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EU Food Law and Policy

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Title I - General Food Law

Title II – Food Information to Consumers

Title III – Genetically Modified Food

Title I

General Food Law

Chapter 1
History of EU food law

The history of EU food law is interesting on several accounts and can serve as a barometer of European integration.

1. First harmonisation efforts

The Community legislator considered harmonising national legislations governing foodstuffs at a very early stage. One of the very first directives ever adopted by the Council, as soon as 1962, was fixing the list of the only colouring matters authorised for use in foods for human use[1]. In general, the first harmonisation works in the food sector are marked by pragmatism and devoid of theoretical foundation.

In 1968, the Council adopted a Resolution on the measures to be taken in the veterinary sector[2], which was followed, in 1969, by a Resolution drawing up a programme for the elimination of technical barriers to trade in foodstuffs[3]. This program was foreseeing the adoption of directives dealing with some horizontal questions (additives, food contact materials, labelling) and to a large number of vertical questions (cocoa, jam, butter, pasta, beer, wine, etc.). In 1974, a similar programme was foreseen in the veterinary, phytosanitary and animal nutrition sectors[4].

2. Vertical harmonisation

An important harmonisation effort was thus undertaken in the 70s. Whilst the many measures adopted, which cannot possibly be detailed here, undoubtedly contributed to improve the legislative framework in terms of protection of human, animal and plant health, progress towards an actual common market in the food sector was nonetheless extremely slow. The harmonisation work, which implied the adoption of detailed technical texts, was often stumbling over the need to obtain unanimity amongst the

1 Council Directive of 23 October 1962 (OJ L 115, 11.11.1962, p.2645-2654).
2 Council Resolution of 12 March 1968 on Community measures to be taken in the veterinary sector (OJ C 22, 18.3.1968, p. 18–21).
3 Council Resolution of 28 May 1969 drawing up a programme for the elimination of technical barriers to trade in foodstuffs which result from disparities between the provisions laid down by Law, Regulation or Administrative Action in Member States (OJ C 76, 17.6.1969, p. 5–7).
4 Council Resolution of 22 July 1974 on the veterinary, plant health and animal feedingstuff sectors (OJ C 92, 6.8.1974, p. 2–3).

Member States (which were nine at that time). At the end of 1976, Council had only adopted five vertical Directives in the food sector (on cocoa and chocolate, sugar, honey, fruit juices and preserved milk – the so-called "breakfast Directives")[5].

Considering the very modest progress made under the program of vertical harmonisation, the Commission withdrew in 1976 a first batch of proposals (on mayonnaise and emulsified sauces, beer, ice cream, confectionary, bread), for which adoption was only a distant prospect or which had been in the meantime overtaken by technical progress after years of discussion before Council. A second series of proposals (on meat extracts, pasta, margarine, soft drinks) were withdrawn in 1979 for the same reasons.

3. The 'Cassis de Dijon' communication

The same year, on 20 February 1979, the Court handed down its judgement in Case 120/78 ('Cassis de Dijon')[6]. This Judgement would have a major impact on the harmonisation policy in the food sector notably because of the consequences which the Commission derived from it.

In its Communication concerning the consequences of the 'Cassis de Dijon' judgment[7], which it published in October 1980, the Commission indicated the conclusions in terms of policy which it was drawing from the Court's guidance. "Whereas Member States may, with respect to domestic products and in the absence of relevant Community provisions, regulate the terms on which such products are marketed, the case is different for products imported from other Member States. Any product imported from another Member State must in principle be admitted to the territory of the importing Member State if it has been lawfully produced, that is, conforms to rules and processes of manufacture that are customarily and traditionally accepted in the exporting country, and is marketed in the territory of the latter."

The Commission further drew important consequences for the work of harmonization which would "henceforth have to be directed mainly at national laws having an impact on the functioning of the common market where barriers to trade to be removed arise from national provisions which are admissible under the criteria set by the Court".

5 A number of measures had further been adopted in the veterinary and phytosanitary sectors.

6 Judgment of the Court of Justice of 20 February 1979 in Case 120/78 *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein* [1979] ECR p. 649.

7 Communication from the Commission concerning the consequences of the judgment given by the Court of Justice on 20 February 1979 in case 120/78 ('Cassis de Dijon'), OJ C 256, 3.10.1980, p. 2–3.

In practical terms, the 'Cassis de Dijon' approach marked the end of vertical harmonisation. In the following years, the Commission refrained from proposing any new measure aimed at regulating a product or a category of products. Existing vertical Directives, and notably the "breakfast Directives"[8], were however maintained and updated whenever necessary.

As it had announced, the Commission thus concentrated its efforts towards harmonising national laws having an impact on the functioning of the common market while being justified under the criteria set out by the Court, in particular the protection of public health and the information of consumers.

4. The White Paper on completing the internal market

In January 1985, the new President of the Commission, Mr Jacques Delors, forcefully declared that in order to achieve the main objective of the EEC Treaty (i.e. the creation of a single market) all internal European borders should be eliminated by the end of 1992. Therefore, in June 1985 the Commission forwarded to the European Council a White Paper on completing the internal market[9].

The Annex to the White Paper, listing all the measures which had to be adopted by 31 December 1992 in order to complete the internal market, did not cover the food sector. However, it was followed, a few months later, by a Commission Communication on food legislation[10] indicating the measures to be adopted in order to complete the internal market in the food sector.

8 Directive 1999/4/EC of the European Parliament and of the Council of 22 February 1999 relating to coffee extracts and chicory extracts (OJ L 66, 13.3.1999, p. 26); Directive 2000/36/EC of the European Parliament and of the Council of 23 June 2000 relating to cocoa and chocolate products intended for human consumption (OJ L 197, 3.8.2000, p. 19); Council Directive 2001/110/EC of 20 December 2001 relating to honey (OJ L 10, 12.1.2002, p. 47); Council Directive 2001/111/EC of 20 December 2001 relating to certain sugars intended for human consumption (OJ L 10, 12.1.2002, p. 53); Council Directive 2001/112/EC of 20 December 2001 relating to fruit juices and certain similar products intended for human consumption (OJ L 10, 12.1.2002, p. 58); Council Directive 2001/113/EC of 20 December 2001 relating to fruit jams, jellies and marmalades and sweetened chestnut purée intended for human consumption (OJ L 10, 12.1.2002, p. 67); Council Directive 2001/114/EC of 20 December 2001 relating to certain partly or wholly dehydrated preserved milk for human consumption (OJ L 15, 17.1.2002, p. 19)

9 Completing the Internal Market: White Paper from the Commission to the European Council (Milan, 28-29 June 1985), COM (85)310, June 1985.

10 Communication on food legislation – COM (85)603, November 1985.

5. The Single European Act

In the meantime, the Milan European Council (28-29 June 1985) had welcomed the programme established in the White Paper and decided, by a majority of its members, to call an intergovernmental conference with the brief of drawing up the amendments to the EEC Treaty required for the completion of the internal market. The Commission's proposals for these amendments were finalised in the form of a "Single European Act" by the Ministers for Foreign Affairs meeting in Intergovernmental Conference on 27 January 1986.

The Single European Act included three major changes to the Community decision-making process which would have a major impact on harmonisation policy, in particular in the food sector:

Firstly, it was allowing qualified majority voting in the Council, acting in cooperation with the European Parliament, where unanimity had henceforth been required.

Secondly, it was allowing the adoption of several types of measures, including regulations, for the purpose of establishing the internal market, where Directives had hitherto been the only instrument available.

Thirdly, it was allowing the legislative branch (i.e. the European Parliament and the Council) to delegate to the Commission, assisted by so called 'comitology committees' consisting of Member States' representatives, the mission of establishing and maintaining detailed and technical provisions, for the implementation of harmonisation measures adopted by Council and Parliament.

Until the Single European Act, all the measures that were adopted in the veterinary sector and in the food sector had a clear objective: to achieve the free movement of food and food products within the internal market. This was indeed the only objective allowed under Article 100 EEC (now Article 115 TFEU), the only legal basis available at the time for the purpose of the approximation of legislations.

Thus, until the late 80s, food safety was only a secondary objective for the European legislator. The adoption of the Single European Act, in 1986, marked an important change in this respect. The new Article 100a EEC introduced by the Single European Act (now Article 114 TFEU) not only allowed for the adoption by qualified majority of measures having as their object the establishment and functioning of the internal market, but it also

provided that the Commission, the Council and the Parliament should, in proposing or adopting measures concerning health, safety, environmental protection and consumer protection, aim at a "high level of protection, taking account in particular of any new development based on scientific facts". At least from thereon, it was clear that the European legislator was not only allowed to act with food safety in mind, but indeed that ensuring food safety was part of its actual mission. Nonetheless, throughout the 90s, the EU food policy remained a piecemeal effort, mainly driven by the objectives of the common agricultural policy and the establishment of the single market.

6. The food scares of the 90s

The various food scares that shattered the EU agriculture and food market in the 90s, and notably the BSE[11] crisis, mingled with consumer concerns about the use of growth-hormones and antibiotics in cattle and about GM food, clearly demonstrated the inadequacy of the EU framework for food safety.

In 1997, the Commission launched an important debate on the European food legislation and its capacity of truly meeting its objectives. The Green Paper on the general principles of food law in the European Union[12] was, on the one hand, answering a request from Parliament and Council to simplify EU food law which was scattered amongst numerous and complex legal instruments and, on the other hand, trying to address some of the concerns that had been raised during the BSE crisis. Amongst other things, the Commission was wondering whether it was appropriate to apply the same general rules to agricultural production and to the agri-food industry, despite the differences between the two sectors.

The Green Paper generated interesting debates, notably in the European Parliament. However, the Commission did not follow it up with any legislative proposal. Therefore, when Belgium and the European Union were struck by the dioxin crisis in the first half of 1999, criticism of the Commission reached new levels. Whilst the resignation of the Commission lead by Mr Jacques Santer was not directly linked to the dioxin crisis, there was little doubt that the non-transparent manner in which the Commission had handled the BSE crisis a few years earlier weighted heavily against it in mid-1999.

11 Bovine Spongiform Encephalopathy, also known as ‘mad cow disease’.
12 The General Principles of Food Law in the European Union, Commission Green Paper, COM (97) 176 final, 30 April 1997.

The various food scares that shattered the EU agriculture and food market in the 90s, mingled with consumer concerns about hormones and GMOs, clearly demonstrated the inadequacy of the EU framework for food safety. Whilst food controls were still largely in the hands of Member States, it became clear that there was an expectation in the general public that the EU institutions should have long taken over and that the BSE and dioxin crisis, notably, were as much a failure of the EU as a failure of the most concerned Member States. This was clearly on Mr Romano Prodi's mind, the designate-president of the European Commission when he addressed the European Parliament, in October 1999. "*The European public has lost confidence in both national and European food and drug regulators*" he said. "*They no longer trust their governments or the scientists. In my view, we have to take the initiative and look toward the idea of an independent European food and drug agency to help win back consumer confidence*"[13].

By then, the European Commission had already shaken up its organizational chart to create a new Directorate-General for Health and Consumers (DG SANCO)[14], to include the former Directorate-General for Consumer Policy and Consumer Health Protection (DG XXIV)[15], the Directorate for Public Health previously located in the Directorate for employment, industrial relations & social affairs (DG V), and the Food legislation service that was hitherto a part of the Directorate-General for Enterprises (DGIII).

7. The White Paper on Food Safety and Regulation (EC) 178/2002

Under the direction of Commissioners Liikanen and Byrne, the Commission promptly produced a blue-print for a "radical new approach to food safety"[16]. In sharp contrast with previous legislative programmes, the White Paper on food safety was making it clear that structural reforms were as much necessary as a legislative overhaul.

To support the newly created DG SANCO, in which the FVO[17] was to play a major part, it was proposed:

13 The idea to create the European equivalent of the US-FDA had already been discussed in the European Parliament a decade earlier (see: Raferty Report on the food industry, Doc. PE 128.325)..

14 In 2014, DG SANCO lost the Consumer Protection Directorate and became the Directorate-General for Health and Food Safety (DG SANTE).

15 DG XXIV had been created in 1997 to have the particular responsibility for consumer health. All the relevant scientific committees and responsibility for inspection and control were thus placed under the authority of the Commissioner for Consumer Policy and Health Protection. See the Commission Communication on Consumer health and food safety – COM (97) 183 final of 30 April 1997.

16 White Paper on Food Safety – COM (99)719 of 12 January 2000.

17 FVO – the Food and Veterinary Office (nowadays the Directorate F of DG SANTE) had already been established in 1997.

- to create an independent agency for risk assessment;
- to streamline procedures for the adoption of EU food safety measures by the Commission, assisted by a single committee representing the Member States; and to institutionalize information mechanisms such as the all-important Rapid Alert System for Food and Feed[18].

The Commission was further proposing a set of measures aiming at a more coherent and more integrated organisation of food safety, including:

- a global and integrated approach, governing the entire food chain;
- a clear definition of the role and responsibilities of all participants in the food chain; and
- traceability of all food and feed, and their ingredients.

The White Paper was finally advocating the need to harmonise national food control systems in the European Union, and to extend these controls to the external borders of the European Union, in order to prepare for the forthcoming enlargement of the Union. It was also recommending a permanent dialogue with consumers and business operators in order to restore mutual trust. The Annex to the White Paper was listing 84 measures which had to be adopted in order to implement the principles it was laying down.

The White Paper marks a complete shift of paradigm: EC food law had hitherto been entirely concerned with the completion or the maintenance of the internal market, but the White Paper is devoid of any such consideration and is totally devoted to guaranteeing the safety of the food chain.

There was instant and wide-spread support for the reform ideas outlined in the White Paper on food safety, which the Commission thus followed up with an appropriate proposal[19]. To their credit, Council and Parliament did not drag their feet and adopted Regulation (EC) No 178/202 in record time[20].

This Regulation includes the key elements, announced in the White Paper, which paved the way to the new food safety policy of the EU:

18 A rapid alert system for food had been operating on an informal basis since September 1979. See: DEBOYSER P., *Le droit communautaire relatif aux denrées alimentaires*, Bruxelles, E. Story-Scientia, 1989, pp. 223-231.

19 OJ C 96 E of 27.3.2001, p. 247.

20 Regulation (EC) No 178/2002 of the European Parliament and the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31 of 1.2.2002, p. 1).

- it lays down the general principles and requirements of food law (including traceability and the first ever codification of the precautionary principle);
- it establishes EFSA – the European Food Safety Authority[21], as well as the Standing Committee on the Food Chain and Animal Health (SCOFCAH); and
- it lays down new procedures in matters of food safety, including the Rapid Alert System[22], and a number of procedures to deal with emergency situation and crisis management[23].

In the White Paper the Commission had outlined a radical revision of the Union's food safety hygiene rules, under which food operators, right through the food chain, would bear primary responsibility for food safety.

In 2004, Parliament and Council adopted a package of four regulations, three of them containing the hygiene rules and the fourth one dealing with official controls .

The hygiene regulations merge, harmonise and simplify detailed and complex hygiene requirements previously contained in a number of Council Directives covering the hygiene of foodstuffs and the production and placing on the market of products of animal origin. They innovate in making a single, transparent hygiene policy applicable to all food and all food operators right through the food chain "from the farm to the fork", together with effective instruments to manage food safety and any future food crises throughout the food chain.

8. 'Smarter rules for safer food'

In 2013, the Commission proposed to Parliament and Council a package of measures to strengthen the enforcement of health and safety standards for the whole agri-food chain[24]. The proposals, presented under the label 'Smarter rules for safer food', were aiming at modernizing and simplifying the EU legislation in the areas of official controls, animal health, plant health and planting materials, cutting down almost 70 pieces of EU

21 'Authority' is actually a misnomer, for what was proposed was the classic model of an 'agency'. It seems that Commissioner David Byrne was particularly keen on the term "authority", having been involved himself in the creation of the Irish Food Authority. The « Joint Statement of the European Parliament, the Council of the EU and the European Commission on decentralised agencies » (PE-CONS 00000/2011 – C7-0000/2011) actually recommends to align names of existing agencies, particularly where this would not affect the established image of the agency, which is the case of EFSA, as the acronym would not change.

22 Better known as the RASFF – the Rapid Alert System for Food and Feed, established under Article 50-52 of Regulation (EU) No 178/2002.

23 Articles 53 and 54 of Regulation (EU) No 178/2002.

24 http://ec.europa.eu/dgs/health_consumer/pressroom/animal-plant-health_en.htm

legislation to 5 and reducing the red-tape on processes and procedures for farmers, breeders, producers, processors and distributors to make it easier for them to carry out their profession.

The provisions aiming at protecting animals against transmissible diseases, forming the new "Animal Health Law" of the EU, were adopted in March 2016.[25] They will apply from 21 April 2021

The measures aiming at protecting plants against pests, now referred to as the new "Plant Health Law" of the EU, were adopted in October 2016.[26] They came into application on 14 December 2019.

And finally, the new "Official Control Regulation" was adopted by Parliament and Council in March 2017.[27] This Regulation, and a number of implementing measures, also came into application on 14 December 2019.

9. Transparency and sustainability of the EU risk assessment of food

In 2013, the Commission decided to carry out a 'fitness check' of Regulation (EC) 178/2002, including a focus on simplification and the reduction of regulatory costs and burdens[28].

The outcome of the 'fitness check' of Regulation (EC) 178/2002, was quite positive in respect of the 'general food law' part of the Regulation. The report came to the conclusion that the general food law was "generally fit for purpose" and "in line with the vision and expectations outlined in the White Paper". Gaps and room for improvement were mainly identified in relation with the interpretation, implementation and enforcement of the secondary legislation.

The 'fitness check' also looked specially at the functioning of the RASFF and EFSA. Both were found to operate to general satisfaction. However, quite separately from the 'fitness

25 Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law'), OJ L 87 of 31.3.2016 p. 1-207.

26 Regulation (EU) 2016/2031 of the European Parliament of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council, OJ L 317, 23.11.2016, p. 4–104.

27 Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, OJ No L95 of 7.4.2017, p. 1-142.

28 Annex to Commission Communication 'Regulatory Fitness and Performance (REFIT): Results and next steps', COM (2013)685.

check', public criticism of both the RASFF and EFSA became very prominent in the wake of the finopril crisis[29] (for RASFF) and in the context of the renewal of the authorisation of glyphosate[30] (for EFSA). In its response to this uproar, the Commission reaffirmed that the RASFF was operating satisfactorily, but announced that it was considering making changes in respect of the functioning of EFSA, mostly in relation with the funding and public availability of scientific studies.

In April 2018 the European Commission tgus formally proposed to Parliament and Council a targeted revision of Regulation (EC) 178/2002, which was adopted by Parliament and Council on 20 June 2019[31], and came into application on 27 March 2021.

Regulation (EU) 2019/1381, amending Regulation (EC) 178/2002, aims at increasing the transparency of the EU risk assessment in the food chain, by:

- ensuring more transparency in the risk assessment process, by giving citizens automatic access to all studies and information submitted by industry;
- increasing the independence of studies by requiring that all commissioned studies be notified to the European Food Safety Authority;
- strengthening the governance of EFSA, by involving Member States, civil society and European Parliament in the management of the Authority; and
- developing a more comprehensive risk communication process through a general plan for risk communication to be adopted.

29 In November 2016, the Dutch Authorities were alerted by an anonymous source that fipronil (a substance used in a remedy to destroy the poultry mite) was being used in poultry farms, but failed to communicate the findings to other Member States. In July and August 2017 millions of chicken eggs were blocked from sale or withdrawn from the market in the Netherlands, Belgium, Germany and France after elevated levels of fipronil were discovered. This incident was wrongly hailed as a failure of the RASFF, whilst actually demonstrating the importance of the RASFF, and the paramount necessity for Member States to notify through the RASFF the food safety information that comes to their knowledge.

30 Glyphosate is a broad-spectrum systemic herbicide and crop desiccant. It was brought to the market for agricultural use by Monsanto in 1974 under the trade name Roundup. Farmers quickly adopted glyphosate compounds for agricultural weed control, especially after Monsanto introduced glyphosate-resistant Roundup Ready genetically modified crops, enabling farmers to kill weeds without killing their crops. It is by far the most commonly use pesticide in the world. In March 2015, the World Health Organization's International Agency for Research on Cancer (IARC) classified glyphosate as "probably carcinogenic in humans. In contrast, the European Food Safety Authority (EFSA) concluded in November 2015 that "the substance is unlikely to be genotoxic (i.e. damaging to DNA) or to pose a carcinogenic threat to humans". The WHO and FAO Joint committee on pesticide residues issued a report in 2016 stating the use of glyphosate formulations does not necessarily constitute a health risk, and giving admissible daily maximum intake limits (one milligram/kg of body weight per day) for chronic toxicity. The European Chemicals Agency (ECHA) classified glyphosate as causing serious eye damage and toxic to aquatic life, but did not find evidence implicating it as a carcinogen, a mutagen, toxic to reproduction, nor toxic to specific organs.

31 Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, OJ L 231, 6.9.2019, p. 1–28.

In it is worth noting that in March 2019, the Court of Justice had already overturned an EFSA decision to withhold access to documents from industry used for the assessment of glyphosate, the already mentioned active substance in Monsanto's Roundup pesticide, during the process for the renewal of its authorization.[32]

10. The European Green Deal – 'From Farm to Fork'

It has been estimated that nearly 800 million people in the world don't have enough food to eat[33] and that global food production would need to increase by 60% to feed the more than 9 billion people expected to live on our planet by 2050. Despite the fact that natural resources are diminishing, roughly one third of food produced in the world for human consumption is wasted. In the EU alone, around 88 million tonnes of food waste are generated annually with associated costs estimated at 143 billion euros.[34]

Climate change poses an additional critical threat to global food production, and in turn, food production and consumption have a profound effect on greenhouse gas emissions and our ability to keep global temperatures at safe levels.

It therefore did not come as a surprise that the European Green Deal agenda, which was meant to be the signature project of the Commission lead by Ms Ursula von der Leyen before Covid-19 struck, included an important component aiming at supporting European farmers with a new "Farm to Fork Strategy" on sustainable food along the whole value chain.

The European Green Deal is a response to climate change and environmental-related challenges. It is a new growth strategy that aims to transform the EU into a fair and prosperous society, with a modern, resource-efficient and competitive economy where there are no net emissions of greenhouse gases in 2050 and where economic growth is decoupled from resource use. It was outlined in a Communication from the Commission published in December 2019.[35]

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32 Judgment of the General Court (Eighth Chamber) of 7 March 2019 in Case T-329/17 - Hautala and Others v EFSA and Judgment of the General Court (Eighth Chamber) of 7 March 2019 in Case T-716/14 - Tweedale v EFSA.

33 https://www.awarenessdays.com/awareness-days-calendar/world-hunger-day-2020/

34 "Estimates of European food waste levels", Åsa Stenmarck (IVL), Carl Jensen (IVL), Tom Quested (WRAP), FUSIONS, European Commission (FP7), Coordination and Support Action – CSA.

35 "The European Green Deal", Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, (2019) 640 final, Brussels, 11.12.2019.

The Communication presented an initial roadmap of the key policies and measures needed to achieve the European Green Deal. In the agri-food sector, the Communication was envisionung to make European food, already "famous for being safe, nutritious and of high quality" the new "global standard for sustainability". It noted that although the transition to more sustainable systems has started, feeding a fast-growing world population remains a challenge under current production patterns. Food production still results in air, water and soil pollution, contributes to the loss of biodiversity and climate change, and consumes excessive amounts of natural resources, while an important part of food is wasted. At the same time, low quality diets contribute to obesity and diseases such as cancer."

The Communication on a 'Farm to Fork' Strategy, which was presented by the Commission in Spring 2020[36], aims to accelerate the EU's transition to a sustainable food system that should:

- have a neutral or positive environmental impact,
- help to mitigate climate change and adapt to its impacts,
- reverse the loss of biodiversity,
- ensure food security, nutrition and public health, making sure that everyone has access to sufficient, safe, nutritious, sustainable food, and
- preserve affordability of food while generating fairer economic returns, fostering competitiveness of the EU supply sector and promoting fair trade.

The strategy sets out both regulatory and non-regulatory initiatives, with the common agricultural and fisheries policies as key tools to support a just transition.

The Communication was accompanied by an action plan[37] that foresaw 27 legislative and non-legislative measures to be adopted or submitted to Council and Parliament over a timespan running from 2020 to 2024. This action plan actually included a number of elements that had been on the agri-food policy agenda for a while, from the use of pesticides to food labelling to waste management, as well as aspects stirred up by the

36 "A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system", Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, COM (2020) 381 final, Brussels, 20.5.2020.

37 COM (2020) 381 final, Annex.

ongoing review of the EU food safety system. These elements were complemented by new concerns for food security, which had hithertro been taken for granted in the EU except for the most deprived, the environmental impact of food production and supply, and food affordability in a fair economic environment.

One of the flag initiatives announced in the Farm to Fork Strategy is a proposal for a legislative framework for sustainable food systems (FSFS) which was expected to be adopted by the Commission by the end of 2023, but has yet to materialize. The purpose would be to accelerate and make the transition to more sustainable food systems easier, to reinforce policy coherence at both EU and national level, to strenghthen the resilience of food safety systems and to promote sustainability in all food-related policies.

A number of aspects of the Farm to Fork strategy have generated concerns amongst stakeholders, notably farmers, reinforing their latent discomfort with the ongoing reform of the EU common agricultural policy. With this in mind, the Commission has launched, in January 2024, a Strategic Dialogue on the Future of Agriculture[38] that will bring together farmers, local food store owners, European retailers, consumer organisations, environmental groups, financial institutions, and academia to share ideas and listen to farmers' needs. In February 2024, the Commissioçn presented[39] "options to reduce the administrative burden on EU farmers, and is working on actions to improve the position of farmers in the food chain and to improve the enforcement against unfair trading practices."

38 https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/european-green-deal/agriculture-and-green-deal/strategic-dialogue-future-eu-agriculture_en

39 https://ec.europa.eu/commission/presscorner/detail/en/IP_24_1002

Chapter 2
General principles of food law

Before the adoption of Regulation (EC) No 178/2002, EU food law was made of a coherent but disperse body of legislations: the general objectives of EU food law were not spelled out, the main terms used were nowhere defined, and the general principles of food law were not expressed anywhere. One of the main purposes of Regulation (EC) No 178/2002, next to the setting up of EFSA and the reform of procedures, was to follow upon the discussions around the 1997 Green Paper[40] and to lay down in legislation the general principles of food law in the EU. Chapter II of Regulation (EC) No 178/2002 is entitled "General Food Law" and contains four sections:

- Section 1 - General principles of food law,
- Section 2 - Principles of transparency,
- Section 3 - General obligations of food trade, and
- Section 4 - General requirements of food law.

Sections 1 to 3 regroup obligations addressed to authorities and Section 4 deals with requirements imposed upon food business operators. The separation between Section 1 and 2 does not make much sense[41] and both are thus covered under the present Chapter 2 (General principles of food law), whilst Section 3 is covered under Chapter 3 (General obligations of food trade) and Section 4 is dealt with in Chapter 4 (General requirements of food law).

11. Objectives

Regulation (EC) No 178/2002 provides[42] that food law shall pursue one or more of the general objectives of:

- a high level of protection of human life and health, and
- the protection of consumers' interests, including fair practices in food trade,

taking account of, where appropriate, the protection of:

40 See above No11 and footnote 12.
41 Section 1 is said, in Article 4(2), to contain the rules which authorities should follow when food law measures are taken, but the Principles of transparency laid down in Section 2 are also relevant in such circumstances and might as well have been included in Section 1.
42 Article 5(1).

- animal health and welfare,
- plant health and
- the environment.

This is a very modern definition of the objectives of food law: references to "consumers' interests" and "the environment" were unheard of as legitimate objectives for food legislation until the adoption of Regulation (EC) No 178/2002.

The Regulation further adds[43], almost as an afterthought[44], that food law shall aim to achieve the free movement of food and feed in the European Union. In this respect, Regulation (EC) No 178 is institutionalising the change of paradigm that EU food law underwent in the White Paper on Food Safety. Hitherto, the primary objective of EU food law had been to harmonise national legislations or to contribute to the completion of the single market. From the White Paper onwards, the main objectives are clearly food safety and the consumer interest, and the free movement of food and feed has become a secondary objective[45].

12. Scope

The respective scopes of Regulation (EC) No 178/202 and of Chapter II – "General Food Law" are defined separately[46] but they are largely similar: they both relate to all stages of production, processing and distribution of food and feed[47].

In addition, the Regulation does not apply to primary production[48] for private domestic use or to the domestic preparation, handling or storage of food for private domestic consumption[49].

13. Definitions

The definitions laid down in Regulation (EC) No 178/2002[50] do not technically form part of the Chapter on general food law, as they are meant only for the purpose of Regulation (EC) 178/2002. However, these definitions are systematically referred to by all

43 Article 5(2).
44 And possibly to justify the choice or Article 95 TEEC (Article 114 TFEU) as the main legal basis of the Regulation.
45 In this respect, see also the changing role of EFSA, hereunder at No 22.
46 Article 1(3) and Article 4(1) respectively.
47 For the definition of 'stages of production, processing and distribution' see Article 3(16).
48 For the definition of 'primary production' see Article 3(17).
49 Article 1(3).
50 Article 2 and 3.

subsequent legislation and can therefore be regarded as belonging to broader the general food law.

The most important definition is that of "food" (or "foodstuff", as they used to be called under previous legislation [51]), which means: "*any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans*"[52].

Just as important as this definition is the positive list of products which are included in the definition, and the negative list of those who are not.

Drinks, chewing gum, water and other substances "*intentionally incorporated into the food during its manufacture, preparation or treatment*"[53] are in the positive list. Thus, in contrast with previous legislation[54], ingredients are now included in the definition of food. In particular, food additives are food, but residues and contaminants are not: the former are intentionally added to food, but the latter are not.

Amongst the products which are not included in the definition of food are: live animals unless they are prepared for placing on the market for human consumption (e.g. oysters), plants prior to harvesting, medicinal products within the meaning of the pharmaceutical legislation, cosmetics within the meaning of the cosmetics legislation, tobacco and tobacco products, narcotic and psychotropic substances, and – as indicated above, residues and contaminants[55].

An important consequence of the wording of the negative list is that the borderline between a food and a medicinal product is to be found in the pharmaceutical legislation. Under the combination of Regulation ((EC) No 178/2002 and Directive 2001/83/EC[56], "*any substance or combination of substances presented as having properties for treating or preventing disease in human beings*" is thus a medicinal product, not a food. As the

51 See for instance Directive 2000/13/EC of the European Parliament and the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (OJ L 109 of 6.5.2000, p. 29).
52 Article 2, first *alinea*.
53 Article 2, second *alinea*.
54 e.g. Directive 2000/13/EC.
55 Article 2, third *alinea*.
56 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

Court of Justice put it in a judgment from 2005[57], "*only the provisions of Community law specific to medicinal products apply to a product which satisfies equally well the conditions for classification as a foodstuff and the conditions for classification as a medicinal product*". This construction has wide-ranging consequences which are beyond the purpose of this commentary.

14. Risk analysis

The principles for risk analysis are laid down in a *Codex* document[58]. Risk Analysis is described in this document as a process consisting of three components: risk assessment, risk management, and risk communication[59].

It is further specified that risk analysis should be:

- applied consistently and in a non-discriminatory manner to issues of national food control and food trade[60];
- open, transparent and documented; and
- evaluated and reviewed as appropriate in the light of newly generated scientific data.

In the EU, Regulation (EC) No 178/2002 provides that "in order to achieve the general objective of a high level of protection of human health and life, food law shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure"[61]. Indeed, food law is not always about food safety: labelling and nutrition for instances, whilst sometimes very important for food safety (e.g. labelling of allergens), are mainly laid down for the purpose of consumer information and, as such, not based on risk analysis.

One should not underestimate the importance of laying down the principles of risk analysis in the EU legislation. This indeed allows any interested party to challenge in the EU courts any decision adopted, by the EU itself or by a national authority, in breach of these principles. Previously, the main redress would have been through… the WTO.

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57 Joined cases C-211/03, C-299/03 and C-316/03 to C-318/03 HLH Warenvertrieb and Orthica [2005] ECR I – 5230.

58 "Working Principles for Risk Analysis for Food Safety for Application by Governments" http://www.codexalimentarius.net/input/download/.../CXG_062e.pdf. This document is based on another Codex document: the "Work Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius".

59 The definition of risk analysis is laid own in Regulation (EC) No 178/2002 under Article 3(10).

60 Under Regulation (EC) No 178/2002, see "General obligations of food trade" and below, Chapter IV.

61 Article 6(1).

According to the *Codex* Working Principles, there should a functional separation of risk assessment and risk management to the degree practicable, in order to:

- ensure the scientific integrity of the risk assessment,
- to avoid confusion over the functions to be performed by risk assessors and risk managers and
- to reduce any conflict of interest.

In the European Union, this has led to risk assessment being entrusted to an independent agency (EFSA)[62]. Risk management, in contrast, is in the hands of the European Institutions (European Commission, Parliament and Council) and the Member States.

In the *Codex* Working Principles, precaution is said to be an inherent element of risk analysis and, while this is mentioned in connection of uncertainty in risk assessment and risk management, there is little guidance provided on how to proceed in case of uncertainty and notably scientific uncertainty. The EU has gone much further in this respect, under the heading "precautionary principle"[63].

15. Risk assessment

The first component of risk analysis – risk assessment - is a scientifically based process consisting of the following steps:

- hazard identification - the identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods;
- hazard characterization - the qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents which may be present in food;
- exposure assessment - the qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant;
- risk characterization - the qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or

62 The European Food Safety Authority, established by Regulation (EC) No 178/2002. See above, No **Erreur ! Source du renvoi introuvable.** and note 21.

63 See Article 7 of Regulation (EC) No 178/2002 and below, No 17.

potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment.

Because of the importance of risk assessment in the risk analysis process, it is important to guarantee the independence of experts. Three aspects of independence are highlighted in the *Codex* Working Principles:

- Conflict of interests - Experts involved in risk assessment including government officials and experts from outside government should be objective in their scientific work and not be subject to any conflict of interest that may compromise the integrity of the assessment.
- Identity - Information on the identities of these experts, their individual expertise and their professional experience should be publicly available, subject to national considerations.
- Selection - These experts should be selected in a transparent manner on the basis of their expertise and their independence with regard to the interests involved, including disclosure of conflicts of interest in connection with risk assessment.

In line with these principles, Regulation (EC) No 178/2002 provides [64] that "risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner". In the EU, the independence of staff and experts is actually under constant scrutiny by the media and the European Parliament, and therefore taken very seriously[65].

16. Risk management

The second component of risk analysis – risk management - is the process, distinct from risk assessment, of weighing policy alternatives in consultation with all interested parties considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices and, if needed, selecting appropriate prevention and control options.

The *Codex* Working Principles provide that risk management decisions should be based on *Codex* standards and related texts, as well as the result of risk assessment, taking into

64 Article 6(2).
65 In particular in EFSA.

account, where appropriate, other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade.

In the EU, these principles are the subject of much more detailed provisions in respect of taking into account:

- international standards (below, *a)*),
- the result of risk assessment - (below, *b)*),
- other legitimate factors (below, *c)*), and
- the precautionary principle (below, No 17).

a) Taking into account international standards

Where the *Codex* Working Principles provide that "risk management decisions should be based on *Codex* standards and related texts", Regulation (EC) No 178/2002 goes further by stipulating that it is not only existing international standards, but also those which the completion is imminent, which shall be taken into consideration[66] in the development or adaptation of food law. This presumably refers not just to *Codex* standards but also to IPPC[67] and OIE[68] standards.

An exception is however foreseen for cases:

- where the relevant international standard or part of it would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives of food law, or
- where there is a scientific justification, or
- where aligning on the relevant international standard would result in a different level of protection from the one determined as appropriate in the Community.

b) Taking into account the result of risk assessment

In line with the *Codex* Working Principles, Regulation (EC) No 178/2002 provides[69] that "risk management shall take into account the results of risk assessment, and in particular,

66 This principle is somehow misplaced in Article 5(3).

67 The International Plant Protection Convention (IPPC) is an international plant health agreement, established in 1952, that aims to protect cultivated and wild plants by preventing the introduction and spread of pests. See also, here under at No 27.

68 The *Office International des Epizooties* (OIE) is the intergovernmental organisation responsible for improving animal health worldwide. It was created through the international Agreement signed on January 25th 1924. In May 2003 the Office became the World Organisation for Animal Health but kept its historical acronym OIE. See also, here under at No 27.

69 Article 6(3).

the opinions of [EFSA], other factors legitimate to the matter under consideration and the precautionary principle […]".

It is clear from this wording that risk management measures can depart from the outcome of risk assessment. Firstly, the wording used ("take into account") in itself suggest that there is no obligation on risk managers to follow the risk assessors. Secondly, the result of risk assessment is placed at the same level as other legitimate factors and as the precautionary principle, as elements which must be taken into account when adopting risk management measures.

However, it can be reasonably expected that where risk managers are deviating from the result of risk assessment, their decision would fully motivated.

c) Taking into account other legitimate factors

Science is a necessary basis for both risk assessment and risk management, but it is rarely a sufficient basis in itself. Actually, scientists themselves have values and risk assessment is often based on both scientific and non-scientific considerations. It is therefore only natural that risk managers would also base their decisions on other factors than science alone.

This is recognized in the *Codex* Working Principles, which provide that risk management "decisions should be based on risk assessment […] taking into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade […]"[70]. This formulation is already quite restrictive, as it only recognizes "the health protection of consumers" and "the promotion of fair trade practices". In addition, reference is made to Appendix III[71] to the *Codex* Manual of Procedure, which lays down criteria for the consideration of the other legitimate factors. These are narrowing even further the potential for deviating from risk assessment when adopting risk management decisions.

As one could expect, the EU institutions have not felt the same urge to restrict the range of "other factors legitimate to the matter under consideration" which risk managers may take into account when taking decisions. Whilst the text of Regulation (EC) 178/2002[72]

70 Ibid. note 39, at No 32.
71 Appendix III: Statements of Principle on the Role of Science in the Codex Decision-Making Process and the Extent to which other Factors are Taken into Account.
72 Article 6(3) of Regulation (EC) No 1787/2002.

does not place any restriction on the kind of "other legitimate factors" which may be taken into consideration, the preamble[73] indicates that the other legitimate factors include: "societal, economic, traditional, ethical and environmental factors and the feasibility of controls".

17. Precautionary principle

Risk managers are thus dependent on risk assessment and on the scientific input on which it is based. The globalisation of the food market and the legal framework that WTO rules provide for it have only reinforced the case for providing a science base to decisions in matters of food safety as these inevitably impact on trade.

However, as scientists themselves would admit, science does not always have an immediate and consensual answer to all questions. Firstly, new risks often emerge, or new circumstances develop, in such a manner that the scientific community has not yet had, materially, the possibility to pronounce on the importance or the acuity of a given risk. Secondly, it is not unusual, as new risks emerge, that scientists are struggling to agree among themselves on the potential danger for mankind. In this respect, food safety is not different from any other sector where science is crucial for the assessment of risks.

Despite the clear expression of the precautionary in matters of food safety under Regulation (EC) No 178/202[74], the principle is very often misunderstood or misquoted and its application is frequently called for out of context, in particular by NGOs, the press or politicians. A full analysis and explanation of the precautionary principle is therefore in order.

a) The precautionary principle in EU environmental law

The problem is well known in environmental law and it is indeed in this area that the German doctrine has for the first formulated the "precautionary principle" (*Vorsorgeprinzip)* which underpins a combination of vigilance concepts and protection plans. This principle was introduced in a number of international rules in the environment area, such as the 1992 Rio Declaration on Environment and Development[75]

73 Recital 19.
74 See Article 7 and above under d).
75 See: Principle 15 – "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

Whilst the Convention on Biological Diversity[76] does not mention the precautionary principle, its additional protocol – the Cartagena Protocol on Biosafety[77] - expressly refers to it, by providing that its objective must be pursued "in accordance with the precautionary approach contained in Principle 15 of the Rio Declaration"[78]. In addition, the Protocol provides that "lack of scientific certainty due to insufficient relevant scientific information and knowledge […] shall not prevent a Party from taking a decision […] in order to avoid or minimize […] potential adverse effects"[79].

In the legal order of the European Union, the introduction of the precautionary principle had to await the adoption of the Maastricht Treaty: Article 174(2) TEC[80] provides that the EU environment policy is based, amongst other, on the precautionary principle. However, it is worth noting that Article 174(2) does not define the precautionary principle or the manner in which it operates[81].

b) The precautionary principle in the WTO system

In the WTO system, reference is made to the precautionary system, albeit implicitly, in the Agreement on Sanitary and Phytosanitary measures (SPS)[82]. The Agreement indeed provides that "in cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members"[83]. However, it is also stated that "in such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or

76 The Convention was opened for signature on 5 June 1992 at the United Nations Conference on Environment and Development (the Rio "Earth Summit") and entered into force on 29 December 1993. http://www.cbd.int/convention/text/

77 Cartagena Protocol on Biosafety to the Convention on Biological Diversity is an international agreement which aims to ensure the safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health. It was adopted on 29 January 2000 and entered into force on 11 September 2003. http://bch.cbd.int/protocol/

78 Article 1 of the Protocol.

79 Article 10(6).

80 Nowadays: Article 191(2) TFEU.

81 See: De Sadeleer N., The Precautionary Principle in European Community Health and Environmental Law: Sword or Shield for the Nordic Countries, in De Sadeleer N. ed., *Implementing the Precautionary Principle*, London, 2008.

82 http://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm

83 Article 5(7) first sentence.

phytosanitary measure accordingly within a reasonable period of time"[84]. This probably explains why they have been so few references to this provision under the WTO Dispute Resolution Mechanism[85].

In the "Hormones case"[86], the European Union was actually not basing its defence on Article 5.7 SPS, presumably because it did not consider that its ban on the marketing of beef meat treated with hormones was based on a demonstrated risk, and not on scientific uncertainty. There was however an important discussion about the mere existence of the precautionary principle in the proceedings before the Appellate Body[87].

The basic submission of the European Communities was that the precautionary principle was, or had become, "a general customary rule of international law" or at least "a general principle of law". It meant, in the view of the European Communities, that it was not necessary for all scientists around the world to agree on the "possibility and magnitude" of the risk, nor for all or most of the WTO Members to perceive and evaluate the risk in the same way[88].

The United States, on the other hand, did not consider that the precautionary principle represented customary international law and suggested it was more an "approach" than a "principle". Canada, too, took the view that the precautionary principle had not yet been incorporated into the corpus of public international law; however, it conceded that the "precautionary approach" or "concept" was "an emerging principle of law"[89].

The Appellate Body exerted much… caution in its Report, noting that "*the status of the precautionary principle in international law continues to be the subject of debate among academics, law practitioners, regulators and judges. The precautionary principle is regarded by some as having crystallized into a general principle of customary international environmental law. Whether it has been widely accepted by Members as a principle of general or customary international law appears less than clear. We consider, however, that it is unnecessary, and probably imprudent, for the Appellate Body in this appeal to take a position on this important, but abstract, question. We note […] that the*

84 Article 5(7) seconde sentence.
85 The Dispute Resolution Mechanism is laid down in Chapter II.
86 WT/DS26/R/USA and WT/DS48/R/CAN.
87 WT/DS26/AB/R and WT/DS48/AB/R.
88 *Ibid*. at No 121.
89 *Ibid*. at No 122.

precautionary principle, at least outside the field of international environmental law, still awaits authoritative formulation."[90]

Furthermore, the Appellate Body made an all-important general interpretative ruling that the SPS Agreement allocates the evidentiary burden to the party (here: the U.S. and Canada) claiming that an SPS measure adopted by another party (here: the European Communities) is inconsistent with the obligations assumed under the SPS Agreement. It is only after such a prima facie determination had been made that the onus may be shifted to the defending party to bring forward evidence and arguments to disprove the complaining party's claim. The Appellate Body also ruled that the fact that a Member's measure is not based on an international standard in accordance with Article 3(1) SPS does not mean that the burden is on that Member to show that its SPS measure is consistent with Article 3(3) SPS.[91]

c) The precautionary principle in the case-law of the European Court of Justice

Within the European Union, it can be argued that some of the developments under the "Cassis de Dijon" case-law of the Court of Justice are tantamount to an empirical application of the precautionary principle. For instances, in a series of judgments relating to the addition of vitamins and minerals to food[92], the Court held that "*where it is shown that uncertainties continue to exist in the current state of scientific research* […] *Community law does not […], in principle, preclude a Member State from prohibiting, save for prior authorisation"* the marketing of the foodstuffs concerned.

The Court had already made an important step towards recognizing the precautionary principle in matters of food safety in a judgment of 1998 concerning bovine spongiform encephalopathy (BSE)[93]. In this case, the United Kingdom was seeking the annulment of a Commission decision prohibiting the intra-Community trade in beef and bovine products originating in the United Kingdom. The Court indicated that "*where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks*

90 *Ibid*. at No 123.
91 *Ibid*. at No 109.
92 Case 174/82 *Sandoz* [1983] ECR 2445; case 227/82 *Van Bennekom* [1983] ECR 3883; Case C-192-01 *Commission v Denmark* [2003] ECR I-9693; and Case C-24/00 *Commission v France* [2004] ECR II.
93 Case C-180/96 *United Kingdom v Commission* [1998] ECR I-2265; see also case C-157/96, *The Queen v Ministry of Agriculture, Fisheries and Food* [1998] ECR I-2211.

become fully apparent". This statement of the Court can be regarded as the judicial definition of the precautionary principle[94]. In the same judgment, the Court further noted that such measures would only be questionable if it had been demonstrated that they were manifestly inappropriate and disproportionate with regard to the objective being pursued. In addition, the Court laid stress on the fact that "*the contested decision was adopted as an emergency measure, temporarily banning exports*" and that the Commission had recognisded in its decision "*the need to review the contested decision following an overall examination of the situation*". Without actually mentioning the term "precaution" in its judgment, the Court had actually both affirmed and delineated the precautionary principle.

Further guidance was then provided, in 2002, by the Court of First Instance in the *Artegodan* case[95]. According to the Court of First Instance, the scope of application of the precautionary principle has to be extended to all areas of EU action, with a view to ensuring an increased level of protection of health, the environment and consumer safety. This extension is justified by the requirements to pursue an increased level of consumer (Article 153 TEC), environmental (Articles 6 and 174 TCE), and health (Articles 3 and 152 TEC) protection. As the Court of First Instance explained, "*since the Community institutions are responsible, in all their sphere of activity, for the protection of public health, safety and the environment, the precautionary principle can be regarded as an autonomous principle stemming from the above mentioned Treaty provisions"*.

In a subsequent judgment of 2004, the Court of Justice itself, referring to its own, above-mentioned judgments concerning the addition of vitamins and nutrients to food, clarified that, where Member States take restrictive measures for the protection of human health in a context of scientific uncertainty, they are actually acting "*in accordance with the precautionary principle*"[96].

d) The precautionary principle in the 2000 Commission Communication

In the meantime (February 2000), the Commission had published a Communication[97] with a view to informing all interested parties of the manner in which it intended to apply the precautionary principle.

94 De Sadeleer N., *op. cit*.
95 Joined cases 7-74/00, T-76/00, T-83/00 to T-85/00, T-132/00 and T-141/00 *Artegodan* 2002 [ECR] Page II-04945.
96 Case C-41/02, *Commission v Netherlands* [2004] ECR, paragraph 44.
97 Communication from the Commission of 2 February 2000, COM (2000) 1 final.

The Commission had indeed identified that the precautionary principle was evolving in different policy areas in such a manner that the principle itself was becoming misunderstood, leading to potential intentional or unintentional abuse.

The Communication therefore described the use of the precautionary principle in a range of policy areas, placing it within a structured approach to the analysis of risk, and in particular the management of risk. It also established guidelines for the application of the precautionary principle in order to build a common understanding of how to assess, appraise, manage, and communicate risk where science is not yet fully able to evaluate it.

The Communication further laid down, within its guidelines, the checks necessary to avoid inappropriate use of the principle and to prevent it being used as a disguised form of trade protectionism.

e) The precautionary principle in Regulation (EC) No 178/2002

However useful the guidance provided by the Communication, it did not address a number of uncertainties, notably about the application of the precautionary principle by the Member States, as this aspect was not dealt with in the Communication.

Any remaining uncertainties were removed, at least in the field of food law, by the adoption of Regulation (EC) No 178/202. In a hitherto totally unseen manner, whether in the EU or anywhere else, Article 7 of the Regulation elevates the precautionary principle to a general principle of food law.

The first paragraph of Article 7 provides that:

- *in specific circumstances where,*
- *following an assessment of available information,*
- *the possibility of harmful effects on health is identified*
- *but scientific uncertainty persists,*
- *provisional risk management measures*
- *necessary to ensure the high level of health protection chosen in the Community*
- *may be adopted,*
- *pending further scientific information for a more comprehensive risk assessment.*

The second paragraph of Article 7 lays down two sets of limitations:

Measures adopted on the basis of paragraph 1

- *shall be proportionate and*
- *no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community,*
- *regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration.*

The measures shall be reviewed within a reasonable period of time, depending:

- *on the nature of the risk to life or health identified and*
- *the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.*

18. Risk communication

Communication, by an authority, is the discipline of informing, guiding and motivating individuals, institutional and public groups, about any issue under the competence of the said authority.

Good communication is a two-way process; it is about imparting as well as receiving information. Indeed, there can be no good communication without accurate information, which implies the collection, collation and analysis of reliable data.

Risk communication – the third component of risk analysis – is the interactive exchange of information and opinions throughout the risk analysis process, concerning: risk, risk-related factors, and risk perceptions. This exchange should take place among: risk assessors, risk managers, consumers, industry, the academic community, and other interested parties. It should include the explanation of risk assessment findings, and the basis of risk management decisions[98].

The objective of risk communication is to promote the appropriate involvement of all interested parties in the risk analysis process, and ultimately to foster public trust and confidence.

The greatest challenge in risk communication is the information to the public during crisis or emergency situations: this is when communication is the most needed but also the most

98 Article 3(13) of Regulation (EC) No 178/2002.

difficult, giving the often incomplete information available and the time constraints. It is essential, in crisis or emergency situations:

- to communicate early, and thereafter regularly;
- to avoid speculation, and provide confirmed information only
- to avoid either denying or underplaying the crisis, or exaggerating the risk and alarming unnecessarily the public;
- to provide authoritative and reliable information only, which does not exclude the admission of uncertainty or doubt.

The controversy surrounding the extension of the authorization of the pesticide glyphosate, in the last quarter of 2017, as clearly shown that if it is to be effective, risk communication must go beyond information: it is henceforth obvious that both risk assessors (EFSA in this case) and risk managers (the Commission) must engage in actual dialogue with consumers and the public at large if they want to convince them about the objectiveness and science base of their assessments and decisions.

19. Protection of consumers' interest

The protection of consumers' interests is elevated by Regulation (EC) No 178/2002 to a 'general principle of food law', reflecting the already mentioned[99] inclusion of the protection of consumers interests in the general objectives of food law.

Article 8 spells out this objective both in a positive and in a negative manner. Firstly, it is indicated that food law "*shall provide a basis for consumers to make informed choices in relation to the foods they consume*". Secondly, it is prohibiting any practice "*which may mislead the consumer"*, such as *"fraudulent or deceptive practices"* and "*the adulteration of food*".

The Commission proposal also included, as a second paragraph, a more detailed provision concerning the labelling, advertising and presentation of food, but this provision has been moved by Council to the 'requirements of food law', to become Article 16 of the Regulation[100].

99 Above, No 11.
100 A hint is given in Article 8 which has a 8(1) but no 8(2)!

20. Principles of transparency

Articles 9 and 10, forming Section 2 of Chapter II ("General Food Law") of Regulation (EC) No 178 202, contain the principles of transparency of EU food law.

Article 9, which requires an "*open and transparent public consultation, directly or through representative bodies, during the preparation, evaluation and revision of food law, except where the urgency of the matter does not allow it*" is pretty mundane in today's world.

Article 10 is a let-down insofar as it refers to access to documents, which is only mentioned *en passant*[101], whereby the access to document held by food safety authorities, including the European Food Safety Authority (EFSA), is governed by the general provisions applicable in the matter[102]. Access to documents is an increasingly important feature in the activities of the European Medicines Agency (EMA) and EFSA. Both agencies have recently been facing legal challenges aiming either at preventing them from disclosing information[103] or, on the contrary, at forcing them to publish information that they meant to protect.[104]

One defining moment in respect of the transparency of decisions in matters of food safety was the already alluded to controversy on the extension of the authorization of glyphosate.[105] The Regulation soon to be formally adopted by Parliament and Council on the transparency and sustainability of the risk assessment in the food chain will introduce a change in paradigm in terms of transparency in matters of food safety.[106]

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101 The first draft of the Commission proposal that lead to the adoption of Regulation (EC) No 178/2002 contained provisions on access to document inspired by the so-called Aarhus Convention (the United Nations Economic Commission for Europe (UNECE) Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters). This part of the draft was slashed by the Commission's Legal Service and Secretariat General.

102 As far as EFSA is concerned, reference is made to Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ 2001 L 145, p. 43).

103 Case T-44/13, AbbVie v. EMA; Case T-44/13 R AbbVie v EMA; Case T-73/13, InterMune v EMA and Case C-390/13 P(R) EMA v InterMune.

104 Case T-214/11, Monsanto v. EFSA. EFSA had refused to disclose the names of experts who had submitted comments on a guidance document relating to the scientific documents to be included in applications for authorisation to place plant protection products and the active substances contained in those products on the market. The General Court ruled that EFSA was entitled to deny access to this information in order to protect the privacy and the integrity of the individuals concerned.

105 Above, No 18 in fine.

106 See No 10 above and footnote No 37.

More useful is the obligation imposed on public authorities (whether at Union or Member State level) to take appropriate steps to inform the general public whenever there are reasons to suspect that a food may present a risk for human health. Such information must identify "to the fullest extent possible" the food concerned, the risk that it may present and the measures taken to deal with it. The Court of Justice has interpreted this provision as "*not precluding national legislation allowing information to be issued to the public mentioning the name of a food and the name or trade name of the food manufacturer, processor or distributor, in a case where that food, though not injurious to health, is unfit for human consumption*".[107]

These provisions are complemented by the second sentence of Article 17(2) which is arguably misplaced in the 'general requirements of food law', the part of Regulation (EC) 178/2002 dealing with the obligations incumbent on food business operators, which are the subject of the next chapter of this commentary.

107 Case C-636/11 Karl Berger v Freistaat Bayern.

Chapter 3
General obligations of food trade

The provisions on General Food Law of Regulation (EC) No 178/2002 contain so-called "General obligations of food trade", notably those related to the observance of international standards, and those relating to the treatment of products which are either imported into the EU or exported from the EU. These provisions actually complete and reinforce the obligations of food trade which result from the international agreements that the EU and its Member States have signed and ratified or entered into.

Whilst very few states around the world have introduced their international obligations of food trade as general principles under their internal legal system, it is appropriate and very useful for economic operators that the EU has done so. Indeed, those obligations of food trade which have been incorporated in the EU general food law can be sanctioned under the EU internal legal system, as opposed to the food trade obligations which result from the participation of the EU in the WTO system which can only be enforced through the lengthy and cumbersome WTO adjudication system, which is, in addition, reserved to WTO members and thus not available to economic operators.

21. EU food trade

With a turnover of over € 1 trillion and an added value of more than € 200 billion the food and drink industry is the largest manufacturing sector in the EU. It employs over 4 million workers, in nearly 300.000 companies, 99 % of which are small and medium companies if not micro-enterprises. It is also a sector into which huge investments have been made over the last decades, with the aim to ensure food safety, to improve food quality, and to generate consumer confidence.

For many years, the EU has been the world's largest importer of agri-food products, and in particular of commodities for which there is either little or no EU production, such as for tea, coffee, cocoa, spices and tropical fruits, or because EU production falls short of demand, as is the case for fish and animal feed. These raw materials largely supply the EU food processing industry which goes on to produce high value goods for domestic consumption or for export to third countries.

The value of EU exports of agri-food has been continuously increasing since 2005, at an average pace of 8% per year and outpacing growth of non-agricultural exports. In 2010, the EU became for the first time a net exporter of agri-food products and it has since consistently run a trade surplus. In 2013, the EU also became the largest global exporter of agri-food products; more than half of the EU exports of agri-food consist of prepared foodstuffs. In 2015, EU agri-food exports totalled 129 billion euros, with a growth of 6% compared to 2014, despite the significant export losses to one of its most important export markets, following the import ban imposed by the Russian authorities on a large number of the EU products, notably meat, dairy products and fruit and vegetables. In the same year, 2015, EU agri-food imports totalled 113 billion euros, also showing a rising trend compared to the previous year (+ 9%). Hence, the trade balance showed a positive surplus of 16 billion euros. Agri-food trade represents about 7% of the EU trade value, and accounts for 25% of the positive EU trade balance.

22. The EU trade policy

Trade relations with non-EU countries are an exclusive competence of the EU. Thus, only the EU, and not individual Member States, can legislate on trade matters and conclude international trade agreements. By acting together as one, EU Member States have greater leverage when making trade deals with other countries or discussing trade issues on the global scene. This, in turn, allows the EU to project its rules and values in and to shape globalization, especially on issues like human rights, working conditions and environmental protection.[108]

The scope of the EU's exclusive competence covers not just trade in goods, but also: services, commercial aspects of intellectual property, public procurements and foreign direct investment. In addition, the EU also has exclusive competences in related areas such as transport and capital movements.

EU trade agreements help to do that in two ways. Trade agreements enable European businesses to compete more effectively abroad and export more to countries and regions outside the EU. This increase in trade in turn allows the economy to grow, meaning that more jobs are created. It also gives consumers a wider choice of products at lower prices.

108 For details, see: http://ec.europa.eu/trade/policy/policy-making/

The EU trade policy – also known as the EU "common commercial policy" – is laid down in Article 207 of the Treaty on the Functioning of the European Union (TFEU).

23. The WTO system

The World Trade Organization (WTO) is a global international organization, which superseded the General Agreement on Tariffs and Trade (GATT) in 1995 in regulating international trade. Its purpose is to ensure that trade flows as smoothly, predictably and freely as possible. The WTO has many roles: it operates a global system of trade rules, it acts as a forum for negotiating trade agreements, in particular multilateral trade agreements, it settles trade disputes between its members and it supports the needs of developing countries.[109]

Both the European Union (EU) and its Member States are members of the WTO. The European Commission represents the EU and its Member States at relevant WTO meetings.

The WTO agreement replaced the General Agreement on Tariffs and Trade (GATT) in 1994. The GATT however remains the legal framework for trade in goods and provides that members (i.e. WTO Members) may apply exceptions to the free movement of goods in order to protect human, animal or plant health, provided that they do not use these exemptions as disguised protectionism.

WTO Members' rights and obligations in respect of trade in agri-food products are further laid down in two WTO agreements:

- the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) concerns the application of measures governing: food safety, animal health and plant health;
- the Agreement on Technical Barriers to Trade (the TBT Agreement) which concerns trade in goods in general, including agri-food products.

24. The TBT Agreement

The expression "technical barriers to trade" (TBTs) designates the mandatory technical requirements that products should meet in order to be placed on the market. Such

109 https://www.wto.org/english/thewto_e/whatis_e/who_we_are_e.htm

requirements typically relate to the specific characteristics that a product should have, such as its size, shape, design, packing, marking, labelling, advertising, functionality or performance. The specific procedures used to check whether a product is in compliance with these requirements are also covered by the definition of TBTs. These so-called "conformity assessment procedures" include, for example, product testing, inspection and certification activities.

TBTs are usually introduced by government authorities with a legitimate public policy objective in mind such as:

- informing consumers about the characteristics of the product and protecting them from deceptive practices;
- safeguarding the environment;
- ensuring fair competition between business operators;
- ensuring the effectiveness of official controls.

TBTs however often have a significant impact on trade, in particular for newcomers and small and medium enterprises (SMEs). Adjusting products and production processes to comply with different requirements in export markets, as well as demonstrating compliance with these requirements, increase production costs and time-to-market, and can ultimately hurt global trade.

The objective of the WTO Agreement on Technical Barriers to Trade (TBT Agreement) is to ensure that, as quantitative restrictions (quotas and tariffs) are progressively eliminated in international trade, they are not replaced by measures having an equivalent effect, masqueraded as technical barriers to trade. The TBT Agreement does not in any way undermine the right of governments to take measures to pursue legitimate public policy objectives, such as the ones mentioned above; it simply aims to ensure that such measures are prepared, adopted and applied according to some basic principles, in order to minimise their impact on trade.

The five basic principles at the core of the TBT agreement are the following:

- Transparency: a WTO Member planning to introduce a measure that might have an impact on trade must notify in to the WTO and take into account comments submitted by other WTO Members.

- Non-discrimination: a measure that might have an impact on trade may not treat domestic products more favorably than imported products ("national treatment"), nor should it discriminate between imports from various other WTO Members ("most favoured nation").
- Proportionality: a measure should not be more trade restrictive than necessary to achieve the legitimate goal pursued.
- Use of international standards: whenever possible, technical regulations should be based on international standards.
- Equivalence: WTO Members should consider accepting technical regulations of other Members as equivalent to their own, provided that these measures are an effective way of addressing the objective being pursued.

25. The SPS Agreement

The Agreement on Sanitary and Phytosanitary Measures (the SPS Agreement) was concluded during the Uruguay Ground and, like the WTO Agreement and the TBT Agreement, came into force on 1 January 1995. It covers the measures which are adopted by WTO Members to protect food and feed safety, animal health and plant health.

SPS measures are likely to affect international trade perhaps even more than TBT measures. WTO Members are entitled to adopt measures to protect food and feed safety provided that, in doing so, they respect a set of general principles laid down in the SPS Agreement. The five basic principles laid down in the TBT agreement (transparency, non-discrimination, proportionality, use of international standards and equivalence) are reproduced in very similar terms in the SPS Agreement. The latter however adds two further principles which reflect the particular nature of SPS measures, which are meant to deal with risks: risks to human health, animal health and plant health.

Firstly, the SPS agreement establishes explicitly that any sanitary and phytosanitary measure must be “based on scientific principles” and may not be maintained “without sufficient scientific evidence”[110]. WTO Members are allowed to decide “the appropriate level of sanitary or phytosanitary protection” they want to apply on their territory and may even provide for a “higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standard”, provided that there is

110 Article 2.2. and Article 5.2.

a "scientific justification" for this departure[111] and they "that take into account the objective of minimizing negative trade effects".[112]

Secondly, the SPS measures have to be adapted to regional conditions[113] : when measures restricting importations from another WTO Member are based on the prevalence of pests or diseases on the territory of that Member, but it can be demonstrated that some parts of this territory are actually free of the considered pests or disease, then the importing Member shall recognize this and enforce the concept of "regionalization".

26. Obligations of transparency

Both the TBT Agreement and the SPS Agreement require that WTO Members inform each other about legislative proposals that might have an impact on imports.

In particular, WTO Members are expected to:

- notify draft measures at an early stage, when it is still possible to take comments from other Members into account;
- allow sufficient time[114] for other Members to make comments;
- take comments from other Members into account;
- ensure publication of adopted measures;
- allow a reasonable period[115] between publication and entry into force.

It has recently[116] been proposed that WTO Members should also notify well in advance any restrictions that they may impose on their exports of agri-food products. Such measures are sometimes adopted to guarantee and adequate supply of essential commodities on the domestic market or to keep prices in check when there is a shortage of certain foods.

111 Article 2.3.
112 Article 5.4.
113 Article 6.
114 Article 2.9.2 of the TBT Agreement does not specify a specific time.
115 Article 2.1.2 of the TBT Agreement does not specify a specific time. In US-Clove Cigarettes, the Appellate Body indicated a period of 6-month as being a "reasonable interval" between publication and entry into force.
116 11th WTO ministerial meeting, Buenos Aires, 10-13 December 2018. India's restrictions on its food exports seemed targeted by countries like Singapore in particular.

The WTO is maintaining very useful databases where all TBT[117] and SPS[118] notifications can be found as well as the specific trade concerns which have been raised by other Members further to the notification.

27. Obligations relating to international standard

Under both the TBT Agreement and the SPS Agreement, WTO Members are required to take international standards into account when they consider enacting measures which may impact international trade.

A similar requirement is however laid down in Regulation (EC) No 178/2002. Actually, as already mentioned[119], the requirement laid down in the EU general food law goes beyond the international practice, as it calls for alignment on international standards which either exist or are about to be completed.

The international standards which are referred to here are those laid down by the three international standard-setting bodies (ISSBs) referenced in the SPS Agreement: the Codex Alimentarius Commission (Codex), the World Organization for Animal Health (OIE), and the International Plant Protection Convention (IPPC).

a) Codex Alimentarius Commission

The Codex Alimentarius Commission is a joint operation of the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). Its main purpose is to protect the health of consumers and to ensure fair practices in international food trade. In addition to standards for specific food (e.g. fruits and vegetables, oils and fats, etc.), the Codex Alimentarius includes general standards covering matters such as food labelling, food hygiene, food additives and pesticide residues, as well as guidance for the performance of official controls, import and export inspections and the issuance of certificates.

All the EU Member States are members of the Codex Alimentarius Commission. In 2003, the EU also joined, sharing the competence with the Member States depending on the level of harmonisation in the matter at stake.[120]

117 The Technical Barriers to Trade-Information Management System (TBT IMS). http://tbtims.wto.org/
118 The SPS Information Management System (SPS IMS). http://spsims.wto.org/
119 Article 5(3). See above, No 16.
120 Council Decision of 17 November 2003 on the accession of the European Community to the Codex Alimentarius Commission, OJ L 309 of 26/11/2003, pp. 14-21.

b) World Organisation for Animal Health (OIE)

The OIE[121] is an intergovernmental organisation responsible for improving animal health worldwide. It was established in 1924 and currently has 180 member countries. All 28 EU Member States are members. The European Commission has formal observer status at the OIE under a Memorandum of Understanding concluded in 2011.

OIE's primary objective is to protect the health of animals and to ensure a safe and fair trade in animals and animal products worldwide, by ensuring transparency in the global animal disease situation and by publishing health standards for international trade. It also sets guidelines for animal welfare although this mandate does not fall under the WTO SPS agreement.

c) International Plant Protection Convention (IPPC)

The International Plant Protection Convention is an international treaty aiming to prevent the introduction and spread of pests of plants and plant products, and to promote appropriate measures for their control. It issues so-called international standards for phytosanitary measures (ISPMs).

All EU Member States have signed the IPPC. The European Commission is coordinating EU positions but is not itself a party to the Convention.

The EU general food law further requires[122] the EU and the Member States to contribute to the development of international standards, and to give particular attention to the special needs of developing countries in order to ensure that international standards do not create unnecessary obstacles to their exports.

28. Food imported into the EU

Food imported into the EU for placing on the market in the EU must conform with all the relevant requirements of EU food law.[123] There are two alternatives, however: the first concerns the case where the EU has recognised conditions prevailing outside the EU as being equivalent to the EU requirements; the second results from specific agreements existing between the EU and the exporting country (see below, No 30). Both occasions are very rare.

121 Having its seat in Paris, France, the organization is still referred to by the acronym derived from its French name, l'*Office International des Epizooties*.
122 Article 13.
123 Article 11.

As the largest importer of agri-food in the world, the EU has put in place a comprehensive framework for import controls. The intensity of import controls varies according to the level of perceived risks associated with various categories of products: animals and products of animal origin, plants and plant products, and other products.

a) Animals and products of animal origin

Live animals and products of animal origin present a high level of risk as they can transmit serious human and animal diseases. These products can only be imported from countries which have been specifically authorised to export a given category of products (e.g. beef, pork, poultry, fish, milk, eggs, game, honey, etc.). Once authorised for a given category, the non-EU country concerned must communicate to the European Commission a positive list of the establishments (farms, slaughterhouses, fishing vessels, processing plants, etc.) authorised to produce for exportation to the EU, which they have inspected and found to be compliant with conditions at least equivalent to those laid down by EU legislation.

Consignments of products of animal origin can only enter the EU through an official 'border inspection post' of a Member State, where they will be submitted to a veterinary border control. This will always include a documentary check and an identity check. The purpose of the documentary check will be to verify that the consignment is accompanied by a health certificate issued by the competent authorities of the exporting country and guaranteeing that the products being exported are in conformity with the applicable EU requirements. The purpose of the identity check is to verify the consistency between the documents or certificates and the products being imported. A physical check (e.g. laboratory analysis to verify the presence of residues of contaminants or unauthorized substances, or to rule out microbial contamination, for instance) will only be performed randomly or because of a previous history of non-compliance.

b) Plants and plant products

Imports of live plants and plant products are also considered to be of high risk as they may result in the introduction of new pests and plant diseases on the EU territory with potentially disastrous effects on crops and the natural environment. Live plants and certain plant products specified in the legislation must therefore be accompanied by an

official phytosanitary certificate delivered by the competent authority of the exporting country.

Import controls, consisting of documentary, identity and, in some cases, physical checks are performed at approved points of entry or, in the case of physical checks, at the place of destination where specific conditions are met and a derogation has been duly granted by the national authorities.

c) Other food

Most food and notably prepared foodstuffs of non-animal origin are considered not to pose an intrinsic risk to food safety, animal health or plant health. For these products, controls on imports are carried out by the Member States on the basis of their multi-annual official control plans.

When a specific risk is identified in respect of some of these products, for instance as a result of a sharp increase in RASFF[124] notifications concerning a category products imported from a non-EU Member State, mandatory pre-import controls at Designated Points of Entry (DPE) may be imposed on an ad hoc basis.[125] The list of these commodities, which often include nuts and certain fruits and vegetables, and the applicable controls are reviewed by the Commission and the Member States on a quarterly basis.

29. Food exported from the EU

Very few countries around the world are restricting their food exports at least in relation to reasons of food safety[126]. The EU does so under its general food law provisions. The services of the European Commission had established that in a number of cases batches of food which could no longer possibly be put on the market in the EU after RASF[127] alerts at been exported outside of the EU to be placed on the market in non-EU countries. Thus, Article 12 of Regulation (EC) No 178/2002 provides food exported or reexported

124 The Rapid Alert System for Food and Feed. See Article 50-52 of Regulation (EC) No 178/2002.

125 Commission Regulation (EC) No 669/2009 of 24 July 2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC (Text with EEA relevance). OJ L 194, 25.7.2009, p. 11–21.

126 Food exports are more classically restricted to protect supply on the domestic market. See also above N° 26.

127 The RASF (Rapid Alert System for Food) was the predecessor of the RASFF, the rapid alert system established by Article 50 of Regulation (EC) No 178/2002.

from the EU must comply with the relevant requirements of food EU food law, unless they conform either with the legislation of the importing country, or with a request from the importing country[128].

Where this is not the case, and in particular where food has been found not to conform with EU food safety requirements, it can only be exported or re-exported "if the competent authorities of the country of destination have expressly agreed, after having been fully informed of the reason s for which and the circumstances in which the food or feed concerned could not be placed on the market" in the EU[129]. However, even when this condition is met, the food cannot be exported if it is 'injurious to health'[130].

Unfortunately, the above provisions only cover food which has been either produced in the EU or imported in the EU to be subsequently re-exported: they don't cover food rejected at the external border of the EU.

Finally, where a bilateral agreement has been concluded between the EU or one of its Member States[131] and a non-EU country, food exported from the EU or from that Member State must comply with the provisions of the agreement.[132]

30. Bilateral trade agreements

As already explained,[133] trade policy is an exclusive competence of the EU. The Commission negotiates with non-EU countries on behalf of the EU, after having obtained a negotiation mandate, setting out the general objectives to be achieved in the agreement, from the Council. As negotiations are ongoing, the Commission reports regularly to Council and Parliament. Once negotiations are completed, the Commission presents the tentative agreement to Council for approval; Parliament is associated, under modalities varying according to the circumstances.[134]

Although the EU continues to attribute the highest priority to the multilateral process and to the Doha Development Agenda,[135] the fact that the multilateral negotiations mediated

128 Article 12(1) first paragraph.
129 Article 12(1) second paragraph.
130 On the notion of 'injurious to health', see below No 32.
131 Presumably, this refers to bilateral agreements concluded by a Member State and a third country before the establishment of the EU or before the accession of said Member Sate to the EU. See above No 38 and below No 49.
132 Article 12(2).
133 Above, No 22.
134 See Article 218 TFEU.
135 See: https://www.wto.org/english/tratop_e/dda_e/dda_e.htm

by the WTO are struggling to deliver results in terms of trade liberalisation, the EU has, over the last decade, engaged in a series of bilateral trade negotiations with a number of trade partners with a view to seeking a higher degree of tariff liberalisation and improved access to third country markets. Agreements concluded in recent years or currently being negotiated have become more ambitious and comprehensive in scope.[136] Apart from free trade agreements,[137] which typically include a section on sanitary and phytosanitary conditions, the EU has also concluded a series of bilateral agreements with single countries or groups of countries from outside the EU which specifically concern sanitary and phytosanitary measures or even sometimes just veterinary matters.[138]

136 See: "Cumulative economic impact of future trade agreements on EU agriculture", Report written for the JRC by: Boulanger Pierre, Dudu Hasan, Ferrari Emanuele, Himics Mihaly and M'BArek Robert; Publication Office, 2016.

137 http://trade.ec.europa.eu/doclib/docs/2006/december/tradoc_118238.pdf

138 See: https://ec.europa.eu/food/safety/international_affairs/agreements_en.

Chapter 4
General requirements of food law

The 'general requirements of food law', is the part of the 'General Food Law' which contains all obligations falling upon food business operators, as opposed to the rest of 'General Food Law' which concerns public authorities.

31. Food business operators

The term 'food business' was known, and actually defined in the food hygiene legislation before Regulation (EC) No 178/2002 [139]. It used to refer to any undertaking carrying out any of the activities related to: the preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling or offering for sale or supply of food. In line with the stated objective of covering all aspects of the food production chain as a continuum from and including primary production up to and including sale or supply to the final consumer[140], Regulation (EC) No 178/2002 defines 'food business' as "*any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food*".[141]

The term 'food business operator' was not defined, but ubiquitous in the food hygiene legislation before Regulation (EC) No 178/2002. Because of its importance and its wide use in food law in general and in Regulation (EC) No 178/2002 in particular, the latter provides the following definition: 'food business operator' means: "*the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control*".[142]

32. Food safety requirements

Article 14 of Regulation (EC) No 178/2002, laying down the 'food safety requirements', is one of the most important sets of provisions of Regulation (EC) No 178/2002, not least

139 See Article 2 of Council Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs. This Directive was repealed by Regulation (EC) No 852/2004.
140 See Recital 12 of Regulation (EC) No 178/2002.
141 Article 3(2).

because there was considerable disharmony[143] in the matter amongst Member States before the coming into force of Regulation (EC) 178/2002.

It immediately appears that the food safety requirements are not expressed positively. Instead, the Regulation merely prohibits the placing on the market of food which is unsafe[144] and provides that a food must be deemed to be unsafe if it is either 'injurious to health' or 'unfit for human consumption'[145]. These two expressions are not defined but criteria are laid down[146] which are to be used when determining whether a food must be deemed either 'injurious to health' or 'unfit for human consumption'. These criteria clearly suggest that the former relates to the risk which the consumption of the food may entail, whilst the latter relates to the physical state of the food, e.g. contamination, putrefaction, deterioration or decay. One might thus say that the 'injurious to health' notion is a static one - the food is inherently unsafe - whilst the 'unfit for human consumption' is a dynamic one: the food may have been safe at an earlier point, but it is no longer because of the state in which it is found at the time of considering the matter.

It is important to understand that the two notions are not mutually exclusive; quite the contrary. When a food is found to be 'unfit for human consumption', there is actually a very high likelihood that it also presents a risk for human health. One might have conceived a system whereby the circumstance that a food is 'unfit for human consumption' would have served as an indicator that the food may be presenting a risk for human health, leaving it to the control authorities to demonstrate that it actually does. It is precisely with a view to avoiding that any time and resources are waisted in bringing such a demonstration that the legislator has laid down an irrebuttable presumption that a food which is found to be 'unfit for human consumption' is thereby 'unsafe' in the sense of Regulation (EC) No 178/2002. It is unfortunate that the Court of Justice did not make this point when it was given an opportunity to rule on the matter[147]; the Court admittedly came to the right result, albeit through a somewhat cumbersome route.

Article 14 provides very useful insight as to the circumstances which shall be taken into account when determining whether a food should be considered 'unsafe'[148], 'injurious to

143 See Recital 26) of the Regulation.
144 Article 14(1).
145 Article 14(2).
146 Article 14(4) and 14(5) respectively.
147 Case C-636/11 Karl Berger v Freistaat Bayern.
148 Article 14(3).

health'[149] or 'unfit for human consumption'[150]. This construction does not make 'unsafe' an autonomous notion: the criteria provided in this respect are just applicable two the two aspects of being 'unsafe': 'injurious to health' and 'unfit for human consumption'.

Article 14 has further been written with the obvious intent of clarifying a number of matters which had been hitherto controversial. In particular, it lays down a series of *prima facie* presumptions:

- Where a food, which has been found unsafe, is part of a batch, the entire batch is deemed to be unsafe, unless it is proved otherwise[151].
- Food that complies with specific Union provisions governing food safety, or in their absence with the specific provisions laid down by Member States, is deemed to be safe insofar as the aspect covered by these specific provisions are concerned [152]. Such conformity does however not prevent the competent authorities from restricting the placing on the market or withdrawing from the market where they have reasons to believe that the food is unsafe.

Article 14 does not deal with the reverse situation, where a food does not comply with the specific Union or national provisions governing its safety. Certainly, such food must be considered as unsafe within the meaning of Article 14. However, the conditions under which the said food may nonetheless be placed on the market, in whole or in part, will depend on the prescriptions or the specific Union or national provisions being considered.[153]

33. Presentation

Article 16 provides that the labelling advertising and presentation of food may not mislead consumers.

This provision mirrors a similar clause[154] which has been incorporated into the 'General principles of food law'[155]. It results, from the placing of Article 16 under the 'General

149 Article 14(4).
150 Article 14(5).
151 Article 14(6)
152 Article 14(7) and (9).
153 See also Article 17(1) and below No 24. For further clarifications on Article 14, see: Guidance on the implementation of Articles 11, 12, 16, 17, 18, 19 and 20 of Regulation (EC) No 178/2002 on general food law. Conclusions of the Standing committee on the food chain and animal health. 20 December 2004.
154 Article 8.
155 See above No 19.

Requirements of Food Law' rather than from the neutral wording, that not misleading the consumer is an obligation falling upon food business operators.[156]

More than anything else, Article 16 appears like a lost opportunity to impose on business operators a positive obligation to provide consumers with complete, meaningful and understandable information about the food they place on the market. As will be discussed below, in Part II, the Union legislation on 'Food Information to Consumers' goes much further than merely requiring operators not to mislead the consumer.

34. Responsibilities

The purpose of Article 17 appears to be twofold.

Firstly, it clarifies and extends to all areas of food law, the principle according to which primary responsibility for ensuring compliance with food law, and in particular the safety of the food, remains with the food business[157]. The role of competent authorities, in contrast, is to enforce food law and to carry appropriate controls to monitor and verify that food business operators fulfil their obligations under food law at all stages of production, processing and distribution. The importance of this provision should not be underestimated, despite its unfortunate location amongst the 'General Requirements of Food Law'. It indeed clearly establishes that in the European Union, the Member States – not the Union – are in charge of official controls[158] and related activities, and that it is for them the penalties applicable to infringements of food law[159].

Secondly, Article 17 settles a very sensitive controversy in many Member States about the respective responsibilities of various food business operators along the food chain. By laying down explicitly, albeit very succinctly, that food business operators "at all stages of production, processing and distribution *within the business under their control* shall ensure that foods […] satisfy the requirements of food law *which are relevant to their activities* and shall verify that such requirements are met", Article 17 clearly establishes a joint responsibility for all operators along the food chain, whereby each link in the food

156 On the relation between Article 16 of Regulation 178/2002 and the EU food labelling provisions, see: Judgment of the Court of 4 June 2015 in Case C 195/14 paragraph 34.
157 Article 17(1).
158 Article 17(2).
159 See, for instance, the Judgment of the Court of 13 November 2014 in Case C 443/13. It is for the national court to determine whether the penalty at issue in the main proceedings observes the principle of proportionality referred to in Article 17(2) of Regulation No 178/2002.

chain should take the measures necessary to ensure compliance with food law requirements within the context of its own specific activities.

35. Traceability

Traceability is a well-known concept in quality management. It is defined by the International Standard Organisation as "*the ability to trace the history, application or location of an entity by means of recorded information*" [160]. However, its compulsory application to food, for reasons of food safety, was unknown until the end of the 90's.

Food traceability is not an objective in itself; it is a tool which may serve a number of purposes. As already indicated, it is widely used in quality management. It is also an effective tool for the purpose of guaranteeing the veracity of information provided about some characteristics of the food, such as information about the provenance of the food or of one of its ingredients (e.g. country of origin), about the production method (e.g. 'organic' or 'genetically modified'[161]), or about the respect of religious prescriptions (e.g. 'halal' or 'kosher'). Finally, and this is the context in which traceability is being discussed here, traceability is an essential tool for risk containment in the case of food scares.

The importance of traceability in food safety crisis was dramatically demonstrated in the Belgian dioxin crisis of 1999[162]. The experience gained during the latter crisis obviously inspired the authors of the White Paper on Food Safety[163], which places unprecedented emphasis on the need for a holistic approach to the safety of the food chain ('From farm to fork') and on traceability as a gold standard to operate targeted and accurate withdrawals and to provide control officials and consumers with appropriate information, thereby avoiding the potential for unnecessary wider disruption in the event of food safety problems[164].

It was therefore little surprise that traceability was introduced as a general requirement of food law in Regulation (EC) No 178/2002. Yet, this was a world premiere, and it was harshly criticised by some third countries when the Commission proposal was notified to

160 ISO 8402:1994.
161 For the traceability of GM food, see below No 109.
162 See above No 7.
163 See above No 8.
164 See recital 28 of Regulation (EC) No 178/2002.

WTO. In the meantime, a large number of countries around the world have adopted similar requirements[165].

Regulation (EC) No 178/2002 defines 'traceability' as "*the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution"*[166]. It may have been simpler to define traceability as "the ability to trace a product through the production and distribution chain", since the rest of the definition is actually dealing with the scope of the obligation. Come to think about it, the definition provided is so tautological (traceability/ability to trace) that it was probably not needed!

This view is even reinforced when one reads the actual traceability requirement of Regulation (EC) No 178/2002, which is laid down in Article 18(1): '*The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution.*' As can be seen, the scope of the traceability requirement is very broad. However, it is not as broad as to include products such as veterinary medicinal products, plant protection products, fertilisers and contaminants in general. These substances are not intended or expected to be incorporated into food[167]. Food contact materials are not covered either, but their traceability is required under specific rules, adopted in 2004[168]

The practical implications of this general requirement are spelled out in Article 18(2) and 18(3).

Firstly, Article 18(2) provides that "*food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed*". This obligation is commonly referred to as 'one step back'. The manner in which the relevant information has to be kept is not prescribed: it is merely indicated

165 The United States were actually amongst the critics of the EU traceability scheme at the time of the WTO notification. This did not prevent them from adopting, less than two years later, a monstrous traceability scheme as part of the Bioterrorism Act (2002). 9/11 had obviously been a wake-up call!

166 Article 3(15) of Regulation (EC) n° 178/2002.

167 It should be noted that some of these products are covered by specific Regulations or Directives that may even impose more stringent requirements on traceability.

168 Regulation (EC) N° 1935/2004 of 27 October 2004 (OJ L 338, 13.11.2004, p.4).

that "*operators shall have in place systems and procedures which allow for this information to be made available to the competent authorities on demand"*.

Secondly, Article 18(3) lays down that "*food and feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the competent authorities on demand.*" This obligation is referred to as 'one step forward'. It is worth noting that here, businesses are only required to identify their customers who are themselves businesses; obviously retailers do not have to identify their immediate customers when they are final consumers.

Article 18(4) further requires food or feed which is placed on the market in the Community to be "*adequately labelled or identified to facilitate its traceability, through relevant documentation or information in accordance with the relevant requirements of more specific provisions*".

Most of these 'more specific provisions' are laid down either in the marketing and quality standards adopted in the context of the common organisation of the market for agricultural products (e.g. fruits and vegetables, fish and fishery products, eggs, etc.), or in primary legislation covering specific food (e.g. genetically modified food)[169] . In addition, Article 18(5) allows the Commission to adopt implementing acts for the purpose of specifying the traceability requirements "in respect of certain sectors"[170]. The Commission has used this possibility to lay down specific traceability requirements for products of animal origin[171].

As has been seen, Article 18 is worded in terms of its goal and intended result, rather than in terms of prescribing how that result is to be achieved. Where more detailed requirements have been laid down in 'more specific provisions', these obviously apply but they can never detract from the general obligations laid down in Article 18. In the absence of specific provisions, great flexibility is left to business operators, and this has

169 Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 2 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24). See below, No 119.

170 This obviously precludes the adoption of implementing measures generally covering all food on the market.

171 Commission Implementing Regulation (EU) No 931/2011 of 19 September 2011 on the traceability requirements set by Regulation (EC) No 178/2002 of the European Parliament and the Council for food of animal origin (OJ L 242/2 of20.9.2011).

led to some difficulties of interpretation, which prompted the Commission to issue a Guidance document in 2004[172].

Amongst other useful clarification, the 2004 Guidance confirms the generally accepted view that Regulation (EC) No 178/202 does not require business operators to match inputs and outputs ('internal traceability'). Nor is there any requirement for records to be kept identifying how batches are split and combined within a business to create particular products or new batches.[173]

The traceability provisions of Regulation (EC) No 178/202 do not have an extra-territorial effect outside the EU. They cover all stages of production, processing and distribution in the European Union. In the case of products imported from third countries, it falls upon the importer established in the EU to start the traceability chain. Since the EU importer shall be able to identify from whom the product was exported in the third country, the requirements of Article 18 and their objective is deemed to be satisfied.[174]

Article 18 of Regulation (EC) No 178/2002 broke new ground in food law. In the meantime, traceability (or 'product tracing' as the Americans prefer to call it) has made its way in most food legislations around the World, and in a number of *Codex Alimentarius* standards[175]. Much experience has been gained since the entering into force of Regulation (EC) No 178/2002 and the publication of the 2004 Guidance, and one might wonder, particularly after the 'horse meat' scandal, whether further, more detailed legislation would not be needed. Whether this could be achieved through an implementing regulation under Article 18(5) which would cover food of non-animal[176] origin is open for debate.

36. Prevention

Several provisions of the 'General Requirements of Food Law' combine in imposing on business operators an obligation to prevent the placing on the market of food which is unsafe.

172 See above, footnote 119.
173 *Ibid*. at II.3.2.ii.
174 *Ibid*. at II.3.1.iii
175 See, notably: *Principles for traceability/product tracing as a tool within a food inspection and certification system*. CAC/GL 60-2006.
176 Admittedly, horse meat is a product of animal origin and was already covered under Regulation (EU) No 931/2011.

Thus, business operators have to ensure that food under their control satisfy the requirements of food law which are relevant to their activities and have to verify that such requirements are met[177].

Food business operators further have to collaborate with the competent authorities to avoid or reduce risks posed by food which they supply or have supplied[178].

As a consequence, it is reasonable to expect that business operators identify and regularly review the critical points in their processes and ensure that controls are applied at these points[179].

37. Transparency

The information of competent authorities by the food business operators is an important element for market surveillance as it enables the competent authorities to monitor whether the business operators have taken the appropriate measures to address the risks posed by a food placed on the market and to order or take additional measures if necessary. Therefore, where a food business operator realizes that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it must henceforth inform the competent authorities and, in some cases, the consumer. Several situations may indeed occur:

- Where the food is still within the control of the business operator, there is no need to inform the authorities[180]. In such case, the food business operator is still in a position to remedy the non-compliance by its own means, without a need to request cooperation from other operators.
- Where the food has left the immediate control of the food business operator, the competent authorities must be informed[181] and appropriate measures must be taken.
- Where the product may have reached the consumer, the operator must effectively and accurately inform the consumer of withdrawal measures undertaken and of the reasons for the withdrawal.

177 Article 17(1).
178 Article 19(4).
179 See : The Key Obligations of Food and Feed Business Operators, https://ec.europa.eu/food/sites/food/files/safety/docs/gfl_req_business_operators_obligations_en.pdf
180 Article 19(1) by implication.
181 Article 19(1).

- Where the product has been placed on the market and may be injurious to health, the business operator must inform the authorities of the action taken to prevent risks to the final consumer[182].

38. Recall or withdrawal

In addition to informing the competent authorities in case of emergency as just explained, business operators may also have to withdraw products from the market, or event recall them as the case may be.

Where the food has left the immediate control of the food business operator, it shall be withdrawn from the market[183]. Withdrawing implies that the product will not be distributed, displayed or offered to consumers[184]. The withdrawal is compulsory where the food is not in compliance with the food safety requirements, and it has left the immediate control of the food business operator.

Where the food may have reached the consumer, the operator must inform consumers effectively and appropriately of the reason for any withdrawal and, if necessary, recall from consumers products already supplied to them, unless other measures (e.g. appropriate information) are sufficient to prevent risks[185]. A recall aims at achieving the return of an unsafe product that has already been supplied or made available to consumers[186].

Sometimes, a distributor or retailer may have to initiate itself procedures to withdraw from the market products, notably where they are in possession of information giving them reason to consider or to believe that a food not under its immediate control, is non-compliant with the food safety requirements[187].

Withdrawals and recalls may, in addition, be decided by the competent authorities whenever such measures are justified.

182 Article 19(3).
183 Article 19(1).
184 See Article 8(h) of Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, OJ L 11/4 of 15.1.2002.
185 Article 19(1).
186 See Article 8(g) of Directive 2001/95/EC.
187 Article 19(2).

39. Cooperation

Food business operators have, under the 'General Food Safety Requirements', an obligation to cooperate with the competent authorities on action taken to avoid or reduce risks posed by a food which they supply or have supplied[188].

This obligation falls on all participants in the food chain, within the limits of their respective activities. For instance, distributors and retailers must pass on relevant information to trace a food, and cooperate in the action taken by producers, processors, manufacturers or competent authorities[189].

As part of their obligation to cooperate, business operators should not prevent or discourage any person form cooperating with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a food[190].

40. Liability

Unsafe food are the cause of numerous deaths and injuries every year in the European Union. Responsibility for the civil consequences of injuries caused by unsafe food may lie with any of the participants to the food chain, although it may be more convenient for the injured party to seek compensation from the last participant in the chain, i.e. the retailer, with whom a contractual relationship exists.

Regulation (EC) No 178/2002 however does not allocate the matter, other than to refer to the provisions of the so-called Product Liability Directive[191].

188 Article 19(4).
189 Article 19(2).
190 Article 19(3).
191 Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products. OJ L 210, 7.8.1985, p. 29.

Title II

Food Information to Consumers

Chapter 1
General framework

41. History

Originally, the European Community had determined labelling rules that applied to certain foodstuffs or to certain categories of foodstuffs. Thus, most of the "vertical" Directives adopted in the 70's and early 80's actually included labelling rules applicable to the products concerned. However, it soon became clear that it was preferable to approach the labelling of foodstuffs in a "horizontal" manner, i.e. by way of a set of general rules that would apply to all foodstuffs placed on the market.

The Commission therefore initiated works, in close collaboration with the Member States' experts and the stakeholders concerned, based on the principles agreed in the framework of the *Codex Alimentarius* Committee. This work resulted in the adoption, at the end of 1978, of Directive 79/112/EEC[192]. This Directive, ahead of its time in many respects, served as a model for many third countries and, in the absence of a general food law, became the cornerstone of the European food legislation from 1980 to 2000.

Directive 79/112/EEC was amended several times, notably by Directive 89/395/EEC[193], which extended its scope, eliminated several derogations and introduced a new allocation of responsibilities between the Council and the Commission for the purpose of adopting the implementation measures required by the Directive.

In 2000, twenty years after the adoption of Directive 79/112/EEC, it seemed necessary, in view of the numerous and substantial amendments that had been brought to it, to consolidate the text of Directive 79/112/EEC and this was the purpose of Directive 2000/13/EC[194]. The latter was in turn amended several times, in particular by Directive

192 Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer (OJ No L 33 of 8.2.1979, p. 1).

193 Council Directive 89/395/EEC of 14 June 1989 amending Directive 79/112/EEC on the approximation of the laws of the Member States relating to labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer (OJ L 186, 30.6.1989, p. 17–20).

194 Directive 2000/13/EC of the European Parliament and the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (OJ L 109 of 6.5.2000, p. 29).

2003/89/EC[195], which made it mandatory to list, amongst the ingredients of foodstuffs, all allergenic substances, irrespective of the quantity used; even wine and alcoholic beverages were concerned by this requirement.

In January 2008, the Commission submitted to Parliament and Council a new proposal which ended up in the adoption, on 25 October 2011, of Regulation (EU) No 1169/2011[196] on the provision of food information to consumers. This new Regulation, which combines into one single legislation the provisions on general labelling from Directive 2000/13/EC and those on nutrition labelling from Directive 90/496/EC (see below, Chapter IV), considerably changed existing food information requirements in the EU. These new rules are in application since December 2014, except for the obligation to provide nutrition information which are came in to force in December 2016.

42. Purpose

The main purpose of Directive 79/112/EEC was to ensure the free movement of goods within the European Community. This Directive however made a crucial contribution to improving the information and protection of consumers, in such a manner that it can actually be regarded as the first legislative step ever adopted by the European legislator in favour of consumers.

In contrast, providing a high level of consumer protection in relation to food information is the main purpose of Regulation (EU) No 1169/2011, whilst ensuring the smooth functioning of the internal market appears to be a subsidiary objective[197].

43. Scope

The scope of Regulation (EU) No 1169/2011 is, in many respects, broader than the scope of both Directive 79/112/EEC and Directive 2000/13/EC.

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195 Directive 2003/89/EC of the European Parliament and the Council of 10 November 2003 amending Directive 2000/13/EC amending Directive 2000/13/EC as regards indication of the ingredients present in foodstuffs (OJ L 308 of 25.11.2003, p 15).

196 Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304 of 22.11.2011, p. 18).

197 See Article 1(1) and Article 3 of Regulation (EU) No 1169/2011.

Firstly, where the two Directives dealt with "the labelling, presentation and advertising" of food, Regulation (EU) No 1169/2011 applies to all instances of "food information", which is defined as all "information concerning a food and made available to the final consumer by means of a label, other accompanying material, or any other means including modern technology tools or verbal communication"[198].

Secondly, the scope of Directive 79/112/EEC was purposely limited to food to be delivered as such to the ultimate consumer, thus excluding upstream products which still have to be treated or transformed before reaching the form in which they would be delivered to the ultimate consumer. Whilst Directive 2000/13/EC was in principle applicable to both 'pre-packed' and 'non-prepacked'[199] it actually provided that Member States would adopt detailed rules concerning the manner in which not pre-packed food were to be labelled; in the absence of such rules, the requirements of the Directive were in fact not applied to non-prepacked food. The Commission proposal towards Regulation (EU) No 1169/2011 was seemingly applicable to all pre-packed and non-prepacked food. This was probably a mistake as the consequences of such a bold move were not considered in the necessary impact assessment that preceded the proposal. This was promptly corrected during discussions in Council, and Regulation (EU) No 1169/2011 eventually provides that only the indication of allergenic substances is compulsory for non-prepacked food; other labelling items are only compulsory where and, in the manner, required by Member States.

Regulation (EU) No 1169/2011 also clearly applies to the distant selling of food, as specific provisions are laid down in this respect, and notably the obligation that most of the mandatory information required under the Regulation must "be available before the purchase is concluded and shall appear on the material supporting the distance selling or be provided through other appropriate means clearly identified by the food business operator".[200]

198 Article 2.2(a).

199 'Pre-packed' food means: any single item for presentation as such to the ultimate consumer and to mass caterers, consisting of a foodstuff and its packaging in such a way that the content cannot be altered without opening or changing the packaging. Note, however, that 'pre-packed' food were referred to in Directive 2000/23/EC as 'pre-packaged'.

200 Article 14.

44. Definitions

Regulation (EU) No 1169/2011 concerns 'food information', where Directive 79/112/EEC and Directive 2000/13/EC essentially dealt with the labelling, presentation and advertising of foodstuffs. 'Food information' is defined as: any information concerning a food and made available to the final consumer by means of a label, other accompanying material, or any other means including modern technology tools or verbal communication[201].

Like Directive 79/112/EEC, Directive 2000/13/EC only contained two definitions, for 'labelling' and for 'pre-packed foodstuff'. Regulation (EU) No 1169/2011, which is modelled on Regulation (EC) No 178/2002[202], offers in contrast a long list of definitions and refers otherwise to a number of definitions laid down in Regulation (EC) No 178/2002 and in Regulation (EC) No 852/2004 on the hygiene of foodstuffs[203].

Worth noting are the definitions of: 'ingredient' (see below, No 14), 'prepacked food', 'legal name' and 'customary name', 'place of provenance', 'field of vision', and 'engineered nanomaterial'.

45. General principles of food information

Regulation (EU) No 1169/2011 includes a set of general principles of food information[204].

On the one hand, there is a reiteration of the need to pursue a high level of protection of consumers' health and interests when adopting food information law provisions. However, reference is also made to the free movement of goods within the Union, to the legitimate interests of producers and to the promotion of the production of quality products. It is also provided that there should be an open and transparent public consultation before food information law is adopted, and an appropriate transition period before such law comes into force.

201 Article 2(2)a).
202 Regulation (EC) No 178/2002 of the European Parliament and the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31 of 1.2.2002, p. 1).
203 Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ No L 226, 25.6.2004, p. 3).
204 Chapter II.

On the other hand, Regulation (EU) No 1169/2011 requires that the European Food Safety Authority be consulted before the adoption of any measure in the field of food information law which is likely to have an effect on public health.

46. Fair information practices

EU rules on the provision of food information to consumers can be classified in two categories: obligations 'to do', and obligations 'not to do'. Thus, for instance, food information must include specific items (the so-called 'mandatory particulars'), such as a list of ingredients: this is an obligation 'to do'. An example of an obligation 'not to do' can be found in the clause providing that food information may not mislead the consumer.

The obligations 'not to do' are particularly important because of the wide manner in which they can be construed. Regulation (EU) No 1169/2011 lists five manners in which the consumer might be misled, which are thus prohibited:

(a) firstly, food information may not mislead the consumer as to the characteristics of the food and, in particular, as to its nature, identity, properties, composition, quantity, durability, country of origin or place of provenance, method of manufacture or production[205];

(b) secondly, food information may not attribute to the food effects or properties which it does not possess[206];

(c) thirdly, food information may not suggest that the food possesses special characteristics when in fact all similar foods possess such characteristics, in particular by specifically emphasising the presence or absence of certain ingredients and/or nutrients[207];

(d) fourthly, food information may not suggest the presence of a particular food or an ingredient, while in reality a component naturally present or an ingredient normally used in that food has been substituted with a different component or a different ingredient [208];

205 Article 7(1)a). See, for instance, the Judgment of the Court of 4 June 2015 in Case C 195/14. The labelling of the product was showing depictions of raspberries and vanilla flowers, although of the food did not contain any of these. The fact that the list of ingredients did not mention raspberries and vanilla did not change the assessment that the labelling was misleading.

206 Article 7(1)b).

207 Article 7(1)c).

208 Article 7(1)d).

(e) fifthly, food information may not attribute to any food the property of preventing, treating or curing a human disease, nor refer to such properties[209].

It is important to note an essential difference between (a), (b) and (d) on the one hand, and (c) and (e) on the other hand: the latter refer to statements that cannot be made irrespective of a possible substantiation. Thus, for instance, it is not permitted to suggest, in the labelling, presentation or advertising of a food, that this food can prevent or cure a human disease, even if this circumstance could be scientifically established[210].

The obligations 'not to do' are frequently used by food information officers and have been the subject of numerous judgments by the European Court of Justice.[211]

47. Responsibilities

In line with similar provisions laid down by Regulation (EC) No 178/2002[212], Regulation (EU) No 1169/2011 clarifies the responsibilities of food business operators in relation to the provision of food information.

In principle, this responsibility lies with the operator under whose name or business name the food is marketed or, if that operator is not established in the Union, the importer of the food into the Union market[213].

48. Voluntary food information

Regulation (EU) No 1169/2011 is mainly concerned with the mandatory particulars which food information must include (see Chapter II, below). This, however, does not preclude that additional information be provided, on a voluntary basis, by the concerned food business operators.

In addition to the already mentioned[214] general requirement not to mislead the consumer (see 'Fair information practices' above) Regulation (EU) No 1169/2011 lays down that food information provided on a voluntary basis:

- shall not be ambiguous or confusing for the consumer,

209 Article 7(3).
210 Compare with 'reduction of disease risk claims', below, No 57(d).
211 See, for instance Judgment of the Court of 4 June 2015 in Case C 195/14, and the important considerations provided by the Court at § 36 and § 44.
212 Article 17.
213 Article 8(1).
214 Above, No 46.

- shall, where appropriate, be based on relevant scientific data, and
- shall not be displayed to the detriment of the space available for mandatory food information.

The Commission is entrusted with the task of adopting implementing acts on the application of the above requirements to three categories of voluntary food information[215]. In an unusual combination of devolutory powers, the Commission is even allowed to provide, in a delegated act, for additional categories of voluntary food information which may be the subject of an implementing act[216].

49. National measures

Regulation (EU) No 1169/2011 provides for what can be described as 'total' and 'complete' harmonization[217]. Thus, Member States should not be able to adopt national provisions departing from or complementing the provisions of Regulation (EU) No 1169/2011, unless authorised by Union law. As the case may be, such national measures should not prohibit, impede or restrict the free movement of goods that are in conformity with the Regulation.

Regulation (EU) No 1169/2011 provides itself for a series of circumstances under which Member States may adopt national measures going beyond the provisions of the Regulation.

First and foremost, Member States may adopt measures requiring additional mandatory particulars for specific types or categories of foods, justified on certain grounds[218]. Member States who wish to make use of this possibility must notify in advance the Commission and the other Member States of the measures envisaged and give the reasons justifying them, thus triggering the procedure laid down in the Regulation[219]. Where the additional mandatory requirement relates to the indication of the country of origin or place of provenance of the food, Member States are required to establish that there is a link between certain qualities of the food and its origin or provenance, and to provide evidence

215 Article 36(3).
216 Article 36(4).
217 Patrick Deboyser, *Le rapprochement des législations dans la Communauté européenne*, Bruxelles, 1991, Presses de l'ULB, 128 p.
218 Article 39(1) and below, Chapter II, 6).
219 Article 45.

that the majority of consumers attach significant value to the provision of that information.[220]

Second, Member States may adopt national measures different from the provisions of Regulation (EU) No 1169/2011 in respect of certain categories of products, such as milk and milk products[221] and alcoholic beverages[222], and in respect of certain labelling particulars[223].

Thirdly, Member States may require the indication of some food information particulars, other than the information about the presence of allergenic substances which is always mandatory, in respect of those foods that are offered for sale without pre-packaging, or which are packed on the sales premises at the consumer's request or prepacked for direct sale.

50. Delegated acts and implementing measures

Regulation (EU) No 1169/2011 includes no less than fifteen detailed and comprehensive annexes, some of them very technical. As it may be necessary to amend these annexes, in order to take into account technical progress, scientific developments, or the need to protect consumers' health or need for information, the Commission is habilitated to modify the annexes by means of delegated acts adopted in accordance with the procedure laid down in the Regulation[224].

In addition, Regulation (EU) No 1169/2011 provides for a number of circumstances under which the Commission is conferred the power to adopt delegated acts. In some cases, this power is only granted for a period of 5 years, which is tacitly extended for another 5 years, unless the Parliament or the Council opposes such extension[225]. In some cases, the delegation of power to the Commission may be revoked at any time by Parliament or Council[226].

220 Article 39(2). See also below No 55.
221 Article 40.
222 Article 41.
223 Article 42 and Article 43.
224 See: Article 51.
225 Article 51(1).
226 Article 51(3).

Regulation (EU) No 1169/2011 also provides for the adoption of implementing measures by the Commission, assisted from the Standing Committee on the Food Chain and Animal Health[227].

It is specifically indicated that both implementing measures and delegated acts must provide for an appropriate transitional period for application and have to come into force on 1 April in any calendar year[228]. This is an excellent principle of good governance; ironically, Parliament and Council did not apply it to themselves by having Regulation (EU) No 1169/2011 applying from 13 December 2014, or from 13 December 2016 for the clause making nutrition labelling mandatory![229]

227 See Article 58(1) of Regulation (EC) No 178/2002 and Article 5 of Regulation (EU) No 182/2011.
228 Article 47(1.b).
229 See: Article 55.

Chapter 2
Mandatory food information

51. Principles governing mandatory food information

The 'mandatory food information' refers to the information particulars that are required to be provided to the final consumer on all prepacked food.

Regulation (EU) No 1169/2011 classifies mandatory food information in three categories[230]:

(a) information on the identity and composition, properties or other characteristics of the food;

(b) information on the protection of consumers' health and the safe use of a food;

(c) information on nutritional characteristics so as to enable consumers, including those with special dietary requirements, to make informed choices.

52. List of mandatory particulars

Regulation (EU) No 1169/2011 lists the food information particulars which are mandatory for prepacked food[231]:

(a) the name of the food (below: No 13);

(b) the list of ingredients (below, No 14);

(c) any ingredient or processing aid causing allergies or intolerances (below, No 14);

(d) the quantity of certain ingredients or categories of ingredients (below, No 14);

(e) the net quantity of the food (below, No 16a);

(f) the date of minimum durability or the 'use by' date (below, No 16b);

(g) any special storage conditions and/or conditions of use (below, No 16c);

(h) the name or business name and address of the food business operator (below, No 16d);

230 Article 4(1).
231 Article 9(1).

(i) the country of origin or place of provenance, where required (below, No 15);

(j) instructions for use where it would be difficult to make appropriate use of the food in the absence of such instructions (below, No 16c);

(k) the actual alcoholic strength by volume, in the case of beverages containing more than 1,2 % by volume (below, No 16e);

(l) a nutrition declaration (below, Chapter III).

There are two more particulars which are mandatory under EU legislation although there are not mentioned in Regulation (EU) No 1169/2011.

Firstly, Directive 79/581/EEC[232], as amended by Directive 88/315/EEC[233], provides that all foodstuffs (and not just those sold prepacked) must bear the selling price, as well as an indication of the unit price (some derogation apply).

Secondly, Directive 89/396/EEC[234] provides that all foodstuffs must bear an indication allowing the identification of the lot to which they belong. A 'lot' means a batch of sales units of a foodstuff produced, manufactured or packaged under practically the same conditions. The Directive does not prescribe a specific format for the indication of the lot. These provisions are of the utmost importance for the purpose of traceability and food safety withdrawals and recalls.

53. Name of the food

The name of the food is the first mandatory particular listed by Regulation (EU) No 1169/2011. Two cases are foreseen.

If the relevant laws, regulations and administrative provisions, whether at Union or national level, define a foodstuff and provide for a legal name, the use of that name is compulsory.

In the absence of a legal name, the name of the food shall be its customary name, or, if there is no customary name or the customary name is not used, a descriptive name of the food shall be provided.

232 Council Directive 79/581/EEC of 19 June 1979 on consumer protection in the indication of the prices of foodstuffs (OJ L 158, 26.6.1979, p. 19–21).

233 Council Directive 88/315/EEC of 7 June 1988 amending Directive 79/581/EEC on consumer protection in the indication of the prices of foodstuffs (OJ L 142, 9.6.1988, p. 23–26).

234 Council Directive 89/396/EEC of 14 June 1989 on indications or marks identifying the lot to which a foodstuff belongs (OJ L 186, 30.6.1989, p. 21–22).

Where the legal name to be used is provided for by national legislation rather than EU harmonised legislation, it is normally the name provided for by the legislation of the Member State where the food is marketed. Problems may thus occur where this name is different from the name used in the Member State where the food is manufactured. In the past, these problems were solved under the 'Cassis de Dijon' principle[235]. Regulation (EU) No 1169/2011 expressly provides that the use in the Member State of marketing of the name of the food under which the product is legally manufactured and marketed in the Member State of production shall be allowed. However, where the application of other provisions of the Regulation would not enable consumers in the Member State of marketing to know the true nature of the food and to distinguish it from foods with which they could confuse it, the name of the food must be accompanied by other descriptive information which shall appear in proximity to the name of the food. Moreover, the name of the food in the Member State of production may not be used in the Member State of marketing when the food which it designates in the Member State of production is so different, as regards its composition or manufacture, from the food known under that name in the Member State of marketing that additional descriptive information would not be sufficient to ensure the correct information for consumers.

Just as importantly, the designation of the food may not be a reserved name where the conditions for using the reserved name are not met. Names may be reserved with respect to the origin of the product (e.g. the name 'feta' is reserved for the sheep cheese originating in Greece[236]). Other names may be reserved with respect to their composition (e.g. purely plant-based products cannot, in principle, be marketed with designations such as 'milk', 'cream', 'butter', 'cheese' or 'yoghurt', which are reserved by EU law for animal products; there are however exceptions such as 'coconut milk', 'peanut butter' and 'cream crackers'[237]).

Regulation (EU) No 1169/2011 further provides some important conditions concerning the name of the food.

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235 See the Commission communication of 24.10.1989 on the free movement of foodstuffs (COM(89)256).

236 "Feta" is actually a protected designation of origin (PDO) for a white cheese soaked in brine, originating in some parts of Greece. See: Judgment of the Court of Justice in Joined Cases C-465/02 and C-466/02 Federal Republic of Germany and Kingdom of Denmark v Commission of the European Communities.

237 See Commission Decision of 20 December 2010 listing the products referred to in the second subparagraph of point III(1) of Annex XII to Council Regulation (EC) No 1234/2007 (notified under document C(2010) 8434), and Judgment of the Court of Justice on 14 June 2017 in Case C-422/16, Verband Sozialer Wettbewerb eV v TofuTown.com GmbH.

On the one hand, the name of the food may not be replaced with a name protected as intellectual property, a brand name or a fancy name. These can however accompany the name of the food.

On the other hand, Annex VI of the Regulation lays down mandatory particulars which must accompany the name of the food under certain circumstances. In particular, the name of the food must include or be accompanied by particulars as to the physical condition of the food or the specific treatment which it has undergone (for example, powdered, refrozen, freeze-dried, quick-frozen, concentrated, smoked) in all cases where omission of such information could mislead the purchaser.

Two specific treatments are specifically dealt with.

Firstly, and this is an important improvement on Directive 2000/13/EC, Annex VI of Regulation (EU) No 1169/2011 specifically provides that in the case of foods which have been frozen before sale and which are sold defrosted, the name of the food shall be accompanied by the designation 'defrosted', except where defrosting has no negative impact on the safety or quality of the food. Indeed, the freezing and later defrosting of certain foods, especially meat and fishery products, limits their possible further use and may also have an effect on their safety, taste and physical quality. It is therefore appropriate that the consumer should be appropriately informed where a product has been defrosted[238].

Secondly, foods treated with ionising radiation must bear one of the following indications: 'irradiated' or 'treated with ionising radiation', and other indications as stated in Directive 1999/2/EC concerning foods and food ingredients treated with ionising radiation[239].

Annex VI of Regulation (EU) No 1169/2011 also provides that foods in which a component or ingredient that consumers expect to be normally used or naturally present has been substituted with a different component or ingredient, the labelling shall bear - in addition to the list of ingredients, and in close proximity to the name of the product - a clear indication of the component or the ingredient that has been used for the partial or whole substitution.

238 See Recital (28) of Regulation (EU) No 1169/201.

239 Directive 1999/2/EC of the European Parliament and of the Council of 22 February 1999 on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation (OJ L166, 13.3.1999, pp. 16-22).

Finally, Annex VI of Regulation (EU) No 1169/2011 contains important provisions concerning the designation of meat products, meat preparations and fishery products, in particular concerning minced meat, formed meat and formed fish.

54. List of ingredients

The mandatory inclusion of a list of ingredients in the labelling of prepacked foods is the subject of a complex set of provisions in Regulation (EU) No 1169/2011, which it is obviously not possible to detail here in full.

'Ingredients' are defined as all substances or products, including flavourings, food additives and food enzymes, and all constituents of a compound ingredient, used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form. Because their presence in the food is not intentional, residues are not considered as 'ingredients'[240].

The list of ingredients, which must be preceded by a suitable heading which consists of or includes the word 'ingredients', must include all the ingredients of the food, in descending order of weight, as recorded at the time of their use in the manufacture of the food. In the list, ingredients must be designated by their specific name, where applicable, in accordance with the rules applying to the name of the food and in Annex VI of the Regulation. The Annex contains:

- specific provisions concerning the indication of ingredients by descending order of weight (Part A);
- the designation of certain ingredients by the name of a category rather than a specific name (Part B);
- the designation of certain ingredients, such as additives, by the name of their category, followed by their specific name or, if appropriate, their E number (Part C);
- the designation of flavourings (Part D); and
- the designation of compound ingredients (Part E).

A number of derogations from the obligation to include a list of ingredients are laid down.

240 Article 2(2)f).

Firstly, a series of foods (e.g. fresh fruits and vegetables, cheese, butter, fermented milk and cream) are not required to bear a list of ingredients[241].

Secondly, under specific circumstances, some constituents, such as processing aids and carriers, may be omitted from the list of ingredients[242].

Thirdly, a certain number of derogations result from the special regime laid down in the Regulation for certain categories of food, such as bottles intended for reuse, small packaging and containers, and… alcoholic beverages[243]. The latter derogation can only be explained by the considerable influence exerted on EU institutions by the wine lobby. In contrast, 'The Brewers of Europe' announced on 1 April 2015 that the beer sector had committed to go beyond the existing EU regulation when it comes to informing consumers about ingredients and nutrition information. This move was welcomed by both the European Commission and the European Bureau of Consumers' Union (BEUC).

The Commission was supposed to produce by December 2014 a report addressing whether alcoholic beverages should be covered in the future by the obligation to list the ingredients and, in particular, by the requirement to provide the information on the energy value, and the reasons justifying possible exemptions. The report was eventually published on 13 March 2017, but it is a bit of a let-down. All it does, is to invite the industry to propose, within a year, a harmonised approach aiming to provide consumers with information about the ingredients present in alcoholic beverages and the nutritional value of alcoholic beverages. This proposal will be assessed by the Commission. Should the Commission consider the self-regulatory approached proposed by the industry as unsatisfactory, it would then launch an impact assessment to review further available options in line with Better Regulation principles.

Fortunately, the above derogations are without prejudice to the obligation of labelling any ingredient or processing aid causing allergies or intolerances used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form[244]. The substances or products which are known to causing allergies or intolerances are listed in Annex II of Regulation (EU) No 1169/2011. The Commission has published in July 2017 a notice to assist consumers, businesses and national authorities in understanding

241 Article 19 .
242 Article 20.
243 Article 16.
244 See Article 9(1)c and Article 21 of Regulation (EU) No 1169/2011.

the new requirements of Regulation (EU) No 1169/2011 related to the indication of the presence of certain substances or products causing allergies or intolerances.[245]

When the name of an ingredient appears in the name of the food or is emphasized on the labelling in words or pictures, or when the ingredient is usually associated with the name of the food by the consumer, a quantitative indication of the ingredient is required[246]. The quantitative indication (which is usually referred to as QUID or 'quantitative ingredient declaration') is to be expressed as a percentage, corresponding to the quantity of the ingredient at the time of its use and must appear either next to the name of the food or in the list of ingredients in connection with the ingredient in question. Detailed rules, including derogations, are laid down in Annex VIII to the Regulation. In addition, the Commission published in November 2017 a notice providing for businesses and national authorities on the application of the principle of quantitative ingredients declaration (QUID).[247]

55. Country of origin or place of provenance

The provisions of Regulation (EU) No 1169/2011 on country of origin and place of provenance are somewhat unfortunate.

Admittedly, the corresponding provision in Directive 79/112/EEC and Directive 2000/13/EC was very basic: it merely required "corrective" origin-marking where failure to disclose the place of origin or provenance might mislead the consumer to a material degree as to the true origin or provenance of the foodstuff[248]. This clause addressed in particular situations where the product bears a label or sign (national symbols, emblems, etc.) which may raise doubts as to its real origin. In addition, the mandatory indication of the country of origin was required by a large number of specific EU provisions, most of them contained in the common organisation of the market of the relevant products (e.g. fruits and vegetables, honey, wine, beef and beef products, eggs, fish, olive oil, etc.).

245 Commission notice of 13 July 2017 relating to the provision of information on substances or products causing allergies or intolerances as listed in Annex II to Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers (2017/C 428/01), OJ C428 of 13.12.2017, p. 1-5.

246 Article 9(1)d and Article 22 of Regulation (EU) No 1169/2011.

247 Commission Notice on the application of the principle of quantitative ingredients declaration (QUID) (2017/C 393/05), OJ C 397 of 21.11.2017, p. 5-12.

248 Article 3(8) of Directive 2000/13/EC.

National regulations and practices making the marketing of various products subject to the appearance of the name of the country in which they were manufactured on the packaging or on the product itself were strictly monitored by the Commission, at a time when it still cared about the completion of the single market[249], and regularly condemned by the Court of Justice. As the Court explained in a ruling from 1985[250], *"it has to be recognized that the purpose of indications of origin or origin-marking is to enable consumers to distinguish between domestic and imported products and that this enables them to assert any prejudices which they may have against foreign products. As the Court has had occasion to emphasize in various contexts, the Treaty, by establishing a common market and progressively approximating the economic policies of the Member States seeks to unite national markets in a single market having the characteristics of a domestic market. Within such a market, the origin-marking requirement not only makes the marketing in a Member State of goods produced in other Member States in the sectors in question more difficult; it also has the effect of slowing down economic interpenetration in the Community by handicapping the sale of goods produced as the result of a division of labour between Member States"*. Compared with this admirable conception, Regulation (EU) No 1169/2011 is a let-down, on several accounts.

It all starts with confusion between origin and provenance. Directive 2000/13/EC distinguished between the place of origin (the place where a product had been manufactured or obtained) and the place of provenance (the place from which a product was coming). The place of origin and the place of provenance could be, or not, a country. Regulation (EU) No 1169/2011 radically departs from this system. It uses two notions: the country of origin (which is determined in accordance with Articles 23 to 26 of Regulation (EEC) No 2913/92[251]) and the 'place of provenance' (which means: any place where a food is indicated to come from, and that is not the 'country of origin')[252]. Does this imply that the 'place of provenance' is actually the 'place of origin' where the 'place of origin' is a geographical zone other than a country? Clarification from the Commission would be welcome.

249 See for instance, MEMO/89/4 of 24/02/1989 - Recent Commission actions to complete the internal market : application of Treaty rules in the free circulation of goods.

250 Case 207/*83 Commission v United Kingdom*, [1985] ECR 01201, paragraph 17.

251 Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code (OJ L 302, 19.10.1992, p. 1)

252 Article 2(g).

These definitions already raise several problems.

Firstly, it is unfortunate to restrict the indication of origin to the indication of the country of origin, in the context of origin labelling for food. Secondly, to refer to the customs definition of country of origin in the context of food labelling is highly inappropriate. The purpose of the EU customs code is to regulate trade with third countries; the determination of the country of origin is paramount for the establishment of tariffs, quotas, anti-dumping rights, etc. Considering that less than 5 % of food products placed on the EU market are imported from third countries, and that mandatory origin labelling is only justified where the product concerned actually possesses specific characteristics which are capable of distinguishing it from the point of view of its geographical origin - a concern which has no bearing on the customs definition of origin - one could have done much better than referring to the EU customs code in this instance.

One gets even more worried when reading Articles 23 to 26 of Regulation (EEC) No 2913/92. Article 23, which provides that in the case of goods wholly obtained or produced in a country the 'country of origin' shall be the said country, does not raise any problem, but then these cases never raised a problem under Directive 2000/13/EC either. In contrast, the reference to Article 24 in Regulation (EU) No 1169/2011 is a recipe for disaster. Article 24 provides that "goods whose production involved more than one country shall be deemed to originate in the country where they underwent their last, substantial, economically justified processing […] resulting in the manufacture of a new product or representing an important stage of manufacture."

Take the case of orange juice. The vast majority of orange juice on the European market is made from concentrate. Suppose that the oranges originate from and are made into concentrate in Spain, but the actual reconstitution (through the addition of water) is taking place in Belgium. The reconstitution is the last substantial transformation, resulting in a different product and so the country of origin is … Belgium! Under the previous legislation, the country of origin would have been Spain, which seems appropriate because this is the origin which confers its specific characteristics to the products. Admittedly, Regulation (EU) No 1169/2011 provides that where the country of origin of a food is given and where it is not the same as that of its primary ingredient, the country of origin of the primary ingredient in question shall also be given[253]. But how good is a

253 Article 26(3)(a).

legislation which must resort to compensate to a fundamental flaw in its design? And what about the result of these contortions: the juice will have to be labelled as a Belgian fruit juice made with Spanish oranges[254].

That origin labelling should not be routinely required was forcefully explained by the Court of Justice in the above-mentioned judgement[255]: *"If the national origin of goods brings certain qualities to the minds of consumers, it is in manufacturers' interests to indicate it themselves on the goods or on their packaging and it is not necessary to compel them to do so. In that case, the protection of consumers is sufficiently guaranteed by rules which enable the use of false indications of origin to be prohibited. Such rules are not called in question by the EEC Treaty."*

This conception seems to have been lost on the EU legislator in 2011! There is no doubt that there is a demand, cumulatively very strong, from consumers, consumer groups, national politicians and the European Parliament for more origin labelling on all sorts of food, and in particular meat. The 'horse meat' scandal has made the pressure on the Commission even stronger. Needless to say, origin labelling is a very poor tool to combat fraud, and fraud on the origin, because it cannot be detected by testing, is considerably easier than fraud on the content of the food.

Regulation (EU) No 1169/2011 [256] actually contemplates extending the mandatory indication of the country of origin or place of provenance to:

(a) types of meat other than beef ;

(b) milk;

(c) milk used as an ingredient in dairy products;

(d) unprocessed foods;

(e) single ingredient products;

(f) ingredients that represent more than 50 % of a food.

254 Fruit juices are otherwise governed by Council Directive 2001/112/EC of 20 December 2001 relating to fruit juices and certain similar products intended for human consumption (OJ L 10, 12.1.2002, p. 58–66).
255 See note 152.
256 Article 26(5).

To this effect the Commisssion was requested, by 13 December 2014, to submit reports to the European Parliament and the Council regarding the mandatory indication of the country of origin or place of provenance for these foods.

Following the scandal of horsemeat labelled as beef in ready-made dishes, the Commission promised to anticipate a report on the possibility of making it mandatory to state the origin of all meat used as an ingredient. This report was finally published on 17 December 2013[257]. To its credit, the Commission did not bow to the emotional pressure of consumer groups, MEPs and French ministers. Instead, the Commission considers three scenarios: i/ maintaining origin labelling on a voluntary basis, as is the case today; ii/ introducing mandatory labelling on the basis of EU/non-EU origin; and iii/ introducing mandatory labelling indicating the specific EU member state or the specific third country. The report also assesses the costs of these three scenarios and eventually sends the debate back before the Council and the European Parliament.

Eventually, the Commission adopted Regulation (EU) No 1337/2013 [258] which sets out the modalities requiring (with some exceptions) the indication of the place of rearing and the place of slaughter for prepacked fresh, chilled and frozen meat of swine, sheep, goats and poultry. Theses new rules became applicable as of 1 April 2015. The European Parliament had requested the extension of obligatory origin labelling to meat in ready-to-eat meals, but the European Commission rejected such an extension before due to the additional costs that would arise for the consumers and may lead to fragmentation of the single market.

The Commission has further commissioned external studies on the application of "voluntary origin" labelling of food and on the mandatory indication of country of origin or place of provenance of: meat used as an ingredient; types of meat other than beef, swine, sheep, goat and poultry; milk and milk used as an ingredient in dairy products; and unprocessed foods, single ingredient products and ingredients that constitute over 50% of a food. Although no announcement has been officially made yet, the Commission seems to have come to the conclusion that requiring the mandatory indication of the origin of

257 Report from the Commission to the European Parliament and the Council regarding the mandatory indication of the country of origin or place of provenance for meat used as an ingredient (COM(2013)755).

258 Commission implementing Regulation (EU) No 1337/2013 of 13 December 2013 laying down rules for the application of Regulation (EU) No 1169/2011 of the European Parliament and of the Council as regards the indication of the country of origin or place of provenance for fresh, chilled and frozen meat of swine, sheep, goats and poultry (OJ L 335, 14.12.2013, p. 19-22.

milk and dairy products, and rabbit, bird and deer meat would generate such additional cost for producers that this would offset potential benefits to consumers.

In the meantime, a number of Member States have notified to the Commission, and subsequently adopted – in the absence of objection from the Commission – national measures requiring the indication of origin for certain food, in particular milk and dairy product. Regulation (EU) No 1169/2011 specifically provides[259] that Member States may introduce measures concerning the mandatory indication of the country of origin of certain foods, but only "where there is a proven link between certain qualities of the food and its origin or provenance". In addition, when notifying such measures to the Commission, Member States must provide "evidence that the majority of consumers attach significant value to the provision of that information". The Commission appears to have been quite generous in accepting, albeit tacitly, that tese conditions were met.

56. Other mandatory particulars

a) Net quantity

The net quantity of a food must be indicated, using the metric system. For liquid products, the net quantity is expressed in units of volume (litres, centilitres or millilitres); for other products, it is expressed in units of mass (kilograms or grams).

Detailed rules and derogations are laid down in Annex IX of Regulation (EU) No 1169/2011.

b) Date marking

All food need to be bear either a 'minimum durability date' or a 'use-by date'.

The 'minimum durability date' indicates the date until which the food retains its specific properties when properly stored[260].

The date must be preceded by the words: 'Best before:' followed by the date itself or by a reference to where the date is given on the labelling. Detailed rules and derogations are laid down in Annex X of Regulation (EU) No 1169/2011.

The Commission is however considering the extension of the number of products that can be sold without a 'best before...' date. Dry pasta, candy, rice, sterilised canned food,

259 Article 39(2). See above No 49.
260 Article 2(2)(r).

jams, hard cheese, pickled vegetables and glass water bottles, for instance, could lose the mention, and Member states could be given the right to extend this list. Data suggests that around 100 million tons of food is wasted in Europe annually, and misunderstanding of the meaning of the 'best before...' date is often put forward as contributing significantly to this problem.

In the case of highly perishable foods, the date of minimum durability shall be replaced by the 'use by' date. At the expiry of the 'use by' date a food shall be deemed to be unsafe[261].

Where appropriate, a time limit for consumption after opening the package must also be indicated[262].

The date of freezing is required in the case of frozen meat and meat preparations and frozen unprocessed fishery products[263].

c) Storage conditions, conditions of use and instructions for use

The next food information particular is only mandatory in certain cases. Where the food concerned requires special storage conditions or conditions of use, those conditions must be indicated[264].

In addition, instructions for use must also be indicated whenever it would be difficult to make an appropriate use of the food in the absence of such instructions[265].

As already indicated[266], foods which have been frozen before sale and which are sold defrosted must bear the indication "defrosted". Whilst Regulation (EU) No 1169/2011 does not say as much, this may be taken as an indication that the foods concerned should not be refrozen by the consumer.

d) Name and address of the food business operator responsible for the food

The obligation to indicate the name and address of a business operator[267] must be read in conjunction with the provision on responsibilities[268]; it must be said, however, that

261 Article 24(1).
262 Article 25(2).
263 Annex III, point (6.1) and Annex X point (3).
264 Article 9(1)(g) and Article 25(1).
265 Article 9(1)(j).
266 Above (3).
267 Article 9(1)(h).
268 Article 8(1).

the two provisions appear to be mutually referring. They require the indication, on the package or on a label attached to it, of the name and address of the food business operator under whose name the food is marketed. If that operator is not established in the Union, the legal requirement is not clear: the name and address of said operator can certainly be replaced by the name and address of the importer into the Union, but the text can also be read as requiring the indication of name and address of the importer, as was the case under Directive 2001/13/EC.

Directive 2000/13/EC allowed Member States to retain national provisions which were requiring the additional indication of the factory or packaging centre, in respect of home production, on the labelling of foods. During the negotiations that led to the adoption of Regulation (EU) No 1169/2011, Council considered a suggestion to introduce a similar requirement at Union level, but the idea was eventually not retained[269].

e) Alcoholic strength

The actual alcoholic strength by volume has to be indicated in the case of beverages containing more than 1,2 % by volume of alcohol[270].

57. Additional mandatory particulars for specific foods

The above food information particulars are mandatory for all foods, under the conditions specified and without prejudice to the derogations provided for.

However, Regulation (EU) No 1169/2011 lays down a number of additional mandatory particulars for specific foods or categories of foods[271]. The foods and food categories concerned, and the corresponding mandatory particulars, are listed in Annex III. The Commission is entitled to amend this Annex by means of delegated acts and may thus lay down further mandatory particulars for specific types or categories of foods[272].

In principle, Member States should not adopt or maintain national measures laying down additional mandatory particulars, whether for all foods or for certain types or categories of food[273]. However, Regulation (EU) No 1169/2011 establishes a procedure, under the

269 See the answer given by Commissioner Andriukaitis on 6 May 2015 to a written question from Nicola Caputo MeP.
270 Article 9(1)(k) and Annex XII.
271 Article 10.
272 Article 10(2).
273 Article 38(1).

control of the Commission, allowing Member States to require additional mandatory particulars for specific types or categories of foods, justified on one of the following grounds:

- the protection of public health,
- the protection of consumers,
- the prevention of fraud,
- the protection of intellectual property rights, indications of provenance, registered designations of origin and the prevention of unfair competition[274].

58. Omission of certain mandatory particulars

Like Directive 2000/13/EC, Regulation (EU) No 1169/2011 provides for a number of derogations to the list of mandatory particulars which it lays down.

Firstly, with the notable exception of the mandatory indication of substances capable of causing allergies or intolerances, the provision of the mandatory particulars of food information are not compulsory for non-prepacked foods, unless the concerned Member State has adopted national measures requiring the provision of some or all the particulars[275].

Secondly, the provision of a list of ingredients and of a nutrition declaration is not required for beverages containing 1,2 % by volume of alcohol[276]. Once again, the powerful wine lobby has managed to maintain this totally unjustified derogation. The Commission is required to provide a report by 14 December 2014 addressing whether alcoholic beverages should in future be covered.

More understandable are the derogations provided for glass bottles intended for reuse[277], and for packaging and containers the largest surface of which has an area of less than 10 cm^2 [278].

As will be explained below[279], a number of foods are exempted from the requirement of the mandatory nutrition declaration.

274 Article 39(1) and above, No 9.
275 Article 44.
276 Article 16(4), and Article 41.
277 Article 16(1).
278 Article 16(2).
279 Chapter III.

Member States may only provide for further derogations from the mandatory indication of the particulars provided for in Regulation (EU) No 1169/2011 where specifically foreseen by the Regulation[280].

59. Availability, placement and presentation of mandatory particulars

In principle, the mandatory particulars must appear directly on the package or on a label attached to the package[281].

In order to reflect the fact that nowadays food information is provided to the consumers by other means than labelling, Regulation (EU) No 1169/2011 provides that the Commission may establish, by means of a delegated act, criteria subject to which certain mandatory particulars may be expressed by means other than on the package or on the label[282].

One of the areas in which Regulation (EU) No 1169/20911 improves significantly on the previous regime, laid down in Directive 2000/13/EC, is the presentation of mandatory particulars.

Firstly, the mandatory particulars must be easily visible and, where appropriate, indelible. They must be marked in a conspicuous place and may not in any way be hidden, obscured, detracted from or interrupted by any other intervening material[283]. In addition, the name of the food, the net quantity and, for beverages containing more than 1,2 % by volume of alcohol, the alcoholic strength must appear in the same field of vision[284].

Secondly, the mandatory particulars must be clearly legible, and this is where Regulation (EU) No 1169/2011 is breaking new ground, by laying down the minimum font size that must be used when displaying mandatory particulars on the package or on an attached label[285]. Unfortunately, no rules are specified in respect of contrast (e.g. dark letters on a clear background, or the other way round), but the Commission is entitled to lay down further legibility rules by means of a delegated act[286].

280 Article 40.
281 Article 12(2).
282 Article 12(3) and (4).
283 Article 13(1)
284 Article 13(5) and (6). Compare with Article 13(3) of Directive 2000/13/EC.
285 Article 13(2), Article 13(3) and Annex IV.
286 Article 13(4).

The mandatory particulars must be indicated with words and numbers[287]. Pictograms and symbols may only be used in addition to words and numbers; however, the Commission may lay down, by means of a delegated act, circumstances under which pictograms or symbols may be used instead of words and numbers[288], which may be particularly useful where the mandatory particulars are displayed in several languages.

60. Language requirements

Regulation (EU) No 1169/2011 provides that the mandatory particulars must appear in a language easily understood by the consumers of the Member State where a food is marketed[289]. This means that all the particulars do not necessarily have to be indicated in the language or in all the languages used in the Member State where the food is marketed[290]. However, Member States may rule that, within their own territory, the mandatory particulars must be given in one or more languages from among the official languages of the Union[291].

Member States may not lay down further restrictions on the use of languages. In particular, they may not preclude the particulars from being indicated in several languages[292]. Nor can they lay down that the indication of particulars in one language must be displayed in characters similar or greater than those used in another language[293].

287 Article 9(2).
288 Article 9(3).
289 Article 15(1).
290 Case 27/80 *Fietje* [1980] ECR 03839.
291 Article 15(2).
292 Article 15(3).
293 This matter was submitted to the ECJ in 1988, but the case was withdrawn before the Court could rule on it. Case 210/88 *Commission v. Italy*.

Chapter 3
Nutrition labelling

61. History

It is already long ago that producers and distributors have been voluntarily introducing nutrition information on some of the products they were placing on the market. The content and presentation of that information was however anything but harmonised, with the result that the information thus provided was not really understood or valued by consumers, especially because the nutrition information was provided to actually make the product more attractive, rather than for the information of consumers. It was thus felt that some sort of legal underpinning was necessary.

Work started at international level, within the *Codex Alimentarius* Commission, at the end of the 1970's. Guidelines on nutrition labelling were adopted in July 1985.

Since several Member States were contemplating the adoption of national legislation derived from the *Codex* guidelines, it seemed appropriate to develop a common EEC legislation on the subject, in order to guarantee the proper functioning of the internal market. In October 1988, the Commission submitted two proposals for Directives to Council. The first one was making nutrition labelling compulsory. The second one dealt with the content of nutrition labelling: it was introducing a standardised format for nutrition labelling, whether this labelling was mandatory or whether it was affixed on a voluntary basis. Only the second proposal was adopted by Council, in the form of Directive 90/496/EEC[294]. This Directive provided for the possibility of adapting it to technical progress, and this possibility was used twice[295].

Perhaps the most important innovation of Regulation (EU) No 1169/2011 is that it makes nutrition labelling compulsory and that it introduces a modernized, standardised format for nutrition labelling, in line with the current concerns about obesity and related diseases. The provisions on compulsory nutrition labelling will only apply from 13 December 2016.

294 Directive 90/496/EEC of the Council of 24 September 1990 on nutrition labelling for foodstuffs (OJ L 276 of, 6.10.1990, p. 40).

295 Commission Directive 2003/120/EC of 5 December 2003 amending Directive 90/496/EEC on nutrition labelling for foodstuffs (OJ L 333 of 20.12.2003, p. 51). Commission Directive 2008/100/EC of 28 October 2008 amending Council Directive 90/496/EEC on nutrition labelling or foodstuffs as regards recommended daily allowances, energy conversion factors and definitions (OJ L 285 of 29.10.2008, p. 9).

Between 13 December 2014, when Regulation (EU) No 1169/2011 will enter into application, and 13 December 2016, when nutrition labelling will become compulsory, where the nutrition declaration is provided on a voluntary basis, it will have to comply with the provisions of Regulation (EU) 1169/2011.

Since Directive 90/496/EEC will apply until 13 December 2014, the date at which it will be repealed and replaced by Regulation (EU) 1169/2011, it is appropriate to briefly describe its regime.

62. Directive 90/496/EEC

Under Directive 90/496/EEC, nutrition labelling is still optional for producers and distributors. However, where a nutrition claim appears on labelling, in presentation or in advertising, with the exclusion of generic advertising, nutrition labelling becomes compulsory.

Where nutritional labelling is provided, whether on a voluntary basis or because a nutrition claim is being used, it must conform to the provisions of the Directive.

Under the Directive, where nutrition labelling is provided, the information to be given must 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,

- any of the minerals or vitamins listed in the Annex and present in significant amounts as defined in that Annex.

The nutrition information 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 must be printed in legible and indelible characters in a conspicuous place.

Directive 90/496/EEC further lays down important modalities, like the manner in which the energy value to be declared must be calculated, but these are beyond the boundaries of this commentary.

63. Regulation (EU) No 1169/2011

As has already been indicated, Regulation (EU) No 1169/2011 repeals Directive 90/496/EEC as from 13 December 2014[296], and makes nutrition labelling mandatory as from 13 December 2016, in accordance with the provisions it lays down[297]. Between 13 December 2014 and 13 December 2016, where nutrition labelling is provided on a voluntary basis or because a nutrition claim is being made, it must conform to the provisions of Regulation (EU) No 1169/2011.

Regulation (EU) No 1169/2011 thus makes nutrition labelling compulsory from 13 December 2016, through the addition of a new item in the list of mandatory particulars, which it calls the 'nutrition declaration'[298].

Regulation (EU) No 1169/2011 devotes an entire section to the 'nutrition declaration'[299]. This Section does not apply to food supplements[300] and natural mineral waters[301], and applies only in a complementary manner to foodstuffs intended for particular nutritional uses[302]. Moreover (and one more shame on the EU institutions), the nutrition declaration is not mandatory for beverages containing more than 1,2 % by volume of alcohol[303].

296 Article 53(1).
297 Article 55.
298 Article 9(l).
299 Section 3 of Chapter IV.
300 Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the Approximation of the laws of the Member States relating to food supplement (OJ L 183 of 12.7.2002, p. 51).
301 Directive 2009/54/EC of the European Parliament and of the Council of 18 June 2009 on the exploitation and marketing of natural mineral waters (Recast) (OJ L 164 of 26.6.2009, p.45).
302 Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses and specific (OJ No L 124 of 20.5.2009, p. 21).cle 4(1) of that Directive.
303 Article 16(4). See also above, No 18.

Like all mandatory particulars of food information, with the notable exception of the indication of allergenic substances, the nutrition declaration is only compulsory for prepacked products[304]. Member States may of course decide to extend the obligation to non-prepacked products[305]. In developed countries, people typically eat and drink about one-third of their calories away from home and therefore providing nutrition information in restaurants and canteens is certainly be useful. In the United States, chain restaurants and similar retail food establishments have to provide calorie information for standard menu items on menus and menu boards and a succinct statement about suggested daily caloric intake, while other nutrient information (e.g. total fat, saturated fat, trans fat, cholesterol, sodium, total carbohydrates, fibre, sugars, and protein) has to be made available in writing on request[306]. The United States also require vending machines to display calorie information about the food items available; even though most items would bear that information on the packaging, it is often not visible before the purchase is made[307].

Finally, Regulation (EU) No 1169/2011 lays down a comprehensive list[308] of foods which are exempted from the compulsory nutrition declaration (e.g. unprocessed products that comprise a single ingredient or category of ingredients).

64. Content of the nutrition declaration

In the United States, where nutritional labelling has been mandatory since the 90's, no less than 13 items have to be declared. Studies have however shown that providing too much information may be counterproductive, leading to consumer confusion about what is important and how the label should be used.

The Commission had proposed[309] to limit the nutrition declaration to 6 items (energy, fat, saturates, carbohydrates, sugars and salt) which was already one item (sugars) too much in our view. Eventually, Regulation (EU) No 1169/2011 requires seven mandatory items in the nutrition declaration[310]: the energy value and the amounts of fat, saturates, carbohydrate, sugars, protein and salt.

304 See above, No 43.
305 Article 44(b). See also above, No 49.
306 21001 Note/text CFR 101.11
307 Ibid.
308 Annex V.
309 COM(2008) 40 final of 30.1.2008. 2008/0028 (COD).
310 Article 30(1).

Protein was thus added, and the justification is not apparent: energy value apart, which is a must in a nutrition declaration, the other items represent nutrients which consumers are trying to avoid or at least limit (fat, saturates, carbohydrate, sugars and salt) in trying to make healthy choices. Thus, the amount of protein does not really belong there, and could have been left to the second list.

Trans fats[311] would probably have been a better candidate for the seventh spot. They are however included in the saturates and highlighting them may have prompted consumers to choose products with a low amount of trans fats but higher amounts of other saturated fats, which would actually be anything but a healthy choice. Regulation (EU) No 1169/2011 however requested[312] the Commission to produce a report, by 13 December 2014, to assess the need of providing information on trans fats to consumers or restricting their use. The report was published on 3 December 2015 [313]. The main conclusion was that "a legal limit for industrial TFA content would be the most effective measure in terms of public health, consumer protection and compatibility with the internal market". It was followed up by a public consultation and an impact assessment[314]. It can reasonably be expected that a policy decision will be taken by the Commission in 2018 but it is unlikely to be a proposal to amend Regulation (EU) No 1169/2011.

The second list[315] includes further items which may be added, in whole or in part, on a voluntary basis: mono-unsaturates, polyunsaturates, polyols, starch, fibre and vitamins or minerals.

Where the nutrition declaration is not compulsory, but is nonetheless provided on a voluntary basis, the nutrition declaration must conform to the above requirements[316]. However, in the case of non-prepacked food, the voluntary nutrition declaration may be limited either to energy, or to energy, fat, saturates, sugars, and salt[317]. In the case of beverages containing more than 1,2 % by volume of alcohol, the voluntary nutrition declaration may be limited to the energy value[318].

311 Trans fats are a particular type of fats that may be produced industrially as partially hydrogenated oils. Trans fats can also be naturally present in the fat of cows, sheep or goats, such as in meat or dairy products.
312 Article 30(7).
313 https://ec.europa.eu/food/sites/food/files/safety/docs/fs_labelling-nutrition_trans-fats-report_en.pdf
314 http://ec.europa.eu/smart-regulation/roadmaps/docs/2016_sante_143_trans_fats_en.pdf
315 Article 30(2).
316 Article 36(1).
317 Article 30(5).
318 Article 30(4).

Regulation (EU) No 1169/2011 provides detailed rules for the calculation of the energy value[319] which are beyond the purpose of this commentary.

The energy value and the amounts of nutrients must refer to the food as sold. However, where appropriate, the information may relate to the food after preparation, provided that sufficiently detailed preparation instructions are given and the information relates to the food as prepared for consumption[320].

65. Expression per 100 g or per 100 ml – Reference intakes

An important issue, when discussing nutrition labelling, is whether the energy value and the amounts of the nutrients to be declared, should be expressed per 100 g or per 100 ml, or rather on a per portion basis or per consumption unit. The first method makes it easier to compare between similar products. The second method (a per portion basis or per consumption unit) makes it easier to calculate, for instance, the total of calories one ingests on the day; this is also the method preferred in North America.

Regulation (EU) No 1169/2011, in line with previous EU legislation (Directive 90/496/EEC) requires the energy value and the amount of nutrients to be declared to be expressed per 100 g or per 100 ml[321].

However, and this is an important innovation brought by Regulation (EU) No 1169/201, the energy value and the amount of nutrients to be declared may also be provided as a percentage of the reference intakes set out in the Regulation[322]. In the case of vitamins and minerals, it is actually mandatory to express their declaration as a percentage of the reference intakes, in addition to the expression per 100 g or per 100 ml[323].

Reference intakes are guidance daily intakes for certain nutrients, which under current voluntary nutrition labelling schemes are often referred to as "Recommended Daily Amounts". The concept of including the % reference intake on food packaging is not new. It is already required under EU legislation for vitamins and minerals when listed, and many food manufacturers already include the reference amount for most nutrients on their voluntary labelling. Comparing the nutrient content of a foodstuff to a reference intake

319 Article 31 and Annex
320 Article 31(3).
321 Article 32(2).
322 Article 32(4).
323 Article 32(3).

enables the consumer to better understand the relevance of the information provided on the label for their overall diet. Regulation (EU) No 1169/2011 lists the reference intakes for vitamins and minerals, for the energy value and for those nutrients which must be included in the nutrition declaration[324].

The reference intakes take into account the figures that are currently used by the industry on a voluntary basis and those that are set out in the legislation of other countries. For instance, the reference intake for energy of an average adult is: 8 400 kJ/ 2 000 kcal. Thus, if a given food contains 1 680kJ/ 400 kcal per 100 g or 100 ml, this declaration may be accompanied by the following statement: "20 % of the reference intake - Reference intake of an average adult: 8 400 kJ/ 2 000 kcal"[325].

66. Expression on a per portion basis or per consumption unit

As already indicated, expressing the energy value in particular on a per portion basis or per consumption unit makes it easier to calculate the number of calories consumed on the day, for those who have that in mind. Apart from the fact that the expression per 100 g or 100 ml is the preferred method in Europe, notably because it facilitates comparisons between products, the expression on a per portion basis raises the problem that portion sizes are hardly harmonised in Europe, where there still are important differences in the diet of many countries. Regulation (EU) No 1169/2011 however provides that the energy value and the amounts of nutrients may be expressed per portion and/or per consumption unit, on a voluntary basis[326]. There are several conditions:

- this method of expression is supplementary and may never replace the expression per 100 g or 100 ml[327].
- it must be easily recognisable by the consumer,
- the portion or the unit used must be quantified on the label[328], in close proximity to the nutrition declaration[329], and the number of portions or units contained in the package must be stated.

324 Annex XIII.
325 Article 32(5).
326 Article 33.
327 Article 33(1)(a).
328 Article 33(1).
329 Article 32(4).

The expression on a per portion basis or per consumption unit may come in addition or in place of the expression as a percentage of the reference intakes[330], except for vitamins and minerals where it can only come as an addition of the expression as a percentage of the reference intakes[331].

67. Presentation – 'Front-of-pack' labelling

In the past, nutrition information was often hidden on the back of packs and written in very small characters. This was all the more surprising, and regrettable, that this information was, in most cases, provided on a voluntary basis. Regulation (EU) No 1169/2011 therefore laid down some presentation requirements.

Firstly, it is provided that all the components of the nutrition declaration must be included in the same field of vision and must be presented together in a clear format[332].

Secondly, the Regulation proposes an order of presentation[333], which is however not compulsory.

Thirdly, the nutrition declaration must be presented, if space permits, in tabular format with the numbers aligned. Where space does not permit, the declaration can appear in linear format.

Unfortunately, Council and Parliament have not withheld the clause in the Commission proposal that required the mandatory nutrition declaration (energy, fat, saturates, carbohydrate, sugars, and salt) to be included in the principal field of vision (so-called 'front-of-pack' labelling) of the package.

Regulation (EU) No 1169/2011 however allows repeating in the labelling either the energy value alone or the energy value together with the amounts of fat, saturates, sugars, and salt (but not the amount of protein!)[334]. Where this is done, the repeated information must be presented in the principal field of vision ('front-of-pack') and using at least the minimum font size that must be used when displaying mandatory particulars[335].

330 Article 33(1)(c).
331 Article 33(1)(b).
332 Article 34(1).
333 Annex XV.
334 Article 30(3).
335 See above, No 39 and Article 13(2), Article 13(3) and Annex IV.

68. Further work

Perhaps more than any other part of Regulation (EU) No 1169/2011 the provisions on the nutrition declaration are a work in progress.

Following further work is foreseen:

- the possibility for the Commission to adopt delegated acts to amend the list of mandatory particulars in the nutrition declaration[336];
- the obligation for the Commission to present, by 13 December 2014, to assess the impact of appropriate means that could enable consumers to make healthier food choices including, among others, the provision of information on trans fats or restrictions on their use[337];
- the possibility for the Commission to adopt an implementing act setting out detailed rules for the uniform implementation of the calculation rule[338];
- the obligation for the Commission (no deadline specified) to adopt implementing acts laying down rules on the expression per portion or per consumption unit for specific categories of foods[339];
- the possibility for the Commission to adopt implementing acts regarding the energy value and amounts of nutrients which can be regarded as negligible[340];
- the possibility for the Commission to adopt implementing acts regarding the manner of presenting the nutrition declaration[341];
- the obligation for the Commission to present, by 13 December 2017, a report on the use of additional forms of expression and presentation, on their effect on the internal market and on the advisability of further harmonisation of those forms of expression and presentation[342];
- the obligation for the Commission (no deadline specified) to adopt implementing acts on additional forms of expression and presentation[343].

The latter is, by far, the most important work in progress.

336 Article 30(6).
337 Article 3(7.
338 Article 31(4).
339 Article 33(5).
340 Article 34(5).
341 Article 34(6).
342 Article 35(5).
343 Article 35(6).

69. Additional forms of expression and presentation

Currently, some business operators are using a variety of forms of expression in an effort to make the nutrition information better understandable by consumers. These include expression of fat, saturates, sugars and salt using terms like: 'high', 'medium' and ''low', or, even more telling, using the so-called 'traffic lights' system, where 'high' is shown on a red background, 'medium' on a yellow background, and 'low' on a green background. Sometimes, the use of such schemes is even encouraged by the authorities. While the EU food industry wants to be able to use such additional forms of expression, it is stubbornly opposed to their mandatory introduction.

Regulation (EU) No 1169/2011 however allows[344] additional forms of expression and presentation, such as graphics or symbols, to be used by food business operators on a voluntary basis, and always as an addition to the mandatory presentation laid down in the Regulation. These additional forms of expression or presentation, which may be using graphical forms or symbols in addition to words or numbers, can only be used if a number of conditions are met[345]. These criteria comprise the requirements that the additional forms are based on sound and scientifically valid consumer research and do not mislead the consumer.

The Member States are required to ensure an appropriate monitoring of the additional forms of expression or presentation of the nutrition declaration that are present on the market in their territory[346]. They are also expressly allowed to recommend to food business operators the use of one or more additional forms of expression or presentation of the nutrition declaration. In such case, they must provide the Commission with the details of such additional forms of expression and presentation[347].

The United Kingdom notified a voluntary front-of-pack 'traffic light' scheme ranking sugars, fat, saturated fatty acids and salt by assigning the colour green, amber or red according to the content in the relative nutrient per 100g. It has been argued that this classification was overly simplistic and suggested that it could hinder the free movement of goods within the EU. The Commission, under strong pressure from Italian producers fearing that this may adversely affect the marketing of products such as salami and olive

344 Article 35.
345 Article 35(1).
346 Article 35(3).
347 Article 35(2).

oil, initiated in October 2014 an infringement procedure against the United Kingdom for breach of the Treaty rules on the free movement of goods; this procedure was however abandoned in 2016.

In March 2017, six global food companies (Coca-Cola, Mars, Mondelēz, Nestlé, Pepsi and Unilever) all committed to a colour labelling scheme (the so-called Evolved Nutrition Label), using portions as a reference, for the EU market under which green, amber and red labels — so-called traffic lights — will show the relative nutritional information of products, based on portion sizes. This move has sharply divided the European food industry.

In France, the Government issued in November 2017 a decree recommending that food companies and supermarkets use the so-called NutriScore system, a colour palette ranging from green to red to warn consumers about levels of sugar, salt or saturated fat in food products. As requested under Regulation (EU) No 1169/2011 France had notified the draft decree to the Commission earlier in the year and it is understood that six Member States (Czech Republic, Germany, Hungary, Italy, Poland and Spain) filed so-called "detailed opinions" objecting to the measure. However, the Commission did not oppose the French measure, as it is merely a recommendation to food business operators, something which, as already indicated, is expressly allowed under the Regulation.

Some schemes, logically more palatable to the industry, only highlight the positive nutritional value of foods that meet the criteria used. The Nordic Keyhole system, the Healthy Choice label and the Guiding Stars scheme fall in this category.

At EU level, the Commission was supposed to present, by 13 December 2017, a report on the use of additional forms of expression and presentation, on their effect on the internal market and on the advisability of further harmonisation of those forms of expression and presentation. However, at the end of 2017, a Commission spokesperson announced that that the presentation of the report would be delayed until the end of 2018.

70. The 'Farm to Fork Strategy'

In 20 May 2020, the European Commission adopted its 'Farm to Fork Strategy for a fair, healthy and environmentally friendly food system' as part of the European Green Deal[348].

348 See above, No 10.

With a view to making it easier for consumers to choose healthy and sustainable diets, which would benefit their health and quality of life and reduce health-related costs, the 'Farm to Fork Strategy' announces that the Commission will propose 'harmonised mandatory front-of-pack nutrition labelling to enable consumers to make informed and health-conscious food choices'.

A Commission 'Report to the European Parliament and the Council regarding the use of additional forms of expression and presentation of the nutrition declaration' was accompanying this communication[349]. The report broadly confirms the potential of front-of-pack labelling schemes, in particular evaluative schemes, to help consumers make health-conscious food choices, and concludes that "it seems appropriate to introduce harmonised mandatory front-of-pack nutrition labelling at EU-level". The Commission thus announces that it will "in due course prepare a legislative proposal in line with the objectives of the Farm to Fork Strategy and with better regulation principles".

The Farm to Fork strategy announced a series of further initiatives aiming at improveing the sustainability of food information to conumers.

- Firstly, the European Commission indicated its intention to propose setting up nutrient profiles to restrict the promotion (via nutrition and health claims) of foods high in fat, sugars and/or salt.
- Secondly, the Commission announced that it was considering the opportunity of extending the mandatory indication of origin or provenance for certain products, while fully taking into account the impacts on the single market. This action would allow consumers to better identify the origin of food and facilitate consumers' informed and sustainable food choices.
- Thirdly, further to a study which it had published in 2018 which had concluded that up to 10% of all food waste generated in the EU could be linked to date marking ("best before" and "use by" dates), the Commission confirmed in the Farm to Fork Strategy that it thought appropeiate to revise existing EU rules on date marking to address the misunderstanding and misuse of the "use by" and "best before" dates in particular.

349 COM (2020)207 of 20/05/2020. file:///C:/Users/deboy/Downloads/COM(2020)207_0-1.pdf

- Fourthly, as already announced in its "Europe's Beating Cancer Plan" of 3 February 2021, the Commission reiterated that it will propose to introduce the mandatory indication of the list of ingredients and the nutrition declaration on labels of all alcoholic beverages.

The Farm to Fotrk Strategy was promptly followed-up, on 23 December 2020, by a Commission inception impact assessment[350] on front-of-pack nutrition labelling and nutrient profiles, origin labelling, date marking, outlining the Commission's initial analysis of the problems, policy objectives and different solutions as well as the likely impacts. This was followed a few months later by a second inception impact assessment[351] on the labelling of alcoholic beverages (list of ingredients and nutrition declaration). The Commission opened public consultation on both inception impact assessment and the feedback was published on the DG SANTE website[352]. In December 2021, the Commission launched yet another open public consultation to consult all citizens and stakeholders on the different initiatives for revising EU legislation on the very same issues and, in March 2022, it announced that it had received more than 3.000 contributions and published a summary report on them[353].

Perhaps more importantly, the European Food Safety Authority (EFSA) provided a 'Scientific advice for the development of harmonised mandatory front-of-pack nutrition labelling and the setting of nutrient profiles for restricting nutrition and health claims on foods'[354] in March 2022. Additional input was finally (?) provided, by the Joint Research Centre (JRC) which published in September 2022 four reports synthesising the current scientific evidence regarding front-of-pack nutrition labelling, origin labelling and digital means to convey food information, as well as analyse the market in terms of labelling of alcoholic beverages.

A Commission proposal to revise the regulatory framework on 'food information to consumers' and on 'nutrition and health claims' is now long overdue.

350 Inception impact assessment - Ares (2020)7905364. https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12749-Food-labelling-revision-of-rules-on-information-provided-to-consumers_en

351 Inception impact assessment – Ares (2021)4128214. https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13028-Food-labelling-revision-of-rules-on-information-provided-to-consumers-for-alcoholic-beverages_en

352 See the two footnotes above.

353 Ares (2022)3403916. https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12749-Food-labelling-revision-of-rules-on-information-provided-to-consumers/public-consultation_en

354 https://www.efsa.europa.eu/en/news/nutrient-profiling-scientific-advice-eu-farm-fork-initiative

It may well be that the Commission is waiting for progress on some of the other aspects of the its plans for a new 'Sustainability Labelling Framework', namely those relating to animal welfare labelling [355] and 'green claims' [356], and the provision of consumer information relating to the climate, environmental and social aspects of food products.

355 For the state of play on this subject, see : https://food.ec.europa.eu/animals/animal-welfare/other-aspects-animal-welfare/animal-welfare-labelling_en

356 See : https://ec.europa.eu/environment/eussd/smgp/initiative_on_green_claims.htm

Chapter 4
Nutrition and health claims

71. History

Regulation (EU) No 1169/2011, like Directive 79/112/EEC and Directive 2000/13/EC before it, prohibits the conveying of information which is capable of misleading the consumer to a material degree. This general clause is illustrated with examples of typical instances which may mislead consumers[357]. For instance, it is prohibited to attribute to the food effects or properties which it does not possess, or to suggest that the food possesses special characteristics when in fact all similar foods possess such characteristics, in particular by specifically emphasising the presence or absence of certain ingredients and/or nutrients. Moreover, Regulation (EU) No 1169/2011 prohibits to attribute to any food the property of preventing, treating or curing a human disease and any reference to such properties.

Directive 2000/13/CEE, like Directive 79/112/EEC, laid down that Council would draw up a non-exhaustive list of claims capable of misleading the consumer, the use of which must at all events be prohibited or restricted[358]. The Commission submitted several proposals to this effect to Council and Parliament. All these proposals failed in Parliament, save the last one, which ended up as Regulation (EC) No 1924/2006[359].

72. Definition and scope

A 'claim' means: any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics[360].

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357 See above, No 26.
358 Article 2(2) of Directive 2000/13/EE.
359 Regulation (EU) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ L 12 of 18.01.2006, p. 3), as amended by: Regulation (EC) No 107/2008 of the European Parliament and of the Council of 15 January 2008 (OJ L 39 of 13.2.2008, p. 8), and Regulation (EC) No 109/2008 of the European Parliament and of the Council of 15 January 2008 (L 39 of 13.2.2008, p. 14). See also: Corrigendum (OJ L 12 of 18.1.2007, p. 3).
360 Article 2(2.1).

Regulation (EC) No 1924/2006 applies to "nutrition claims" and "health claims" (see below, No 35) which are made in commercial communications, whether in the labelling, presentation or advertising of foods to be delivered as such to the final consumer.

The Regulation applies to all food put up for sale to the final consumer or to mass caterers, whether prepacked, packed at the point of sale or non-prepacked, including fresh products such as fruit, vegetables or bread.

Trade marks, brand names and fancy names appearing in the labelling, presentation or advertising of a food which may be construed as a nutrition or health claim are covered by the Regulation and can only be used if they meet the conditions laid down, including the need for an authorisation as the case may be[361]. However, generic descriptors (denominations) which have traditionally been used to indicate a particularity of a class of foods or beverages which could imply an effect on human health (e.g. 'probiotics') may be benefit from an exemption, on application by the food business operators concerned[362]

Logically, beverages containing more than 1,2 % by volume of alcohol may not bear health claims. As far as nutrition claims are concerned, only nutrition claims referring to low alcohol levels, or the reduction of the alcohol content, or the reduction of the energy content may be made[363].

73. Nutrient profiles

The introduction of 'nutrient profiles', which operate as conditions for the use of nutrition and health claims, is perhaps the most innovative clause in Regulation (EC) No 1924/2006; it is also the most controversial one. The purpose is to avoid a situation where nutrition or health claims mask the overall nutritional status of a food product, which could mislead consumers when trying to make healthy choices in the context of a balanced diet. The only object of nutrition profiles is to regulate the conditions under which nutrition or health claims may be made.

361 However, an authorization is not needed provided where the trade mark, brand name or fancy name is accompanied by a related nutrition or health claim in that labelling, presentation or advertising which complies with the provisions of this Regulation. See Article 1(3).

362 A decision to this effect must be adopted under the regulatory procedure with scrutiny. See Article 1(4).

363 Article 3(3) and (4).

It was foreseen that, after having consulted EFSA, the Commission would establish specific nutrition profiles by 19 January 2009[364], based on scientific knowledge about diet and nutrition, and their relation to health and taking into account in particular:

(a) the quantities of certain nutrients and other substances contained in the food, such as fat, saturated fatty acids, trans-fatty acids, sugars and salt/sodium;

(b) the role and importance of the food (or of categories of food) and the contribution to the diet of the population in general or, as appropriate, of certain risk groups including children;

(c) the overall nutritional composition of the food and the presence of nutrients that have been scientifically recognised as having an effect on health.

Although EFSA delivered its opinion in January 2008[365], the Commission has so far failed to adopt the nutrient profiles. It has however conducted specific and extensive consultations of stakeholders on the subject. Besides numerous contacts with consumers and public health groups and the different sectors of the food industry, stakeholders were consulted in two meetings of a working group on nutrient profiles of the Advisory Group on the Food Chain and Animal and Plant Health on 8 July and 28 November 2008[366]. Member State experts were consulted within the Commission expert working group on nutrition and health claims, in which EFSA also participated. In 2016, the Commission announced that it was carrying out an evaluation of the Regulation with regard to nutrient profiles, in the context of its Better Regulation Communication. It is thus unlikely that the nutrient profiles will be adopted anytime soon.

The Regulation allows two important derogations to the system of nutrient profiles.

Firstly, nutrition claims referring to the reduction of fat, saturated fatty acids, trans-fatty acids, sugars and salt/sodium are allowed without reference to a profile for the specific nutrient/s for which the claim is made, provided that these claims otherwise comply with the conditions laid down in the Regulation[367].

364 Article 4(1).
365 http://www.efsa.europa.eu/en/efsajournal/pub/644.htm
366 Summary report of the Working Groups of the Advisory Group on the Food Chain and Animal and plant Health on nutrient profiles Held in Brussels on 8 July and 28 November 2008. http://ec.europa.eu/food/committees/advisory/sum_wg_11072008.pdf
367 Article 4(2)(a).

Secondly, nutrition claims are allowed, despite the fact that a single nutrient exceeds the corresponding nutrient profile, provided that a statement about the specific nutrient appears in close proximity to, on the same side and with the same prominence as the claim. This important concession, which - like the previous one only concerns nutrition claims - was necessary to have the concept of nutrient profiles approved by Parliament when Regulation (EC) No 1924/2006 was adopted[368].

74. General conditions

The Regulation first lays down certain obligations 'not to do'[369]. Thus, nutrition and health claims may not:

(a) be false, ambiguous or misleading;

(b) give rise to doubt about the safety and/or the nutritional adequacy of other foods;

(c) encourage or condone excess consumption of a food;

(d) state, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general.

(e) refer to changes in bodily functions which could give rise to or exploit fear in the consumer, either textually or through pictorial, graphic or symbolic representations.

In addition, both nutrition claims and health claims may only be used if certain conditions are fulfilled[370]:

(a) the presence, absence or reduced content in a food or category of food of a nutrient or other substance in respect of which the claim is made has been shown to have a beneficial nutritional or physiological effect;

(b) the nutrient or other substance for which the claim is made is contained in the final product in a significant quantity or in a quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence; or

(c) the nutrient or other substance for which the claim is made is in a form that is available to be used by the body;

368 Article 4(2)(b)
369 Article 3.
370 Article 5.

(d) the quantity of the product that can reasonably be expected to be consumed provides a significant quantity of the nutrient or other substance to which the claim relates.

Moreover, the use of nutrition and health claims shall only be permitted if the average consumer can be expected to understand the beneficial effects as expressed in the claim.

Finally, nutrition and health claims must be based on and substantiated by generally accepted scientific evidence. It is for the food business operator who makes a nutrition or health claim to justify the use of the claim. The competent authorities of the Member States may request a food business operator or a person placing a product on the market to produce all relevant elements and data establishing compliance with the Regulation[371].

75. Typology

Regulation (EC) No 1924/2006 defines two main categories of claims: 'nutrition claims' and 'health claims'.

A 'nutrition claim' means: any claim which states suggests or implies that a food has particular beneficial nutritional properties due to:

- the energy (calorific value) it provides, provides at a reduced or increased rate, or does not provide; and/or
- the nutrients or other substances it contains, contains in reduced or increased proportions, or does not contain[372].

A 'health claim' means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health[373].

Amongst 'health claims', the Regulation brings a distinction between three types of claims:

- 'reduction of disease risk claim', i.e. claims that state, suggest or imply that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease[374];
- 'claims referring to children's development and health[375];

371 Article 6.
372 Article 2(2)(4).
373 Article 2(2)(5).
374 Article 14(1)(a) and Article 2(2)(6).
375 Article 14(1)(b).

- 'function claims'[376], which are referred to in the Regulation as 'health claims other than those referring to the reduction of disease risk and to children's development and health'.

There are three kinds of 'function claims':

- those describing or referring to the role of a nutrient or other substance in growth, development and the functions of the body[377],
- those describing or referring to psychological and behavioural functions[378];
- those describing or referring to slimming or weight control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet [379].

76. Nutrition claims

Nutrition claims are only authorised if they are listed in Regulation (EC) No 1924/2006 and if they conform with the conditions laid down in the Regulation[380].

a) List of authorised nutrition claim

The list of authorised nutrition claim is laid down in the Annex to Regulation (EC) No 1924/2006. It is largely based on the work of *Codex Alimentarius* and lays down the specific conditions for using the corresponding claim.

For instance:

- a claim that the product does not contain sugar ('sugars-free') can only be made if the product does not contain more than 0,5 g of sugar per 100 g or per 100 ml;
- a claim that a food is low in sugars ('low sugars') may only be made where the product contains no more than 5 g of sugars per 100 g for solids or 2,5 g of sugars per 100 ml for liquids.

The list of authorised nutrition claim being exhaustive, it was of course important to provide for updates by the Commission through the regulatory committee procedure[381].

This possibility was used:

376 This designation is suggested by the Commission in its Guidelines adopted in 2007. http://ec.europa.eu/food/food/labellingnutrition/claims/guidance_claim_14-12-07.pdf
377 Article 13(1)(a).
378 Article 13(1)(b).
379 Article 13(1)(c).
380 Article 8(1).
381 Article 8(2).

- firstly, to add to the list some claims relating to omega-3, mono-unsaturated fats, poly-unsaturated fats and unsaturated fats, as well as the conditions for their use[382],
- secondly, to add to the list the claim "no added sodium/salt" and the corresponding conditions, and to restrict the use of the claims "reduced saturated fat" and "reduced sugars"[383].

b) Conditions for use

These conditions are first and foremost the general conditions which have been mentioned above and which concern both nutrition claims and health claims.

In addition, Regulation (EC) No 1924/2006 lays down a specific condition which concerns comparative nutrition claims. This condition provides that:

- a comparison may only be made between foods of the same category, taking into consideration range of foods of that category. The difference in the quantity of a nutrient and/or the energy value must be stated and the comparison shall relate to the same quantity of food;
- a comparative nutrition claims must compare the composition of the food in question with a range of foods of the same category, which do not have a composition which allows them to bear a claim, including foods of other brands.

The Commission published in 2007 important guidelines[384], adopted in the form of conclusions from the Standing Committee on the Food Chain and Animal Health, which, among others, clarify the conditions for using comparative claims.

77. Health claims

Health claims are in principle prohibited, unless:

- they comply with the general conditions applicable to all claims,
- they comply with the specific conditions applicable to health claims, and

382 Commission Regulation (EU) No 116/2010 of 9 February 2010 amending Regulation (EC) No 1924/2006 of the European Parliament and of the Council with regard to the list of nutrition claims (OJ L37 of 10.2.2010, p. 16).

383 Commission Regulation (EU) No 1047/2012 of 8 November 2012 amending Regulation (EC) No 1924/2006 with regard to the list of nutrition claims (OJ L 310/36 of 9.11.2012, p. 36).

384 http://ec.europa.eu/food/food/labellingnutrition/claims/guidance_claim_14-12-07.pdf

- they are authorised in accordance with the Regulation and included in the lists of authorised claims adopted in accordance with the Regulation.

a) Specific conditions

Typically, there are some obligations "not to do" and some obligations "to do".

Firstly, it is prohibited to refer to general, non-specific benefits of the nutrient or food for overall good health or health-related well-being, unless this reference is accompanying a specific authorised health claim.

Secondly, it is prohibited:

- to suggest that health could be affected by not consuming the food;
- to make reference to the rate or amount of weight loss are prohibited;
- to make reference to recommendations of individual doctors or health professionals and other associations, with the exception of those which have been authorised, with this in mind, by Community or national provisions.

In terms of obligations "to do", health claims are only permitted if the following information is included in the labelling, or if no such labelling exists, in the presentation and advertising[385]:

- a statement indicating the importance of a varied and balanced diet and a healthy lifestyle;
- the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect;
- where appropriate, a statement addressed to persons who should avoid using the food; and
- an appropriate warning for products that is likely to present a health risk if consumed to excess.

b) Function claims

Health claims are normally the subject of specific authorisations. However, function claims, which Regulation (EC) 1924/2006 calls 'health claims other than those referring to the reduction of disease risk and to children's development and health' may be

385 Article 10(2).

authorised if they appear on a Community list which is being established as will be indicated hereafter. In addition, these claims must be:

- based on generally accepted scientific evidence; and
- well understood by the average consumer.

For the purpose of establishing the list of authorised function claims, it was foreseen that the Member States would provide the Commission with lists of the claims concerned by 31 January 2008 at the latest, accompanied by the conditions applying to them and by references to the relevant scientific justification[386]. It seems that Member States have not been very selective on this occasion, since some 44.000 claims were declared to the Commission. The Commission itself seems to have use some discretion, as the number of claims had been reduced to less than 5.000 by the time the Commission sought the opinion of EFSA, as foreseen by the Regulation.

EFSA finalised the evaluation of the 'function claims' claims prioritised by the Commission by the end of June 2011 and has published 341 opinions providing scientific advice on 2,758 'function claims'. The complete list was published on the EFSA website in the form of an Access database in May 2010[387].

This led to the adoption of Commission Regulation (EU) No 432/201[388]. This Regulation establishes a list of 222 function claims. These can be used on foods, provided that the conditions laid down in the Regulation are met.

b) Reduction of disease risk claims

As already indicated, 'reduction of disease risk claim' means any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease.

Before the adoption of Regulation (EC) No 1924/2006, any reference to a human disease was prohibited in the labelling, presentation or advertising of foods to be delivered as such to the final consumer, whether under Directive 79/112/EEC or under Directive 2000/13/EC[389]. Regulation (EC) No 1924/2006 considerably softened that prohibition[390]

386 Article 13.
387 http://www.efsa.europa.eu/en/topics/topic/article13.htm
388 Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health (OJ L 136 of 25.05.2012, p. 1).
389 Article 2(1)(b).
390 Article 14(1).

by allowing, on a case by case basis, the authorisation of 'reduction of disease risk claims'.

'Reduction of disease risk claims' are of course subject both to the general conditions of use applying to all nutrition and health claims, and to their specific conditions applying to health claims. In addition, the labelling or, if no such labelling exists, the presentation or advertising must also bear a statement indicating that the disease to which the claim is referring has multiple risk factors and that altering one of these risk factors may or may not have a beneficial effect[391]. This requirement reflects the fact that diet is one of the many factors influencing the onset of certain human diseases; other factors such as age, genetic predisposition, the level of physical activity, the consumption of tobacco and other drugs, environmental exposure and stress may all influence the onset of human diseases.

'Reduction of disease risk claims' may only be used where they have been expressly authorised under the authorisation procedure laid down in the Regulation.

c) Claims referring to children's development and health

Regulation (EC) No 1924/2006 makes a fine distinction between 'claims referring to children's development and health'[392] and 'claims describing or referring to the role of a nutrient or other substance in growth, development and the functions of the body'[393], the latter being a function claim.

To say that the difference is not obvious is an understatement. The Commission must have realised this because it prompted it to publish Guidance[394] which, whilst not explaining the reason behind the two distinct categories, nonetheless makes it clear that «claims referring to children's development and health» are those which refer exclusively to the development and health of children; thus, the scientific data supporting these claims must be valid for children only. The Guidance also clarifies what is to be understood under the term "children": these are persons who have completed their growth, and an age limit of 18 years is given as an indication.

391 Article 14(2).
392 Article 14(1).
393 Article 13, paragraph premier, letter a).
394 Guidance on the implementation of Regulation No 1924/2006 on nutrition and health claims made on foods – Conclusions of the Standing Committee on the Food Chain and Animal Health.

These claims are subject to the same procedure as 'reduction of disease risk claims': they can only be used after having been authorised on a case by case basis.

d) Authorisation procedure

Regulation (EC) No 1924/2006 lays down three procedures for the authorisation of health claims. All of them end up with a Commission decision, based on a scientific opinion from EFSA.

The first procedure is to be used for the adoption of the Community list of functional claims, based on the notifications made by the Member States during the transition period [395], and for any changes to this list based on generally accepted scientific evidence[396]. This is a classic regulatory procedure with scrutiny [397].

The second procedure, laid down in Article 15 (Application for authorisation), Article 16 (Opinion of EFSA), Article 17 (Community authorisation) and Article 19 (Modification, suspension and revocation of authorisations) is to be used for the authorization of:

- reduction of disease risk claims, and
- claims referring to children's development and health.

This is a classic Community authorisation procedure. Decisions are also being taken under a regulatory procedure with scrutiny.

The third procedure, laid down in Article 18, is to be used for the addition of claims to the list of authorised functional claims based on newly developed scientific evidence or which include a request for the protection of proprietary data.

This is a simplified Community authorization procedure. Decisions are taken by the Commission (no regulatory procedure) where the EFSA opinion was in favour of authorizing the claim, unless the applicant has requested data protection, in which case the regulatory procedure without scrutiny is applicable. If the opinion of EFSA does not support the granting of an authorization, the regulatory procedure with scrutiny is applicable.

395 Article 15(3).
396 Article 15(4).
397 Article 25(3).

78. Data protection

Food companies often invest considerable amounts in gathering the information and data supporting an application under this Regulation. It would therefore be unfair to allow any competitor to use the corresponding health claim. Therefore, in order to stimulate research and development within the agri-food industry, it seemed appropriate to protect the investment made by innovators by providing that he scientific data and other information in the application may not be used for the benefit of a subsequent applicant for a period of five years from the date of authorisation[398] [399].

The limitation in time is justified in order to avoid the unnecessary repetition of studies and trials, and to facilitate access to claims by small and medium-sized enterprises (SMEs), which rarely have the financial capacity to carry out research activities. Indeed, data protection does not prevent a second application within the period of data exclusivity: any competitor may file his own application, provided that it is based on fresh information and data. In this respect, the length of their protection appears to be somewhat too long: if the health claim is worth it, competitors will not hesitate to generate their own data, especially as they are almost certain of the outcome. A data protection of 2-3 years would probably have provided more effective protection.

79. EU Register of nutrition and health claims made on foods

For the sake of transparency and in order to avoid multiple applications in respect of claims which have already been assessed, Regulation (EC) No 1924/2006 provides for the establishment of a public Register containing the lists of such claims[400]. The 'EU Register of nutrition and health claims made on foods' has been established and is being maintained by the Commission[401].

The Register includes the following:

- Permitted nutrition claims and their conditions of use (this is the only part which is currently populated).
- Authorised health claims, their conditions of use and applicable restrictions, if any;
- Non-authorised health claims and the reasons for their non-authorisation;

398 Article 21.
399 This provision was clearly inspired by the pharmaceutical legislation.
400 Article 20.
401 http://ec.europa.eu/nuhclaims/

- EU legal acts for the specific health claims;
- National measures mentioned in Art. 23(3) of Regulation (EC) 1924/2006.

Health claims authorised on the basis of proprietary data are to be recorded in a separate Annex to the Register together with the relevant information.

As an appendix to the Register, the Commission also publishes valuable information on:

- Health claims submitted as Article 13(1) 'function claims' but that do not qualify as such.
- Health claims not related to human health which cannot consequently be used on foods.
- Health claims for combinations of substances where health claims are already authorised for some of the individual substances.
- Some 'function claims', for which the assessment by EFSA or the consideration by the Commission is not finalised. These include health claims: under further assessment; referring to botanical substances; or under further consideration by the Commission and EU countries.
- Some health claims subject to the individual authorisation procedure pending a decision.

80. State of play

Since 14 December 2012[402], producers may no longer use claims which cannot prove their beneficial effect on consumers' health. This date indeed marked the end of the transitional period laid down in Regulation (EC) No 1924/2006 for industry to adapt their packaging and stop using unproven claims[403].

The list, laid down in Regulation Commission Regulation (EU) No 432/2012, contains 222 function claims. Following claims are included:

- Calcium is needed for the maintenance of normal healthy bones;
- Reduced consumption of saturated fat contributes to the maintenance of normal cholesterol levels;
- Reduced consumption of sodium contributes to the maintenance of normal blood pressure;

402 Six months after the entry into force of Commission Regulation (EU) No 432/2012.
403 See: http://europa.eu/rapid/press-release_IP-12-479_en.htm

- Melatonin helps reduce the time it takes to fall asleep;
- Plant sterols and plant stanols (used in margarines and yoghurts) contribute to the maintenance of normal cholesterol levels.

In principle, functions claims not included in the list may not be used on foods in the European Union. Claims which could not be substantiated include:

- Green tea helps maintain normal blood pressure.
- Royal jelly benefits the immune system and/or vitality.
- Taurine (found in energy drinks), when combined with vitamins and minerals, boosts mental performance.
- Glucosamine helps maintain joints.

However, a number of claims referring to effects of plant or herbal substances, commonly known as 'botanical' substances, are still under evaluation by EFSA or under consideration by the Commission[404]. These claims have been published on the website of the Commission[405] and may continue to be used pursuant to Article 28(5) and (6) of Regulation (EC) No 1924/2006[406].

Since 2016, the Commission has been carrying out an evaluation of the Regulation with regard to nutrient profiles and health claims made on plants and their preparations.[407] In May 2020, the Commission eventually published the result of this evaluation[408]. Further consultations have taken place on the subject, the outcome of which is likely to inform the proposal that the Commission is preparing under its 'Farm to Fork Strategy'[409]

404 See recital 10 of Regulation (EU) No 432/2012.
405 http://ec.europa.eu/food/food/labelling nutrition/claims/index_en.htm
406 See recital 11 of Regulation (EU) No 432/2012 and Article 28(5) and (6) of Regulation (EC) No 1924/2006.
407 https://ec.europa.eu/food/safety/labelling_nutrition/claims/refit_en
408 Commission Staff Working Document – Executive summary of the evaluation of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods with regard to nutrient profiles and health claims made on plants and their preparations and of the general regulatory framework for their use in foods. SWD (2020) 96 final, Brussels, 20.5.2020.
409 See above at No 70.

Title III

Genetically Modified Food

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Chapter 1
Introduction to modern biotechnology

The objective of this chapter is to present in a simple way scientific information that is necessary to understand what is a GMO. The reader is referred to specialised textbook for a deeper insight on the matter.

81. What is a GMO?

a) What is an organism?

An organism is a biological entity capable of replication. A tomato plant, for example, is an organism, but so is the tomato itself. Animals and bacteria are also organisms.

b) What is the "genetic material" of organisms?

Organisms are made of cells. Each cell has a nucleus, which could be described as the 'brain' of the cell: it contains all the information the cell needs throughout its entire life. This information is stored in several structures called 'chromosomes'.

Each chromosome is made of DNA coiled tightly to form a spiral. It is composed of two strands of DNA twisted together in a double helix.

c) What is DNA?

The DNA is a string of nucleotides that bind to each other, joining the two spirals.

There are four different types of nucleotides: A (adenine), T (thymine), (C) cytosine and G (guanine). They have specific shapes so that A always pairs with T, and C always pairs with G.

This "base pairing" mechanisms ensures identical replication of DNA strands during cell division and the assembly of separate pieces of DNA.

d) What is a "gene"?

A gene is a specific piece, or length of DNA. There are thousands of genes on a single chromosome. Each gene encodes the information for the construction of a single protein. Proteins control the traits of living organisms.

DNA has an identical structure in all living things. Because the genetic code is universal, the possibility is raised that genes can be transferred between completely different species.

e) What is a "genome"?

The whole of an organism's genetic material is called a "genome". In a manner, the genome is a repertory of all the genes composing an organism.

Like the human genome, the genome of higher plants (rice, maize, wheat) has only been recently sequenced.

f) What is a "genetic modification"?

The process of transferring, removing or altering genetic information by the modification of DNA is commonly called 'genetic modification'.

Genetic modification may occur, and actually occurs naturally, leading to modifications in the traits (characteristics) of plants and animals.

g) What is a "genetically modified organism"?

A genetically modified organism (GMO) is an organism in which the genetic material has been altered through recombinant DNA (rDNA) technology, i.e. in a way that does not occur naturally by mating and/or natural recombination.

When a foreign gene is inserted in the organism, or when a native gene of the organism is deleted, altered or silenced, the cells of the GMO will produce different proteins (or a different set of proteins).

h) What is a "transgene"?

The modification of the genetic material of an organism usually consists of the insertion of foreign genes into the cells of the receiving organism (as opposed to deleting, altering or silencing a native gene of the organism). The foreign gene which is inserted is called a "transgene".

The transgene may originate from another organism of the same species or from an organism of a different species. It is indeed common to introduce through transgenesis a gene from a bacteria into the genetic material of a plant.

Physical characteristics (phenotypes) of plants have been modified for centuries and are still mainly modified through conventional breeding methods where desired traits, or agronomic characteristics are selected and used intensively in traditional crossing programmes. These new traits may result from the new combination of existing genes or from mutations (that may occur naturally or be induced by specific techniques).

The difference between transgenesis and conventional breeding practices is that the latter do not allow for the crossing (and therefore the transfer of genes) outside the natural species barriers. It is this aspect which is generating much of the scientific and (at least for some applications) ethical debate over GMOs.

82. How to make a GM plant?

a) Identification of genes of interest

Identifying and locating genes for agriculturally important traits is currently the most limiting step in the transgenic process.

Usually, identifying a single gene involved with a trait is not sufficient; scientists must understand how the gene is regulated, what other effects it might have on the plant, and how it interacts with other genes active in the same biochemical pathway.

Public and private research programs are investing heavily into new technologies to rapidly sequence and determine functions of genes of the most important crop species.

b) DNA Extraction

In the second step, the DNA of the gene of interest is extracted from the selected organism that has the desired trait. The techniques for extracting DNA are beyond the scope of this course.

c) Gene cloning

The gene of interest, i.e. the single gene that codes for the desired trait, must then be located, isolated and cloned (i.e. amplified in a bacterial vector).

d) Gene design

Once the gene of interest has been isolated and cloned, it must undergo several modifications before it can be effectively inserted into a plant.

A promoter sequence must be added for the gene of interest to be correctly expressed (i.e., translated into a protein product). The promoter is the on/off switch that starts the gene sequence and controls when and where in the plant the gene of interest will be expressed.

The termination sequence signals to the cellular machinery that the end of the gene sequence has been reached.

A selectable marker gene is added to the gene "construct" in order to identify plant cells or tissues that have successfully integrated the transgene (see below: Selection). As for the gene of interest, a marker gene also requires promoter and termination sequences for proper function.

Among the most important tools used for gene design are enzymes that perform specific functions on DNA. Restriction enzymes, for instance, recognize and cut the DNA at a specific region of the DNA. Other enzymes known as ligases join the ends of two DNA fragments. These and other enzymes enable the manipulation and amplification of DNA, essential components in joining the DNA of two unrelated organisms.

e) Transformation

Transformation is the heritable change in a cell or organism brought about by the uptake and establishment of introduced DNA.

There are a number of different methods and technologies for the introduction of foreign DNA into plants. These methods vary in their ability to control where the foreign gene will be inserted in the cell's own DNA, or to provide insertions that will be stable. However, none of these methods allow a perfect control of the modification. This is one reason why some consider that the process may have adverse consequences for human health and the environment.

Cells from any part of the plant can divide and multiply into another complete plant. Every time the cell replicates and divides, all of the genes are copied, including the newly inserted gene(s).

The transferred piece of DNA at the specific location where it has successfully been inserted or re-inserted into the host organism, is commonly referred to as a "transformation event."

f) Selection

A selection process is necessary because achieving incorporation and expression of the transformation event in plant cells is a rare occasion, occurring in just a few percent of the targeted tissues or cells. Selectable marker genes, which are included in the gene construct, encode proteins that provide resistance to agents that are normally toxic to plants, such as antibiotics or herbicides. Only plant cells that have integrated the selectable marker gene will survive when grown on a medium containing the appropriate antibiotic or herbicide.

g) Regeneration

To obtain whole plants from transgenic tissues such as immature embryos, these are grown under controlled environmental conditions in a series of media containing nutrients and hormones, a process known as tissue culture. Once whole plants are generated and produce seed, evaluation of the progeny begins. This regeneration step has been a stumbling block in producing transgenic plants in many species, but specific varieties of most crops can now be transformed and regenerated.

h) Screening

Intrinsic to the production of genetically modified plants is an extensive screening process to check whether the inserted gene has been stably incorporated without detrimental effects to other plant functions, product quality, or the intended ecosystem. Initial evaluation includes attention to: the activity of the introduced gene, the stable inheritance of the gene and unintended effects on plant growth, yield, and quality

i) Backcrossing

If a plant passes these tests, most likely it will be crossed with improved varieties of the crop. This is because only a few varieties of a given crop can be efficiently transformed, and these generally do not possess all the producer and consumer qualities required of modern cultivars. The initial cross to the improved variety must be followed by several cycles of repeated crosses to the improved parent, a process known as backcrosssing. The goal is to recover as much of the improved parent's genome as possible, with the addition of the gene of interest from the transformed parent.

j) Evaluation

The next step in the process is multi-location and multi-year evaluation trials in greenhouse and field environments to test the effects of the transgene and overall performance. This phase also includes evaluation of environmental effects and food safety.

83. What happens to the progeny of a GMO?

The introduced or modified genes are transmitted to the progeny in the same way than the other genes. It is nevertheless worth to mention that biotechnology can also be used to provide sterile plants or to improve the purity of seeds.

The most famous and controversial example of this type of applications is the so-called "terminator" technology that leads to sterile seeds. This application has never been used in commercial plants.

84. What happens to the DNA of a GMO when transformed into food?

The fate of DNA of a GMO is exactly the same as that of DNA from non-modified organisms since it has the same physical and chemical characteristics. The amount and the quality of DNA present in food and feed depends on the degree and type of processing that is applied during the production process.

Other less controversial applications of what is also called "biological containment" are still under development and could be used in the future. For example, the modification of the DNA present in chloroplasts (by contrast to the nuclear DNA) would allow to avoid the presence of transgenes in pollen since chloroplastic DNA is only transmitted by the female plants. Fresh genetically modified tomatoes contain intact DNA; by contrast, ketchup made from these tomatoes will contain degraded DNA. Oil made from genetically modified soybean or rapeseed normally does not contain modified DNA because of the way it has been processed.

85. What are the risks of GM plants?

When considering the safety of a GM plant, one distinguishes the intended effects from the unintended effects.

The intended effects are the objective of the genetic modification. It may be, for example, the production of a new protein at a certain level or the suppression of the production of an existing protein.

Unintended effects are undesired consequences of the genetic modification. These undesired consequences may be intrinsically linked to the desired trait (e.g. if one introduces a new protein that will metabolise an herbicide, the plant is likely to accumulate residues of the herbicide) or not linked to the desired trait (e.g. if the transgene is inadvertently introduced within a gene of the plant and therefore modifies the functioning of this gene).

Risks from both intended and unintended effects are detailed in the following sections, which deal with risks for public health and risks for the environment.

86. Risks for public health

a) Toxicity

Many plants contain toxins. Some toxins are self-defence substances to protect the plant against disease or stress, or against grazing, while the function of others is unknown. The level of toxins in a particular food can vary widely depending on the environmental stresses, and treatment conditions throughout the plant's life.

Through genetic manipulation, plants which do not naturally contain toxins may become toxic or capable of inherent toxin production (and hence toxicity). This can be dangerously enhanced in many ways. For example, inserted genes may produce toxic proteins in intolerable amounts or can silence other genes which produce counter-toxin agents which balance the toxicity of the organism for human consumption.

b) Allergenicity

One of the public's biggest concerns related to GM foods is that an allergen (i.e. a protein that causes an allergic reaction) could accidentally be introduced into a food product. Allergenicity screening is a very important part of safety testing before a crop can enter into the food market. A variety of tests and questions must be considered to determine whether the food poses any increased risk of allergenicity.

There is no evidence so far that genetically engineered foods are more likely to cause allergic reactions than are conventional foods. Tests of several dozen transgenic foods for allergenicity have uncovered only a soybean that was never marketed and the now-famous StarLink corn. Although the preliminary finding is that StarLink corn is probably not allergenic, the scientific debate continues. Every year some people discover that they have

developed an allergy to a common food such as wheat or eggs, and some people may develop allergies to one or several transgenic foods in the future, but there is no evidence that the production of a GMO as such would pose more of a risk than conventional foods.

c) Horizontal gene transfer

Horizontal gene transfer takes place where an organism transfers genetic material to another cell that is not its offspring. Horizontal gene transfer may occur through the transfer of insertion events between ingested GM food products and resident gut microflora and the subsequent integration of the DNA in the receiving microflora. After ingestion of GM products, DNA is rapidly degraded in fragments that may still be detected in the stomach and intestine of animals. These fragments can in theory be taken up into the cells and nuclei of the receiving organism.

d) Antibiotic resistance

The most conceptually problematic case of horizontal gene transfer is the transfer of antibiotic resistance genes to gastrointestinal bacteria. Antibiotic resistance genes are inserted as “markers”.

These may sometimes remain in the genetically modified organism. When ingested, fragments of that DNA could be taken up by gastrointestinal bacteria. The uptake of antibiotic resistance genes could potentially result in the development of antibiotic resistance of human bacteria against known antibiotic medication. Thus, important and existing medical treatments might become ineffective in the fight against severe diseases.

In response to public concerns, scientists have been advised to avoid using antibiotic resistance genes in GM plants. Alternative marker strategies are being used in the vast majority of the GM plants that have been recently developed.

e) Changes in nutrient levels

How do genetically engineered foods compare with conventional foods in nutritional quality? This is an important issue, and one for which there will probably be much research in the future, when crops that are engineered specifically for improved nutritional quality will be marketed.

The central question surrounding GM crops that are currently available is whether plant breeders have accidentally changed the nutritional components that we associate with conventional cultivars of a crop.

Industry studies submitted in support of applications for permission to sell transgenic crops indicate that the nutritional components that are commonly tested are similar in transgenic foods and conventional foods.

87. Risks for the environment

a) Effects on non-target organisms

GMO crops that are insect pest resistant are described below. They are designed to produce proteins which are toxic for specific groups of insects. For the moment, these proteins are all derived from the soil bacterium *Bacillus thuringensis* (Bt).

Nevertheless, specific Bt toxins are thought to have adverse effects on non-target organisms, namely insects which are not pests of crops, on birds (that would feed on Bt plants), or on microflora/microfauna (e.g. soil micro-organisms which would be affected by toxin exudates from the roots of Bt crops).

b) Invasiveness

GM plants with inserted genes such as herbicidal or insecticidal genes might cause a problem of invasiveness and persistence in the environment. The "resistance-gene" may outcross into other plants surrounding the crop such as wild relatives, neighbouring non-GM crops of the same species or volunteers (i.e. re-growth of a previous crop in a subsequent crop).

This transfer of genetic material may then confer the selectable advantage, such as insecticidal properties, to the wild relatives, giving them a competitive edge over other members of the same species and other plant species in the same community. The plant could become invasive of and persistent in natural habitats. This phenomenon may negatively impact local and regional biodiversity. Rapeseed, for instance, is characterized by high out-crossing rate, high reproductive coefficient and long longevity of seeds in soil; it also has many cross-compatible species. Higher risks of transgene dispersal may exist in rapeseed than in other crops.

c) Effect on soil

Plants have an impact on the soil ecosystem when they grow or decay.

The interaction between plants and soil micro-organisms is very complex; this is especially the case in the close vicinity of plant roots where exchanges occur between the plant and the soil and its microorganisms. Much more research must be done before we understand the relationships that occur between micro-organisms and conventional crops. Attempts to discover whether transgenic plants are changing the soil environment, and whether they are changing it in good ways or bad ways, are hindered by the current lack of basic scientific knowledge in this area.

Biodiversity - Preservation of centre of origin

88. Biodiversity – Centre of origin - Coexistence

a) Biodiversity – centre of origin

Genetically modified crops may pose a particular threat to their particular species centre of origin. The centre of origin of a species is an invaluable and irreplaceable source of genetic material for plant breeding. It is usually characterized by the highest observable levels of genetic variability. A given centre of origin of natural biodiversity for a particular species could be placed at particular risk by cross pollination from genetically modified varieties of the same species to wild relatives.

Pollenisation of conventional crops by surrounding transgenic crops raises concerns about separation distances to ensure purity of crops and about who must pay if unwanted genes move into a neighbour's crop.

b) Co-existence

Many factors influence the potential for gene flow from crop to crop. Some crops are highly out-crossing, with pollen carried to other fields by wind and by insects. Other species are highly self-pollinating, with little potential for pollen transfer to neighbouring plants. Because of the differences among crops species, every case must be evaluated individually for potential to contribute to gene flow from transgenic to conventional crops.

What level of GM presence, if any, should be allowed in products that are sold as organic or conventional? Should GM farmers and companies bear responsibility for preventing gene flow, or should conventional and organic farmers pay to protect their products from

gene flow? Should GM versions of out-crossing plants be banned to prevent pollenisation of neighbouring crops, while GM versions of self-pollinating plants could be permitted? Should technologies of biological containment be encouraged and if yes, should the right of the farmers to produce its own seeds be more protected?

89. Animal cloning

Plants have been produced by cloning for many years by taking a small part of a plant and growing another one from it. This has been used on a larger commercial scale for some time with some fruit and vegetables, for example bananas.

The technology has more recently been applied to animals. Animal cloning consists in producing an animal that is essentially a copy of the original. The technique most commonly used is known as somatic cell nucleus transfer (SCNT). A genetic copy of an animal is produced by replacing the nucleus of an unfertilised ovum (egg cell) with the nucleus of a body (somatic) cell from the animal to form an embryo. The embryo is then transferred to a surrogate dam where it then develops until birth. 'Dolly the sheep' was the first known animal to have been cloned, in 1996.

The cloning of an animal does not improve the animal's performance. Yet breeders may consider cloning to increase the quantity of reproductive material (semen or embryos) of a particularly valuable animal. Animal cloning has been used for some years, notably in the United States, but not in the European Union.

Because cloning does not involve any genetic modification, a clone is not a GMO and food derived from a cloned animal is not a genetically modified food. Currently, in the European Union, the marketing of food from clones would require pre-market approval under the Novel Food Regulation[410], based on a scientific food safety assessment by the European Food Safety Authority (EFSA). So far, no European or foreign food business operator has applied for an authorisation to market food produced by using the cloning technique.

EFSA carried out a scientific risk assessment in 2008 on cloning and concluded that there is no indication of any difference for food safety on meat and milk of clones and their offspring compared with those of conventionally bred animals, but however recognised.

410 Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L43 of 14.2.1997, p. 1-6).

This opinion was confirmed in 2009, 2010 and 2012. However, in its latest opinion EFSA recognised "that animal health and welfare concerns continue to be associated with this technology"[411].

On 18 December 2013, the European Commission presented two proposals for legislation on animal cloning.

The first proposal, for a Directive of Parliament and Council[412], aims at banning animal cloning for farming purposes in the European Union for bovine, porcine, ovine, caprine and equine species, as well as imports of cloned animals and embryos. The proposal, which refers to Article 43 TFUE (Common Agricultural Policy), justifies a ban on cloning because of the cloning-related animal welfare concerns raised in the Update of the European Food Safety Authority's (EFSA) scientific opinion.

The second proposal, for a Council Directive[413], foresees a ban on the marketing of food (e.g. meat and dairy products) from cloned animals in the European Union. It is not based on animal welfare concerns, nor is there any mentioning of a food safety issue with the products from cloned animals. It is based on the so-called 'flexibility clause' in Article 352 TFEU, which requires unanimity in the Council, and which the European Parliament can veto, but not amend.

Neither proposal covers offspring from cloned animals and products derived from these offsprings. In a press release, Health Commissioner Borg explained that labelling for fresh meat from offspring of cloned animals could be required at a later date.

In its opinion[414] on the two proposals, the European Parliament took a much a harder line than the one proposed by the Commission and called for a ban on the cloning of all farm animals, their descendants and products derived from them, including imports.

Whilst the two proposals have not been withdrawn by the Commission, there appears to be very little prospect for them to be passed in the foreseeable future.

411 http://www.efsa.europa.eu/en/press/news/120705.htm

412 COM(2013) 892 final of 18.12.2013 - Proposal for a Directive of the European Parliament and of the Council on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes .

413 COM(2013) 893 final of 18.12.2013 - Proposal for a Directive of the European Parliament and of the Council on the placing on the market of food from animal clones.

414 http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P8-TA-2015-0285+0+DOC+XML+V0//EN

90. New breeding techniques

Over the last decade, new methods for crop breeding have appeared which allow to edit plants in simpler and more precise ways than conventional gene modification. The new breeding techniques, such as CRISPR/Cas, are said to allow for the production of better crops more quickly than in the past.

An interesting debate has developed as to whether the plants produced through these new breeding techniques should fall under the rules governing genetically modified organisms, food and feed in the EU. The reason put forward against the application of the legislation governing genetic modifications appears to be that such application would harm innovation and stifle the introduction of new breeds that could help meet challenges such as pests, disease and environmental factors.[415] The only serious argument supporting an exemption from the GM legislation is that most of the new breeding techniques are based on mechanisms that occur in nature and identical plants could be produced with conventional (non-GM) breeding techniques. This however, is also true in the case of many genetic modifications which do not involve transgenesis.

In 2017, the High-Level Group of the Commission's Scientific Advice Mechanism (SAM) released an "Explanatory Note on New techniques in Agricultural Biotechnology"[416] which provides an overview of new techniques and explains the differences and similarities with conventional breeding and established techniques of genetic modification. It does not however address the issue of the applicable legislation. The Commission further organised, on 28 September 2017, a high-level conference on "Modern Biotechnologies in Agriculture – Paving the way for responsible innovation"[417] with a view to stimulating an informed and open debate among all stakeholders. However, the Commission has not yet issued a legal interpretation of the regulatory status of products generated by new plant-breeding techniques.

415 The US Department of Agriculture (USDA) decided in April 2016 not to submit to the agency's regulatory process a mushroom genetically modified with the gene-editing tool CRISPR–Cas9, making it the first CRISPR-edited organism to receive a green light from the US government.

416 https://ec.europa.eu/research/sam/index.cfm?pg=agribiotechnology

417 https://ec.europa.eu/info/events/conference-modern-biotechnologies-agriculture-paving-way-responsible-innovation-2017-sep-28_en

Chapter 2
Developments and applications

91. Delayed ripening

Ripening is a normal phase in the maturation process of fruits and vegetables. Upon its onset, it only takes about a few days before the fruit or vegetable is considered inedible. This unavoidable process brings significant losses to farmers and consumers alike. At present, many foods are harvested under-ripe to avoid losses from the softening of fruits and vegetables, but this also means that other aspects of ripening such as flavour development and sugar production do not occur. Scientists have been working to delay ripening so that farmers have more flexibility in marketing their goods.

The first ever GM crop to be marketed, in 1994, was the Flavr-Savr tomato produced by Calgene in the U.S., modified to delay ripening. In 1996, branches of Safeway and Sainsbury's supermarkets throughout the UK started to sell tomato purée made from genetically modified tomatoes; this was the first time that food made from a GMO had been sold in Europe. Although there was at the time no legal requirement to label the products as GM, both supermarkets adopted an 'open' policy: leaflets were available describing the product, its benefits to the environment and consumers, the technology, and the regulatory process through which the product had had to pass. The GM purée was available at a cost of 29 pence for 170 grams, alongside conventional purée from the same brand, which cost slightly more: 29 pence for a mere 142 grams. In November 1997, Safeway announced that they had sold three quarters of a million cans of the product, and that average sales per store of the GM puree exceeded those of the conventional equivalent. However, as opposition to GM foods was mounting, both Safeway and Sainsbury's withdrew products from sale in 1999.

92. Herbicide tolerance

Weeds are a constant problem for farmers. Not only do they compete with crops for water, nutrients, sunlight, and space but they also harbour insect and disease pests; clog irrigation and drainage systems; and undermine crop quality. If left uncontrolled, weeds can reduce crops significantly.

Farmers can fight weeds with tillage, hand weeding, herbicides, or typically a combination of all techniques. Unfortunately, tillage leaves valuable topsoil exposed to wind and water erosion. For this reason, reduced or no-till technology in an increasing agricultural practice.

Herbicide-tolerant crops offer farmers a useful tool in fighting weeds and are compatible with no-till methods. These crops are genetically modified to create a tolerance to broad-spectrum herbicides, in particular glyphosate and glufosinate. The resistance against these herbicides comes from genes which were also isolated from soil micro-organisms.

A major environmental concern associated with herbicide-tolerant crops is their potential to create new weeds through out-crossing with wild relatives or simply by persisting in the wild themselves. As for the uses of all herbicides, appropriate management practices have to be put in place so as to avoid the development of such tolerant weeds.

93. Insect resistance

Plant pests cause a lot of problems to farmers, who have had very little recourse other than to continuously spray their plants with pesticides. Unfortunately, some of these pesticides pose health risks to people who are exposed to them.

The most common insect resistance gene used in agriculture is the Bt gene. Bt stands for *Bacillus thurigiensis*, a common soil bacterium so called because it was first isolated in the Thuringia region of Germany. Bt produces a protein which paralyses the larvae of some harmful insects, including the European and the Asian corn borers, the cotton bollworm, and the potato beetle, all of which are common plant pests with devastating effects. When ingested by the larva of the target insect, the Bt protein is activated and punctures the mid-gut leaving the insect unable to eat; the insect dies within a few days.

Bt is easily cultured by fermentation. Thus, over the last 40 years, Bt proteins have been used as an insecticide by farmers worldwide. Organic farming in particular has benefited from Bt insecticides as it is one of the very few pesticides permitted by organic standards. Whether it is applied as spray or granules, the efficiency of the insecticide is often limited because the target organisms do not come into contact with the insecticide, e.g. when the larvae is on the underside of leaves or has already penetrated the plant.

Scientists have thus taken the Bt gene responsible for the production of the insecticidal protein from the organism and incorporated it in plants. Thus, modified plants have a built-in round the clock mechanism of protection against targeted pests.

Bt corn and Bt cotton have been promoted as a means to reduce the spraying of pesticides. Bt cotton is the only crop for which claims of reduced spraying are clear. Bt corn was also shown to be effective in the area that are invested with the targeted pest such as the European corn borer in Spain. However, these GMOs have limited interest when the conditions (areas, climatic conditions of a given year) are such that the targeted pest is not present or only present to a limited extend.

94. Stacked genes

Research now extends to the development of stacked gene events where two or more genes of interest are introduced into the same genome. This may be achieved either through co-transformation or through conventional crossing of two GM varieties each expressing one of the particular GM characteristics. To date the most common stacked genes are those created by combining herbicide tolerant and insecticidal traits.

95. Nutritional enhancement

Following the initial yield-focused aim of genetic modification, refined genetic modification techniques subsequently focused on providing new value-enhancing traits. Genetic modification has developed beyond on-farm benefits (offering the potential ability to change the quality of a product) to the improvement of nutrient content. Examples include high oleic acid soybeans that contain less saturated fat than conventional soybean oil, and GM canola producing oil with a healthier composition (e.g. containing unsaturated omega-3 fatty acids). Some of these modified products no longer require chemical hydrogenation and hence will not contain trans-fatty acids, which have been linked to cardiovascular diseases.

96. Virus resistance

Several potato varieties have been modified to resist potato leafroll virus (PRLV) and potato virus (PVY). Just as people and animals get inoculations to prevent disease these GM potato varieties, which are currently grown in Australia, Canada and the U.S. are protected from certain viruses

Another example of this technology, is the virus-resistant GM papaya, which contains a viral gene that encodes for the coat protein of papaya ringspot virus (PRSV). This protein provides the papaya plant with built-in protection against PRSV. Such papayas are commercially grown in Hawaii since 1998 and are currently being developed in other countries producing papaya such as Thailand.

97. Tissue culture

Plants usually reproduce by forming seeds through sexual reproduction: egg cells in the flowers are fertilized by pollen from the stamens of the plants. In sexual reproduction, DNA from both parents is combined in a somewhat unpredictable manner, and it can take several years of careful greenhouse work to breed a plant with desirable characteristics. However, researchers have now developed several methods of growing exact copies of plants without seeds, through a method called tissue culture.

Tissue culture is the cultivation of plant cells and tissues on specifically formulated nutrient media. Under the right conditions, an entire plant can be regenerated from a single cell. Tissue culture is used predominantly in developing countries for the production of disease-free, high quality planting material and the rapid production of many uniform plants.

Tissue culture is used extensively in banana production in Africa and in the Philippines.

Tissue culture as such is not considered as a technique leading to a GMO under the EU legislation. It is however often combined with the introduction of a transgene leading to the production of a GMO.

98. Fortification

Vitamin A, one of the most important nutrients in maintaining life and health, is usually deficient in people eating a rice-heavy diet. Vitamin A is. Dietary lack or deficiency of vitamin A leads to severe clinical symptoms. Worldwide, an estimated 125 million children are deficient in vitamin A; amongst them, around 1-2 million die and half a million become irreversibly blind each year as a result of vitamin-A deficiency. Furthermore, vitamin A deficiency exacerbates diarrhoea, respiratory disease and childhood diseases such as measles. However, oral delivery of vitamin A poses problems, mainly because of the lack of a transport and distribution structure in some of the most badly affected regions.

Provitamin-A is not produced by traditional rice varieties. However, a compound naturally present in immature rice endosperm can be used to produce provitamin-A with the help of several enzymes not normally found in rice. Two genes from daffodil and one from a bacterium were thus inserted in the rice genome to develop a new GM rice, called ‘golden rice’ because of the slightly yellow starchy part of the grain resulting from the added beta-carotene. These three genes produce the enzymes necessary to convert natural rice compounds to provitamin-A. When ‘golden rice’ is ingested, the human body splits the provitamin-A to make vitamin. The inserted genes are controlled by specific promoters such that the enzymes and the provitamin-A are only produced in the rice endosperm.

Although the inventors of 'golden rice' claim that the technology can ultimately contribute to the reduction of vitamin A deficiency in many poor and disadvantaged people, a number of organizations oppose its implementation. Some claim that 'golden rice' is a proverbial 'Trojan horse' that uses our sympathy for the poor and disadvantaged to gain acceptance for genetically modified crops. Others feel that 'golden rice' will not be able to provide vitamin A in levels that will be beneficial, or that malnutrition will prevent the vitamin A that is available from being absorbed by the body. Another opinion is that even if 'golden rice' could help prevent vitamin A deficiency, it would not be socially accepted by cultures that value white rice.

In order to fulfil the goal of helping prevent vitamin A-deficiency in the poor and disadvantaged of developing countries, golden rice has to reach subsistence farmers free of charge and restrictions. A "Golden Rice Humanitarian Board" was established to determine which institutions would initially receive golden rice, and to ensure that all regulations concerning the handling and use of genetically modified organisms would be followed. Currently, the Humanitarian Board has partner institutions in the Philippines, India, China, Vietnam, Indonesia, and Africa.

These institutions will be responsible for evaluating the need for golden rice, analysing and comparing the pros and cons of alternative measures, and setting a framework for the implementation of 'golden rice' that best suits the needs of the areas the institutions serve. The institutions will also be responsible for transferring the trait into the best locally-adapted lines by traditional breeding practices and direct transformation techniques, as

well as ensuring the varieties used will be important to the poor, and not fashionable varieties for the middle class.

99. GM animals

a) AquaBounty Salmon

For the purpose of speeding up the growing process of salmon, researchers at AquaBounty Technologies have transferred into the genome of the Atlantic salmon a growth hormone-regulating gene from a Pacific Chinook salmon and a promoter from an ocean pout. The transferred genes code the so-called anti-freeze protein (AFP), which is known to activate the growth hormone of some fish species, notably allowing them to grow during the winter months, a period during which they normally put up little weight. The fish thus grows to market size in 16 to 18 months rather than three years.

This GM salmon has been awaiting the U.S. Food and Drug Administration's approval since 1996. In 2014, FDA issued for public comment a draft environmental assessment (EA) related to the agency's review of AquaBounty Technologies' GM salmon. FDA's preliminary finding is that an approval of this application, under the specific conditions proposed in the application, would not have a significant impact on the U.S. environment.

b) Enviropig

In February 2002, Health Canada was notified by the University of Guelph that 11 piglets weighing about 20 kilograms had been inadvertently turned into feed and fed to chickens and turkeys. The pigs were part of the much-touted "Enviropig" research effort at the university; they had died at birth or were killed shortly thereafter and should have been incinerated. However, they had instead been stored in a refrigerator with bodies of animals meant to be sent to the renderers and were accidentally taken away with them. At the rendering plant, they were reduced to fats and proteins, sent to a feed mill and became part of 675 tonnes of poultry feed. Roughly 60 per cent of it was sold to egg farmers, about 40 per cent to turkey farmers and the remainder to broiler-chicken producers. The purpose of the "Enviropig" project is to develop transgenic lines of pigs that use plant phosphorus more efficiently. The manure from monogastric animals such as pigs and chickens, contains a higher concentration of phosphorus than is suitable for repetitive field application because monogastric animals are unable to use an indigestible form of phosphorus called phytate present in the cereal grain diet. The novel trait enables the

modified pigs to degrade the indigestible phytate and absorb the phosphate eliminating the need to supplement the diet with readily available phosphate, and as a consequence the phosphorus content of the manure is reduced by as much as 75%. Digestion of the phytate also allegedly leads to improvements in digestion of minerals, proteins and starch in the diet.

In February 2003, the U.S. Food and Drug Administration (FDA) said that it was tracking down as many as 386 piglets that had been genetically engineered and wrongfully sold into the U.S. food supply. The focus of the FDA investigation was on pigs raised by researchers at the University of Illinois. They had modified the animals with two genes: one was a cow gene that increases milk production in the sow, the other, a synthetic gene, with the potential of making the milk easier for piglets to digest. The ultimate goal was to raise bigger pigs faster.

100. Some expected future developments

Many crops, like rice, are reaching the limit of maximum yield as imposed by their genes. In the 1960s, introduction of a single gene through conventional breeding, such as the "dwarfing" gene, had a major impact on the increase of agricultural productivity. Many believe that traditional breeding cannot increase yield much further and breaking these "yield barriers" will probably require (genetic) modification of entire metabolic pathways to enhance or re-direct the plant's resources into useful products.

However remarkable the recent progress in rice cultivation techniques and on the rice plant itself, rice production must increase if it is to keep pace with world population growth.

China, which produces nearly one third of the total rice output, has seen its production reducing each consecutive year in the last 5 years. Reversing this trend won't be easy as China has one of the lowest rates of arable land in the world. But when it comes to rice production, freshwater supply is the name of the game. Whilst research has allowed for substantial gains in the amount of freshwater needed to grow rice, it still takes about 3.000 litters of water to grow … 1 kg of rice. Figure this: to produce 1 ton of rice, you need a bit less than 1 hectare of arable land, and 3 million litters of freshwater. Per capita availability of fresh water in China is lower than in any African country safe Egypt. One way to address freshwater shortages would be to create a high-yielding tropical rice plant

that grows on dry but irrigated land (like maize or wheat) instead of in flooded paddies. Aerobic rice already exists in the form of upland rice varieties which withstand drought but they are low-yielding and cannot be used as a single crop which is what Asian farmers want to do.

Recent progress in genomics, notably the sequencing of the rice genome, may allow significant development in rice production. Identification of the genes responsible for various stresses raises the possibility of developing rice varieties which might grow with less water, at higher or lower temperatures or higher altitude.

Salty soils are an increasing problem in many parts of the world. Many crop plants, including tomatoes, are killed by high salt levels in soil and irrigation water. The development of a salt-tolerant tomato offers the possibility that tomatoes could be grown on land that was previously unavailable for agriculture. Scientists at the University of California and the University of Toronto have developed a tomato plant that is able to tolerate high levels of salt and that holds the salt in its leaves, so the fruit will not taste salty. It will take an estimated three years before salt-tolerant tomatoes are available commercially.

Decaffeinated coffee is now made by treating coffee beans to remove the caffeine. One method uses organic solvents to extract the caffeine, which causes some consumers to be concerned that residues from the solvents will remain in the coffee they drink. Other methods are criticized for removing some of the desirable, flavor-producing components along with the undesirable caffeine. Scientists have recently identified different genes that lead to the production of caffeine in coffee beans and tea leaves. If these genes can be "turned off" in some plants, coffee and tea trees could be developed that would produce naturally decaffeinated products with full flavour and aroma.

While announced since a long time, it seems now that a diversity of new applications is reaching an advanced stage and that one should expect a much broader diversity of traits (being drought tolerance or modified oil composition) to seek commercial clearance in the coming years.

Chapter 3
Environmental release of GMOs

101. Directive 2001/18/EC

EU legislation on GMOs has been in place since the early 1990s. This specific legislation has two main objectives:

- to protect health and the environment, and
- to ensure the free movement of safe and healthy genetically modified products across the European Union.

Directive 2001/18/EC[418] on the deliberate release into the environment of GMOs is the main instrument[419] governing the environmental release of GMOs in the environment. It applies to two types of activities:

- the experimental release of GMOs into the environment, i.e. the introduction of GMOs into the environment for experimental purposes (for example in connection with field tests), is mainly regulated by Part B of the Directive;
- the placing on the market of GMOs (GMOs from now on being defined as a product containing GMOs or consisting of such organisms), for example the cultivation, importation or transformation of GMOs into industrial products, is mainly regulated by Part C of the Directive;

The release of a GMO into the environment consists of an introduction of the GMO into the environment, without any precise confinement measure being taken to restrict the contact between this GMO and the population or the environment in general. Such a release may be carried out for experimental purposes or in connection with the placing on the market of a GMO. Experimental releases of GMOs into the environment are mainly carried out for the purposes of study, research, demonstration and development of novel varieties. The behaviour of the GMO in an open environment and its interactions with

418 Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ No L 106 of 17.4.2001, p. 18).

419 See also: Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (Recast) (OJ No L 125 of 21.05.2009, p. 75).

other organisms and the environment are studied. The experimental releases are mainly subject to the provisions of Part B of Directive 2001/18/EC.

If the results of the experimental release are positive, the company may decide to place the GMO on the market, i.e. make it available to third parties either free of charge or for a fee. This is a later stage in the development and use of the GMOs which consists, for example, in transferring a GMO free of charge between commercial partners or the marketing of the GMO. Hence, the GMO may be placed on the market for purposes of cultivation, importation, or transformation into different products. The placing on the market of a GMO is mainly governed by the provisions of Part C of Directive 2001/18/EC.

Directive 2001/18/EC introduces:

- principles for environmental risk assessment (see below);
- mandatory post-market monitoring requirements, including on long-term effects associated with the interaction with other GMOs and the environment;
- mandatory information to the public;
- a requirement for Member States to ensure labelling and traceability at all stages of the placing on the market, a Community system for which is provided for by Regulation (EC) No 1830/2003 on traceability (see below);
- information to allow the identification and detection of GMOs to facilitate post-market inspection and control;
- validity of the approvals for the release of GMOs to be limited to a maximum of ten years;
- an obligation to consult the European Parliament on decisions to authorise the release of GMOs and
- the possibility for the Council of Ministers to adopt or reject a Commission proposal for authorisation of a GMO by qualified majority.

102. Procedure for authorizing the experimental release of GMOs

A person or a company who wishes to introduce GMOs into the environment for experimental purposes must first obtain written authorisation to this end. This authorisation is issued by the competent national authority of the Member State within whose territory the experimental release is to take place, on the basis of an evaluation of the risks presented by the GMO or GMOs for the environment and human health.

To obtain this authorisation, the applicant (called "the notifier") must submit an application (called "the notification") containing the particulars set out in Article 6 of Directive 2001/18/EC. These particulars must include an evaluation of the environmental risks which the notifier has carried out.

The decision to authorize - or reject - the release of the GMO is exclusively incumbent on the competent national authority which has received the notification. Hence the authorisation procedure is a purely national one. This corresponds to a feature of the authorisation of release for experimental purposes: the authorisation to proceed with this release applies only in the Member State in which the notification has been submitted. However, the other Member States and the European Commission may make observations to be examined by the competent national authority. If the competent national authority considers that the notification complies with the requirements of Directive 2001/18/EC, it authorises the release. If the competent national authority considers that the notification does not meet the conditions laid down in Directive 2001/18/EC, it rejects the notification.

In the event of authorisation, the notifier may release the GMO in compliance with the conditions set out in this authorisation.

103. Procedure for authorising the placing on the market of GMOs

Ever since the competence for processing the application for the authorization of GMO in the European Union has been transferred from DG ENVI to DG SANCO (now: DG SANTE) of the European Commission, a request for the authorization of a GMO to be used for cultivation and in food and feed has to be lodged under Regulation (EC) 1829/2003[420]. Whilst this Regulation certainly allows for so-called 'one-door – one key' applications, it does not rule out separate applications under its own provisions for the use as food and feed, and under Directive 2001/18/EC for the use for cultivation. Separate applications are however discouraged – to put it mildly - on the website of DG SANTE[421]. It follows that the authorization procedure described hereunder is – in fact – only applicable where the GMO for which authorization for cultivation is sought is not to be used in food or feed.

420 See below, No 111 and following.

421 http://ec.europa.eu/food/plant/gmo/new/authorisation/index_en.htm : "If the GMO is to be used in food or feed with cultivation in the EU: companies need applying both cultivation and food/feed purposes under the same Regulation."

Under Directive 2001/18/EC, a company intending to market a GMO - mainly with a view to commercialisation - must first obtain a written authorisation to this end. The GMO placed on the market will be defined as a "product consisting of a GMO" or a "product containing a GMO".

As opposed to the release for experimental purposes, the authorisation procedure for placing the GMO on the market is not a purely national one. It involves all Member States and Community institutions. This can be explained by the fact that the authorisation of the placing on the market of a GMO implies the free movement of the authorised products throughout the territory of the European Union. Hence all Member States are concerned. The application (called "notification") is first submitted to the competent national authority of the Member State which issues the final written authorisation permitting the placing on the market of the product in question within the Community. The notification must include the particulars listed in Article 13 of Directive 2001/18/EC, to allow a full evaluation of the environmental risks. Having received the notification, the national authority must issue an opinion which will take the form of an "assessment report". This assessment report may be favourable or unfavourable. In the event of an unfavourable report, the authorisation procedure is terminated. However, the company may submit a new notification for the same GMO to the competent national authority of another Member State. This authority may eventually issue a different report.

In the event of a favourable opinion for the placing on the market of the GMO concerned, the Member State, after having received the notification and produced the assessment report, informs the other Member States via the European Commission. The other Member States and the Commission examine the assessment report and may issue observations and objections. If there are no objections by other Member States of the European Commission, the competent authority that carried out the original assessment authorises the placing on the market of the product. The authorised product may then be placed on the market throughout the European Union in conformity with any conditions set out in the authorisation. The authorisation has a maximum duration of ten years and may be renewed provided certain conditions are met (for example on the basis of the result of the follow-up of the placing on the market).

If objections are raised, the procedure provides for a conciliation phase between the Member States who object, the notifier and the Commission. The objective of this phase

is to resolve the outstanding questions. If at the end of the conciliation phase the objections are maintained, a decision must be taken at European level. The Commission first asks for the opinion of the European Food Safety Authority, composed of independent scientists, highly qualified in the fields associated with medicine, nutrition, toxicology, biology, chemistry and other similar disciplines.

The Commission then presents a draft decision to the Regulatory Committee composed of representatives of the Member States for an opinion. If the Committee gives a favourable opinion by qualified majority, the Commission adopts the decision.

If not, the draft Decision is submitted to the Council of Ministers for adoption or rejection by qualified majority. If the Council does not act within three months, the Commission can adopt the decision. During the notification process, the public is also informed and has access to the publicly[422] available data, such as: the summary notification format, the assessment reports of the competent authorities, or the opinion of the European Food Safety Authority.

104. Risk assessment of GMOs

The safety of GMOs in respect to health and the environment depends on the characteristics of the recipient organism (or parent organism), the inserted genetic material, the final organism that is produced, the recipient environment and the interaction between the GMO and the environment. The objective of the environmental risk assessment is to identify and evaluate potential adverse effects of the GMO(s). These include direct or indirect, immediate or delayed effects, taking into account any cumulative and long-term effects on human health and the environment which may result from the deliberate release or placing on the market of the GMO(s). The environmental risk assessment also requires evaluation in terms of how the GMO was developed and examines the potential risks associated with the new gene products produced by the GMO (for example toxic or allergenic proteins), and the possibility of gene-transfer (for example of antibiotic resistance genes).

The risk assessment methodology, reproduced in Annex II to Directive 2001/18/EC, is as follows:

422 http://gmoinfo.jrc.it/.

- identification of any characteristics of the GMO(s) which may cause adverse effects;
- evaluation of the potential consequences of each adverse effect;
- evaluation of the likelihood of the occurrence of each identified potential adverse effect;
- estimation of the risk posed by each identified characteristic of the GMO(s)
- application of management strategies for risks resulting from the deliberate release or placing on the market of GMO(s);
- determination of the overall risk of the GMO(s).

105. GMOs authorised for release into the environment

Under the legislation governing the deliberate release of GMOs into the environment (Directive 2001/18/EC and, previously, Directive 90/220/EC) numerous GMOs (maize, oil seed rape, soybean, chicory) have been approved for different uses: for cultivation, for import and processing or for use as feed and food. However, since 1990, only three GMOs have been authorised for cultivation, and only one product (MON810 maize) was still authorised as of 1 March 2018.

a) Maize MON 810

The first GMO to have been authorised in the European Union, and the only one still authorized as of 1 March 2018, is MON 810, a Bt maize engineered by Monsanto to protect the crop against a harmful pest – the European corn borer. It was authorised in 1998, under Directive 90/220/EEC (the predecessor of Directive 2001/18/EC). Renewal of the authorization is pending.[423]

In 2013, MON 810 was cultivated in 5 Member States with a total coverage of almost 150,000 hectares, which represents less than 1.5% of the total EU maize surface, and 0,23% of the 55,1 million hectares of genetically modified maize cultivated worldwide. Spain is the only Member State where the production is significant (137,000 hectares). The 4 other Member States in which MON 810 was cultivated in 2013 were: Portugal (9,278 hectares), Czech Republic (3,052 hectares), Romania (217 hectares) and Slovakia (189 hectares).

423 http://ec.europa.eu/food/dyna/gm_register/gm_register_auth.cfm?pr_id=11.

Eight Member States (Austria, Bulgaria, Greece, Germany, Hungary, Italy, Luxembourg and Poland) have adopted safeguard measures (see below, No 86) and prohibited the cultivation of the GM maize MON810 on their territories. France also had a cultivation ban in place until August 2013, when it was annulled by the French Conseil d'Etat. All safeguard clauses submitted to EFSA have been declared scientifically unfounded. This situation was however modified by Directive (EU) 2015/412 which gives Member States more flexibility to decide on the cultivation of genetically modified crops, under certain conditions.[424]

b) Amflora Potato

In March 2010, the Commission authorised the cultivation and industrial processing in the EU of a second GMO: a genetically modified potato, known as Amflora. The use of its starch by-products as feed and the adventitious presence in food were simultaneously authorised under Regulation (EC) No 1829/2003. Austria, Greece, Hungary, Luxembourg and Poland promptly notified to the Commission the prohibition of the cultivation of the Amflora potato on their territory.

The potato is no longer cultivated in the EU since 2011, and cultivation is unlikely to resume in the foreseeable future since the Commission's authorisation was annulled, on procedural grounds, by the General Court in December 2013[425].

c) Maize 1507

No other GMO is more emblematic of the conundrum of GM approvals than Pioneer's maize 1507, which encodes the resistance to the European corn borer and tolerance to glufosinate-containing herbicides. The event has been long authorised in the European Union for importation as food and feed, but not for cultivation. The European Food Safety Authority (EFSA) has delivered a favourable opinion on the request for cultivation in several scientific assessments.[426]

Pioneer had submitted its original application for the authorisation of maize 1507 for cultivation under Directive 2001/18/EC in 2001. Six years later, in 2007, Pioneer initiated a first action for failure to act before the General Court of the European Union

424 See below, No 106.
425 Case T-240/10, *Hungary v. Commission*, [2013] ECR 0000.
426 The latest EFSA opinion can be found at: https://www.efsa.europa.eu/en/efsajournal/pub/4659.

against the Commission for not having presented a decision of authorisation of maize 1507 for vote to the Regulatory Committee. This action was closed by the Court following the proposal by the Commission, in February 2009, of a draft decision of authorisation to the Regulatory Committee, which however failed to deliver an opinion.

In 2010, Pioneer launched a second action for failure to act against the Commission, and in September 2013, the General Court declared that the Commission had failed to act under Directive 2001/18/EC by not submitting to the Council a proposal for a Decision in conformity with the comitology procedure.[427]

All attempts by the Commission to issue an authorization have failed so far. The Commission last submitted a draft implementing decision to the Standing Committee on the Food Chain and Animal Health on 14 September 2017: 12 Member States voted in favour, 12 voted against, and 4 abstained. However, on 24 October 2017, the European Parliament adopted a resolution calling on the Commission to withdraw that draft.[428]

106. Safeguard measures and subsidiarity

A so-called safeguard clause[429] in Directive 2001/18/EC provides that where a Member State has justifiable reasons to consider that a GMO, which has received written consent for placing on the market, constitutes a risk to human health or the environment, it may provisionally restrict or prohibit the use and/or sale of that product on its territory. Similar national bans of cultivation have been introduced under a similar provision under the legislation on the placing on the market of seeds. Furthermore, some Member States have made use of the notification procedures[430] set out in TFEU which requires putting forward new scientific evidence relating to the protection of the environment or the working environment. In almost all cases, the scientific justifications put forward by the Member States to justify their unilateral measures have proved to be base-less. [431]

427 Case T-164/10, Pioneer v. Commission, [2013] ECR 0000.
428 http://www.europarl.europa.eu/sides/getDoc.do?type=MOTION&reference=B8-2018-0122&format=XML&language=EN
429 Article 23 of Directive 2001/18/EC. There is a similar clause, with the same effect, in Regulation (EC) No 1829/2003 (Article 34).
430 Article 114(5) and (6) TFEU.
431 For a discussion on the conditions for adopting national safeguard measures, see: Joint cases C-58/10 to C-68/10, *Monsanto et.al v. Ministère de l'Agriculture et de la Pêche*, [2010] ECR 0000.

At the end of 2009, Mr Barroso indicated in his Political Guidelines for the new Commission (Barroso II) that the Commission was now intending to combine a science-based Union authorisation system on the cultivation of GMOs, with more flexibility to decide whether or not they wish to cultivate GMOs on their territory without affecting the risk assessment provided in the system of Union authorisations of GMOs, either in the course of the authorisation procedure or thereafter. It was hoped that granting that possibility to Member States would ease the authorisation process.

After long and protracted discussion, Directive (EU) 2015/412[432] was eventually adopted in March 2015. This Directive modifies the authorization procedure laid down in Directive 2001/18/EC by providing the possibility for a Member State to demand that the geographical scope of the notification submitted in accordance with the Directive be adjusted to the effect that all or part of the territory of that Member State be excluded from cultivation. [433] The Commission presents this demand of the Member State to the notifier, who has to respond within an established time limit. Where the notifier agrees with limitation of the geographical scope, the limitation is implemented in the written consent issued under Directive 2001/18/EC, or under the decision adopted by the Commission under Directive 2001/18/EC or under Regulation (EC) 1829/2003, as the case may be.

Whilst most restrictions to the geographical scope of notifications or authorisations are likely to be implemented at the stage of granting or renewing the consent or the authorisation, Directive 2001/18/EC as amended also foresees the possibility for Member States to adopt reasoned measures restricting or prohibiting the cultivation of a GMO, or of a group of GMOs defined by crop or trait, in all or part of their territory after authorization. The grounds which can justify such restrictions must be 'in conformity with Union law, reasoned, proportional and non-discriminatory and, in addition' and related to environmental or agricultural policy objectives, or other compelling grounds such as town and country planning, land use, socioeconomic impacts, coexistence and public policy.

Directive (EU) 2015/412 expressly[434] states its provisions may allow for restrictions to the cultivation of GMOs, and not to their free circulation and import, and that these

432 Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory (OJ L 68 of 13.3.2015 p. 1-8). See in particular the new Article 26 b (Cultivation).

433 The modification applies mutatis mutandis in the context of Regulation (EC) 1829/2003.

434 Recital (16).

restrictions should, furthermore, be in conformity with the Treaties, in particular as regards the principle of non-discrimination between national and non-national products and the principle of proportionality. Furthermore, the measures adopted by the Member States under the new provisions will be subject to a procedure of scrutiny and information at Union level, whereby the Commission is given an opportunity to comment upon them. One is however clearly left with the impression that Member States will be very much able henceforth to ban the cultivation of GMOs on their territory, if they so will. Whether this will facilitate in the future the authorization of GMOs in the EU, whenever the conditions for authorization will be met, is an entirely different matter.

107. Genetically modified seeds

EU legislation on seeds, notably Directive 98/95/EC[435], specifies that national authorities that have agreed to use a seed on their territory must notify this acceptance to the Commission. The Commission examines the information supplied by the Member State concerned and its compliance with Community seeds legislation.

In the event of compliance, the Commission includes the variety concerned in the "Common Catalogue of Varieties of Agricultural Plant Species" which means the seed can be marketed throughout the EU. The seed legislation furthermore requires that GMO seed varieties have to be authorised in accordance with either Directive 2001/18/EEC or, when the seed is intended for use in food or feed, in accordance with Regulation (EC) No 1829/2003 before they are included in the Common Catalogue and marketed in the EU.

Genetically modified seed varieties must be labelled in accordance with Council Directive 98/95/EEC. The label must show clearly that it is a genetically modified variety. Legislation on the marketing of forestry reproductive material also requires prior authorisation of genetically modified material in line with the requirements of Directive 2001/18. EU rules governing the marketing of vine material in line with Directive 2001/18 have also been adopted[436]. At the present time, more than 140 varieties of the genetically

435 Council Directive 98/95/EC of 14 December 1998 amending, in respect of the consolidation of the internal market, genetically modified plant varieties and plant genetic resources, Directives 66/400/EEC, 66/401/EEC, 66/402/EEC, 66/403/EEC, 69/208/EEC, 70/457/EEC and 70/458/EEC on the marketing of beet seed, fodder plant seed, cereal seed, seed potatoes, seed of oil and fiber plants and vegetable seed and on the common catalogue of varieties of agricultural plant species (OJ N° L 25 of 01.02.1999 p. 1).

436 Council Directive 2002/11/EC of 14 February 2002 amending Directive 68/193/EEC on the marketing of material for the vegetative propagation of the vine and repealing Directive 74/649/EEC (OJ N° L 53 of 23.2.2002, p. 20).

modified maize MON810, the only GMO authorized for cultivation in the EU, are registered in the common catalogue.

108. Traceability

Traceability can be defined as the ability to trace products through the production and distribution line.

For example, if a genetically modified grain constitutes the raw material of a food or feed product, the company selling the grain would have to inform any purchaser that it is genetically modified, together with more specific information allowing the specific GMO to be precisely identified. The company is also obliged to keep a register of business operators who have bought the seed. Equally the farmer would have to inform any purchaser of the harvest that it is genetically modified and keep a register of operators to whom he has made the harvest available. A food producer receiving the harvest and transforming into a food or feed ingredient will have to inform its customer that the food or feed ingredient is produced from a GMO. A food or feed processor purchasing this food or feed ingredient to incorporate it into a food or feed will have to inform its clients that the food or feed contains a GM ingredient, and so on.

The general objectives of a traceability system are to facilitate:

- control and verification of labelling indications;
- targeted monitoring of potential effects on health and the environment, where appropriate;
- withdrawal of products that contain or consist of GMOs where an unforeseen risk to human health or the environment is established.

Products which consist of GMOs or which contain GMOs and food products derived from GMOs, which have been authorised under the procedure referred to in Directive 2001/18/EC (Part C) or under Regulation (EC) No 1829/2003, are subject to traceability requirements in application of Regulation (EC) No 1830/2003.

The traceability rules make it mandatory on the operators concerned, i.e. all persons who place a product on the market or receive a product placed on the market within the Community, to be able to identify their supplier and the companies to which the products have been supplied.

The traceability requirement varies depending on whether the product consists of or contains GMOs (Article 4 of Regulation (EC) No 1830/2003) or has been produced from GMOs (Article 5 of Regulation (EC) No 1830/2003). Hence, two hypotheses must be distinguished:

Operators must ensure that the following two particulars are transmitted in writing to the operator receiving the product:

- an indication that the product or some of its ingredients contains or consists of GMOs or is produced from GMOs and
- the unique identifier(s) assigned to those GMOs, in the case of products containing or consisting of GMOs.

In the case of products consisting of or containing mixtures of GMOs to be used only and directly as food or feed or for processing, the information relating to the unique identifiers may be replaced by a declaration of use by the operator, accompanied by a list of the unique identifiers for all those GMOs that have been used to constitute the mixture.

Operators must ensure that the information received is transmitted in writing to the operator receiving the product.

109. Cartagena Protocol

The EU is a party to the Cartagena Protocol on Biosafety[437] annexed to the UNEP's Convention on Biological Diversity. It entered into force on 11 September 2003. The overall purpose of this United Nations agreement is to establish common rules to be followed in transboundary movements of GMOs in order to ensure, on a global scale, the protection of biodiversity and of human health.

The incorporation of the Cartagena Protocol on Biosafety into EU legislation relies on a wide range of biotechnology legislation governing the use of GMOs within the European Union, including imports. The cornerstone of this legal framework is Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms. It is supplemented by Regulation (EC) No 1946/2003[438] on the transboundary movements of GMOs, which was adopted in June 2003.

437 http://www.cbd.int/doc/legal/cartagena-protocol-en.pdf.

438 Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ No L 287/1 of 05.11.2003).

The main features of the Regulation are:

- the obligation to notify exports of GMOs intended for deliberate release into the environment and secure express consent prior to a first transboundary movement;
- the obligation to inform the public and third countries on EU legislation and decisions on GMOs, as well as on accidental releases of GMOs;
- a set of rules for the export of GMOs intended to be used as food, feed or for processing;
- provisions for identifying GMOs for export.

110. Co-existence

The cultivation of GM crops clearly has implications for the organisation of agricultural productions. Pollen flow between adjacent fields is a natural phenomenon. Because of the labelling requirements for GM food and feed, this may have economic implications for farmers who want to produce traditional plants intended for food. The objective of co-existence measures, in areas where GMOs are cultivated, is to avoid the unintended presence of GMOs in other products, preventing the potential economic loss and the impact of traces of GM crops in non-GM crops, such as conventional and organic crops.

On 23 July 2003 the Commission adopted a Recommendation[439] on guidelines for the development of national strategies and best practices to ensure the co-existence of genetically modified crops with conventional and organic farming. These guidelines stated that approaches to co-existence needed to be developed in a transparent way, based on technical guidelines and in co-operation with all stakeholders concerned. The guidelines were based on experiences with existing segregation practices (e.g. in certified seed production); at the same time, they ensured an equitable balance between the interests of farmers of all production types.

The Commission published in 2009 the second report[440] on national strategies for coexistence of GM crops with conventional and organic farming. The report showed that 15 Member States adopted legislation on coexistence while three more notified draft legislations. It acknowledged that experience gained over the recent years suggested that Member States need more flexibility to take into consideration their particular local,

439 Commission Recommendation 2003/556/EC of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming (OJ No L 189/36 of 29.07.2003).

440 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2009:0153:FIN:EN:PDF

regional and national conditions when defining measures to organise the cultivation of GM, conventional and organic crops.

In 2010, the Commission issued a new Recommendation on co-existence of GM crops with conventional and/or organic crops[441], which allows more flexibility to Member States taking into account their local, regional and national conditions when adopting co-existence measures. It recognises that Member States may adopt measures to avoid the unintended presence of GMOs in other products below the labelling threshold of 0.9%. When co-existence measures are not sufficient to prevent the unintended presence of GMOs in conventional or organic crops, Member States may restrict GMO cultivation in large areas of their territory. Such restriction measures need to be proportionate to the objective pursued (i.e. protection of particular needs of conventional or organic farming).

As Member States are now allowed to prohibit the cultivation of GMOs on their territory[442], Directive 2001/18/EC as amended[443] provides that, as of 3 April 2017, Member States in which GMOs are cultivated will have to take appropriate measures in border areas of their territory with the aim of avoiding possible cross-border contamination into neighbouring Member States in which the cultivation of those GMOs is prohibited.

441 Commission Recommendation of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops (OJ C 200 of 22.07.2010 p. 1-5).
442 See No 86, above.
443 Article 26a paragraph 1a.

Chapter 4
Genetically modified food and feed

111. Regulation (EC) No 1829/2003

Regulation (EC) No 1829/2003 applies to applications for the placing on the market in the territory of the European Union of the following products:

- GMOs for food and feed use
- food and feed containing GMOs, consisting of such organisms or produced from GMOs (in the Regulation these are called: "genetically modified food" and "genetically modified feed").

The Regulation stipulates that the products to which it applies must not:

- have adverse effects on human health, animal health, or the environment;
- mislead the consumer or user;
- differ from the food/feed they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous for human beings (and for animals in the case of genetically modified feed).

The Regulation puts in place a centralised, uniform and transparent EU procedure for all applications for placing on the market, whether they concern the GMO itself or the food and feed products derived there from.

This means that business operators may file a single application for the GMO and all its uses: a single risk assessment is performed and a single authorisation is granted for a GMO and all its uses (cultivation, importation, use as or in food or feed, processing into food, feed or industrial products). If one of these uses concerns food, all the uses (cultivation, processing into industrial products, etc.) may be treated under Regulation (EC) No 1829/2003[444]. The Regulation also ensures that experiences such as with Starlink maize in the US (a GM maize which was only authorised for feed but was found in food) are avoided: in the EU, GMOs likely to be used as food and feed can only be authorised for both uses.

444 Actually, DG SANTE's website suggests that a request for the authorization of a GMO to be used for cultivation and in food and feed has to be lodged under Regulation (EC) 1829/2003.

The Commission has recently proposed to extend the solution agreed in Directive (EU) 2015/412 by the European Parliament and by the Council on GMO cultivation[445] to GM food and feed. It has thus submitted a proposal[446] to amend Regulation (EC) No 1829/2003 in order to allow Member States to adopt measures restricting or prohibiting the use of products authorised under the Regulation "provided that such measures are: (a) reasoned and based on compelling grounds in accordance with Union law which shall, in no case, conflict with the risk assessment carried out pursuant this Regulation; and (b) proportional and non-discriminatory"[447]. Whilst Member States would not be able to restrict the placing of products on the market, or their purchase by operators or consumers, they would however be allowed to ban their use on their territory! One might not think highly of Directive (EU) 2015/412, but at least one will admit that it is workable. This proposal is not. If it was adopted and implemented in the way it is proposed, it would completely disrupt the Union market for animal feed.

112. Procedure

The authorisation, valid throughout the Community, is granted subject to a single risk assessment process under the responsibility of the European Food Safety Authority and a single risk management process involving the Commission and the Member States through a regulatory committee procedure.

Regulation (EC) No 1829/2003 lays down the procedure for issuing authorisations for placing on the market of genetically modified food and feed, in which, the Commission plays an important role.

Applications are submitted first to the competent authority of one Member State. The application must clearly define the scope of the application, indicate which parts are confidential, a labelling proposal and a detection method. When the application covers products containing or consisting of GMOs, a monitoring plan of the effects on the environment must also be included. The national authority must acknowledge receipt in writing within 14 days and inform EFSA. The application and any supplementary information supplied by the applicant must be made available to EFSA, which is

445 See No 86 above.
446 Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1829/2003 as regards the possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory (COM(2015)177/2).
447 See Article 1, introducing a new Article 34a in the Regulation.

responsible for the scientific risk assessment covering both the environmental risk and human and animal health safety assessment. Its opinion will be made available to the public and the public will have the opportunity to make comments. In general, a time limit of six months for the EFSA opinion will be respected. This time limit can be extended if EFSA has to request further information from the applicant. A draft guidance document for the risk assessment of GM plants and derived food and feed is available from EFSA.

Within three months of receiving the opinion of EFSA[448], the Commission must draft a proposal for granting or refusing authorisation. Granting an authorisation can only be considered in case of favourable EFSA opinion. The Commission may diverge from EFSA's opinion, but it must then justify its position. The Commission's proposal is subject to the opinion of the Standing Committee on the Food Chain and Animal Health, composed of representatives of the Member States. The proposal is for an implementing measure within the meaning of Article 291 TFEU2. The mechanism for control by Member States of the Commission's exercise of implementing powers under Article 291 TFEU is set out in Regulation (EU) No 182/2011 (the 'Comitology' Regulation)[449]:

- if there is a qualified majority of Member States in favour of the Commission's draft decision (positive opinion) the Commission must adopt the decision;
- if there is a qualified majority against the draft decision (negative opinion) the Commission cannot adopt the decision.

Where no opinion either in favour or against the Commission proposal can be obtained by qualified majority, the matter is referred to an appeal committee, also composed of Member State representatives, where the above described alternative applies again. When it comes to the authorization of GMOs or GM food and feed, there has never been a qualified majority one way or the other either in the Standing Committee or in the Appeal Committee. In such cases the Commission may adopt the proposal but is very reluctant to do so, all the more when the European Parliament has indicated to the Commission, under its right of scrutiny[450] that, in its view, the draft implementing decision exceeds the

448 EFSA opinions are published at: http://www.efsa.europa.eu/EFSA/ScientificPanels/efsa_locale-1178620753812_GMO.htm.

449 Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers, OJ L 55, 28.2.2011, page 13.

450 See Article 11 of Regulation (EU) No 182/2011.

implementing powers provided for in Regulation (EC) No 1829/2003. [451] The Commission has decided to address this problem by laying down a proposal aiming at bringing 'targeted changes to the rules on comitology procedures', in particular by introducing a voting system in the Appeal Committee where the double majority (55% of Member States representing 65% of population) required for the forming of a positive or negative opinion will be calculated based only on Member States taking part in the vote.[452]

Products authorised are entered into a public register of GM food and feed. Authorisations are granted for a period of 10 years, subject where appropriate to a post-market monitoring plan.

Authorisations are renewable for 10-year periods. Applications for renewal have to be submitted within 9 years following the date of authorisation. The products may then continue to be placed on the market as long as a new decision is adopted.

113. Risk assessment of GM food and feed

As indicated above, the risk assessment of GM food and feed is carried out by EFSA, and it is based on scientific dossiers presented by applicants. The GMO Panel, which carries the evaluation frequently asks applicants for further scientific information, study results or clarifications before processing their applications if it is not satisfied with the original dossier – this happens in around 95% of cases. The GMO Panel applies the strict criteria laid down in the EU regulatory framework in relation to GMO applications to ensure its evaluations meet the highest scientific standards. Each of the following aspects is considered for all applications:

- Molecular characterisation of the GM product, taking into account the characteristics of the donor and recipient organism.
- Compositional, nutritional, and agronomic characteristics of the GM product.

451 For a recent resolutuon of Parliament in this sense, see: European Parliament resolution of 1 March 2018 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 87427 × MON 89034 × NK603 (MON-87427-7 × MON-89Ø34-3 × MON-ØØ6Ø3-6) and genetically modified maize combining two of the events MON 87427, MON 89034 and NK603, and repealing Decision 2010/420/EU (D054771-02 – 2018/2569(RSP)).

452 Proposal for aRegulation of the European Parliament and of The Council amending Regulation (EU) No 182/2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers. COM(2017) 85 of 14.2.2017, 2017/0035 (COD).

- Potential toxicity and allergenicity of the GM product.
- Potential environmental impact following a deliberate release of the GM product and taking into account its intended uses either for import, processing or cultivation.

EFSA has prepared several guidance documents for the risk assessment of GMOs and derived food and feed. These documents, which largely reflect *Codex Alimentarius* guidelines, detail the type of scientific data that applicants must include in GMO applications and outline the risk assessment approach to be applied. All guidance documents are publicly available on the EFSA website.

114. GM food and feed authorised in the EU

Products from numerous GMOs can legally be marketed in the EU as food or feed[453]. These are in particular:

- products (food, food additives or feed) derived from 12 GM cotton lines;
- products (food, food ingredients, feed, and products other than food or feed) containing, consisting of or produced from 27 GM maize lines;
- products (feed or feed materials) produced from 1 GM bacteria and from 1 GM yeast (GMMs);
- products (food, food ingredients, feed and products other than food and feed) containing, consisting of or produced from 5 oilseed rape lines;
- products (food, food ingredients, feed and products other than food and feed) containing, consisting of or produced from 19 GM soybean lines; and
- products (food, food ingredients and feed) produced from 1 GM sugar beet line.

Further applications for the placing on the market of food products have been introduced in accordance with the authorisation procedure provided for in Regulation (EC) No 1829/2003.

115. Reference laboratories

Regulation (EC) No 1829/2003 provides that applicants for authorisation should propose appropriate methods for sampling, identification and detection, and provide control samples and samples of the genetically modified food and feed in order to facilitate official control. The methods submitted must be validated by the European Union

453 For an updated list, see: http://ec.europa.eu/food/dyna/gm_register/index_en.cfm.

Reference Laboratory for GM Food and Feed (EU-RL GMFF), formerly known as Community reference laboratory[454].

The EU-RL GMFF has additional responsibilities under the Food and Feed Regulation (EC) No 882/2004 notably the coordination of the National Reference Laboratories (NRLs) with regard to details of analytical methods, including reference methods and training were necessary. The CRL is also responsible for coordinating the application by the national reference laboratories of these methods, and for the provision of scientific and technical assistance to the Commission, especially in cases where Member States contest the results of analyses[455].

116. Unauthorised GM material

Regulation (EC) 1829/2003 did not provide any tolerance for the presence of unauthorised GM material in food or feed, except for a transitional measure concerning the adventitious or technically unavoidable presence of GM material which has benefited from a favourable risk assessment[456].

In 2011 the Commission however adopted a regulation[457] which addresses the EU business operator's legal uncertainty when marketing feed imported from non-EU countries by setting a technical zero at a level of 0.1%, the lowest level of GM material considered by the EU Reference Laboratory for the validation of quantitative methods. Certain conditions apply. Unfortunately, this provision does not apply to food.

117. Labelling of GM food and feed

Food and feed consisting of or containing GMOs and food and feed produced from GMOs are subject to the labelling requirements laid down in Regulation (EC) No 1829/2003 and 1830/93. Labelling informs the consumer and user of the product, hence allowing them to make an informed choice.

454 See Article 32 and the Annex to Regulation (EC) No 1829/2003, and Commission Regulation (EC) No 1981/2006 of 22 December 2006 on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003, OJ L 368 of 23.12.2006, p. 99.

455 For further information, see the website of the EU-RL GMFF: http://gmo-crl.jrc.ec.europa.eu/default.htm.

456 See Article 47 of Regulation (EC) 1829/2003. The threshold was 0,5 %.

457 Commission Regulation (EC) 619/2011 of 24 June 2011 laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorisation procedure is pending or the authorisation of which has expired, JO L166, 25.06.2011 p. 9-15.

Generally speaking, for all pre-packaged products consisting of or containing GMOs, Regulation (EC) No 1829/2003 requires that operators indicate on the label: "This product contains genetically modified organisms" or "This product contains genetically modified [(name of organism(s)]". In the case of non-pre-packaged products offered to the final consumer or to mass caterers (restaurants, hospitals, canteens and similar caterers) these words must appear on, or in connection with, the display of the product. The labelling requirements also apply to highly refined products, such as oil obtained from genetically modified maize, regardless of whether DNA or proteins derived from genetic modification are contained in the final product or not.

The requirements of Regulation (EC) No 1830/2003 (see below at No 119) imposing each operator of the food and feed chain to inform his clients that the product sold is a GM food and feed ensures a smooth operation of these labelling rules.

However, in line with the general EU rules on labelling, Regulation (EC) No 1829/2003 does not require labelling of products such as meat, milk or eggs obtained from animals fed with genetically modified feed or treated with genetically modified medicinal products. Nor are these products subject to traceability requirements.

The same rules apply to animal feed, including any compound feed that contains transgenic soy. Corn gluten feed produced from transgenic maize must also be labelled, in compliance with Article 25 of Regulation (EC) No 1829/2003, so as to provide livestock farmers with accurate information on the composition and properties of feed.

EU legislation does not include provisions concerning the labelling of products as 'GM-free', but several Member States adopted measures either to prohibit or restrict such labelling, or to lay down requirements that products must meet to be labelled as 'GM-free'. The Commission has published a study commissioned to an external contractor on the issue, and has obviously come to the conclusion that there is no need for a measure at EU level.[458]

118. Labelling threshold for adventitious presence of GM material (0,9 %)

Conventional products, i.e. products created without recourse to genetic modification, may be accidentally contaminated by GMOs during harvesting, storage, transport or processing. This does not only apply to GMOs. In the production of food, feed and seed,

458 https://ec.europa.eu/food/plant/gmo/traceability_labelling_en.

it is practically impossible to achieve products that are 100% pure. Taking this into account, the legislation has laid down limits above which conventional food and feed must be labelled as products consisting of GMOs, containing GMOs or produced from GMOs. Conventional products are thus not subject to traceability and labelling requirements if they contain traces of authorised GMOs below a limit of 0.9%, provided the presence of this material is adventitious or technically unavoidable. This is the case when operators demonstrate to the competent authorities that they have taken adequate measures to avoid the presence of this material.

119. Traceability of GM food and feed

Regulation (EC) No 1830/2003, which has already been described for Operators must ensure that the following particulars are transmitted in writing to the operator receiving the product:

- an indication of each of the food ingredients which are produced from GMOs;
- an indication of each of the feed materials or additives which are produced from GMOs;
- in the case of products for which no list of ingredients exists, an indication that the product is produced from GMOs.

Operators must hold the information for a period of five years from each transaction and be able to identify the operator by whom and to whom the products have been made available. In order to respect these traceability requirements, it is important that each operator has in place a system to allow the information to be kept and to make it available to the public authorities on demand. Transmission and record-keeping of this information reduces the need for sampling and testing of products.

120. WTO challenges

Following complaints by the US[459], Canada[460] and Argentina[461] against the EU on the application of its legislation on biotech products, the WTO Dispute Settlement Body (DSB) adopted on 21 November 2006 three panel reports[462] which found a violation of the WTO Sanitary and Phytosanitary (SPS) Agreement on three grounds:

459 WT/DS291/R
460 WT/DS292/R
461 WT/DS293/R
462 http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds291_e.htm

- the application of a general *de facto* moratorium on approval of GM products from June 1999 to August 2003;
- the existence of undue delays with respect to 23 product-specific applications (out of the 27 cases considered by the Panel);
- national safeguard measures introduced by 6 Member States before the establishment of the panel, which were found not to be based on an appropriate risk assessment.

Subsequently, the EU and the three complainants agreed to engage in bilateral technical discussions on biotech-related issues, which would not be limited to issues of implementation of the WTO panel recommendations. These discussions have had diverging results:

- The EU and Canada reached a mutually agreed solution of their dispute on 15 July 2009[463].
- The European Commission announced on 18 March 2010 that a similar agreement had been reached between the EU and Argentina[464].
- The US made a general retaliation request on 17 January 2008. On 6 February 2008, the EU objected to the US retaliation request. The matter was referred to arbitration under Article 22.6 of the WTO Dispute Settlement Understanding at the special meeting of the DSB held on 8 February 2008. On 15 February 2008, and according to the sequencing agreement concluded between the US and the EU, both parties requested the suspension of Article 22.6 procedures. The chairman of the arbitration panel suspended those procedures on 18 February 2008. Those procedures can only be resumed following the examination of compliance of the panel report by the EU through an arbitration procedure under Article 21.5 of the Dispute Settlement Understanding (DSU). The US and the EU continued technical discussions in 2008. The last round of discussions took place in October 2008.

In the meantime, the EU had of course reformed its regulatory framework for genetically modified food and feed, with the adoption of Regulation (EC) No 1829/2003, and had also resumed the granting of marketing authorizations for GMOs and GM food and feed.[465] For a while, the US threatened to challenge the labelling and traceability

463 IP/09/1142 of 15 July 2009.
464 IP/10/325 of 18 March 2010.
465 See above, at No 114.

provisions of Regulation (EC) No 1829/2003, but they never actually requested consultations on the matter, possibly because they had realised that there was not a chance that the EU labelling and traceability provisions would be found in contradiction with the Technical Barriers to Trade (TBT) Agreement. In the meantime, labelling of GM ingredients in food is mandatory in the US.[466]

466 The bill mandating GMO labelling on food and beverage products was signed into law by President Obama 28 July 2016, but implementing measures still need to be adopted by the U.S. Department of Agriculture (USDA).