importance of the food/feed/beverage industry and the related issues of law and policy ..	3
The EC’s changing approach to food law – a continuous stream of new measures	4
The multidisciplinary nature of food law	5
European food law has developed exponentially over the last 20 years	6
EU food law as a “microcosm” of EU law in general	6
Some early cases after Cassis de Dijon	7
The German beer case	7
Italian pasta case	8
Imports of yoghurt-type products in France	8
Many similar issues remain unresolved after 20 years	8
Dutch restrictions on imports of cheese containing nisin	9
Community law before the 1985 White Paper	9
The 1985 White Paper on completing the Internal Market – the “new approach”	10
Mutual recognition	11
The 1985 White Paper’s legislative programme and timetable	11
The Commission Communications of 1985 and 1989 on food law	11
The underlying rationale for the “new approach”	12
Mandatory notification of national technical regulations in the food area – preventing new obstacles under Article 28 EC	13
Labelling is a particularly delicate problem	13
Recent case law on labelling	14
Commission Green Paper on the general principles of food law in the European Union (1997)	15
Simplification and rationalisation of Community foodstuffs legislation	16
Greater use of Regulations instead of Directives is also advocated	16
Maintenance of a high level of protection	17
Management of serious and urgent public health risks	17
The need for effective implementation of internal market rules	18
The need for a comprehensive approach	19
The legal base issue	19
The precautionary principle	19
Shifting the burden of proof compared with “classical” EU law	20
Pfizer Animal Health v Council of the European Union	20

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Food safety: the European Food Safety Authority	23
Other EU bodies in the food law area	24
A general Regulation on food law, following the Green and White Papers of 1997 and 2000	24
Recent European Court case law in the area of food law	25
New legislation on organic food	35
The impact and legal status of genetically modified organisms (GMOs) in EU law	36
Regulation 1829/2003 EC on genetically modified food and feed.....	37
Regulation 1830/2003 EC on labelling and traceability of GMO products.....	38
Rules to protect geographical indications and traditional specialities	39
New legislation on food supplements, additives, novel foods, foodstuffs for nutritional and dietetic uses	41
Novel Foods	42
Food additives, flavourings and enzymes	42
International aspects of food.....	42
The Precautionary Principle and the WTO	43
EU – US dispute on poultry	44
EU – US dispute on GMOs.....	44
Conclusion	45

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Introduction and background

1. There is probably no other area of European law which affects the citizens so directly as food law. The shelves in any supermarket demonstrate the massive internationalisation and increase in choice in food products now available to the consumer. At the same time, consumers have never been so aware of the link between food and health, including issues such as quality, additives, composition, nutrition health claims and risk. Issues such as BSE, GMOs and the bird flu scare have heightened the awareness and interest of citizens and public authorities (at national, European and international levels), leading to a more intense debate on the regulation of this industry than possibly in any other sector.
2. Recent concerns on the increasing problems of obesity in children and the need for the public authorities to play a role in areas such as education, advertising and providing dietary advice, have provoked action at European as well as national level.² Similarly, press reports of possible health risks from additives which have already been approved at European level, emphasise the need for constant monitoring of product authorisations in the light of developments in scientific knowledge.³

The importance of the food/feed/beverage industry and the related issues of law and policy

3. The food industry is the leading manufacturing sector in Europe in terms of turnover, value added, employment and number of companies. It comes above even the car and chemical industries. Turnover in 2006 was € 870 billion, with employment at just over 4 million. Many SMEs are involved in the food sector (283,000). Innovation is crucial to the food industry and to a large extent is undertaken by SMEs. It is obvious that science and regulation are increasingly interactive in the food industry, not least against the background of “food scares” over the last 20 years or so. This has led, generally, to the division of responsibilities between regulators, risk managers, risk assessors and those responsible for ensuring food safety, including the judiciary.

² The EU Platform for Action on Diet, Physical Activity and Health, launched in March 2005, is perhaps the most high profile health project managed by the Commission, under Commissioner Vassiliou. A White Paper on obesity was published by the Commission on 30 May 2007. Although action will be based initially on a voluntary approach, “hard law” measures may be adopted from 2010, if the “soft law” approach is deemed unsatisfactory.

³ Recent UK press reports mentioned specifically additives and colorants such as E102 (tartrazine), E104 (quinoline yellow), E110 (sunset yellow FCR) and several others as causing a wide range of illnesses in adults and children.

The EC's changing approach to food law – a continuous stream of new measures

4. In the past, the EC's approach to food law was pragmatic or case by case, even if food law as a generic issue has attracted a number of White Papers by the Commission since 1985. Since 2000 however, the EC has approached the issue on a more holistic basis, not just from "farm to fork", but from the beginning to the end of the food cycle. This involves an inter-disciplinary approach, looking at new technologies such as neuro-sciences, biotechnologies and nanotechnologies.
5. The key issue for the EC (and Member States) is to balance the interests of industry (for example in having rapid approvals for new products) with those of consumers (especially as regards food safety). Despite the Commission's policy (in the context of "better regulation") to "do less, but to do better", there is no doubt that EC food law in the form of secondary legislation is now more voluminous than ever. This does not in my view mean that the new Regulations and Directives are not "good law" however or do not meet the EU's own "better regulation" criteria.
6. In 2006, new rules were agreed on vitamins, minerals and other nutrients⁴, together with a new labelling regime for health claims⁵. New measures were also agreed in 2008 on food enzymes, flavourings, additives and ingredients.⁶ All these new measures have to be seen against the background of the 2002 Regulation laying down general principles and requirements for food law (Regulation 178/2002), establishing the European Food Safety Authority (EFSA). They also reflect entirely legitimate increasing public awareness of the relationship between diet and health, and the role of law and policy in this respect.
7. As far as food safety is concerned, the Annual Reports from the European Commission-managed Rapid Alert System for Food and Feed reflect the attention now being given to monitoring the safety of food. The 2007 report shows that 7354 initial and follow-up notifications were transmitted through the RASFF system. This high number is mainly attributed to the increase of the additional information notifications⁷ which were 13.5% higher than in 2006. This system extends to third countries as well as the EU. China and Turkey were apparently the two top problem countries of origin with 645 risk notifications between them (most risk notifications

⁴ Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods OJ L 404 , 30/12/2006.

⁵ Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods OJ L 404, 30.12.2006.

⁶ Proposal for a regulation establishing a common authorisation procedure for food additives, food enzymes and food flavourings. Proposal for a regulation on food enzymes and amending Council Directive 83/417/EEC, Council Regulation 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation 258/97. Proposal for a regulation on food additives. Proposal for a regulation on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation 1601/91, Regulations 2232/96 and 110/2008 and Directive 2000/13/EC. These measures were adopted by the Council on 30 October 2008.

⁷ Information notifications concern a food or feed that was placed on the market for which a risk has been identified, but for which the other members of the network do not have to take immediate action, because the product has not reached their market or is no longer present on their market or because the nature of the risk does not require any immediate action.

cover nuts, food and vegetables, fish, crustaceans and molluscs). The Commission's Legislative and Work Programme for 2009 mentions that the Commission aims to revise the Implementing Measures for the RASFF with the objective of ensuring the uniform operation of the RASFF by all the members of the network.

8. Even if there has been a rash of new EC legislation in the last ten or so years, scientific developments and changes of the marketplace, required that these be reviewed and updated regularly. The 1997 rules⁸ on novel foods are a case in point. GMOs and novel foods are now covered by separate Regulations. One issue is the speed of the approval process which is said to take two years in the EU, but three months in the US (under the FDA). 32 foods have been approved under the Novel Foods Regulation in the last ten years, with three applications being rejected. There are plans to revise the law on Novel Foods; the Commission put forward a draft Regulation⁹ in early 2008. The ongoing review of EC labelling legislation is another example of a field where (despite the relatively recent consolidation and modernisation of rules in 2000), the law needs to be reviewed and updated to reflect changes in a fast-moving industry and in society. The Commission made a proposal for a new labelling Regulation in early 2008 which is currently out for consultation in the Member States. As the final text will require approval by the Council and the Parliament, it is not expected to be published until at least 2010.
9. In December 2006, the EU adopted a new Regulation¹⁰ that prohibits nutrition and health claims which encourage consumers to purchase a product but are false, misleading or not scientifically proven. This legislation sets out the conditions that must be met if nutrition and health claims are to be used as advertising on a food product. For instance, if it is claimed that a food is high in fibre, the product must contain at least 6 g of fibre per 100 g or at least 3 g of fibre per 100 kcal. For industry, it is important to have a thorough knowledge of this legislation when using claims on products. To obtain authorisation for a new claim or to amend the existing list in the Regulation, a manufacturer must submit an application to the Member State concerned, which then forwards it to the EFSA. The Commission then makes a decision on the use of the claim on the basis of the EFSA's opinion.

The multidisciplinary nature of food law

10. Food law brings together industrial, commercial, scientific and medical issues, but is also much affected by culture and tradition. The view has been expressed for example that Americans are more ready to trust "science" once products have been approved by the Food and Drug Administration (FDA). In Europe, even if products are demonstrated scientifically to be harmless or risk-free, there may still be public reluctance to consume them or even allow them on the market. GMOs are a case in point, where the WTO's recent ruling in the case brought by the US against the EC

⁸ Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients OJ L 43, 14.2.1997, p. 1–6.

⁹ Proposal for a Regulation of the European Parliament and of the Council on novel foods Brussels, 14.1.2008 COM(2007) 872 final.

¹⁰ Regulation 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods OJ L 404, 30.12.2006.

in favour of GMOs (or condemning certain aspect of the EU's ban on imports of GMOs), may meet reluctance on the part of European retailers and consumers to market GMO products, despite clear labelling. Differences of opinion may exist even within the 27 Member States of the EU. In February 2006, the Council rejected a Commission proposal for Hungary to overturn its national veto on biotech maize. They also rejected a Commission request for an end to the Austrian ban on GMOs in December 2006. Such situations (involving crucial issues of human health) cannot be resolved by a simple application of the legal rules and procedures.

11. Rules on advertising for food and beverages are now an intrinsic part of EU food law. The Health Claims Regulation is an example of this. Nonetheless, despite the existence of Community legal regimes on particular issues, Member States still take "national" decisions, taking into account the health and welfare of their own populations. In 2006, the UK and Romania banned advertisements on children's food with high quantities of salt, fat or sugar. Discussion continues on the form and content of advertising (or, more accurately, communications between manufacturers, wholesalers, retailers and consumers), e.g. through labelling, for example including guideline daily amounts (GDAs) or the "traffic light", i.e. colour coded labelling scheme.

European food law has developed exponentially over the last 20 years

12. Following the Commission's initiatives in 1985-1987 in the context of the launch of the Single Market (essentially the "new approach"), new impetus was provided by the BSE crisis in the mid-1990s. This led to fundamental reforms of EU secondary legislation, institutional and organisational reforms (notably in the Commission and with the creation of the European Food Safety Authority (EFSA)), the separation of responsibility for risk assessment and management on the one hand and legislation on the other and a new legal regime for GMOs and novel foods. The regulatory mill continues to turn and the European Courts continue to handle a significant number of cases, embracing conditions for authorising GMOs and novel foods, Member State restrictions on the marketing of nutritional foods, as well as "classic" cases on mutual recognition under the *Cassis de Dijon*¹¹ principle.

EU food law as a "microcosm" of EU law in general

13. EU food law illustrates almost all the general principles of EU law. These include:
 - the development of fundamental EU rules on the free movement of goods (Articles 28-30 EC);
 - the impact of ECJ cases, e.g. *Cassis de Dijon* ("small cases make big law");

¹¹ Case C-120/78 *Rewe-Zentrale AG v Bundesmonopolverwaltung für Branntwein* [1979] ECR 649.

- the origins of the Single Market in the Commission's White Paper on completing the internal market (1985)¹²;
- the trend, in secondary legislation, from “total harmonisation” to a “new approach” based on “minimum harmonisation and mutual recognition of equivalent standards and procedures”;
- the erosion of the mutual recognition principle as a result of diminished mutual trust and confidence, following health scares related to food such as that on BSE, leading to the emergence of the “precautionary principle” and a certain “rebalancing” of the burden of proof in free movement cases;
- the impact of science on EU regulatory and judicial decision-making (e.g. GMOs);
- the institutional impact in the EU (especially the Commission), with the expansion of officials concerned with health, safety, scientific assessments related to manufacture, marketing and risk assessment (e.g. DG SANCO) and the creation of the European Food Safety Authority (EFSA) and other scientific committees;¹³
- the tendency for international regulation of food law to follow (at a distance) the broad lines of EU law.

Some early cases after *Cassis de Dijon*

14. Four cases in particular arose in the late 1980s which deserve comment. Although involving relatively “banal” products (beer¹⁴, pasta¹⁵, cheese¹⁶ and yoghurt), the cases demonstrate the national passions (and protectionist forces) which can be aroused over food and drink. In those days, the Commission as “guardian of the Treaties” had to decide (in considering Article 226 EC infringement procedures) whether there were legitimate concerns about human health or whether we were confronting national protectionism.

The German beer case

15. The German beer market had been protected for decades by German legislation (the *Reinheitsgebot*). This legislation was typical of “purity laws” existing in many Member States. The Commission took the view that, in most cases at least, this type of legislation – although ostensibly to protect health – was protectionist in nature. Within the Commission, a rearguard action was fought by German interests to

¹² Adopted unanimously by the European Council in Milan in June 1985.

¹³ The institutional complexity of the Commission's organisation on food law-related issues is formidable: DGs Trade, Enterprise, Agriculture, Environment, Internal Market, as well as Health and Consumer Protection are all involved.

¹⁴ Case 178/84 *Commission v Germany* [1987] ECR 01227.

¹⁵ Case 407/85 *Drei Glocken* [1988] ECR 4233.

¹⁶ Case 53/80 *Eyssen* [1981] ECR 409.

prevent Article 226 proceedings being launched. Once the case came to the ECJ however, the Court had no difficulty in finding that the German legislation was in breach of Article 28 EC. Enforcement in practice was another matter. Beer traders were forced to bring other actions in the German courts in order to enforce the judgment won by the Commission and indeed to claim damages for breach of fundamental rules of Community law.¹⁷

Italian pasta case

16. Italy restricted imports of “soft wheat” pasta from Germany. The Commission considered the launch of Article 226 proceedings. Again, political opposition prevented the launch of infringement proceedings. In essence, although no argument on health grounds could be raised, the Italians argued that – on quality grounds – soft wheat pasta was inferior to pasta made with durum wheat and should therefore not be allowed on the market. An action was brought by an importer in the Italian courts and a reference was made to the ECJ under Article 234 EC. Once again, the ECJ had no difficulty in holding that no legitimate grounds existed for Italy to restrict imports and that consumers should be allowed to choose Italian or German pasta. European law could not dictate taste or even (at that stage) impose quality standards.

Imports of yoghurt-type products in France

17. The “quality” argument arose again in this case. “Yogho-Yogho” was a product manufactured in the Netherlands and marketed in other Member States. Import restrictions were imposed in France. Again, no attempt was made to deploy the health argument, but France alleged that:
 - the term “yoghurt” should be confined to natural or untreated yoghurt products with living bacteria;
 - the term “yogho-yogho” was such as to mislead consumers and that therefore any restriction was not caught by Article 28 EC.
18. For political reasons (i.e. French opposition) the case was not pursued by the Commission under Article 226 EC and the matter was not raised in the national courts. As a result, the full range of yoghurt products has not been allowed to circulate freely in the Single Market (in effect the “single market” has been fragmented and consumer choice denied). Competition between manufacturers has been distorted and some national markets (e.g. France) have been closed to imports almost completely.

Many similar issues remain unresolved after 20 years

19. Despite a wealth of consultative papers, secondary legislation and case law over the last 20 years, many of the same issues as arose in the late 1980s are still present today. The legal status of yoghurt and yoghurt-type products under EC law is a case

¹⁷ Joined Cases C-46/93 and C-48/93 *Brasserie du Pêcheur v Bundesrepublik Deutschland* [1996] ECR I-01029.

in point (see case study discussed in Annex I of this paper). In the first Delors Commission (1985-1995) and as a result of French pressure, infringements were not launched by the Commission, partially on the grounds that it was not the Commission's responsibility to use Article 226 infringement procedures to promote the marketing of products of inferior quality. The Commission's qualifications to make such a judgment were not entirely clear then or now. Nonetheless, the Commission has increasingly become involved in assessments of "quality" in the food sector, as well as in issues such as health and nutrition.

Dutch restrictions on imports of cheese containing nisin

20. In contrast to the beer, pasta and yoghurt cases, real considerations of health (at least superficially) arose in the "nisin in cheese" case¹⁸. This was one of the first cases in which the Commission was called upon to use scientific assessments. The Court upheld the Dutch legislation in this case. The Court said that:

*"In view of the uncertainties prevailing in the various Member States regarding the maximum level of nisin which must be prescribed in respect of each preserved product intended to satisfy the various dietary habits, it does not appear that such a prohibition, although restricted only to products intended for sale on the domestic market of the State concerned, constitutes a "means of arbitrary discrimination or a disguised restriction on trade between Member States" within the meaning of [Article 30]."*¹⁹

Community law before the 1985 White Paper

21. Before 1985, there was a strong tendency for the Commission to propose "vertical" Directives aimed at the total harmonisation of national rules on individual products in order to remove obstacles to free movement and to create a level-playing field. Examples included honey²⁰, chocolate²¹, coffee extracts²², sugar²³, fruit juices²⁴, dried milk²⁵, jellies and marmalade²⁶, preserved milk²⁷, and natural mineral waters²⁸.

¹⁸ Case 53/80 *Officier van Justitie v. Koninklijke Kaasfabriek Eysen BV* [1981] ECR 409-432.

¹⁹ *Ibid*, para 16.

²⁰ Council Directive 74/409/EEC of 22 July 1974 on the harmonisation of the laws of the Member States relating to honey. (OJ L 221, 12/08/1974 P. 0010 – 0014).

²¹ Council Directive 73/241/EEC of 24 July 1973 on the approximation of the laws of the Member States relating to cocoa and chocolate products intended for human consumption. (OJ L 228, 16/08/1973 P. 0023 – 0035).

²² Council Directive 77/436/EEC of 27 June 1977 on the approximation of the laws of the Member States relating to coffee extracts and chicory extracts. (OJ L 172, 12/07/1977 P. 0020 – 0024).

²³ Council Directive 73/437/EEC of 11 December 1973 on the approximation of the laws of the Member States concerning certain sugars intended for human consumption. (OJ L 356, 27/12/1973 P. 0071 – 0073).

²⁴ Council Directive 75/726/EEC of 17 November 1975 on the approximation of the laws of the Member States concerning fruit juices and certain similar products. (OJ L 311, 01/12/1975 P. 0040 – 0049).

²⁵ Council Directive 76/118/EEC of 18 December 1975 on the approximation of the laws of the Member States relating to certain partly or wholly dehydrated preserved milk for human consumption. (OJ L 024, 30/01/1976 P. 0049 – 0057).

²⁶ Council Directive 79/693/EEC of 24 July 1979 on the approximation of the laws of the Member States relating to fruit jams, jellies and marmalades and chestnut purée. (OJ L 205, 13/08/1979 P. 0005 – 0016).

The 1985 White Paper recognised the need for change. Article 100 (now Article 94 EC) required unanimity in Council voting, although Article 43 (now Article 37 EC) allowed QMV for veterinary and phytosanitary measures. The Single European Act (SEA) in 1986 introduced Article 100(a) (now Article 95 EC), providing for the enactment of Single Market measures by QMV. In addition, the Council recognised on 16 July 1984 (Conclusions on Standardisation) that, given the essential equivalence of objectives of national legislation, mutual recognition could be an effective strategy for bringing about a common market in the trading sense. This strategy was based on Articles 28-30 EC, which prohibit national measures which have an excessively and unjustifiably restrictive effect on free movement. Presciently, the White Paper (para. 64) recognised that “*a strategy based totally on harmonisation would be over-regulatory, would take a long time to implement, would be inflexible and could stifle innovation.*”

The 1985 White Paper on completing the Internal Market – the “new approach”

22. The 1985 White Paper (para. 65) outlined the “chosen strategy”, based on:

- minimum harmonisation of “essential requirements” for health and safety;
- mutual recognition of national regulations and standards. Foodstuffs were identified as a sector which was particularly apt for the application of new approach. It is worth quoting the White Paper in full on this matter (para. 71, third indent):

“In the foodstuffs sector, Community legislative action has been concentrated, and will continue to be concentrated, on issuing “horizontal” Directives governing the use of food additives, labelling regulations etc., where the essential need to protect the health and safety of consumers is involved. In line with the “new approach”, and in line with the recommendations of the Dooge Committee, the Commission will propose more efficient procedures for the implementation of Article 100 harmonisation in this sector. This approach will be based on the principle of delegating to the Commission, advised by the Scientific Committee for Food, the task of drawing up and managing the more detailed and technical aspects of these Directives, leaving the Council free to concentrate on the essential safety and health criteria which must be observed. To this end, the Commission will submit a communication to the Council and to the European Parliament before the end of 1985, and it will propose the extension of Directive 83/189/EEC to the food sector.”

²⁷ Council Directive 76/118/EEC of 18 December 1975 on the approximation of the laws of the Member States relating to certain partly or wholly dehydrated preserved milk for human consumption. (OJ L 024, 30/01/1976 P. 0049 – 0057).

²⁸ Council Directive 80/777/EEC of 15 July 1980 on the approximation of the laws of the Member States relating to the exploitation and marketing of natural mineral waters. (OJ L 229, 30/08/1980 P. 0001 – 0010).

Mutual recognition

23. In the White Paper (para. 77), the Commission recalled the fact that the ECJ (notably in *Cassis de Dijon*) had recognised that full harmonisation was not essential either for health/safety reasons or from an industrial point of view and stated that “immediate and full recognition of differing quality standards, food composition rules etc. must be the rule”. In language which is still relevant today (and where the issue of mutual recognition is still unclear) the Commission continued:

“In particular, sales bans cannot be based on the sole argument that an imported product has been manufactured according to specifications which differ from those used in the importing country. There is no obligation on the buyer to prove the equivalence of a product produced according to the rules of the exporting State. Similarly, he must not be required to submit such a product to additional technical tests nor to certification procedures in the importing State. Any purchaser, be he wholesaler, retailer or the final consumer, should have the right to choose his supplier in any part of the Community without restrictions. The Commission would use all the powers available under the Treaty, particularly Articles 28-30, to reinforce the principle of recognition.”

The 1985 White Paper’s legislative programme and timetable

24. Despite the “new approach”, food law is one of the most densely regulated areas of EU law. In 1985, the Commission did not immediately or unconditionally abandon the “vertical harmonisation” method, as can be seen from proposals on products such as cocoa and chocolate, coffee, starches, fruit juices and jams. Nonetheless, the Commission did introduce general (“horizontal”) Directives in areas such as food additives, materials and articles in contact with food, particular nutritional uses, food labelling, sampling and methods of analysis and a procedure for managing existing “vertical” Directives.

The Commission Communications of 1985 and 1989 on food law²⁹

25. Recognising that food law was a particularly important area for the internal market, the Commission announced in its 1985 Communication:
- the extension of mutual recognition of national regulations and standards to food law;
 - “a more efficient mechanism” for harmonisation of laws;
 - the extension of the “mandatory notification of technical standards” Directives to foodstuffs.³⁰

²⁹ COM(85) 603 final of 8.11.1985 and OJ C 271/3 on the free movement of foodstuffs with the European Community.

26. The Commission identified 50 sectors falling within the general category of food legislation (this “old approach” dates back to 1969). The Commission noted substantial progress in “horizontal” areas (additives, labelling and other general matters) and very slow progress in “vertical” sectors (specific foods). The Commission identified the *Cassis de Dijon* case (ruling and subsequent judgments) – especially the proportionality principle – as the legal underpinning of its new approach. Future Community legislation on foodstuffs were therefore limited to provisions justified by the need to:
- protect public health;
 - provide consumers with information and protection in matters other than health; and
 - ensure fair trading and provide for the necessary public controls.

The underlying rationale for the “new approach”

27. The more limited approach to EU legislation was based on the fact that:
- it is neither possible nor desirable to “straitjacket” the culinary riches of so many (now 27) Member States;
 - legislative rigidity concerning product composition prevents the development of new products and is therefore an obstacle to innovation and commercial flexibility;
 - the taste and preferences of consumers should not be a matter for regulation.
28. The Commission in particular took a stand (backed by the ECJ) against “compositional rules” or “recipe legislation”, whereby one Member State prevented imports from another Member State of products similar to but not of the same composition as its own local produce. The only caveat in this context was the need to protect consumers against misleading practices and producers against unfair competition. The Commission also rejected the suggestion that a lack of Community compositional rules would lead to a reduction in quality. The Commission recognised however (presciently) that increased administrative cooperation between Member States would be essential in order to make the new system work..

³⁰ Despite voluminous EU legislation on foodstuffs, most standards are still enacted at national level. Compliance with the mandatory notification requirement of Directive 98/34 is therefore crucial to avoid fragmentation of the Single Market by differing national standards which constitute restrictions to trade in terms of Article 28 EC.

Mandatory notification of national technical regulations in the food area – preventing new obstacles under Article 28 EC

29. Directive 98/34/EC (as amended) lays down a procedure for the provision of information in the field of technical standards and regulations. When the Commission adopts or proposes the adoption of binding Community acts a specific temporary standstill period has been established in order to prevent the introduction of national measures from compromising the adoption of binding Community acts by the Council or the Commission in the same field. This is to ensure transparency, legal certainty and the proper functioning of the internal market.
30. The standstill period to be exercised by the Member State can range from three months from the date of receipt by the Commission of the draft technical Regulation to four months for the adoption of a draft technical Regulation in the form of a voluntary agreement or to six months with the adoption of any other draft technical Regulation (except for draft rules on services). A maximum standstill period of 12 months is possible if the Commission finds that the Member State draft technical Regulation is covered by a Community legislative proposal.
31. Case C-194/94 *CIA Security* illustrated the importance of these general principles underlying Directive 98/34/EC. Belgium failed to notify a decree concerning the prohibition of the marketing of alarm systems until their authorisation to the Commission pursuant to Directive 83/189 (as amended by Directive 98/34). The ECJ ruled that the decree's standards constituted a technical Regulation that ought to have been notified and moreover the original provisions concerning the standstill period were directly effective. This meant in practice that Belgium could not invoke or rely on its (un-notified) technical legislation to impede imports of products which did not meet the specifications.

Labelling is a particularly delicate problem

32. The aim must be for balance or compromise in providing sufficient information for consumers, whilst avoiding unnecessarily detailed provisions. This aim is not helped by the distinct legislative provisions that cover a plethora of items, including GMOs, sweeteners, meats and alcohol. Directive 2000/13 as amended is the most general in the sense that it sets out the requirements for the labelling, presentation and advertising of foodstuffs. The aim of this Directive is to provide consumers, especially those suffering from food allergies or intolerances, with fuller information on the composition of products through more exhaustive labelling. A further sensitive issue is that of health claims and nutritional labelling, where a Regulation was adopted under the co-decision on 20 December 2006.³¹
33. The Commission in its attempt to identify a coherent overall approach to labelling, launched a dialogue with key stakeholders in February 2006 in a consultation paper³². The Commission was seeking stakeholders' views on the way the EU deals with labelling issues for food and non-food products. The results of the consultation

³¹ OJ L12/3 of 18.1.2007.

³² http://ec.europa.eu/food/food/labellingnutrition/betterregulation/index_en.htm.

demonstrated that stakeholders did not question the main purpose of the legislation on labelling and that they did not desire a change in its core components. It was made clear however, that some aspects of the legislation could be improved, notably its piecemeal approach and the lack of coordination of implementation dates.

34. On 1 January 2008, the Commission proposed a draft Regulation³³ with the aim of modernising the food labelling rules and creating a level playing field for all operators. The key elements of the Commission's proposal include the following:
- certain compulsory information would still have to be included (which should be clear, easy to read and not misleading);
 - compulsory information would include name of the product, the list of ingredients, the "best before" or "use-by dates", any special conditions of use and the name and address of the manufacturer;
 - front-of-pack nutrition information would become mandatory for nearly all pre-packaged processed foods;
 - mandatory information would have to be printed in a minimum size (3mm) with a significant contrast between the writing and the background;
 - mandatory allergen labelling would be required not just for pre-packed food but also for food sold in restaurants and other catering establishments;
 - ready to drink mixed alcoholic beverages ("alcopops") would have to have an ingredients list;
 - country of origin or place of provenance labelling on food would remain voluntary unless its absence could mislead consumers.
35. The Commission's proposal has been transmitted to the Council and the Parliament for consideration under the co-decision procedure. If it is adopted, the front-of-pack mandatory information would not apply until three years after the entry into force of the Regulation to give industry the time to adjust.

Recent case law on labelling

36. The Commission recently brought an action³⁴ against Italy in relation to a national law obliging manufacturers to indicate the origin of poultry meat from other Member States. The Commission considers that the Italian law breaches Directive 2000/13 because it requires labelling where the Directive would not; indications of origin are only required under the Directive where failure to give such particulars

³³ COM(2008) 40 final of 30.1.08.

³⁴ Action brought on 25 August 2008 - *Commission of the European Communities v Italian Republic* (Case C-383/08).

might mislead the consumer to a material degree as to the true origin or provenance of the foodstuff. The Commission considers that the consumer would not be misled by a failure to indicate the origin of poultry and that the measure in question creates an obstacle to trade. Italy claims it introduced the measure in response to the bird flu crisis despite the fact that measures have been taken at the Community level. The outcome of this case is awaited.

Commission Green Paper on the general principles of food law in the European Union (1997)³⁵

37. Coming 12 years after the 1985 White Paper, and after 10 years of the “new approach”, the Green Paper was an important milestone. Note however that it preceded the “food crisis” of the early 2000s. In particular it preceded the “twin turning points” of BSE and GMOs. The Green Paper covered:

- the simplification and rationalisation of Community food law;
- a review of existing Community legislation;
- maintenance of a high level of protection;
- ensuring the effective implementation and enforcement of internal market rules; and
- the external dimension (WTO, CODEX Alimentarius and bilateral agreements).

38. The Green Paper identified six basic goals for Community food law:

- to ensure a high level of protection of public health, safety and the consumer;
- to ensure the free movement of goods within the internal market;
- to ensure that the legislation was primarily based on scientific evidence and risk assessment;
- to ensure the competitiveness of European industry and enhance its export prospects;
- to place primary responsibility for safe food on industry, producers and suppliers, using hazard analysis and critical control points (HACCP) type systems, which must be backed up by effective official control and enforcement;
- to ensure the legislation is coherent, rational and user-friendly.

³⁵ COM(1997) 176 final of 30.4.1997.

39. As a whole, the regulatory approach was to cover the whole food chain “from the stable to the table”. This implied an unprecedented level of cooperation – at national, EU and institutional levels – between regulators and supervisors in the “primary” sectors (e.g. agriculture and fisheries) and in “downstream” areas (e.g. processed products). It is not clear at all that such inter-departmental cooperation has yet been achieved. Even in the Commission, cooperation between DGs Agri, Fish, Markt and Sanco is far from settled. Two related issues were:
- a) the extent to which primary agricultural production and the processed foodstuff sector should be brought within the same set of general rules;
 - b) the principle of producers’ liability for defective products to be made obligatory for primary agricultural production.

Simplification and rationalisation of Community foodstuffs legislation

40. There must be a serious question mark whether the current state of food law in the EU is either “rational or simple”. Food law would seem to be (possibly with financial services) a prime target for review under the “better regulation” heading.³⁶ In its 1997 Green Paper, the Commission admitted that full respect for subsidiarity could result in the progressive dismantling of the internal market as a result of new national legislative initiatives. Clearly, a balance has to be struck between regulation at the national, European and international levels, with rigorous use being made by the Commission of Directive 98/34.

Greater use of Regulations instead of Directives is also advocated

41. The constant need to update legislation points to the use of simplified procedures. The full co-decision procedure is lengthy and tends to lead to unnecessarily complex measures, notably as a result of amendments added in the Council, but especially in the Parliament. At the same time, the Council’s insistence of the use of Directives rather than directly-applicable Regulations, leads to:
- Linguistic complications and uncertainties due to the need for national transposition in 21 official languages;
 - Delays in implementation due to slow national legislative procedures;
 - Inaccurate or incomplete transposition in national law;
 - Limited possibilities for enforcement in national courts, as a result of the absence of “horizontal direct effect” of Directives, as compared with Regulations.
42. On a positive note, there are indications that the Council (in particular) and the Parliament are willing to consider greater use of Regulations in the food law sector. In 2004, 2006 and 2007 respectively, Regulations were adopted on microbiological

³⁶ As indicated above in the case of labelling, it appears that some steps in this direction are now being taken.

sampling and testing of foodstuffs and on nutrition and health claims made on foods and organic labelling and production.³⁷ In 2008, four new proposals approved by the Council were in the form of regulations.

Maintenance of a high level of protection

43. This concept is at the heart of the Community legal order (Articles 30 and 95(3)) and central to the credibility of the EU system of food law.³⁸ The Commission states that:

“Protective measures should be based on risk assessment, taking into account all relevant risk factors, including technological aspects, the best available scientific evidence and the availability of inspection sampling and testing methods. Where a full risk assessment is not possible, measures should be based on the precautionary principle. ... Independence and objectivity of scientific advice and scientific committees must be guaranteed at all levels.”

Consumer needs and concerns must complement scientific advice in EU decision-making. The Community system needs *“adequate means to take preventative action against serious and urgent public health risks.”*

44. Key action items for the Commission in this area are to ensure that:

- the most recent and complete scientific evidence (prior consultation of independent scientific experts) is taken into account in the legislative process (“risk assessment”);³⁹
- a precautionary approach is taken where scientific evidence is incomplete or unconvincing;
- to ensure that all participants in the food chain are responsible for the safety and wholesomeness of food (product liability);
- control measures are taken at all critical points throughout the food chain, including for imported foodstuffs;
- appropriate measures are taken to ensure correct information to the consumer about the nature and content of foodstuffs;
- the responsibilities of the various controlling agents (e.g. producers, Member States authorities, Commission services, independent experts etc.) are clearly defined.

Management of serious and urgent public health risks

³⁷ Regulation 882/2004, Regulation 1924/2006 and Regulation 834/2007.

³⁸ See also Articles 152 on public health and 153 on consumer protection.

³⁹ The principle of scientific cooperation on food issues were set out in Directive 93/5/EEC of 25.2.1993.

45. Safeguard clauses are included in all Community legislation for the protection of public health.⁴⁰ These clauses allow Member States to apply restrictions to the marketing of a product or a substance if there is a good reason to suppose that it constitutes a danger, even if (formally) it conforms to existing Community Regulations. A “rapid alert system” was established in 1994 and is now set out in Directive 92/59/EEC. Also under this Directive, the EC was given powers on general product safety, to intervene and remove from the internal market products which present serious and immediate risks to consumers. The Commission acts on information received from Member States. Veterinary health measures are taken under the relevant sector Directives and Directive 852/2004 on hygiene (which revised the legislation as originally set out in Directive 93/43) and provides for provisional emergency measures by the Commission, ratified by a Committee procedure.
46. This procedure was discussed by the ECJ in *UK v Commission*.⁴¹ In this case (involving BSE in the UK) the ECJ recognised that, in applying these procedures, paramount importance must be accorded to the protection of public health, even at the expense of serious and possibly damage to commercial and social interests. There is a distinction between the safeguard clauses in the veterinary Directives, applying both to products imported from third countries and products in intra-Community trade. The safeguard clause in Article 10 of the original General Hygiene Directive, in contrast, is limited to imported products only.
47. The recent outbreaks of avian influenza have given rise to both animal and public health concerns. The Commission is dealing with these concerns by both pre-emptive risk reduction measures and control measures. As far as legislative measures are concerned, Directive 2005/94/EC⁴² includes measures such as preventive vaccination and new measures to be applied on holdings where cases of low pathogenic avian influenza have been confirmed. Member States have been obliged to implement this legislation since July 31, 2007. The Commission has also imposed import bans⁴³ on live birds and potentially risky poultry products such as fresh poultry meat and untreated feathers from all countries and regions which have detected and confirmed outbreaks of avian influenza. These import restrictions are reviewed and updated in line with the disease situation in the country concerned.

The need for effective implementation of internal market rules

48. As in other sectors, the need for effective implementation is as great if not greater than the need for suitable legislation. Implementation and enforcement is not merely a question of Commission infringement procedures under Article 226 EC. In addition to litigation in national courts and the possible use of Article 234 EC, in food law as in other sectors, the use of “peer review” mechanisms through standing

⁴⁰ Example Article 23, Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.

⁴¹ C-180/96 *UK v Commission* [1996] ECR I-03903.

⁴² Directive 2005/94/EC on Community measures for the control of avian influenza and repealing Directive 92/40/EEC, OJ L 010, 14.01.2006.

⁴³ Import restrictions have so far been imposed on Romania, Israel, North Korea, Russia and Turkey.

committees is more valuable, not only on interpretation issues but also on enforcement. At the same time, the notification of new national technical measures under Directive 98/34 (as extended to food products and as recently amended) is of crucial importance. The “standstill” and “rollback” provisions of this Directive allow the Commission and Member States to prevent the emergence of new national obstacles to free movement.

The need for a comprehensive approach

49. The Commission stresses that, although EU food law is now almost completely “harmonised” (or at least coordinated at EU level), it has grown pragmatically and empirically. Many layers of amendments lead to possible duplication, complexity and non-transparency of rules. Greater cohesion is necessary, embracing the whole food chain, including primary or environmental inputs at the beginning of the chain and embracing consumer protection and manufacturers’ liability at the end of the chain. This implies the need to ensure consistency between the CAP, environmental policy, food and nutritional science and trade or industry policy.

The legal base issue

50. The successive amendments to the Treaties (Single European Act, Maastricht, Amsterdam and Nice Treaties), gradually extending the substantive scope of the EC’s competence, have given rise to increasingly complex issues concerning the legal base of measures in the food sector. Article 95 (especially para. 3) provides the general legal basis for internal market legislation and requires the Commission to take as a base a high level of protection concerning health, safety, environmental and consumer protection; Article 152 EC provides that health protection requirements shall form a constituent part of the Community’s other policies. Article 153 requires the Community to contribute to the attainment of a high level of consumer protection. Likewise, Article 174 requires Community policy to contribute to the protection of human health, as one component of environmental policy.

The precautionary principle⁴⁴

51. The delicate and difficult decision-making background to the precautionary principle was summarised by the Commission in its 2000 Communication as follows:

“Decision-makers are constantly faced with the dilemma of balancing the freedom and rights of individuals, industry and organisations with the need to reduce the risk of adverse effects to the environment, human, animal or plant health. Therefore, finding the correct balance so that the proportionate, non-discriminatory, transparent and coherent actions can be taken, requires a structured decision-making process with detailed scientific and other objective information.”

⁴⁴ The legal literature on the precautionary principle is voluminous. The starting point is the Commission’s Communication (COM(2000) 1 of 2.2.2000). See also I. Forrester, *The Dangers of too much Precaution*, in Essays for Judge David Edward (2003). See also K. Lenaerts, “*In the Union we trust*” – *Trust enhancing principles of Community law*, 40 years of the Common Market Law Review. Vol. 41, No. 2, April 2004.

52. In the Single Market context, a clear concern was to avoid disguised protectionism. The precautionary principle is part of a “structured approach to the analysis of risk” comprising risk assessment, risk management and risk communication. The use of the precautionary principle presupposes that potentially dangerous effects of a phenomenon, product or process have been identified and that scientific evaluation does not allow the risk to be determined with sufficient certainty. Any action taken on the basis of the precautionary principle should be:
- (i) proportional to the chosen level of protection;
 - (ii) non-discriminatory in application;
 - (iii) consistent with similar measures already taken;
 - (iv) based on an examination of the potential benefits and costs of action or lack of action;
 - (v) subject to review in the light of scientific data; and
 - (vi) capable of assigning responsibility for producers of scientific evidence necessary for a more comprehensive risk assessment.

Shifting the burden of proof compared with “classical” EU law

53. Traditionally, the burden of proof in restricting trade was on the Member State seeking to invoke the “derogation” in Article 30 EC or one of the “mandatory requirements”. Although, as recent case law makes clear, the ECJ will be vigilant to avoid abuse of the precautionary principle, at the very least the introduction of the principle has resulted in a sharing of the burden of proof between producers and exporters on the one side and importers (and the respective authorities) on the other. It would be too much to say that exporters must now demonstrate that their products are not only not harmful but positively healthy; nonetheless all economic operators (and the respective authorities) now share the responsibility to produce scientific evidence, which can be weighed by decision-makers.⁴⁵

Pfizer Animal Health v Council of the European Union⁴⁶

54. Although concerned more with feed than with food, the *Pfizer* case was a landmark ruling, coinciding with the publication by the Commission of its Communication on the precautionary principle. In summary, the CFI’s ruling confirmed the broad discretion (subject to a number of conditions) of the EU institutions in decision-making involving science and risk, whilst also confirming the limited role of the EU Courts in exercising their function of judicial review.
55. In particular, the Court:

⁴⁵ The greatest impact of this precautionary approach is probably felt in the approval process for new food or feed products, where the European Food Safety Authority (EFSA) in Parma, has very extensive powers.

⁴⁶ T-13/99 R. *Pfizer Animal Health SA/NV v Council of the European Union* [1999] ECR II-01961.

- confirmed the integration of the precautionary principle (originally set out in Article 174(2) EC) into all areas of Community policy;
- the EU institutions could lay down for themselves guidelines for the exercise of their discretionary powers, including in the area of scientific evaluation and risk assessments;
- where there is scientific uncertainty as to the existence or extent of risks to human health, the EU institutions can take protective measures using the precautionary principle without having to wait for the reality and seriousness of those risks to be fully apparent. Risk assessments cannot therefore be required to provide the Community institutions with conclusive scientific evidence on the reality of risk and the seriousness of the potential adverse effects;
- however, preventive measures cannot be based on “a purely hypothetical approach to risk”. They must be “adequately backed up by scientific data available at the time when the measure was taken”;
- the precautionary principle applies therefore in situations which are not hypothetical but where the extent of risk has not yet been fully demonstrated;
- the purpose of risk assessment is to assess the degree of probability of a certain product or procedure having adverse effects on human health and the seriousness of any such adverse effects;
- the level of risk which the EU institutions have to determine is the “critical probability threshold for adverse effects on human health and for the seriousness of those possible effects”;
- even if the institutions may not take a purely hypothetical approach, neither do they have to ensure the highest technically possible level of human health protection. Levels of risk are decided on a case-by-case basis;
- scientific risk assessment must be carried out before any preventive measures are taken;
- “scientific risk assessment” means the identification and characterisation of a hazard, the assessment of exposure to the hazard and the characterisation of the risk;
- scientific advice must be based on the best scientific information available and the most recent results of international research. It must also be based on the principles of excellence, independence and transparency;

- the fact that full scientific risk assessment may be a lengthy process does not prevent public authorities from taking preventive measures when these appear essential given the level of risk to human health which the authority has deemed unacceptable for society. The public authorities must have considerable discretion in managing that “balancing exercise”;
- in their decision-making, the EU institutions enjoy a broad discretion, in particular to determine a level of risk deemed unacceptable for society. This discretion extends to the establishment of the factual basis of its action;
- judicial review must be limited. The courts are not entitled to substitute their assessment of the facts for those of the Community institutions. The courts are confined to checking whether the exercise of discretion is vitiated by a “manifest error or misuse of powers”;
- the Community institutions must “examine carefully and impartially all the relevant aspects of the individual case”, respecting the principles of excellence, transparency and independence;
- the Community institutions are not bound by the scientific opinion given by the scientific committee (e.g. the Scientific Committee for Animal Nutrition). The EU institutions can “assess the value of the opinion delivered by the committee to check that their reasoning is full, consistent and relevant”. If the Community institution disregards the opinion it must provide specific reasons in order to compare its decision with that of the committee. The statement of reasons must be on a scientific level at least commensurate with that of the opinion in question;
- if the Community institutions withdraw authorisation from an additive without first having obtained a scientific opinion from the competent scientific committees, this must only happen in exceptional circumstances and where there are “adequate guarantees of scientific objectivity that the Community institutions may, when they are required to assess particularly complex facts of a technical or scientific nature, adopt a preventative measure withdrawing an authorisation without obtaining an opinion from the scientific committee”;
- the Community Courts are not entitled to assess the merits either of the scientific points of view argued before them and to substitute their assessment for that of the Community institutions. The test is whether the Community institutions could “reasonably take the view that they had a proper scientific basis for a link between the use of the additive and the likely development of an adverse reaction in humans”;

- the principle of proportionality requires the least restrictive measure to be adopted;
- the Community institutions enjoy the powers set out above even if their use provokes adverse economic consequences and even substantial adverse consequences for certain traders. The protection of public health takes precedence over economic circumstances.⁴⁷

Food safety: the European Food Safety Authority

56. Regulation (EC) No 178/2002 as amended by Regulation (EC) No 1642/2003 and Regulation (EC) No 575/2006 provides the main legal basis for the governance of food safety in the EU. It formally established the European Food Safety Authority (EFSA based in Parma, Italy) along with a Standing Committee (the Committee) on the Food Chain and Animal Health (SCFCAH). They work alongside the National Authorities and the Commission to ensure that unsafe food is not placed on the internal market and thereby achieving a high level of public health. Moreover, Regulation 178/2002 envisages an integrated way to achieve this purpose that encompasses public and business operator participation.
57. The EFSA is endowed with a separate legal personality. The main responsibilities of the EFSA include, *inter alia*, providing independent scientific advice on food safety and other related matters such as animal health and welfare, plant health, GMOs, providing opinions on technical food issues in order to shape policies and legislation relating to the food chain, assisting the Commission in emergencies by providing scientific advice within ad hoc crisis management units and establishing a permanent dialogue with the general public to keep it informed of potential or emerging risks.
58. The Standing Committee is made up of representatives of the Member States and is chaired by a representative of the Commission. The Committee's mandate covers the entire food supply chain. With regard to procedural matters, the Commission may adopt the implementing measures only if they obtain a favourable opinion from the Committee, given by a qualified majority of the Member States. Failing that, the proposed measure is referred to the Council, which takes a decision by a qualified majority. However, if the Council fails to reach a decision, the Commission adopts the implementing measure unless the Council opposes it by a qualified majority.
59. Article 53 of Regulation (EC) No 178/2002 provides for an emergency procedure to allow the Committee to intervene by taking certain measures. For example, in emergencies the Commission may provisionally adopt measures after consulting the Member States concerned and informing the other Member States. As soon as possible, and at most within ten working days, the measures taken are confirmed, amended, revoked or extended in accordance with the regulatory procedure explained above, and the reasons for the Commission's decision are made public without delay. The Committee may also examine any issue falling under Community

⁴⁷ See further, I. Forrester, The Dangers of too much precaution; in A True European (Essay for Judge David Edward), 2004.

provisions, either at the initiative of the Chairman or at the written request of one of its members.

Other EU bodies in the food law area

60. Other important regulatory bodies in the area of EC Food law include the Food and Veterinary Office (FVO) which is responsible for monitoring Member States' and third countries' compliance with Community veterinary, phytosanitary and food hygiene legislation, thus helping to maintain consumer confidence in the safety of food products. To this end, the FVO performs audits, controls and inspections *in situ* to check whether the safety and food hygiene regulations are being observed along the entire production chain, either in Member States themselves or in countries that export to the EU. It then passes on its findings and recommendations to the national and Community authorities and the general public. Lastly, the Scientific Committee for designations of origin, geographical indications and certificates of specific character assists the Commission in the examination of all the technical problems involved in the recording of names of agricultural products and foodstuffs and of disputes between the Member States.

A general Regulation on food law, following the Green and White Papers of 1997 and 2000

61. Regulation 178/2002 lays down general principles and requirements of food law, establishes the European Food Safety Authority (EFSA) and lays down procedures in matters of food safety. This general Directive is based on Articles 37 (the basic Treaty provision on the common agricultural policy), 95 (the basic Treaty provision on Single Market legislation and including Article 95(3) requiring a high level of protection for health, safety, the environment and consumers), 133 (the common commercial policy) and 152(4)(b) (protection of public health in the veterinary and phytosanitary fields). This Directive was not based on the public health or consumer protection provisions. Regulation 1829/2003 on genetically modified foods and feed has precisely the same legal base, with the exception of the external trade provision in Article 133.
62. Regulation 178/2002 is the culmination of a process starting in 1997 with the Green Paper, followed by the White Paper on Food Safety in 2000⁴⁸ and leading to Regulation 178/2002. The Regulation is clearly an important “horizontal” measure, particularly as regards procedures applicable in the food law area. Thus, the Regulation contains both substantive and procedural provisions, including:
- general principles of food law (general objectives, risk analysis, precautionary principle, protection of consumers’ interests, transparency, general obligations of the food trade, food and feed safety requirements, traceability, responsibility and liability);
 - the European Food Safety Authority’s missions and tasks, organisation and operations including the drawing up of scientific studies and the

⁴⁸ COM(1999) 719 final.

provision of scientific and technical systems, the rapid alert system, independence, transparency, confidentiality and communication;

- a rapid alert system, crisis management and emergencies.

63. The Regulation calls for a number of comments as follows:

- (i) appropriately, the measure is a “Regulation” rather than “Directive” and does not require transposition into national law;
- (ii) the Regulation recognises the need for the free movement of safe and wholesome food as an essential aspect of the internal market, but also the need to ensure a high level of protection of human life and health;
- (iii) it recognises that significant differences still exist between national food laws and that a transitional period is necessary for these to be eliminated;
- (iv) the measure recognises the need for new procedures at Community level to identify and respond to food safety problems and establishes the European Food Safety Authority (EFSA), as well as the Standing Committee on the food chain and animal health for this purpose;
- (v) the Regulation does not replace the existing case law of the European Courts, nor does it in any way codify existing horizontal and (above all) vertical measures;
- (vi) despite this overarching measure, EC food law remains voluminous and disperse in many legal texts (see the annex to this paper for a summary of the key legislative measures, as well as the key cases decided by the European Courts in the area of food law).

Recent European Court case law in the area of food law

64. Despite attempts to systematise and (to a certain extent) consolidate EC food law (or at least to rationalise it), a significant number of important cases have been decided by the European Courts in the last few years. The fact that these cases almost all involve “re-visiting” the underlying principles in the *Cassis de Dijon* case law demonstrates the continuing sensitivity of food law for Member States and the fact that considerable doubt continues to exist “at the margins”, as regards the scope of Member States’ discretion in restricting imports.

65. Some of the more important of these are as follows.

The Kellogg's cornflakes case⁴⁹

66. The Netherlands prohibited marketing of Kellogg's breakfast cereals fortified with vitamin D and folic acid and energy bars fortified with folic acid manufactured by Inkosport Nederland. The Commission brought an action against the Netherlands under Article 226 EC on the grounds that these measures were contrary to Article 28 and not justified under Article 30 EC. The Commission said that the Dutch scheme for derogating from the market prohibition went beyond (i.e. was too difficult to obtain) what was necessary for health protection in that it required both that the addition of micro-nutrients not be harmful and that they met an actual nutritional need. The Court was asked to rule exclusively on this latter point and not on the legality of the prohibition/derogation system as a whole.
67. The Court found that the Dutch administrative practice which allowed these products to be marketed only if their enrichment met a nutritional need in the Netherlands' population and without ascertaining whether the fortified foodstuffs may be a substitute for foodstuffs already marketed for which the addition of these nutrients is mandatory, was in breach of Article 30 (now Article 28 EC). The Court noted that, although vitamins and minerals are not as a general rule harmful in themselves, they may have special harmful effects if taken to excess as part of the general nutrition, the composition of which cannot be foreseen or monitored. Thus, the fact that foodstuffs may be fortified with a nutrient does not mean they are free of risk. In practice, the Dutch authorities always insisted on the need to prove the existence of an actual nutritional need. Both parties agreed that Netherlands practice was a measure having equivalent effect to a quantitative restriction under Article 28 EC. Imports were likely to suffer particularly under the Dutch law, given the need to prove nutritional need.
68. The Court paid particular attention to the Dutch justification of the need to protect public health. The Court accepted that, in the absence of harmonisation and if doubts existed under the current state of scientific research, Member States had a wide discretion to require prior authorisation for marketing of foodstuffs. The Court held therefore (para. 44) that "*Community law does not preclude legislation of the Member State prohibiting in accordance with the precautionary principle, save for prior authorisation, the marketing of foodstuffs when nutrients other than those whose addition is lawful under that legislation have been added thereto.*" In analysing the precautionary principle and referring to its earlier case law (para. 45), the Court cited Articles 174 EC (environmental protection) and 152 EC (public health), both Articles containing the need to protect human health.⁵⁰ Nonetheless, in exercising their discretion, Member States must respect the principle of

⁴⁹ Case C-41/02 *Commission v Netherlands*.

⁵⁰ See, to that effect, Case C-157/96 *National Farmers' Union and Others* [1998] ECR I-2211, paragraphs 63 and 64; Case C-236/01 *Monsanto Agricoltura Italia and Others* [2003] ECR I-8105, paragraphs 128 and 133; *Commission v Denmark*, paragraph 49; and *Commission v France*, paragraph 56; see also, to that effect, Case T-13/99 *Pfizer Animal Health v Council* [2002] ECR II-3305, paragraphs 139 and 140; Case T-70/99 *Alpharma v Council* [2002] ECR II-3495, paragraphs 152 and 153; and Case T-177/02 *Malagutti-Vezinhet v Commission* [2004] ECR II0000, paragraph 54.

proportionality, i.e. measures must be confined to “what is actually necessary to ensure the safeguarding of public health”.

69. The measures must be proportional to the objective pursued, which could not have been attained by measures which are less restrictive of intra-Community trade. Article 30 EC is an exception to fundamental Treaty rules and thus must be interpreted strictly. It is for national authorities which invoke it to show “in the light of national nutritional habits and in the light of the results of international scientific research” that their rules are necessary to give effective protection to the interests referred to in that provision and, in particular, that the marketing of the products in questions poses a real risk for public health.
70. The prohibition on marketing therefore has to be based on “*a detailed assessment of the risk alleged by the Member State.*” A decision to prohibit marketing of a fortified foodstuff can only be adopted “*if the real risk for public health alleged appears sufficiently established on the basis of the latest scientific data available at the date of adoption of the decision.*” The national authorities must appraise “*the degree of probability of harmful effects on human health from the addition of certain nutrients to foodstuffs and the seriousness of those potential effects.*” In this context, “*it could be appropriate to take into consideration the cumulative effects of the presence on the market of several sources, natural or artificial, of a particular nutrient and of the possible existence in the future of additional sources which can reasonably be foreseen*”.
71. The Court accepted that the assessment of these factors will involve uncertainty in science and in practice. Uncertainty is inseparable from the precautionary principle and affects the scope of the Member States’ discretion and the manner in which the precautionary principle is applied. Thus, a Member State may take protective measures without having to wait until the existence and gravity of those risks become apparent.⁵¹ The risk assessment cannot however be based on purely hypothetical considerations.⁵²
72. The Court held that:

“A proper application of the precautionary principle requires, in the first place, the identification of the potentially negative consequences for health of the proposed addition of nutrients and, secondly, a comprehensive assessment of the risk for health based on the most reliable scientific data available and the most recent results of international research.”

Crucially, the Court continues that:

“Where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm

⁵¹ See Case C-157/96 *National Farmers' Union and Others* [1998] ECR I-2211.

⁵² See Case C-236/01 *Monsanto Agricoltura Italia and Others* [2003] ECR I-8105.

to the public health persist should the risk materialise, the precautionary principle justifies the adoption of restrictive measures." (emphasis added)

The Court concluded, in condemning the Netherlands, that:

"By applying an administrative practice under which foodstuffs for everyday consumption fortified with vitamins A and D, etc. ... lawfully produced and marketed in other Member States, may be marketed in the Netherlands when they are neither substitution products nor reconstituted foodstuffs, only if that enrichment meets a nutritional need in the Netherlands population and, in addition, without ascertaining whether those fortified foodstuffs might be a substitute for foodstuffs already marketed for which the addition of those nutrients is mandatory, the Netherlands has failed to fulfil its obligations under Article 30 [28] EC." (emphasis added)

The food supplements case⁵³

73. Directive 2002/46 prohibits with effect from 1 August 2005 the marketing of foodstuffs which do not comply with Annex I and II of the Directive. The claimants, a European-wide association of manufacturers of food supplements, maintained that the provisions of Article 3 in conjunction with Article 4(1) and Article 15(b) of Directive 2002/46 were incompatible with Community law and consequently void. The claimants challenged the inadequacy of Article 95 as the legal basis of the Directive and further asserted that the Directive infringed the general principles of subsidiarity, proportionality and equal treatment.
74. AG Geelhoed found that Directive 2002/46/EC infringed the principle of proportionality. The Directive did not state clearly whether private parties could submit substances for evaluation with a view to having them included in the positive lists (Annex II) and failed to provide a minimum guarantee for protecting private parties' interests.
75. The Court, however, did not follow the opinion of AG Geelhoed and reasoned at paragraph 68 that:

"in view of the need for the Community legislature to take account of the precautionary principle when it adopts, in the context of the policy on the internal market, measures intended to protect human health (see, to that effect, Case C-157/96 National Farmers' Union and Others [1998] ECR I-2211, paragraph 64, and Case C-180/96 United Kingdom v Commission [1998] ECR I-2265, paragraph 100, and Case C-41/02 Commission v Netherlands [2004] ECR I-0000, paragraph 45), the authors of Directive 2002/46 could reasonably take the view that an appropriate way of reconciling the objective of the internal market, on the one hand, with that relating to the protection of human health, on the other, was for entitlement to free movement to be reserved for food supplements containing substances about which, at the time

⁵³ Case C-154/04 and C-155/04 *Alliance for Natural Health and Others*. Judgment 12/7/2005.

when the directive was adopted, the competent European scientific authorities had available adequate and appropriate scientific data capable of providing them with the basis for a favourable opinion, whilst giving scope, in Article 4(5) of the directive, for obtaining a modification of the positive lists by reference to scientific and technological developments. (emphasis added)

76. The Court ruled that Articles 3, 4(1) and 15(b) of Directive 2002/46 (i.e. the use of positive lists) were appropriate measures for achieving the prevention of marketing of foodstuffs that do not comply with the Directive. The obligation of the Community legislature to ensure a high level of protection of human health did not go beyond what was necessary to achieve that objective.

The *De Groot en Slot Allium* case⁵⁴

77. In its judgment of 10 January 2006, the ECJ had to consider whether a type of shallot produced in the Netherlands and placed on a “positive list” under Community Directives 92/33 and 70/458 could be blocked by the French authorities, either under the Directives or under Article 30 EC. The ECJ held (para 66) that the shallots in question had not been properly registered on the list under Directive 70/458 by the Dutch authorities. The Court examined Directives 70/458 and 92/33 together. As far as Article 28 EC was concerned however, without the French referring court having raised the issue, the ECJ held that Article 28 EC precluded national rules such as that enacted by France.
78. The Court noted (para 74) that an obligation imposed on producers to use unknown or less well-known denominations in another market was liable to make the marketing of these products⁵⁵ more difficult and therefore to constitute a barrier to the free movement of goods (*Commission v Spain*⁵⁵). The ECJ added (para 75) that such barriers could be accepted if they were “*necessary to satisfy “mandatory requirements” or “exigences imperatives”*”.
79. Thus, Member States have a right to check that consumers are properly informed about products, in order to choose their products as a result of this information. Member States can therefore insist that traders modify their denomination of a food product when a product presented under a certain denomination is so different, from the point of view of its compositions and manufacture, from products generally known under the same denomination in the Community and which could not be considered as falling into the same category. On the other hand, where minor differences occur, normal labelling ought to be sufficient to provide the necessary information for the consumers.
80. In the present case, the differences between traditional shallots and those grown in the Netherlands essentially had to do with their method of reproduction. Otherwise, the two types were very similar in their external appearance. Thus, appropriate labelling could clarify the matter for the consumer. The French measure therefore went too far and was disproportionate.

⁵⁴ Case C-147/04.

⁵⁵ Case C-12/00.

The Lidl Italia case⁵⁶

81. This case is interesting because *Cassis de Dijon* (the “classic” case in the food law sector and indeed in EC internal market law more generally) was a case about the alcoholic strengths of certain beverages and whether differences in alcoholic strengths justified restrictions on marketing. In this case, the ECJ held that no breach of EC law was involved where a Member State punished an importer for marketing an alcoholic product with an inaccurate statement on the product label of the alcoholic strength by volume of the product. This decision was based on Articles 2, 3 and 12 Directive 2000/13 on the labelling, presentation and advertising of foodstuffs.
82. The key issue in this case was whether Lidl (the distributor in Italy) which had no means of checking the alcoholic strength of the product packaged abroad) could be made liable for the distribution of the product. The Court held that the Italian legislation, imposing liability on distributors as well as on producers, was within the scope of Directive 2000/13. The ECJ clearly took into account the primary need for consumer protection in holding that the responsibilities of operators in the food sector should cover every stage of the production, processing and distribution of the goods, this extending to as wide a field of operators as possible.

The Ahokainen case⁵⁷

83. This case concerned a criminal prosecution in Finland for the illegal import of ethyl alcohol. The Finnish Court asked the ECJ for an interpretation of Articles 28 and 30 EC, as to whether a licensing requirement for the import of alcohol into Finland was caught by Article 28 and, if so, could be justified under Article 30. The ECJ referred (interestingly) to its *Cassis de Dijon* and *Keck and Mithouard* case law in holding that:
- all trading rules enacted by Member States which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade must be considered to be measures having an effect equivalent to quantitative restrictions and thus prohibited by Article 28. Even rules applied without distinction to domestic and imported products, the application of which to imported products is likely to reduce their sale volume, constituted in principle measures having equivalent effect prohibited by Article 28 EC;
 - nonetheless, national provisions restricting or prohibiting certain selling arrangements that, first, apply to all relevant traders operating within the national territory and, second, affect in the same manner, in fact and in law, the marketing of domestic products and those from other Member States are not liable to hinder, directly or indirectly, actually or potentially, trade between Member States within the meaning of the case law initiated by *Dassonville*;

⁵⁶ C-315/05.

⁵⁷ C-434/04.

- more particularly, as regards prior import authorisations, the ECJ has ruled that national provisions which require, even as a pure formality, import licenses or any other similar procedure are in principle contrary to Article 28 EC;
- this is particularly so where such a system adds to the costs of these goods (see *Franzen*⁵⁸) because in such cases there is more than “mere” restriction or prohibition of certain selling arrangements.

84. The finding of the Court in this case (where the ECJ clearly wanted the Finnish courts to determine the proportionality issue against the facts of the particular case) was that:

“Articles 28 and 30 EC do not preclude a system, such as that laid down by the law on alcohol, which makes the importation of un-denatured ethyl alcohol of an alcoholic strength of more than 80% subject to obtaining prior authorisation, unless it appears that, in the circumstances of law and of fact which characterise the situation in the Member State concerned, the protection of public health and public order against the harm caused by alcohol can be secured by measures having less effect on intra-Community trade.”

85. This is an interesting example of the ECJ setting out and confirming existing principles, but leaving the national court to apply Community law on the facts.

The *Commission v Denmark*⁵⁹ case

86. This case involved Danish restrictions on “enriched foodstuffs” lawfully produced or marketed in other Member States. Denmark sought to allow imports of these products with added nutrients only when they meet a need in the Danish population – a form of “host country control” or a reversal of the doctrine in *Cassis de Dijon*. The ECJ held that such practice was in breach of Article 28 EC.

87. The case arose through a complaint made to the Commission by an economic operator. The Commission followed the normal Article 226 procedure. The Danish authorities relied on the *Sandoz*⁶⁰ case as regards the test under Article 30 for restricting imports. The Commission insisted that the Danish authorities would have at least to outline the scientific data upon which they based their refusal of authorisation, as well as the reasons why the vitamin and mineral content of the relevant products represents a threat to public health.

88. For the Commission, the absence of nutritional need, is not in itself a justification under Article 30. General preoccupations relating to a desired composition of the nutritional regime of the population of a State cannot constitute a lawful justification for obstacles to trade. The Commission said that the *Sandoz* case was authority for

⁵⁸ C-189/95.

⁵⁹ Case C-192/01.

⁶⁰ Case C-174/82.

the proposition that two particular vitamins in the products in question were found to pose a risk to public health. The Commission said that the paragraph in *Sandoz*, to the effect that a prohibition on marketing food stuffs to which vitamins have been added is contrary to the principle of proportionality when the addition meets a nutritional need, cannot be argued a contrario to say that when there is no nutritional need then the addition of vitamins poses a risk to public health and therefore justifies a restriction on trade.

89. The Commission relied on *EFTA Surveillance Authority v Norway*⁶¹ to the effect that a mere finding of the absence of a nutritional need is not enough to justify a general prohibition on food stuffs enriched with vitamins or minerals. The effect on human health had to be demonstrated by a detailed analysis of the risks (i.e. scientific data).
90. In its ruling, the ECJ sets out the fundamental principles under Articles 28 and 30 referring particularly to *Dassonville*⁶² the German beer case and *Commission v Spain*⁶³. In this case, the dispute was on Article 30 not Article 28, since it was admitted that the Danish measure constituted a restriction. The ECJ said (para 42):

“In default of harmonisation and to the extent that uncertainties continue to exist in the current state of scientific research [it is for Member States] to decide on their intended level of protection of human health and life and on whether to require prior authorisation for the marketing of food stuffs, always taking into account the requirements of the free movement of goods within the Community.”

91. The ECJ went on that the discretion of the Member States is “particularly wide” where it is shown that uncertainties continue to exist in the current state of scientific research as to certain substances such as vitamins. But in exercising their discretion, Member States have to comply with the principle of proportionality (para 45). Therefore they have to choose measures which are “actually necessary” and “proportional to the objective pursued” and “which could not have been obtained by measures which are less restrictive in the area of intra-Community trade”. Article 30 is to be interpreted strictly, as a derogation from a fundamental principle. National authorities therefore have to demonstrate, in the light of national nutritional habits and in the light of the results of international scientific research that their rules are necessary to give effective protection to the interests referred to in Article 30 and to demonstrate that the marketing of the products poses a real risk to public health. The ECJ concluded that (para 47):

“A prohibition on the marketing of food stuffs to which nutrients have been added must therefore be based on a detailed assessment of the risk alleged by the Member State in invoking Article 30. The risk must be sufficiently established on the basis of the latest scientific data available at the date of adoption of such decision (para 48).”

⁶¹ EFTA Court Report 2000/01.

⁶² Case C-178/84.

⁶³ Case C-12/00.

92. The ECJ also dealt in some detail with the precautionary principle. It stated that “in accordance with the precautionary principle” a Member State may take protective measures without having to wait until the reality and seriousness of the risks are fully demonstrated but, a risk assessment must not be made on purely hypothetical considerations”.
93. Referring to the *National Farmers Union*⁶⁴ case and the *Monsanto*⁶⁵ cases, the Court allowed, so far as scientific evidence is concerned, not only the assessment of an individual product with a definite quantity of nutrients but also “the cumulative effect of the presence on the market of several sources, natural or artificial, of a particular nutrient and of the possible existence in the future of additional sources which can reasonably be foreseen”.
94. The ECJ accepted that in such cases there may be “a high degree of scientific and practical uncertainty”. The proper application of the precautionary principle presupposes “the identification of the potentially negative consequences for health of the proposed edition of nutrients and secondly a comprehensive assessment of the risk to health based on the most reliable scientific data available and the most recent results of international research”. If such data is insufficient, inclusive or imprecise, then protective measures can still be taken provided they are non-discriminatory and objective. The criterion of “nutritional need of the population” can play a role in the detailed assessment by that Member State of the risk posed by nutrients for public health. However, the absence of a need in a particular population for a particular nutrient cannot “by itself justify a total prohibition”. The Danish measures in the present case were therefore disproportionate.

The *Rosengren* case⁶⁶

95. It is remarkable that, in 2007, both the ECJ and the EFTA Court were still examining the scope and effect of Articles 28 and 30 EC in the food and beverage sector. This reflects the sensitivity of many aspects of trade in these products and the difficulty in distinguishing restrictive measures taken genuinely on health grounds, from those which (intentionally or otherwise) protect national producers or monopolies. The *Rosengren* case concerned orders for wine placed by individuals in Sweden with producers in Spain. The imports were confiscated by the Swedish customs authorities. The case raised the issue whether the Swedish ban on direct imports for private individuals could fall within the retail monopolies manner of operation and therefore was not in breach of Article 28 EC but rather should be examined under Article 31 EC. The issue also arose as to whether any such ban could be considered justified and proportionate in order to protect health and life of humans. As far as the operation of the monopoly is concerned, the ECJ confirmed (para. 17) that this had to be considered under Article 31 EC and related case law (the latest case being *Franzen*⁶⁷).

⁶⁴ Case C-157/96.

⁶⁵ Case C-236/01.

⁶⁶ C-170/04 (judgment of 5 June 2007).

⁶⁷ C-189/95.

96. The effect on intra-Community trade was to be considered under Article 28 EC (also in accordance with *Franzen*). Because imports were excluded from the monopolies' function, the ECJ held (para. 22) that the issue of imports (and controls on imports) did not “relate to the very existence of that monopoly”. On the other hand, the fact that the Swedish law “channelled consumers who wished to acquire beverages toward the monopoly” meant that this was “liable to affect the operation of that monopoly”. However, since the Swedish law did not “relate to the methods of retail sale of alcoholic beverages on Swedish territory”, the ban “cannot be regarded as constituting a rule relating to the existence or operation of the monopoly”. Therefore, Article 31 EC was irrelevant in the present case. Only Article 28 EC was therefore applicable.
97. The Court recalled that Article 28 is a fundamental principle of the Treaty⁶⁸ and referred to the “classic” case law of *Dassonville* and cases decided under it (see in particular *Commission v Denmark*⁶⁹). As far as justification under Article 30 is concerned, the ECJ noted (para 39) that the health and life of humans ranked foremost among the assets or interests protected by Article 30 EC and it is for the Member States, within the limits imposed by the Treaty, to decide what degree of protection they wished to assure (*Deutsche Apoteker Verband*⁷⁰). The Court then referred to its case law on controlling trade in alcoholic products to prevent the harmful effects caused to the health of humans and society (including alcohol abuse), in particular *Ahokainen and Leppik*.⁷¹
98. The ECJ noted that there was no discriminatory intent or effect in the Swedish legislation or its implementation (*Gourmet International Products*⁷²). The ECJ also said (para 43) that the least restrictive method of achieving the policy goal must be used. The Swedish government invoked the “general need to limit the consumption of alcohol”. The Court found in this respect (para 47) that:
- “in the light of the alleged objective of limiting generally the consumption of alcohol in the interests of protecting the health and life of humans, that prohibition, because of the rather marginal nature of its effects in that regard, must be considered unsuitable for achievement of that objective.”*
99. As far as the protection of young people is concerned, the ECJ said that any derogation from Article 28 EC had to be interpreted restrictively and it was for the Member States to show that their rules were consistent with the principle of proportionality, i.e. necessary to achieve the declared objective and that that objective could not be achieved by less extensive prohibitions or restrictions or ones which had less effect on intra-Community trade. The ECJ held (para 51) that the Swedish measure went “manifestly beyond what is necessary for the objective sought”. The Court’s conclusion therefore (para 58) was that the Swedish measure:

⁶⁸ Case C-147/04 *De Groot en Slot Allium*.

⁶⁹ Case C-192/01.

⁷⁰ Case C-322/01.

⁷¹ Case C-434/04.

⁷² Case C-405/98.

- is unsuitable for obtaining the objective of limiting alcohol consumption generally;
- it is not proportionate for obtaining the objectives of protecting young persons against the harmful effects of such consumption; and
- could not be justified under Article 30 on the grounds of protection of health and life of humans.

New legislation on organic food

100. On 28 June 2007, the Council adopted a new Regulation⁷³ to further the development of Europe's organic food sector. In 2005, in the European Union of 25 Member States, around 6 million hectares were either farmed organically or were being converted to organic production. This marks an increase of more than 2 per cent compared with 2004. Over the same period, the number of organic operators grew by more than 6 percent.
101. The new regulation:
- lays down more explicitly the objectives, principles and production rules for organic farming while providing flexibility to account for local conditions and stages of development,
 - assures that the objectives and principles apply equally to all stages of organic livestock, aquaculture, plant and feed production as well as the production of organic foods,
 - clarifies the GMO rules, notably that GMO products continue to be strictly banned for use in organic production and that the general threshold of 0.9 percent accidental presence of approved GMOs applies also to organic food, close the loophole under which the unintended presence of GMOs above the 0.9 percent threshold does not currently preclude the sale of products as organic,
 - renders compulsory the EU logo for domestic organic products, but allow it to be accompanied by national or private logos in order to promote the "common concept" of organic production,
 - does not prohibit stricter private standards,
 - ensures that only foods containing at least 95 percent organic ingredients can be labelled as organic,
 - allows non-organic products to indicate organic ingredients on the ingredients list only,

⁷³ Regulation (EC) No 834/2007 Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 OJ L 189/1 20.7.2007.

- does not include the restaurant and canteen sector, but allow Member States to regulate this sector if they wish, pending a review at EU level in 2011,
- reinforces the risk-based control approach and improve the control system by aligning it to the official EU food and feed control system applying to all foods and feeds, but maintaining specific controls used in organic production,
- sets out a new, permanent import regime, allowing third countries to export to the EU market under the same or equivalent conditions as EU producers,
- requires the indication of where the products were farmed, including for imported products carrying the EU-logo,
- creates the basis for adding rules on organic aquaculture, wine, seaweed and yeasts,
- makes no changes to the list of permitted substances in organic production, and requires publication of demands for authorisation of new substances and a centralised system for deciding on exceptions,
- contains detailed rules from the old Regulation, including amongst others the lists of substances, control rules and other detailed rules.

The impact and legal status of genetically modified organisms (GMOs) in EU law

102. Genetically modified organisms (GMOs) can be defined as organisms in which the genetic material (DNA) has been altered in a way that does not occur naturally by mating or natural recombination. The most common types of GMOs that have been developed and commercialised are genetically modified crop plant species, such as genetically modified maize, soybean, oil-seed rape and cotton varieties.
103. EU legislation that has been in place since the early 90s has two main objectives:
 - to protect human health and the environment; and
 - to ensure the free movement of safe genetically modified products in the European Union.
104. Directive 2001/18/EC on the deliberate release into the environment of GMOs. This Directive applies to two types of activities:
 - the experimental release of GMOs into the environment; and
 - the placing on the market of GMOs.
105. The first activity is influenced by the principles for environmental risk assessment. Companies must obtain written authorisation from the competent national authority. The second activity concerns a company intending to market a GMO. Unlike the

authorisation for the first activity, the second involves all Member States. The application or notification is first submitted to the competent national authority. That body will issue an opinion (in the form of an assessment report). If that is unfavourable, the company may submit a new notification in another Member State. In the event of a favourable opinion the national authority informs the other Member States via the Commission. They may issue observations and objections. If that is the case, a decision must be taken at a European level. The Commission asks for the opinion of the EFSA. It then presents a draft decision to the regulatory committee composed of representatives of the Member States for an opinion. If approved by QMV, the Commission adopts the decision. If not, the draft decision is submitted to the Council of Ministers for adoption or rejection by QMV.

106. An important aspect of this Directive and the second activity is that Member States may invoke a 'safeguard clause' whereby it may provisionally restrict or prohibit the use/sale of that product in its territory. e.g. January 2005, Hungary invoked the safeguard clause in order to prohibit the cultivation of MON 810 maize in its territory.
107. The Directive also requires that applications for authorisation must be accompanied by a full health and environmental risk assessment, detailed information on the GMO, its release conditions, interaction with the environment, monitoring, waste and contingency plans, labelling and packaging proposals. The level of appropriate health and environmental protection chosen in this Directive is a level of 'no risk'.
108. The authorisation process is based on the precautionary principle⁷⁴. Consequently, it is the applicant who has to demonstrate the 'safety' or 'lack of harm' of each individual product.

Regulation 1829/2003 EC on genetically modified food and feed

109. This applies to applications for the placing on the market in the territory of the EU of GMOs for food and feed use and food and feed containing GMOs, consisting of such organisms or produced from GMOs (in the Regulation these are called: "genetically modified food" and "genetically modified feed"). The Regulation provides that the relevant products must not have adverse effects on human or animal health, or the environment and moreover must not mislead the consumer or user.
110. The Regulation puts in place a centralised, uniform and transparent EU procedure for all applications for placing on the market, whether they concern the GMO itself or the food and feed products derived therefrom. The Regulation furthermore provides a 'one door, one key' principle whereby business operators may file a single application for the GMO and all its uses (authorised by the EFSA subject to a single risk assessment process and a single risk management process involving the Commission and the Member States through a regulatory committee procedure). A split application under Directive 2001/18 and Regulation 1829/2003 is also possible.

⁷⁴ Article 8 of the Preamble of the Directive.

Regulation 1830/2003 EC on labelling and traceability of GMO products

111. The general objectives are to facilitate:
- control and verification of labelling claims;
 - targeted monitoring of potential effects on health and the environment, where appropriate; and
 - withdrawal of products that contain or consist of GMOs where an unforeseen risk to human health or the environment is established.
112. Regulation 1830/2003 covers all GMOs that have received EU authorisation for their placing on the market. Traceability provides the means to trace products through the production and distribution chains. The traceability rules oblige the operator to identify their supplier and the companies to which the products have been supplied. The traceability requirements vary depending on whether the product consists of or contains GMOs (Article 4) or has been produced from GMOs (Article 5).
113. With regard to labelling, the overriding intention is to allow consumers the ability to make informed choices. The Regulation requires that operators indicate on a label “This product contains genetically modified organisms” or “This product contains genetically modified [(name of organism(s))]”. Regulation 1829/2003 lays down specific labelling requirements for genetically modified food and feed. Besides these specific labelling requirements, GM food is subject to the labelling requirements as provided for Directive 2000/13 concerning the labelling, presentation and advertising of foodstuffs.
114. Conventional products (products created without recourse to genetic modifications) that are accidentally contaminated by GMOs during harvesting, storage, transport or processing are not subject to traceability and labelling requirements if they contain traces of these GMOs below a limit of 0.5- 0.9% as set out in Regulation 1829/2003 (Article 47 & Article 12) provided the presence of this material is adventitious or technically unavoidable.
115. The Commission’s in-house research centre (Joint Research Centre-JRC) provides scientific support for EU legislation on traceability and cultivation and consumption of GMOs.
116. On 12 April 2006 the Commission gave its support to an approach proposed by Commissioners Kyprianou and Dimas on further steps to improve the scientific consistency and transparency for decisions on GMOs⁷⁵. The Commission proposed different practices that could be implemented during the scientific evaluation phase: EFSA could be invited to liaise more with national scientific bodies and the Commission will fully exercise its regulatory competences foreseen in the basic

⁷⁵ Press Release, Brussels 12 April 2006, IP/06/498.

legislation to specify the legal framework in which the EFSA assessment is to be carried out.

117. The Commission also suggested changes in the decision-making phase. The Commission will address specific risks identified in the risk assessment or substantiated by Member States by introducing, on a case by case basis, additional proportionate risk management measures in draft decisions to place GMO products on the market, as appropriate. Lastly, where in the opinion of the Commission a Member State's observation raises important new scientific questions not properly or completely addressed by the EFSA opinion, the Commission may suspend the procedure and refer the question back for further consideration.
118. In *Austria v Commission*⁷⁶, Austria challenged a Commission decision which refused the applicant Member State permission to derogate from legislation harmonising GMO authorisation in the EU. Austria wished to create a GMO-free zone in its upper Province⁷⁷ and claimed that Article 95(5) EC entitled it to do so.
119. Under Article 95(5) EC, a Member State could notify the Commission if it wishes to introduce new national measures based on '*new scientific evidence or on... grounds of a problem specific to a Member State arising from the adoption of the harmonisation measure...*'. The applicants notified the Commission of their new measure. The notification was intended to secure, on the basis of Article 95(5) EC, a derogation from Directive 2001/18/EC. The CFI held that the notified measure did not meet the requirements of Article 95(5). The applicants also referred to the 'precautionary principle'⁷⁸ to justify their argument that the notified measure was a preventive action within the meaning of Article 174(2) EC. However, since the requirements of Article 95(5) EC were not met, the CFI did not expand on the precautionary principle⁷⁹.

Rules to protect geographical indications and traditional specialities

120. Since 1992, the Community has had in place two Regulations designed to promote traditional agricultural products and foodstuffs that have specific characters linked either to their geographical origin or to their production method. The two Regulations are: Council Regulation (EEC) 2081/92⁸⁰ on the protection of geographical indications (PGI) and designations of origin (PDO) for agricultural products and foodstuffs⁸¹; and Council Regulation (EEC) 2082/92⁸² on certificates

⁷⁶ Joined Cases T-366/03 and T-235/04 judgment of the ECJ 5.10.2005.

⁷⁷ The notified measure was intended to prohibit the cultivation of seed and planting material composed of or containing GMOs and the breeding and release, for the purposes of hunting and fishing, of transgenic animals.

⁷⁸ See *supra* paragraph 38.

⁷⁹ The applicants raised four pleas in law alleging (i) infringement of the right to be heard, (ii) breach of the obligation to state reasons, (iii) infringement of Article 95(5) EC and (iv) breach of the precautionary principle.

⁸⁰ OJ L 208, 24.7.1992 (no longer in force)

⁸¹ Protection consists in reserving the use of PGIs and PDOs for agricultural products and foodstuffs which have been produced and/or processed in the regions or places designated by these names, in accordance with specific conditions concerning their production or processing.

⁸² OJ L 208, 24.7.1992 (no longer in force)

of specific character for agricultural products and foodstuffs⁸³. These Regulations were adopted to ensure that consumers have access to clear information regarding the products they are purchasing. They were also aimed at assisting rural economies by protecting and promoting products that have special characteristics from being copied or imitated. Council Regulation 2081/92 was adopted to provide additional protection for agricultural products or foodstuffs from specified geographical areas⁸⁴.

121. Concerns have been raised that the regime enshrined in Regulation 2081/92 could be seen as a form of protectionism. In October 2003, a WTO dispute panel was established to consider the complaints brought by Australia and the US and to determine whether the EU rules on geographical indications ('GI') are compatible with WTO rules⁸⁵. Against the background of the current WTO negotiations that are focusing on liberalising trade in agricultural products, this case was of interest for many WTO members. The concern stems from the fact that this EU Regulation is not exactly a measure of trade liberalisation as it is viewed as limiting import competition for much of its farm and food sector. The WTO's Dispute Settlement Body adopted the panel report on 20 April 2005⁸⁶.
122. The Panel agreed with the US and Australia that the EU's PDO Regulation does not provide national treatment to other WTO Members' rights holders and products. The Panel held that registration of a GI from a country outside the EU is contingent upon the government of that country adopting a system of GI protection equivalent

⁸³ Foods certified under this scheme may carry the words 'traditional speciality guaranteed' and a standard Community logo to assist consumers to identify products formally covered by the scheme.

⁸⁴ An example of a Decision of the Commission to register as a PDO of a registered agricultural product originating from a specified geographic area can be contested before the ECJ, is the recent Feta cheese' case (Joined Cases *Germany v Commission* C-465/02 and *Denmark v Commission* C-466/02, 25.10.2005). In 1994 the Greek Authorities applied to the Commission for the registration of the name Feta. The Commission after conducting a survey to decide whether 'Feta' had become a generic name or not, it registered Feta as a PDO in 1996. However, as Feta is produced in other Member States, including Denmark and France, the Danish and French Governments opposed the registration and brought an action for annulment of the registration to be annulled under Article 230 of the Treaty. In 1996, the ECJ found that the Commission had not taken into account the fact that the name Feta has been produced for a considerable time in Member States other than Greece. It concluded that the registration of Feta as a PDO should be annulled. In October 1999, the Commission sent a questionnaire to each of the Member States regarding the production and consumption of Feta within their countries and consulted a Scientific Committee on this issue. The Commission then concluded that the designation Feta is not generic because the production and consumption of Feta is heavily concentrated in Greece. Thus, Feta was registered as a PDO in 2002. The ECJ in its 2005 judgment (where Germany and Denmark claimed that the Commission's decision should be overruled) upheld the Commission's decision of 2002 that Feta is a PDO for Greece and that this name may not become generic. The ECJ had run its examination as to whether Feta is a generic name on three levels: (1) the ECJ noted that the production of Feta has remained concentrated in Greece, (2) more than 85% of Community consumption of Feta, per capita and per year, takes place in Greece and (3) Feta is commonly marketed with labels referring to Greek cultural traditions and civilisations.

⁸⁵ Australia and the USA argued that the EU rules violate WTO obligations on national treatment and most favoured nation principle, as it does not allow non-EU countries to register geographic names for protection in the Community unless they offer reciprocal protection for EU geographic names under their national system.

⁸⁶ WTO Panel Reports DS174 and DS290.

WTO Report: http://www.wto.org/english/news_e/news05_e/panelreport_174_290_e.htm

Press Release: http://www.wto.org/english/news_e/news05_e/dsb_20apr05_e.htm#adoption.

to that of the Community and offering reciprocal protection to the EU's PGIs/PDOs. In addition, the Regulation requires applications and objections from other WTO Members to be examined and transmitted by the governments of those Members, and requires those governments to operate systems of product inspection similar to EU Member States.

123. The Panel agreed with the EU that, although its PGI/PDO Regulation allows it to register GIs even when they conflict with a prior trademark, the Regulation as written, *'is sufficiently constrained to qualify as a 'limited exception' to trademark rights'*. However, the Panel did agree with the US and Australia that the WTO's TRIPS Agreement⁸⁷ does not allow unqualified coexistence of GIs with prior trademarks. The TRIPS Agreement requires that trademark owners be given the right to prevent use of subsequent GIs where confusion is likely to result. Applying this provision to the facts, the Panel pointed out that there was no evidence that the co-existence of trademarks and subsequent GIs resulted in the likelihood of confusion. Concluding, there was no finding that the substance of the EU's PDO/PGI system is inconsistent with WTO obligations.
124. Two new Regulations were adopted in March 2006, to clarify and streamline rules for PGI and PDO⁸⁸, and for traditional specialities⁸⁹. The Regulations are intended to ensure full compatibility with the April 2005 WTO panel finding⁹⁰. The Regulation on PGI and PDO, now brings the system into conformity in the two areas that were criticised: firstly by formally deleting a requirement that the third country should apply similar protection on a reciprocal and equivalent basis, and secondly by allowing third country operators to submit applications and objections directly to the Commission rather than through their governments.

New legislation on food supplements, additives, novel foods, foodstuffs for nutritional and dietetic uses

125. Over the last 20 years, the EU has moved from a purely "reactive" approach to the protection of human health (i.e. assessing whether restrictions imposed on the free movement of goods under Article 30 EC were justified or not) to a more positive approach. For instance, a Directive on food supplements was adopted in 2002⁹¹, which establishes harmonized rules in relation to supplements to ensure that products put on the market are safe and that they are appropriately labeled so that consumers can make informed choices. The Directive has an annex which lists the permitted vitamin or mineral preparations that may be added for specific nutritional purposes to food supplements.

⁸⁷ TRIPS Article 16.1.

⁸⁸ Council Regulation (EC) No 510/2006 of 20 March 2006, L 93/12, 31.3.2006.

⁸⁹ Council Regulation (EC) No 509/2006 of 10 March 2006, L 91/1, 31.3. 2006.

⁹⁰ The EU had to implement the WTO ruling by 3 April 2006.

⁹¹ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements. (OJ L 183, 12/07/2002 P. 0051 – 0057).

Novel Foods

126. In early 2008, the Commission adopted a proposal⁹² to revise the law on Novel Foods which is currently set out in Regulation 258/97. The Commission's objective is to improve access of innovative foods to the EU markets whilst ensuring food safety for consumers. Novel foods would be subject to a centralised authorisation procedure whereby the Commission would receive an application for authorisation and the EFSA would carry out a scientific assessment on the product. This would increase efficiency of the process as the applicant would make a single application for approval for all the possible uses of the product in question. To encourage companies to invest in developing new foods and food production techniques, the draft Regulation proposes data protection rules which would protect the novel foodstuff once authorised. Additionally, special provisions would be made for foods which have not been traditionally sold in the EU but which have a safe history of use in third countries, to encourage trade.

Food additives, flavourings and enzymes

127. The Commission adopted a package of legislative proposals in 2006 to introduce harmonising legislation on food enzymes for the first time and to modernise the existing rules on flavourings and additives. The proposals were recently adopted by the Council. The new legislation will create a simplified common approval procedure for additives, flavourings and enzymes, based on scientific opinions from EFSA.
128. In general terms, it may be said that Community food legislation across the board is now becoming more sophisticated, more reliant on independent scientific assessment and shows a tendency towards Community rather than national level authorisations. This is certainly the case in the field of nutrition and health claims made on foods.

International aspects of food

129. Modern society has witnessed an exponential growth in the global trade in food products. This means that food related issues are inevitably international in character. For instance, in November 2008, the US Food and Drug Administration opened an inspection office in Beijing, China to ensure that China exports safer products to the US and the rest of the world. The idea is that Chinese some foodstuffs will be checked before leaving China, rather than relying solely on inspection at US borders. The US plans to open similar inspection offices in India, South America, and the Middle East. It will be interesting to see if the US feels the need to open such an office in the EU in the light of the comprehensive food law and emergency procedures in already in place in Europe.

⁹² Proposal for a Regulation of the European Parliament and of the Council on novel foods Brussels, 14.1.2008 COM(2007) 872 final.

The Precautionary Principle and the WTO

130. The Beef Hormones case involved a challenge to the EU import ban on beef treated with growth hormones on grounds that it violated the SPS Agreement (Agreement on the Application of Sanitary and Phytosanitary Measures)⁹³. Two Panel Reports concluded that the EC import ban was against the SPS Agreement. The EC appealed against those Reports before the WTO Appellate Body. On 16 January 1998, the Appellate Body adopted its Report in the case EC Measures Concerning Meat and Meat Products (Hormones)⁹⁴. The Appellate Body reversed some of the Panels' findings but it confirmed their finding that the EC ban on imports of hormone-treated meat was inconsistent with Articles 3.3 and 5.1⁹⁵ SPS Agreement, since it was not based on risk assessment within the meaning of the SPS Agreement.
131. The Appellate Body found the ban illegal because, although it was neither discriminatory nor disproportionate, there was no "rational relationship" between the measure and the risk assessment. The reasoning of the Appellate Body was that the scientific evidence for the measure was not deemed sufficiently specific, and therefore the measure was not based on risk assessment. Secondly, the Appellate Body distinguished theoretical uncertainty from the notion of identifiable risk. It held that there will always be some theoretical uncertainty, since science can never guarantee that a substance will never have an undesirable impact on health.
132. This ruling has been received with mixed feelings. For example, it was viewed as a ruling that contributes to the legitimacy of the precautionary principle, which makes science 'a necessary but not decisive component of the regulatory process'⁹⁶. Others argue the contrary by saying that, this ruling failed to accommodate the political discretion that must accompany scientific uncertainty⁹⁷.

⁹³ The ban was implemented by Directive 85/649, replaced subsequently by Directive 96/22. The original ban involved a prohibition on the use of hormonal substances for fattening farm animals within the EC. At a later stage the prohibition also covered the import of hormone-treated animals and meat into the EC. The result of the import ban was that it led to a stop of all existing imports of US and Canadian meat into the EC. After the WTO was established, the US and Canada started dispute settlement procedures of the WTO against the EC ban on imports of hormone-treated meat.

⁹⁴ WT/DS26/AB/R, WT/DS48/AB/R.

⁹⁵ Article 3.3 SPS provides: 'Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary protection that would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 Article 5...Notwithstanding the above, all measures which result in a level of sanitary or phytosanitary protection different from that which would be achieved by measures based on international standards, guidelines or recommendations shall not be inconsistent with any other provision of this Agreement'.

Article 5.1 SPS reads as follows; 'Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, on the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organisations'.

⁹⁶ Howse, 'Democracy, Science and Free Trade: Risk Regulation on Trial at the WTO', (2000) 98:2329, *Mich.L.R.*

⁹⁷ Ni Chaoimb, 'Trading in Precaution. A Comparative Study of the Precautionary Jurisprudence of the European Court and the WTO's Adjudicating Body', (2006) 33(2):139, *Legal Issues of Economic Integration*

EU – US dispute on poultry

133. In 1997, the EU imposed a ban on poultry coming from the United States because producers in the US use a low-concentration chlorine wash to reduce harmful pathogens found in carcasses. The practice is not permitted under the EU food safety rules. The US has continually expressed its annoyance over this ban as it believes that it is not based on scientific justifications. The EU and the US met early in 2008 in the forum of the Transatlantic Economic Council to discuss the issue and the US requested that poultry imports that have undergone the chlorine wash process in the US be permitted to enter the EU. A complete termination of the ban was seen as going too far by the Commissioner in charge of food safety, Androulla Vassiliou, who therefore included strict conditions in her proposal ending the restriction. Many in the Commission, particularly Industry Commissioner Guenter Verheugen, were initially hostile to these strict conditions, but eventually let the proposal through.
134. The Commission's proposal was put before the Standing Committee on the Food Chain and Animal Health on 2 June 2008, which delivered an opinion against it. The European Parliament has also given a negative opinion on the proposal due to concerns that it would allow the authorisation of imports that could undermine European standards. The Commission's proposal, which includes a rule that only whole poultry carcasses - not parts or cuts - may be treated; a single substance is used in slaughterhouses before carcasses enter the chilling room; potable water is used for rinsing; and poultry meat must be clearly labelled to say it has either been 'treated with antimicrobial substances' or 'decontaminated by chemicals', will be voted on by the Council of EU agricultural ministers by qualified majority at some point before February 2009.

EU – US dispute on GMOs

135. The present EU legislation for authorising GMOs is in conformity with WTO rules. Furthermore, the legislation takes account of the requirements of the Cartagena Protocol on Biosafety (2003). This UN agreement establishes common rules to be followed in cross-border movements of GMOs (incorporated into EC law by Directive 2001/18/EC and Regulation 1946/2003).
136. Even though the legislative measures for authorising GMOs are generally deemed to be in conformity with WTO rules, there have nonetheless been complaints by WTO members to the Dispute Settlement Body. In May 2003, the US, supported by Canada and Argentina, launched a WTO case against the EU concerning the moratorium imposed by the EU on new authorisations. The Commission halted the approval of new GM varieties in 1998, but began limited approvals again in May 2004, after the US launched the WTO case⁹⁸.
137. The US argued that GMOs that are considered to be safe in the US should be deemed to be safe for the rest of the world. They also opposed GMO traceability rules in the EU because they allegedly constitute an obstacle to US commodity

⁹⁸ http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds293_e.htm

exports. The US, with Canada and Argentina, sought a ruling by the WTO to prevent European-style restrictions on GMO foods from spreading to Africa, China and other parts of the world⁹⁹.

138. The WTO Panel ruled on 7 February 2006 that the EU's moratorium on GM products, effective between June 1999 and August 2003, was illegal and that Austria, France, Germany, Greece, Italy and Luxembourg had no legal grounds to impose their own unilateral import bans¹⁰⁰. The Commission described the ruling as “a mixed bag” that criticised former EU regulatory measures but would not impact on the current legislation, which was brought into force after the complaint was filed in 2003¹⁰¹.
139. The Commission decided not to appeal against the WTO ruling, criticised by several NGOs, which insist that countries have a right to ban GM products. The US stated that the ruling would mean that the EU would have to speed up its GM approval system, although the Commission has shown it is not willing to open the floodgates to GM products. The EU has authorized some of the GM products covered by the WTO case, although France (the current holder of the Presidency of the EU Council) has set up a working group to consider proposals for changes to the current authorisation process for GM products. A Council decision is due to be taken in December 2008, but Member States are still far from a compromise. Some Member States wish to retain the possibility of prohibiting the planting of GM crops in certain ecologically sensitive or protected areas, whereas others only want that type of restriction if there is a scientifically-based protection measure. France's proposal that GM authorisations should take socio-economic factors into account as well as scientific safety evaluations, have not obtained a consensus in the Council.

Conclusion

140. 23 years after the Commission's White Paper on completing the internal market (accompanied by separate communications on Community legislation on foodstuffs and on a consumer protection policy), the treatment of food and drink under EU law is highly-regulated but not without controversy. The political dimension arises because of close relationship between food and drink and health, but also because food law is probably the area of EU law closest to the European citizens. Hence, the emphasis on consumer protection (including clear and comprehensive information through labelling), the avoidance (or minimisation) of risk and the protection and enhancement of health.
141. The last 23 years have seen a number of “landmark” consultative documents produced by the Commission, copious legislation and a steady flow of cases through the European Courts, both on the basis of Articles 226 and 234 EC.

⁹⁹ Bloomberg, 8 February 2006, <http://www.bloomberg.com/apps/news?pid=10000085&sid=aOhAZsCZvmNU&refer=europe>.

¹⁰⁰ Financial Times, 8 February 2006.

¹⁰¹ *Ibid.*

142. Against this background, a number of tentative conclusions may be drawn as follows:

- it is excessively simplistic to say that EU food law revolves around a tension between Articles 28 and 30 EC, although in essence, producers and traders do have a right to market their products throughout the EU on the same conditions as those prevailing in their home State (*Cassis de Dijon*). And importing countries may restrict trade only the grounds set out in Article 30, including “mandatory requirements”;
- the balance or tension between these provisions is still litigated in the European Courts nearly 30 years after *Cassis de Dijon*, although there is now an almost complete body of “horizontal” food and feed legislation in the EU which, in practical terms, ought to render the “primary rules” in Articles 28-30 less important;
- legislative and judicial recognition of the “precautionary principle” complicate the relationship between Articles 28 and 30 EC, in essence tilting the balance or giving the benefit of any scientific doubt in favour of the Member State wishing to restrain trade (provided that the principles of proportionality and “least restrictive effect” are respected);
- understanding, interpreting and applying “science” creates a formidable challenge for the EU institutions, including the European Courts, even if the ECJ refuses to “second guess” the scientific analysis made by the Commission and other EU institutions provided it is supported by adequate reasoning;¹⁰²
- the political dimension of EU food law is demonstrated by the Commission’s exercise of discretion in initiating Article 226 EC infringement proceedings against Member States and by the importance of Article 234 EC references from national courts, even in apparently “straightforward” cases;
- major reforms have been made in EU law in the last 10 years (many in the last 3 years) and these will take time to “bed down”;
- meanwhile, the legal difficulties which have arisen in a few products should not obscure the massive surge in trade in food and drink products over the last 20 years, giving European consumers an incomparable choice of quality products at reasonable prices.

¹⁰² i.e. provided the institutions do not commit a “manifest error of appreciation”.

ANNEX I

Case study: EC harmonisation in the yoghurt sector

1. The free circulation of food products in the internal market, although regulated by increasingly dense secondary legislation, is governed essentially by Articles 28-30 EC Treaty. These fundamental provisions guarantee the movement of goods subject only to restrictions on grounds, *inter alia*, of human health, the protection of industrial or commercial property or “mandatory requirements”¹⁰³. The Commission has repeatedly underlined that secondary legislation (e.g. Regulations and Directives) should not only observe Articles 28-30, but also that issues such as quality specifications or rules on the composition of products, which are not related to the protection of public health, should not be subject to secondary regulation at all. The general rule is therefore one of minimum harmonisation at EU level, with mutual recognition of national rules or standards being the norm.
2. However, the prospect of harmonisation in relation to certain food types raises its head on a regular basis at EU level, with one notable example of this being the yoghurt sector. Back in 1987 the ECJ examined the restrictive French laws which prevented frozen yoghurt being sold in France as yoghurt. The subject of what is yoghurt is once more being discussed in the EU thanks to a possible Commission Regulation. In summer 2003, DG Agri of the Commission first circulated a draft Regulation laying down additional rules on the common organisation of the markets of milk and milk products for yoghurt and yoghurt-like products to dairy producers. The draft Regulation has caused significant controversy as a number of its provisions potentially infringe the principles of free movement of goods and the mutual recognition of national rules by preventing the free circulation of certain types of yoghurt within the EU.
3. Whilst there is currently no harmonising legislation at EU level which specifically governs the production, marketing and sale of yoghurt, manufacturers and retailers clearly must comply with general EU legislation in the fields of health and safety, labelling and consumer protection¹⁰⁴.
4. The draft Regulation seeks to define yoghurt and yoghurt-like products in a text that includes provisions governing product designation, composition¹⁰⁵ and Member State monitoring of the Regulation’s application. The draft Regulation is flawed in its approach to two key ways: (i) the definition of yoghurt is too narrowly defined and does not follow the wider general definition contained in the FAO’s Codex for

¹⁰³ See, the general principles of food law in the European Union, Commission Green Paper of 30.4.97, COM (97) 176 final. See also the free movement of goods in the European Community, Peter Oliver, (4th edition), 2003.

¹⁰⁴ Directive 2000/13/EC is the main piece of Community legislation which governs “*the labelling, presentation and advertising of foodstuffs*”. This has recently been amended by Directive 2003/89/EC *as regards indication of the ingredients present in foodstuffs*.

¹⁰⁵ The Commission indicated in 1985 and confirmed in 1997 that it would no longer seek to harmonise “quality specifications” relating to the composition and manufacture of foodstuffs (see the 1997 Green Paper at p. 8).

fermented milks 2003¹⁰⁶ ('the Codex 2003'), technological development within the yoghurt sector and Community law and policy on the free movement of goods; and (ii) it discriminates in favour of probiotic yoghurt not only in the definitions of yoghurt and yoghurt-like products but also in a definition of probiotic bacteria. This definition states as 'fact' the scientifically controversial claim that probiotic bacteria "benefit the health of the consumer, if ingested regularly in sufficient quantities" (Article 4).

5. The definition of yoghurt – Codex 2003 definitions. Yoghurt is defined by the Codex 2003 as "fermented milk" which uses "symbiotic cultures of *Streptococcus thermophilus* and *Lactobacillus delbrueckii* subsp. *bulgaricus*" in the fermentation process. "Fermented milk" is defined as "a milk product obtained by fermentation of milk, which milk may have been manufactured from products obtained from milk with or without compositional modification as limited by the provision in Section 3.3, by the action of suitable microorganisms and resulting in reduction of pH with or without coagulation (iso-electric precipitation). These starter microorganisms shall be viable, active and abundant in the product to the date of minimum durability. If the product is heat-treated after fermentation the requirement for viable microorganisms does not apply." Pasteurised or heat-treated yoghurt is milk that has been fermented using *Streptococcus thermophilus* and *Lactobacillus delbrueckii* subsp. *bulgaricus*. Following the fermentation process the yoghurt undergoes pasteurisation or heat-treatment, an industrial process applied to ensure the product's preservation.
6. Within the European Union there is no single definitive definition of yoghurt. Member States have adopted different definitions of yoghurt, varying in relation to recognition of the bacteria which need to be involved in the fermentation process, from what processes the fermented milk can undergo to what flavourings may be added to the final product. Many Member States recognise that yoghurt which has undergone pasteurisation does not need to have live bacteria at the time of consumption. There is also a recognition in a majority of Member States of yoghurt and yoghurt products which have undergone industrial processes e.g. liophilisation, drying, freezing¹⁰⁷. In many Member States the legislation does not prevent other flavourings and ingredients being added to the fermented milk for the product to be called yoghurt e.g. chocolate, vanilla essence etc¹⁰⁸. Any EU harmonising legislation should be drafted in full awareness of the diversity of the concept of yoghurt across the EU and, bearing in mind the key EU principles of mutual recognition and free movement of goods, particularly where it can be shown that the interests of consumers are protected and EU labelling requirements are complied with by manufacturers.

¹⁰⁶ See paragraph 2.1 for the general applicable definitions. The Codex was adopted at the Twenty-sixth session of the Joint FAO/WHO Standards Programme Codex Alimentarius Commission in Rome, 30 June – July 2003. This replaces Codex Standard for Yoghurt and Sweetened Yoghurt (CODEX STAN A-11(a)-1975) and Codex Standard for Flavoured Yoghurt and Products Heat-Treated after Fermentation (CODEX STAN A-11(b)-1976).

¹⁰⁷ This last process being explicitly validated by the ECJ judgment in *Smanor* (see further below).

¹⁰⁸ A non-exhaustive list of Member States who allow such additions to be made includes France, the UK, Germany, Austria, Finland, Sweden, Estonia, Lithuania and Latvia.

7. The draft Regulation seeks to impose “additional requirements” on the definition of yoghurt in the Codex 2003 on the basis of seeking to guarantee “an adequate product quality” (second recital). This ‘quality’ argument is not only scientifically contentious but is also in breach of the Commission’s principle of not attempting to regulate the alleged “quality” of foodstuffs. The ninth recital states that the “notion of yoghurt” should “be reserved” to products that have “the presence of living bacteria in large quantities”¹⁰⁹. This definition represents the position of a minority of Member States¹¹⁰ and is at odds with the wider definition of yoghurt recognised in Member States. The Codex 2003 does not require living bacteria to be present within milk fermented by *Streptococcus thermophilus* and *Lactobacillus delbrueckii* subsp. *bulgaricus* for the product to be designated as yoghurt.¹¹¹ Further, it should be noted that other major jurisdictions have rejected such a restrictive definition e.g. the USA’s Food and Drug Administration (‘FDA’) has decided not to adopt a proposal which requires yoghurt to have a minimum level of live and active characterising yoghurt cultures at the time of manufacture¹¹².
8. Whilst the draft Regulation aims to provide for ‘the common organisation of the market in milk and milk products for yoghurt and yoghurt-like products’, such a goal is undermined by the Regulation’s failure to provide a single binding definition of yoghurt. Instead, the draft Regulation allows Member States to choose for themselves whether or not they will recognise heat-fermented yoghurt as ‘yoghurt’ (tenth recital and Article 6(4)), thereby leading to the fragmentation of the Single Market. The tenth recital refers to “*different traditions in the Member States regarding the use of the term ‘yoghurt’*” in relation to “*heat treatment after fermentation*” as a justification for allowing each Member State to decide independently whether or not to designate pasteurised yoghurt. To allow Member State national “traditions” or consumption habits to be the key criterion for product designation clearly undermines the EC principle of mutual recognition and is contrary to ECJ case law in the area of free movement of food products¹¹³.
9. The wording of the draft Regulation allows Member States to prohibit the marketing of pasteurised yoghurt as yoghurt despite the fact it demonstrates all the characteristics of yoghurt set out within the Codex 2003. Such national rules would constitute a measure having equivalent effect to a quantitative restriction within the

¹⁰⁹ The draft Regulation fails to define what is meant by “the presence of living bacteria in large quantities” – at what point should bacteria be counted? What does “large” mean in numerical terms? How could Member States feasibly monitor this? This definition is unworkable, unnecessary and against core Community principles. Food regulators in other jurisdictions e.g. the FDA in the USA, have not allowed such a restrictive definition

¹¹⁰ Currently the majority of Member States allow the free circulation of yoghurt products that have undergone industrial treatment (including freezing, pasteurisation and drying).

¹¹¹ It should be noted that whilst Paragraph 7.1.2 of the Codex 2003 allows countries to choose whether or not heat treated fermented milks should be called “heat treated fermented milk” or otherwise this is within the context of consumer protection, adequately dealt with by EC by consumer labelling laws which oblige manufacturers to set out processes that foodstuffs have undergone. Further, sale of goods in the jurisdiction of the EC restricts independent action of Member States where this is harmful to intra-Community trade and unnecessary (e.g. on health or consumer protection grounds) due to the principle of mutual recognition.

¹¹² See the Communication of the International Dairy Foods Association (‘IDFA’) and the Milk Industry Foundation (‘MIF’) dated 26 January 2004.

¹¹³ See further comment below on the ECJ case law in this area.

meaning of Article 28 (ex-Article 30), requiring producers of pasteurised yoghurts to incur large additional costs in the labelling and marketing of products, to face reduction in sales and, in some member states, to incur heavier import duties as the pasteurised yoghurt will be taxed as a dessert rather than a dairy product.

10. The ECJ stated in *Fietje*¹¹⁴ that “*although the extension to imported products of an obligation to use a certain name on the label does not wholly preclude the importation into the Member State concerned of products originating in other Member States or in free circulation in those States, it may none the less make their marketing more difficult ... (and) is thus capable of impeding, at least indirectly, trade between Member States*”. This was recognised by both the ECJ and Advocate General Mischo, in the *Smanor* case¹¹⁵, to be a relevant factor in relation to “deep-frozen yoghurt” in France. The French legislation prohibited the marketing and sale of deep frozen yoghurt as ‘yoghurt’ requiring it to be sold as ‘deep-frozen fermented milk’. Although the legislation applied without discrimination to all yoghurts marketed and sold in France, it clearly had an adverse effect on all deep-frozen yoghurts imported by *Smanor* as the company was required to change the packaging and marketing strategy of their products in order to comply with French law¹¹⁶.
11. Consumer sales resistance. Product recognition is clearly key to the successful marketing and sale of a product. The ECJ in *Smanor* recognised that “*the name proposed by the French government, ‘deep-frozen fermented milk’ is less familiar to consumers than ‘deep-frozen yoghurt’*”. Advocate General Mischo recognised in *Smanor* that repackaging and marketing of the product could have a direct impact on product sales as there might be “*serious sales resistance on the part of many consumers who would perhaps be tempted to buy ‘deep-frozen yoghurt’ but are not necessarily attracted by the name ‘deep-frozen fermented milk’*”¹¹⁷. Just as consumers are more familiar with the term ‘deep-frozen yoghurt’ than ‘deep-frozen fermented milk’, consumers are more familiar with the term ‘pasteurised yoghurt’ than ‘fermented milk’.
12. Community case law¹¹⁸ has established that in the absence of common rules relating to marketing of a certain product, obstacles to the free movement of goods within the Community which result from disparities between the national laws must only be accepted in so far as such rules, applicable without distinction to domestic and imported products, can be justified as necessary in accordance with one of the grounds of public interest set out in Article 30 (ex-Article 36). It is not contrary to public interest for pasteurised yoghurt to be called a yoghurt. The product is

¹¹⁴ Case 27/80, (1980) ECR 3839 at paragraph 10, see also paragraph 15 of *Oosthoek's Uitgeversmaatschappij*, case 286/81, (1982) ECR 4575 .

¹¹⁵ Case 298/87, ECJ judgment and AG Opinion: (1988) ECR 4489.

¹¹⁶ Note that there was no issue within the *Smanor* case as to whether or not yoghurt should contain live bacteria, a characteristic required by French law, as the frozen product contained live bacteria.

¹¹⁷ Advocate General Mischo's opinion, paragraph 18.

¹¹⁸ E.g. Case 120/78 *REWE* (“*Cassis de Dijon*”), 20 February 1979 (1979) ECR 649; Case 178/84 *Commission v Germany* (the “*Beer Case*”) (1987) ECR 1227 and the *Smanor* judgment itself (paragraphs 14-19).

scientifically proven to be a safe one, indeed it is a product of significant nutritional value¹¹⁹.

13. The Commission's "Guide to the Concept and Practical Application of Articles 28-30"¹²⁰ clearly emphasises the need for Article 30 derogations to be applied restrictively and logically: "*Measures may be justified on the grounds of consumer protection but, in what may be termed the 'golden rule', the fundamental principle is that the sale of a product should not be prohibited when the consumer can be sufficiently protected by adequate labelling requirements*"¹²¹. All pasteurised yoghurts marketed and sold within the Community must clearly mark the pasteurisation process on their product label to comply with Article 5(3)¹²² of labelling Directive 2000/13/EC¹²³, and, therefore, the consumers must be fully informed that the product has undergone a type of physical treatment.
14. On the issue of product designation and labelling it should be noted that the relevant practice in relation to foodstuffs is to ensure that the name indicates the "true nature of the food". Indeed, the Codex General Standard for the Labelling of Prepackaged Foods¹²⁴ states, at paragraph 4.1.1 that "[t]he name shall indicate the true nature of the food and normally be specific and not generic". The wording of Article 6 of the draft Regulation allows Member States to call pasteurised yoghurt "fermented milk". Fermented milk is a generic and not a specific denomination of the food, yoghurt being only one type of fermented milk. Furthermore all yoghurts, and not just pasteurised yoghurts, are "fermented milks", making designation of this name only to pasteurised yoghurts illogical. Pasteurised yoghurt like any other yoghurt is milk which has been fermented by cultures of *Streptococcus thermophilus* and *Lactobacillus delbrueckii* subsp. *bulgaricus* in the fermentation process. The only distinction between pasteurised yoghurt and short life yoghurt is the process that the yoghurt undergoes post-fermentation i.e. pasteurisation (a process marked on the label).
15. Following the *Smanor* judgment, the Commission issued an Interpretative Communication on the names under which foodstuffs are sold¹²⁵. The Commission concluded that a Member State "*is legitimately entitled to refuse to allow a product which has undergone treatment and no longer contains live bacteria, to be described as 'yoghurt' or by any other name containing a reference to yoghurt.*" In making

¹¹⁹ There is also no suggestion in the draft that Member States can prohibit the pasteurised yoghurt from being sold but, rather, that they are free to force producers to sell the product under a different name. This of course amounts to a measure of equivalent effect, contrary to Article 28 EC.

¹²⁰ Issued by DG Internal Market in January 2001.

¹²¹ See page 22, section 6.

¹²² Article 5(3) states: "*The name under which the product is sold shall include or be accompanied by particulars as to the physical condition of the foodstuff or the specific treatment which it has undergone (e.g. powdered, freeze-dried, deep-frozen, concentrated, smoked) in all cases where omission of such information could create confusion in the mind of the purchaser*".

¹²³ The recent amending Directive 2003/89/EC as regards indication of the ingredients present in foodstuffs does not amend this element of, Directive 2000/13/EC. The original wording of Article 5(3) remains in its entirety.

¹²⁴ CODEX STAN 1-1985 (Rev 1-1991).

¹²⁵ OJ C 270/2 15/10/91.

this statement the Interpretative Communication misread the *Smanor* judgment, a judgment which dealt exclusively with the freezing process and, indeed, in relation to this concluded that yoghurt which had been subject to the freezing process *could* still be called yoghurt. No other processes were considered as part of the judgment. The Codex Standard which was in force at the date of the *Smanor* judgment and at the date of publication of the Interpretative Communication explicitly recognised that heat-treated products could be classified as yoghurt: “*products heat-treated after fermentation are products as described under Sections 2.1 [namely “Flavoured Yoghurt”] which have been submitted to a heat-treatment after fermentation. They need not contain viable and abundant micro-organisms*” (emphasis added)¹²⁶.

16. Food law, like many other areas of law must evolve over time. Technological advances over the last 100 years have allowed new methods of food preservation to evolve. Pasteurisation is one such preservation method and it is universally accepted as a safe method of preservation that allows both consumers and retailers to benefit from products that have a longer shelf life. International definitions of food have evolved to recognise advances in food technology and Community legislation should also reflect these advances. It is wrong to exclude products that have undergone safe food processing and are clearly labelled as having undergone those processes.⊕

¹²⁶ See Section 2.2 of “Codex Standard for Flavoured Yoghurt (Yoghurt) and Products Heat-Treated after fermentation”, CODEX STAN A-11(b).

ANNEX II

Key Policy Documents, Legislation and CasesPolicy Documents

- Commission White Paper on completing the internal market - COM (85) 310 final
- Commission Green Paper on the General Principles of Food Law in the European Union - COM (97) 176 final
- Commission White Paper Consumer Health and Food Safety - COM (97) 183 final
- Commission White Paper on Food Safety - COM (99) 719 final
- Communication from the Commission on the Precautionary Principle – COM (2000) 1 final
- Commission Green Paper on promoting healthy diets and physical activity; a European dimension for the prevention of overweight, obesity and chronic diseases - COM (2005) 637 final

Legislation

- Council Regulation (EEC) 2081/92 on the protection of geographical indications (PGI) and designations of origin (PDO) for agricultural products and foodstuffs.
- Council Regulation (EEC) 2082/92 on certificates of specific character for agricultural products and foodstuffs.
- Council Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations.
- Council Directive 98/81/EC amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms.
- Directive 2000/13/EC relating to the labelling, presentation and advertising of foodstuffs.
- Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.
- Regulation (EC) No 178/2002 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.
- Regulation (EC) No 1829/2003 on genetically modified food and feed.
- Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

- Directive 2005/94/EC on Community measures for the control of avian influenza.
- Council Regulation (EC) No 510/2006 on the protection of geographical indications (PGI) and designations of origin (PDO) for agricultural products and foodstuffs.
- Council Regulation (EC) No 509/2006 on certificates of specific character for agricultural products and foodstuffs.
- Regulation 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods.
- Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods.
- Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91.

Cases

- Case C-120/78 *Rewe-Zentrale AG v Bundesmonopolverwaltung für Branntwein* [1979] ECR 649.
- Case 53/80 *Eyssen* [1981] ECR 409.
- Case 178/84 *Commission v Germany* [1987] ECR 01227.
- Case 407/85 *Drei Glocken* [1988] ECR 4233.
- Joined Cases C-46/93 and C-48/93 *Brasserie du Pêcheur v Bundesrepublik Deutschland* [1996] ECR I-01029.
- Case C-180/96 *UK v Commission* [1996] ECR I-03903.
- Case C-157/96 *National Farmers' Union and Others* [1998] ECR I-2211.
- T-13/99 *R. Pfizer Animal Health SA/NV v Council of the European Union* [1999] ECR II-01961.
- Case C-236/01 *Monsanto Agricoltura Italia and Others* [2003] ECR I-8105.
- Case C-41/02 *Commission v Netherlands* Judgment 2/12/2004.
- Case C-132/03 *Ministero della Salute v. Codacons* Judgment 26/5/2005.
- Cases C-154/04 & C-155/04 *Alliance for Natural Health, Nutri-Link v. Secretary of State for Health* Judgment 12/7/2005.
- Cases T-366/03 & T-235/04 *Austria v Commission*, Judgment 5.10.2005

- Cases C-465/02 & C-466/02 *Germany v Commission and Denmark v Commission*, Judgment 25.10.2005

ANNEX III

Scientific Committees advising the EU institutions

Examples of Scientific Committees:

- Scientific Committee on Consumer Products
- Scientific Committee on Health and Environmental Risks
- Scientific Committee on Emerging and Newly-Identified Health Risks
- Inter-Committee Coordination Group: assists the Commission on matters relating to the coordination of the three Scientific Committee, including matters relating to the harmonisation of risk assessment)
- The above committees are managed by DG Health and Consumer Protection (SANCO). They provide the Commission with scientific advice to enable it to prepare policy and legislative proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to the new or emerging problems which may pose an actual or potential threat to health. Their work is complementary to the risk assessment activities of the European Food Safety Authority (EFSA) and European Medicines Evaluation Agency (EMEA).

European Food Safety Agency (EFSA)

Functions

- Core activity: providing independent scientific advice on food safety issues throughout the food chain. Its work covers
- Risk assessment (divorced from risk management) including risk or regulated substances such as food additives, flavourings, enzymes, additives for animal feed, GM food and feed.
- Not part of Commission nor answerable to it.
- Controlled by Board acting in independent capacity, not national representatives.
- Works in close collaboration with national safety regulators.
- Structure
 - Management Board
 - Advisory Forum
 - Scientific Committee and Panels
 - Secretariat

European Food Safety Agency

Scientific Committee

Eight scientific panels:

- Food additives, flavorings, processing aids, materials in contact with food (AFC)
- Additives and products in animal feed (FEEDAP)
- Plant Health, Plant Protection Products (PPR)
- Genetically Modified Organisms (GMO)
- Dietetic products, nutrition and allergies (NDA)
- Biological hazards (BIOHAZ)
- Contaminants in the food chain (CONTAM)
- Animal health and Welfare (AHAW)

Made up of leading independent scientists from all over Europe (and in a few cases from beyond), appointed following an open call for expression of interest.