

Original article

An update of EU legislation (Directives and Regulations) on food-related issues (Safety, Hygiene, Packaging, Technology, GMOs, Additives, Radiation, Labelling): presentation and commentsIoannis S. Arvanitoyannis,^{1*} Stefania Choreftaki² & Persefoni Tserkezou²

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Summary This review aims at providing an update of the current European Union (EU) Regulations and Directives on food-related issues. Initially, a brief presentation of EU legislation in terms of structure (horizontal, vertical) was attempted. EU Regulations and Directives were classified into the following categories: food safety (Hazard Analysis Critical Control Points, pesticides, radioactive, hormones, contaminants, freezing – ionisation, food additives, flavourings, packaging), genetically modified organisms, food quality, labelling, food products of plant or animal origin, imports from third countries. Apart from a synoptical presentation of all laws related to the above-mentioned topics, proper tables were compiled where the main points of each law are cited in conjunction with its effect on previous laws (repeal, modification, amendments, replacement). In such a way the reader can rapidly acquire a first approach to the topic of his interest.

Keywords EU legislation, food packaging, food safety, GMOs, Hazard Analysis Critical Control Points, labelling.

Introduction in EU legislation

Over the last 15 years a number of food safety crises (bovine spongiform encephalopathy (BSE), dioxins, high pesticide and antibiotic content in several foods, high nitrate content, presence of coliforms in drinking water, usage of Sudan Red 1 and formation of acrylamide among others) occurred within the framework of the European Union (EU), thus resulting in great losses of human lives and capital. These crises made EU citizens more alert but also increased considerably the EU legislative task in an attempt to undertake preventive instead of corrective measures. One of

the top priority areas was dealing with the safety and hygiene Directives. In July 2000, the European Commission published a package of five measures to update and consolidate the seventeen existing hygiene Directives. The package was intended to introduce consistency and clarity throughout the food production chain from 'farm to fork'. After nearly 4 years of negotiations, the texts were adopted on 29 April 2004 and published in the *Official Journal of the European Union* on 30 April 2004. The legislation will apply on 1 January 2006 (except Directive 2002/99 on animal health rules) (http://www.food.gov.uk/foodindustry/regulation/europeleg/eufoodhygieneleg/#h_1). The farm-to-fork approach of the legislation embraces primary production, in many cases, for the first time. Primary producers will need to follow good

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practice and manage their operations as set out in Annex 1 of Regulation 852/2004.

In practical terms, the requirements on primary producers amount, in the main, to fairly basic hygiene procedures. Primary producers must ensure that hazards are acceptably controlled and respect other existing legislation. Primary producers will not be required to apply Hazard Analysis Critical Control Points (HACCP)-based procedures. Primary producers will have to be registered with competent authorities, although existing forms of registration may be used for this purpose. Stakeholders are being consulted on the form the controls will take to ensure they are practicable and can be addressed in Good Practice Guides to be initiated by industry with support from other stakeholders.

Another issue of great importance for the EU consumer following the consumer studies that have been carried out is the GM (novel food) area, which led to a confrontation between the USA and the EU. A novel food is defined as a food or food ingredient, which does not have a significant history of consumption within the EU prior to May 1997. All novel foods are subject to a pre-market safety assessment under the Novel Foods Regulation (EC) No. 258/97. The Food Standards Agency Board is satisfied that the current safety assessment procedures for GM foods are sufficiently robust and rigorous to ensure that approved GM foods are as safe as their non-GM counterparts, and pose no additional risk to the consumer. Each GM food is assessed for safety, including its toxicological, nutritional and allergenic potential, on a case-by-case basis before it can be approved for marketing.

In the White Paper on Food Safety, the Commission announced its intention to put forward a proposal to amend Directive 90/496/EEC on nutrition labelling of foods in order to bring the provisions on nutritional labelling in line with consumer needs and expectations. In January 2003, the Commission launched a consultation among Member States and stakeholders with a view to preparing a proposal amending Council Directive 90/496/EEC on nutrition labelling. Following a review of these comments, the Commission has published a draft report on the application of Directive 90/496/EEC on nutrition labelling for food-stuffs. Prior to drawing up a

proposal to amend Directive 90/496/EEC, the Health and Consumer Protection Directorate General Services have launched (January 2004) a further consultation document on nutrition labelling of food-stuffs which contains targeted considerations.

Surveys stand for an essential component of the EU preparatory work, prior to putting together new Directives or Regulations, and have the following objectives: (a) to protect consumer safety, the authenticity of food and nutritional quality of the UK diet, (b) to allow consumers to make informed choices, (c) to assess the effectiveness of legislation and Codes of Practice, (d) to monitor trends both in terms of concentrations and geographical location and (e) to enable consumer exposure assessments to be made. Some of the most preoccupying areas of the EU legislation are chemical contaminants either in food *per se* or from food content materials, food additives, food authenticity/adulteration, nutrients in food, radionuclides in food and microbiological contamination of food (<http://www.food.gov.uk/science/surveillance>). For most people in the EU, access to potable and clean water in quite abundant quantities is taken for granted. Most people do not realise however that many human activities put a burden on the quality and quantity of water. All polluted water, whether polluted by households, industry or agriculture, returns back, one way or another, to the environment and may cause damage to human health or the environment. However, it is interesting to know that there have been several EU Directives such as the new European Water Policy Water Framework Directive (2000/60/EC), Priority substances under Article 16 of the Water Framework Directive Discharges of Dangerous Substances Directive (91/271/EEC), Water pollution caused by nitrates from agricultural sources (91/676/EEC) and Drinking Water Directive (98/83/EC).

The Food Supplements Directive 2002/46/EC came into force in July 2002. The Directive and these Regulations apply from 1 August 2005. One of the provisions of this Directive is for lists of nutrients and their sources that can be included in food supplements. The first list covers the vitamins and minerals that may be used in food supplements (such as vitamin C, calcium, iron). It excludes six minerals (tin, silicon, nickel, boron,

cobalt and vanadium) that are currently used in food supplements on sale in the UK. The second list covers the chemical forms (sources) of those vitamins and minerals that may be used. These lists can be added to following a favourable opinion on individual nutrients or nutrient sources from the European Food Safety Authority (EFSA) after consideration of a dossier containing safety data. The requirements for companies who wish to use an ingredient in the UK after 1 August 2005 that is not yet included in Annex 2 of the Directive are: (a) a product containing that ingredient must have been on the market before 12 July 2002, (b) a dossier has been submitted to the European Commission through a competent authority in a Member State by 12 July 2005. The UK will give derogation for nutrients and nutrient sources where a dossier has either been submitted to the UK or to another EU Member State. Companies who wish to use nutrients or nutrient sources in other Member States should check with the relevant competent authority on their requirements with respect to granting derogation. The Food Standards Agency has granted derogation for the nutrient sources listed in the table below allowing them to continue to be used in food supplement in accordance with Article 4 (6)(a) and (b) of Directive 2002/46/EC. These products (used by any operator) are allowed to remain on the market until 31 December 2009 providing EFSA has not given an unfavourable opinion (<http://www.food.gov.uk/foodindustry/vitmin/>).

Other areas of special interest are the imports from third countries and the sampling methodologies/processes which vary considerably depending on food the contaminant (nature, concentration) to be determined.

Topics/categories covered under EU legislation

Food safety

Recent trends in global food production, processing, distribution and preparation are creating an increasing demand for food safety research in order to ensure a safer global food supply (<http://www.who.int/foodsafety/en/>). The EU integrated approach to food safety aims at assuring a high level of food safety, animal health, animal welfare

and plant health within the EU through coherent farm-to-table measures and adequate monitoring, while ensuring the effective functioning of the internal market. The implementation of this approach involves the development of legislative and other actions in order to: (a) assure effective control systems and evaluate compliance with EU standards in the food safety and quality, animal health, animal welfare, animal nutrition and plant health sectors within the EU and in third countries in relation to their exports to the EU, (b) manage international relations with third countries and international organisations concerning food safety, animal health, animal welfare, animal nutrition and plant health and (c) manage relations with the EFSA and ensure science-based risk management (http://europa.eu.int/comm/food/intro_en.htm).

HACCP

This section comprises five very recent laws (EC 178/2002, EC 852/2004, EC 853/2004, EC 854/2004, EC 882/2004) which will enter into force either on 1 January 2005 or 1 January 2006.

Regulation (EC) No. 178/2002 (entry into force 1 January 2005) has three main axes: (a) Provides the basis for the assurance of a high level of protection of human health and consumers' interest in relation to food, taking into account the diversity in the supply of food, including traditional products, while ensuring the effective functioning of the internal market. It establishes common principles and responsibilities, the means to provide a strong scientific base, efficient organisational arrangements and procedures to underpin decision-making in matters of food and feed safety. (b) Lays down the general principles governing food and feed at Community and national level. It establishes the EFSA. (c) It shall apply to all stages of production, processing and distribution of food and feed. It shall not apply to primary production for private domestic use or to the domestic preparation, handling or storage of food for private domestic consumption. The food law shall aim at the prevention of: (a) fraudulent or deceptive practices, (b) the adulteration of food and (c) any other practices which may mislead the consumer. The requirements of food safety are: (1) Food shall not be placed on the market if it is unsafe. (2) Food shall be deemed to be unsafe if it

is considered to be: (a) injurious to health and (b) unfit for human consumption. The requirements of feed safety are summarised as follows: (1) Feed shall not be placed on the market or fed to any food-producing animal if it is unsafe. (2) Feed shall be deemed to be unsafe for its intended use if it is considered to: (a) have an adverse effect on human or animal health and (b) make the food derived from food-producing animals unsafe for human consumption. The EFSA comprises: (a) a Management Board, (b) an Executive Director and his staff, (c) an Advisory Forum and (d) a Scientific Committee and Scientific Panels. Its task shall be to: (a) provide the Community institutions and the Member States with the best possible scientific opinions, (b) promote and coordinate the development of uniform risk assessment methodologies, (c) provide scientific and technical support to the Commission, (d) commission scientific studies, (e) search for, collect, collate, analyse and summarise scientific and technical data, (f) undertake action to identify and characterise emerging risks, (g) establish a system of networks of organisations operating and be responsible for their operation, (h) provide scientific and technical assistance in the crisis management procedures implemented by the Commission with regard to the safety of food and feed, (i) provide scientific and technical assistance, (j) ensure that the public and interested parties receive rapid, reliable, objective and comprehensible information, (k) express independently its own conclusions and orientations and (l) undertake any other task assigned to it by the Commission. A rapid alert system for the notification of a direct or indirect risk to human health deriving from food or feed is hereby established as a network. The emergency measures taken in the case of food or feed imported from a third country are: (i) suspension of imports of the food or feed in question from all or part of the third country concerned and, where applicable, from the third country of transit, (ii) laying down special conditions for the food or feed in question from all or part of the third country concerned and (iii) any other appropriate interim measure.

Regulation (EC) No. 852/2004 (entry into force 1 January 2006) lays down general rules for food business operators on the hygiene of food-stuffs, taking particular account of the following princi-

ples: (a) primary responsibility for food safety rests with the food business operator, (b) it is necessary to ensure food safety throughout the food chain, starting with primary production, (c) it is important, for food that cannot be stored safely at ambient temperatures, particularly frozen food, to maintain the cold chain, (d) general implementation of procedures based on the HACCP principles, together with the application of good hygiene practice, should reinforce food business operators' responsibility, (e) guides to good practice are a valuable instrument to aid food with food hygiene rules and with the application of the HACCP principles, (f) it is necessary to establish microbiological criteria and temperature control requirements based on a scientific risk assessment and (g) it is necessary to ensure that imported foods are of at least the same hygiene standard as food produced in the Community, or are of an equivalent standard. The Regulation shall not apply to: (a) primary production for private domestic use, (b) the domestic preparation, handling or storage of food for private domestic consumption, (c) the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer and (d) collection centres and tanneries which fall within the definition of food business only because they handle raw material for the production of gelatine or collagen. The HACCP principles consist of the following: (a) identifying any hazards that must be prevented, eliminated or reduced to acceptable levels, (b) identifying the CCPs at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels, (c) establishing critical limits at CCPs which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards, (d) establishing and implementing effective monitoring procedures at CCPs, (e) establishing corrective actions when monitoring indicates that a CCP is not under control, (f) establishing procedures, which shall be carried out regularly, to verify that the measures outlined are working effectively and (g) establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined.

Another Regulation (EC No. 853/2004; entry into force 1 June 2006) has no application in relation to: (a) primary production for private domestic use, (b) the domestic preparation, handling or storage of food for private domestic consumption, (c) the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer, (d) the direct supply, by the producer, of small quantities of meat from poultry and lagomorphs slaughtered on the farm to the final consumer or to local retail establishments directly supplying such meat to the final consumer as fresh meat and (e) hunters who supply small quantities of wild game or wild game meat directly to the final consumer or to local retail establishments directly supplying the final consumer. It applies without prejudice to: (a) relevant animal and public health rules, including more stringent rules laid down for the prevention, control and eradication of certain transmissible spongiform encephalopathy (TSE), (b) animal welfare requirements and (c) requirements concerning the identification of animals and the traceability of products of animal origin. Food business operators shall adopt the following specific hygiene measures: (a) compliance with microbiological criteria for food-stuffs, (b) procedures necessary to meet targets set to achieve the objectives of this Regulation, (c) compliance with temperature control requirements for food-stuffs, (d) maintenance of the cold chain, (e) sampling and analysis.

According to EC Regulation No. 854/2004 (entry into force 1 January 2006), audits of good hygiene practices (GHP) shall verify that food business operators apply procedures continuously and properly concerning at least: (a) checks on food-chain information, (b) the design and maintenance of premises and equipment, (c) pre-operational, operational and post-operational hygiene, (d) personal hygiene, (e) training in hygiene and in work procedures, (f) pest control, (g) water quality, (h) temperature control and (i) controls on food entering and leaving the establishment and any accompanying documentation. The official veterinarian shall carry out inspection tasks in slaughterhouses, game handling establishments and cutting plants placing fresh meat on the market in accordance with the general require-

ments as regards: (a) food chain information, (b) ante-mortem inspection, (c) animal welfare, (d) post-mortem inspection, (e) specified risk material and other animal by-products and (f) laboratory testing. When the competent authority identifies non-compliance it shall take action to ensure that the food business operator remedies the situation. Such action shall include: (a) the imposition of sanitation procedures, (b) the restriction or prohibition of the placing on the market, import or export of products of animal origin, (c) monitoring or, if necessary, ordering the recall, withdrawal and/or destruction of products of animal origin, (d) authorisation to use products of animal origin for purposes other than those for which they were originally intended, (e) the suspension of operations or closure of all or part of the food business concerned for an appropriate period of time, (f) the suspension or withdrawal of the establishment's approval, (g) in the case of consignments from third countries, seizure followed by destruction or re-dispatch and (h) any other measure that the competent authority deems appropriate.

Regulation (EC) No. 882/2004 (entry into force 1 January 2006) lays down general rules for the performance of official controls to verify compliance with rules aiming at: (a) preventing, eliminating or reducing to acceptable levels risks to humans and animals, either directly or through the environment and (b) guaranteeing fair practices in feed and food trade and protecting consumer interests, including feed and food labelling and other forms of consumer information. Member States shall ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency, so as to achieve the objectives of this Regulation taking account of: (a) identified risks associated with animals, feed or food, feed or food businesses, the use of feed or food or any process, material, substance, activity or operation that may influence feed or food safety, animal health or animal welfare, (b) feed or food business operators' past record as regards compliance with feed or food law or with animal health and animal welfare rules, (c) the reliability of any own checks that have already been carried out and (d) any information that might indicate non-compliance. Official controls on feed and food shall include the following activities: (a) examination of any control systems that feed and food business operators

have put in place and the results obtained, (b) inspection of primary producers' installations, raw materials, semi-finished products, materials and articles intended to come into contact with the food, cleaning and maintenance products and processes, labelling, presentation and advertising, (c) checks on the hygiene conditions in feed and food businesses, (d) assessment of procedures on good manufacturing practices (GMP), GHP, good farming practices and HACCP, (e) examination of written material and other records which may be relevant to the assessment of compliance with feed or food law, (f) interviews with feed and food business operators and with their staff, (g) the reading of values recorded by feed or food business-measuring instruments, (h) controls carried out with the competent authority's own instruments to verify measurements taken by feed and food business operators and (i) any other activity required to ensure that the objectives of the Regulation are met.

A summary of the EU Regulations related to HACCP is given in Table 1.

Pesticide contamination

The pesticide contamination is covered by three rather old Directives (76/895/EEC, 86/362/EEC, 90/642/EEC), which appeared over a period of 13 years between 1977 and 1990.

EU Directive 76/895/EEC (entry into force 1 January 1977) concerned products intended either for human or, in exceptional cases, animal consumption. For the purposes of this Directive the term 'pesticide residues' comprises the residual traces of pesticides, as well as any of the toxic breakdown or metabolised products listed, present in or on the products to which the Directive applies. Member States may not prohibit or impede the putting on the market within their territories of the products referred, on the ground that they contain pesticide residues if the quantity of these residues does not exceed the maximum acceptable levels. When a Member State considers that a maximum level might endanger the health of humans or of animals other than harmful organisms, that Member State may temporarily reduce that level in its own territory. In that case it shall immediately notify the other Member States and the Commission of the measures taken with a statement of the reasons thereof.

EU Directive 86/362/EEC (entry into force 7 August 1986) applies to the following crops: wheat, rye, barley, oats, maize, paddy rice, buckwheat, millet, grain sorghum, Triticale and other cereals. The maximum permitted levels of pesticide residues exceeds to 0.1 mg kg^{-1} and concerns bromomethane, carbon disulphide, carbon tetrachloride, hydrogen cyanide, cyanides expressed as hydrogen cyanide, hydrogen phosphide, phosphides expressed as hydrogen phosphide. The Directive claims that Member States (a) shall ensure that the products referred do not, from the time they are put into circulation, present a danger to human health as a result of the presence of pesticide residues, (b) may not prohibit or impede the putting into circulation within their territories of the products referred, on the ground that they contain pesticide residues, if the quantity of such residues does not exceed the maximum levels, (c) shall prescribe that the products referred, may not contain, from the time they are put into circulation, levels of residues of pesticides greater than those specified, (d) shall take all necessary measures to ensure, at least by check sampling, compliance with the maximum levels. There is no application to the products intended for: (i) export to third countries, (ii) the manufacture of products other than food-stuffs and (iii) sowing.

EU Directive 90/642/EEC (entry into force 14 December 1990) also applies to products intended for export to third countries. However, the maximum pesticide residue levels shall not apply in the case of products treated before export where it can be satisfactorily proved that: (1) the third country of destination requires that particular treatment in order to prevent the introduction of harmful organisms into its territory or (2) the treatment is necessary in order to protect the products against harmful organisms during the transport to the third country of destination and storage there. The Directive shall not apply to the products referred, where it can be established by appropriate evidence that they are intended for: (a) the manufacture of products other than food-stuffs and animal feed or (b) sowing or planting. The products or the parts of them shall not contain, from the time they are put into circulation, pesticide residue levels higher than those specified. In the case of dried products for which maximum levels are not fixed, the maximum level applicable

Table 1 EU Regulations (main points and comments) related to Hazard Analysis Critical Control Points

Regulation – Title	Main points	Comments
Regulation (EC) No. 178/2002 (entry into force 1 January 2005) General principles and requirements of food law, establishment of the European Food Safety Authority and report of procedures in matters of food safety	General principles, principles of transparency, general obligations of food trade, general requirements of food law Mission and tasks, organisation, operation, financial provisions of the EFSA Need for independence, transparency, confidentiality and communication of the EFSA Rapid alert system, crisis management and emergencies Procedures and final provisions relative to food safety	
Regulation (EC) No. 852/2004 (entry into force 1 January 2006) Hygiene of food-stuffs	Food business operators' obligations National and Community guides for good hygiene practice Requirements of imports and exports Final provisions relatively implementing measures and transitional arrangements	
Regulation (EC) No. 853/2004 (entry into force 1 June 2006) Specific hygiene rules for food of animal origin	Specific rules on the hygiene of food of animal origin for food business operators Not applicable to food containing both products of plant origin and processed products of animal origin Food business operators' obligations Trade (documents, special guarantees) Final provisions relatively implementing and transitional measures, specific decisions, the Committee procedure and the consultation of the EFSA	
Regulation (EC) No. 854/2004 (entry into force 1 January 2006) Specific rules for the organisation of official controls on products of animal origin intended for human consumption	Official controls in relation to community establishments, general principles of official controls and actions in the case of non-compliance Procedures concerning imports or products of animal origin and fishery products Final provisions relatively specific decisions, report to the European Parliament and to the Council	
Regulation (EC) No. 882/2004 (entry into force 1 January 2006) Official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules	Official controls of Member States relatively general obligations, competent authorities, sampling and analysis, crisis management, official controls on the introduction on food and feed of third countries and financing of official controls Reference laboratories Administrative assistance and cooperation in the areas of food and feed The control plans and the training of the control staff are necessary National and Community enforcement measures and adoption of Community legislation Conditions of imports and Community activities	Repeals EU Directive 70/373/EEC 85/591/EEC 89/397/EEC 93/99/EEC 95/53/EC <i>Decisions</i> 93/383/EEC from 1 January 2006 98/728/EC from 1 January 2006 1999/313/EC from 1 January 2006

shall be that laid down in the list, taking into account the residue concentration caused by the drying process. Member States shall ensure, at least by check sampling, compliance with the

maximum levels. The competent authority or authorities of the Member States shall draw up forward programmes laying down the nature and frequency of the inspections to be carried out.

Table 2 EU Directives (main points and comments) focused on pesticide contamination

Directive – Title	Main points	Comments
EU 76/895/EEC (entry into force 1 January 1977)	Applicable to products intended for human and animal nutrition	Amendments EU Directive 80/428/EEC (entry into force 11 September 1980)
Setting of maximum residue levels of pesticides in fruit and vegetables	Not applicable to products exported to third countries Formal sampling to inspect whether the maximum residue levels are kept	81/36/EEC (entry into force 26 February 1981) 82/528/EEC (entry into force 4 August 1982) 88/298/EEC (entry into force 20 May 1988) 89/186/EEC (entry into force 10 March 1989) 93/58/EEC (entry into force 12 July 1993) 96/32/EC (entry into force 18 June 1996) 97/41/EC (entry into force 1 August 1997) 1999/65/EC (entry into force 8 July 1999) 2000/24/EC (entry into force 4 May 2000) 2000/57/EC (entry into force 19 October 2000) 2002/66/EC (entry into force 9 August 2002) 2002/71/EC (entry into force 29 August 2002) 2002/79/EC (entry into force 4 November 2002) 2003/60/EC (entry into force 14 July 2003) Regulation (EEC) No. 3768/85 (entry into force 1 January 1986) No. 807/2003 (entry into force 5 June 2003) Replacement, correction and amendment of articles
EU 86/362/EEC (entry into force 7 August 1986)	Not applicable to products exported to third countries, for not edible or drinkable products and for those intended for sowing or planting	Amendments EU Directive 86/363/EEC (entry into force 7 August 1986) 88/298/EEC (entry into force 20 May 1988) 93/57/EEC (entry into force 8 July 1993) 94/29/EEC (entry into force 23 July 1994) 95/39/EC (entry into force 11 September 1995) 96/33/EC (entry into force 18 June 1996) 97/41/EC (entry into force 1 August 1997) 97/71/EC (entry into force 18 December 1997) 98/82/EC (entry into force 1 November 1998) 1999/65/EC (entry into force 8 July 1999) 1999/71/EC (entry into force 1 August 1999) 2000/24/EC (entry into force 4 May 2000) 2000/42/EC (entry into force 1 July 2000) 2000/48/EC (entry into force 23 August 2000) 2000/58/EC (entry into force 19 October 2000) 2000/81/EC (entry into force 11 January 2001) 2001/39/EC (entry into force 21 June 2001) 2001/48/EC (entry into force 4 July 2001) 2001/57/EC (entry into force 21 August 2001) 2002/23/EC (entry into force 27 March 2002) 2002/42/EC (entry into force 11 June 2002) 2002/66/EC (entry into force 9 August 2002) 2002/71/EC (entry into force 29 August 2002) 2002/76/EC (entry into force 27 September 2002) 2002/79/EC (entry into force 4 November 2002) 2002/97/EC (entry into force 7 January 2003) 2003/60/EC (entry into force 14 July 2003) 2003/62/EC (entry into force 22 June 2003)
Setting of maximum residue levels of pesticides in cereals	Products that contain pesticide residues that exceed the maximum levels are prohibited from circulation Sampling to inspect whether the maximum residue levels are kept	Regulation (EC) No. 807/2003 (entry into force 5 June 2003) Filling, amendment and replacement of articles

Table 2 (Continued)

Directive – Title	Main points	Comments
EU 90/642/EEC (entry into force 14 December 1990) Setting of maximum residue levels of pesticides in certain products of plant origin including fruit and vegetables	Register of list of fruit and vegetables containing the maximum residue limits and of list containing residues of pesticides and their maximum levels Commission should be annually informed for the maximum residue limits Products that contain pesticide residues that exceed the maximum levels are prohibited from circulation	Amendments EU Directive 93/58/EEC (entry into force 12 July 1993) 94/30/EC (entry into force 23 July 1994) 95/38/EC (entry into force 11 September 1995) 95/61/EC (entry into force 18 June 1996) 97/41/EC (entry into force 1 August 1997) 97/71/EC (entry into force 7 January 1998) 98/82/EC (entry into force 1 November 1998) 1999/65/EC (entry into force 8 July 1999) 1999/71/EC (entry into force 1 August 1999) 2000/24/EC (entry into force 4 May 2000) 2000/42/EC (entry into force 1 July 2000) 2000/48/EC (entry into force 23 August 2000) 2000/57/EC (entry into force 19 October 2000) 2000/58/EC (entry into force 19 October 2000) 2000/81/EC (entry into force 11 January 2001) 2001/35/EC (entry into force 19 May 2001) 2001/39/EC (entry into force 21 June 2001) 2001/48/EC (entry into force 4 July 2001) 2001/57/EC (entry into force 21 August 2001) 2002/5/EC (entry into force 6 February 2002) 2002/23/EC (entry into force 27 March 2003) 2002/42/EC (entry into force 11 June 2002) 2002/66/EC (entry into force 9 August 2002) 2002/71/EC (entry into force 29 August 2002) 2002/76/EC (entry into force 27 September 2002) 2002/79/EC (entry into force 4 November 2002) 2002/97/EC (entry into force 7 January 2003) 2002/100/EC (entry into force 27 January 2003) 2003/60/EC (entry into force 14 July 2003) 2003/62/EC (entry into force 22 June 2003) 2003/69/EC (entry into force 22 July 2003) Regulation (EC) No. 806/2003 (entry into force 5 June 2003) Amendment of the Directive relatively with the maximum residue limits (MRLs)

All EU Directives related to pesticide contamination are given in Table 2.

Radioactive contamination

In the name of the EC Regulation there are three Regulations (EC No. 3954/87, 2219/89 and 737/90) referring to radioactive contamination.

Regulation (EC) No. 3954/87 (entry into force 2 February 1988) laid down the procedure for determining the maximum permitted levels of radioactive contamination of food-stuffs and of feeding stuffs which may be placed on the market following a nuclear accident or any other case of radiological emergency which is likely to lead to or has led to significant radioactive contamination of

food-stuffs and feeding stuffs. In the event of the Commission receiving official information on accidents or on any other case of radiological emergency, substantiating that the maximum permissible levels are likely to be reached or have been reached, it will immediately adopt, if the circumstances so require, a Regulation rendering applicable those maximum permissible levels. The period of validity of any Regulation shall be as short as possible and shall not exceed 3 months. The Regulation applies to baby foods, dairy products, liquid food-stuffs and feedstuffs. There are maximum permitted levels for: isotopes of strontium, notably Sr-90, isotopes of iodine notably I-131, alpha-emitting isotopes of plutonium

and transplutonium elements, notably Pu-239, Am-241 and for all other nuclides of half-life greater than 10 days, notably Cs-134 and Cs-137.

In Regulation (EC) No. 2219/89 (entry into force 25 July 1989), the conditions for exporting food-stuffs and feeding stuffs after a nuclear accident or any other radiological situation likely to lead to significant radioactive contamination of food-stuffs and feedstuffs are laid down. Food-stuffs and feeding stuffs in which the level of radioactive contamination exceeds the relevant maximum permitted levels may not be exported. The Member States shall carry out checks to ensure that the maximum permitted levels are observed. Each Member State shall communicate to the Commission the fullest information on the application of this Regulation, and in particular on any cases where the maximum permitted levels have been exceeded. The Commission shall forward this information to the other Member States.

Regulation (EC) No. 737/90 (entry into force 1 April 1990) applies to milk and dairy products for which the maximum permitted level of radioactivity is 370 Bq kg^{-1} . The accumulated maximum radioactive level in terms of Cs-134 and Cs-137 shall be: 370 Bq kg^{-1} for milk and milk products and 600 Bq kg^{-1} for all other products concerned.

The titles, main points and comments of the EU Regulations about radioactive contamination are summarised in Table 3.

Contamination from substances with hormonal action and other substances

According to EU Directive 96/22/EC (entry into force 23 May 1996), Member States shall prohibit: (a) the placing on the market of stilbenes, stilbene derivatives, their salts and esters and thyrostatic substances for administering to animals of all species and (b) the placing on the market of beta-agonists for administering to animals, the flesh and products of which are intended for human consumption. They shall, also, prohibit (i) the administering to a farm or aquaculture animal of substances having a thyrostatic, androgenic or gestagenic action and of beta-agonists, (ii) the holding of animals on a farm, the placing on the market or slaughter for human consumption of farm animals or of aquaculture animals which contain the substances referred or in which the presence of such substances has been established, (iii) the placing on the market for human consumption of aquaculture animals to which substances have been administrated and of processed products derived from such animals, (iv) the placing on the market of specific animals and (v)

Table 3 EU Regulations (main points and comments) dealing with radioactive contamination

Regulation – Title	Main points	Comments
Regulation (EC) No. 3954/87 (entry into force 2 January 1988) Determination of maximum permitted levels of radioactive contamination of food-stuffs and of feedstuffs following a nuclear accident or any other case of radiological emergency	Maximum permitted levels of radioactive contamination of food-stuffs and of feedstuffs in case of nuclear accident Duration of each regulation exceeds up to 3 months Any food-stuff or feedstuff that exceeds the maximum permitted levels is banned from the market disposal	Amendment Regulation (EC) No. 2218/89 Replacement of the Annex (entry into force 25 July 1989)
Regulation (EC) No. 2219/89 (entry into force 25 July 1989) Special conditions for exporting food-stuffs and feedstuffs following a nuclear accident or any other case of radiological emergency	Conditions for exporting food-stuffs and feedstuffs after a nuclear accident Any food-stuff or feedstuff that exceeds the maximum permitted levels is banned from exportation	
Regulation (EC) No. 737/90 (entry into force 1 April 1990) Conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station	Application for products originating from third countries Determination of maximum accumulated radioactivity of Cs134 and Cs137 Control measures in case of non compliance	Amendment Regulation (EC) No. 616/2000 Replacement of articles (entry into force 24 March 2000)

the processing of specific kinds of meat. Member States may authorise: (1) the administering to farm animals, for therapeutic purposes, of 17-beta-oestradiol, testosterone and progesterone and derivatives, (2) the administering for therapeutic purposes of authorised veterinary medicinal products containing: (i) allyl trenbolone, administered orally, or beta-agonists to equidae and pets, (ii) beta-agonists, in the form of an injection to induce tocolysis in cows when calving. The competent national authorities carry out the official checks without prior notice. Member States shall also prohibit the importation from third countries: (a) farm or aquaculture animals to which products or substances referred have been administered by any means whatsoever or to which substances or products referred have been administered, unless those substances or products were administered in compliance with the provisions and requirements laid down and the withdrawal periods allowed in international recommendations have been observed and (b) meat or products obtained from animals the importation of which is prohibited.

In agreement with EU Directive 96/23/EC (entry into force 23 May 1996) substances having anabolic effect and unauthorised substances are: (1) stilbenes, stilbene derivatives, and their salts and esters, (2) antithyroid agents, (3) steroids, (4) resorcylic acid lactones including zeranol and beta-agonists. In addition to this are veterinary drugs and contaminants: (A) antibacterial substances, including sulphonamides, quinolones, (B) other veterinary drugs (anthelmintics, anticoccidials, carbamates and pyrethroids, sedatives, non-steroidal anti-inflammatory drugs, other pharmacologically active substances) and (C) other substances and environmental contaminants (organochlorine compounds including PCBs, organophosphorus compounds, chemical elements, mycotoxins, dyes). The plan used to carry out the required inspections shall: (a) provide for detection of groups of residues or substances according to type of animal, (b) specify in particular the measures for detection of the presence of the substances referred in the animals, in the drinking water of the animals and in all places where the animals are bred or kept and residues of the aforementioned substances in live animals, their excrement and body fluids and in animal tissues and products such as meat, milk, eggs and honey

and (c) comply with the sampling rules and levels. Member States may have official random checks conducted: (i) during the manufacture of the substances and during their handling, storage, transport, distribution and sale or acquisition, (ii) at any point in the animal feeding stuffs production and distribution chain and (iii) throughout the production chain of animals and raw materials of animal origin covered by this Directive. Where illegal treatment is established, the competent authority must ensure that the livestock is immediately placed under official control. Where there is evidence of residues of authorised substances or products of a level exceeding the maximum limit for residues, the competent authority shall carry out an investigation in the farm of origin or departure, as applicable, to determine why the above limit was exceeded. In the event of repeated infringements of maximum residue limits when animals are placed on the market by a farmer or products are placed on the market by a farmer or a processing establishment, intensified checks on the animals and products from the farm and/or establishment in question must be carried out by the competent authorities for a period of at least 6 months, products or carcasses being impounded pending the results of analysis of the samples.

Some representative points and comments of the EU Directives regarding contamination from substances with hormonal action and other substances are given in Table 4.

Contaminants

A rather recent Regulation (EC) No. 466/2001 (entry into force 5 April 2002) covers several foods both of plant and animal origin: (1) fresh spinach, preserved-deep frozen or frozen spinach, fresh lettuce regarding nitrates, (2) round nuts, nuts, dried fruit, cereals, milk regarding aflatoxins, (3) milk, infant formulae, meat of bovine animals, sheep, pig and poultry, edible offal of cattle, sheep, pig and poultry, muscle meat of fish, muscle meat of wedge sole, crustaceans, bivalve molluscs, cephalopods, cereals, vegetables, fruit, berries, fats and oils, fruit juices, wines, horsemeat, liver and kidney of cattle, sheep, pig and poultry, rice, soybeans regarding heavy metals (lead, cadmium, mercury). Member States may, where justified, authorise for a transitional period the placing on the market of fresh lettuces and fresh spinach,

Table 4 EU Directives (main points and comments) for contamination from substances with hormonal action and other substances

Directive – Title	Main points	Comments
EU 96/22/EC (entry into force 23 May 1996) The prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists	The placing on the market and the administering to farm animals of substances having a thyrostatic action or substances having an oestrogenic, androgenic or gestagenic action and of stilbenes and beta-agonists are prohibited Certain of these substances may be used for therapeutic purposes provided their use is controlled	Repeals EU Directive 81/602/EEC from 1 July 1997 EU Directive 88/146/EEC from 1 July 1997 EU Directive 88/299/EEC from 1 July 1997
EU 96/23/EC (entry into force 23 May 1996) Measures to monitor certain substances and residues thereof in live animals and animal products	The monitoring substances are divided into two groups: substances having anabolic effect and unauthorised substances on the one hand, and veterinary drugs and contaminants on the other Determination of the official control measures and of those taken in the event of infringement	Repeals EU Directive 85/358/EEC from 1 July 1997 EU Directive 86/469/EEC from 1 July 1997 EU Directive 89/197/EEC from 1 July 1997 EU Directive 91/664/EEC from 1 July 1997

Regulation – Title	Main points	Comments
Regulation (EC) No. 466/2001 (entry into force 5 April 2002) Setting maximum levels for certain contaminants in food-stuffs	Setting of maximum levels for certain contaminants in food-stuffs	No comments

Table 5 EU Regulation (main points and comments) related to contaminants

grown and intended for consumption in their territory, with nitrate levels higher than those set as maximum levels. Member States shall communicate to the Commission by 30 June of each year, the results of their monitoring and report on the measures taken and the progress made with regard to the application and improvement of codes of good agricultural practice to reduce nitrate levels in lettuce and spinach. This information shall also contain the data on which their codes of good agricultural practice are based. The summary of Regulation No. 466/2001 is given in Table 5.

Biological safety

As cosmetics and medicinal products are nowadays on the rise, two Regulations have been recently introduced (EC 999/2001 and 2160/2003).

Regulation (EC) No. 999/2001 (entry into force 1 July 2001) has no application to: (a) cosmetic or medicinal products or medical devices, or to their starting materials or intermediate products, (b) products which are not intended for use in human food, animal feed or fertilisers, or to their starting

materials or intermediate products, (c) products of animal origin intended for exhibition, teaching, scientific research, special studies or analysis and (d) live animals used in or intended for research. Each Member State shall carry out an annual programme for monitoring BSE and scrapie. Member States shall inform the Commission of the emergence of a TSE other than BSE. All official investigations and laboratory examinations shall be recorded. Finally, Member States shall submit an annual report to the Commission. According to the Regulation, the following are prohibited: (i) the feeding to any farmed animal of protein derived from mammals, (ii) the feeding to any mammal of processed animal protein derived from mammals and (iii) the feeding to any ruminant of rendered ruminant fat. The following tissues shall be designated as specified risk materials: (a) the skull, including the brain and eyes, the tonsils and the spinal cord of bovine animals aged over 12 months and the intestines of bovine animals of all ages, (b) the skull including the brain and eyes, the tonsils and the spinal cord of ovine and caprine

animals aged over 12 months and the spleen of ovine and caprine animals of all ages, (c) the entire head (excluding the tongue) of bovine animals aged over 6 months, and the intestines of animals of all ages, (d) the vertebral column of bovine animals aged over 30 months, (e) the skull including the brain and eyes, the tonsils, the spinal cord of ovine and caprine animals aged over 12 months and the spleen of ovine and caprine animals of all ages. All these shall be removed from slaughterhouses, cutting plants, high-risk processing plants or premises. Any animal suspected of being infected by a TSE shall be placed under an official movement restriction until the results of a clinical and epidemiological examination are known. Where the competent authority decides that the possibility of infection with a TSE cannot be ruled out, the animal shall be killed, if it is still alive; its brain and all other tissues, as the competent authority may determine, shall be removed and sent to an officially approved laboratory. When the presence of a TSE has been officially confirmed, the following measures shall be applied as soon as possible: (i) all parts of the body of the animal shall be completely destroyed, (ii) an inquiry shall be carried out to identify all animals at risk and (iii) all animals and products of animal origin that have been identified as being at risk, shall be killed and completely destroyed. The use of ruminant materials for the production of the following products of animal origin is prohibited: mechanically recovered meat, dicalcium phosphate intended as feeding stuffs for livestock, gelatine, unless it is produced from ruminant hides, derivatives made from rendered ruminant fat and rendered ruminant fat.

The purpose of Regulation (EC) No. 2160/2003 (entry into force 12 December 2003) is to ensure that proper and effective measures are taken to detect and to control salmonella and other zoonotic agents at all relevant stages of production, processing and distribution, particularly at the level of primary production, including in feed, in order to reduce their prevalence and the risk they pose to public health. This Regulation shall cover: (a) the adoption of targets for the reduction of the prevalence of specified zoonoses in animal populations, (b) the approval of specific control programmes established by Member States and food and feed business operators, (c) the adoption of

specific rules concerning certain control methods applied in the reduction of the prevalence of zoonoses and zoonotic agents, (d) the adoption of rules concerning intra-Community trade and imports from third countries of certain animals and products thereof. It shall not apply to primary production: (a) for private domestic use or (b) leading to the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the primary products to the final consumer. Each Member State shall designate a competent authority or competent authorities for the purpose of this Regulation and notify the Commission thereof. The Community targets for the reduction of the prevalence of zoonoses and zoonotic agents consist at least of a numerical expression of: (a) the maximum percentage of epidemiological units remaining positive; and/or the minimum percentage of reduction in the number of epidemiological units remaining positive, (b) the maximum time limit within which the target must be achieved, (c) the definition of the epidemiological units, (d) the definition of the testing schemes necessary to verify the achievement of the target and (e) the definition, where relevant, of serotypes with public health significance or of other subtypes of zoonoses or zoonotic agents. To achieve the Community targets, Member States shall establish national control programmes for each zoonosis and zoonotic agent. National control programmes shall cover at least the following stages of the food chain: feed production, primary production of animals, processing and preparation of food of animal origin. After a Member State submits a national control programme, the Commission shall have 2 months within which to request any further relevant and necessary information from that Member State. The Member State shall provide such further information within 2 months of receiving such a request. The Commission shall, within 2 months of receiving such further information or, if it did not request further information, within 6 months of the submission of the control programme, establish whether it complies with relevant rules, including this Regulation in particular.

The basic points and repeals of the EU legislation focused on biological safety are stated in Table 6.

Table 6 EU Regulations (main points and comments) with regard to biological safety

Regulation – Title	Main points	Comments
Regulation (EC) No. 999/2001 (entry into force 1 July 2001) Rules for the prevention, control and eradication of certain Transmissible Spongiform Encephalopathies	Rules for the prevention, control and eradication of TSEs in animals Application to the production and placing on the market of live animals and products of animal origin and in certain specific cases to exports thereof Member States shall carry out an annual programme for monitoring BSE and scrapie The feeding to ruminants of protein derived from mammals is prohibited The specified risk material shall be removed and destroyed	No comments
Regulation (EC) No. 2160/2003 (entry into force 12 December 2003) The control of Salmonella and other specified food-borne zoonotic agents	Measures to detect and to control Salmonella and other zoonotic agents Application to production, processing and distribution Designation of a competent authority for each Member State and arrangement of responsibilities Arrangement of control plans Imports from third countries only if specific conditions are met	No comments

Technological aspects

The purpose is to address and overcome specific scientific and technological hurdles that impact on the performance of functional foods based on probiotic–prebiotic interactions. Such hurdles include the lack of strong knowledge of the primary factors for probiotic viability, stability and performance as well as of probiotic–prebiotic interactions. The project will systematically explore effects of processing on functionality of probiotics and on probiotic performance, apply selected processing techniques for prebiotic modification, and use the information generated for new process and product options (http://europa.eu.int/comm/research/quality-of-life/ka1/home_en.htm). Technology aspects deal with technical aspects of food service, especially as they relate to practical, commercial and public health issues. It covers market trends in the usage of food service technology, and essential health and safety information. It includes contributions from specialists in market research; consumer science; psychology; economics; modelling and simulation; food technology; food preservation; safety and hazard analysis; equipment design and engineering (<http://www.blackwellpublishing.com/journal.asp?ref1471-5732>).

Freezing – ionisation

EU Directive 89/108/EEC (entry into force 10 January 1989) applied to quick frozen foods

which are food-stuffs which (a) have undergone a suitable freezing process known as ‘quick-freezing’ whereby the zone of maximum crystallisation is crossed as rapidly as possible, depending on the type of the product, and the resulting temperature of the product (after thermal stabilisation is continuously maintained at a level at -18°C or lower at all points) and (b) which are marketed in such a way as to indicate that they possess this characteristic. Ice cream and other ices shall not be regarded as quick frozen food-stuffs. The cryogenic media authorised, to the exclusion of all others, for use in direct contact with quick-frozen food-stuffs shall be: air, nitrogen and carbon dioxide. The temperature of quick-frozen food-stuffs must be stable and maintained, at all points in the product at -18°C or lower, with possibly brief upward fluctuation of no more 3°C during transport. The Member States shall: (a) ensure that the equipment used for quick freezing, storage, transport, local distribution and retail display cabinets is such that compliance with the requirements of this Directive can be guaranteed and (b) conduct random official checks on the temperature of quick-frozen food-stuffs. Quick-frozen food-stuffs intended for supply to the ultimate consumer must be packed by the manufacturer or packer in suitable pre-packaging which protects them from microbial or other forms of external contamination and against drying.

According to EU Directive 1999/2/EC (entry into force 10 March 1999) food irradiation may be authorised only if: (a) there is a reasonable technological need, (b) it presents no health hazard and is carried out under the conditions proposed, (c) it is of benefit to the consumer and (d) it is not used as a substitute for hygiene and health practices or for good manufacturing or agricultural practice. Food irradiation may be used only for the following purposes: (i) to reduce the incidence of food-borne disease by destroying pathogenic organisms (ii) to reduce spoilage of food-stuffs by retarding or arresting decay processes and destroying spoilage organisms, (iii) to reduce loss of food-stuffs by premature ripening, germination or sprouting and (iv) to get rid of food-stuffs of organisms harmful to plant or plant products. Sources of ionising irradiation are (a) gamma rays from radionuclides ^{60}Co or ^{137}Cs , (b) X-rays generated from machine sources operated at or below a nominal energy (maximum quantum energy) level of 5 MeV and (c) electrons generated from machine sources operated at or below a nominal energy (maximum quantum energy) level of 10 MeV. It can be assumed for the purpose of the determination of the wholesomeness of food-stuffs treated with an overall average dose of 10 kGy or less that all radiation chemical effects in that particular dose range are proportional to the dose. The labelling of food-stuffs treated with ionising radiation shall be governed by the specific provisions. Such a food-stuff may not be imported from a third country unless it complies with the conditions which apply to those food-stuffs, is accompanied by documents showing the name and address of the facility which carried out the irradiation treatment, was treated in an irradiation facility approved by the Community.

EU Directive 1999/3/EC (entry into force 10 March 1999) laid down the establishment of a Community initial positive list of food and food ingredients, that may be treated with ionising radiation, together with the maximum doses authorised for the intended purpose. Treatment of the products in question with ionising radiation may be carried out only in accordance with the provisions of the framework Directive. The food-stuffs that may be treated with ionising radiation are dried aromatic herbs,

spices and vegetable seasonings. The maximum overall average absorbed radiation dose should be 10 kGy.

A summary of the EU legislation related to freezing (ionisation) is provided in Table 7.

Food additives – flavourings

The EU Directives were among the first ones developed because additives were always considered of great importance for prolonging the shelf-life of foods. However, numerous problems (high toxicity, poisoning and even deaths) occurred due either to deliberate or non-deliberate use of additives. These Directives (ten in total) came into force over a long period of time (1962–1996).

EU Directive 62/2645/EEC (entry into force 26 October 1963) claimed that Member States shall not authorise the use for colouring food-stuffs intended for human consumption of any colouring matters other than those listed in Annex I. It shall not affect national rules concerning: (i) natural substances which are used in the manufacture of certain food-stuffs because of their aromatic, rapid or nutritive properties but which also have a subsidiary colouring property (paprika, turmeric, saffron and sandalwood) and (ii) colouring matters authorised for colouring the shells of hard boiled eggs, tobacco, manufactured tobacco and for stamping meat, citrus fruit, cheese-rinds, the shells of eggs and other external parts not usually consumed with the food-stuffs. The Member States shall, for diluting or dissolving the colouring matters, authorise the use of the following products only: sodium carbonate and sodium hydrogen carbonate, sodium chloride, sodium sulphate, glucose, lactose, sucrose, dextrans, starches, ethanol, glycerol, sorbitol, edible oils and fats, beeswax and water. The colouring matters are required to satisfy the following criteria of purity: (1) For inorganic impurities they should not contain (a) more than 5 mg kg^{-1} of arsenic and more than 20 mg kg^{-1} of lead, (b) more than 100 mg kg^{-1} of antimony, copper, chromium, zinc, barium sulphate taken separately and more than 200 mg kg^{-1} of these products taken together, (c) cadmium, mercury, selenium, tellurium, thallium, uranium or chromates, or soluble combinations of barium in detectable quantities. (2) For organic impurities they should not contain: (a)

Table 7 EU Directives (main points and comments) for freezing: ionisation

Directive – Title	Main points	Comments
EU 89/108/EEC (entry into force 10 January 89) Approximation of the laws of the Member States relating to quick-frozen food-stuffs for human consumption	Air, nitrogen and carbon dioxide are the permitted cryogenic agents Maintenance of specific temperatures of distribution and storage and appropriate labelling Packaging in pre-packages Sampling procedures and methods of analysis for the control of the temperatures	Amendments EU Directive 92/1/EEC Measures for monitoring of temperature in the means of transport, warehousing and storage (entry into force 11 February 92) EU Directive 92/2/EEC Establishment of a method of sampling and analysis for the control of the temperatures (entry into force 11 February 92)
EU 1999/2/EC (entry into force 10 March 1999) The approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation	Application to the manufacture, marketing and importation of food-stuffs treated with ionising radiation No application to food-stuffs exposed to ionising radiation generated by measuring or inspection devices under conditions No application for the irradiation of food-stuffs which are prepared for patients Community list of food-stuffs which may be treated with ionising radiation Specific limits of maximum dose of irradiation	
EU 1999/3/EC (entry into force 10 March 1999) On the establishment of a Community list of foods food ingredients treated with ionising radiation	Establishment of a Community initial positive list of food and food ingredients that may be treated with ionising radiation, together with the maximum doses authorised for the intended purpose	

2-naphthylamine, benzidine, amino-4-diphenyl or their derivatives, (b) polycyclic aromatic hydrocarbons, (c) synthetic organic colouring matters more than 0.70% of free aromatic amines, (d) synthetic organic colouring matters more than 0.75% of intermediate synthetic products other than free aromatic amines, (e) synthetic organic colouring matter more than 4% of accessory colouring matters, (f) sulphonated organic colouring matters more than 0.72% of substances extractable by diethyl ether. Member States may authorise the use of pigment rubine and of burnt umber, whether or not mixed with paraffin wax or with other harmless substances, only for colouring cheese-rinds. This Directive shall apply to chewing gum insofar as the latter contains any colouring matter.

EU Directive 78/663/EEC (entry into force 1 February 1980) applied to specific criteria of purity for emulsifiers, stabilisers, thickeners and

gelling agents for use in food-stuffs. These specific purity criteria concern: chemical name, chemical description, appearance, content, volatile matter, fluoride, ash, gelatin and other proteins, water absorption, methanol-ethanol-isopropanol content, karaya gum, tannin, starch or dextrin, pyruvic acid, nitrogen, etc.

In EU Directive 81/712/EEC (entry into force 6 August 1981), methods of analysis of certain categories of additives are stated in order to verify that they satisfy criteria of purity. The additives concerned are: colouring matters, preservatives and antioxidants. Methods of analysis relating to the criteria of purity of food additives include: (1) determination of substances extractable with diethyl ether from water-soluble sulphonated organic colouring matters intended for food-stuffs, (2) determination of formic acid, formates and other oxidisable impurities in acetic acid (E 260), potassium acetate (E 261), sodium diacetate

(E 262) and calcium acetate (E 263), (3) determination of non-volatile substances in propionic acid (E 280), (4) determination of the loss of mass on drying of sodium nitrite (E 250), (5) limit test for salicylic acid in ethyl *p*-hydroxybenzoate (E 214), ethyl-*p*-hydroxybenzoate, sodium salt (E 215), *n*-propyl *p*-hydroxybenzoate (E 216), *n*-propyl *p*-hydroxybenzoate, sodium salt (E 217), methyl *p*-hydroxybenzoate (E 218), methyl *p*-hydroxybenzoate, sodium salt (E 219), (6) determination of free acetic acid in sodium diacetate (E 262), (7) determination of sodium acetate in sodium diacetate (E 262), (8) limit test for aldehydes in sorbic acid (E 200), sodium, potassium and calcium sorbates (E 201, E 202, E 203) and propionic acid (E 280), (9) determination of the peroxide number in lecithins (E 322), (10) determination of toluene-insoluble matter in lecithins (E 322), (11) limit test for reducing substances in sodium, potassium and calcium lactates (E 325, E 326, E 327), (12) determination of volatile acids in orthophosphoric acids (E 338), (13) limit test for nitrate in orthophosphoric acid (E 338), (14) determination of water-insoluble substances present in mono-, di- and tri-sodium orthophosphates and mono-, di- and tri-potassium orthophosphates (E 339(i), E 339(ii), E 339(iii), E 340(i), E 340(ii) and E 340(iii)), (15) determination of the pH of food additives.

EU Directive 88/388/EEC (entry into force 30 June 1988) has no application to edible substances and products intended to be consumed as such, with or without reconstitution, substances which have exclusively a sweet, sour or salt taste and material of vegetable or animal origin, having inherent flavouring properties, where they are not used as flavouring sources. Member States shall take all measures necessary to ensure that: (a) flavourings do not contain any element or substance in a toxicologically dangerous quantity and that they do not contain more than 3 mg kg⁻¹ of arsenic, 10 mg kg⁻¹ of lead, 1 mg kg⁻¹ of cadmium and 1 mg kg⁻¹ of mercury, (b) the use of flavourings does not result in the presence in food-stuffs as consumed of undesirable substances in quantities greater than those specified therein, (c) the use of flavourings and of other food ingredients with flavouring properties does not result in the presence of substances in quantities greater than those specified. The following shall be adop-

ted: (A) the list of substances or materials authorised in the Community as additives necessary for the storage and use of flavourings, products used for dissolving and diluting flavourings and additives necessary for the production of flavourings where such additives are not covered by other Community provisions, (B) where necessary the methods of analysis needed to verify compliance, the procedure for taking samples and the methods for qualitative and, where appropriate, quantitative analysis of flavourings in or on food-stuffs and the specific criteria of purity for given flavourings, (C) the microbiological criteria applicable to flavourings and the designation criteria.

EU Directive 88/389/EEC (entry into force 22 June 1988) claims that the Commission shall, within 24 months of adoption of this Directive and after consultation of the Member States, establish an inventory of flavouring sources composed of food-stuffs, and of herbs and spices normally considered as foods, flavouring sources composed of vegetable or animal raw materials not normally considered as foods, flavouring substances obtained by appropriate physical processes or by enzymatic or microbiological processes from vegetable or animal raw materials, chemically synthesised or chemically isolated flavouring substances chemically identical to flavouring substances naturally present in food-stuffs or in herbs and spices normally considered as foods, chemically synthesised or chemically isolated flavouring substances chemically identical to flavouring substances naturally present in vegetable or animal raw materials not normally considered as foods and chemically synthesised or chemically isolated flavouring substances other than those referred, used for the production of smoke flavourings and process flavourings and the reaction conditions under which they are prepared.

EU Directive 89/107/EEC (entry into force 28 August 1989) states that the term 'food additive' means any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its

by-products becoming directly or indirectly a component of such foods. This Directive shall not apply to: (a) processing aids, (b) substances used in the protection of plants and plant products, (c) flavourings for use in food-stuffs, (d) substances added to food-stuffs as nutrients. The categories of food additives are: colour, preservative, anti-oxidant, emulsifier, emulsifying salt, thickener, gelling agent, stabiliser, flavour enhancer, acid, acidity regulator, anti-caking agent, modified starch, sweetener, raising agent, anti-foaming agent, glazing agent, flour treatment agent, firming agent, humectant, sequestrant, enzyme, bulking agent, propellant gas and packaging gas. The Council shall adopt: (i) a list of additives, the use of which is authorised to the exclusion of all others, (ii) the list of food-stuffs to which these additives may be added, the conditions under which they may be added and, where appropriate, a limit on the technological purpose of their use, (iii) the rules on additives used as carrier substances and solvents, including where necessary their purity criteria. Food additives not intended for sale to the ultimate consumer may be marketed only if their packaging or containers bear the following information: (a) for food additives sold singly or mixed with each other, the name for each additive (b) either the statement 'for use in food' or the statement 'restricted use in food' or a more specific reference to its intended food use, (c) if necessary, the special conditions of storage and use, (d) directions for use, (e) a mark identifying the batch or lot, (f) the name or business name and address of the manufacturer or packager, or of a seller established within the Community, (g) an indication of the percentage of any component which is subject to a quantitative limitation in a food or adequate compositional information to enable the purchaser to comply with any Community provisions.

EU Directive 94/35/EC (entry into force 10 September 1994) covers food additives, hereinafter referred to as 'sweeteners', which are used to impart a sweet taste to food-stuffs or as table-top sweeteners. It shall not apply to food-stuffs with sweetening properties. The presence of a sweetener in a food-stuff is permissible in compound food-stuffs with no added sugar or energy-reduced, in compound dietary food-stuffs intended for a low-calorie diet and in compound food-stuffs with a

long shelf-life or if the food-stuff is intended to be used solely in the preparation of a compound food-stuff which conforms to this Directive. The sales description of a table-top sweetener must include the term '...-based table-top sweetener', using the name(s) of the sweetening substance(s) used in its composition. The labelling of a table-top sweetener containing polyols and/or aspartame must bear the following warnings: polyols: 'excessive consumption may induce laxative effects' or aspartame: 'contains a source of phenylalanine'.

EU Directive 94/36/EC (entry into force 31 December 1995) applies to food additives, hereinafter referred to as 'colours', which are substances which add or restore colour to a food, and include natural constituents of food-stuffs and natural sources which are normally not consumed as food-stuffs as such and not normally used as characteristic ingredients of food. Also, preparations obtained from food-stuffs and other natural source materials obtained by physical and/or chemical extraction resulting in a selective extraction of the pigments relative to the nutritive or aromatic constituents are colours. From the scope of this Directive, food-stuffs, whether dried or in concentrated form and flavourings incorporated during the manufacturing of compound food-stuffs, because of their aromatic, sapid or nutritive properties together with a secondary colouring effect and also colours used for the colouring of the inedible parts of food-stuffs, are excluded. The presence of a colour in a food-stuff is permissible: (i) in a compound food-stuff other one mentioned in Annex II of the Directive to the extent that the colour is permitted in one of the ingredients of the compound food-stuff or (ii) if the food-stuff is destined to be used solely in the preparation of a compound food-stuff and to such an extent that the compound food-stuff conforms to the provisions of the Directive. Food-stuffs which may not contain added colours are: unprocessed food-stuffs, all bottled or packed waters, milk, chocolate milk, butter milk, cream and cream powder, oils and fats of animal or vegetable origin, eggs and eggs products, flour, bread, pasta, sugar, fruit, vegetables, fish, wine, honey, etc. Member States, within 3 years from the adoption of this Directive, shall establish systems to monitor the consumption and colours and report their findings to the

Commission. The Commission shall report to the European Parliament, within 5 years from the adoption of this Directive, on changes, which have been taken place in the colours market, the levels of use and consumption.

EU Directive 95/2/EC (entry into force 25 March 1995) covers: preservatives, antioxidants, carriers, acids, acidity regulators, anti-caking agents, anti-foaming agents, bulking agents, emulsifiers, emulsifying salts, firming agents, flavour enhancers, foaming agents, gelling agents, glazing agents, humectants, modified starches, packaging gases, propellants, raising agents, sequestrants, stabilisers and thickeners. For the purposes of this Directive the following are not considered as food additives: (a) substances used for treatment of drinking water, (b) products containing pectin and derived from dried apple pomace or peel of citrus fruits, or from a mixture of both, by the action of dilute acid followed by partial neutralisation with sodium or potassium salts, (c) chewing gum bases, (d) white or yellow dextrin, roasted or dextrinated starch, starch modified by acid or alkali treatment, bleached starch, physically modified starch and starch treated by amylolytic enzymes, (e) ammonium chloride, (f) blood plasma, edible gelatin, protein hydrolysates and their salts, milk protein and gluten, (g) amino acids and their salts other than glutamic acid, glycine, cysteine and cystine and their salts and having no additive function, (h) caseinates and casein and (i) inulin. The Directive does not apply to: unprocessed food-stuffs, honey, non-emulsified oils-fats of animal or vegetable origin, butter, pasteurised-sterilised milk-plain pasteurised cream, unflavoured-live fermented milk products, natural mineral water, coffee and coffee extras, unflavoured leaf tea, sugars, dry pasta, natural unflavoured buttermilk. The presence of a food additive in a food-stuff is permissible: (i) in a compound food-stuff other than one mentioned, to the extent that the food additive is permitted in one of the ingredients of the compound food-stuff or (ii) if the food-stuff is destined to be used solely in the preparation of a compound food-stuff and to an extent such that the compound food-stuff conforms to the provisions of this Directive.

Regulation (EC) No. 2232/96 (entry into force 23 November 1996) sets general criteria for the use of flavouring substances: (a) The use of flavouring

substances may be authorised provided that they present no risk to the health of the consumer and that their use does not mislead the consumer. (b) To be able to assess the possible harmful effects of a flavouring substance, the latter must be subjected to appropriate toxicological evaluation. When a flavouring substance contains or consists of a genetically modified organism (GMO), the evaluation of the safety of this flavouring substance must take into account environmental safety. (c) All flavouring substances must be kept constantly monitored and must be re-evaluated whenever necessary. In order to check whether the flavouring substances contained in the register comply with the general use criteria, a programme for the evaluation of these flavouring substances shall be adopted within 10 months of the register being adopted. That programme shall define in particular: (i) the order of priorities according to which the flavouring substances are to be examined, taking into account their uses, (ii) the time limits, (iii) the flavouring substances which are to be the subject of scientific cooperation.

Some representative points and comments (amendments, repeals) of the EU Directives/Regulations about food additives and flavourings are given in Table 8.

Food-stuffs intended for specific nutritional uses

According to the EU Directive 89/398/EEC (entry into force 16 May 1990) food-stuffs for particular nutritional uses are food-stuffs which, owing to their special composition or manufacturing process, should be clearly distinguishable from food-stuffs for normal consumption. A particular nutritional use must fulfil the particular nutritional requirements: (i) of certain categories of persons whose digestive processes or metabolism are disturbed, (ii) of certain categories of persons who are in a special physiological condition, (iii) of infants or young children in good health. Such specific Directives may cover in particular: essential requirements as to the nature or the composition of the products, provisions regarding the quality of raw materials, hygiene requirements, permitted changes, a list of additives, provisions regarding labelling, presentation and advertising, sampling procedures and methods of analysis for checking compliance with the requirements. To permit efficient official monitoring of those

Table 8 EU Directives/Regulations (main points and comments) dealing with food additives and flavourings

Directive – Title	Main points	Comments
EU 62/2645/EEC (entry into force 26 October 1963) Colouring matters authorised for use in food-stuffs intended for human consumption	Lists of colouring matters which may be used to treat food-stuffs, together with their conditions of use. They only apply to colouring matters imported into the Community Procedures to be followed when one of the colouring matters constitutes a danger to human health Labelling requirements	Amendments Amendments, corrections and completions of the EU Directive 62/2645/EEC EU Directive 65/409/EEC (entry into force 31 December 1966) EU Directive 67/653/EEC Corrections of the annexes of the EU Directive 62/2645/EEC (entry into force 1 January 1968) EU Directive 68/419/EEC Addition of a phrase in article 12 of the Directive (entry into force 20 December 1968) EU Directive 70/358/EEC Replacement of an article and addition of provisions (entry into force 13 July 1970) EU Directive 76/399/EEC Amendment of the annex (entry into force 6 April 1976) EU Directive 78/144/EEC Replacement of an article and of the annex, amendment of the annex (entry into force 1 February 1979) EU Directive 81/20/EEC Addition of substances in annex 2 (entry into force 1 July 1981)
EU 78/663/EEC (entry into force 1 February 1980) Specific criteria of purity for emulsifiers, stabilisers, thickeners and gelling agents for use in food-stuffs	List of specific purity criteria to be met by emulsifiers, stabilisers, thickeners and gelling agents	Amendments EU Directive 82/504/EEC Amendment of article and annex (entry into force 1 January 1984) EU Directive 90/6121/EEC Amendment of annex (entry into force 12 November 1991) EU Directive 92/4/EEC Amendment of annex (entry into force 1 June 1993)
EU 81/712/EEC (entry into force 6 August 1981) Community methods of analysis for verifying that certain additives used in food-stuffs satisfy criteria of purity	Community methods of analysis for verifying that certain additives used in food-stuffs satisfy purity criteria	
EU 88/388/EEC (entry into force 30 June 1988) Flavourings for use in food-stuffs and source materials for their production	Application only to imported flavourings used or intended for use in or on food-stuffs to impart odour and/or taste, and to source materials used for their production Register of list of authorised substances or materials, methods of analysis, etc. Obligatory marks in labelling	Amendments EU Directive 91/71/EEC (entry into force 7 February 1991) Determination of clues written on labels
EU 88/389/EEC (entry into force 22 June 1988) Establishment of an inventory of the source materials and substances used in the preparation of flavourings	Establishment of an inventory within 24 months of adoption of this Directive	

Table 8 (Continued)

Directive – Title	Main points	Comments
EU 89/107/EEC (entry into force 28 August 1989) On the approximation of the laws of the Member States concerning food additives authorised for use in food-stuffs intended for human consumption	For food additives used as ingredients during the manufacture or preparation of food and which are part of the finished product The only substances which may be used as food additives are those included in the approved lists and then only under the conditions of use mentioned in those lists Information requirements on labelling and packaging of additives for sale to both the consumer and the manufacturer	Amendment EU Directive 95/45/EC Determination of purity criteria of substances (entry into force 29 September 1995)
EU 94/35/EC (entry into force 10 September 1994) Sweeteners for use in food-stuffs	Application to food additives used to impart a sweet taste to food-stuffs, together with those destined for a particular nutritional use or for use as table-top sweeteners Authorisation of two new intense sweeteners: sucralose and the salt of aspartame and acesulfame Reduction of the maximum usable dose for cyclamates in certain food categories Permission of the exhaustion of stocks which do not comply with the legislation	Amendments EU Directive 96/83/EC Amendment of articles and of the annex and filling of a table (entry into force 26 February 1997) EU Directive 2003/115/EC Replacement of articles (entry into force 29 January 1994)
EU 94/36/EC (entry into force 31 December 1995) Colours for use in food-stuffs	Application to the colours used in authorised food-stuffs Prohibition of the use of colours in certain food-stuffs, including mineral water and whole milk	
EU 95/2/EC (entry into force 25 March 1995) Food additives other than colours and sweeteners	Determination of the substances which are regarded as food additives, of the food-stuffs in which these additives may be used and their conditions of use	Repeals EU Directive 64/54/EEC EU Directive 70/357/EEC EU Directive 74/329/EEC EU Directive 83/463/EEC Amendments EU Directive 96/85/EC Authorisation of the use of Eucheuma seaweed as a new food additive (entry into force 4 April 1997) EU Directive 98/72/EC Various additions and changes to the Directive and its annexes (entry into force 4 November 1998) EU Directive 2001/5/EC Approval of the use of some new additives which had been authorised on a temporary basis at national level, i.e. propane, butane and iso-butane (entry into force 24 February 2001) EU Directive 2003/52/EC Temporarily authorisation of the use of the food additive E 425 konjac both in jelly mini-cups and in any other jelly confectionery because it has been found to be dangerous (entry into force 17 July 2003)

Table 8 (Continued)

Directive – Title	Main points	Comments
Regulation (EC) No. 2232/96 (entry into force 23 November 1996) Flavouring substances used or intended for use in or on food-stuffs	The Member States must notify a list of the flavouring substances which may be used in or on food-stuffs marketed on their territory Adoption of a programme for evaluation of these flavouring substances within 10 months of the register being adopted	EU Directive 2003/114/EC Authorisation of a new food additive (hydrogenated poly-1-decene) which has been found to be suitable for human consumption (entry into force 20 November 2003)

food-stuffs the following specific provisions shall apply: (i) when a product is placed on the market for the first time the manufacturer or the importer shall notify the competent authority of the Member State where the product is being marketed by forwarding it a model of a label used for the product, (ii) where the same product is subsequently placed on the market in another Member State the manufacturer or the importer shall provide the competent authority with the same information together with a notification of the recipient of the first notification, (iii) where necessary, the competent authority shall be empowered to require the manufacturer or the importer to produce the scientific work and the data establishing the products' compliance with the Directive, (iv) Member States shall communicate to the Commission the identity of the competent authorities and any other useful information on them, (v) 4 years after notification of this Directive the Commission shall sent the Council a report.

EU Directive 91/321/EEC (entry into force 30 May 1991) laid down compositional and labelling requirements for infant formulae and follow-on formulae intended for use by infants in good health in the Community. It also provides for Member States to give effect to principles and aims of the International Code of Marketing of Breast-Milk Substitutes dealing with marketing, information and responsibilities of health authorities. The essential composition of infant formulae when reconstituted as instructed by the manufacturer comprises: (1) Energy (minimum 250 kJ, maximum 315 kJ). (2) Proteins (a) formulae manufactured from unmodified cows' milk proteins

(minimum 0.56 g/100 kJ, maximum 0.7 g/100 kJ), (b) formulae manufactured from modified cows' milk proteins (minimum 0.45 g/100 kJ, maximum 0.7 g/100 kJ), (c) formulae manufactured from soy protein isolates, alone or in a mixture with cows' milk proteins (minimum 0.56 g/100 kJ, maximum 0.7 g/100 kJ), (d) in all cases, the addition of amino acids is permitted solely for the purpose of improving the nutritional value of the proteins, and only in the proportions necessary for that purpose. (3) Lipids (minimum 0.8 g/100 kJ, maximum 1.5 g/100 kJ). The use of the following substances is prohibited: (a) sesame seed oil, cotton seed oil, fats containing more than 8% trans isomers of fatty acids, (b) lauric acid, (c) myristic acid, (d) linoleic acid. (4) Carbohydrates (minimum 1.7 g/100 kJ, maximum 3.4 g/100 kJ). Only the following carbohydrates may be used: lactose, maltose, sucrose, malto-dextrins, glucose syrup or dried glucose syrup, pre-cooked starch, gelatinised starch naturally free of gluten. (5) Mineral substances: formulae manufactured from cows' milk proteins per 100 kJ sodium, potassium, chloride, calcium, phosphorus, magnesium, iron, zinc, copper, iodine.

EU Directive 96/5/EC (entry into force 8 March 1996) covers food-stuffs for particular nutritional use fulfilling the particular requirements of infants and young children in good health in the Community and are intended for use by infants while they are being weaned, and by young children as a supplement to their diet and/or for their progressive adaptation to ordinary food. They comprise: (a) 'processed cereal-based foods' which are divided into the following four categories: simple

cereals which are or have to be reconstituted with milk or other appropriate nutritious liquids, cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid, pastas which are to be used after cooking in boiling water or other appropriate liquids, rusks and biscuits which are to be used either directly or, after pulverisation, with the addition of water, milk or other suitable liquids and (b) 'baby foods' other than processed cereal-based foods. There should be an arrangement of the quantities of cereal content, protein, carbohydrates, lipids, minerals and vitamins.

In EU Directive 96/8/EC (entry into force 17 March 1997), foods for use in energy-restricted diets for weight reduction are specially formulated foods which, when used as instructed by the manufacturer, replace the whole or part of the total daily diet. They are divided in two categories: (a) products presented as a replacement for the whole of the daily diet and (b) products presented as a replacement for one or more meals of the daily diet. The labelling of the products concerned shall bear the following mandatory particulars: (a) the available energy value expressed in kJ and kcal, and the content of proteins, carbohydrates and fat, expressed in numerical form, per specified quantity of the product ready for use as proposed for consumption, (b) the average quantity of each mineral and each vitamin, expressed in numerical form, per specified quantity of the product ready for use as proposed for consumption, (c) instructions for appropriate preparation, when necessary and a statement as to the importance of following those instructions, (d) if a product, when used as instructed by the manufacturer, provides a daily intake of polyols in excess of 20 g day⁻¹, there shall be a statement to the effect that the food may have a laxative effect, (e) a statement on the importance of maintaining an adequate daily fluid intake, (f) for products for diets: a statement that the product provides adequate amounts of all essential nutrients for the day and a statement that the product should not be used for more than 3 weeks without medical advice shall be included. There should be an arrangement of the quantities of: energy, protein, fat, dietary fibre, vitamins and minerals.

EU Directive 1999/21/EC (entry into force 27 April 1999) applies to 'dietary foods for special

medical purposes' which are a category of foods for particular nutritional uses specially processed or formulated and intended for the dietary management of patients and to be used under medical supervision. They are intended for the exclusive or partial feeding of patients with a limited impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food-stuffs or certain nutrients contain therein or metabolites, or with other medically determined nutrient requirements, whose dietary management cannot be achieved only by notification of the normal diet, by other foods for particular nutritional uses, or by a combination of the two. Those foods are classified into the following three categories: (a) nutritionally complete foods with a standard nutrient formulation which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom they are intended, (b) nutritionally complete foods with a nutrient adapted formulation specific for a disease, disorder or medical condition which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom they are intended and (c) nutritional incomplete foods with a standard formulation or a nutrient-adapted formulation specific for a disease, disorder or medical condition which are not suitable to be used as the sole source of nourishment. The labelling shall bear the following mandatory particulars: (a) the name under which these products are sold as 'foods for special medical purposes', (b) the available energy value and the content of protein, carbohydrate and fat, (c) the average quantity of each mineral and vitamin, (d) the content of components of protein, carbohydrate and fat, and of other nutrients and their components, (e) information on the osmolality or the osmolarity of the product where appropriate, (f) information on the origin and the nature of the protein and/or protein hydrolysates contained in the product. The labelling shall in addition bear the following particulars, preceded by the words 'important notice' or their equivalent: (a) a statement that the product must be used under medical supervision, (b) a statement whether the product is suitable for use as the sole source of nourishment, (c) a statement that the product is intended for a specific age group, (d)

where appropriate, a statement that the product poses a health hazard when consumed by persons who do not have the diseases, disorders or medical conditions for which the product is intended.

Following EU Directive 2002/46/EC (entry into force 12 July 2002) 'food supplements' are food-stuffs, the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop-dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities. Maximum amounts of vitamins and minerals present in food supplements per daily portion of consumption as recommended by the manufacturer shall be set, taking the following into account: (a) upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into account, as appropriate, the varying degrees of sensitivity of different consumer groups and (b) intake of vitamins and minerals from other dietary sources. Substances that can be used in the manufacture of food supplements are vitamins, minerals, vitamin substances and mineral substances. The labelling shall bear the following particulars: (a) the names of the categories of nutrients or substances that characterise the product or an indication of the nature of those nutrients or substances, (b) the portion of the product recommended for daily consumption, (c) a warning not to exceed the stated recommended daily dose, (d) a statement to the effect that food supplements should not be used as a substitute for a varied diet, (e) a statement to the effect that the products should be stored out of the reach of young children.

The titles, main points and comments of the EU Directives for food-stuffs intended for specific nutritional uses are summarised in Table 9.

Packaging

Packaging *per se* and the food-packaging interactions were considered an issue of crucial importance because several problems, ranging from poisoning to death, occurred over the years. Most of these problems were either due to usage of

inappropriate packaging materials or migration (of monomers, oligomers, catalysts, colorants, etc.). A great number of Directives (more than ten) were published to fill this gap on packaging issues.

According to EU Directive 75/106/EEC (entry into force 19 June 1976), it relates to pre-packages containing the liquid products measured by volume for the purpose of sale in individual quantities of between 5 and 10 L inclusive. This Directive shall not apply to pre-packages containing the products which are vatted, bottled and labelled in volumes not exceeding 0.25 L and are intended for professional use and which are intended either for consumption on board aircraft, ships and trains or for sale in duty-free shops. The pre-packages may be marked with the EEC mark. The actual contents of pre-packages may be measured directly by means of weighing instruments or volumetric instruments or, in the case of liquids, indirectly, by weighing the pre-packed product and measuring its density. Irrespective of the method used, the error made in measuring the actual contents of a pre-package shall not exceed one-fifth of the tolerable negative error for the nominal quantity in the pre-package. The procedure for measuring the actual contents of a pre-package may be the subject of domestic regulations in each Member State. The checking of pre-packages shall be carried out by sampling and shall be in two parts: a check covering the actual contents of each pre-package in the sample and another check on the average of the actual contents of the pre-packages in the sample. A batch of pre-packages shall be considered acceptable if the results of both these checks satisfy the acceptance criteria. For each of these checks, there are two sampling plans: one for non-destructive testing, i.e. testing which does not involve opening the package and the other for destructive testing, i.e. testing which involves opening or destroying the package.

EU Directive 76/211/EEC (entry into force 23 January 1976) relates to pre-packages containing products relating to the making-up by volume of certain pre-packaged liquids, and intended for sale in constant unit nominal quantities which are: equal to values predetermined by the packer, expressed in units of weight or volume, not less than 5 g or 5 mL and not more than 10 kg or

Table 9 EU Directives (main points and comments) focused on food-stuffs intended for specific nutritional uses

Directive – Title	Main points	Comments
EU 89/398/EEC (entry into force 16 May 1990) Approximation of the laws of the Member States related to food-stuffs intended for particular nutritional uses	Concerns the particular nutritional requirements of certain categories of persons The use of the adjectives 'dietetic' or 'dietary' is prohibited in the labelling, presentation and advertising of food-stuffs for normal consumption Disposal on the retail market in pre-packaged form	Repeal EU Directive 77/94/EEC is repealed Amendments EU Directive 96/84/EC Introduction of a procedure allowing a 2-year marketing authorisation for food- stuffs which otherwise would not comply with the composition rules laid down by the specific Directives. (entry into force 11 March 1997) EU Directive 1999/41/EC Reduction of the list of food-stuff catego- ries in respect of which the adoption of specific directives is envisaged Focus specifically on foods for persons suffering from carbohydrate-metabolism disorders (diabetes). (entry into force 8 July 2000)
EU 91/321/EEC (entry into force 30 May 1991) Infant formulae and follow-on formulae	Rules for the marketing of infant formulae and follow-on formulae intended for use by infants in good health in the Community and also provides for Member States to give effect to the principles and aims of the International Code of Marketing of Breast-milk Substitutes Stipulation of authorised food ingredients, compositional criteria, substances which may be used in the manufacture of the formulae concerned, sales names, compulsory label information, etc. Advertising is restricted to publications specialising in baby care and scientific publications	Amendments EU Directive 96/4/EC Rules for labelling infant formulae and follow-on formulae. (entry into force 18 March 1996) EU Directive 1999/50/EC Reduction of the maximum level of pesticide residues in infant formulae and follow-on formulae to 0.01 mg kg ⁻¹ . (entry into force 22 June 1999) EU Directive 2003/14/EC Strengthening of the protection of infants by introducing stronger detective con- trols for a small number of particularly dangerous pesticides or metabolites of pesticides (entry into force 6 March 2003)
EU 96/5/EC (entry into force 8 March 1996) Processed cereal-based foods and baby foods for infants and young children	Applicable for food-stuffs for particular nutritional use which fulfil the particular requirements of infants and young children in good health Not applicable to milks intended for young children Processed cereal-based foods and baby foods shall be manufactured from ingredients whose suitability for particular nutritional use by infants and young children has been established by generally accepted scientific data Specific labelling	Amendments EU Directive 98/36/EC Amendment of annexes and addition of a new annex in Directive 96/5/EC. (entry into force 22 June 1998) EU Directive 1999/39/EC Reduction of the maximum permissible level of pesticide residues in processed cereal-based foods and baby foods to 0.01 mg kg ⁻¹ List of the pesticides which must not be used in agricultural products intended for the production of processed cereal- based foods and baby foods (entry into force 28 May 1999)
EU 96/8/EC (entry into force 17 March 1997) On foods intended for use in energy-restricted diets for weight reduction	Foods for use in energy-restricted diets for weight reduction are specially formulated foods which, when used as instructed by the manufacturer, replace the whole or part of the total daily diet Specific labelling, advertising and presentation	

Table 9 (Continued)

Directive – Title	Main points	Comments
EU 1999/21/EC (entry into force 27 April 1999) Dietary food-stuffs for special medical purposes	The formulation of dietary foods for special medical purposes shall be based on sound medical and nutritional principles Specification of the name under which these food-stuffs are sold in the eleven official languages of the European Union Specific labelling and official monitoring	
EU 2002/46/EC (entry into force 12 July 2002) Approximation of the laws of the Member States relating to food supplements	Applicable to concentrated sources of nutrients marketed in dose form in order to supplement nutrient intake in a normal diet Not applicable to medicinal products Food supplements may only contain specific vitamins and mineral salts Specific labelling and monitoring system	

10 L. A pre-package within the meaning of this Directive is the combination of a product and the individual package in which it is pre-packed. A product is pre-packed when it is placed in a package of whatever nature without the purchaser being present, and the quantity of product contained in the package has a predetermined value and cannot be altered without the package either being opened or undergoing a perceptible modification. All pre-packages must bear an indication of the weight or volume of the product, known as 'nominal weight' or 'nominal volume', which they are required to contain. Pre-packages containing liquid products shall be marked with their nominal volume and pre-packages containing other products shall be marked with their nominal weight, except in the case of trade practice or national regulations which provide otherwise and which are identical in all Member States, or in the case of contrary Community rules. If trade practice or national regulations are not the same in all Member States for a category of products or for a type of pre-package, those pre-packages must at least show the metrological information corresponding to the trade practice or national regulations prevailing in the country of destination.

In EU Directive 78/142/EEC (entry into force 1 February 1978), the presence of vinyl chloride monomer in, and possible migration from, materials and articles prepared with vinyl chloride polymers or copolymers, hereinafter called 'materials and articles', which in their finished state are intended to come into contact with food-stuffs, or which are in contact with food-stuffs and are intended for that purpose is analysed. Materials and articles must not pass onto food-stuffs, which

are in or have been brought into contact with such materials and articles as vinyl chloride detectable by the method, which complies with the criteria laid down in this Directive. Maximum vinyl chloride monomer level in materials and articles laid down 1 mg kg^{-1} in the final product. Criteria applicable to the method of determining the level of vinyl chloride in materials and articles and of determining vinyl chloride released by materials and articles: (1) the level of vinyl chloride in materials and articles and the level of vinyl chloride released by materials and articles to food-stuffs are determined by means of gas-phase chromatography using the 'headspace' method, (2) for the purposes of determining vinyl chloride released by materials and articles to food-stuffs, the detection limit shall be 0.701 mg kg^{-1} and (3) vinyl chloride released by materials and articles to food-stuffs is in principle determined in the food-stuffs. When the determination in certain food-stuffs is shown to be impossible for technical reasons, Member States may permit determination by simulants for these particular food-stuffs.

According to EU Directive 80/232/EEC (entry into force 17 March 1980) the products shall be divided into three groups: (a) products sold by weight or by volume, (b) products sold by weight or by volume and put up in the rigid containers and (c) products put up in aerosol form. Food products in which the Directive shall apply are: butter, margarine, emulsified or non-animal and vegetable fats (low fat spreads), fresh cheeses except 'petits suisses' and other cheeses put up in the same way, table and cooking salt, impalpable sugars, red or brown sugars, candy sugars, cereal products (excluding foods for infants), dried

vegetables, dried fruits, ground or unground roasted coffee, chicory and coffee substitutes, frozen products (fruit and vegetables and pre-cooked potatoes for chips, fish fillets and portions, breaded or not breaded, fish fingers).

In EU Directive 82/711/EEC (entry into force 4 November 1982) reference is made to plastic materials and articles, that is to say to materials and articles and parts thereof: (a) consisting exclusively of plastics or (b) composed of two or more layers of materials, each consisting exclusively of plastics, which are bound together by means of adhesives or by any other means, which, in the finished product state, are intended to come into contact or are brought into contact with food-stuffs and are intended for that purpose. For the purposes of this Directive, *plastics* shall mean the organic macromolecular compounds obtained by polymerisation, polycondensation, polyaddition or any other similar process from molecules with a lower molecular weight or by chemical alteration of natural macromolecules. Silicones and other similar macromolecular compounds shall also be regarded as plastics. Other substances or matter may be added to such macromolecular compounds. However, the following shall not be regarded as *plastics*: (i) varnished or unvarnished regenerated cellulose film, (ii) elastomers and natural and synthetic rubber, (iii) paper and paperboard, whether modified or not by the addition of plastics, (iv) surface coatings obtained from paraffin waxes, including synthetic paraffin waxes, and/or micro-crystalline waxes and mixtures of the waxes listed in the first indent with each other and/or with plastics. The tests are to be carried out using all the simulants mentioned below, taking a fresh sample of the plastic material or article for each simulant: distilled water or water of equivalent quality, 3% acetic acid (w/v) in aqueous solution, 15% ethanol (v/v) in aqueous solution, rectified olive oil, if for technical reasons connected with the method of analysis it is necessary to use different simulants, olive oil must be replaced by a mixture of synthetic triglycerides or by sunflower oil.

EU Directive 93/10/EEC (entry into force 24 March 1994) claimed that it shall apply to regenerated cellulose film within the meaning of the description given in Annex I which either: (a) constitutes a finished product in itself or (b) forms

part of a finished product containing other materials, and which is intended to come into contact with food-stuffs or which, by virtue of its purpose, does come into such contact. This Directive does not apply to: (a) regenerated cellulose film which, on the side intended to come into contact with food-stuffs or which, by virtue of its purpose does come into such contact, has a coating exceeding 50 mg dm^{-2} , (b) synthetic casings of regenerated cellulose. Printed surfaces of regenerated cellulose film shall not come into contact with the food-stuffs. Member States shall: (i) permit, as from 1 January 1994, the trade in and use of regenerated cellulose film which is intended to come into contact with food-stuffs complying with this Directive, (ii) prohibit, as from 1 January 1994, the trade in and use of regenerated cellulose film which is intended to come into contact with food-stuffs not complying with this Directive, (iii) prohibit, as from 1 January 1995, the trade in and use of regenerated cellulose film which is intended to come into contact with food-stuffs.

The aim of EU Directive 94/62/EC (entry into force 31 December 1994) was to harmonise national measures concerning the management of packaging and packaging waste in order, on the one hand, to prevent any impact thereof on the environment of all Member States as well as of third countries or to reduce such impact, thus providing a high level of environmental protection, and, on the other hand, to ensure the functioning of the internal market and to avoid obstacles to trade and distortion and restriction of competition within the Community. To this end, this Directive lays down measures aimed, as a first priority, at preventing the production of packaging waste and, as additional fundamental principles, at reusing packaging, at recycling and other forms of recovering packaging waste and, hence, at reducing the final disposal of such waste. This Directive covers all packaging placed on the market in the Community and all packaging waste, whether it is used or released at industrial, commercial, office, shop, service, household or any other level, regardless of the material used. This Directive shall apply without prejudice to existing quality requirements for packaging such as those regarding safety, the protection of health and the hygiene of the packed products or to existing

transport requirements. For the purposes of this Directive, *packaging* shall mean all products made of any materials of any nature to be used for the containment, protection, handling, delivery and presentation of goods, from raw materials to processed goods, from the producer to the user or the consumer. Packaging consists only of: (a) sales packaging or primary packaging, (b) grouped packaging or secondary packaging, (c) transport packaging or tertiary packaging. Member States shall take the necessary measures to attain the following targets covering the whole of their territory: (a) no later than 5 years from the date by which this Directive must be implemented in national law, between 50% as a minimum and 65% as a maximum by weight of the packaging waste will be recovered, (b) within this general target, and with the same time limit, between 25% as a minimum and 45% as a maximum by weight of the totality of packaging materials contained in packaging waste will be recycled with a minimum of 15% by weight for each packaging material and (c) no later than 10 years from the date by which this Directive must be implemented in national law, a percentage of packaging waste will be recovered and recycled. The Commission shall promote, in particular, the preparation of European standards relating to: (i) criteria and methodologies for life-cycle analysis of packaging, (ii) the methods for measuring and verifying the presence of heavy metals and other dangerous substances in the packaging and their release into the environment from packaging and packaging waste, (iii) criteria for a minimum content of recycled material in packaging for appropriate types of packaging, (iv) criteria for recycling methods, (v) criteria for composting methods and produced compost and (vi) criteria for the marking of packaging. Member States shall ensure that the sum of concentration levels of lead, cadmium, mercury and hexavalent chromium present in packaging or packaging components shall not exceed the following: (a) 600 ppm by weight 2 years after the date 30 June 1996, (b) 250 ppm by weight 3 years after 30 June 1996, (c) 100 ppm by weight 5 years after 30 June 1996. Information for users of packaging Member States shall take measures, within 2 years of the date referred to in Article 22 (1), to ensure that users of packaging, including in particular consumers,

obtain the necessary information about: (i) the return, collection and recovery systems available to them, (ii) their role in contributing to reuse, recovery and recycling of packaging and packaging waste, (iii) the meaning of markings on packaging existing on the market and (iv) the appropriate elements of the management plans for packaging and packaging waste.

In EU Directive 97/23/EC (entry into force 29 July 1997) applies to the design, manufacture and conformity assessment of pressure equipment and assemblies with a maximum allowable pressure PS greater than 0.5 bar. Member States shall not, on grounds of the hazards due to pressure, prohibit, restrict or impede the placing on the market or putting into service under the conditions specified by the manufacturer of pressure equipment or assemblies which comply with this Directive and bear the CE marking indicating that they have undergone conformity assessment. Pressure equipment and assemblies the conformity of which has been assessed by a user inspectorate shall not bear the CE marking. The pressure equipment and assemblies referred to may be used only in establishments operated by the group of which the inspectorate is part. The group shall apply a common safety policy as regards the technical specifications for the design, manufacture, inspection, maintenance and use of pressure equipment and assemblies. The user inspectorates shall act exclusively for the group of which they are part. The CE marking shall be affixed in a visible, easily legible and indelible fashion to each item of pressure equipment, which is complete or is in a state permitting final assessment. It is not necessary for the CE marking to be affixed to each individual item of pressure equipment making up an assembly. Individual items of pressure equipment already bearing the CE marking when incorporated into the assembly shall continue to bear that marking. Where the pressure equipment or assembly is subject to other Directives covering other aspects which provide for the affixing of the CE marking, the latter shall indicate that the pressure equipment or assembly in question is also presumed to conform to the provisions of this Directive. Pressure equipment must be designed, manufactured and checked, and if applicable equipped and installed, in such a way as to ensure its safety when put into service in accordance with

the manufacturer's instructions, or in reasonably foreseeable conditions. In choosing the most appropriate solutions, the manufacturer must apply the principles set out below in the following order: (i) eliminate or reduce hazards as far as is reasonably practicable, (ii) apply appropriate protection measures against hazards which cannot be eliminated and (iii) where appropriate, inform users of residual hazards and indicate whether it is necessary to take appropriate special measures to reduce the risks at the time of installation and/or use. Where the potential for misuse is known or can be clearly foreseen, the pressure equipment must be designed to prevent danger from such misuse or, if that is not possible, adequate warning given that the pressure equipment must not be used in that way. The method of operation specified for pressure equipment must be such as to preclude any reasonably foreseeable risk in operation of the equipment. Particular attention must be paid, where appropriate, to: (a) closures and openings, (b) dangerous discharge of pressure relief blow-off, (c) devices to prevent physical access while pressure or a vacuum exists, (d) surface temperature taking into consideration the intended use and (e) decomposition of unstable fluids. The manufacturer must ensure the competent execution of the provisions set out at the design stage by applying the appropriate techniques and relevant procedures, especially with a view to the aspects set out below. Preparation of the component parts (e.g. forming and chamfering) must not give rise to defects or cracks or changes in the mechanical characteristics likely to be detrimental to the safety of the pressure equipment. Permanent joints and adjacent zones must be free of any surface or internal defects detrimental to the safety of the equipment. The properties of permanent joints must meet the minimum properties specified for the materials to be joined unless other relevant property values are specifically taken into account in the design calculations. Where there is a risk that the manufacturing process will change the material properties to an extent, which would impair the safety of the pressure equipment, suitable heat treatment must be applied at the appropriate stage of manufacture. Suitable procedures must be established and maintained for identifying the material making up the components of the equip-

ment, which contribute to pressure resistance by suitable means from receipt, through production, up to the final test of the manufactured pressure equipment.

EU Directive 2002/16/EC (entry into force 15 March 2002) is applicable to materials and articles which, in the finished product state, are intended to come into contact or are brought into contact with food-stuffs and are intended for that purpose and which are manufactured with or contain one or more of the following substances: (a) 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether (hereinafter 'BADGE'), and some of its derivatives, (b) bis(hydroxyphenyl)methane bis(2,3-epoxypropyl)ethers (hereinafter 'BFDGE'), and some of their derivatives, (c) other novolac glycidyl ethers (hereinafter 'NOGE'), and some of their derivatives. For the purposes of this Directive, *materials and articles* are: (i) materials and articles made of any type of plastics, (ii) materials and articles covered by surface coatings and (iii) adhesives. This Directive shall not apply to containers or storage tanks having a capacity greater than 10 000 L or to pipelines belonging to or connected with them, covered by special coatings called 'heavy-duty coatings'. The sum of the migration levels of the following substances: (a) BADGE, (b) BADGE.H₂O, (c) BADGE.HCl, (d) BADGE.2HCl, (e) BADGE.H₂O.HCl shall not exceed the following limits: (i) 1 mg kg⁻¹ in food-stuffs or in food simulants (analytical tolerance excluded) or (ii) 1 mg/6 dm² in accordance of this Directive.

According to proposal of Regulations COM(2003)0689 and COD(2003)0272 the target of this Regulation is to ensure the effective functioning of the internal market in relation to materials and articles intended to come into contact with food-stuffs, while providing the basis for securing a high level of protection of human health and the interests of consumers. This Regulation shall apply to materials and articles, including active and intelligent food contact materials and articles, which in their finished state: (a) are intended to be brought into contact with food or (b) are already brought into contact with food and are intended for that purpose or (c) can reasonably be expected to be brought into contact with foods or to transfer their constituents to food. This Regulation shall not apply to: (a) materials and

articles which were manufactured and placed on the market before 1 January 1980 and which are supplied as antiques, (b) covering or coating products, such as the products covering cheese rinds, prepared meat products or fruits, which form part of food and may be consumed together with this food and (c) fixed public or private water supply equipment. *Active food contact materials and articles* means materials and articles that are intended to extend the shelf-life or to maintain or improve the condition of packaged food. They are designed to deliberately incorporate components that would release or absorb substances into or from the packaged food or the environment surrounding the food. *Intelligent food contact materials and articles* means materials and articles, which monitor the condition of packaged food or the environment surrounding the food. Materials and articles shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could: (i) endanger human health or (ii) bring about an unacceptable change in the composition of the food or a deterioration in the organoleptic characteristics thereof. For the groups of materials and articles and where appropriate, combinations of those materials and articles, specific measures may be adopted in accordance with the Directive. Those specific measures may include: (a) a list of the substances the use of which is authorised to the exclusion of all others, (b) purity standards for substances, (c) special conditions of use for substances and/or the materials and articles in which they are used, (d) specific limits on the migration of certain constituents or groups of constituents into or onto food, taking due account of other possible sources of exposure to those constituents, (e) an overall limit on the migration of constituents into or onto food, (f) provisions aimed at protecting human health against hazards arising from oral contact with materials and articles, (g) other rules to ensure compliance with this Directive, (h) basic rules for checking compliance with this Directive, (i) rules concerning the collection of samples and the methods of analysis to check compliance with this Directive, (j) additional provisions for ensuring traceability of materials and articles, (k) provisions requiring that the Commission establishes

and maintains a publicly available Community Register ('Register') of authorised substances, materials or articles. The applicant may, in accordance with the procedure laid down in this Directive, apply for a modification of the existing authorisation. The application shall be accompanied by the following: (a) a reference to the original application, (b) a technical dossier containing the new information according to the guidelines, (c) a new complete summary of the technical dossier in a standardised form. The traceability of the materials and articles shall be established at all stages of manufacture, processing and distribution. Business operators shall have in place systems and procedures to allow the identification of the businesses from which and to which the materials or articles and, where appropriate, substances or products used in their manufacture have been supplied. That information shall be made available to the competent authorities on demand. The materials and articles, which are placed on the market in the Community shall be adequately labelled or identified to facilitate their traceability through relevant documentation or information. List of groups of materials and articles which may be covered by specific measures: active and intelligent materials and articles, adhesives, ceramics, cork, elastomers and rubbers, glass, ion-exchange resins, metals and alloys, paper and board, plastics, printing inks, regenerated cellulose, textiles, varnishes and coatings, waxes and wood.

All EU Directives/Regulations dealing with packaging are given in Table 10.

GMOs in EU trade

Any GM foods intended for sale in the EU are subject to a rigorous safety assessment, which is the responsibility of the EFSA. Although the safety assessments are carried out in accordance with the GM Food and Feed Regulation EC No. 1829/2003, the final decision still rests with Member States, which vote on each GM food (<http://www.food.gov.uk/gmfoods/>). A GMO is an organism whose genetic structure has been altered by incorporating a gene that will express a desirable trait. Most often the transferred gene allows the organism to express a trait that will add to its desirability to producers or consumers of the

Table 10 EU Directives (main points and comments) dealing with packaging

Directive – Title	Main points	Comments
EU 75/106/EEC (entry into force 19 June 1976) Approximation of the laws of the Member States relating to the making-up by volume of certain prepackaged liquids	Application to packages containing liquid products, measured by volume and intended for sale in unit quantities varying between 5 and 10 L All prepackages must bear an indication of the volume of the liquid which they are required to contain	Amendments EU Directive 78/89/EEC (entry into force 1 January 80) EU Directive 79/1005/EEC (entry into force 1 January 1981) EU Directive 85/10/EEC (entry into force 20 December 1985) EU Directive 88/316/EEC (entry into force 30 June 1988) EU Directive 89/676/EEC (entry into force 1 July 1990) Replacement and repeal of specific parts of articles and annexes
EU 76/211/EEC (entry into force 23 January 1976) Approximation of the laws of the Member States relating to the making-up by weight or by volume of certain prepackaged products	Application to prepackages containing products, except liquids, intended for sale in constant unit nominal quantities All prepackages must bear an indication of the weight or volume of the product	Amendment EU Directive 78/891/EEC (entry into force 29 September 1978) Replacements relatively the technical progress in the annexes
EU 78/142/EEC (entry into force 1 February 1978) Approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with food-stuffs	Materials and articles which are intended to come into contact with food-stuffs can transfer vinyl chloride monomer to these articles in quantities liable to endanger human health The Directive specifies that such materials and articles must not contain vinyl chloride monomer in a quantity exceeding 1 mg kg ⁻¹ of finished product and must not pass on to food-stuffs more than 0.01 mg kg ⁻¹ of vinyl chloride monomer	
EU 80/232/EEC (entry into force 17 March 1980) Approximation of the laws of the Member States relating to the ranges of nominal quantities and nominal capacities permitted for certain prepackaged products	This Directive shall apply to products put up in prepackages It shall not apply to prepackaged products intended solely for professional use The products referred to in Directive shall be divided into three groups	

end product. GMOs are theorised to reduce production costs due to reduced chemical and mechanical needs in planting, maintenance, and harvest. The most obvious benefits to consumers are the nutrition implications. The biotechnology of gene transfer allows for the opportunity of creating plants that will produce food that is more

nutrient dense. The most obvious nutrition concern with GMOs is the risk of allergic reactions. Other potential risks are: spread of pest resistance or herbicide tolerance to wild plants, inadvertent toxicity to benign wildlife, and increasing control of agriculture by biotechnology corporations (<http://ohioline.osu.edu/hyg-fact/5000/5058.html>).

Table 10 (Continued)

Directive – Title	Main points	Comments
EU 82/711/EEC (entry into force 4 November 1982)	Relating to testing migration of constituents of plastic materials and articles intended to come into contact with food-stuffs	Amendments EU Directive 93/8/EEC (entry into force 22 March 93)
Laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with food-stuffs	Migration tests may be carried out using simulants Verification of compliance of migration into food-stuffs shall be carried out under the most extreme conditions of time and temperature foreseeable in actual use	EU Directive 97/48/EC (entry into force 1 September 97) Lists of simulants which are used in testing migration Replacement of the annexes
EU 93/10/EEC (entry into force 1 January 1994)	This Directive shall apply to regenerated cellulose film This Directive does not apply to regenerated cellulose film which, on the side intended to come into contact with food-stuffs or which, by virtue of its purpose does come into such contact, has a coating exceeding 50 mg dm ⁻² and synthetic casings of regenerated cellulose Printed surfaces of regenerated cellulose film shall not come into contact with the food-stuffs	Repeal EU Directive 83/229/EEC from 1 January 94 Amendments EU Directive 93/111/EEC (entry into force 17 December 1993) Replacement of a part of an article EU Directive 2004/14/EC (entry into force 24 March 2004) Addition and replacement in articles
EU 94/62/EC (entry into force 31 December 1994)	Packaging and packaging waste	This Directive aims to harmonise national measures concerning the management of packaging and packaging waste in order to prevent any impact thereof on the environment, to ensure the functioning of the internal market and to avoid obstacles to trade This Directive covers all packaging placed on the market in the Community and all packaging waste, whether it is used or released at industrial, commercial, office, shop, service, household or any other level, regardless of the material used Labelling of packaging Concentration levels of heavy metals present in packaging
		Repeal EU Directive 85/339/EEC from 30 June 1996) Amendments EU Directive 97/129/EC (entry into force 12 March 1997) Identification system for packaging materials EU Directive 97/138/EC (entry into force 12 March 1997) Formats relating to the database system EU Directive 1999/42/EC (entry into force 3 February 1999) Measures relating to packaging and packaging waste EU Directive 1999/177/EC (entry into force 28 February 1999) Conditions for a derogation for plastic crates and plastic pallets in relation to the heavy metal concentration levels EU Directive 1999/823/EC (entry into force 12 December 1999) Confirming the measures notified by the Netherlands on packaging and packaging waste EU Directive 2001/171/EC (entry into force 1 March 2001)

Table 10 (Continued)

Directive – Title	Main points	Comments
EU 97/23/EC (entry into force 29 July 1997) Approximation of the laws of the Member States concerning pressure equipment	This Directive applies to equipment and assemblies subject to a maximum allowable pressure PS exceeding 0.5bar The products referred to in Directive shall be divided into three groups. The proposal determines the objectives or <i>essential requirements</i> which the abovementioned equipment must satisfy at the time of manufacture and before it is placed on the market The assessment procedures depend on the risk inherent in the pressure equipment Where the materials used in the manufacture of the pressure equipment are not covered by a harmonised standard, they may, at the request of one or more of the materials or equipment manufacturers, be eligible for a European materials approval certificate Before being placed on the market, pressure equipment and assemblies must bear the 'CE' conformity marking	Establishing the conditions for a derogation for glass packaging in relation to the heavy metal concentration levels EU Directive 2001/524/EC (entry into force 18 July 2001) Publication of references for standards EN 13428:2000, EN 13429:2000, EN 13430:2000, EN 13431:2000 and EN 13432:2000 Repeal Article 22 of EU Directive 76/767/EEC from 29 November 1999
EU 2002/16/EC (entry into force 15 March 2002) Use of certain epoxy derivatives in materials and articles intended to come into contact with food-stuffs	Materials and articles containing certain substances may transfer significant levels of these substances to food-stuffs (migration), particularly when used as additives, and thus represent a potential risk to human health It shall apply to plastic materials and articles, materials and articles covered by surface coatings, and adhesives Specific migration limits for BADGE and BFDGE and their derivatives The use and/or presence of BADGE and BFDGE may only be continued until 31 December 2004	Repeal EU Directive 2001/61/EC
Proposal of Regulation COM(2003)0689 COD(2003)0272 Materials and articles intended to come into contact with food	Authorisation of the placing on the market of two types of packaging which act 'intelligently' in contact with food-stuffs A positive list of authorised substances may be established Authorisation of the marketing of new plastics by authorising the use of new substances in their manufacture Establishment of the requirements which must be met regarding the traceability of food contact materials from production to sale The new 'active' packaging will provide information on its properties on the label itself	Repeals Decision EU 80/590/EC Decision EU 89/109/EC

Developments at the European level have contributed significantly to the recent increase in public awareness of some of the implications of

genetic modification. A number of measures already exist at the European level, the aim of which is to provide a legal framework for the

control of GM crops and food. In order to take account of recent scientific developments, the EU is currently undertaking a review of legislation in this area. At present, legislation is divided into two main areas: (i) the contained use of Genetically Modified Micro organisms (GMMs) and (ii) the deliberate release and the marketing of products containing GMOs (http://www.tjg.co.uk/topical/europe/euro_organisms.html).

GMOs

A novel food is defined as a food or food ingredient, which does not have a significant history of consumption within the EU prior to May 1997. All novel foods are subject to a pre-market safety assessment under the Novel Foods Regulation (EC) No. 258/97. The Food Standards Agency Board is satisfied that the current safety assessment procedures for GM foods are sufficiently robust and rigorous to ensure that approved GM foods are as safe as their non-GM counterparts, and pose no additional risk to the consumer. Each GM food is assessed for safety, including its toxicological, nutritional and allergenic potential, on a case-by-case basis before it can be approved for marketing (<http://www.food.gov.uk/gmfoods/>).

EU Directive 90/219/EEC (entry into force 23 October 1991) claims that 'contained use' is any operation in which micro-organisms are genetically modified or in which such GMOs are cultured, stored, used, transported, destroyed or disposed of and for which physical barriers, or a combination of physical barriers together with chemical and/or biological barriers, are used to limit their contact with the general population and the environment. There is no application to the storage, transport, destruction or disposal of GMOs, which have been placed on the market under Community legislation, which includes a specific risk assessment similar to that provided in this Directive. Techniques of genetic modification are: (a) recombinant DNA techniques using vector systems, (b) techniques involving the direct introduction into a micro-organism of heritable material prepared outside the micro-organism, (c) cell fusion or hybridisation techniques. Techniques of genetic modification to be excluded from the Directive, on condition that they do not involve the use of GMOs as recipient or parental organisms,

are mutagenesis, the construction and use of somatic animal hybridoma cells, cell fusion of cells from plants which can be produced by traditional breeding methods and self-cloning of non-pathogenic naturally occurring micro-organisms. Criteria for classifying GM micro-organisms are: recipient or parental organism, vector/insert, GM micro-organisms, other GM micro-organisms. The competent authorities shall ensure that, where necessary, before an operation commences, an emergency plan is drawn up for the protection of human health and the environment and information on safety measures and on the correct behaviour to adopt in the case of an accident is supplied.

According to EU Directive 90/220/EEC (entry into force 23 October 1991) 'deliberate release' means any intentional introduction into the environment of a GMO or a combination of GMOs without provisions for containment such as physical barriers together with chemical and/or biological barriers used to limit their contact with the general population and the environment. Techniques of genetic modification to be excluded from this directive, on condition that they do not involve the use of GMOs as recipient or parental organisms, are: mutagenesis and cell fusion of plant cells where the resulting organisms can also be produced by traditional breeding methods. The notification for placing in the market shall include: (a) a technical dossier supplying the information necessary for evaluating the foreseeable risks which the GMO or combination of GMOs may pose to human health or the environment, together with the methods used and the bibliographic reference to them, (b) a statement evaluating the impacts and risks posed by the GMOs to human health or the environment from the uses. In no case may the following information be kept confidential: description of the GMO or GMOs, name and address of the notifier, purpose and location of the release, methods and plans for monitoring of the GMO or GMOs and for emergency response and the evaluation of foreseeable effects, in particular any pathogenic and/or ecologically disruptive effects.

In EU Directive 2001/18/EC (entry into force 17 April 2001) the laws, regulations and administrative provisions of the Member States should be approximated and human health and the

environment should be protected when: (1) carrying out the deliberate release into the environment of GMOs for any other purposes than placing on the market within the Community, (2) placing on the market GMOs as or in products within the Community. This Directive shall not apply to: (a) organisms obtained through the techniques of genetic modification, (b) the carriage of GMOs by rail, road, inland waterway, sea or air. The information relating to the release into the environment should be: (1) purpose of the release, (2) foreseen dates and duration of the release, (3) method by which the genetically modified plants will be released, (4) method for preparing and managing the release site, prior to, during and post-release, including cultivation practices and harvesting methods, (5) approximate number of plants or plants m^{-2} . The information relating to the conditions of release and the receiving environment is: (1) description of the proposed deliberate release, (2) foreseen dates of the release and time planning of the experiment including frequency and duration of releases, (3) preparation of the site previous to the release, (4) size of the site, (5) methods to be used for the release, (6) quantities of GMOs to be released, (7) disturbance on the site (type and method of cultivation, mining, irrigation or other activities), (8) worker protection measures taken during the release, (9) post-release treatment of the site, (10) techniques foreseen for elimination or inactivation of the GMOs at the end of the experiment, (11) information on, and results of, previous releases of the GMOs. The potential adverse effects of GMOs may include: disease to humans, disease to animals and plants, altered susceptibility to pathogens, effects on the dynamics of populations of species in the receiving environment and the genetic diversity of each of these populations.

Following EU Directive 2004/204/EC (entry into force 23 March 2004) the registers shall be available to the public. The information recorded shall be divided as follows: (a) a set of data accessible to the public and (b) a set of data comprising additional confidential data, accessible only to the Member States, the Commission and the EFSA. The following shall be recorded in the registers: (a) details concerning the notifier and responsible persons, (b) general information

concerning the GMOs (commercial name, unique identifier of the GMOs, the Member State of notification, the notification number, the decision authorising the GMOs), (c) information on the insert, (d) information concerning the detection and identification methods and (e) information on the lodging, storage and supply of samples.

In EU Directive 2004/643/EC the product may be used as any other maize, with the exception of cultivation and uses as or in food, and may be placed on the market subject to the following conditions: (a) the period of validity of the written consent shall be for a period of 10 years, (b) the unique identifier of the product shall be MON-00603-6, (c) the consent holder shall make control samples available to the competent authorities on request, (d) the words 'This product contains GMO' or 'This product contains GM maize' shall appear either on a label or in a document accompanying the product and (e) as long as the product has not been authorised for the placing on the market for the purpose of cultivation, the words 'not for cultivation' shall appear either on a label or in a document accompanying the product.

EU Directive 2004/657/EC claims that sweet maize from genetically modified maize line Bt11, as designated and specified, may be placed on the Community market as a novel food or novel food ingredient. The product and the following information shall be entered in the Community register of genetically modified food. The information to be entered in the Community Register of GM food and feed is: (a) authorisation holder (name, address, company), (b) designation and specification of the product (sweet maize, fresh or canned, that is progeny from traditionally crosses of traditionally bred maize with genetically modified maize line Bt11), (c) labelling ('GM sweet corn'), (d) method for detection, (e) unique identifier (SYN-BT011-1), (f) information required to the Cartagena Protocol, (g) conditions or restrictions on the placing on the market of the product (not applicable), (h) post-market monitoring requirements (not appropriate).

Regulation (EC) No. 258/97 (entry into force 14 May 1997) shall apply to the placing on the market within the Community of foods and food

ingredients which have not hitherto been used for human consumption to a significant degree within the Community and which fall under the following categories: (1) foods and food ingredients containing or consisting of GMOs, (2) foods and food ingredients produced from, but not containing, GMOs, (3) foods and food ingredients with a new or intentionally modified primary molecular structure, (4) foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae, (5) foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use, (6) foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances. This Regulation shall not apply to: (1) food additives, (2) flavourings for use in food-stuffs, (3) extraction solvents used in the production of food-stuffs. Foods and food ingredients falling within the scope of this Regulation must not present a danger for the consumer, mislead the consumer or differ from foods or food ingredients which they are intended to replace. The following additional specific labelling requirements shall apply to food-stuffs in order to ensure that the final consumer is informed of: (a) any characteristic or food property such as composition, nutritional value or nutritional effects, intended use of the food which renders a novel food or food ingredient no longer equivalent to an existing food or food ingredient, (b) the presence in the novel food or food ingredient of material which is not present in an existing equivalent food-stuff and which may have implications for the health of certain sections of the population, (c) the presence in the novel food or food ingredient of material which is not present in an existing equivalent food-stuff and which gives rise to ethical concerns and (d) the presence of an organism genetically modified by techniques of genetic modification. Where a food or food ingredient falling contains or consists of a GMO, the information required in the request for placing on the market shall be accompanied by: (i) a copy of the written consent

and (ii) the complete technical dossier supplying the relevant information.

According to Regulation (EC) No. 1139/98 (entry into force 1 September 1998) foods and food ingredients which are to be delivered as such to the final consumer produced, in whole or in part, from genetically modified soybeans or genetically modified maize. It has no application to food additives, flavourings for use in food-stuffs or extraction solvents used in the production of food-stuffs. The specified food-stuffs shall be subject to the additional specific labelling requirements. The specified food-stuffs in which neither protein nor DNA resulting from genetic modification is present shall not be subject to the said additional specific labelling requirements. Finally, a list of products not subject to the additional specific labelling requirements shall be drawn up.

The main objective of Regulation (EC) No. 1829/2003 (entry into force 7 November 2003) objective is to: (a) provide the basis for ensuring a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to GM food and feed, while ensuring the effective functioning of the internal market, (b) lay down Community procedures for the authorisation and supervision of GM food and feed and (c) lay down provisions for the labelling of GM food and feed. It applies to GMOs for food use, to food containing or consisting of GMOs and to food produced from or containing ingredients produced from GMOs. Food referred must not have adverse effects on human health, animal health or the environment, mislead the consumer and differ from the food, which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer. The application for authorisation shall be sent to the national competent authority of a Member State. The national competent authority shall: (i) acknowledge receipt of the application in writing to the applicant within 14 days of its receipt. The acknowledgement shall state the date of receipt of the application, (ii) inform without delay the EFSA, (iii) shall make the application and any supplementary information supplied by the applicant available to the Authority. The Authority shall (i) inform without delay the other Member States

and the Commission of the application and shall make the application and any supplementary information supplied by the applicant available to them, (ii) make the summary of the dossier available to the public. The Community reference laboratory shall be responsible for: (a) reception, preparation, storage, maintenance and distribution to national reference laboratories of the appropriate positive and negative control samples, (b) testing and validation of the method for detection, (c) evaluating the data provided by the applicant for authorisation for placing the food or feed on the market and (d) submitting full evaluation reports to the Authority.

Regulation (EC) No. 1830/2003 (entry into force 7 November 2003) is applicable at all stages of the placing on the market to: products consisting of, or containing GMOs placed on the market in accordance with Community legislation, food produced from GMOs, placed on the market in accordance with Community legislation and to feed produced from GMOs placed on the market in accordance with Community legislation. Regarding traceability, at the first stage of the placing on the market of a product consisting of or containing GMOs, including bulk quantities, operators shall ensure that the following information is transmitted in writing to the operator receiving the product: that it contains or consists of GMOs and the unique identifier assigned to those GMOs in accordance with the Regulation. Regarding labelling, operators shall ensure that: (i) for pre-packaged products consisting of, or containing GMOs, the words 'This product contains GMOs' or 'This product contains GM... (name of organism)' appear on a label, (ii) for non-pre-packaged products offered to the final consumer the words 'This product contains GMOs' or 'This product contains GM... (name of organism)' shall appear on, or in connection with the display of the product. When placing products produced from GMOs on the market, operators shall ensure that the following information is transmitted in writing to the operator receiving the product: an indication of each of the food ingredients which is produced from GMOs, an indication of each of the feed materials or additives which is produced from GMOs and in the case of products for which no list of ingredients exists, an indication that the product is produced from GMOs.

Regulation (EC) No. 65/2004 (entry into force on the date of its publication in the *Official Journal of the European Union*) claims that where consent or authorisation is granted for the placing on the market of a GMO: (a) the consent or authorisation shall specify the unique identifier for that GMO, (b) the Commission, on behalf of the Community, or, where appropriate, the competent authority that has taken the final decision on the original application shall ensure that the unique identifier for that GMO is communicated as soon as possible, in writing, to the Biosafety clearing house, (c) the unique identifier for each GMO concerned shall be recorded in the relevant registers of the Commission. The formats for unique identifiers are overall format (e.g. CED-AB891-6 or CE-ABC891-5), applicant/consent holder component: the first two or three alphanumeric digits represent the applicant/consent holder followed by a dash (e.g. CED- or CE-), transformation event component: the second set of five or six alphanumeric digits should represent the specific transformation events which are the subject of the application for the placing on the market and/or consent (e.g. AB891- or ABC891-) or verification component: the final digit of the unique identifier is for verification, which shall be separated from the rest of the unique identifier digits by a dash (e.g. -6 or -5).

Regulation (EC) No. 641/2004 claims that the application shall include the following: (i) the monitoring plan, (ii) a proposal for labelling complying with the requirements of specific identification, (iii) a proposal for post-market monitoring regarding the use of the food for human consumption or the feed for animal consumption is not necessary. The notifications submitted in accordance with the regulation shall clearly identify the products covered by the notification, include relevant information and studies which demonstrate that the product complies with the requirements, clearly indicate which parts of the notification are considered to be confidential, together with a verifiable justification and those parts shall be submitted in separate documents, include methods of detection, sampling and identification.

In Regulation (EC) No. 641/2004 (entry into force 18 April 2004) the application for authorisation of GM food and feed shall include the

following: (a) the monitoring plan, (b) a proposal for labelling, (c) a proposal for a unique identifier for the GMO in question, (d) a proposal for labelling in all official Community languages, (e) a description of the methods of detection, sampling and specific identification of the transformation event and (f) a proposal for post-market monitoring. In the case of an application of authorisation the national competent authority shall: (i) acknowledge receipt of the information supplied by the applicant, (ii) inform the Authority without delay, (iii) make the request and the information supplied by the applicant available to the Authority and (iv) make available the Authority the initial assessment report. The Authority shall make available the application and any other supplementary information supplied by the applicant to the Commission and the other Member States and make the summary of the dossier. Regarding notification for existing products they shall: (a) clearly identify the products covered by the notification, (b) include relative information and studies, (c) clearly indicate which parts of the notification are considered to be confidential and (d) include a description of the methods of detection, sampling and specific identification of the transformation event. The notifications of feed containing, consisting of, or produced from GMOs which have been authorised shall include: (i) the identification of the feed additives to be covered by the number or the EC number, where applicable and (ii) a copy of the authorisation.

The Proposal for Regulations COM/2002/0085 and COD 2002/0046 (entry into force 27 October 2002) applies to the establishment of a common system of notification and information for exports to third countries of GMOs in order to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of GMOs that may have adverse effects on the conservation and the sustainable use of biological diversity, taking also into account risks to human health. The Regulation shall not apply to: pharmaceuticals for human use and to GMOs intended for deliberate release into the environment that are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health. The information required in notifications includes: (a) name, address and contact details of the

exporter, (b) name, address and contact details of the importer, (c) name and identity of the GMO, as well as the domestic classification, if any, of the biosafety level of the GMO in the state of export, (d) intended date or dates of the transboundary movement, if known, (e) taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety, (f) centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate, (g) taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety, (h) description of the nucleic acid or the modification introduced, the technique used and the resulting characteristics of the GMO, (i) intended use of the GMO, (j) quantity or volume of the GMO to be transferred, (k) a previous and existing risk assessment report, (l) suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate, (m) regulatory status of the GMO within the state of export, (n) result and purpose of any notification by the exporter to other states regarding the GMO to be transferred, (o) a declaration that the above-mentioned information is factually correct.

A summary of the EU Directives/Regulation related to GMOs is found in Table 11.

Food quality

Food quality is covering food marketing, consumer research, sensory science and nutrition, as well as food research and development, and quality assurance. It is aimed at food industry professionals and researchers aiming to match consumer preferences and food quality (http://www.elsevier.com/wps/find/journaldescription.cws_home/405859/description#description). The aim is to provide advice for schemes on best practice and help consumers by promoting best practice among assurance schemes. It covers relevant legislation, advice on the setting and delivery of production standards, and transparency for consumers. Food safety is the prime

Table 11 EU Directives and Regulations (main points and comments) for GMOs

Directive – Title	Main points	Comments
EU 90/219/EEC (entry into force 23 October 1991) Contained use of G.M. Micro-organisms	Measures for limited use of G.M. Micro-organisms Not applicable to certain techniques of genetic modification Measures for avoidance of adverse effects in human health and environment Emergency plan in case of an accident and regular inspections	Amendments EU Directive 98/81/EC Additional elements for the articles. (entry into force 5 December 1998)
EU 90/220/EEC (entry into force 23 October 1991) Deliberate release into the environment of GMOs	Protective measures for human health and environment Not applicable to certain techniques of genetic modification Measures for avoidance of adverse effects Activities of Member States for deliberate release into the environment of GMOs for research, development and market placing purposes	Amendments EU Directive 97/35/EC Additional elements for the disposal on the market of products which contain GMOs Regulation (EC) No. 258/97 and Regulation (EC) No. 1139/98 Labelling of food containing proteins or DNA derived from genetic modification. (entry into force 1 January 2002 and enforcement for 10 years)
EU 2001/18/EC (entry into force 17 April 2001) Deliberate release into the environment of GMOs	Measures of authorisation of the release and disposal on the market of GMOs Obligatory controls after the disposal of GMOs on the market Consultations with the public and labelling of GMOs	Repeal EU Directive 90/220/EEC since 17 October 2002 Amendment Regulation (EC) No. 1830/2003 (entry into force 7 November 2003)
EU 2004/204/EC (entry into force 23 March 2004) Arrangements for the operation of the registers for recording information on genetic modifications in GMOs	Lists of information of genetic modification in GMOs Lists should contain detailed report of documents Lists are publicly available	
EU 2004/643/EC Placing on the market of a maize product (<i>Zea mays</i> L. line NK603) GM for glyphosate tolerance	Product should be as safe as conventional (equivalence principle) Handling, packaging and protection as conventional Obligatory recordation of the code MON-00603-6 (unique) Measures for labelling and traceability in all stages of the market promotion	
EU 2004/657/EC Placing on the market of a sweet corn from GM maize line Bt11 as a novel food or novel food ingredient Regulation (EC) No. 258/97 (entry into force 14 May 1997) Novel food and novel food ingredients	Product should be as safe as conventional Obligatory labelling as 'GM sweet corn' Obligatory recordation of the code SYN-BTØ11-1 (unique) No more controls after placing on the market Placing on the market within the Community of foods and food ingredients which have not been used for human consumption to a significant degree within the Community before Not applicable to food additives, flavourings and extraction solvents Specific requirements for labelling Specific procedure for food-stuffs containing GMOs	Replacement EU Directive 90/220/EC

Table 11 (Continued)

Directive – Title	Main points	Comments
Regulation (EC) No. 1139/98 (entry into force 1 September 1998)	Application to food and food ingredients which are produced from GM soybean or GM corn	Replacement Regulation (EC) No. 1813/97
The compulsory indication of the labelling of certain food-stuffs produced from GMOs	No application to food additives and condiments	Amendments
	No application to products which are legally produced, labelled and imported, commercialised in the Community	Regulation (EC) No. 49/2000 (entry into force 31 January 2000)
		Regulation (EC) No. 50/2000 (entry into force 31 January 2000)
		Additional elements for certain articles of the Regulation
Regulation (EC) No. 1829/2003 (entry into force 7 November 2003)	Measures for human and animal health protection, Community procedures of approval, inspection and labelling of GM food and feed	Replacements
GM food and feed	Approvals are applicable for 10 years with the potential of renewal	Regulation (EC) No. 1139/98
Regulation (EC) No. 1830/2003 (entry into force 7 November 2003)	Traceability of products consisting of, or containing GMOs and food-stuffs, feed produced from GMOs	Regulation (EC) No. 49/2000
Traceability and labelling of GMOs and traceability of food and feed products produced from GMOs	Application for all stages of disposal on the market	Regulation (EC) No. 50/2000
	Specific demands on labelling	
	Inspection, control measures and sanctions in case of infringement	
Regulation (EC) No. 65/2004 (entry into force on the date of its publication in the <i>Official Journal of the European Union</i>)	Unique identifier for each GMO which is placed on the market	
Establishment of a system for the development and assignment of unique identifiers for GMOs	Not applicable to pharmaceuticals intended for human and veterinary use	
Regulation (EC) No. 641/2004 (entry into force 18 April 2004)	Transformation of applications and statements in the applications	
The authorisation of new GM food and feed, the notification of existing products and adventitious or technically unavoidable presence of GM material which has benefited from a favourable risk evaluation	Requirements of input on the market of certain products	
	Transitional measures for adventitious or technically unavoidable presence of GM material which has benefited from a favourable risk evaluation	
Proposal for a Regulation COM/2002/0085 – COD 2002/0046 (entry into force 27 October 2002)	Establishment of a notifying system and exchanging information on the exports of GMO to third countries	
The transboundary movement of GMOs	No application for pharmaceuticals for human use	
	Surveillance, submission of reports and imposition of sanctions for any infringement	

condition for food quality and an absolute, non-negotiable must. This is also true of compliance with legally established standards for the environment and animal welfare as they relate to the

protection of natural resources and requirements of an ethical nature, in addition to the characteristics of the products. Legislation in the food safety field started in the 1960s and grew more

intensely in the 1990s with the advent of the single market. The 1992 and 1999 CAP reforms emphasised agri-environmental measures and aid for extensification, and also in 1992 there was the introduction of European quality labels. Community legislation cannot and should not take over entirely from that of the Member States and attempt to cover all aspects of quality; rather, it should seek to work in tandem on pursuing a policy to foster quality (http://europa.eu.int/comm/agriculture/foodqual/index_en.htm).

Labelling: general provisions

Labelling has been a major issue in the EU food legislation. Labelling refers not only to consumption date (best before) but to percentage ingredients, presence of GM foods, potential allergens, adulteration and ethical issues.

EU Directive 90/496/EEC (entry into force 1 October 1990) relates to the nutrition labelling of food-stuffs to be delivered as such to the ultimate consumer. It shall also apply to food-stuffs intended for supply to restaurants, hospitals, canteens and other similar mass caterers. This Directive shall not apply to natural mineral waters or other waters intended for human consumption and diet integrators/food supplements. Where nutrition labelling is provided, the information to be given shall consist of either group 1 or group 2 in the following order: Group 1: (a) energy value, (b) the amounts of protein, carbohydrate and fat. Group 2: (a) energy value, (b) the amounts of protein, carbohydrate, sugars, fat, saturates, fibre and sodium. Where a nutrition claim is made for sugars, saturates, fibre or sodium, the information to be given shall consist of group 2. Nutrition labelling may also include the amounts of one or more of the following: starch, polyols, mono-unsaturates, polyunsaturates, cholesterol or any of the minerals or vitamins. The energy value to be declared shall be calculated using the following conversion factors: (i) carbohydrate (except polyols) 4 kcal g^{-1} – 17 kJ g^{-1} , (ii) polyols 2.4 kcal g^{-1} – 10 kJ g^{-1} , (iii) protein 4 kcal g^{-1} – 17 kJ g^{-1} , (iv) fat 9 kcal g^{-1} – 37 kJ g^{-1} , (v) alcohol (ethanol) 7 kcal g^{-1} – 29 kJ g^{-1} , (vi) organic acid 3 kcal g^{-1} – 13 kJ g^{-1} . The information covered by this Directive must be presented together in one place in tabular form, with the numbers aligned if space permits. Where space does not permit,

the information shall be presented in linear form. It shall be printed in legible and indelible characters in a conspicuous place. Member States shall ensure that the information covered by this Directive appears in a language easily understood by purchasers, unless other measures have been taken to ensure that the purchaser is informed. This provision shall not prevent such information from being indicated in more than one language. Member States shall refrain from laying down requirements more detailed than those already contained in this Directive concerning nutrition labelling. The declaration of the energy value and of the proportion of nutrients or their components shall be numerical. The units to be used are the following: (1) energy (kJ and kcal), (2) protein, carbohydrate, fat (g), (3) fibre, sodium, cholesterol (mg). Information shall be expressed per 100 g or per 100 mL.

EU Directive 2000/13/EC (entry into force 26 May 2000) concerns the labelling of food-stuffs to be delivered as such to the ultimate consumer and certain aspects relating to the presentation and advertising thereof. This Directive shall apply also to food-stuffs intended for supply to restaurants, hospitals, canteens and other similar mass caterers. The following particulars alone shall be compulsory on the labelling of food-stuffs: (1) the name under which the product is sold, (2) the list of ingredients, (3) the quantity of certain ingredients or categories of ingredients, (4) in the case of pre-packaged food-stuffs, the net quantity, (5) the date of minimum durability or, in the case of food-stuffs which, from the microbiological point of view, are highly perishable, the 'use by' date, (6) any special storage conditions or conditions of use, (7) the name or business name and address of the manufacturer or packager, or of a seller established within the Community, (8) particulars of the place of origin or provenance where failure to give such particulars might mislead the consumer to a material degree as to the true origin or provenance of the food-stuff, (9) instructions for use when it would be impossible to make appropriate use of the food-stuff in the absence of such instructions, (10) with respect to beverages containing more than 1.2% by volume of alcohol, the actual alcoholic strength by volume. Ingredients need not be listed in the case of: (a) fresh fruit and vegetables, including potatoes, which have not

been peeled, cut or similarly treated, carbonated water, the description of which indicates that it has been carbonated, fermentation vinegars derived exclusively from a single basic product, provided that no other ingredient has been added, (b) cheese, butter, fermented milk and cream, provided that no ingredient has been added other than lactic products, enzymes and micro-organism cultures essential to manufacture, or the salt needed for the manufacture of cheese other than fresh cheese and processed cheese, (c) products comprising a single ingredient, where the trade name is identical to the ingredient name or the trade name enables the nature of the ingredient to be clearly identified. The net quantity of pre-packaged food-stuffs shall be expressed in units of volume in the case of liquids or in units of mass in the case of other products, using litre, centilitre, millilitre, kilogram or gram, as appropriate. The date of minimum durability of a food-stuff shall be the date until which the food-stuff retains its specific properties when properly stored. Subject to Community provisions imposing other types of date indication, an indication of the durability date shall not be required for: (1) fresh fruit and vegetables, including potatoes, which have not been peeled, cut or similarly treated. This derogation shall not apply to sprouting seeds and similar products such as legume sprouts, (2) wines, liqueur

wines, sparkling wines, aromatised wines and similar products obtained from fruits other than grapes, and beverages and manufactured from grapes or grape musts, (3) beverages containing 10% or more by volume of alcohol, (4) soft drinks, fruit juices, fruit nectars and alcoholic beverages in individual containers of more than 5 L, intended for supply to mass caterers, (5) bakers' or pastry cooks' wares which, given the nature of their content, are normally consumed within 24 h of their manufacture, (6) vinegar, (7) cooking salt, (8) solid sugar, (9) confectionery products consisting almost solely of flavoured and/or coloured sugars, (10) chewing gums and similar chewing products and (11) individual portions of ice-cream.

A summary of the EU Directives related to labelling (general provisions) is given in Table 12.

Labelling

Regulation (EEC) No. 1576/89 (entry into force 15 June 1989) lays down the general rules on the definition, description and presentation of spirit drinks. For the purposes of this Regulation spirit drink shall mean an alcoholic liquid intended for human consumption, having particular organoleptic qualities and a minimum alcoholic strength of 15% vol. and produced either directly by the distillation, with or without added flavourings, of natural fermented products, and/or by the

Table 12 EU Directives (main points and comments) related to labelling; general provisions

Directive – Title	Main points	Comments
EU 90/496/EEC (entry into force 1 October 1990) Approximation of the laws of the Member States relating to food supplements	Nutrition labelling of food-stuffs for the ultimate consumer and for mass caterers Not applicable to natural mineral waters or any other waters intended for human consumption or to diet integrators/food supplements Nutrition labelling is not compulsory The declared energy value and amount of nutrients shall be given in figures using specific units of measurement	Amendment EU Directive 2003/120/EC (entry into force 26 October 1990) Addition of an article
EU 2000/13/EC (entry into force 26 May 2000) Approximation of the laws of the Member States relating to the labelling, presentation and advertising of food-stuffs	Application to pre-packed food-stuffs with final receiver the consumer and mass caterers No application to products which are exported from the Community Obligatory recordation of specific elements	Repeal EU Directive 79/112/EEC Amendments EU Directive 2001/101/EC (entry into force 14 December 2001) Addition of an annex EU Directive 2003/89/EC (entry into force 24 November 2004) Replacement of an article

maceration of vegetable substances and/or the addition of flavourings, sugars or other sweetening products and/or other agricultural products to ethyl alcohol of agricultural origin and/or to distillate of agricultural origin and/or to spirit as defined in this Regulation or by the mixture of a spirit drink with one or more other spirit drinks, ethyl alcohol of agricultural origin, distillate of agricultural origin or spirit, one or more alcoholic drinks, one or more drinks. Categories of spirit drink and their alcoholic strength: (a) rum (37.5%), (b) whisky/whiskey (40%), (c) grain spirit (35%), (d) wine spirit (37.5%), (e) brandy or Weinbrand (36%), (f) grape marc spirit or grape marc (37.5%), (g) fruit marc spirit (37.5%), (h) raisin spirit or raisin brandy (37.5%), (i) fruit spirits (37.5%), (j) cider spirit, cider brandy or perry spirit (37.5%), (k) gentian spirit (37.5%), (l) fruit spirit drinks (25%), (m) juniper-flavoured spirit drinks (25%), (n) caraway-flavoured spirit drinks (30%), (o) aniseed-flavoured spirit drinks (25%), (p) bitter-tasting spirit drinks or bitter, (q) vodka, (r) liqueur, (s) egg liqueur/advocaat/avocat/Advokat and (t) liqueur with egg. Labelling: (a) the name under which the products are sold shall be one of the names to be used exclusively for such products, (b) where the labelling indicates the raw material used to produce the ethyl alcohol of agricultural origin, each agricultural alcohol used must be mentioned in descending order of quantity used, descending order of quantity used, (c) the name under which the spirit drinks are sold may be supplemented by the term 'blend' where the product has undergone blending and (d) saving exceptions, a maturation period may be specified only where it refers to the youngest alcoholic component and provided that the product was aged under revenue supervision or supervision affording equivalent guarantees, (e) the conditions under which the labelling may specify a maturation period and those relating to the raw materials used, (b) the conditions governing the use of sales descriptions which imply that the product has been matured, together with any exceptions and the conditions for equivalent controls, (f) the special provisions governing the use of terms referring to a certain property of the product, such as its history or the method by which it is prepared, (g) the rules governing the labelling of products in containers not intended

for the final consumer, including any derogations from the labelling rules to take account, in particular, of warehousing and transport.

Regulation (EEC) No. 1601/91 (entry into force 17 June 1991) lays down the general rules on the definition, description and presentation of aromatised wines, aromatised wine-based drinks and aromatised wine-product cocktails. Aromatised wine shall mean a drink: (i) obtained from wines with the exception of retsina table wine and possibly with added grape must, grape must in fermentation and/or fresh grape must with fermentation arrested by the addition of alcohol, as defined by Community legislation, (ii) which has been flavoured with the aid of natural flavouring substances and/or natural flavourings preparations or aromatic herbs and/or spices and/or flavouring food-stuffs, (iii) which has generally been sweetened and has possibly been coloured with caramel and (iv) which has a minimum actual alcoholic strength by volume of 14.5% vol. or more and a maximum actual alcoholic strength by volume of less than 22% vol. and a minimum total alcoholic strength by volume of 17.5% vol. or more. However, for those products which bear the description 'dry' or 'extra dry', the minimum total alcoholic strength by volume shall be set at 16% vol. and 15% vol. respectively. Categories of aromatised wine are: (a) vermouth, (b) bitter aromatised wine and egg-based aromatised wine. Categories of aromatised wine-based drink are: (i) sangria, (ii) clarea, (iii) zurra, (iv) bitter soda, (v) kalte ente, (vi) guehwein, (vii) maiwein and (viii) maitrak. The descriptions may also include the following particulars, with the sugar content being expressed as invert sugar: (1) 'extra-dry' in case of products with a sugar content of less than 80 g L⁻¹, (2) 'dry' in case of products with a sugar content of less than 50 g L⁻¹, (3) 'semi-dry' in case of products with a sugar content of between 50 and 90 g L⁻¹, (4) 'semi-sweet' in case of products with a sugar content of between 90 and 130 g L⁻¹ and (5) 'sweet' in case of products with a sugar content of more than 130 g L⁻¹.

Regulation (EEC) No. 2081/92 (entry into force 24 July 1993) lays down rules on the protection of designations of origin and geographical indications of agricultural products intended for human consumption. For the purposes of this Regulation: (a) *designation of origin* means the name of a

region, a specific place or, in exceptional cases, a country, used to describe an agricultural product or a food-stuff originating in that region, specific place or country and the quality or characteristics of which are essentially or exclusively due to a particular geographical environment with its inherent natural and human factors, and the production, processing and preparation of which take place in the defined geographical area, (b) *geographical indication* means the name of a region, a specific place or, in exceptional cases, a country, used to describe an agricultural product or a food-stuff originating in that region, specific place or country and which possesses a specific quality, reputation or other characteristics attributable to that geographical origin and the production and/or processing and/or preparation of which take place in the defined geographical area. This Regulation shall apply to: (1) food-stuffs (beer, natural mineral waters and spring waters, beverages made from plant extracts, bread, pastry, cakes, confectionery, biscuits and other baker's wares and natural gums and resins), (2) agricultural products (hay and essential oils). The product specification shall include at least: (a) the name of the agricultural product or food-stuffs, including the designation of origin or the geographical indication, (b) a description of the agricultural product or food-stuff including the raw materials, if appropriate, and principal physical, chemical, microbiological and/or organoleptic characteristics of the product or the food-stuff, (c) the definition of the geographical area and, if appropriate, (d) evidence that the agricultural product or the food-stuff originates in the geographical area, (e) a description of the method of obtaining the agricultural product or food-stuff and, if appropriate, the authentic and unvarying local methods, (f) the details bearing out the link with the geographical environment or the geographical origin, (g) details of the inspection structures, (h) the specific labelling details relating to the indication PDO or PGI, whichever is applicable, or the equivalent traditional national indications, (i) any requirements laid down by Community and/or national provisions. Registered names shall be protected against: (a) any direct or indirect commercial use of a name registered in respect of products not covered by the registration insofar as those products are comparable to the products

registered under that name or insofar as using the name exploits the reputation of the protected name, (b) any misuse, imitation or evocation, even if the true origin of the product is indicated or if the protected name is translated or accompanied by an expression such as 'style', 'type', 'method', 'as produced in', 'imitation' or similar, (c) any other false or misleading indication as to the provenance, origin, nature or essential qualities of the product, on the inner or outer packaging, advertising material or documents relating to the product concerned, and the packing of the product in a container liable to convey a false impression as to its origin, (d) any other practice liable to mislead the public as to the true origin of the product.

Furthermore, Regulation (EEC) No. 2200/96 (entry into force 1 January 1997) claims that it shall apply to fresh fruits, which are: apple, apricot, avocado, grapes, lemon, kiwifruit, tangerine, cherry, melon, water melon, orange, pear, strawberry, nectarine, peach and plum, and vegetables which are: artichoke, bean, carrot, celery, garlic, onion, spinach, chicory, lettuce, pepper, cabbage, cauliflower, vegetable marrow, leek, pea, eggplant, cucumber, tomato and endive.

Regulation (EC) No. 2815/98 (entry into force 31 October 2001) claims that the designation of origin shall relate to a geographical area and may mention only: (a) a geographical area whose name has been registered as a protected designation of origin or protected geographical indication and/or (b) for the purposes of this Regulation: a Member State, the European Community, a third country. The designation of origin, where this indicates the European Community or a Member State shall correspond to the geographical area in which the 'extra virgin olive oil' or 'virgin olive oil' was obtained. However, in the case of blends of 'extra virgin olive oils' or 'virgin olive oils' in which more than 75% originates in the same Member State or in the Community, the main origin may be designated provided that it is followed by the indication 'selection of (extra) virgin olive oils more than 75% of which was obtained in ... (designation of origin)'. An extra virgin or virgin olive oil shall be deemed to have been obtained in a geographical area for the purposes of this paragraph only if that oil has been extracted from olives in a mill located within that area.

In Regulation (EC) No. 1439/99 (entry into force 14 September 1999) it should apply to wine which is sold in the Community. Categories of wine in which the Regulation is set: (a) table wine, (b) table wine with geographical indication, (c) wine produced in specific areas and (d) imported wine.

According to Regulation (EC) No. 1760/2000 (entry into force 14 August 2000), each Member State shall establish a system for the identification and registration of bovine animals. The system for the identification and registration of bovine animals shall comprise the following elements: (a) ear tags to identify animals individually, (b) computerised databases, (c) animal passports and (d) individual registers kept on each holding. With the exception of transporters, each keeper of animals shall keep an up-to-date register and once the computerised database is fully operational, report to the competent authority all movements to and from the holding and all births and deaths of animals on the holding, along with the dates of these events, within a period fixed by the Member State of between 3 and 7 days of the event occurring. Member States may extend the maximum period and provide for special rules applicable to movements of bovine animals when put out to summer grazing in different mountain areas. The measures necessary for the implementation of this Title shall be adopted in accordance with this Regulation. These measures concern in particular: (a) provisions concerning ear tags, (b) provisions concerning the passport, (c) provisions concerning the register, (d) minimum level of controls to be carried out, (e) application of administrative sanctions, (f) transitional measures required to facilitate the application of this title. The label shall contain the following indications: (i) a reference number or reference code ensuring the link between the meat and the animal or animals. This number may be the identification number of the individual animal from which the beef was derived or the identification number relating to a group of animals, (ii) the approval number of the slaughterhouse at which the animal or group of animals was slaughtered and the Member State or third country in which the slaughterhouse is established. The indication shall read: 'Slaughtered in (name of the Member State or third country) (approval number)', (iii) the

approval number of the cutting hall which performed the cutting operation on the carcass or group of carcasses and the Member State or third country in which the hall is established. The indication shall read: 'Cutting in (name of the Member State or third country) (approval number)'. Voluntary labelling specifications shall indicate: A) the information to be included on the label, B) the measures to be taken to ensure the accuracy of the information, C) the control system which will be applied at all stages of production and sale, including the controls to be carried out by an independent body recognised by the competent authority and designated by the operator or the organisation. These bodies shall comply with the criteria set out in European Standard EN 45011 and D) in the case of an organisation, the measures to be taken in relation to any member which fails to comply with the specifications.

In Regulation (EC) No. 1321/2002 (entry into force 1 August 2002) the said producers shall subsequently be inspected regularly. They shall keep current records, for a minimum of 6 months following dispatch, of the number of birds by type of poultry system showing also the number of birds sold and the names and addresses of the purchasers and quantities and source of feed supply. The definitions given are applicable to the poultry cuts. The sample sizes should be at least as follows: (i) chicken breast: half of the breast, (ii) chicken breast fillet: half of the boned breast without skin, (iii) turkey breast, turkey breast fillet and boned leg meat: portions of about 100 g.

Regulation (EC) No. 318/2003 (entry into force 25 February 2003) is related to checks carried out in the packing centres on graded eggs ready for dispatch and not to checks on eggs leaving the packing centres. In order to ensure proper land management and to prevent a build-up of harmful diseases, the open-air runs for laying hens may need to be rotated. Birds should be given even access to the whole paddock area and, where rotation on extensive free range system with at least 10 m² per hen is practised, each bird should be ensured at all times at least 2.5 m².

The titles, main points and comments of the EU Regulations about labelling are summarised in Table 13.

Table 13 EU Regulations (main points and comments) for labelling

Regulation – Title	Main points	Comments
Regulation (EEC) No. 1576/89 (entry into force 15 June 1989)	The minimum alcoholic strength by volume below which a product may not be marketed in the territory of the EU is laid down	Amendments Regulation (EEC) No. 3280/92 (entry into force 16 November 1992)
General rules on the definition, description and presentation of spirit drinks	Addition of specific substances to the products	Addition to an article Regulation (EEC) No. 3378/94 (entry into force 1 January 1995) Addition of articles
Regulation (EEC) No. 1601/91 (entry into force 17 June 1991)	Three categories of drinks according to their wine content, their alcoholic strength, and whether they contain added alcohol	Amendments Regulation (EEC) No. 3279/92 (entry into force 16 November 1992)
Laying down general rules on the definition, description and presentation of aromatised wine, aromatised wine-based drinks and aromatised wine-product cocktails		Regulation (EC) No. 3378/94 (entry into force 1 January 1995) Regulation (EC) No. 2061/96 (entry into force 3 November 1996) Addition and replacement of articles
Regulation (EEC) No. 2081/92 (entry into force 24 July 1993)	No application to wine products or to spirit drinks Names that have become generic may not be registered	Amendments Regulation (EC) No. 535/97 (entry into force 15 April 1997)
Protection of geographical indications and designations of origin for agricultural products and food-stuffs	To be eligible to use a PDO or a PGI an agricultural product or food-stuff must comply with a specification The indications PDO, PGI or equivalent traditional national indications may appear only on agricultural products and food-stuffs that comply with this Regulation	Regulation (EC) No. 1068/97 (entry into force 28 June 1997) Regulation (EC) No. 2796/2000 (entry into force 10 January 2001) Completion of articles
Regulation (EEC) No. 2200/96 (entry into force 1 January 1997)	Marketing standard for fresh fruits and vegetable Laying down a list of fresh fruits and vegetable	
Labelling of fresh fruits and vegetable		
Regulation (EC) No. 2815/98 (entry into force 31 October 2001)	The designation of origin shall relate to a geographical area	
Marketing standards for olive oil	The 'extra virgin olive oil' and 'virgin olive oil' whose shall be packaged in an establishment approved for that purpose Designation of origin checks in the packaging plants	
Regulation (EC) No. 1439/99 (entry into force 14 September 1999)	Labelling is compulsory and it contains information about the origin of wine	
Marketing standards for wine	Categories of wine and rules for the marketing standards	
Regulation (EC) No. 1760/2000 (entry into force 14 August 2000)	Every Member State must set up a cattle identification and registration system Compulsory labelling of beef and beef products	Repeal Regulation (EC) No. 820/97 Amendment Regulation (EC) No. 1825/2000
Establishment of a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products		Addition for traceability, labelling and controls of bovine animals and their products. (entry into force 1 September 2000)

Table 13 (Continued)

Regulation – Title	Main points	Comments
Regulation (EC) No. 1321/2002 (entry into force 1 August 2002) Marketing standards for poultry meat	Mark of designation of origin for fresh and frozen poultry meat only in the case of imports from countries out of the Community Inspections for designation of origin in the packaging plants	Repeal Regulation (EC) No. 1906/90
Regulation (EC) No. 318/2003 (entry into force 25 February 2003) Certain marketing standards for eggs	Obligatory sign of designation of origin on eggs packaging originated from a third country Inspections in the plants of packaging	

Food products

For fundamentals of the science and technology associated with harvesting, processing, packaging, preservation, storage, distribution, marketing, and safety of marine food products of commerce, refer <http://www.fst.vt.edu/undergraduate.courses.html>. For the purpose of preventing the use in commerce of meat and meat food products which are adulterated, the Secretary shall make, by inspectors appointed for that purpose, an examination and inspection of all cattle, sheep, swine, goats, horses, mules, and other equines before they shall be allowed to enter into any slaughtering, packing, meat-canning, rendering, or similar establishment, in which they are to be slaughtered and the meat and meat food products thereof are to be used in commerce; and all cattle, sheep, swine, goats, horses, mules, and other equines found on such inspection to show symptoms of disease shall be set apart and slaughtered separately from all other cattle, sheep, swine, goats, horses, mules, or other equines, and when so slaughtered the carcasses of said cattle, sheep, swine, goats, horses, mules, or other equines shall be subject to a careful examination and inspection, all as provided by the rules and regulations to be prescribed by the Secretary (<http://www.washingtonwatchdog.org/documents/usc/index.html>). Milk and milk products for import into the EU must fulfil certain basic animal health criteria for import into the EU. This ensures that milk and milk products also conform to the animal health requirements laid down in Community legislation and is intended to safeguard the animal health situation in the

EU. Legislation lays down sensory attributes of milk and dairy products important in evaluation and judging product quality. It is also related to production and processing methods affecting milk and dairy product quality as determined by organoleptic evaluation, training in different sensory techniques for use in dairy products manufacturing and quality control (http://europa.eu.int/comm/food/animalproducts/milk/index_en.htm).

Water quality

EU Directive 75/440/EEC claims that surface water shall be assumed to conform to the relevant parameters if samples of this water taken at regular intervals at the same sampling point and used in the abstraction of drinking water, show that it complies with the parametric values for the water quality in question, in the case of: 95% of the samples for parameters conforming to those specified and 90% of the samples in all other cases, and if in the case of the 5% or 10% of the samples which do not comply: (a) the water does not deviate from the parametric values in question by more than 50%, except for temperature, pH, dissolved oxygen and microbiological parameters, (b) there can be no resultant danger to public health, (c) consecutive water samples taken at statistically suitable intervals do not deviate from the relevant parametric values. The definition of the standard methods of treatment for transforming surface water of categories A1, A2 and A3 into drinking water includes: category A1 (simple physical treatment and disinfection, e.g. rapid filtration and disinfection), category A2 (normal

physical treatment, chemical treatment and disinfection, e.g. pre-chlorination, coagulation, flocculation, decantation, filtration, disinfection) and category A3 (intensive physical and chemical treatment, extended treatment and disinfection e.g. chlorination to break-point, coagulation, flocculation, decantation, filtration, adsorption, disinfection).

With regard to EU Directive 79/923/EEC Member States: (a) shall, within a 2-year period following the notification of this Directive, designate shellfish waters, (b) may subsequently make additional designations, (c) may revise the designation of certain waters owing, in particular, to factors unforeseen at the time of designation, (d) shall establish programmes in order to reduce pollution and to ensure that designated waters conform to the values set by the Member States, within 6 years following designation. Where the competent authority records that the quality of designated waters is appreciably higher than that which would result from the application of the values set, the frequency of the sampling may be reduced. Where there is no pollution and no risk of deterioration in the quality of the waters, the competent authority concerned may decide that no sampling is necessary. If sampling shows that a value set is not respected, the competent authority shall establish whether this is the result of chance, a natural phenomenon or pollution and shall adopt appropriate measures. The exact sampling point, the distance from this point to the nearest point where pollutants are discharged and the depth at which the samples are to be taken shall be fixed by the competent authority of each Member State on the basis of local environmental conditions, in particular. The reference methods of analysis to be used for calculating the value of the parameters concerned are set out. Laboratories, which employ other methods, shall ensure that the results obtained are equivalent or comparable to those specified.

According to EU Directive 98/83/EC, Member States may exempt from the provisions of this Directive: water intended exclusively for those purposes for which the competent authorities are satisfied that the quality of the water has no influence, either directly or indirectly, on the health of the consumers concerned and water intended for human consumption from an indi-

vidual supply providing less than 10 m³ a day as an average or serving fewer than fifty persons, unless the water is supplied as part of a commercial or public activity. The parametric values set shall be complied with: (i) in the case of water supplied from a distribution network, at the point, within premises or an establishment, at which it emerges from the taps that are normally used for human consumption, (ii) in the case of water supplied from a tanker, at the point at which it emerges from the tanker, (iii) in the case of water put into bottles or containers intended for sale, at the point at which the water is put into the bottles or containers, (iv) in the case of water used in a food-production undertaking, at the point where the water is used in the undertaking. The following parameters are being inspected: aluminium, ammonium, chloride, *Clostridium perfringens* (including spores), colour, conductivity, hydrogen ion concentration, iron, manganese, odour, oxidisability, sulphate, sodium, taste, colony count in 22 and 27 °C, coliform bacteria, total organic carbon, turbidity.

All the EU Directives related to water quality are given in Table 14.

Oils: fats

EU Directive 96/3/EC claims that the bulk transport in sea-going vessels of liquid oils or fats which are to be processed, and which are intended for or likely to be used for human consumption, is permitted in tanks that are not exclusively reserved for the transport of food-stuffs, subject to the following conditions: (i) that, where the oil or fat is transported in a stainless steel tank, or tank lined with epoxy resin or technical equivalent, the immediately previous cargo transported in the tank shall have been a food-stuff, or a cargo from the list of acceptable previous cargoes set out in the Annex, (ii) that, where the oil or fat is transported in a tank of materials other than those in point (i), the three previous cargoes transported in the tanks shall have been food-stuffs, or from the list of acceptable previous cargoes set out in the Annex. The captain of the sea-going vessel transporting, in tanks, bulk liquid oils and fats intended for or likely to be used for human consumption shall keep accurate documentary evidence relating to the three previous cargoes carried in the tanks concerned, and the

Table 14 EU Directives (main points and comments) focused on water quality

Directive – Title	Main points	Comments
EU 75/440/EEC (entry into force 16 June 1977) The quality required of surface water intended for the abstraction of drinking water	Demands required for the quality of surface water intended for the abstraction of drinking water Not applicable to subterranean and subsaline water Variations in the case of floods or other natural disasters are accepted	Amendments EU Directive 79/869/EEC Methods of measurement, sampling frequency and parameter analysis Amendment, repeal and replacement of articles. (entry into force 9 October 1981) EU Directive 91/692/EEC Standardisation of reports concerning the application of specific directives for the environment Articles replacement. (entry into force 1 January 1993)
EU 79/923/EEC (entry into force 5 November 1981) Quality required of shellfish waters	Applicable to coastal and brackish waters in order to support shellfish life Criteria for minimum demanded quality of shellfish waters Two-year period for Member States to designate shellfish waters Decline in case of exceptional weather or geographical conditions	Amendment EU Directive 91/692/EEC Standardisation of reports concerning the application of specific directives for the environment. (entry into force 1 January 1993)
EU 98/83/EC (entry into force 25 December 1998) Quality of water intended for human consumption	Application for human health protection from potential contamination Not applicable to natural, mineral waters and waters which are medicinal products Demands for limited material migration in plants of drinking water	Repeal of EU Directive 80/778/EEC

effectiveness of the cleaning process applied between these cargoes.

Regulation (EC) No. 2991/94 lays down standards for: milk fats, fats and fats composed of plant and/or animal products with a fat content of at least 10% but less than 90% by weight, intended for human consumption. The fat content excluding salt must be at least two-thirds of the dry matter. The Regulation applies also to products which remain solid at a temperature of 20 °C, and which are suitable for use as spreads. The products may not be supplied or transferred without processing to the ultimate consumer either directly or through mass caterers, unless they meet the requirements set out. It has no application to the designation of products the exact nature of which is clear from traditional usage and/or when the designations are clearly used to describe a characteristic quality of the product and to concentrated products (butter, margarine, blends) with a fat content of 90% or more. The following information must be indicated in the labelling and

presentation of the products: the sales description, the total percentage fat content by weight at the time of production for products, the vegetable, milk or other animal fat content in decreasing order of weighted importance as a percentage by total weight at the time of production for compound fats and the percentage salt content must be indicated in a particularly legible manner in the list of ingredients.

Regulation (EC) No. 1019/2002 lays down specific standards for retail-stage marketing of olive oils and olive-pomace oils. Oils shall be presented to the final consumer in packaging of a maximum capacity of 5 L. Such packaging shall be fitted with an opening system that can no longer be sealed after the first time it is opened and shall be labelled. However, in the case of oils intended for consumption in mass caterers, the Member States may set a maximum capacity exceeding 5 L. Certain categories of oil are: (a) extra virgin olive oil, (b) virgin olive oil, (c) olive oil composed of refined olive oils and virgin olive

Table 15 EU Directive and Regulations (main points and comments) with regard to oils: fats

Directive – Title	Main points	Comments
EU 96/3/EC (entry into force 17 February 1996)	Definition of equivalent conditions to ensure the protection of public health and the safety and wholesomeness of the food-stuffs concerned	
Hygiene of food-stuffs as regards the transport of bulk liquid oils and fats by sea	The bulk transport in sea-going vessels of liquid oils or fats is permitted in tanks that are not exclusively reserved for the transport of food-stuffs Register of the three previous cargoes carried in the tanks concerned, and the effectiveness of the cleaning process applied between these cargoes	
Regulation (EC) No. 2991/94 (entry into force 1 January 1996)	Application to milk fats and fats composed of plant and/or animal products Not applicable to concentrated products	
Marketing standards for olive oil	The products are supplied to the consumer only after processing Products imported into the Community must comply with the Directive	
Regulation (EC) No. 1019/2002 (entry into force 1 November 2002)	Specific standards for retail-stage marketing of the olive oils and olive-pomace oils Oils shall be presented to the final consumer in packaging of a maximum capacity of 5 L	Amendment Regulation (EC) No. 1964/2002 (entry into force 1 July 2002)
Standards for spreadable fats	Specific way of labelling	The products which were legally produced, were labelled and got into circulation before 1 January 2003 will be marketed until the consumption of the stocks

oils and (d) olive-pomace oil. Only extra virgin and virgin olive oil may bear a designation of origin on the labelling.

Some representative points and comments (repeals, modifications, amendments) of the EU Directive/Regulations for oils (fats) are given in Table 15.

Production and placing on the market: milk

In EU Directive 89/384/EEC (entry into force 1 July 1990) the Member States should ensure that the checks on the freezing point of untreated milk are carried out according to the following detailed procedures: (1) the untreated milk of each holding must be checked regularly by random sampling and (2) if the results of the check refute the suspicion of water being added, the untreated milk may be used for producing heat-treated milk. Where the milk of a single holding is delivered directly to a treatment establishment, these samples are to be taken when the milk is collected from the holding with precautions however being taken to prevent any fraud during transport either before unloading at the treatment establishment or

when the milk is delivered there directly by the farmer. If the results of a check lead the competent authority to suspect that water is being added, it shall take an authentic sample of the holding. An authentic sample is a sample representing the milk of one completely supervised morning or evening milking beginning not less than 11 h or more than 13 h after the previous milking. Where milk is delivered from several holdings, samples may only be taken when the untreated milk enters the treatment establishment or collection or standardisation centre with spot checks however being carried out on the holdings.

Following the EU Directive 92/46/EEC (entry into force 1 January 1994), milk and milk-based products must not come from a surveillance zone established under this Directive, unless the milk has undergone, under the supervision of the competent authority, initial pasteurisation (71.7 °C for 15 s) followed by: (a) a second heat treatment resulting in a negative reaction to the peroxidase test or (b) a drying procedure including heating having an effect equivalent to the heat treatment or (c) a second treatment whereby pH is

reduced and kept for at least 1 h at less than 6. If the milk is not collected within 2 h of milking, it must be cooled to a temperature of 8 °C or lower in the case of daily collection or 6 °C if collection is not daily. While the milk is being transported to the treatment and/or processing establishment, the temperature of the cooled milk must not exceed 10 °C unless the milk has been collected within 2 h of milking. In the case of treatment establishments, heat-treatment equipment approved or authorised by the competent authority, fitted with: (i) an automatic temperature control, (ii) a recording thermometer, (iii) an automatic safety device preventing insufficient heating, (iv) an adequate safety system preventing the mixture of heat-treated milk with incompletely heated milk, (v) an automatic recording device for the safety system referred to in the preceding indent or a procedure for monitoring the system's effectiveness. However, when approving establishments, the competent authorities may authorise different equipment with equivalent performance guarantees and equal assurances with regard to hygiene. The operator or manager of the processing establishment must

take all necessary steps to ensure that the raw milk is heat treated or used, in the case of products made with raw milk: (i) as soon as possible after acceptance if the milk has not been refrigerated, (ii) within 36 h of acceptance if the milk is kept at a temperature not exceeding 6 °C, (iii) within 48 h of acceptance if the milk is kept at a temperature not exceeding 4 °C, (iv) within 72 h for buffalo, sheep and goat milk. However, for technological reasons concerning the manufacture of certain milk-based products, the competent authorities may authorise the times and temperatures referred to in the above indents to be exceeded.

All EU Directives dealing with production and placing on the market (milk) are given in Table 16.

Controls and food hygiene rules

EU Directive 85/591/EEC (entry into force 23 December 1987) claims that sampling and analysis are necessary because of the following criteria: (a) the need to ensure that Community law is uniformly applied, (b) the existence of barriers to intra-Community trade, (c) the permanent or recurrent nature of the criteria. The Directive

Table 16 EU Directives (main points and comments) related to production and placing on the market: milk

Directive – Title	Main points	Comments
EU 89/384/EEC (entry into force 1 July 1990) Establishing the detailed procedures for carrying out checks to ensure that the freezing point of untreated	Laying down the health and animal health requirements for heat-treated milk intended for intra-Community trade Technical descriptions of the various milk treatments Milk treatment establishments and collecting and standardisation centres must be approved by Member States Inspections of milk production holdings to ensure hygiene requirements are fulfilled Rules for transportation of milk	Amendment EU Directive 92/608/EEC (entry into force 20 January 1993)
EU 92/46/EEC (entry into force 1 January 1994) Laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products	Definitions (raw milk, heat treated milk, etc.) General conditions of hygiene in treatment establishments and processing establishments Production holdings (i.e. farms, where milk is produced) shall undergo regular checks to ensure that hygiene requirements are being complied with the Directive Rules for transportation of milk Measures for use by Member States in the case of the outbreak of disease Veterinary experts are authorised to undertake spot checks where this is required for uniform application of the Directive	Amendments EU Directive 92/47/EEC (entry into force 1 January 1994) EU Directive 94/71/EEC (entry into force 31 December 1994) Addition and corrections in the Articles and Annexes Repeal EU Directive 85/397/EEC from 1 January 1994

shall take account of the state of scientific and technical knowledge, in particular, of proven methods of sampling and analysis. The introduction of the measures shall not preclude Member States from using other tested and scientifically valid methods provided that this does not hinder the free movement of products recognised as complying with the rules by virtue of Community methods. The methods of analysis introduced shall comply with the criteria set out above. Where a Member State has detailed evidence that a measure adopted in accordance with Directive is inappropriate in a particular case for technical reasons or because it is insufficiently conclusive for the examination of an important health question, that Member State may temporarily suspend the measure in question in its territory but only for that particular case. It shall immediately inform the other Member States and the Commission thereof and give reasons for its decision. The Commission shall examine as soon as possible the evidence given by the Member State and then consult the Member States within the Standing Committee for Foodstuffs, after which it shall deliver its opinion forthwith and take appropriate measures. The member State which has suspended the Community measure may, in that event, continue to do so until the amendments enter into force.

According to the EU Directive 89/397/EEC (entry into force 20 June 1991), *official control of foodstuffs* means an inspection by the competent authorities of the compliance: (a) of food-stuffs, (b) of food additives, vitamins, mineral salts, trace elements and other additives intended to be sold as such, (c) of materials and articles intended to come into contact with food-stuffs, with provisions aimed at preventing risks to public health, guaranteeing fair commercial transactions or protecting consumer interests, including provisions on consumer information. Control shall comprise one or more of the following operations in accordance with the conditions laid down in Articles 6–9 and in the light of the examination to be carried out: (1) inspection, (2) sampling and analysis, (3) inspection of staff hygiene, (4) examination of written and documentary material and (5) examination of any verification systems set up by the undertaking and of the results obtained. The following shall be subject to inspection: (a) the

state and use which is made at the different stages, premises, offices, plant surroundings, means of transport, machinery and equipment, (b) raw materials, ingredients, technological aids and other products used for the preparation and production of food-stuffs, (c) semi-finished products, (d) finished products, (e) materials and articles intended to come into contact with food-stuffs, (f) cleaning and maintenance products and processes and pesticides, (g) processes used for the manufacture or processing of food-stuffs, (h) labelling and presentation of food-stuffs and (i) preserving methods.

In EU Directive 93/43/EEC (entry into force 14 December 1995), known as the HACCP requirement Directives, *food hygiene* means all measures necessary to ensure the safety and wholesomeness of food-stuffs. The measures shall cover all stages after primary production (the latter including, for example, harvesting, slaughter and milking), during preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling and offering for sale or supply to the consumer. The Directive applies (1) general requirements for food premises, (2) specific requirements in rooms where food-stuffs are prepared, treated or processed, (3) requirements for movable and/or temporary premises (such as marquees, market stalls, mobile sales vehicles), (4) transport, (5) fittings and equipment with which food comes into contact shall be kept clean, (6) food waste, (7) water supply, (8) personal hygiene, (9) provisions applicable to food-stuffs and (10) training food business operators shall ensure that food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity.

In EU Directive 93/99/EEC (entry into force 1 May 1995), the laboratory assessment becomes very clear as Member States shall: (a) apply the criteria laid down in European Standard EN 45002 and (b) require the use of proficiency testing schemes as far as appropriate. The Commission shall appoint and designate specific officials to cooperate with the competent authorities of the Member States to monitor and evaluate the equivalence and effectiveness of official food control systems operated by the competent authorities of the Member States. The Commission shall send regular reports to the Member

States concerned on the work of its specific officials. In criminal proceedings, the information can be used only with the prior consent of the sending Member State in accordance with, for those Member States who are parties to them, the international conventions and agreements in force on mutual assistance in criminal affairs. Where a Member State has rules permitting free access by persons to information held by competent authorities, this fact must be revealed at the time of the request to another Member State or during the exchange of information if no such request occurs. If it is not possible for the receiving Member State to restrict the giving out of the information in this way, it shall not be contrary to the terms of this Directive for the sending Member State to withhold the information. When, during the exchange of information, it becomes clear that there may have been a case of non-compliance of Community laws or rules or national law of either the receiving Member State or the sending Member State, the competent authority in the Member State in whose territory the alleged non-compliance has taken place shall, in due time, report back to the competent authority in the other Member State on any action that may have been undertaken to deal with the alleged non-compliance and also on any action which has taken, including any action to try to prevent a reoccurrence of the alleged non-compliance.

Following the EU Directive 2002/99/EC (entry into force 1 January 2005) which came into force on 1 January 2005, products of animal origin shall be obtained from animals which (a) do not come from a holding, establishment, territory or part of a territory subject to animal health restrictions applicable to the animals and products concerned, under the rules, (b) in the case of meat and meat products, were not slaughtered in an establishment in which animals infected or suspected of being infected with one of the diseases or carcasses or parts thereof of such animals were present during the slaughtering or production process, unless such suspicion has been ruled out, (c) in the case of aquaculture animals and products. Laying down lists of the third countries or regions of third countries from which imports of specified products of animal origin are permitted. A third country shall appear on such lists only if a Community audit of that country has taken place

and demonstrates that the competent veterinary authority provides appropriate guarantees as regards compliance with Community legislation. Certificates must (a) consist of a single sheet of paper or more pages that are part of a single and indivisible sheet of paper, (b) bear a unique identifying number (where the certificate consists of a sequence of pages, each page must indicate this number) and (c) be issued before the consignment to which it relates leaves the control of the competent authority of the country of dispatch. Lists of the third countries or regions of third countries from which imports of specified products of animal origin are permitted. A third country shall appear on such lists only if a Community audit of that country has taken place and demonstrates that the competent veterinary authority provides appropriate guarantees as regards compliance with Community legislation. When drawing up or updating those lists, particular account shall be taken of: (a) the legislation of the third country, (b) the organisation of the competent veterinary authority and its inspection services in the third country, the powers of these services, the supervision to which they are subject, and the means at their disposal, including staff capacity, to apply their legislation effectively, (c) the actual animal health requirements applying to the production, manufacture, handling, storage and dispatch of products of animal origin intended for the Community, (d) the assurances which the competent veterinary authority of the third country can give regarding compliance or equivalence with the relevant animal health conditions, (e) any experience of marketing the product from the third country and the results of any import controls carried out, (f) the results of Community inspections and/or audits carried out in the third country, in particular, the results of the assessment of the competent authorities or, where the Commission so requests, the report submitted by the competent authorities of the third country on the inspections which they have carried out, (g) the health status of livestock, other domestic animals and wildlife in the third country, with particular regard to exotic animal diseases and any aspects of the general health situation in the country which might pose a risk to public or animal health in the Community, (h) the regularity, speed and accuracy with which the third country supplies information

on the existence of infectious or contagious animal diseases in its territory, particularly the notifiable diseases listed by the World Organisation for Animal Health (OIE) or, in the case of diseases of aquaculture animals, the notifiable diseases listed in the Aquatic Animal Health Code of the OIE and (i) the rules on the prevention and control of infectious or contagious animal diseases in force in the third country and their implementation, including rules on imports from other countries.

According to EU Directive 2004/41/EC (entry into force 20 May 2004), repealing certain Directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption. The Directives which are repealed are: (i) 64/433/EEC (health conditions of the production and marketing of fresh meat), (ii) 71/118/EEC (health problems affecting the production and placing on the market of fresh poultry meat), (iii) 72/461/EEC (health problems affecting intra-Community trade in fresh meat), (iv) 77/96/EEC (examination for *Trichinella spiralis* upon importation from third countries of fresh meat derived from domestic swine), (v) 77/99/EEC (health problems affecting the production and marketing of meat products and certain other products of animal origin), (vi) 80/215/EEC (animal health problems affecting intra-Community trade in meat products), (vii) 89/362/EEC (general conditions of hygiene in milk production holdings), (viii) 89/437/EEC (hygiene and health problems affecting the production and the placing on the market of egg products), (ix) 91/492/EEC (laying down the health conditions for the production and the placing on the market of live bivalve molluscs), (x) 91/493/EEC (laying down the health conditions for the production and the placing on the market of fishery products), (xi) 91/494/EEC (animal health conditions governing intra-Community trade in and imports from third countries of fresh poultry meat), (xii) 91/495/EEC (concerning public health and animal health problems affecting the production and placing on the market of rabbit meat and farmed game meat), (xiii) 92/45/EEC (public health and animal health problems relating to the killing of wild game meat), (xiv) 92/46/EEC (laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based

products), (xv) 92/48/EEC (laying down the minimum hygiene rules applicable to fishery products caught on board certain vessels) and (xvi) 94/65/EEC (laying down the requirements for the production and placing on the market of minced meat and meat preparations).

A summary of the EU Directives focused on controls and food hygiene rules is given in Table 17.

Imports from third countries and intra-Community trade: general provisions

EU Directive 89/662/EEC (entry into force 22 December 1989) claims that for the purposes of this Directive veterinary check means any physical check and/or administrative formality which applies to the products and which is intended for the protection, direct or otherwise, of public or animal health. Products not subject to Community harmonisation are: (1) rabbit and game meat, (2) raw milk and milk products, (3) aquaculture products intended for human consumption, (4) fishery products intended for human consumption, (5) live bivalve molluscs intended for human consumption, (6) game and rabbit meat products, (7) blood, (8) offal of animal fats, greaves and by-products of rendering, (9) honey, (10) snails intended for human consumption and (11) frogs' legs intended for human consumption. Member States shall ensure that during the checks carried out at the places where products from a third country may be brought into Community territory, such as ports, airports and frontier posts with third countries, the following measures are taken: (a) a documentary check is made on the products' origin, (b) where products are imported from third countries, they must be sent, under customs supervision, to inspection posts in order that veterinary checks may be carried out and (c) products of Community origin shall be subject to the rules.

According to EU Directive 90/425/EEC (entry into force 26 July 1990), diseases or epizootic diseases are: foot and mouth disease (FMD), classical swine fever (CSF), African swine fever (ASF), swine vesicular disease, Newcastle disease (ND), rinderpest, peste des petits ruminants, vesicular stomatitis, blue tongue, African horse sickness, viral equine encephalomyelitis, Teschen disease, avian influenza, sheep and goat pox,

Table 17 EU Directives (titles, main points and comments) on controls and food hygiene rules

Directive – Title	Main points	Comments
EU 85/591/EEC (entry into force 23 December 1987) Introduction of Community methods of sampling and analysis for the monitoring of food-stuffs intended for human consumption	Methods of sampling and analysis must be adopted by the Commission and the Council when necessary Member States may use tested and scientifically valid methods provided that this does not hinder the free movement of products	
EU 89/397/EEC (entry into force 20 June 1991) Official control of food-stuffs	Member States must ensure that the competent authorities have, or have access to, a sufficient number of suitably qualified and experienced staff in such areas as (veterinary) medicine, chemistry, microbiology, food technology, food hygiene and law The authorities responsible for the evaluation of the laboratories must meet the general criteria applicable to the official laboratory accreditation bodies set out in European Standard EN 45003 This Directive shall not apply to metrological control	
EU 93/43/EEC (entry into force 14 December 1995) Hygiene of food-stuffs	This Directive lays down the general rules of hygiene for food-stuffs and the procedures for verification of compliance with these rules The preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling and offering for sale or supply of food-stuffs shall be carried out in a hygienic way Member States will encourage the sectors concerned to draw up guides which will serve as a reference for observing good hygiene practice Enforcement European Standard of the EN 29000 series	
EU 93/99/EEC (entry into force 1 May 1995 and 1 November 1998) Article 3 Additional measures concerning the official control of food-stuffs	Member States shall apply the criteria laid down in European Standard EN 45002 in the laboratories Member States must ensure that the competent authorities have, or have access to, a sufficient number of suitably qualified and experienced staff	
EU 2002/99/EC (entry into force 1 January 2005) Laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption	This Directive lays down the general animal health rules governing all stages of the production and the introduction from third countries of products of animals Member States shall take measures to ensure that food business operators do not cause the spread of diseases transmissible to animals Member States shall ensure that products of animal origin intended for human consumption are subjected to veterinary certification A third country shall appear on lists only if a Community audit of that country has taken place and demonstrates that the competent veterinary authority provides appropriate guarantees as regards compliance with Community legislation	

Table 17 (Continued)

Directive – Title	Main points	Comments
EU 2004/41/EC (entry into force 20 May 2004) Repealing certain directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption	This Directive repeals 16 other Directives	Amendments EU Directive 89/662/EEC (entry into force 31 December 1992) 92/118/EEC (entry into force 30 June 1996) 95/408/EEC (entry into force 31 December 1996) Replacements and repeals of Articles and Annex

Lumpy skin disease, rift valley fever and contagious bovine pleuropneumonia. This Directive applies to live animals (bovine and porcine animals, equidae from third countries, bovine animals from third countries, sheep). However, it should be made clear that this Directive does not apply to live animals (goats, live poultry, domestic rabbits) and products (waste pathogens and hatching eggs). Member States shall ensure that only the animals and products fulfilling the following conditions may be the subject of trade: (a) the animals and products must fulfil the animal health requirements of the Member State of destination, (b) they must come from holdings, centres or organisations which are subject to regular official veterinary checks, (c) they must be identified in accordance with the requirements of Community rules and be registered in such a way that the original or transit holding, centre or organisation can be traced, (d) they must be accompanied by health certificates and/or any other documents for the animals and products, by the rules of the Member State of destination, (e) susceptible animals, or products of susceptible animals, must not originate from holdings, centres or organisations comply with the requirements, (f) where the transport operation involves several places of destination, animals and products must be grouped together in as many consignments as there are places of destination and (g) where animals and products comply with Community rules are intended for export to a third country through the territory of another Member State.

In EU Directive 91/174/EEC (entry into force 1 January 1992), the Member States should ensure that the following shall not be prohibited, restricted or impeded on zootechnical grounds: (i) intra-Community trade in pure-bred breeding animals of the bovine species, (ii) intra-Community trade in the semen and embryos of pure-bred breeding animals of the bovine species, (iii) the establishment of herd-books, provided that they comply with the requirements laid down to the Directive, (iv) the recognition of organisations or associations which maintain herd-books and (v) intra-Community trade in bulls used for artificial insemination. The following shall be determined in accordance with this Directive: (i) performance monitoring methods and methods for assessing cattle's genetic value, (ii) the criteria governing the recognition of breeders' organisations and associations, (iii) the criteria governing the establishment of herd-books, (iv) the criteria governing entry in herd-books and (v) the particulars to be shown on the pedigree certificate.

Furthermore, EU Directive 91/496/EEC (entry into force 1 July 1992) claims that Member States shall ensure that: (a) importers are obliged to give one working day's notice to the veterinary staff of the border inspection post where the animals are to be presented specifying the number, nature and estimated time of arrival of the animals, (b) the animals are conveyed directly under official supervision, where applicable, to a quarantine centre, (c) the animals may not leave such post or centre unless proof has been supplied in the form of the certificate, (d) the customs authority does not

authorise release for free circulation in the territories unless proof has been supplied that the requirements have been fulfilled. Member States shall submit to the Commission the list of border inspection posts responsible for carrying out veterinary checks on animals and shall provide the following information: (a) nature of the border inspection post (port, airport, road checkpoint, rail checkpoint), (b) nature of the animals which could be checked at the border inspection post in question given the equipment and veterinary staff available, indicating any animals that cannot be checked at those border inspection posts and for registered equidae the operating hours of a specially approved border inspection post, (c) staff assigned to veterinary checks, number of official veterinarians and number of specially qualified auxiliary staff or assistants, (d) description of the equipment and premises available for carrying out the documentary check, the physical check, sampling, the general tests and the specific tests ordered by the official veterinarian, (e) capacity of the premises available to house animals where necessary pending the test results, (f) nature of the equipment allowing a rapid exchange of information and (g) volume of trade. Quarantine centres must: (i) be placed under the permanent control and under the responsibility of the official veterinarian, (ii) be located at a distance from holdings or other places where animals are kept which are likely to be infected by contagious diseases and (iii) have an efficient control system so as to ensure adequate surveillance of the animals.

EU Directive 92/65/EEC (entry into force 29 July 1992) claims that diseases which are applied to this Directive are ND, avian influenza, psittacosis, American foulbrood, FMD, brucellosis (*Brucella* spp.), tuberculosis, CSF and ASF. Member States shall take the necessary measures to ensure that: (i) have the animals held examined regularly, (ii) notify the competent authority, (iii) comply with the specific national measures to control a disease which is of particular importance to a given Member State, (iv) place on the market, for the purposes of trade, only animals which show no signs of disease and which come from holdings or areas not subject to any ban on animal health grounds and with respect to animals not accompanied by a health certificate or a commercial document and (v) comply with the require-

ments ensuring the welfare of the animals held. Semen collection centres must: (1) be placed under the supervision of a centre veterinarian, (2) have different and physically separate premises for accommodating and isolating animals, collecting semen, cleaning and disinfecting equipment, processing semen, storing semen, (3) be built or kept separate in such a way as to prevent any contact with animals outside the centre and (4) have premises which are easily cleaned and disinfected.

EU Directive 92/118/EEC (entry into force 4 April 1993) applies to the following products: milk for human consumption, animal casings, hides and skins, pet food containing low-risk materials, bones and bone products, processed animal protein, blood and blood products of animal origin, serum from equidae, rabbit meat and farmed game meat and apiculture products. Member States shall ensure that: (1) trade in and imports of products of animal origin together with gelatins not intended for human consumption are not prohibited or restricted for animal health or public health reasons other than those arising from the application of this Directive or from Community legislation and in particular any safeguard measures taken, (2) any new product of animal origin whose placing on the market in a Member State checks the possibility of having disease or a risk to human health and (3) the other products of animal origin may not be the subject of trade or importation from third countries unless they meet the requirements of this Directive. Under the procedure provided: (a) specific requirements shall be established – in particular for the protection of the Community from certain exotic diseases or diseases transmissible to man – or guarantees equivalent to those conditions, (b) a Community list shall be drawn up of third-country establishments which satisfy the requirements of this Directive, (c) the nature of any treatment or the measures to be taken to avoid recontamination of animal casings, eggs and egg products shall be established. The decisions provided for in the Directive must be taken on the basis of evaluation and, if appropriate, the opinion of the Scientific Veterinary Committee, of the real risk of the spread of serious transmissible diseases or of diseases transmissible to man which could result from movement of the product, not only for the species from which the product originates but also for other species which

could carry the disease or become a focus of disease or a risk to public health. Experts from the Commission and the Member States shall carry out on-the-spot inspections to verify whether the guarantees given by the third country regarding the conditions of production and placing on the market can be considered equivalent to those applied in the Community. The Commission, acting on proposals from the Member States, shall appoint the experts from the Member States responsible for these inspections. These inspections shall be made on behalf of the Community, which shall bear the cost of any expenditure involved.

EU Directive 96/23/EEC (entry into force 23 May 1996) is primarily focused on residues of therapeutic substances. For the purposes of this Directive, *residue* shall mean a residue of substances having a pharmacological action, of their metabolites and of other substances transmitted to animal products and likely to be harmful to human health, *official sample* shall mean a sample taken by the competent authority which bears a reference to the species, the type, the quantity concerned, the method of collection and particulars identifying the sex of the animal and the origin of the animal or of the animal product. Monitoring plan for the detection of residues or substances shall: (a) provide for detection of groups of residues or substances according to type of animal, (b) specify in particular the measures for detection of the presence of residues of the aforementioned substances in live animals, their excrement and body fluids and in animal tissues and products such as meat, milk, eggs and honey and (c) comply with the sampling rules and levels laid down in the Directive. The laboratories shall be responsible for: (a) coordinating the work of the other national laboratories responsible for residue analysis, in particular by coordinating the standards and methods of analysis for each residue or residue group concerned, (b) assisting the competent authority in organising the plan for monitoring residues, (c) periodically organising comparative tests for each residue or residue group assigned to them, (d) ensuring that national laboratories observe the limits laid down, (e) disseminating information supplied by Community reference laboratories and (f) ensuring that their staff are able to take part in further training

courses organised by the Commission or by Commission reference laboratories.

According to EU Directive 97/78/EEC (entry into force 19 February 1998), the official veterinarian shall carry out the following checks: (a) an identity check on each consignment to ascertain that the products correspond to the information given in the accompanying certificates or documents (i) where products of animal origin arrive in containers, verification that the seals fixed by the official veterinarian, are intact and that the information appearing thereon corresponds to that given in the accompanying document or certificate, (ii) in other cases, for all types of product, a check that the stamps, official marks and health marks identifying the country and establishment of origin are present and conform to those on the certificate or document and in addition, for wrapped or packaged products, a check on the specific labelling provided for in veterinary legislation), (b) a physical check on each consignment (in order to ascertain that the products satisfy the requirements of Community legislation and are in a fit state to be used for the purpose specified in the accompanying certificate or document). Border inspection posts must: (a) be located in the immediate vicinity of the point of entry into an area which is designated by the customs authorities, (b) be placed under the authority of an official veterinarian, who shall be effectively responsible for the checks. The official veterinarian may be assisted by specially trained auxiliary staff. Products which are to be monitored pursuant to Community legislation from the border inspection post of arrival to the establishment at the place of destination shall be forwarded under the following conditions: (i) the consignments in question shall be dispatched from the border inspection post of arrival to the establishment at the place of destination under the supervision of the competent authority in leak-proof vehicles or containers sealed by the competent authorities, (ii) the official veterinarian at the border inspection post concerned shall inform the veterinary authority in charge of the establishment at the place of destination of the consignment of the place of origin and the place of destination of the product via the ANIMO network, (iii) the products shall undergo, in the establishment at the place of destination, the treatment defined in the relevant

Community legislation, (iv) the official veterinarian responsible for an intermediate warehouse, shall be informed by the management of the establishment of destination or of the intermediate warehouse of the arrival of the product at its destination, and shall within 15 days notify the official veterinarian at the border inspection post who notified him of the shipment. Before submitting a proposal for granting such derogations in respect of products from a given third country, the Commission shall submit a report to the Standing Veterinary Committee of that third country taking account the following: (a) the guarantees offered by the third country in question for all or part of its territory with respect to compliance with Community requirements, including those for residue checks, (b) the health situation of animals in the third country concerned, (c) information on the general health situation in the country, (d) nature of the measures applied by the third country for monitoring and combating disease, (e) structures, skills, independence and qualifications of the veterinary service or other competent services, (f) compliance with the minimum standards laid down by Community law with regard to production hygiene, (g) type of product or products and its/their potential health risk, (h) outcome of the Community inspection or national inspection visits, (i) outcome of the import checks carried out and (j) an analysis of the risk involved owing to the nature of the products to be imported, their presentation or mode of transport used.

Some representative points and comments (repeals, amendments) of the EU Directives with regard to imports from third countries and intra-Community trade (general provisions) are given in Table 18.

Production and placing on the market: meat

In EU Directive 91/495/EEC (entry into force 1 January 1993), the Member States may authorise: (a) the direct supply of rabbit meat by a small producer to a private individual for his own consumption, (b) the supply of fresh rabbit meat in small quantities, by farmers who produce rabbits on a small scale either directly to the final consumer at those local markets which are closest to their farms or to a retailer with a view to direct sale to the final consumer, provided that such

retailer conducts his business in the same locality as that of the producer or in a neighbouring locality. The said possible derogation shall not include itinerant sales, mail order sales and, as far as the retailer is concerned, sales on a market. The official service may authorise the slaughter of farmed game in the place of origin, where it cannot be transported, in order to avoid any risk for the handler or to protect the welfare of the animals. This authorisation may be granted provided that: (i) the herd undergoes regular veterinary inspection and is not under any restrictions, (ii) a request is submitted by the owner of the animals, (iii) the official service is informed in advance of the date of slaughtering of the animals, (iv) the holding has a centre for mustering wild animals where an ante-mortem inspection of the group for slaughter can be carried out, (v) the holding has premises suitable for the slaughter, sticking and bleeding of the animals, (vi) slaughter by means of sticking and bleeding is preceded by stunning, which must be carried out in the conditions laid down in this Directive, (vii) the slaughtered and bled animals are hung as quickly as possible after slaughter and are transported under satisfactory hygiene conditions to a slaughterhouse, it must be transported in a container or means of transport in which the ambient temperature is maintained at between 0 and 4 °C. Evisceration must be carried out no later than 3 h after stunning and (viii) during transportation to the slaughterhouse the slaughtered animals are accompanied by a certificate issued by the veterinary service attesting to the favourable outcome of the ante-mortem inspection, the correct conduct of bleeding and the time of slaughter. Rabbits shall be declared totally unfit for human consumption where the post-mortem inspection reveals the following: (i) diseases transmissible to man or animals, (ii) malignant or multiple tumours, multiple abscesses, (iii) extensive parasitic infestation in the subcutaneous or muscle tissues, (iv) presence of residues of forbidden substances or residues in excess of permitted Community levels, including substances with a pharmacological effect, (v) poisoning, (vi) extensive injuries or extensive blood or serum imbibition, (vi) anomalies as regards colour, smell or taste and (vii) anomalies as regards consistency, particularly oedema, or severe emaciation.

Table 18 EU Directives (main points and comments) related to imports from third countries and intra-Community trade: general provisions

Directive – Title	Main points	Comments
EU 89/662/EEC (entry into force 22 December 1989) Veterinary checks in intra-Community trade with a view to the completion of the internal market	The Directive laid down detailed rules governing veterinary checks on animals entering the Community from third countries Member States shall ensure that the products intended for trade have been obtained, checked, marked and labelled in accordance with Community rules A documentary check by the competent authorities must be carried out for each consignment of animals from third countries If a serious animal health reason warrants, the Commission may prohibit or apply special conditions to imports of animals originating directly or indirectly in the third country concerned	Amendments EU Directive 91/496/EEC (entry into force 24 September 1991) EU Directive 92/67/EEC (entry into force 14 September 1992) EU Directive 92/118/EEC (entry into force 4 April 1993) Laying down the principles governing the organisation of veterinary checks on animals entering the Community from third countries
EU 90/425/EEC (entry into force 26 July 1990) Veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market	This Directive affected neither checks on the welfare of animals during transport nor checks carried out as part of tasks conducted in a non-discriminatory manner by authorities Checks at origin Checks on arrival at destination If a serious animal health reason warrants, the Commission may prohibit or apply special conditions to imports of animals originating directly or indirectly in the third country concerned	Amendments – EU Directive 90/539/EEC (entry into force 1 January 1992) 90/675/EEC (entry into force 31 December 91) 91/67/EEC (entry into force 1 January 1993) 91/174/EEC (entry into force 1 January 1992) 91/496/EEC (entry into force 1 January 1992) 91/628/EEC (entry into force 1 January 1993) 92/60/EEC (entry into force 1 July 1992) 92/65/EEC (entry into force 1 January 1994) 92/102/EEC (entry into force 1 January 1994 for porcine animals and 1 January 1995 for ovine and caprine animals) 92/118/EEC (entry into force 1 January 1994) 2002/33/EC (entry into force 19 November 2002)
EU 91/174/EEC (entry into force 1 January 1992) Laying down zootechnical and pedigree requirements for the marketing of pure-bred animals	The Directive applies to the marketing of pure-bred animals and their semen, ova and embryos, other than those of bovine, porcine, ovine, caprine and equine species Member States must ensure that intra-Community trade in pure-bred animals and their semen, ova or embryos may not be prohibited, restricted or impeded on zootechnical or pedigree grounds Definitions (veterinary check, etc.)	Replacement of Articles and Annexes
EU 91/496/EEC (entry into force 1 July 1992) Laying down the principles governing the organisation of veterinary checks on animals entering the Community from third countries	Veterinary checks in respect of animals from third countries entering the Community shall be carried out by the Member States Organisation and effects of checks Requirements for the transportation of animals from one third country to another If the animals do not satisfy the requirements laid down in the Community rules, the competent authority may order their placement in quarantine, their re-exportation or their slaughter Veterinary experts from the Commission shall check that the inspection posts and quarantine centres satisfy the conditions for approval	Repealing EU Directive 72/462/EEC Amending EU Directive 96/43/EC (entry into force 1 July 1996) Addition in the Annex of this Directive

Table 18 (Continued)

Directive – Title	Main points	Comments
EU 92/65/EEC (entry into force 29 July 1992) Laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules	The Directive laid down the animal health requirements for the placing on the market in the European Union (EU) of animals and products of animal origin Definitions (trade, animals, approved body, institute or centre, etc.) Laying down the animal health requirements applicable to trade in ruminants, bees, lagomorphs, foxes, cats and dogs Laying down the animal health requirements applicable to trade in semen, ova and embryos of certain animals like equidae, sheep and goats	Amendments Regulation (EC) No. 998/2003 (entry into force 3 July 2003) EU Directive 2004/68/EC (entry into force 20 May 2004) Changes in the lists of Annexes of compulsorily notifiable diseases
EU 92/118/EEC (entry into force 4 April 1993) Laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules	The Directive covers certain products of animal origin, in particular animal casings intended for human consumption and processed animal proteins intended for human consumption Trade in or imports of any new product of animal origin must be authorised by the Council, following assessment by the Commission and an opinion from the European Food Safety Authority Specific conditions may be imposed, especially in order to protect the EU from certain exotic diseases and diseases transmissible to man	Amendments – EU Directive 94/466/EC (entry into force 1 December 94) 94/723/EC (entry into force 1 December 1994) 95 January EC (entry into force 21 January 1995) 95/338/EC (entry into force 30 September 1995) 95/339/EC (entry into force 30 September 1995) 96/103/EC (entry into force 20 September 1996) 96/340/EC (entry into force 1 July 1997) 96/90/EC (entry into force 16 January 1997) 96/405/EC (entry into force 19 June 1997) 1999/724/EC (entry into force 1 June 2000) 2000/7/EC (entry into force 1 January 2001) 2003/721/EC (entry into force 1 January 2004) Additions and replacements of Articles and Annexes
EU 96/23/EEC (entry into force 23 May 1996) Measures to monitor certain substances and residues thereof in live animals and animal products	The substances to be monitored are divided into two groups: substances having anabolic effect and unauthorised substances on the one hand and veterinary drugs and contaminants on the other Definitions (official sample, approved laboratory and residue) Monitoring plans for the detection of residues or substances Official control measures	Repeals EU Directive 85/358/EEC EU Directive 86/469/EEC EU Directive 89/187/EEC EU Directive 91/664/EEC These are repealed from 1 July 1997
EU 97/78/EEC (entry into force 19 February 1998) Laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries	This proposal applies to products from third countries Definitions (products, documentary check, import, etc.) A documentary check by the veterinary staff of the border inspection post or by the competent authorities must be carried out on each consignment of products from third countries The Directive defines the conditions governing the transportation of products from one third country to another Veterinary experts from the Commission verify that the border inspection posts satisfy the approval requirements	Amendment EU Directive 1999/67/EC (entry into force 18 November 1999) Correction in the definitions and changes in the Articles

EU Directive 92/45/EEC (entry into force 4 October 1992) specifies that Member States shall ensure that wild game meat: (a) comes from wild game which: (i) has been killed in a hunting area by means authorised under national legislation governing hunting and (ii) immediately after killing has been prepared and transported within a maximum of 12 h to a processing house. The official veterinarian must ensure that wild game meat is excluded from human consumption: (i) if it is found to contain defects or if it has been seized in accordance with this Directive, (ii) if the checks have revealed the presence of a disease communicable to man, (iii) if it comes from animals which have ingested substances which are likely to make the meat dangerous or harmful to human health and on which a decision has been taken and (iv) if, without prejudice to any Community legislation applicable to ionisation, it has been treated with ionising or ultra-violet radiation or by means of substances likely to affect its organoleptic properties or using colourings other than those used for health marking. Hygiene in respect of the preparation of wild game and the cutting and handling of wild game meat which must undergo the following operations immediately after killing: (i) large wild game must be drawn and eviscerated, (ii) the thoracic viscera, even if detached from the carcass, and the liver and the spleen, must accompany the game and be identified in such a way that the official veterinarian can carry out the post-mortem inspection of the viscera in conjunction with the rest of the carcass, the other abdominal viscera must be removed and inspected on the spot. The head may be removed as a trophy, (iii) small wild game meat may be totally or partially eviscerated on the spot or in a processing house where the game is transported to the said house at an ambient temperature not exceeding 4 °C within 12 h of being killed. Wild game meat must be chilled immediately after the operations so that the internal temperature is +7 °C or lower in the case of large game meat or +4 °C or lower in the case of small game meat. If the external temperature is not sufficiently low, killed game meat must be moved as soon as possible, and in any event not more than 12 h after being killed, to a wild game-processing house or to a collection centre. Evisceration must be carried out without undue delay upon arrival at the wild game-processing house, if

it has not been carried out on the spot. The lungs, heart, liver, kidney, spleen and mediastinum may either be detached or left attached to the carcass by their natural connections. Until the inspection has been completed, it must not be possible for carcasses and offal not inspected to come into contact with carcasses and offal already inspected, and the removal, cutting, or further treatment of the carcass shall be forbidden. It must not be possible for meat detained or declared unfit for human consumption, stomachs, intestines and inedible by-products to come into contact with meat declared fit for human consumption, and the former must be placed as soon as possible in special rooms or containers located and laid out in such a way as to avoid any contamination of other meat. The dressing, handling, further treatment and transport of meat, including offal, must be performed in compliance with all hygiene requirements. Packaged meat must be stored in a separate room from exposed meat. The competent authorities shall lay down specific rules applicable to inspection of trophies to be kept by the hunter. Supervision by the official veterinarian as regards health control of cut wild game meat and stored wild game meat must include the following tasks: (i) supervision of the entry and exit of meat, (ii) health inspection of meat held in processing houses, (iii) health inspection of meat prior to cutting and when it leaves the processing houses referred to in the second indent, (iv) supervision of the cleanliness of the premises, facilities and instruments and of staff hygiene, including their clothing and (v) any other supervision which the official veterinarian considers necessary for ensuring compliance with this Directive.

According to EU Directive 94/65/EEC (entry into force 1 January 1996), minced meat must meet the following requirements: (a) the fresh meat from which it is obtained must: (i) where it has been frozen or deep-frozen, be obtained from fresh boned meat which has been stored for no longer than 18 months for beef and veal, 12 months for sheep meat and 6 months for pig meat, after freezing or deep-freezing, in a cold store. However, the competent authority may authorise the boning of pig meat and sheep meat on the spot immediately before mincing where this operation is carried out in satisfactory conditions of hygiene and quality, (ii) where it has been

chilled, be used within no more than 6 days after slaughter of the animals or within no more than 15 days after slaughter of the animals in the case of boned, vacuum-packed beef and veal, (b) the minced meat must have undergone cold treatment within a period of not more than 1 h after portioning and wrapping, except where processes requiring the lowering of the internal temperature of the meat during production are used, (c) the minced meat must be packaged and presented in one of the following forms: (i) chilled and in this case obtained from meat and cooled to an internal temperature below $+2^{\circ}\text{C}$ in the shortest time possible, (ii) deep-frozen and in this case obtained from meat and cooled to an internal temperature below -18°C as quickly as possible, (d) the minced meat must not have been subjected to ionising radiation or ultraviolet treatment and (e) possibly combined with the name of the species of animal from which the meat was obtained, may be used on packages only if the requirements are met for those designations. Production plants must have at least: (a) a room for mincing and wrapping separate from the cutting room and equipped with a recording thermometer or recording telethermometer, (b) a room for packaging, (c) a room or cabinets for storing salt and (d) refrigeration equipment enabling the temperatures. Conditions for the production of minced meat: (1) meat must be examined before mincing or cutting up, in accordance with Article 7. All soiled and suspect parts shall be removed and condemned before the meat is minced. (2) minced meat may not be obtained from scrap cuttings, scrap trimmings or from mechanically recovered meat, (3) minced meat may be deep-frozen only once, (4) immediately after production the minced meat must be hygienically wrapped and, after packaging, be cooled to and stored at certain temperatures.

The titles, main points and comments of the EU Directives about production and placing on the market (meat) are summarised in Table 19.

Specific provisions: bovine and porcine animals

EU Directive 64/432/EEC (entry into force 30 June 1964) makes clear that for the purposes of this Directive, *animal for slaughter* means a bovine animal or swine intended to be taken on arrival in the country of destination directly to a slaughterhouse or to a market adjoining a slaughterhouse

under whose rules all animals may be removed, in particular after the market, only to a slaughterhouse approved for this purpose by the competent central authority. In the latter case, the animals must be slaughtered at that slaughterhouse not later than 72 h after arriving at the market and *animals for breeding or production* means bovine animals and swine other than those referred to in (b), including those intended for breeding, milk or meat production, or draft purposes. Bovine animals and swine covered by this Directive must: (a) show no clinical sign of disease on the day of loading, (b) have been obtained from a holding which officially fulfils the following conditions: (i) it shall be situated in the centre of an epizootic-free area, (ii) it shall, for at least 3 months prior to consignment, have been free from FMD and bovine brucellosis in the case of bovine animals and from FMD, bovine and porcine brucellosis, swine fever and contagious porcine paralysis (Teschen disease) in the case of swine, (iii) it shall, for at least 30 days prior to consignment, have been free from all other compulsorily notifiable diseases which are contagious or infectious for the animal species in question, (c) in the case of animals for breeding and production, the official veterinarian may certify that the animals have remained on the holding during the 30 days preceding loading and placed under official veterinary supervision, it being thus possible to certify that they belong to the holding, (d) be identified by an official or officially approved earmark or, in the case of swine, by a permanent identification stamp, (e) be sent direct from the holding to the actual place of loading: (i) without coming into contact with cloven-hoofed animals other than bovine animals and swine which fulfil the conditions laid down for intra-Community trade, (ii) segregated into animals for breeding or production and animals for slaughter, (iii) in transport vehicles or containers which have first been cleansed and disinfected with a disinfectant officially authorised in the exporting country, (f) be loaded for transportation to the country of destination at a specific place at the centre of an epizootic-free area, (g) after loading be sent directly and as quickly as possible to the frontier post of the exporting country and (h) be accompanied during transportation to the country of destination by a health certificate which shall be

Table 19 EU Directives (titles, main points and comments) for production and placing on the market: meat

Directive – Title	Main points	Comments
EU 91/495/EEC (entry into force 1 January 1993) Public health and animal health problems affecting the production and placing on the market of rabbit meat and farmed game meat	Laying down requirements concerning public health and animal health problems affecting the production and placing on the market of rabbit meat and farmed game meat Definitions (rabbit meat, farmed game meat, etc.) Rules applicable to the production and placing on the market of rabbit meat Rules applicable to the production and marketing of farmed game meat Slaughtering, cutting and processing establishments must be approved by the Member States	Amendment EU Directive 94/65/EEC (entry into force 1 January 1996) Addition in the Annex
EU 92/45/EEC (entry into force 4 October 1992) Public health and animal health problems relating to the killing of wild game and the placing on the market of wild game meat	Laying down public health and animal health rules applicable to the killing of wild game and to the preparation and placing on the market of wild game meat This Directive shall not apply to small numbers of wild game Definitions (wild game, large wild game, wild game meat, collection centre, etc.) Provisions applicable to Community production and trade of wild game meat	Amendment EU Directive 92/116/EEC (entry into force 4 April 1993) Replacement and correction of the Articles and Annexes
EU 94/65/EEC (entry into force 1 January 1996) Laying down the requirements for the production and placing on the market of minced meat and meat preparations	Laying down rules for the production, placing on the market in the Union and importing of meat preparations and minced meat This Directive shall not apply to meat preparations and minced meat which are produced in retail shops This Directive shall not apply to mechanically recovered meat for industrial use Placing on the market of minced meat Placing on the market of meat preparations	Repeal EU Directive 88/657/EEC from 1 January 1996

drawn up on the day of loading, in the language of the country of destination at least, and be valid for 10 days. Bovine animals for slaughter, if over 4 months old, must in addition: (a) have been vaccinated not less than 15 days and not more than 4 months before loading against types A, O and C of the FMD virus, using an inactivated virus vaccine approved and controlled by the competent authority of the exporting country. However, the period of validity of the vaccination shall be extended to 12 months in the case of bovine animals revaccinated in Member States where such animals are vaccinated annually and where they are systematically slaughtered when they contract FMD, (b) if they do not come from an officially tuberculosis-free bovine herd, have reacted negatively to an intradermal tuberculin test, (c) if they do not come from an officially

brucellosis-free bovine herd nor from a brucellosis-free bovine herd have shown a brucella count lower than 30 IU of agglutination per millilitre when given a sero-agglutination test complying with the provisions of the Directive.

EU Directive 72/462/EEC (entry into force 1 January 1976) is applicable to importations from third countries of (i) domestic bovine animals and swine for breeding, production or slaughter and (ii) fresh meat of domestic animals of the following species: bovine animals, swine, sheep and goats, and solipeds. However, it shall not apply to: (a) animals intended exclusively for grazing or draft purposes, on a temporary basis, in the vicinity of the Community frontiers, (b) meat forming part of travellers' personal luggage and intended for their personal consumption, insofar as the amount or quantity transported does not exceed 1 kg per

person and provided that the meat comes from a third country or part of a third country, (c) meat sent as small packages to private persons provided that such meat is not imported by way of trade, insofar as the quantity sent does not exceed 1 kg and provided that the meat comes from a third country or part of a third country and (d) meat for consumption by the crew and passengers on means of transport using international routes. The Member States shall only authorise the importation of the animals referred to in this Directive if they come from non-Member States: (a) free from any disease to which the animals are susceptible (i) for 12 months, in respect of cattle plague exotic FMD, contagious pleuro-pneumonia, ASF and contagious porcine paralysis (Teschen disease), or (ii) for 6 months, in respect of blue tongue disease and contagious vesiculate stomatitis), (b) which have not been vaccinated during the preceding 12 months against the diseases to which animals are susceptible. The Member States shall authorise the importation of bovine animals and swine only on production of a certificate drawn up by an official veterinarian of the exporting non-Member State. This certificate must: (a) be issued on the day of loading of the animals for consignment to the country of destination, (b) be worded at least in one of the official languages of the country of destination and in one of the official languages of the country carrying out the import inspection, (c) the original of this certificate must accompany the animals, (d) provide proof that the bovine animals and swine meet the conditions laid down in this Directive and those laid down in pursuance thereof with regard to imports from third countries, (e) consist of one single sheet of paper and (f) be made out in the name of one single addressee. The Member States shall prohibit the importation of: (a) fresh meat from boars or cryptorchid pigs, (b) fresh meat containing residues of oestrogenous or thyrostatic substances, antibiotics, antimony, arsenic, pesticides or other substances which are harmful or likely to make the consumption of fresh meat dangerous or harmful to human health insofar as these residues are in excess of the permitted level, (c) fresh meat treated with ionising or ultraviolet rays, and also fresh meat from animals which have been treated with tenderisers or other products likely to alter their organoleptic composition or nature, (d) fresh meat to which

have been added substances for the purpose of public health stamping, (e) fresh meat from animals which have been found to have tuberculosis in any form whatsoever and which were certified as having tuberculosis following a positive tuberculin reaction, (f) fresh meat from animals which after slaughter are found to have tuberculosis in any form whatsoever, or to be carrying several cysticerci live or dead, or in the case of swine, to be carrying threadworms, (g) fresh meat from animals slaughtered too young, (h) parts of the carcass or offal with traumatic lesions incurred shortly before slaughter, (i) blood, (j) fresh meat minced or treated in a similar fashion and (k) fragments of muscular or fatty tissue and other tissues resulting from the cutting and boning of the meat or adhering to the bone and fragments of muscular and other tissues of the head, except the tongue.

Following EU Directive 77/96/EEC (entry into force 1 January 1979), fresh meat originating in third countries which contains skeletal muscles shall be examined under the supervision and responsibility of an official veterinarian in order to be admitted to intra-Community trade. The examination shall take place in a slaughterhouse approved in the exporting country. The examination shall take place before the health marking. If it is not possible to carry out the examination in the exporting country, the Member State for which the fresh meat is intended may authorise its importation provided that the examination is carried out within its territory at the time of the public health inspection. The authorisation for a slaughterhouse to carry out the examination and of a cutting plant to cut up bone meat which has undergone such examination, or the authorisation for an establishment to carry out the freezing treatment. The Member States shall draw up and communicate to the Commission the list of the inspection posts at which the examination and the freezing may be carried out. They shall ensure that these posts have the equipment necessary for carrying out the operations in question.

EU Directive 77/504/EEC (entry into force 1 January 1979) specifies that the Member States shall ensure that the following shall not be prohibited, restricted or impeded on zootechnical grounds: (i) intra-Community trade in pure-bred breeding animals of the bovine species, (ii) intra-

Community trade in the semen and embryos of pure-bred breeding animals of the bovine species, (iii) the establishment of herd-books, provided that they comply with the requirements of the Directive, (iv) the recognition of organisations or associations which maintain herd-books and (v) intra-Community trade in bulls used for artificial insemination. The following shall be determined in accordance with the procedure laid down in this Directive: (i) performance monitoring methods and methods for assessing the genetic value of cattle, (ii) the criteria governing the recognition of breeders' organisations and associations, (iii) the criteria governing the establishment of herd-books, (iv) the criteria governing entry in herd-books and (v) the particulars to be shown on the pedigree certificate. Until the entry into force of the provisions provided for in the first, second and third indents of the Directive: (a) the official checks referred to in the first indent of Directive carried out in each Member State and the herd-books in existence at present shall be recognised by other Member States, (b) the recognition of breeders' organisations and associations shall continue to be governed by the rules at present in force in each Member State, (c) the introduction of new herd-books shall continue to meet the conditions at present in force in each Member State. Until the implementation of Community rules on the subject, the conditions applicable to imports of pure-bred breeding animals of the bovine species from non-member countries must not be more favourable than those governing intra-Community trade. Member States shall not authorise the import of pure-bred breeding animals of the bovine species from non-member countries unless they are accompanied by a pedigree certificate certifying that they are entered or registered in a herd-book in the exporting non-member country. Proof must be provided that the animals are either entered or registered and eligible for entry in a herd-book in the Community.

In EU Directive 88/407/EEC (entry into force 1 January 1990), the Member States shall, until 31 December 1992, authorise the admission of semen from bulls giving a negative reaction to the serum neutralisation test or the enzyme-linked immunosorbent assay (ELISA) test for infectious bovine rhino-tracheitis/infectious pustular vulvo-vaginitis

or showing a positive result after vaccination in accordance with this Directive. Member States may, until 31 December 1992, authorise the admission of semen of bulls giving a positive reaction to the serum neutralisation test or the ELISA test for infectious bovine rhino-tracheitis/infectious pustular vulvo-vaginitis and not having been vaccinated in accordance with this Directive. In that case, each consignment must pass an examination by inoculation into a live animal and/or a virus isolation test. This requirement shall not apply in respect of the semen of animals, which, prior to their first vaccination at the insemination centre, reacted negatively to the tests. Member States shall make the admission of semen conditional upon submission of an animal health certificate drawn up by an official veterinarian of the Member State of collection. This certificate must: (a) be drawn up in at least one of the official languages of the Member State of collection and one of those of the Member State of destination, (b) accompany the consignment to its destination in its original form, (c) be drawn up on a single sheet of paper and (d) be made out to a single consignee. A semen collection centre may appear on the list provided for in this Directive only if: (a) it is situated in one of the countries on the list, (b) it fulfils the requirements, (c) it has been officially approved for exports to the Community by the veterinary services of the third country concerned, (d) it is under the supervision of a centre veterinarian of the third country concerned and (e) it is subject to regular inspection by an official veterinarian of the third country concerned at least twice a year. Consideration shall be given to: (a) the health situation in the area surrounding the semen collection centre, with particular reference to the diseases appearing on list A of the International Office of Epizootic Diseases, (b) the state of health of the herd in the semen collection centre, including testing requirements, (c) the state of health of the donor animal and testing requirements and (d) testing requirements in relation to semen. Semen collection centres must: (a) be placed under the permanent supervision of a centre veterinarian, (b) have at least animal housing including isolation facilities such as semen collection facilities including a separate room for the cleaning and disinfection or sterilisation of equipment, a semen processing room which need

not necessarily be on the same site and a semen storage room which need not necessarily be on the same site, (c) be so constructed or isolated that contact with livestock outside is prevented, (d) be so constructed that the animal housing and the semen collecting, processing and storage facilities can be readily cleaned and disinfected, (e) have isolation accommodation which shall have no direct communication with the normal animal accommodation and (f) be so designed that the animal accommodation is physically separated from the semen processing room and both are separated from the semen storage room.

According to the EU Directive 88/661/EEC (entry into force 1 January 1991), Member States may not prohibit, restrict or impede on zootechnical grounds: (i) intra-Community trade in pure-bred breeding pigs or in their semen, ova and embryos, (ii) the establishment of herd-books and (iii) the official approval of breeders' associations or breeding organisations, which establish or maintain herd-book. The following shall be determined in accordance with the rules: (i) methods for monitoring performance and assessing the genetic value of pure-bred breeding pigs, (ii) the criteria governing the establishment of herd-books, (iii) the criteria governing entry in herd-books, (iv) the criteria for approval and supervision of breeders' associations and/or breeding organisations which establish or maintain herd-books and (v) the certificate. The following shall be determined in accordance with the procedure laid down in this Directive: (a) methods for monitoring performance and assessing the genetic value of pure-bred breeding pigs, (b) the criteria governing the establishment of herd-books, (c) the criteria governing entry in herd-books, (d) the criteria for approval and supervision of breeders' associations and/or breeding organisations which establish or maintain herd-books and (e) the certificate. Member States may not prohibit, restrict or impede on zootechnical grounds: (i) intra-Community trade in hybrid breeding pigs or the semen, ova and embryos of such animals, (ii) the establishment of registers, provided that they meet the conditions laid down pursuant to Directive, (iii) the official approval of breeders' associations and/or breeding organisations and/or private undertakings which establish or maintain registers.

EU Directive 89/556/EEC (entry into force 1 January 1991) defines the animal health conditions governing intra-Community trade in and importation from third countries of fresh and frozen embryos of domestic animals of the bovine species. This Directive shall not apply to embryos resulting from *in vitro* fertilisation nor to embryos subjected to sexing, splitting (twinning), cloning or any manipulation which interferes with the integrity of the 'zona pellucida'. Each Member State shall ensure that embryos shall not be sent from its territory to that of another Member State unless they meet the following conditions: (a) they must have been conceived as a result of artificial insemination with semen from a donor sire standing at a semen collection centre, (b) they must have been collected from domestic animals of the bovine species whose health status complies with this Directive, (c) they must have been collected, processed and stored by an embryo collection team and (f) they must be accompanied, during transport to the Member State of destination, by an animal health certificate. Importation of embryos from the territory of a third country or part shall take place only if the embryos: (a) come from donor animals which, immediately prior to the collection of their embryos, have remained for at least 6 months in the territory of the third country concerned, and in a maximum of two herds complying with at least the requirements, (b) comply with the animal health requirements imports of embryos from that country. Consideration shall be given to: (a) the health situation in the area surrounding the place of embryo collection, with particular reference to the diseases appearing on list of the International Office of Epizootic Diseases, (b) the state of health of the herd concerned in the embryo collection, including testing requirements, (c) the state of health of the donor animal and testing requirements and (d) collecting, processing and storing requirements in relation to embryos. If a contagious animal disease which can be carried by embryos breaks out or spreads or if any other reason connected with animal health which might endanger the health of the livestock in a Member State so justify and where: (i) the territory of a Member State is concerned, the safeguard measures are

laid down and (ii) all or part of the territory of a third country is concerned, the Member State of destination shall prohibit the importation of those embryos whether imported directly or indirectly through another Member State, either from the whole of the third country or from part only of its territory.

EU Directive 90/429/EEC (entry into force 31 December 1991) claims that it contains the conditions for the approval of semen collection centres and the conditions relating to the supervision of semen collection centres, the conditions governing the admission of animals to approved semen collection centres and the compulsory routine tests for boars kept at approved semen collection centres, the conditions which semen collected at approved centres must satisfy for the purposes of intra-Community trade. Intra-Community trade in semen requires compliance with regulations concerning collection, processing, storage and transport as well as provisions on protection against the spread of Aujeszky's disease. The Directive lays down that each Member State shall send the list of semen collection centres and their veterinary registration numbers to other Member States and to the Commission. It also lays down that each consignment of semen must be accompanied by an animal health certificate drawn up by an official veterinarian of the Member State of collection. Imports of porcine semen may only be made from those third countries on the list of semen collection centres. Member States shall authorise the import of semen only on submission of an animal health certificate drawn up and signed by an official veterinarian of the third country of collection. The semen must fulfil the animal health requirements adopted for imports of semen from those countries.

According to Decision 1999/879/EC (entry into force 1 January 2000), Member States shall ensure that the placing on the market of bovine somatotrophin on Community territory or within their jurisdiction for the purpose of its marketing and administration thereof to dairy cows by any means whatsoever shall be prohibited. Undertakings buying or producing bovine somatotrophin substances and undertakings authorised in any capacity to market such substances shall be required to keep registers detailing, in chronological order, quantities produced or acquired and those sold or

used for purposes other than placing on the market and the names of the persons to whom such quantities were sold or from whom they were purchased. The above information must be made available to the competent authority at its request and, in the case of computerised records, in the form of a printout. The prohibition shall not affect the production of bovine somatotrophin in the Member States, or imports, for the purposes of its export to third countries.

All EU Directives with regard to specific provisions (bovine and porcine animals) are given in Table 20.

Specific provisions: ovine and caprine animals

EU Directive 72/462/EEC (entry into force 1 January 1976) claims that it shall apply to imports from third countries of domestic bovine animals and swine for breeding, production or slaughter and fresh meat of domestic animals of the following species: bovine animals, swine, sheep and goats, and solipeds. This Directive shall not apply to: (a) animals intended exclusively for grazing or draft purposes, on a temporary basis, in the vicinity of the Community frontiers, (b) meat forming part of travellers' personal luggage and intended for their personal consumption, insofar as the amount or quantity transported does not exceed 1 kg per person and (c) meat for consumption by the crew and passengers on means of transport using international routes. In deciding whether a slaughterhouse, a cutting plant or a cold store situated outside a slaughterhouse or plant may appear on one of the lists referred to Directive shall be taken of: (a) the guarantees which the third country can offer with regard to compliance with the provisions of this Directive, (b) the third country's regulations with regard to administering to animals for slaughter any substances which might affect the wholesomeness of the meat, (c) compliance in each particular case with the provisions of this Directive and (d) the organisation of the meat inspection services of the third country or part of the country, the powers of these services and the supervision to which they are subject. The Member States shall authorise the importation of bovine animals and swine if, before the day of loading for transportation to the country of destination, these animals have remained in the territory or part of the territory of a

Table 20 EU Directives (main points and comments) dealing with specific provisions: bovine and porcine animals

Directive – Title	Main points	Comments
EU 64/432/EEC (entry into force 30 June 1964) Animal health problems affecting intra-Community trade in bovine animals and swine	The Directive applies to intra-Community trade in bovine animals or swine for breeding, production or slaughter Definitions (animal for slaughter, animals for breeding or production, brucellosis-free bovine animal, epizootic free area, etc.) Bovine and porcine animals, on the day of loading, must not display any clinical sign of disease and must be accompanied by a health certificate during transport to the country of destination Animals for slaughter which have been taken on arrival in the country of destination must be slaughtered there as soon as possible	Amendments - EU Directive 80/1098/EEC (entry into force 20 November 80) 80/1274/EEC (entry into force 31 December 80) 81/476/EEC (entry into force 1 July 1981) 82/61/EEC (entry into force 10 February 1982) 82/893/EEC (entry into force 29 December 1982) 83/642/EEC (entry into force 19 December 83) 83/646/EEC (entry into force 21 December 1983) 84/643/EEC (entry into force 30 June 1984) 84/644/EEC (entry into force 30 September 1985) 85/320/EEC (entry into force 19 June 1985) 85/586/EEC (entry into force 24 December 1985) 87/231/EEC (entry into force 10 April 1987) 87/489/EEC (entry into force 30 October 1987) 88/406/EEC (entry into force 27 June 1988) 89/360/EEC (entry into force 6 June 1989) 89/469/EEC (entry into force 28 July 1989) 89/662/EEC (entry into force 22 December 1989) 90/422/EEC (entry into force 9 July 1990) 90/423/EEC (entry into force 26 July 1990) 90/425/EEC (entry into force 26 July 1990) 91/499/EEC (entry into force 16 July 1991) 91/687/EEC (entry into force 19 November 1992) 92/65/EEC (entry into force 29 July 1992) 92/102/EEC (entry into force 8 December 1992) 94/178/EC (entry into force 23 March 1994) 94/42/EC (entry into force 24 August 1994) 95/25/EC (entry into force 18 October 1995) 97/12/EC (entry into force 25 April 1997) 98/46/EC (entry into force 15 July 1998) 98/99/EC (entry into force 31 December 1998) 2000/15/EC (entry into force 3 May 2000) 2000/20/EC (entry into force 4 July 2000) Regulation (EC) No. 3768/85 (entry into force 1 January 1986) No. 535/2002(entry into force 13 April 2002) No. 1226/2002(entry into force 29 July 2002) Replacements and additions of Articles and Annexes
EU 72/462/EEC (entry into force 1 October 1973 Article 23 and 1 January 1976 other provisions) Health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat from third countries	This Directive shall apply to imports from third countries of domestic bovine animals and swine for breeding, production or slaughter and fresh meat of domestic animals This Directive shall not apply to animals intended exclusively for grazing or draft purposes On arrival in the country of destination animals for slaughter must be taken immediately to a slaughterhouse within three working days of entry therein	Amendments - EU Directive 75/379/EEC (entry into force 18 June 75) 77/98/EEC (entry into force 1 July 1978) 81/476/EEC (entry into force 1 July 81) 83/91/EEC (entry into force 15 February 84) 87/64/EEC (entry into force 1 January 1988) 88/489/EEC (entry into force 1 January 89) 88/657/EEC (entry into force 1 January 92) 89/227/EEC (entry into force 30 June 90) 90/423/EEC (entry into force 1 January 92) 91/69/EEC (entry into force 31 December 92)

Table 20 (Continued)

Directive – Title	Main points	Comments
	This Directive set procedures for determining the geographical zones and the establishments from which Member States may authorise importation of live animals and fresh meat	91/266/EEC (entry into force 29 May 91) 91/497/EEC (entry into force 24 September 91) 91/688/EEC (entry into force 1 January 92) 96/91/EC (entry into force 16 January 1997) 97/76/EC (entry into force 16 January 1998) 97/79/EC (entry into force 19 February 1998) Regulation (EC) No. 1452/2001 (entry into force 24 July 2001) Addition, replacement and amendment of Articles and Annexes
EU 77/96/EEC (entry into force 1 January 1979) Examination for trichinae (<i>Trichinella spiralis</i>) upon importation from third countries of fresh meat derived from domestic swine	The Directive establishes a Community system for detecting the presence of trichinae in fresh pigmeat and upon importation of fresh meat from third countries Meat, the examination of which revealed no trichinae, must be marked immediately A Member State may also admit into its territory fresh meat which has not been screened for trichinae in the exporting third country provided that the meat in question undergoes treatment by freezing	Amendments EU Directive 77/96/EEC (entry into force 1 January 1979) 81/476/EEC (entry into force 7 July 81) 83/91/EEC (entry into force 15 May 84) 84/319/EEC (entry into force 1 January 85) 89/321/EEC (entry into force 1 September 89) 94/59/EC (entry into force 12 December 94) Regulation (EEC) No. 3768/85 (entry into force 1 January 1986) Replacements and corrections in the Articles
EU 77/504/EEC (entry into force 1 January 1979) Pure-bred breeding animals of the bovine species	These measures define certain rules on trade in pure-bred breeding animals of the bovine species so as to enable intra-Community trade in these animals to be progressively liberalised Definitions (pure-bred breeding animal of the bovine species, etc.) Performance monitoring methods and methods for assessing the genetic value of cattle	Amendments EU Directive 79/268/EEC (entry into force 1 January 79) 91/174/EEC (entry into force 1 January 92) 94/28/EEC (entry into force 12 July 94) Regulation (EEC) No. 3768/85 (entry into force 1 January 1986) Corrections and replacements in the Articles
EU 88/407/EEC (entry into force 1 January 1990) Laying down the animal health requirements applicable to intra-Community trade in and imports of deep-frozen semen of domestic animals of the bovine species	The Directive lays down the animal health conditions applicable to intra-Community trade in and imports from third countries of both fresh and deep-frozen semen of domestic animals of the bovine species Definitions (semen, semen collection centre, official veterinarian, centre veterinarian, country of collection, etc.) Imports of semen from third countries are restricted to a list of authorised countries to be determined	Amendments EU Directive 90/120/EEC (entry into force 1 April 90) 90/425/EEC (entry into force 26 July 90) 93/60/EEC (entry into force 1 July 1994) 2003/43/EC (entry into force 11 June 03) Corrections of definitions and replacements of Articles
EU 88/661/EEC (entry into force 1 January 1991) Zootechnical standards applicable to breeding animals of the porcine species	Definitions (pure-bred breeding pig, hybrid breeding pig, herd-book and register) Performance monitoring methods for assessing pigs' genetic value Member States may not prohibit, restrict or impede on zootechnical grounds intra-Community trade in pure-bred or hybrid breeding pigs or their semen, ova and embryos	Amendment Regulation (EC) No. 806/2003 (entry into force 5 June 2003) Corrections in the Articles

Table 20 (Continued)

Directive – Title	Main points	Comments
EU 89/556/EEC (entry into force 1 January 1991) Animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species	The Directive lays down animal health conditions for trade between Member States in embryos of domestic cattle and imports from third countries The Directive envisages a system for approving the embryo collection teams in the Member States and in third countries Imports of embryos from third countries are restricted to a list of authorised countries to be drawn up by a procedure involving the Standing Veterinary Committee	Amendments EU Directive 90/425/EEC (entry into force 26 July 90) 93/52/EEC (entry into force 1 January 1994) 94/113/EEC (entry into force 11 February 94) Regulation (EC) No. 806/2003 (entry into force 5 June 2003) Corrections in the Articles
EU 90/429/EEC (entry into force 31 December 1991) Laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the porcine species	The Directive lays down the animal health requirements applicable to intra-Community trade in and imports from third countries of semen of animals of the porcine species Imports of porcine semen may only be made from those third countries on the list of semen collection centres Intra-Community trade in semen requires compliance with regulations concerning collection, processing, storage and transport as well as provisions on protection against the spread of Aujeszky's disease	Amendments Decision 1999/608/EC (entry into force 1 October 1999) Decision 2000/39/EC (entry into force 8 February 2000) Regulation (EC) No. 806/2003 (entry into force 5 June 2003) Replacement of the Articles
Decision 1999/879/EC (entry into force 1 January 2000) The placing on the market and administration of bovine somatotrophin (BST)	This Decision is intended to regulate the marketing and use of bovine somatotrophin or bovine growth hormone within the European Union The Decision thus prohibits the placing on the market of bovine somatotrophin on EU territory for the purpose of its marketing and the administration thereof to dairy cows by any means The production or importation of bovine somatotrophin in the Member States for the purposes of exporting it to third countries continues to be authorised	

non-Member State: (a) for not less than 6 months in the case of animals for breeding or production, (b) for not less than 3 months in the case of animals for slaughter. This period shall date from birth in the case of animals, which are less than 6 or 3 months old respectively. The Member State which carried out the inspection shall take all those measures which it deems to be necessary. These measures may, *inter alia*, include: (a) the placing in quarantine of animals which are suspected of being infected with or contaminated by an infectious disease, (b) sending back animals which cannot be admitted for movement in accordance with these rules, if there are no

objections on animal health grounds, (c) slaughter and destruction of all animals of the consignment in question if the above-mentioned inspection shows evidence or suspicion of one of the epizootic diseases. The Member States shall authorise imports of fresh meat in the form of carcasses, possibly cut in half in respect of swine, and cut in halves or in quarters in respect of bovine animals and solipeds, only if it is possible to reconstruct the entire carcass of each animal. Such importation shall be subject to the conditions that fresh meat must: (a) have been obtained in a slaughterhouse, (b) come from an animal for slaughter which has undergone a post-mortem health

inspection carried out by a veterinary official and been deemed suitable for slaughter in accordance with the provisions of this Directive, (c) have been treated according to the hygiene conditions, (d) have been inspected post-mortem by an official veterinarian and have shown no change except for traumatic lesions incurred shortly before slaughter or localised malformations or changes provided that it is established, if necessary by appropriate laboratory tests, that these do not render the carcase and offal unfit for human consumption or dangerous to human health, (e) be accompanied by a public health certificate, (f) have been stored after post-mortem inspection under satisfactory hygienic conditions in storage plants and (g) have been transported to the country of destination under satisfactory hygienic conditions.

In EU Directive 89/361/EEC (entry into force 1 January 1991), all zootechnical problems arising from intra-Community trade in pure-bred breeding sheep and goats and the semen, ova and embryos thereof are covered. For the purposes of this Directive, the following definition shall apply *pure-bred breeding sheep and goat*: any sheep or goat the parents and grandparents of which are entered or registered in a flock book of the same breed and which is itself entered or registered and eligible for entry therein. Member States may not prohibit, restrict or impede on zootechnical grounds: (i) intra-Community trade in pure-bred breeding sheep and goats and the semen, ova and embryos thereof, (ii) the official approval of breeders' organisations or associations which maintain or establish flock book. The Commission shall determine before 1 January 1991: (i) the criteria for the approval of breeders' organisations and associations which maintain or establish flock books, (ii) the criteria for entry or registration in flock books, (iii) methods for monitoring performance and assessing the genetic value of pure-bred breeding sheep and goats and (iv) the criteria for the approval of a breeding animal for the purpose of using its semen, ova or embryos.

EU Directive 91/68/EEC (entry into force 4 February 1991) claims that ovine and caprine animals: (a) must be identified and registered, the time limit for notifying the national systems for identifying and registering ovine and caprine animals begins running from the date of adoption of this Directive, (b) must show no clinical sign of

disease when inspected by an official veterinarian, such inspection must take place during the 48 h preceding the loading of the ovine and caprine animals, (c) must not come from a holding which is the subject of a prohibition on health grounds and must not have been in contact with animals from such a holding, it being understood that such prohibition shall be linked to an outbreak of any of the following diseases to which the animals are susceptible – brucellosis, rabies and anthrax – after slaughter of the last animal suffering from or susceptible to one of the above-mentioned diseases, the period of prohibition must be at least 42 days in a case of brucellosis, 30 days in a case of rabies and finally, 15 days in a case of anthrax, and must not come from a holding or have been in contact with animals from a holding situated in an established protection zone and from which animals are forbidden to leave, (d) must not be the subject of animal health restrictions introducing Community measures for the control of FMD. The diseases, in which this Directive applies, are FMD, brucellosis (*B. melitensis*), contagious epididymitis (*B. ovis*), anthrax, rabies, scrapie, contagious agalactia, paratuberculosis, caseous lymphadenitis, pulmonary adenomatosis, Maedi Visna and aprine viral arthritis/encephalitis. An officially brucellosis (*B. melitensis*)-free ovine or caprine holding means: (1) a holding: (a) in which all the animals which are susceptible to brucellosis (*B. melitensis*) have been free from clinical or any other signs of brucellosis (*B. melitensis*) for at least 12 months, (b) which contains no ovine or caprine animals which have been vaccinated against brucellosis (*B. melitensis*), save those vaccinated at least 2 years previously, (c) in which two tests separated by an interval of 6 months or more have been carried out, with negative results, on all ovine and caprine animals on the holding over 6 months of age at the time of testing and (d) in which there are only ovine or caprine animals born on the holding or which have come from an officially brucellosis-free or brucellosis-free holding under certain conditions, (2) a holding situated in an officially recognised brucellosis-free Member State or region. The representative number of animals to be tested must, for each holding, consist of the following: (i) all non-castrated male animals over 6 months old, (ii) all animals brought onto the holding since the previous test and (iii) 25% of the

females which have reached the age of reproduction (i.e. which are sexually mature) or are in milk, with a minimum of fifty per holding – except in holdings where there are fewer than fifty such females, in which case all females must be tested.

EU Directive 2004/68/EC (entry into force 20 May 2004) claims that the Commission, with the assistance of the Standing Committee on the Food Chain, draws up a list of (parts of) third countries from which importations of the animals concerned are authorised. In drawing up these lists, it takes particular account of: (i) the legislation of the third country and the organisation and powers of the competent authority and inspection services, (ii) the country's health status and procedures for notifying the Commission and international organisations, (iii) compliance or equivalence with the Community requirements and Community inspections carried out in the third country. Authorised third countries must guarantee that the animals have been checked by a veterinary official and comply with certain animal health conditions taking into account, in particular, the species, age and use of the animal concerned. Each consignment of animals must be accompanied by a veterinary certificate attesting that the animals concerned are hazard-free and providing certain information, such as details on public health, animal health or animal welfare. Derogations may be provided depending on the destination of the animals (zoos, circuses, pet animals) or when animal movements have been prohibited, in the event of a change in the health situation of the country affected by the prohibition. Commission experts may carry out inspections in the third countries in order to verify the compliance or equivalence of the animal health rules.

Some representative points and comments (repeals, modifications, amendments) of EU Directives related to specific provisions (ovine and caprine animals) are given in Table 21.

Specific provisions: poultry

EU Directive 71/118/EEC (entry into force 28 March 1971) claims that it shall apply to trade in fresh meat of domestic animals of the following species: hens, turkeys, guinea-fowls, ducks and geese. All parts of those animals which are fit for human consumption shall be considered to be poultry meat. All poultry meat which has not

undergone any preserving process shall be considered to be fresh meat. However, for the purposes of this Directive, chilled and frozen poultry meat shall be considered to be fresh meat. Each Member State shall ensure that trade is allowed only in fresh poultry meat which meets the following requirements: (a) it has been obtained from a slaughterhouse, (b) it comes from an animal inspected ante mortem by an official veterinarian or by assistants and considered suitable for slaughter for trade in fresh poultry meat, (c) it has been treated under satisfactory hygiene conditions, (d) it has been inspected post-mortem by an official veterinarian or by assistants and found to be fit for human consumption, (e) it bears a health marking, (f) it has been stored after post-mortem inspection under satisfactory hygiene conditions in slaughterhouses or in cold stores and (g) it has been suitably packed and transported under satisfactory hygiene conditions conforming to certain requirements. The following shall be excluded from trade: (a) fresh poultry meat treated with hydrogen peroxide or other bleaching substances or with natural or artificial colouring matters, (b) fresh poultry meat treated with antibiotics, preservatives or tenderisers and (c) fresh poultry meat treated with flavouring substances. All approved slaughterhouses shall be registered on a list and shall each be given a veterinary approval number. Each Member State shall communicate the list of approved slaughterhouses and their veterinary approval numbers to the other Member States and the Commission and notify them of any withdrawal of approval. Veterinary experts must be nationals of a Member State other than those involved in the dispute. A Member State may, if there is a danger that animal diseases may be spread by the introduction into its territory of fresh poultry meat from another Member State, take the following measures: (a) in the event of an outbreak of an epizootic disease in the other Member State, temporarily prohibit or restrict the introduction of fresh poultry meat from the affected areas of that Member State, (b) if an epizootic disease becomes widespread or if there is an outbreak of another serious contagious or infectious animal disease, temporarily prohibit or restrict the introduction of fresh poultry meat from the entire territory of that State.

Table 21 EU Directives (main points and comments) related to specific provision: ovine and caprine animals

Directive – Title	Main points	Comments
EU 72/462/EEC (entry into force 1 October 1973 Article 23 and 1 January 1976 other provisions) Health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat from third countries	This Directive sets procedures for determining the geographical zones and the establishments from which Member States may authorise importation of live animals and fresh meat Member States authorise importation of animals only on presentation of a certificate made out by an official veterinarian of the exporting third country Member States ensure that immediately on arrival in the Community domestic goats and sheep are given an animal health check by an official veterinarian On arrival in the country of destination animals for slaughter must be slaughtered within three working days of entry therein	Amendments EU Directive 75/379/EEC (entry into force 18 June 1975) 77/98/EEC (entry into force 1 July 1978) 81/476/EEC (entry into force 1 July 1981) 83/91/EEC (entry into force 15 February 1984) 87/64/EEC (entry into force 1 January 1988) 88/489/EEC (entry into force 1 January 1989) 88/657/EEC (entry into force 31 December 88) 89/227/EEC (entry into force 30 June 1990) 90/423/EEC (entry into force 18 August 1990) 91/69/EEC (entry into force 31 December 1992) 91/266/EEC (entry into force 29 May 1991) 91/497/EEC (entry into force 24 September 1991) 91/688/EEC (entry into force 1 January 1992) 96/91/EC (entry into force 16 January 1997) 97/76/EC (entry into force 16 January 1998) 97/79/EC (entry into force 19 February 1998) Regulation (EC) No. 1452/2001 (entry into force 24 July 2001) Replacement, correction and addition of the Articles and the Annexes
EU 89/361/EEC (entry into force 1 January 1991) Pure-bred breeding sheep and goats	Definitions (pure-bred breeding sheep, pure-bred breeding goat and flock-book Member States may not prohibit, restrict or impede on zootechnical grounds neither intra-Community trade in pure-bred breeding sheep and goats and their semen, ova and embryos nor the official approval of breeders' organisations which maintain or establish flock-books	
EU 91/68/EEC (entry into force 4 February 1991) Animal health conditions governing intra-Community trade in ovine and caprine animals	Defining the animal health conditions governing intra-Community trade in ovine and caprine animals Definitions (ovine or caprine animals for slaughter, ovine or caprine animals for breeding and fattening, etc.) Rules on control programmes for certain diseases including scrapie, Maedi Visna, caprine viral arthritis/encephalitis, contagious agalactia and paratuberculosis A registration and approval system has been organised to ensure adequate sanitary conditions during trading and during the time spent by animals in their own premises	Amendments Decisions 94/164/EC (entry into force 2 March 1994) 94/953/EC (entry into force 1 January 1995) 2001/298/EC (entry into force 31 July 01) 2001/10/EC (entry into force 20 June 01) 2002/261/EC (entry into force 6 May 2002) 2003/708/EC (entry into force 13 October 03) 2003/50/EC (entry into force 9 July 2003) 2004/554/EC (entry into force 1 June 2004) Regulation (EC) No. 806/2003 (entry into force 5 June 2003) Replacement of the Annexes and addition in the Articles

EU Directive 89/437/EEC (entry into force 31 December 1991) prescribes the hygiene and health requirements concerning the production and the

placing on the market of egg products for direct human consumption or for the manufacture of food-stuffs. However, this Directive shall not

Table 21 (Continued)

Directive – Title	Main points	Comments
EU 2004/68/EC (entry into force 20 May 2004) Laying down animal health rules for the importation into and transit through the Community of certain live ungulate animals	This Directive lays down the animal health rules governing the importation from third countries and transit through the European Union (EU) of certain live ungulates List of authorised third countries Guarantees from the third countries Inspection in third countries This Directive revises Community law, taking account of the evolution of the international standards of the Office International des Épidémiologies (OIE)	Repeal EU Directive 72/462/EEC

apply to: (i) finished food-stuffs manufactured from egg products, (ii) egg products which are obtained in small-scale enterprises and which, without having undergone any treatment, are used for the manufacture of food-stuffs intended for direct sale, without any intermediary, to the consumer or consumed on the spot immediately after having been prepared. The following definition shall also apply *egg products*: products obtained from eggs, their various components or mixtures thereof, after removal of the shell and membranes, intended for human consumption, they may be partially supplemented by other food-stuffs or additives, they may be liquid, concentrated, dried, crystallised, frozen, quick-frozen or coagulated. Member States shall ensure that only egg products which meet the following general requirements are produced as food-stuffs or used in the manufacture of food-stuffs: (a) they must have been obtained from hens', ducks', geese's, turnkeys', guinea-fowl's or quail's eggs, but not a mixture of eggs of different species, (b) they must bear an indication of the percentage of egg ingredients they contain when they are partially supplemented by other food-stuffs or by additives, (c) they must have been treated and prepared in an establishment and satisfy the requirements of this Directive, (d) they must have been prepared under hygienic conditions, (e) they must have undergone a treatment process which enables them to meet *inter alia* the analytical specifications, (f) they must have undergone a health check, (g) they must have been packed, (h) they must be stored and transported, (i) they must bear the mark of wholesomeness where intended for direct human consumption. Establishments must possess at

least: (1) in areas where eggs are stored and where egg products are manufactured or stored, (2) an appropriate number of changing rooms, with smooth, impermeable and washable walls and floors, wash basins and flush lavatories, (3) a separate area and adequate facilities for cleaning and disinfecting fixed and mobile containers and tanks, (4) facilities for the supply of exclusively potable water intended for human consumption, (5) appropriate equipment for protection against pests such as insects and rodents, (6) equipment, couplings and instruments or their surfaces which are intended to come into contact with egg products must be made of smooth material which is easy to wash, clean and disinfect, resists corrosion and does not transfer substances to the egg products in such quantities as to endanger human health, cause deterioration in the composition of the egg products or adversely affect their organoleptic characteristics. Packaging of egg products: (a) egg products must be packaged in satisfactory hygiene conditions so as to ensure that they are not contaminated, (b) the room in which containers are stored must be dust and vermin free, materials for making disposable containers must not be stored on the floor, (c) containers used for egg products must be clean prior to being filled, re-usable containers must be cleaned, disinfected and rinsed before being filled, (d) containers must be brought into the work room in a hygienic manner and must be used without undue delay, (e) immediately after packaging, the containers must be closed and placed in the storage rooms, (f) containers intended for egg products may be used for other food-stuffs if required, provided they are cleaned and disinfected so as not to contaminate

the egg products and (g) containers which are to be used for the transport of egg products in bulk.

EU Directive 90/539/EEC (entry into force 1 January 1992) claims that hatching eggs, day-old chicks, breeding poultry and productive poultry must come from: (1) establishments which fulfil the following requirements: (a) they must be approved and given a distinguishing number by the competent authority, (b) they must not, at the time of consignment, be the subject of any animal health restrictions applicable to poultry, (c) they must not be located in an infected area, (2) a flock which, at the time of consignment, presents no clinical sign or suspicion of disease. However, poultry and hatching eggs must have come from flocks which: (i) have been held in the Community since hatching or for at least 3 months, (ii) present no clinical signs of a contagious poultry disease at the time of consignment, (iii) if there is a vaccination requirement, satisfy the vaccination conditions, (iv) are not the subject of any animal health restrictions applicable to poultry, (v) are not located in an area infected with avian influenza or ND, to be defined in the framework of the measures to combat these diseases to be adopted and (vi) have been found negative in serological tests for *Salmonella pullorum* and *S. gallinarum* antibodies. The status of Member States or regions of Member States from the point of view of ND shall be established by the Commission at the latest 6 months before the date on which the Member States must conform to this Directive. The elements to be taken into consideration for determining this status shall satisfy the following criteria: (i) no ND shall have been detected in the poultry for at least the preceding 12 months, (ii) vaccination against ND in the poultry shall not have been authorised for at least the preceding 12 months, (iii) all breeding flocks shall have been monitored at least once a year for the presence of ND and (iv) the holdings shall contain no poultry which have been vaccinated against ND. Where a Member State draws up or has drawn up a voluntary or compulsory control programme for a disease to which poultry are susceptible, it may present the programme to the Commission, outlining in particular: (i) the distribution of the disease in its territory, (ii) the reasons for the programme, taking into consideration the importance of the disease and the programme's likely

benefit in relation to its cost, (iii) the geographical area in which the programme will be implemented, (iv) the status categories to be applied to poultry establishments, the standards which must be attained in each category, and the test procedures to be used, (v) the programme-monitoring procedures, (vi) the action to be taken if, for any reason, an establishment loses its status and (vii) the measures to be taken if the results of the tests carried out in accordance with the provisions of the programme are positive.

According to EU Directive 92/116/EEC (entry into force 1 January 1994), the model health certificate for fresh poultry meat should contain the following points: (i) identification of meat, (ii) origin of meat, (iii) destination of meat and (iv) attestation. Fresh poultry meat must meet the following conditions: (A) carcasses and offal must: (a) come from an animal inspected before slaughter and considered suitable for slaughter for the placing on the market of fresh poultry meat, (b) have been obtained from an approved slaughterhouse subject to own-checks and to checks by the competent authority, (c) have been treated under satisfactory hygienic conditions, (d) have been inspected post-mortem and not have been found unfit for human consumption, (e) be given a health marking on the understanding that such marking is not necessary for carcasses that are to be cut in the same establishment, (f) after post-mortem inspection have been handled and stored under satisfactory hygienic conditions, (g) have been suitably packaged, (h) have been transported and (i) be accompanied during their transport by either a commercial document. Member States shall ensure that: (a) all farms delivering poultry of the species to slaughterhouses are kept under veterinary supervision, (b) it is guaranteed that: (i) in approved slaughterhouses at least one official veterinarian is present throughout the post-mortem inspection, (ii) in approved cutting plants a member of the inspection team is present at least once a day when meat is being worked on, to check the general hygiene of the plant and the register of fresh meat entering and leaving it and (iii) in cold stores, a member of the inspection team. Fresh poultry meat can be imported into the Community only if it comes from: (a) third countries or parts of third

countries listed in accordance with this Directive and (b) establishments for which the competent authority of the third country has provided the Commission with guarantees that these estab-

lishments meet the requirements of this Directive.

A summary of the EU Directives focused on specific provisions (poultry) is given in Table 22.

Table 22 EU Directives (main points and comments) with regard to specific provisions – poultry

Directive – Title	Main points	Comments
EU 71/118/EEC (entry into force 28 March 1971) Health problems affecting trade in fresh poultry meat	This Directive shall apply to trade in fresh meat of domestic animals of the following species: hens, turkeys, guinea-fowls, ducks and geese All poultry meat which has not undergone any preserving process shall be considered to be fresh meat however, chilled and frozen poultry meat shall be considered to be fresh meat Provisions concerning intra-Community trade and trade within Member States Provisions concerning only intra-Community trade Hygiene requirements for slaughterhouses	Amendment EU Directive 92/116/EEC (entry into force 15 March 1993) Replacement and addition of this Directive
EU 89/437/EEC (entry into force 31 December 1991) Hygiene and health problems affecting the production and the placing on the market of egg products	The Directive covers health problems affecting the production and marketing of egg products for direct human consumption or for use in the manufacture of food-stuffs Definitions (egg products, broken eggs, etc.) Member States are required to comply with a number of similar requirements with respect to the manufacture, handling, packaging, storage and transport of egg products Member States must draw up a list of approved establishments	Amendments EU Directive 89/662/EEC (entry into force 1 July 1992) 91/684/EEC (entry into force 31 December 91) Replacement of Annex and Articles
EU 90/539/EEC (entry into force 1 January 1992) Animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs	Defining the animal health conditions governing intra-Community trade in and imports from third countries of poultry and hatching eggs This Directive does not apply to poultry in trade for exhibitions, shows or contests Definition (poultry, hatching eggs, day-old chicks, etc.) Rules for intra-Community trade Rules for imports from third countries	Amendments – EU Directive 91/494/EEC (entry into force 1 May 1992) 91/496/EEC (entry into force 1 July 1992) 92/65/EEC (entry into force 1 January 1994) 92/369/EEC (entry into force 25 June 1992) 93/120/EC (entry into force 1 January 1995) 1999/90/EC (entry into force 1 July 2000) 2000/505/EC (entry into force 29 August 2000) 2001/867/EC (entry into force 1 January 2002) Replacement in Articles and Annexes
EU 92/116/EEC (entry into force 1 January 1994) Health problems affecting trade in fresh poultry meat	This Directive lays down health rules for the production and placing on the market of fresh poultry meat This Directive shall not apply to the cutting and storage of fresh poultry meat in retail shops or in premises adjacent to sales points Definitions (poultry meat, fresh poultry meat, carcass, etc.) Fresh poultry meat to be marketed must meet certain requirements Commission veterinary experts will be required to make on-the-spot checks Each Member State will draw up a list of its approved establishments	

Specific provisions: meat and meat-based production

EU Directive 72/461/EEC (entry into force 31 December 1977) shall apply to intra-Community trade in fresh meat of domestic bovine animals, swine, sheep and goats and solipeds. All parts of these animals, which are fit for human consumption, shall be considered to be meat. All meat which has not undergone any preserving process shall be considered as fresh meat. However, for the purposes of this Directive chilled and frozen meat shall be considered to be fresh meat. Only fresh meat which fulfils the following requirements may be sent from the territory of one Member State to the territory of another Member State: (a) meat obtained from domestic sheep, goats or solipeds must come from animals which have stayed in the territory of the Community for at least 21 days immediately prior to slaughter or from birth in the case of animals less than 21 days old, (b) the meat must not have been obtained from animals which come from a holding or area which for health reasons is subject to prohibition on animal health problems affecting intra-Community trade in bovine animals and swine, as a result of the outbreak of FMD, swine fever or contagious swine paralysis (Teschen disease) to which the animals in question are susceptible, (c) the meat must not be obtained from slaughterhouses in which cases of FMD, swine fever or contagious swine paralysis (Teschen disease) have been recorded. Should there be an outbreak of one of these diseases, the Member States shall ensure that no meat suspected to be contaminated forms part of intra-Community trade. If there is a danger that animal diseases may be spread by the introduction into its territory of fresh meat from another Member State, take the following measures: (a) in the event of an outbreak of an epizootic disease in the other Member State, it may temporarily prohibit or restrict the introduction of meat from the affected areas of that Member State and (b) if an epizootic disease becomes widespread or if there is an outbreak of another serious contagious or infectious animal disease, it may temporarily prohibit or restrict the introduction of meat from the entire territory of that State.

EU Directive 80/215/EEC (entry into force 31 December 1980) claims that a Member State may take the following measures if there is a danger

that animal diseases may be spread by the introduction of meat products from another Member State into its territory: (a) in the event of an outbreak of classical FMD, CSF or Teschen disease in the other Member State, the introduction of products prepared from the meat of animals which are susceptible to these diseases, other than products which have undergone one of the treatments referred to the Directive, may be temporarily prohibited or restricted from those parts of the territory of the Member State in which the disease has appeared, (b) if an epizootic disease becomes widespread or if there is an outbreak of another serious and contagious or infectious animal disease, the introduction from the entire territory of that State, of products prepared from the meat of animals which are susceptible to these diseases may be temporarily prohibited or restricted. Meat products may be intended for intra-Community trade, which are prepared in whole or in part from or with fresh meat may enter intra-Community trade if they have also undergone one of the following forms of treatment: (a) heat treatment in a hermetically sealed container, with an F_c value of 3–7 or more, (b) where the fresh meat has been obtained from animals which do not come from an infected holding subject to prohibition measures of this Directive: (i) heat treatment different from that referred to in (a) in which the internal temperature is raised to at least 70 °C or (ii) treatment consisting in natural fermentation and maturation of not less than 9 months for boned or boneless hams weighing not less than 5.75 kg and having the following characteristics: a_w value of not more than 0.793 and pH value of not more than 6.

According to EU Directive 91/497/EEC (entry into force 1 January 1993), each Member State shall ensure that carcasses, half carcasses or half carcasses cut into no more than three wholesale cuts, and quarters: (a) have been obtained in a slaughterhouse meeting the conditions laid down in this Directive, (b) come from a slaughter animal inspected ante mortem by an official veterinarian, as a result of such inspection, for slaughter for the purposes of this Directive, (c) have been treated under satisfactory hygiene conditions, (d) have been inspected post-mortem by an official veterinarian and do not show any change except for traumatic lesions which occurred shortly before

slaughter or localised malformations or changes, provided that it is established, if necessary by appropriate laboratory tests, that these lesions, malformations or changes do not render the carcase and offal unfit for human consumption or dangerous to human health, (e) bear a health mark, (f) are accompanied during transportation by the health certificate issued by the official veterinarian, (g) are stored after post-mortem inspection under satisfactory hygiene conditions in establishments and (h) are transported under satisfactory hygiene conditions. Cuts or small pieces or boned meat: (a) are boned or cut in a cutting plant meeting the conditions laid down in this Directive, (b) are boned or cut and come from fresh meat from community or from third countries, (c) have been stored under conditions which comply with this Directive, (d) have been checked by an official veterinarian and (e) meet the wrapping and packaging requirements. However, this Directive shall not apply to: (a) fresh meat intended for uses other than human consumption, (b) fresh meat intended for exhibition, special studies or analysis, provided that official control makes it possible to ensure that the meat is not used for human consumption and that, when the exhibition is over or when the special studies or the analysis have been carried out, the meat, with the exception of that used for the purposes of analysis, is destroyed and (c) fresh meat intended exclusively as supplies for international organisations.

All EU Member States shall prohibit (EU 96/22/EC, entry into force 23 May 1996): (a) the placing on the market of stilbenes, stilbene derivatives, their salts and esters and thyrostatic substances for administering to animals of all species, (b) the placing on the market of beta-agonists for administering to animals the flesh and products of which are intended for human consumption, (c) the administering to a farm or aquaculture animal, by any means whatsoever, of substances having a thyrostatic, oestrogenic, androgenic or gestagenic action and of beta-agonists, (d) the holding, except under official control, of animals on a farm, the placing on the market or slaughter for human consumption of farm animals or of aquaculture animals which contain the substances has been established in this directive unless proof can be given that the animals in question have been treated, (e) the placing on the market for human

consumption of aquaculture animals to which substances have been administered and of processed products derived from such animals, (f) the placing on the market of meat of animals and (g) the processing of the meat. The following may not, however, be authorised: (a) the following hormonal products: (i) products acting as a deposit, (ii) products with a withdrawal period of more than 15 days after the end of treatment, (iii) products: which were authorised under rules, whose conditions of use are not known, for which no reagents or equipment exist for use in the analytical techniques for detecting the presence of residues in excess of the permitted limits, (b) veterinary medicinal products containing beta-agonists which have a withdrawal period of more than 28 days after the end of treatment. Third countries whose legislation authorises the placing on the market and administration of stilbenes, stilbene derivatives, their salts and esters, or of thyrostatic substances for administering to animals of all species may not appear on any of the lists of countries provided for under Community legislation from which Member States are authorised to import farm or aquaculture animals or meat or products obtained from such animals. Member States shall also prohibit the importation from third countries on any of the lists of: (a) farm or aquaculture animals: (i) to which products or substances have been administered by any means whatsoever, (ii) to which substances or products have been administered, unless those substances or products were administered in compliance with the provisions and requirements laid down in this Directive (96/22/EC) and the withdrawal periods allowed in international recommendations have been observed and (b) meat or products obtained from animals the importation.

The titles, main points and comments of the EU Directives about specific provisions (meat and meat-based production) are summarised in Table 23.

Specific provisions: fish and fishery products

According to EU Directive 91/67/EEC (entry into force 1 January 1993), the placing on the market of aquaculture animals shall be subject to the following general requirements: (a) they must show no clinical signs of disease on the day of loading, (b) they must not be intended for

Table 23 EU Directives (main points and comments) for specific provisions: meat and meat-based production

Directive – Title	Main points	Comments
EU 72/461/EEC (entry into force 31 December 1977) Health problems affecting intra-Community trade in fresh meat	This Directive shall apply to intra-Community trade in fresh meat of domestic bovine animals, swine, sheep, goats and solipeds The animals from which the fresh meat is taken must have been in the Community for at least 21 days before slaughter Intra-Community trade in fresh meat of animals coming from an area in which health restrictions apply is forbidden The meat must be obtained in slaughterhouses in which no disease has been recorded	Amendments - EU Directive 74/387/EEC (entry into force 18 July 1974) 75/379/EEC (entry into force 18 June 1975) 77/98/EEC (entry into force 31 December 1982) 80/213/EEC (entry into force 31 December 80) 80/1099/EEC (entry into force 1 July 1981) 81/476/EEC (entry into force 7 July 1981) 83/646/EEC (entry into force 2 January 1984) 84/336/EEC (entry into force 30 June 1984) 84/643/EEC (entry into force 31 December 84) 85/332/EEC (entry into force 1 January 1986) 87/64/EEC (entry into force 1 January 1988) 87/231/EEC (entry into force 31 December 87) 87/489/EEC (entry into force 31 December 88) 89/662/EEC (entry into force 31 December 92) 91/266/EEC (entry into force 21 May 1991) 91/687/EEC (entry into force 1 July 1992) 92/118/EEC (entry into force 30 June 1996) Regulation (EEC) No. 3768/85 (entry into force 20 January 1986) Measures relating to swine vesicular disease, classical swine fever and African swine fever
EU 80/215/EEC (entry into force 31 December 1980) Animal health problems affecting intra-Community trade in meat products	Defining common rules in order to eliminate disparities between Member States concerning health rules affecting meat products The rules applicable to fresh meat must be applied to certain meat products in case of preventing animal diseases If an epizootic disease becomes widespread or if there is an outbreak of another serious animal disease, the introduction of products prepared from the meat of animals which are susceptible to these diseases may be prohibited or restricted	Amendments – EU Directive 80/215/EEC (entry into force 31 December 80) 80/1100/EEC (entry into force 1 July 1981) 81/476/EEC (entry into force 7 July 1981) 85/321/EEC (entry into force 1 January 1986) 87/491/EEC (entry into force 1 January 1988) 88/660/EEC (entry into force 1 April 1989) 89/662/EEC (entry into force 31 December 92) 91/687/EEC (entry into force 1 July 1992) Regulation (EEC) No. 3768/85 (entry into force 1 January 1986) Measures relating to swine vesicular disease, classical swine fever and African swine fever
EU 91/497/EEC (entry into force 1 January 1993) Health problems affecting intra-Community trade in fresh meat to extend it to the production and marketing of fresh meat	The Directive lays down the health conditions applicable to the production and placing on the market of fresh meat intended for human consumption from domestic bovine animals, pigs, sheep, goats and domestic solipeds Definitions (meat, fresh meat, carcass, establishment, etc.) Provisions concerning health requirements for the placing on the market of fresh meat Provisions on meat and animal carcasses declared unfit for human consumption by the official veterinarian Provisions on residue tests carried out on animals or their meat	Amendments EU Directive 95/23/EC (entry into force 1 December 1995) Regulation (EC) No. 806/2003 (entry into force 5 June 2003) Amending a number of technical points which have caused problems of practical application

destruction or slaughter under a scheme for the eradication of a disease, (c) they must not come from a farm which is subject to a prohibition for animal health reasons and must not have been in

contact with animals from such a farm. Aquaculture products being placed on the market for breeding purposes (eggs and gametes) must originate from animals which satisfy the require-

Table 23 (Continued)

Directive – Title	Main points	Comments
EU 96/22/EC (entry into force 23 May 1996) The prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of β -agonists	The purpose of the Directive is to regulate the use in meat of substances having a hormonal or thyrostatic action and of beta-agonists with a view to protecting consumer health and safeguarding the quality of food-stuffs of animal origin The Directive prohibits the placing on the market of thyrostatic substances, stilbenes, stilbene derivatives, their salts and esters, etc. It provisionally prohibits the administration of five hormones to animals intended for human consumption: progesterone, testosterone, trenbolone acetate, zeranol and melengestrol acetate	Amendment EU Directive 2003/74/EC (entry into force 14 October 2003) Replacements in the Articles Repeals – EU Directive 81/602/EEC from 1 July 1997 88/146/EEC from 1 July 1997 88/299/EEC from 1 July 1997

ments laid down in this Directive. Aquaculture products being placed on the market for human consumption must originate from animals, which satisfy the requirements laid down in this Directive. The placing on the market of live fish belonging to the susceptible species, their eggs or gametes, shall be subject to the following additional guarantees: (a) where they are to be introduced into an approved zone, they must be accompanied by a movement document corresponding or certifying that they come from an approved zone or an approved farm. Additional guarantees to be met for the introduction into an approved zone of fish coming from an approved farm situated in a non-approved zone shall be fixed. Pending that decision, national rules shall continue to apply subject to compliance with the general provisions of the Treaty, (b) where they are to be introduced into a farm which, although not situated in an approved zone, they must be accompanied by a movement document corresponding or certifying that they come respectively from an approved zone or from a farm of the same health status as the farm of destination. Live molluscs susceptible to the diseases of a list must be delivered either for direct human consumption or to the preserving industry and shall not be re-laid unless they originate in an approved farm in a non-approved coastal zone or they are temporarily immersed in storage ponds or purification centres which are specially equipped and approved for that purpose by the competent authority and include in particular a system for the treatment and disinfection of residual water. The conditions

for such approval will be determined by the Commission. Aquaculture animals and products must come from third countries or parts thereof appearing on a list drawn up by the Commission. In deciding whether a third country or part thereof may appear on the list referred to in the Directive, particular account shall be taken of: (a) the state of health of the aquaculture animals, particular attention being paid to exotic diseases and the environmental health situation in the third country which might endanger the health of livestock in the Member States, (b) the regularity and rapidity of the information supplied by the country relating to the existence of infectious or contagious diseases of aquaculture animals in its territory, in particular those diseases mentioned in the list of the International Office of Epizootics, (c) the rules of the third country on the prevention and control of diseases of aquaculture animals, (d) the structure of the official services in the third country and their powers, (e) the organisation and implementation of measures to prevent and control infectious or contagious diseases of aquaculture animals and (f) assurances which the third country may provide concerning the rules laid down in this Directive.

Following EU Directive 91/492/EEC (entry into force 14 October 1991), the placing on the market of live bivalve molluscs for immediate human consumption shall be subject to the following conditions: (a) they must originate from production areas which comply with the requirements laid down in this Directive, in the case of Pectinidae, this provision shall apply only to

aquaculture products, (b) they must have been harvested and transported from the production area to a dispatch centre, purification centre, relaying area or processing plant under the conditions laid down in this Directive, (c) where provided for in this Directive, they must have been re-laid in suitable areas approved for that purpose, (d) they must have been handled hygienically, and where appropriate, they must have been purified in establishments approved for that purpose, (e) they must comply with the criteria set out in this Directive, (f) health controls must have been carried out, (g) they must have been appropriately wrapped, (h) they must have been stored and transported under satisfactory conditions of hygiene and (i) they must bear a health mark. Member States shall ensure that persons handling live bivalve molluscs during their production and placing on the market shall adopt all measures necessary to comply with the requirements of this Directive. Persons responsible for dispatch and purification centres shall in particular ensure that: (i) representative numbers of samples for laboratory examination are regularly taken and analysed in order to establish an historical record on the basis of the areas where batches come from and of the health quality of the live bivalve molluscs both before and after handling at a dispatch centre or purification centre, (ii) a register is kept for the permanent record of the results of the various checks and kept for presentation to the competent authority. Provisions applied to imports of live bivalve molluscs from third countries shall be at least equivalent to those governing the production and placing on the market of Community products. The location and the boundaries of production areas must be fixed by the competent authority in such a way as to identify the areas from which live bivalve molluscs: (a) can be collected for direct human consumption, (b) can be collected but only placed on the market for human consumption after treatment in a purification centre, after relaying. Live bivalve molluscs from these areas must not exceed the limits of a five-tube, three-dilution most probable number (MPN) test of 6000 faecal coliforms per 100 g of flesh or 4600 *Escherichia coli* per 100 g of flesh in 90% of samples, (c) can be collected but placed on the market only after relaying over a long period (at least 2 months), whether or not combined with

purification, or after intensive purification for a period to be fixed, so as to meet the requirements under (a). Live bivalve molluscs from these areas must not exceed the limits of a five-tube, three-dilution MPN test of 60 000 faecal coliforms per 100 g of flesh. Any change in the demarcation of production areas and the temporary or definitive closure thereof must be immediately announced by the competent authority to those affected by this Directive and in particular to producers and operators of purification and dispatch centres. Centres must have at least: (1) on premises where live bivalve molluscs are handled or stored, (2) access to an appropriate number of changing rooms, wash basins and lavatories; there must be a sufficient number of washbasins close to the lavatories, (3) adequate equipment for washing tools, containers and equipment, (4) facilities for the supply and, where appropriate, storage of exclusively potable water intended for human consumption or facilities for the supply of clean sea water, (5) equipment and instruments or their surfaces which are intended to come into contact with live bivalve molluscs must be made of corrosion-resistant material which is easy to wash and clean repeatedly.

According to EU Directive 91/493/EEC (entry into force 1 January 1993), the placing on the market of aquaculture products shall be subject to the following conditions: (a) they must have been slaughtered under appropriate conditions of hygiene. They must not be soiled with earth, slime or faeces. If not processed immediately after having been slaughtered, they must be kept chilled, (b) they must have been handled and, where appropriate, packaged, prepared, processed, frozen, defrosted or stored hygienically in establishments and they must have been stored and transported under satisfactory conditions of hygiene. The placing on the market of the following products shall be forbidden: (i) poisonous fish of the following families: Tetraodontidae, Molidae, Diodontidae, Canthigasteridae, and (ii) fishery products containing biotoxins such as ciguatera toxins or muscle-paralysing toxins. When fixing the import conditions of fishery products, particular account shall be taken of: (a) the legislation of the third country, (b) the organisation of the competent authority of the third country and of its inspection services, the powers of such services

and the supervision to which they are subject, as well as their facilities for effectively verifying the implementation of their legislation in force, (c) the actual health conditions during the production, storage and dispatch of fishery products intended for the Community and (d) the assurances which a third country can give on the compliance with the standards. Areas used for the preparation and processing or freezing/quick-freezing of fishery products must have: (a) a non-slip floor that is also easy to clean and disinfect and equipped for easy drainage of water. Structures and fixtures must have limber holds that are large enough not to be obstructed by fish waste and to allow water to drain freely, (b) walls and ceilings that are easy to clean, particularly where there are pipes, chains or electricity conduits, (c) the hydraulic circuits must be arranged or protected in such a way as to ensure that it is not possible for any leakage of oil to contaminate fishery products, (d) adequate ventilation and, where necessary, proper vapour extraction, (e) adequate lighting, (f) appliances for cleaning and disinfecting tools, equipment and fittings and (g) appliances for cleaning and disinfecting the hands with taps that are not hand-operable and with single-use towels. Conditions for frozen products, especially plants must have: (i) freezing equipment sufficiently powerful to achieve a rapid reduction in the temperature so that the temperatures laid down in this Directive can be obtained in the product and (ii) freezing equipment sufficiently powerful to keep products in storage rooms at a temperature not exceeding those laid down in this Directive, whatever the ambient temperature may be. However, for technical reasons related to the method of freezing and to the handling of such products, for whole fish frozen in brine and intended for canning, higher temperatures than those laid down in this Directive are acceptable, although they may not exceed -9°C .

EU Directive 92/48/EEC (entry into force 1 January 1993) makes clear the general hygiene conditions applicable to fishery products on board fishing vessels: (1) The sections of vessels or the containers reserved for the storage of fishery products must not contain objects or products liable to transmit harmful properties or abnormal characteristics to the food-stuffs. These sections or containers must be so designed as to allow them to

be cleaned easily and to ensure that melt water cannot remain in contact with the fishery products. (2) When used, the sections of vessels or the containers reserved for the storage of fishery products must be completely clean and, in particular, must not be capable of being contaminated by the fuel used for the propulsion of the vessel or by bilge water. (3) As soon as they are taken on board, the fishery products must be protected from contamination and from the effects of the sun or any other source of heat. (4) The fishery products shall be handled and stored in such a way as to prevent bruising. The use of spiked instruments shall be tolerated for the moving of large fish or fish which might injure the handler, provided the flesh of these products is not damaged. (5) Fishery products other than those kept alive must undergo cold treatment as soon as possible after loading. However, in the case of fishing vessels where cooling is not possible from a practicable point of view, the fishery products must not be kept on board for more than 8 h. (6) Ice used for the chilling of products must be made from drinking water or clean seawater. Before use, it must be stored under conditions, which prevent its contamination. (7) After the fishery products have been unloaded, the containers, equipment and sections of vessels, which are directly in contact with the fishery products, must be cleaned with drinking water or clean seawater. (8) Where fish is headed and/or gutted on board, such operations must be carried out hygienically and the products must be washed immediately and thoroughly with drinking water or clean seawater. The viscera and parts, which may pose a threat to public health, must be removed and set apart from products intended for human consumption. Livers and roes intended for human consumption must be refrigerated or frozen. (9) Equipment used for gutting, heading and the removal of fins, and containers and equipment in contact with the fishery products, must be made of or coated with a material which is waterproof, resistant to decay, smooth and easy to clean and disinfect. When used they must be completely clean. (10) Staff assigned to the handling of fishery products shall be required to maintain a high standard of cleanliness for themselves and their clothes.

Decision 97/296/EC (entry into force 1 July 1997) lists the countries and territories from which

Table 24 EU Directives (main points and comments) focused on specific provisions: fish and fishery products

Directive – Title	Main points	Comments
EU 91/67/EEC (entry into force 1 January 1993) The animal health conditions governing the placing on the market of aquaculture animals and products	Definitions (aquaculture animals, aquaculture products, fish, crustaceans or molluscs, etc.) The placing on the market of aquaculture animals shall be following general requirements Aquaculture animals and products must come from third countries or parts thereof appearing on a list	Amendments EU Directive 93/54/EEC (entry into force 30 June 1994) 95/22/EC (entry into force 31 December 1995) 97/79/EC (entry into force 19 February 1998) 98/45/EC (entry into force 3 July 1998) Changes in the Articles and Annexes
EU 91/492/EEC (entry into force 14 October 1991) Laying down the health conditions for the production and the placing on the market of live bivalve molluscs	This Directive applies to echinoderms, tunicates and marine gastropods Definitions (bivalve molluscs, clean sea-water, production area, etc.) Provisions for Community production Imports of live bivalve molluscs from third countries Live bivalve molluscs may not be prepared for marketing except in establishments meeting the standards	Amendments EU Directive 97/61/EC (entry into force 18 November 1997) 97/79/EC (entry into force 19 February 1998) Laying down the organisation of veterinary checks
EU 91/493/EEC (entry into force 1 January 1993) Laying down the health conditions for the production and the placing on the market of fishery products	Definitions (fishery products, aqua-culture products, fresh products, etc.) Fishery products which are to be marketed live must at all times be kept under the most suitable survival conditions Certain species that are poisonous or contain biotoxins may not be marketed Fishery products may not be handled except in factory ships or establishments conforming to the standards laid down in this Directive	Amendments EU Directive 95/71/EC (entry into force 30 December 1995) 97/79/EC (entry into force 19 February 1998) Laying down the organisation of veterinary checks and adding in the Articles
EU 92/48/EEC (entry into force 1 January 1993) Laying down the minimum hygiene rules applicable to fishery products caught on board certain vessels	The general hygiene conditions shall apply to fishery products handled on board fishing vessels The additional hygiene conditions shall apply to fishing vessels designed and equipped to preserve fishery products on board under satisfactory conditions for more than 24 h Derogations may only be taken place by fishing vessels before 31 December 1992	
Decision 97/296/EC (entry into force 1 July 1997) Drawing up the list of third countries from which the import of fishery products is authorised for human consumption	List of countries and territories from which importation of fishery products in any form intended for human consumption It is possible the import of third countries before 1 July 1998 Certification that fishery products exported to the Community meet the health requirements	Amendments – Decision 1999/136/EC (entry into force 8 March 1999) 1999/244/EC (entry into force 27 April 99) 1999/277/EC (entry into force 17 May 99) 1999/488/EC (entry into force 12 August 99) 1999/532/EC (entry into force 23 August 99) 1999/814/EC (entry into force 29 December 1999) 2000/88/EC (entry into force 22 February 2000) 2000/170/EC (entry into force 19 March 00) 2000/674/EC (entry into force 24 November 00) 2001/40/EC (entry into force 2 February 2001) 2001/66/EC (entry into force 13 February 2001) 2001/111/EC (entry into force 5 March 2001) 2001/635/EC (entry into force 6 September 2001) 2002/28/EC (entry into force 4 February 2002) 2002/473/EC (entry into force 11 June 2002)

Table 24 (Continued)

Directive – Title	Main points	Comments
		2002/863/EC (entry into force 25 November 02) 2003/303/EC (entry into force 23 May 2003) 2003/606/EC (entry into force 9 September 2003) 2003/764/EC (entry into force 14 November 03) 2004/36/EC (entry into force 3 February 2004) 2004/359/EC (entry into force 10 April 2004) Addition in the list of countries
Regulation (EC) No 104/2000 (entry into force 2 February 2000)	A common organisation of markets in fishery products is hereby established, comprising a price and trading system on competition	Repeals Regulation (EEC) No. 3759/92 from 1 January 2001
The common organisation of the markets in fishery and aquaculture products	Marketing standards and consumer information	Regulation (EEC) No. 105/76 from 1 January 2001
	Conditions for grant of and withdrawal recognition of producer organisations	Regulation (EEC) No. 1772/82 from 1 January 2001
	Production and marketing planning	Amendments
	Trade of fishery products with third countries	Regulation (EC) No. 2065/2001 (entry into force 1 January 2002) Regulation (EC) No. 1767/2004 (entry into force 4 November 2004) Corrections in the Articles of this Directive

importation of fishery products in any form intended for human consumption is authorised. The countries are: United Arab Emirates, Antigua and Barbuda, Albania, the Netherlands, Antilles, Argentina, Australia, Bangladesh, Bulgaria, Brazil, Belize, Canada, Switzerland, Ivory Coast, Chile, China, Colombia, Costa Rica, Serbia and Montenegro, Cuba, Cape Verde, Ecuador, Egypt, Falkland Islands, Gabon, Ghana, Greenland, The Gambia, Guinea Conakry, Guatemala, Guyana, Hong Kong, Honduras, Croatia, Indonesia, India, Iran, Jamaica, Japan, Kenya, South Korea, Kazakhstan, Sri Lanka, Morocco, Madagascar, Mauritania, Mauritius, Maldives, Mexico, Malaysia, Mozambique, Namibia, New Caledonia, Nigeria, Nicaragua, New Zealand, Oman, Panama, Peru, Papua New Guinea, the Philippines, French Polynesia, St. Pierre and Miquelon, Pakistan, Romania, Russia, Saudi Arabia, Seychelles, Singapore, Senegal, Suriname, El Salvador, Thailand, Tunisia, Turkey, Taiwan, Tanzania, Uganda, Uruguay, Venezuela, Vietnam, Yemen, Mayotte, South Africa, Zimbabwe, Armenia, Angola, Azerbaijan, Benin, the Bahamas, Belarus, Republic of Congo, Cameroon, Algeria, Eritrea, Fiji, Grenada, Israel, Myanmar, Solomon Islands, St. Helena, Togo and United States of America.

For the purposes of Regulation (EC) No. 104/2000 (entry into force 2 February 2000), *producer organisation* means any legal entity: (a) set up on the initiative of a group of producers of one or more of the products, in case of frozen, treated or processed products, as the operations in question have been carried out on board fishing vessels, (b) established for the purpose of ensuring that fishing is carried out along rational lines and that conditions for the sale of the members' products are improved, by taking such measures as will encourage the planning of production, promote the concentration of supply, stabilise prices, encourage fishing methods, (c) the rules of association of which require its producer members, in particular, to apply to fishing production and marketing. Member States shall carry out appropriate checks to ensure that each producer organisation fulfils the obligations and shall apply the following penalties in the event that these obligations are not fulfilled: (a) where a producer organisation has failed to draw up an operational programme for the fishing year, it shall not receive any of the financial assistance granted for intervention operation carried out under title for the fishing year concerned, (b) where a producer organisation has not implemented the measures provided for in its operational programme, then for the fishing year

concerned: (i) only 75% of the financial assistance shall be granted for intervention operations carried out under title for the first instance of non-implementation, (ii) only 50% of the above financial assistance shall be granted for the second instance and (iii) none of the above financial assistance shall be granted after any further instance.

All EU Directives/Regulations related to specific provisions (meat and meat-based production) are given in Table 24.

Conclusions

The target of this article was to provide an insight into EU food legislation as EU tends to become one of the largest organisations worldwide. In fact, over the last 10–15 years several food safety crises (BSE, dioxins, high pesticide and antibiotic levels in foods, Sudan Red 1) occurred within the framework of the EU. Some of these crises resulted in great losses of human lives and money, whereas others simply made EU citizens more alert in terms of their everyday nutrition. As a result, the Commission of EU tried to enhance the food safety level by either introducing new stricter Regulations/Directives or modifying the already existing ones. The most important topics such as food safety, GMOs, labelling, packaging, food additives and food contaminants and imports from third countries were presented from the viewpoint of legislation starting from the very first one (sometimes 35–40 years old) up to the most recent ones which have already been voted but their entry in force is not due to occur before 1 January 2006. The incorporation of more than twenty informative tables where the most important points of EU Directives/Regulations are summarised per topic (starting with the most recent EU Directives) is anticipated to serve as a useful source of information on EU food legislation.

References

EU legislation

Food safety

EU Regulations related to HACCP

Regulation (EC) No. 178/2002 (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Regulation&an_doc=2002&nu_doc=178)

Regulation (EC) No. 852/2004 (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Regulation&an_doc=2004&nu_doc=852)

Regulation (EC) No. 853/2004 (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Regulation&an_doc=2004&nu_doc=853)

Regulation (EC) No. 854/2004 (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Regulation&an_doc=2004&nu_doc=854)

Regulation (EC) No. 882/2004 (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Regulation&an_doc=2004&nu_doc=882)

EU Directives focused on pesticide contamination

EU 76/895/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1976&nu_doc=895)

EU 86/362/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1986&nu_doc=362)

EU 90/642/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1990&nu_doc=642)

EU Regulations dealing with radioactive contamination

Regulation (EC) No. 3954/87 (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Regulation&an_doc=1987&nu_doc=3954)

Regulation (EC) No. 2219/89 (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Regulation&an_doc=1989&nu_doc=2219)

Regulation (EC) No. 737/90 (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Regulation&an_doc=1990&nu_doc=737)

EU Directives for contamination from substances with hormonal action and other substances.

EU 96/22/EC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1996&nu_doc=22)

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EU 96/23/EC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1996&nu_doc=23)

EU Regulation related to contaminants

Regulation (EC) No. 466/2001 (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Regulation&an_doc=2001&nu_doc=466)

EU Regulations with regard to biological safety

Regulation (EC) No. 999/2001 (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Regulation&an_doc=2001&nu_doc=999)

Regulation (EC) No. 2160/2003 (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Regulation&an_doc=2003&nu_doc=2160)

Technological aspects

EU Directives for freezing: ionisation

EU 89/108/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1989&nu_doc=108)

EU 1999/2/EC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1999&nu_doc=2)

EU 1999/3/EC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1999&nu_doc=3)

Regulation (EEC) No. 2092/91 (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Regulation&an_doc=1991&nu_doc=2092)

EU Directives dealing with food additives: flavourings

EU 62/2645/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1962&nu_doc=2645)

EU 78/663/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1978&nu_doc=663)

EU 81/712/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1981&nu_doc=712)

EU 88/388/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1988&nu_doc=388)

EU 88/389/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1988&nu_doc=389)

EU 89/107/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1989&nu_doc=107)

EU 94/35/EC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1994&nu_doc=35)

EU 94/36/EC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1994&nu_doc=36)

EU 95/2/EC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1995&nu_doc=2)

Regulation (EC) No. 2232/96 (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Regulation&an_doc=1996&nu_doc=2232)

EU Directives focused on food-stuffs intended for particular nutritional uses

EU 89/398/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1989&nu_doc=398)

EU 91/321/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1991&nu_doc=321)

EU 96/5/EC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1996&nu_doc=5)

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EU 96/8/EC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1996&nu_doc=8)

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EU 2002/46/EC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=2002&nu_doc=46)

EU Directives dealing with packaging

EU Directive 75/106/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1975&nu_doc=106)

EU Directive 76/211/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1976&nu_doc=211)

EU Directive 78/142/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1985&nu_doc=591)

EU Directive 80/232/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1980&nu_doc=232)

EU Directive 82/711/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1982&nu_doc=711)

EU Directive 93/10/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1993&nu_doc=10)

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EU Directive 97/23/EC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1997&nu_doc=23)

EU Directive 2002/16/EC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=2002&nu_doc=16)

Proposal of Regulation COM(2003)0689 COD(2003)0272 (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Regulation-COM&an_doc=2003&nu_doc=0689)

GMOs in EU trade

EU Directives and Regulations for GMOs

EU 90/219/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1990&nu_doc=219)

EU 90/220/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1990&nu_doc=220)

EU 2001/18/EC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=2001&nu_doc=18)

EU 2004/204/EC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=2004&nu_doc=204)

EU 2004/643/EC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=2004&nu_doc=643)

EU 2004/657/EC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=2004&nu_doc=657)

Regulation (EC) No. 258/97 (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Regulation&an_doc=1997&nu_doc=258)

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Regulation (EC) No. 1830/2003 (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Regulation&an_doc=2003&nu_doc=1830)

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Food quality

EU Directives related to labelling: general provisions

EU Directive 90/496/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1990&nu_doc=496)

EU Directive 2000/13/EC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=2003&nu_doc=13)

EU Directives for labelling

Regulation (EEC) No. 1576/89 (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Regulation&an_doc=1989&nu_doc=1576)

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Regulation (EEC) No. 2081/92 (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Regulation&an_doc=1992&nu_doc=2081)

Regulation (EEC) No. 2200/96 (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Regulation&an_doc=1996&nu_doc=2200)

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Regulation (EC) No. 1321/2002 (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Regulation&an_doc=2002&nu_doc=1321)

Regulation (EC) No. 318/2003 (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Regulation&an_doc=2003&nu_doc=318)

Food products

EU Directives focused on water quality

EU 75/440/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1975&nu_doc=440)

EU 79/923/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1979&nu_doc=923)

EU 98/83/EC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1998&nu_doc=83)

EU Directive and Regulations with regard to oils: fats

EU 96/3/EC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1996&nu_doc=3)

Regulation (EC) No. 2991/94 (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Regulation&an_doc=1994&nu_doc=2991)

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EU Directives related to production and placing on the market: milk

EU Directive 89/384/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1989&nu_doc=384)

EU Directive 92/46/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1992&nu_doc=46)

EU Directives on controls and food hygiene rules

EU Directive 85/591/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1985&nu_doc=591)

EU Directive 93/43/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1993&nu_doc=43)

EU Directive 93/99/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1993&nu_doc=99)

EU Directive 2002/99/EC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=2002&nu_doc=99)

EU Directive 2004/41/EC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=2004&nu_doc=41)

EU Directives related to imports from third countries and intra-Community trade: general provisions

EU Directive 89/662/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1989&nu_doc=662)

EU Directive 90/425/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1990&nu_doc=425)

EU Directive 91/174/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1991&nu_doc=174)

EU Directive 91/496/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1991&nu_doc=496)

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EU Directive 92/118/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1992&nu_doc=118)

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EU Directives for production and placing on the market: meat

EU Directive 91/495/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1991&nu_doc=495)

EU Directive 92/45/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1992&nu_doc=45)

EU Directive 94/65/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1994&nu_doc=65)

EU Directives dealing with specific provisions: bovine and porcine animals

EU Directive 64/432/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1964&nu_doc=432)

EU Directive 72/462/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1972&nu_doc=462)

EU Directive 77/96/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1977&nu_doc=96)

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EU Directives related to specific provision: ovine and caprine animals

EU Directive 72/462/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1972&nu_doc=462)

EU Directive 89/361/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1989&nu_doc=361)

EU Directive 91/68/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1991&nu_doc=68)

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EU Directives with regard to specific provisions: poultry

EU Directive 71/118/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1971&nu_doc=118)

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EU Directives for specific provisions: meat and meat-based production

EU Directive 72/461/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1972&nu_doc=461)

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EU Directives focused on specific provisions: fish and fishery products

EU Directive 91/67/EEC (http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=1991&nu_doc=67)

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