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THE REGULATION OF GENETICALLY MODIFIED ORGANISMS IN THE EUROPEAN UNION: THE INTERPLAY OF SCIENCE, LAW AND POLITICS

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"Absence of evidence of harm is not evidence of absence of harm"[1]

1. Introduction

The application in the past decade of modern biotechnology in agricultural production has sparked off in Europe a public debate of unprecedented nature. Almost since the first commercial release in 1994 of a genetically modified tomato in the US market, the opposition to genetically modified organisms (GMOs) has spanned across nations, political ideologies, religious beliefs and activist organizations. This debate is still ongoing, with almost all segments of the society actively participating. It raises primarily questions about trust in science, about transparency in risk governance and about consumer choice.

In the early 1990s, the Community legislature took the lead world-wide. It adopted a horizontal approach to regulation, harmonizing national provisions concerning GMOs and GM micro-organisms with the objective of ensuring free movement of goods in the internal market whilst aiming for a high level of health and environmental protection. However, the public debate and, in some cases, the civil unrest and even disobedience that followed, particularly during the years 1996–2001, rendered revision of the first Community legal framework necessary. Scientific and international legal developments followed soon and they reinforced the need to update and complete the regulatory framework. To understand, therefore, the background of the Com-

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1. This phrase is quoted so frequently that it is difficult to trace its original source. It is quoted here from the last report in which I have seen it mentioned, the UK GM Science Review Panel: GM Science Review – First Report, p. 22, July 2003, available at www.gmsciencedebate.org.uk.

munity's attitude to regulating GMOs and GM products, it is necessary also to take into account the political, socio-economic, scientific and broad ethical concerns that have shaped it.

During these stormy and turbulent years, the legal community in Europe remained almost silent, apparently because of the essentially technical and complex nature of the debate. Few legal articles appeared and even fewer attempted to discuss the interplay of science, law and politics in the regulation of GMOs in the Community.

This article attempts to fill some of the gaps in the discussion on risk governance in this area of Community law. It is organized as follows. Section 2 provides a brief analysis of four basic laws that regulate almost all aspects of production, import, marketing and export of GMOs and GM products in the Community. Section 3 discusses the coexistence of Community and Member State power in the regulation of the GMOs and GM products, by focusing on the pre-emptive effects on State power which the Community harmonization measures and their decentralized implementation and application can have. Finally, Section 4 develops the scientific, economic and other social constraints that have influenced – and seem still to be influencing – the implementation of Community legislation in this area.[2] It is important, however, to bear in mind the obvious difficulties and limitations of developing in the short space of an article more than the bare outlines of an analysis on a subject of such a nature and complexity.

2. The regulatory framework

The objective of this Section is not to provide a complete descriptive analysis of all the existing legislation regulating the import, production, marketing, traceability, labelling and export of GMOs and GM products in the Community. Rather, its focus will be on those aspects of the legislation and implementing measures that are necessary for the ensuing discussion, namely: first, a broad overview of the attitudes of the Community institutions and of the Member States in the decentralized system of managing marketing authorizations of GMOs and GM products in their territory; second, shedding some light on the complexities which the interface of science, law and policy in the area of risk regulation may generate and the implications which those

2. This is the first article in a series of two which the author is preparing. The second article, to be published separately, will attempt to evaluate the conformity of the Community's legislation and implementing measures with the relevant provisions of international law, in particular the WTO Agreements.

complexities can have on the GMOs approval process; and, third, to pave the way for the subsequent review of the legislation and any implementing measures with the relevant provisions of international law and, in particular, the WTO agreements.

The aspects of the Community legislation examined here are: the object and scope of the legislation in question, the appropriate level of health and environmental protection the legislation aims to achieve, the authorization procedure it establishes, the degree of regulatory harmonization it accomplishes and, last but not least, the state of play about its implementation and application by the relevant Community institutions and Member State authorities.

2.1. *General*

The Community legislation regulating nearly all aspects of GMOs and GM products, whether for deliberate release as seeds or for experimental purposes into the environment or for use in food or feed, is of either horizontal or sector specific (vertical) nature. There are several acts of diverse nature and regulatory density, laying down a coherent legislative framework. Only a broad, comprehensive review of all these acts is likely to reveal the common thread that ties them closely together. In the following parts of this section, however, only the basic four pieces of the horizontal Community legislation will be examined, although occasional reference to some other – sector specific – legislation will also be made, when necessary, for the purposes of the analysis. These four acts of Community law are: Directive 2001/18/EC on the deliberate release of GMOs into the environment,[3] Regulation (EC) 258/97 on novel food and food ingredients,[4] Regulation (EC) 1829/2003 on GM food and feed,[5] and Regulation (EC) 1830/2003 on traceability and labelling of GMOs and GM products.[6] The 2000 Cartagena Protocol on Biosafety to

3. 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, O.J. 2001, L 106/1, as last amended by Council Decision 2002/811/EC, O.J. 2002, L 280/27.

4. Regulation No 258/97 of the European Parliament and of the Council of 27 Jan. 1997 concerning novel foods and novel food ingredients, O.J. 1997, L 43/1.

5. Regulation (EC) No 1829/2003 of the European Parliament and of the Council, of 22 Sept. 2003, on genetically modified food and feed, O.J. 2003, L 268/1.

6. Regulation (EC) No 1830/2003 of the European Parliament and of the Council, of 22 Sept. 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, O.J. 2003, L 268/24.

the Convention on Biological Diversity,[7] although equally important, will be discussed for analytical purposes elsewhere.[8]

2.2. *Deliberate release of GMOs into the environment – Directive 2001/18/EC*

2.2.1. *General*

Directive 2001/18 entered into force on 14 April 2001. It repealed, as of 17 October 2002, Council Directive 90/220/EEC,[9] the first Community measure to regulate the deliberate release into the environment of GMOs in the Community. It is the central piece of Community legislation in the area of GMOs regulation. It is the culmination of several years of preparation and discussion with the Council and Parliament and takes into account the latest scientific research and international law developments.

2.2.2. *Object and scope*

Part B of the Directive deals with the deliberate release into the environment of GMOs for experimental (i.e. field trial) purposes, which are in principle limited to the territory of an individual Member State, and Part C deals with the placing of products on the Community market that consist of or contain GMOs. The Directive defines a GMO as "an organism, with the exception of human beings, in which the genetic material [DNA] has been altered in a way that does not occur naturally by mating and/or natural recombination."[10] This has now become the established definition of a GMO in any other piece

7. The Cartagena Protocol on Biosafety was concluded, on behalf of the Community, by Council Decision 2002/628/EC, O.J. 2002, L 201/48, and its provisions were implemented mainly by Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003, O.J. 2003, L 287/1.

8. The author is currently preparing a second article examining, *inter alia*, this Protocol, cf. note 2 *supra*.

9. Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms, O.J. 1990, L 117/15–27.

10. Art. 2(2) of Directive 2001/18. The definition is broad enough to cover "living modified organisms" as defined in Art. 3 of the 2000 Cartagena Protocol on Biosafety to the Convention on Biological Diversity. It should be noted that part 1 of Annex 1A to the Directive defines three techniques of genetic modification that fall within the scope of the Directive, and Part 2 of Annex 1A provides the three techniques of genetic modification that are excluded from its scope. The technology used is often called "modern biotechnology" or "gene technology", sometimes also called "recombinant DNA technology" or "genetic engineering". It allows selected individual genes to be transferred from one organism into another, also between non-related species. See European Commission, Questions and Answers on the Regulation of GMOs in the EU, MEMO/03/196, Brussels, 10 Oct. 2003, available at europa.eu.int/comm/dgs/health_consumer/library/press/press298_en.pdf.

of Community legislation in this area. The Directive also defines "deliberate release" as "any intentional introduction into the environment of a GMO or a combination of GMOs for which no specific containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment".[11] It also defines "placing on the market" to mean "making available to third parties, whether in return for payment or free of charge."[12] The placing on the market also covers imports into the Community. A "product" for the purposes of the Directive is "a preparation consisting of, or containing, a GMO or a combination of GMOs, which is placed on the market."[13]

Recitals 5 and 7 and Article 1 of the Directive clarify its dual objective: first, to protect human health and the environment from the deliberate release of GMOs and, second, to approximate the laws of the Member States on the deliberate release of GMOs and to ensure the safe development of industrial products utilizing GMOs. But the Directive has also other more specific objectives. It introduces a mandatory post-marketing monitoring system of GMOs and traceability at all stages of their placing on the market.[14] It establishes an advanced system for the direct information and consultation of the general public in the authorization procedure.[15] Another objective is to inform the consumers by means of appropriate labelling that a product placed in the market contains GMOs, and of the name of the GMOs.[16] These more specific objectives (monitoring, traceability, information and participation of the public, and labelling requirements) aim at ensuring the broader objectives of protecting human health and the environment, and enabling consumers to exercise effectively their freedom of choice in the market place.

It is also important to note that, by virtue of Council Directives 2002/53/EC[17] and 2002/55/EC,[18] the environmental risk assessment laid down in Di-

11. Ibid., Art. 2(3).

12. Ibid., Art. 2(4), which in addition defines three categories of releases that do not amount to "placing on the market" for the purposes of this Directive.

13. Ibid., Art. 2(7).

14. Recitals 42 and 43, Art. 4(6), 19(3)(f) and 20, and Annex IV to Directive 2001/18.

15. Ibid., recital 46 and Art. 24.

16. Ibid., recital 40 and Art. 13(2)(f), 19(3)(e), 21, 26, and Annex IV (8).

17. Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species, O.J. 2002, L 193/1. Arts. 4 and 7(4)(a) and (b) of this Directive provide that in case of the genetically modified varieties falling within its scope, i.e. beet, fodder plant, cereal, potato and oil and fibre plant, there will be no deliberate release into the environment unless an environmental risk assessment has been carried out in accordance with Directive 2001/18. The variety shall be accepted "only if all appropriate measures have been taken to avoid adverse effects on human health and the environment." According to Art. 16 of the Directive, seed varieties accepted in accordance with its provisions would not be subject to

rective 2001/18 is also made applicable to the inclusion in a common catalogue of varieties of agricultural plant species for certain seeds and plants, as well as to marketing of such vegetable seeds.

The scope of the Directive, therefore, is very broad. Importantly, however, the Directive does not cover products derived from GMOs that are subjected to other manufacturing processes. They are covered by the novel food Regulation and the Regulation on GM food and feed, as it will be explained below.[19]

2.2.3. *Authorization procedure*

The Directive lays down a system of prior notification and approval, at the end of which the competent authority of a Member State, i.e. the one that has received the notification ("lead" Member State), may give or refuse to give, as appropriate, its consent for the deliberate release or the placing on the market of the GMOs, as these terms have been defined above, unless objections are raised in the process by the other Member States or the Commission. The Directive establishes harmonized procedures and criteria that require a case-by-case evaluation of the risks to human health and the environment and a step-by-step introduction of evaluated GMOs into the environment.[20]

As regards the placing of GMOs on the market, Article 13 of the Directive provides that a company intending to market a GMO must first submit an application to the competent national authority of the Member State where the product is to be first placed on the market. The same Article, and Annexes II to IV to the Directive, lay down the documentation and other particulars that the application must include, in particular a full assessment of

any marketing restrictions in the Community.

18. Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed, O.J. 2002, L 193/33. This Directive applies to the production (with a view to marketing) and to the marketing of vegetable seed within the Community. According to Arts. 4(2) and 7(4) of the Directive, the Member States should not officially accept for certification, verification as standard seed and for marketing genetically modified varieties, unless an environmental risk assessment has been carried out in accordance with Directive 2001/18. The variety shall be accepted "only if all appropriate measures have been taken to avoid adverse effects on human health and the environment." According to Art. 16 of the Directive, seed varieties accepted in accordance with its provisions would not be subject to any marketing restrictions in the Community.

19. The exceptions to its broad coverage are mentioned in Art. 12 of Directive 2001/18, which places outside its scope products that are authorized by specific sectoral Community legislation on condition that requirements regarding risk assessment, risk management, labelling, monitoring, information to the public and safeguard clauses are "at least equivalent" to that laid down in the Directive.

20. See e.g. recitals 18 and 24 of the preamble to Directive 2001/18.

the GMO in question in terms of risks to human health and the environment.[21]

For experimental field trial releases, Article 6 lays down the information, evidence and other particulars that the notification should contain for a "standard" authorization procedure, and Article 7 lays down the requirements for the so-called "differentiated" procedure.[22] Only the competent authority of the Member State where the notification was made (the lead authority) is responsible for granting the consent for the *standard* procedure for experimental releases. Conversely, under the *differentiated* procedure for experimental releases and the placing of GMOs on the market under part C of the Directive, all the competent authorities of the Member States may potentially be involved in the evaluation of the applications.

As regards the placing of GMOs on the market, if the competent (lead) national authority gives a favourable opinion on the marketing of the GMO concerned, this Member State informs the other Member States via the Commission. If there are no objections raised by another Member State or the Commission, the competent authority that carried out the original evaluation can grant the consent for the placing on the market of the product.[23] The product may then be placed on the market throughout the Community in conformity with the conditions, if any, attached to that consent.[24] But if "reasoned objections" are raised and maintained according to Articles 15, 17 and 20 of the Directive, a decision has to be taken on them at Community level. According to Article 28 of the Directive, the Commission first asks for the opinion of its relevant scientific committees on "reasoned objections" that

21. Three supplementary Council decisions and one Commission decision have been adopted to implement the Directive, in particular with regard to the specific data and other requirements to be submitted in the notification procedure. They are: Council Decision 2002/811/EC of 3 Oct. 2002 supplementing Annex VII to the Directive, O.J. 2002, L 280/27; Council Decision 2002/812/EC of 3 Oct. 2002 establishing the summary information format, O.J. 2002, L 280/37; Council Decision 2002/813/EC of 3 Oct. 2002 establishing the summary notification information format, O.J. 2002, L 280/62; and Commission Decision 2002/623/EC of 24 July 2002 establishing guidance notes supplementing Annex II to the Directive, O.J. 2002, L 200/22.

22. The difference between the two type of procedures is that the "standard" is complemented by a "differentiated" procedure in terms of the nature and extent of information to be supplied or the time-periods to be respected in the evaluation and release of the GMOs for experimental purposes, which meet certain safety criteria where sufficient experience has been obtained from the releases of certain GMOs in certain ecosystems. See also Annex V to the Directive. The evaluation of the GMOs in a differentiated procedure will be carried out under the "simplified" procedure laid down by Commission Decision 94/730/EC, O.J. 1994, L 292/31.

23. Art. 15(1) and (3) of Directive 2001/18.

24. Ibid., Art. 19.

relate to possible adverse effects on human health and the environment. If the scientific opinion is favourable, the Commission then proposes a draft decision to the relevant committee that, in accordance with Article 30 of the Directive, is the relevant regulatory committee set up by Decision 1999/468/EC on comitology procedures.[25] If the regulatory committee gives a favourable opinion, the Commission adopts the approval decision. If the opinion is not favourable or no opinion is given within the time limit, a 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.[26]

2.2.4. *Appropriate level of protection*

A discussion of the appropriate level of health and environmental protection and of the degree of harmonization achieved by the Directive is relevant for determining the extent of preemption operated by the Directive in Community law. In other words, such a discussion is relevant for delineating the degree of residual subject-matter power that is left to the Member States to take action in their territories in the field covered by the Directive.[27] This subsection will examine the issue of defining the appropriate level of protection in this area. The issue of the degree of harmonization achieved and the attendant Member State pre-emption will be examined in section 3.

The level of risk a society considers acceptable for a specific product, substance, process or activity at a given moment in time is frequently called appropriate level of (health or environmental) protection.[28] Defining this level of protection is a function of many considerations and factors, such as the understanding experts, regulators and lay people have of science and its role as a tool to identify, analyse and predict risk, the nature and extent of the risk (serious, irreversibility, etc.), and the confidence of the general public in the capacity of the regulatory system to avoid, eliminate or reduce risk. It should be noted that although the acceptable level of risk can be defined both in qualitative and quantitative terms, in the Community it is practically never expressed in a precise quantitative manner, such as a one-in-a-million

25. O.J. 1999, L 184/23.

26. During the notification process, the public is also informed and has access to the publicly available data on the Internet, for example the summary notification format, the assessment reports of the competent authorities and the opinion of the Scientific Committees.

27. But this will be also important when examining the compatibility with the relevant provisions of the WTO agreements of the Directive and any implementing measures taken by the Community institutions and/or the Member States with regard to the applications for marketing authorizations submitted for specific products.

28. See e.g. Case T-13/99, *Pfizer* v. *Council*, [2002] ECR II-3305, at para 151, and Case T-70/99, *Alpharma* v. *Council* [2002] ECR II-3945, at para 164.

risk of death from the use of a specific product. It is interesting to note that Community law uses the terms high *level* of health or environmental protection to be achieved,[29] not terms like significant *risk* to be avoided, which is frequently the approach of other jurisdictions (such as of the USA). However, there is no doubt that even a qualitative expression of the acceptable level of risk, such as significant or serious or irreversible risk, also includes or implies a chosen level of health or environmental protection.

The level of protection may, but does not always have to, be chosen in advance of adopting a specific measure or in an abstract manner in framework legislation, like Directive 2001/18. But it may also be decided on a case-by-case basis at the time of taking a specific regulatory measure, in implementation of framework legislation. The Community regulatory system, like most other systems, adopts a mixed approach, which entails defining the appropriate level of protection either in the primary or secondary legislation in a general manner (and through the choice of the procedure to be followed) or when adopting specific implementing measures on applications for the authorization of individual products or processes to be placed on the market.

A combined reading of several provisions of the Directive indicates that its aim is to achieve "a high level of safety for the general population and the environment".[30] Recital 47 of its preamble explains that "the competent authority should give its consent only after it has been satisfied that the release will be safe for human health and the environment." It should be noted that the Directive refers to "the risk" or "a risk", without qualifying adjectives such as "serious" or "irreversible".[31] It is significant that the regulatory action is to be based on the precautionary principle which in this case, according to Article 4(1) of the Directive, requires Member States to ensure that "all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs". The use of the terms "to avoid" and "might arise" in this context imply that there is no tolerance of *identified* risk. The concept of risk in this context is also very wide and covers "any direct or indirect, immediate, delayed or unforeseen effects on human health or the environment."[32] It is important to note that the environmental risk assessment

29. E.g. Arts. 3(p), 95(3), 152(1), 153(1) and 174(2) EC.

30. E.g. Arts. 2(3), 4(1), 16(2) and 23(1) of Directive 2001/18.

31. E.g. Art. 13(2)(h) of Directive 2001/18. However, recital 4 of the preamble to the Directive explains: "Living organisms, whether released into the environment in large or small amounts for experimental purposes or as commercial products, may reproduce in the environment and cross national frontiers thereby affecting other Member States. The effects of such releases on the environment may be irreversible."

32. Ibid., recital 43 of the preamble.

must also take account "of potential long-term effects associated with the interaction with other organisms and the environment."[33] In addition, Annex II to the Directive 2001/18 clarifies that the analysis should examine "the cumulative long-term effects" relevant to the release and the placing on the market of the GMOs.

Therefore, the level of protection chosen in the Directive is a level of no risk, and this explains the obligation placed on the applicant manufacturer to demonstrate the safety of the GMO he wishes to place on the market. Because the regulatory decision is required to be based on the precautionary principle, and especially in light of the way this principle is interpreted and applied in the Community,[34] the burden is on the applicant manufacturer to demonstrate to the satisfaction of the competent authorities the "safety" or "lack of harm" of his product. As the Commission's communication on the precautionary principle has indicated, measures based on the precautionary principle may be adopted when there are "reasonable grounds for concern" or when there are "valid reasons to consider" that there may be a risk.[35] This corresponds to a standard of proof comparable to proof beyond reasonable doubt, set in most Community legislation in the broad area of pre-marketing approval of substances or processes. The candidate products, substances, or processes are deemed to be dangerous unless and until the interested manufacturer carries out the necessary scientific work and demonstrates "adequately" or "sufficiently", i.e. not on the basis of balance of probabilities, the safety of his product, that is he satisfies the determined acceptable level of risk.[36] Because the risk assessment has to be conducted on a case-by-case

33. See Section A., Objectives, of Council Decision 2002/811/EC of 3 Oct. 2002 establishing guidance notes supplementing Annex VII to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, O.J. 2002, L 280/27.

34. See European Commission, Communication on the Precautionary Principle, COM(2000)1 final, 2 Feb. 2000; and European Council, Resolution on the Precautionary Principle, Annex III to Nice European Council Meeting, 7, 8 and 9 Dec. 2000, Presidency Conclusions, available at ue.eu.int/en/Info/eurocouncil/index.htm.

35. See Commission Communication *supra* note 34. See also Christoforou, "The origins, content and role of the precautionary principle in European Community law", in Leben and Verhoeven (Eds.), *Le principe de précaution – Aspects de Droit International et Communautaire* (Ed. Panthéon Assas, L.G.D.J. Diffuseur, Paris, 2002), pp. 205–230.

36. See also, by analogy from another area of Community law, Art. 11 of Council Regulation (EEC) No 2309/93, of 22 July 1993, laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products, O.J. 1993, L 214/1. Moreover, the granting of an authorization does not diminish the general civil and criminal liability of the manufacturer or, where applicable, the person responsible for the placing of the product on the market. See e.g. Art. 14 of Regulation 2309/93, *supra*.

basis, the applicant manufacturer has to demonstrate safety for each individual product, not a class of products.

As already explained, in addition to traceability and monitoring requirements, the Directive imposes a clear labelling requirement for the purpose of informing the consumers. This can serve a dual objective, depending on whether a specific implementing measure, taken for a particular GMO, intends either to enable them to exercise their freedom of choice in the marketplace or to warn them directly of the presence of the GMOs for the purpose of avoiding potential adverse effects (e.g. allergenic effects). As this labelling requirement has to be examined and decided on a case-by-case basis, it follows that it may also contribute to achieving the chosen level of health or environmental protection, as this has been defined above, where a risk has been identified in a risk assessment and the labelling is directly linked to it. The identification of risk is normally obtained by conducting a risk assessment. A formal risk assessment, however, is not always necessary nor does it have to express risk in quantitative terms, as a qualitative expression of risk is also acceptable.[37]

2.3. *Novel foods and novel food ingredients – Regulation (EC) 258/97*

2.3.1. *General*

Regulation No 258/97 on novel foods and food ingredients was until very recently another important piece of Community legislation. But Article 38 of Regulation 1829/2003 on GM food and feed has now modified and substantially reduced its scope. Nevertheless, Regulation 258/97 is discussed here in some detail because several applications to authorize the placing on the market of novel foods and novel food ingredients have been made whilst it was in force and because its scope and implementation have given rise to disputes within the Community and between the Community and third countries.

2.3.2. *Object and scope of the Regulation*

Regulation 258/97 entered into force on 15 May 1997. Its adoption required many years of preparation and discussion in the Council and Parliament, as the first Commission proposal dates from July 1992. The Regulation applies to the placing on the Community market of novel foods and food ingredients which have not hitherto been used for human consumption to a "significant degree", hence the use of the adjective "novel".[38] However, what is a "sig-

37. See e.g. Case T-13/99, *Pfizer*, *supra* note 28, paras. 160–165.

38. The terms "foods" and "food ingredients" are not defined in this Regulation but in Art. 2 of Regulation 178/2002 as regards food (O.J. 2002, L 31/1), and in Directive 2000/13 as regards food ingredients (O.J. 2000, L 109/29).

nificant" degree of consumption of such a food or food ingredient is not defined.

Article 1(2) lays down six categories of novel foods and food ingredients that fall within the scope of the Regulation, i.e. those that: (a) contain or consist of GMOs as defined in Directive 2001/18; (b) are produced from but do not contain GMOs; (c) have a new or intentionally modified primary molecular structure; (d) consist of or are isolated from micro-organisms, fungi or algae; (e) consist of or are isolated from plants and from animals, except those obtained by traditional propagating or breeding and which have a history of safe food use;[39] and (f) those to which has been applied a production process not currently used, when this gives rise to significant changes in the composition or structure affecting their nutritional value, metabolism or level of undesirable substances. But categories (a) and (b) above have now been removed from the scope of Regulation 258/97 by Regulation 1829/2003 on GM food and feed.[40] Of importance is also the fact that Article 2 of Regulation 258/97 excludes from its scope three categories of products covered by other specific Community legislation, that is: food additives,[41] flavourings,[42] and extraction solvents,[43] provided that the safety level under the specific legislation "corresponds to the safety level" of this Regulation.[44]

39. It should be noted that Section X of Part II of the Commission's Recommendation 97/618/EC states *inter alia* that: "Documentation on previous use of the novel food source in the Community or the novel food source and/or the novel food in other parts of the world is important to establish a baseline for assessment. However, history of food use outside the Community is not of itself a guarantee that the novel food can be safely consumed in the Community." See Commission Recommendation 97/618/EC of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97 of the European Parliament and of the Council, O.J. 1997, L 253/1–36. For a useful discussion of the terms "a history of safe food use" see in particular Sheridan, *EU Biotechnology law and Practice – Regulating Genetically Modified and Novel Food Products* (Palladian Law Publishing, 2001) pp. 125–128.

40. However, according to Art. 1(2) of Regulation 258/97, new novel foods or food ingredients may, where necessary, be added in the future to the scope of Regulation 258/97.

41. Council Directive 89/107/EEC of 21 Dec. 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption, O.J. 1989, L 40/27, as last amended by Directive 94/34/EC, O.J. 1994, L 237/1.

42. Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production, O.J. 1988, L 184/61, as last amended by Directive 91/71/EEC, O.J. 1991, L 42/25.

43. Council Directive 88/344/EEC of 13 June 1988 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients, O.J. 1988, L 157/28, as last amended by Directive 92/115/EEC, O.J. 1992, L 409/31.

44. According to Art. 2(3), the Commission is charged with the task of ensuring the correspondence as to the level of safety between the provisions of the different acts.

It is also important to note that, by virtue of Council Directives 2002/53/EC[45] and 2002/55/EC,[46] certain *plant varieties* are accepted on the common catalogue of varieties of agricultural products or for the production or marketing of *vegetable seed* within the Community, only if the food or food ingredient derived from them meet the risk assessment requirements and have already been authorized pursuant to Regulation 258/97.

Recitals 1 and 2 of the preamble to the Regulation clarify that it has two broad objectives: first, to harmonize the national laws in this area that hinder free movement of goods in the Community and, second, to protect public health. Thus, Article 3(1) provides that food and food ingredients "must not present a danger for the consumer", and Article 3(2) requires that any placing on the market should be done in conformity with the procedures and the criteria laid down in the Regulation. The Regulation has, however, two more specific objectives: to avoid misleading, and not to nutritionally disadvantage the consumers.[47] The means employed to achieve these two specific objectives are: first, a single safety assessment and harmonization of the authorization or notification procedure at Community level before placing products on the market and, second, by imposing appropriate labelling requirements.

2.3.3. *Authorization procedure*

The Regulation establishes a dual system for the placing of novel foods and novel food ingredients on the Community market: by *application* to obtain an authorization or by a simple *notification* by the interested party.

45. Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species, O.J. 2002, L 193/1. Arts. 4(5) and 7(5)(a) of this Directive provide that genetically modified plant varieties falling within its scope (i.e. beet, fodder plant, cereal, potato and oil and fibre plant) will not be accepted in the common catalogue unless the food or food ingredient derived from them meets the safety assessment requirements and has already been authorized pursuant to Regulation 258/97. According to Art. 16 of the Directive, seed varieties accepted in accordance with the provisions of this Directive would not be subject to any marketing restrictions in the Community.

46. Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed, O.J. 2002, L 193/33. This Directive applies to the production (with a view to marketing) and to the marketing of vegetable seed within the Community. According to Arts. 4(3) and 7(5) of the Directive, the Member States should not officially accept for certification, verification as standard seed and for marketing genetically modified varieties, unless the food or food ingredient derived from them meets the safety assessment requirements and has already been authorized pursuant to Regulation 258/97. According to Art. 16 of the Directive, seed varieties accepted in accordance with the provisions of this Directive would not be subject to any marketing restrictions in the Community.

47. The meaning of the terms "nutritionally disadvantageous" for the consumers is not defined in the Regulation, but presumably it means something other than dangerous or misleading for the consumer.

The authorization procedure follows a structure similar to the one described above for Directive 2001/18. The applicant, i.e. the person responsible for placing the novel food or food ingredient on the Community market, must submit a request to the competent authority of the Member State in which the product is to be placed on the market for the first time, and forward a copy of it to the Commission. Article 4(2) and (4) and Article 6 of the Regulation lay down the information and data that the applicant has to submit to the competent authority with its request.[48]

The Member State where the application is submitted either carries out the initial assessment itself or requests the Commission to arrange for another Member State to carry it out.[49] The Member State where the initial request was made informs the applicant that he may place the product on the market where no assessment additional to the initial one is required and no reasoned objection by any Member State or the Commission has been presented with regard to its application.[50] If the initial assessment report indicates that an assessment additional to the initial one is required or that a reasoned objection has been raise by a Member State or the Commission, the authorization decision shall be taken at Community level by comitology procedure in accordance with Article 13 of the Regulation.[51] The authorization decision must indicate, as appropriate, the conditions of use, the designation of the product and any specific labelling requirements.

Article 11 of the Regulation, as modified by Article 62(1) of Regulation 178/2002, provides that the European Food Safety Authority (hereinafter EFSA) shall be consulted for "any matter falling within the scope of this Regulation likely to have an effect on public health", including presumably any comment or reasoned objection that relates to public health made by a Member State or the Commission in accordance with this Regulation. Conversely, for any comment or objection that does not relate to public health, but to issues such as the presentation or the labelling of the food or food ingredient or to ethical considerations,[52] the EFSA is not consulted. Such comments or objections are reported directly to the Standing Committee on the

48. Pursuant to Art. 4(4) of the Regulation the Commission has, by Recommendation 97/618/EC of 29 July 1997, laid down the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports, O.J. 1997, L 253/1.

49. Art. 6(2) of Regulation 258/97.

50. Ibid., Art. 4(2).

51. Ibid., Arts. 6(3) and (4), 7 and 13, respectively.

52. Ibid., Arts. 6(4) and 8(1)(c).

Food Chain and Animal Health and decided in accordance with the applicable comitology procedure.

Regulation 258/97 has two specific regulatory features: the concept of substantial equivalence and the specific labelling requirements. They are examined briefly below, as they are crucial in the evaluation of the Regulation and its interaction with the other relevant provisions of Community law and, in particular, of the WTO Agreements.[53]

2.3.4. *Substantial equivalence*

According to Article 3(4) of Regulation 258/97, a novel food or food ingredient that is substantially equivalent to an existing (conventional) counterpart can be placed on the market without having to follow the full evaluation and authorization procedures of the Regulation, as these have been described above. The product may be put on the market by the applicant simply *notifying* the Commission of his decision to do so, provided of course that the other conditions of the Regulation are fulfilled.[54]

It is not Regulation 258/97 itself but the Commission's Recommendation 97/618 that attempts to clarify the content and the important regulatory implications flowing from the use of the concept of substantial equivalence. In essence, it means that if a novel food or food component is found to be (in part or as a whole) substantially equivalent to an existing food or food component, it can be treated in the same manner as the existing (conventional) food with respect to safety, keeping in mind that establishment of substantial equivalence is not a safety or nutritional assessment in itself, but an approach to compare a potential new food with its conventional counterpart. The Regulation uses, therefore, the concept of substantial equivalence as a short cut to a full authorization procedure for certain types of novel foods or food ingredients without requiring a standard safety assessment.[55]

Substantial equivalence is decided either on the basis of "scientific evidence available and generally recognized" or on the basis of an opinion delivered by one of the food assessment bodies of the Member State respon-

53. It is important in relation to the concepts of "like products" and the use of the so-called "process and production method" in the regulation of products in international trade law.

54. Art. 5 of Regulation 258/97. The Commission is simply required to forward within 60 days to the Member States a copy of the notification, and upon request, further details. There is no time limit within which objections, if any, may be raised by the Commission or the Member States. It should be noted that 13 of the novel food products approved so far under Regulation 258/97 concern processed foods and have all been notified as substantially equivalent. See Commission, Questions and Answers, *supra* note 10.

55. See paras. 129 and 137 of the judgment in Case C-236/01, *Monsanto Agricoltura Italia SpA and others* v. *Presidenza del consiglio dei ministri and others (Monsanto)*, reference for a preliminary ruling from the Tribunale Amministrativo Regionale del Lazio, 9 Sept. 2003, nyr.

sible for preparing the initial assessment report referred to in Article 6(2) of the Regulation. According to Article 3(4),[56] substantial equivalence for the purpose of marketing a novel product is decided by reference to the composition, nutritional value, metabolism, intended use and the level of undesirable substances contained in the novel food or food ingredients in question. However, as A.G. Alber has pointed out in his Opinion in the *Monsanto* case,[57] the above criteria, relating essentially to nutritional physiology of the products, are not in themselves adequate in demonstrating equivalence in terms of no risk to human health. In addition, there is considerable leeway in the interpretation of this concept and of the other concepts on which it is based, such as "generally recognized" scientific evidence.[58] This has led to a considerable amount of criticism being levied against it; it was viewed to be inherently anti-scientific because it was thought to provide an excuse for not requiring, *inter alia*, complete toxicological tests.[59] A.G. Alber has also pointed out in his Opinion in *Monsanto* that, on the basis of the existing provisions, it is very difficult in practice to determine with certainty whether substantial equivalence really exists, when the novel food or food ingredient still contains traces of transgenic protein, unless it is shown in a properly conducted risk assessment that the level of transgenic proteins remaining in the novel food or ingredient poses no risk to human health.[60] A distinction is to be made, therefore, between the elements on the basis of which substantial

56. As modified by Art. 38(2) of Regulation 1829/2003 on GM food and feed.

57. See paras. 63–73 of the Opinion of A.G. Alber, of 13 March 2003, in *Monsanto*, *supra* note 55.

58. The first report of the OECD, where the concept of substantial equivalence was – at the request of the USA – initially developed, determines equivalence on the basis of other equally broad concepts, such as "reasonable certainty of no harm" from the newly introduced traits into the novel food, compared to its conventional counterpart. See OECD, *Safety Evaluation of Foods Derived by Modern Biotechnology* (Paris, 1993). For the policy applicable at that time in the USA, see US Food and Drug Administration, *Statement of policy: foods derived from new plant varieties*, Vol. 57, No. 104, Federal Register 22984 (29 May 1992). The OECD considered again certain aspects of the concept of substantial equivalence in 1999 and in 2000 in an attempt to clarify them further: see OECD, *The concept of substantial equivalence in the safety assessment of novel foods,* Food Industry Environmental Network (FIEN), 7 Oct. 1999; and OECD, Task Force for the Safety of Novel Foods and Feeds, C(2000)86/Add.1, 17 May 2000. In the system of Regulation 258/97, any difference or divergence in respect of the applicable criteria are to be resolved by having recourse, when necessary, to the comitology procedure laid down in Art. 13 thereof.

59. See e.g. Millstone, Brunner and Mayer, "Beyond 'substantial equivalence'", 401 *Nature* (1999), 525, and, by the same authors, "Seeking clarity in the debate over the safety of GM foods", 402 *Nature* (1999), 575. See also the Opinion expressed on 26/27 Oct. 2000 by the EC Scientific Steering Committee, Risk assessment in a rapidly evolving field: the case of genetically modified plants, available at europa.eu.int/comm/food/fs/sc/ssc/out148_en.pdf.

60. See paras. 72–73 of the Opinion in *Monsanto*, *supra* note 55.

equivalence is to be determined and the actual safety assessment of the novel food or food ingredient in a specific case, before substantial equivalence can be found to exist.[61] The Court of Justice accepted in *Monsanto*, like A.G. Alber, that the mere presence in novel foods of residues of transgenic protein at certain levels does not preclude those foods from being considered substantially equivalent to existing foods and, consequently, it considered that it is allowed to use the simplified procedure for the purpose of placing those novel foods on the market.[62] This decision means that certain differences, *inter alia* as regards the composition of novel foods, do not necessarily prevent those foods from being deemed substantially equivalent, in accordance with the first subparagraph of Article 3(4) of Regulation No 258/97, given that Article 8 of this Regulation provides that such differences must be specifically mentioned in the labelling.[63] However, the Court made it quite clear that, since the protection of public health is a fundamental objective of Regulation No 258/97, the concept of substantial equivalence cannot be interpreted in such a way that the simplified procedure, which according to the wording of the first subparagraph of Article 3(4) of the Regulation is in the nature of a derogation, amounts to a relaxation of the safety requirements which must be met by novel foods.[64] This signifies that it is not possible to use the simplified procedure in a case where the existence of a risk of potentially dangerous effects on human health can be identified on the basis of the scientific knowledge available at the time of the initial assessment. The Court also found that the precautionary principle should be taken into account.[65]

The Court's decision in the *Monsanto* case also requires that the identification of a risk should normally be carried out "by specialized scientific bodies charged with assessing the risks inherent in novel foods".[66] It is also significant to note that the Court ruled that unpredictable effects on human health which the insertion of foreign genes may produce, if such effects were identifiable as a danger to human health according to available scientific evidence at the time of the initial examination by the competent body, would have to be subjected to a risk assessment, and a finding of substantial equivalence would therefore be excluded.[67] The crucial question, therefore,

61. See e.g. Codex Alimentarius Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology, ALINORM 03/34A, Yokohama, Japan, 11–14 March 2003, paras. 10–25.
62. See *Monsanto*, *supra* note 55, at para 84.
63. Ibid., at para 83.
64. Ibid., at para 80.
65. Ibid., at para 133.
66. Ibid., at paras. 78–79 and 84.
67. Ibid., at para 81.

is to decide whether the "available scientific evidence" at the time of the initial evaluation by the national risk assessment authority indicates possible adverse effects. The judgment of the Court on this point appears to be open to a broad interpretation, as any available scientific evidence – and not only that generated for the initial risk assessment – may be relied on for such a finding.[68] On the other hand, there are no very precise and agreed guidelines on the choice of the comparator conventional product or on the components and other critical nutrients and toxicants to be used in the assessment.[69] This appears to leave considerable leeway to the applicant company and the regulatory authorities in the assessment of equivalence,[70] and this, together with the limited nature of the initial safety assessment, may hamper acceptance of a finding of substantial equivalence by the other Member States.[71]

It should be noted, however, that from the regulatory point of view the above uncertainty in the finding of substantial equivalence has now been considerably reduced in the area of GM food and feed by Article 38(2) of Regulation 1829/2003, which amended Article 3(4) of Regulation 258/97 and confined the application of the concept of substantial equivalence to only two categories of novel food or food ingredients, that is: (a) those consisting of or isolated from micro-organisms, fungi or algae;[72] and (b) those consisting of or isolated from plants and food ingredients isolated from animals.[73] Furthermore, the possible use of the concept of substantial equivalence as a regulatory tool in the area of GM novel foods has been further reduced by the deletion of Article 9 of the Regulation,[74] so that now the full

68. This is particularly the case when national safeguard measures are adopted on the basis of Art. 12 of the Regulation, since in such a case there is only a requirement to carry out as full a risk assessment as possible to the circumstances of the case in question and to adopt a safeguard measure if the available evidence makes it possible reasonably to conclude that it may pose potential risks to human health. See the judgment in *Monsanto*, *supra* note 55, paras. 112–113.

69. See e.g. Noordam, Kok and Kuiper, *Novel Foods and Feed – Regulatory Aspects* (The Hague, Ministry for Economic Affairs, 1998), pp. 21–36, available at www.ez.nl/publicaties/pdfs/24R86.pdf. See also the report by Schenkelaars Biotechnology Consultancy, *GM Food Crops and Application of Substantial Equivalence in the European Union*, commissioned for the Dutch Foundation "Consument & Biotechnologie", The Netherlands, June 2001, available at www.sbcbiotech.nl.

70. See e.g. Millstone et al., op. cit., *supra* note 59, p. 525.

71. See e.g. *Monsanto*, *supra* note 55, para 109, and the report by Schenkelaars op. cit. *supra* note 69.

72. Referred to in Art. 1(2)(d) of the Regulation.

73. Ibid., Art. 1(2)(e).

74. Thus, recital 6 of the preamble to Regulation 1829/2003 on GM food and feed explained that "[w]hilst substantial equivalence is a key step in the procedure for assessment of the safety of genetically modified foods, it is not a safety assessment in itself. In order to ensure clarity, transparency and a harmonized framework for authorization of genetically modified

risk assessment requirements of Directive 2001/18 will be applicable.[75]

2.3.5. *Labelling*

According to Article 6(1) of the Regulation, an application for authorization must contain an appropriate proposal for the presentation and labelling of the novel food or food ingredient. Article 8 of the Regulation imposes, in addition to requirements from other Community legislation concerning labelling of foodstuffs,[76] specific labelling requirements "in order to ensure that the final consumer is informed" of the characteristics or food property that render a novel food or food ingredient "no longer equivalent" to an existing food or food ingredient, such as: the composition, nutritional value or nutritional effects and intended use of food. Consequently, when a novel food or food ingredient is found to be "no longer equivalent",[77] the labelling must indicate "the characteristics or properties modified, together with the method by which that characteristic or property was obtained." It should be noted

food, this notification procedure should be abandoned in respect of genetically modified foods." For the most recent scientific developments on the diminished relevance of this concept in Community law now, see also European Commission, Guidance Document for the Risk Assessment of Genetically Modified Plants and Derived Food and Feed, 6–7 March 2003, prepared for the Scientific Steering Committee by The Joint Working Group on Novel Foods and GMOs, Composed of Members of the Scientific Committees on Plants, Food and Animal Nutrition, available at europa.eu.int/comm/food/fs/sc/ssc/out327_en.pdf.

75. Art. 9 of the Regulation is deleted by virtue of Art. 38(1) of Regulation 1829/2003 on GM food and feed, and the risk assessment and labelling requirements for novel foods and food ingredients containing or consisting of a GMO is now regulated by the updated and stricter requirements of Regulation 1829/2003 and of Directive 2001/18.

76. See Directive 2000/13 of the European Parliament and of the Council of 20 May 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, O.J. 2000, L 109/29.

77. For the purpose of labelling, novel food or food ingredient shall be deemed, pursuant to Art. 8 of Regulation 258/97, to be no longer equivalent "if scientific assessment, based upon an appropriate analysis of existing data, can demonstrate that the characteristics assessed are different in comparison with a conventional food or food ingredient, having regard to the accepted limits of natural variations for such characteristics." It should be noted that it is not only the process or production method used, but also the modified *characteristics* of the novel food that are used in determining substantial equivalence. Thus, Commission Regulation (EC) 50/2000, of 10 Jan. 2000, on the labelling of foodstuffs and food ingredients containing additives and flavourings that have been genetically modified or have been produced from genetically modified organisms, O.J. 2000, L 6/15, clarified in Art. 3, with respect to specified additives and flavourings, that where scientific assessment based on appropriate analysis of existing data demonstrates the *presence* of "protein and/or DNA resulting from genetic modification" they will be considered to be "no longer equivalent". Regulation 50/2000 applied to additives and flavourings that "are, contain or are produced from" GMOs within the meaning of Directive 2001/18. However, Regulation 50/2000 has now been repealed by Art. 37 of Regulation 1829/2003 on GM food and feed.

that the modified characteristics or properties of the novel food as well as the process or production method used to obtain them, which must also be indicated on the label, play a central role in determining substantial equivalence.[78]

Specific labelling is also required in two additional instances. First, when the novel food contains material which is not present in an existing equivalent foodstuff and which "may have implications for the health of certain sections of the population." Second, when the presence of such material "gives rise to ethical concerns". These specific labelling obligations apply to all novel foods and food ingredients, whether subject to the authorization or notification procedure, when they are found to be substantially equivalent.

Therefore, the specific labelling requirements of Regulation 258/97 play a dual role. First, to inform the consumer about *the presence* in the novel foods or food ingredients of certain characteristics or properties, such as the presence of protein and/or DNA resulting form genetic modification, that may be important for the consumer to know or may have ethical concerns. Second, to warn the consumers directly about possible health implications (e.g. allergenicity).[79]

2.3.6. *Appropriate level of protection*

Like Directive 2001/18, it is evident from a combined reading of several provisions of Regulation 258/97 that it pursues a level of protection of no health

78. Another piece of sector specific legislation was Council Regulation 1139/98, which imposed compulsory indication of labelling for genetically modified soya beans and maize, as modified by Commission Regulation 49/2000, which had explicitly *excluded* from the requirement to provide specific labelling with regard to foodstuffs in which "*neither* protein *nor* DNA resulting from genetic modification *is* present". See Art. 2(2) of Council Regulation (EC) No 1139/98 of 26 May 1998 concerning the compulsory indication of the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC, O.J. 1998, L 159/4. It should also be noted that recital 9 of the preamble to Regulation 49/2000 clarified that "1% value should be the tolerance level not only for the adventitious presence of material derived from the above-mentioned genetically modified organisms, but for the combined adventitious presence of such material and any other material placed on the market pursuant to Regulation (EC) No 258/97 derived from other genetically modified organisms." See Commission Regulation (EC) No 49/2000 of 10 Jan. 2000 amending Council Regulation (EC) No 1139/98 concerning the compulsory indication on the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC, O.J. 2000, L 6/13. However, both Regulation 1139/98 and Regulation 49/2000 have now been repealed by Art. 37 of Regulation 1829/2003 on GM food and feed.

79. These findings are of great importance for the analysis of the Regulation under the WTO Agreements, as an informed judgment about its compatibility with the WTO system would require an evaluation of the specific implementing decisions on a case-by-case basis.

risk. Regulation 258/97 also pursues a "no risk of misleading the consumer" policy, subject of course to the tolerance levels for adventitious or technically unavoidable presence to be explained below.[80] As the Court of Justice held in the *Monsanto* case, the objectives pursued by the Regulation should enable the Member States "to avoid novel foods which pose potential risks to human health being offered on the market", and the level of protection implied is that only products that are "without any danger for the consumer" should be authorized.[81] The safety of the novel food and food ingredients must be established by the applicant.[82] He must also provide additional specific labelling to ensure that consumers are "adequately" informed.[83]

2.4. *GM food and feed – Regulation (EC) 1829/2003*

2.4.1. *General*

Regulation 1829/2003 is the other central piece of Community legislation in the GMOs area. Unlike Directive 2001/18, however, the adoption of Regulation 1829/2003 took in total just about two years,[84] a remarkable achievement considering the scope and importance of its regulatory content.

2.4.2. *Object and scope*

Regulation 1829/2003 has two broad objectives. First, to ensure a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed. Second, to ensure the effective functioning of the internal market. To achieve these objectives the Regulation provides for: (a) Community procedures for the authorization and supervision of genetically modified food and feed; and (b) specific provisions for the labelling of genetically modified food and feed.

The scope of the Regulation is also quite broad. Recital 11 of the preamble to the Regulation and Articles 3 and 4(4) explain the scope of the Regulation. An authorization under the Regulation may be granted either to a GMO to be used as a source material for production of food or feed and in products for food and/or feed use which contain, consist of or are produced from it, or to foods or feed produced from a GMO. Thus, where a GMO used

80. See Arts. 3(1) and 12 of Regulation 258/97.
81. See *Monsanto*, *supra* note 55, paras. 113 and 133.
82. Recital 8 of the preamble to and Art. 6(1) of Regulation 258/97.
83. Ibid., Art. 8.
84. The initial Commission proposal was submitted to the Council on 30 July 2001. See O.J. 2001, C 304 E/221.

in the production of food and/or feed has been authorized under this Regulation, foods and/or feed containing, consisting of or produced from that GMO will not need an authorization under this Regulation, but will be subject to the requirements referred to in the authorization granted in respect of the GMO in question. Furthermore, foods covered by an authorization granted under this Regulation will be exempted from the requirements of Regulation 258/97 concerning novel foods and novel food ingredients.[85] In addition, recital 16 of the preamble to the Regulation explains that it covers food and feed produced "*from*" a GMO but not food and feed produced "*with*" a GMO. The determining criterion is whether material derived from the genetically modified source is present in the food or feed.[86]

The scope of the Regulation also extends to certain other food and feed products, i.e. additives, flavourings, animal nutrition and additives in feedingstuffs, for the purpose of safety assessment.[87]

2.4.3. *Authorization procedure*

The Regulation establishes an advance system of prior notification and approval procedure that is the same for GM food and feed. Whilst the application to obtain the authorization is submitted to the national competent au-

85. Except where they fall under one or more of the categories referred to in Art. 1(2)(a) of Regulation 258/97 in respect of a characteristic which has not been considered for the purpose of the authorization granted under Regulation 1829/2003.

86. Thus, *processing aids* which are only used during the food or feed production process are not covered by the definition of food or feed and, therefore, are not included in the scope of this Regulation. Equally, excluded from the scope of the Regulation are food and feed that are manufactured with the help of a genetically modified *processing aid*. Thus, products obtained from animals fed with genetically modified feed or treated with genetically modified medicinal products will not be subject either to the authorization requirements or to the labelling requirements referred to in the Regulation.

87. Thus, recitals 12–15 of the preamble to Regulation 1829/2003 explain that food *additives* authorized under Directive 89/107/EEC (O.J. 1989, L 40/27, as amended by Directive 94/34/EC of the European Parliament and of the Council, O.J. 1994, L 237/1) fall under Regulation 1829/2003 if they contain, consist of or produced from GMOs. Equally, *flavourings* for use in foodstuffs and to source materials falling under Directive 88/388/EEC (O.J. 1988, L 184/61, as amended by Commission Directive 91/71/EEC, O.J. 1991, L 42/25.) which contain, consist of or are produced from GMOs should also fall within the scope of Regulation 1829/2003 for the safety assessment of the genetic modification. In addition, feed materials used in *animal nutrition* under Directive 82/471/EEC (O.J. 1982, L 213/8, as last amended by Directive 1999/20/EC, O.J. 1999, L 80/20.) fall within the scope of Regulation 1829/2003 when they contain, consist of or are produced from GMOs using different technologies that may pose risk to human or animal health and the environment. Finally, *additives* in feedingstuffs to which applies the authorization procedure laid down in Directive 70/524/EEC (O.J. 1970, L 270/1, as last amended by Regulation (EC) No 1756/2002, O.J. 2002, L 265/1), also fall within the scope of Regulation 1829/2003 when they contain, consist of or are produced from GMOs.

thority of a Member State, at the end the authorization as such is granted by the Commission and it is valid for ten (renewable) years throughout the Community.[88] Thus, the Regulation lays down clear rules for the assessment and authorization of GMOs and GM food but responsibilities are shared between Member States and the Community. The Regulation establishes a "one door – one key" procedure for the scientific assessment and authorization of GMOs and GM food and feed resulting in a centralized, clear and transparent Community procedure, where an operator is able to file a single application. Therefore, compared to the authorization procedure of Directive 2001/18 and of Regulation 258/97, the procedure under this Regulation is far more streamlined and less cumbersome than before for the applicants.

Articles 5 for food and 17 for feed of Regulation 1829/2003 lay down the information, data and other particulars that the applicant has to submit in order to obtain the authorization.[89] The data should demonstrate that the food or feed does not have adverse effects on human health or animal health or the environment, does not mislead the consumer and does not differ from the food which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer.[90] The applicant must also provide *inter alia* the following: a designation of the food or feed and its specification, including the transformation event(s) used,[91] a detailed description of the method of production and manufacturing of the product, a proposal for labelling or evidence that the characteristics of the food or feed are not different from those of its conventional counterparts, a reasoned statement that the food or feed does not give rise to ethical or religious concerns, methods for detection, sampling and identification of the

88. Arts. 5(2) and 7(5) for food and Arts. 17(2) and 19(5) for feed of Regulation 1829/2003.

89. Where a product is likely to be used as both food and feed, a single application should be submitted and this should give rise to a single risk assessment and to a single Commission authorization decision. See Art. 27 of Regulation 1829/2003.

90. Ibid., Art. 5(3)(e) and Art. 17(3)(e).

91. The term "transformation event" denotes the event where a conventional organism is "transformed", through the introduction of modified DNA sequences, resulting in the formation of a GMO. It is the introduction of the sequences that ultimately determine the modified characteristics of the GMO, including the likes of insect resistance and herbicide tolerance. In this connection, it should also be explained that the term "unique identifier" is the code of a fixed length of nine alphanumeric digits that is used to indicate the specific transformation event derived from modern biotechnology. It should be unique to that transformation event. See OECD, Guidance for the designation of a unique identifier for transgenic plants, Series on Harmonization of Regulatory Oversight in Biotechnology, No. 23, ENV/JM/MONO(2002)7, 22.02.2002. See now also Commission Regulation (EC) No. 65/2004, of 14 Jan. 2004, establishing a system for the development and assignment of unique identifiers for genetically modified organisms, O.J. 2004, L 10/5.

transformation event (including, when applicable, food or feed produced *from* the GMO food or feed).[92]

The assessment of the application – including where necessary a risk assessment – is carried out by the EFSA, if possible within six months, but it *may* ask the food assessment body of a Member State to carry out the safety assessment or the environmental risk assessment.[93] The EFSA submits its opinion to the Commission, the Member States and the applicant and renders it public, subject to observing the confidentiality requirements. The Commission should prepare, within three months of receiving the opinion of the EFSA, a draft decision to be taken under the relevant comitology procedure.[94] The Commission is entitled to "take into account" the opinion of the EFSA, any "other relevant provisions of Community law" and, most importantly, "other legitimate factors relevant to the matter under consideration."[95] Recital 32 of the preamble to Regulation 1829/2003 explains the significance of the phrase "other legitimate factors relevant to the matter under consideration" as follows: "It is recognized that, in some cases, scientific risk assessment alone cannot provide all the information on which a risk management decision should be based, and that other legitimate factors relevant to the matter under consideration may be taken into account." Other legitimate factors, therefore, are broader factors which, although not directly related to the toxicological properties of the products in question, are relevant in the risk assessment and risk management decision-making. In this regard, it should be noted that recital 19 to Regulation 178/2002 included as legitimate factors societal, economic, traditional, ethical and environmental factors and the feasibility of controls.

Of course, where the Commission's draft is not in accordance with the opinion of the EFSA, the Commission is required to provide "an explanation for the differences." Thus, it is clear that the risk assessment proposed in the opinion of the EFSA, to the extent it has direct risk management implications, is not as such binding on the Commission,[96] which is (with the Coun-

92. As already explained, Regulation 1829/2003, unlike Regulation 258/97, no longer uses the concept of substantial equivalence as a short cut for authorization purposes.

93. Ibid., Arts. 6(3)(b) and (c) and 18(3)(b) and (c). The safety assessment will be carried out in accordance with Art. 36 of Regulation 178/2002. The environmental risk assessment will be carried out pursuant to the relevant provisions of Directive 2001/18. However, when the application concerns GMOs to be used as *seeds* or other *plant-propagating material*, the EFSA *must* ask a national competent authority to carry out the environmental risk assessment.

94. See Arts. 5 and 7 of Decision 1999/468/EC. See also Arts. 7(3) and 19(3) of Regulation 1829/2003.

95. Ibid., Arts. 6(6) and 7(1) for food and Arts. 18(6) and 19(1) for feed.

96. The non-binding nature of the opinions of the scientific committees has been decided several times by the ECJ and CFI in other, comparable, areas of Community law. See e.g. Case C-120/97, *Upjohn*, [1999] ECR I-223, at para 47, and Case C-405/92, *Armand Mondiet*, [1993]

cil) the responsible risk management authority, within the constraints of the relevant comitology procedure.

An authorization may be modified, suspended or revoked, on the basis of a prior opinion of the EFSA, by a Commission decision in accordance with the applicable comitology procedure (regulatory committee).[97] Any safeguard measures concerning products already authorized that are "likely to constitute a serious risk to human health, animal health or the environment" shall be taken in accordance with the emergencies procedure laid down in Articles 53 and 54 of Regulation 178/2002.[98]

2.4.4. *Labelling*

The provisions on labelling are a very important component of Regulation 1829/2003 and have been the subject of considerable discussion in the Council and Parliament and with several trade partners of the Community. Labelling is required for foods that are delivered as such to the final consumer or mass caterers in the Community and which contain or consist of GMOs or are produced from or contain ingredients produced from GMOs.[99] The objective of labelling is triple: to inform consumers and livestock farmers in order to enable them make an informed choice, to warn certain sections of the population of possible health implications, and to identify the characteristics or property which may give rise to ethical or religious concerns.[100]

The labelling must be shown in a clearly visible, legible and indelible manner, and can be expressed in different ways, by the phrases "genetically modified", or "produced from genetically modified", or "contains geneti-

ECR I-6133, at paras. 31–32 and 36 (both judgments holding that the opinion of the scientific committee is not of mandatory but of advisory nature only); see also Case T-13/99, *Pfizer*, *supra* note 28, at paras. 196 and 201 (holding that the Commission is not obliged to follow the opinion of the scientific committee because its opinion is of advisory nature only, and that scientific legitimacy is not a sufficient basis for the exercise of public authority in the regulation of risk).

97. Arts. 10 and 22 of Regulation 1829/2003. As regards GM products currently authorized, Arts. 8 and 20 of the Regulation provide that they will remain eligible for marketing. Operators will, however, be obliged to provide detection methods to the Commission within 6 months of entry into force of the Regulation. Pursuant to Art. 32 and the Annex to the Regulation, the Joint Research Centre (JRC) of the Commission is established as the new Community Reference Laboratory, which will have the main task of validating detection methods. The JRC will continue to work with the "European Network of GMO laboratories". Moreover, existing GM products shall also be entered into the public register and the time limit of 10 years for the authorization from the day when the concerned product was first placed on the market equally applies to them.

98. Ibid., Art. 34.

99. Ibid., Art. 12(1). It also applies to feed, as defined in Art. 15(1) and in accordance with the provisions of Arts. 24–25 of Regulation 1829/2003.

100. See, in particular, recitals 20–22 of the preamble to the Regulation.

cally modified."[101] The labelling should give information about any characteristic or property which renders a food or feed different from its conventional counterpart with respect to composition, nutritional value or nutritional effects or the intended use of the food or feed, and of health implications for humans or animals.[102] Equally, labelling should mention any characteristic or property where the food or feed "may give rise to ethical or religious concerns."[103] It should be pointed out, however, that these specific labelling requirements are applied *irrespective* of the detectability of DNA or protein resulting from the genetic modification in the final product. In this respect, the labelling requirements of this Regulation go one significant step further than those of Regulation 258/97 on novel food and foods ingredients. The process or production method of the GM food or feed is now a relevant factor that can alone justify labelling, whether for the purpose of informing the consumers so as to enable them to exercise their choice in the market place, to warn them of any possible health effects or when it is associated with ethical or religious concerns.

However, no labelling is required for foods or feed that contain material in a proportion no higher than 0.9 per cent of the food ingredients individually (or of each feed) that it contains, provided of course that the responsible operator can demonstrate that the presence of such GM material is adventitious or technically unavoidable and on condition that he has taken the appropriate steps to avoid their presence.[104]

2.4.5. *Appropriate level of protection*

According to Article 1(a), the Regulation provides the basis for ensuring "a high level of protection of human life and health, animal health and welfare, environment and consumer interests" in relation to GM food and feed. The remaining provisions of the Regulation have, therefore, to be read in light of

101. Ibid., Art. 13(1) and 25(2).

102. Art. 6(3)(e) for food and Art. 18(3)(d) for feed of Regulation 1829/2003 require of the EFSA to verify the information and data submitted by the applicant to show that the characteristics of the food or feed "are not different from those of its conventional counterparts", having regard to the accepted limits of natural variations for such characteristics. According to Arts. 5(3)(f) and 13(2)(a) for food and 17(3)(f) and 25(2)(c) for feed, if the food or feed is found to be different with regard to composition, nutritional value or effects, intended use and implications for the health of certain sections of the population or for the health for certain species or categories of animals, then the labelling must mention any such different characteristic or property. In any case, however, according to Arts. 13(3) for food and 25(3) for feed, where such GM products have no conventional counterpart, the labelling must contain appropriate information about the "nature and the characteristics" of the foods or feed concerned.

103. Ibid., Art. 13(2)(b) and 25(2)(d) for food and feed, respectively.

104. Ibid., Art. 12(2) and (3) for food and Art. 24(2) and (3) for feed.

the above overall objectives. In addition, pursuant to Article 1, they have to be interpreted "in accordance" with the general principles laid down in Regulation 178/2002 on food law, amongst which is the precautionary principle.[105]

Thus, when granting an authorization, Articles 4(1) for food and 16(1) for feed clarify how high is to be placed the level of protection which the Regulation aims to achieve: the GM food and feed "must not have adverse effects" on human health, animal health or the environment. The EFSA, when conducting the risk assessment, must apply the environmental safety requirements of Directive 2001/18 in order to ensure that, in the case of GMOs or food containing or consisting of GMOs, "all appropriate measures are taken *to prevent*" the adverse effects on human and animal health and the environment "which *might* arise" from the deliberate release of GMOs.[106] Therefore, it follows from a combined reading of these provisions and the terminology used that there is *no level of risk* that is tolerable in the authorization procedure.[107] Consequently, the level of protection set in the Regulation is set as high as it can be, that is *no risk*, when a risk has of course been identified in the risk assessment.[108]

The inevitable consequence of this no risk standard in the authorization procedure is that emergency (safeguard) measures by the Member States or the Commission can be taken only when "*it is evident*" that the authorized products "are *likely* to constitute a *serious* risk" to human health, animal health or the environment.[109]

105. The general principles of food law are set out in Arts. 5 to 10 of Regulation 178/2002.

106. Ibid., Arts. 6(4) and 18(4).

107. The preparatory history also supports this interpretation. The Commission's initial proposal stated in the relevant part of Art. 4(1)(a) that food "must not present a risk for human health or the environment". The first common position adopted by the Council on 17 March 2003 modified the text of Art. 4(1)(a) to say "must not present an *unacceptable* risk for human health or the environment". See O.J. 2003, C 113 E/31. The introduction of the word "unacceptable", however, was not agreeable to the European Parliament and to a number of Member States, because it implied a certain degree of tolerance for certain kind of risks, in terms of either the magnitude and/or nature of the possible adverse effect. Consequently, the word unacceptable was removed from the text as finally adopted. It should also be noted that since "risk" is a function of the probability of an adverse effect and the severity of that effect, the risk must normally be an *identified* one in a risk assessment. It cannot be a mere hypothetical or totally unknown risk.

108. Significantly, the Regulation also provides that obtaining an authorization does *not lessen* the general civil and criminal liability of any food or feed operator in respect of the food or feed concerned. See Arts. 7(7) and 19(7) of Regulation 1829/2003.

109. Ibid., Art. 34. Notable here is the use of the adjective "*serious*" risk, which does not appear in the section of the Regulation concerning the authorization phase. Since the emergency measures are posterior to authorization and must be adopted under the provisions of

Article 47 of the Regulation lays down also a transitional (for 3 years) measure for the adventitious or technically unavoidable presence of GM material in food or feed which is not higher than 0.5 per cent, but which has benefited from a favourable risk evaluation.[110] Thus, this tolerance (threshold) level applies in food or feed, which contain, consist of or are produced from GMOs, provided the operators are in a position to demonstrate that they have taken the appropriate steps to avoid the presence of such GM materials in the food or feed. Since this transitional tolerance level is limited to GMOs that have already received a favourable risk evaluation, it does not affect the no-risk level of protection as explained above.[111] It is an expression of the principle of reasonableness and its introduction was only meant to facilitate the co-existence of various kinds of agricultural crops and intra-Community and international trade in such products.[112]

Arts. 53 and 54 of Regulation 178/2002, interim protective measures can be adopted provisionally by the Commission or a Member State subject to their extension, amendment or abrogation by subsequent decision at Community level, in accordance with the applicable comitology procedure.

110. Importantly, this covers only favourable risk assessment opinions issued from the relevant Community scientific committees, not such risk assessment opinions issued from third countries. Recital 26 of the preamble to the Regulation explains the rationale of this adventitious or technically unavoidable presence threshold as follows: "It is indispensable that operators strive to avoid any accidental presence of genetically modified material not authorized under Community legislation in food or feed. However, in order to ensure the practicability and feasibility of this Regulation, a specific threshold, with the possibility of establishing lower levels in particular for GMOs sold directly to the final consumer, should be established as a transitional measure for minute traces in food or feed of this genetically modified material, where the presence of such material is adventitious or technically unavoidable and provided that all specific conditions set in this Regulation are met. Directive 2001/18/EC should be amended accordingly. The application of this measure should be reviewed in the context of the general review of the implementation of this Regulation."

111. Art. 43 of the Regulation 1829/2003 amended also Directive 2001/18 by introducing the same tolerance level of 0.5% for adventitious or technically unavoidable presence of traces of a GMO or combination of GMOs in products intended for direct use as food or feed or for processing, provided that these products meet also the other requirements referred to in Art. 47 of Regulation 1829/2003, that is that they have received a favourable risk assessment and that the operators can demonstrate that they have taken the steps necessary to avoid their presence.

112. The preparatory history of the Regulation also demonstrates that the adoption of the two tolerance (threshold) levels for adventitious or technically unavoidable presence was conditional on agreeing to a provision concerning the co-existence of various crops. Thus, Art. 43(2) of Regulation 1829/2003 amended Directive 2001/18 by introducing Art. 26a in it, which provides that the Member States "may take the appropriate measures to avoid the unintended presence of GMOs in other products". Therefore, applying the principle of subsidiarity, the Member States are entitled to regulate the complex and sometimes country – or region – specific problems relating to the co-existence of GM, conventional and organic agricultural crops. The same Article provides that the Commission will gather and coordinate the information and, based on experience, will develop such guidelines. The Commission published on 23 July 2003

The level of protection as applied to labelling, for the purpose of informing the consumers or for reasons of ethical concerns, is set equally high. Frequently, in the production of food, feed or seed it is practically impossible to achieve products that are 100 per cent pure. Minute traces of GMOs in conventional food and feed could arise during cultivation, harvest, transport or processing. This is something that is not particular to GMOs. With this background, the Regulation's objective is to ensure legal certainty and, hence, establishes certain thresholds of adventitious presence above which conventional food and feed have to be labelled as consisting of or containing or being produced from a GMO. Thus, labelling is not required for adventitious presence or for the presence of GMOs that is technically unavoidable up to a 0.9 per cent threshold for both food and feed.[113] This tolerance level, whose application is not provisional, is an expression of the principle of reasonableness rather than an attempt to lower the appropriate level of health or environmental protection.

It should be noted that Regulation 1829/2003 places clearly and squarely the burden on the applicant, who must be established in the Community, to demonstrate "adequately and sufficiently" the safety of the GM food or feed he wishes to place on the market.[114]

Recommendation 2003/556 containing such guidelines for the development of strategies and best practices to ensure the co-existence of GM crops with conventional and organic farming, O.J. 2003, L 189/47.

113. Ibid., Art. 12(2) and 24(2) for food and feed, respectively. Interestingly, recital 24 of the preamble to Regulation 1829/2003 explains the rationale of this tolerance (threshold) level as follows: "Despite the fact that some operators avoid using genetically modified food and feed, such material may be present in minute traces in conventional food and feed as a result of adventitious or technically unavoidable presence during seed production, cultivation, harvest, transport or processing. In such cases, this food or feed should not be subject to the labelling requirements of this Regulation. In order to achieve this objective, a threshold should be established for the adventitious or technically unavoidable presence of genetically modified material in foods or feed, both when the marketing of such material *is authorized* in the Community and when this presence is tolerated by virtue of this Regulation." Therefore, this 0.9% tolerance level applies only to food and feed, which contains, consists of or is produced from GMOs that have already been authorized in the Community. It is obvious that the tolerance thresholds of 0.9% and 0.5% cannot be cumulated, because the first applies only to labelling whilst the second only for the purpose of obtaining the marketing authorization. Before the adoption of Regulation 1829/2003, the tolerance level had been set at 1% of the food ingredients by Commission Regulation 49/2000, which had amended Art. 2(b) of Council Regulation 1139/98. But both of these latter Regulations have now been repealed by Regulation 1829/2003 on GM food and feed.

114. See Arts. 4(3), 5(3)(e), 8(6), 9(3) and 12(3) for food and Arts. 16(3), 17(3)(e), 20(6), 21(3) and 24(3) for feed of Regulation 1829/2003.

2.5. *Traceability and labelling of GMOs and GM products – Regulation (EC) 1830/2003*

2.5.1. *General*

This Regulation is a necessary complement to the two basic acts regulating GMOs and GM products in the Community. Although of horizontal nature, it is the instrument by which the objectives of Directive 2001/18 and of Regulation 1829/2003 can be achieved. It was proposed by the Commission and was adopted by the Council and Parliament at the same time as Regulation 1829/2003 on GM food and feed.

2.5.2. *Object and scope*

The objectives of the Regulation have been substantially clarified and extended in the text finally adopted, compared to the text initially proposed by the Commission.[115] Paragraph 3 of the preamble and Article 1 of the Regulation explain the specific objectives it pursues: a) to facilitate accurate labelling so as to give consumers the right of free and independent choice; b) to monitor the effects on the environment, the ecosystems and human and animal health from harmful or hazardous GM products by enabling the adoption of appropriate measures including, when necessary, the immediate withdrawal of products; and c) to facilitate the smooth functioning of the internal market.[116] The preamble of the Regulation also provides that its objectives have to be pursued in accordance with the precautionary principle.

The traceability and labelling requirements of the Regulation apply to two categories of products: a) products consisting of or containing GMOs, and b) food and feed produced from GMOs.[117] In both cases the products must have been placed on the market in accordance with the other relevant Community legislation applicable to such GM food and feed.[118]

2.5.3. *The nature and scope of the traceability and labelling requirements*

The transmission and holding of information that products contain or consist

115. For the text of the Commission's proposal see O.J. 2001, C 304 E/327 and O.J. 2002, C 331 E/308.

116. Significantly, the legal basis of the Regulation is only Art. 95(1) EC.

117. See Art. 2 of Regulation 1830/2003, except of medicinal products for human or veterinary use falling under Regulation 2309/93.

118. However, pursuant to Regulation 1831/2003 on additives for use in animal nutrition, O.J. 2003, L 268/29, zootechnical additives – used to affect favourably the performance of animals in good health or used to affect favourably the environment – and coccidiostats and histomonostats, when authorized must, if consisting of, contain or produced from GMOs, include the name of the holder of the authorization and, where appropriate, the unique identifier attributed to the GMO, as referred to in Regulation 1830/2003.

of GMOs or are produced from GMOs and of their unique identifiers (codes) at each stage of their placing on the market provide the basis for their appropriate traceability and labelling.[119] The information and codes may be used to access specific information on any specific GMO from the Community register and, thus, to facilitate identification, detection and monitoring in accordance with the provisions of Directive 2001/18/EC. The Regulation thus facilitates a withdrawal from the market of food and feed that can be limited to a GMO which, subsequent to its authorization, is found to pose a risk, or its withdrawal is required for some other valid reason, respecting thus the principle of proportionality. The capacity, therefore, to take this kind of limited and targeted action should prove beneficial to farmers, traders and consumers, when problems in specific cases arise.

The regulatory content and the structure of the Regulation are simple. The traceability requirements consist of obliging operators, at the first stage of placing a product on the market, to ensure the transmission in writing, to the operator receiving the product, of the information that: a) it contains or consists of GMOs, and b) the unique identifier(s) assigned to those GMOs.[120] The operators receiving that information are also obliged to ensure, at all the subsequent stages of the placing of that product on the market, that the information is transmitted in writing to the operators receiving the products.[121] Similar traceability obligations apply when placing products produced *from* GMOs on the market. In such cases, the operators must transmit in writing to the operators receiving the product: a) an indication of each of the food ingredients which is produced *from* GMOs; b) an indication of each of the feed materials or additives which is produced *from* GMOs; and c) for both food and feed, if there is no list of ingredients, an indication that the product is produced *from* GMOs.[122]

To ensure the transmission of such information and identifier(s), the operators are also obliged to have in place "systems and procedures" to allow

119. See Art. 3(4) of Regulation 1830/2003. See also Commission Regulation (EC) No. 65/2004, of 14 Jan. 2004, establishing a system for the development and assignment of unique identifiers for genetically modified organisms, O.J. 2004, L 10/5.

120. Ibid., Art. 4(1).

121. Ibid., Art. 4(2). In case of mixture of GMO products to be used only and directly as food or feed or for processing, the transmission of the information in the subsequent stages may be replaced by a declaration of use, accompanied by a list of the unique identifiers, by the operator, so as to facilitate labelling.

122. Ibid., Art. 5(1). However, pursuant to Art. 5(4), these obligations do not apply to traces of materials produced from GMOs in products for food or feed produced from GMOs in a proportion no higher than the tolerance thresholds established for those GMO materials of 0.9% and 0.5%, in accordance with Arts. 12, 24 and 47 of Regulation 1829/2003 on GM food and feed.

the holding the information and the identification numbers for a period of five years from each transaction, regarding the operator by whom and the operator to whom the products have been marketed.[123] Thus, the objective is to ensure that throughout the whole chain of marketing such GMO products, the information and the unique identifiers are passed from one stage on to the other and can thus be traced back at any moment in time.

The labelling requirements consist in placing on the operators the obligation to ensure that the following words appear on or in connection with the display of certain products: "this product contains genetically modified organisms" or "this product contains genetically modified (name of organism(s))". The products that should bear this kind of labelling are: a) *pre*-packaged products consisting of or containing GMOs; and b) *non-pre*-packaged products sold to the final consumers.[124] However, neither of the above traceability or the labelling requirements apply to traces of GMOs found in products in a proportion no higher than the tolerance threshold of 0.9 per cent, or lower thresholds, established pursuant to Articles 21(2) and (3) of Directive 2001/18 or in other specific Community legislation, as amended by Article 7 of Regulation 1830/2003, provided that they are adventitious or technically unavoidable.[125] Equally, neither of the above traceability or labelling requirements apply to traces of materials consisting or containing GMOs in products, intended for direct use as food or feed or for processing, in a proportion no higher than the threshold established for those GM materials of 0.9 per cent or 0.5 per cent, in accordance with Articles 12, 24 and 47 of Regulation 1829/2003, provided that the traces of GMOs are adventitious or technically unavoidable.[126] Transmission and storage of information will reduce the need for sampling and testing of products. To facilitate a coordinated approach for inspection and control by the Member States, the Commission is developing a system for the assignment of unique identifiers to GMOs and a technical guidance on sampling and testing methods prior to the application of Regulation 1830/2003.[127]

2.5.4. *Appropriate level of protection*

Traceability and labelling requirements for other products have existed in the

123. Ibid., Art. 4(4) and 5(2). However, pursuant to Art. 6(1) of the Regulation, operators are not obliged to hold this information and the identifiers, when other Community legislation provides that this information and the lot numbers are clearly marked on the package, e.g. in case of pre-packaged products.

124. Ibid., Art. 4(6).

125. Ibid., Arts. 4(7) and 7(2).

126. Ibid., Art. 4(8).

127. Ibid., Arts. 8 and 9.

Community for many years.[128] In the case of Regulation 1830/2003, the system it establishes provides effective means to track the movement of GM products through the production and distribution chains. It should be noted that shortly before the Commission submitted its proposal for this Regulation to the Council and Parliament, the *StarLink* crisis in the United States had already erupted.[129] This unfortunate event greatly facilitated the discussion and final adoption of the Commission proposal by the Council and Parliament. Traceability is designed to facilitate monitoring of any effects of GMOs on the environment and to verify the accuracy of labelling claims. It may additionally enable products to be withdrawn from the market, in a targeted and proportionate way, if any unexpected adverse effects arise. Labelling of all foods produced from GMOs, irrespective of whether there is DNA or protein of GM origin in the final product, can also ensure the right of consumers to make a free choice in the market place.

Therefore, the level of protection this Regulation aims to achieve is directly and inextricably linked to the level of protection pursued by Directive 2001/18 and Regulation 1829/2003, the implementation of which it is clearly designed to facilitate. Thus, Article 1 of the Regulation explains that, whilst seeking to ensure the smooth functioning of the internal market, it also recognizes that the withdrawal of authorized GM products, which in appropriate cases may be total, is an appropriate risk management measure in the event they are proven to be hazardous.

3. The co-existence of national and Community legislation in the area of assessing and marketing GMOs and GM products

3.1. *Introduction*

There are a number of other provisions of Community law, in addition to the four basic legislative acts just discussed, that relate to other aspects of GMOs

128. See e.g. Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Regulation No 820/97, O.J. 2000, L 204/1.

129. For a useful description of the chronology of events in the *StarLink* contamination in the US, which was compounded by the absence of any workable system to trace GMOs in the US market, see Bucchini and Goldman, "The Starlink Corn: A Risk Analysis", 110 *Environmental Health Perspectives* (2002), 5–13. See also Nelkin and Marden, "The Starlink controversy – The competing frames of risk disputes", forthcoming in *International Journal of Biotechnology* (2003).

and GM products in the Community. Moreover, their number and regulatory impact is growing constantly. This section will discuss only the effects which the previously analysed legislative acts can have on the power of Member States to regulate the same area in their territory. The analysis here is based essentially on the pre-emptive effect of harmonization measures on Member State power by distinguishing, in particular, between the decentralized application of Community law and the residual State power in this area of risk regulation. The objective here is to identify some of the reasons that have been influencing the regulatory behaviour of the Member States so far and which, in turn, may have had some impact on the attitude of the Community institutions in the evaluation and authorization processes.

3.2. *The degree of harmonization achieved by the Community legislation on GMOs and GM products and the scope of pre-emption on Member State power*

3.2.1. *General*

The rules applicable in Community law to selecting the appropriate legal basis allow the Community courts to subject the legal act, and any possible implementing measures, to a judicial review in order to decide whether the act is within the competence of the Community or the relevant Community institution or within the power of the Member States, and whether the correct procedure and voting majority have been followed.[130] The legal basis, therefore, together with the content of the legal act and the extent of its harmonization and regulatory effect normally determine the division of powers between the Community and its Member States in the area of GMO regulation. The discussion here will focus on Directive 2001/18 but the analysis will be equally applicable to Regulation 258/97 and Regulation 1830/2003, as they are all based on Article 95 EC, have similar structure and achieve a degree of harmonization that is equivalent. Some specific references to Regulation 1829/2003 on GM food and feed will be made separately, as this Regulation is based on a wider list of Treaty Articles.[131]

130. Case C-300/89, *Commission* v. *Council*, [1991] ECR I-2867.

131. Regulation 1829/2003 is based on Arts. 37, 95 and 152(4)(b) EC. Equally, Regulation 187/2002 laying down the general principles and requirements of food law, to the extent that it is made applicable by reference to the acts discussed here, is also based on Arts. 37, 95, 133 and 152(4)(b) EC.

3.2.2. *Degree of harmonization and scope of preemption*

As a general rule and in accordance with the EC Treaty principles of specific attribution of powers,[132] the power which the Community enjoys under Article 95 EC is *a priori* not exclusive. The power it has is shared with the Member States but it has the potential to become exclusive when the specific field or activity is completely (or exhaustively) harmonized by the Community measure in question.[133] This is the so-called principle of preemption of national power because of occupation of the field.[134] The more comprehensive the Community legislation is, the less power is left to the Member States to take action in the same field. It is important, therefore, to examine first the terms of Directive 2001/18 in order to determine the degree of harmonization it has achieved. [135]

It is very important to stress from the outset that Directive 2001/18, in view of its wording and regulatory content, can be considered to have achieved a level of harmonization that is nearly complete (or exhaustive) with regard to its specific objectives, as they have been explained above. Indeed, Article 1(1) provides that GMOs may only be deliberately released or placed on the market in conformity with parts B or C of the Directive. The notification and authorization procedures provide for a decision ultimately to be taken, granting or rejecting the application, at Community level.[136] In addition, Article 22 provides that Member States may not restrict or impede the

132. See Art. 5 EC.

133. See e.g. Case 218/85, *CERAFEL* v. *Albert le Campion*, [1986] ECR 3513, at para 16; Case 255/86, *Commission* v. *Belgium*, [1988] ECR 693, at para 10.

134. On the doctrine of preemption in general and as applied in Community law, see Cross, "Pre-emption of Member State law in the European Economic Community: A framework for analysis", 29 CML Rev. 447–472. See also Weatherill, "Beyond preemption? Shared competence and constitutional change in the European Community", in O'Keeffe and Twomey (Eds.), *Legal Issues of the Maastricht Treaty* (Wiley Chancery, 1994), p. 25; and Kalimo, "Reflections on the scope and pre-emptive effects of Community legislation – a case study on the RoHS Directive", Jean Monnet Working Paper 6/03, NY Univ. School of Law (2003), available at www.jeanmonnetprogram.org.

135. As the placing of GMOs and GM products on the market covers also imports into the Community, the Directive and the other Regulations regulate also trade with third countries. In the external trade relations field, the principle of preemption operates also through the so-called *ERTA* doctrine. See Case 22/70, *Commission* v. *Council (ERTA)*, [1971] ECR 263, paras. 17–19. See also Opinion 2/91, *ILO Convention*, [1993] ECR I-1061, and Opinion 1/94, *WTO Agreements*, [1994] ECR I-5267.

136. See e.g. Case C-6/99, *Association Greenpeace France and Others* v. *Ministère de l'Agriculture et de la Pêche and Others*, [2000] ECR I-1651, at paras. 28 and 47 (holding that a Member State is obliged to issue its consent when no objection has been raised on an application or when an application to place a GMO on the market has received the favourable opinion at Community level. This case concerned the interpretation of Directive 90/220/EEC).

placing on the market of GMOs which comply with the requirements of the Directive.[137]

The preliminary conclusion, therefore, is that the text of the Directive 2001/18 has achieved complete harmonization and that its provisions do not allow Member States to take national action on grounds other than those laid down and under the conditions specified therein. However, before concluding on this point, it is important to examine in more detail what are the grounds and conditions specified in the Directive under which Member States may take implementing action. They relate essentially to the adoption of national safeguard measures and in the processing of the applications for granting a marketing authorization of GMOs and GM products submitted to the national authorities.

Thus, Article 23 of Directive 2001/18 allows Member States to take national safeguard measures and provisionally restrict or prohibit the use and/or sale of a GMO in their territory, when they have "detailed grounds" for considering that a GMO, which has received a consent, "constitutes a risk to human health or the environment".[138] The existence of a safeguard provision in the Directive does not, however, signify that the degree of harmonization achieved is incomplete. In principle the Member States, when acting on the basis of the safeguard provision, will be acting within the harmonized confines of that provision.[139]

As regards marketing authorizations, several other provisions in the Directive allow the Member States to "make comments" or raise "reasoned objections" during the evaluation and authorization procedure.[140] But the Directive does not define what the meaning of these terms or their scope is. It appears, however, from the text of Article 18(1) of Directive 2001/18, read in conjunction with Article 28(1), that these "comments" or "objections", when

137. See e.g. Case 195/84, *Denkavit* v. *Land Nordrhein-Westfalen*, [1985] ECR 3181, at paras. 16, 22 and 30 (holding that the provision of Art. 13 of Council Directive 70/524/EEC concerning additives in feedingstuffs, a provision of similar content to that of Art. 22 of Directive 2001/18, read in conjunction with the other provisions of that Directive and the other Community Directives applicable in that field, indicated the intention of the Community legislator to regulate exclusively or exhaustively that field and, thus, pre-empted national legislation in the same field). The same degree of harmonization has been achieved also by Regulation 258/97 on novel food and food ingredients, Regulation 1829/2003 on GM food and feed and Regulation 1830/2003 on traceability and labelling of GMOs and GM products.

138. See e.g. *Monsanto*, *supra* note 55 (concerning an Italian safeguard measure taken under Art. 12 of Regulation 258/97).

139. It should also be noted that Art. 95(10) EC allows a safeguard clause to be inserted, in appropriate cases, in the Community measure, thereby confirming the pre-emptive effect of the measure in question on the powers of the Member States.

140. See e.g. Arts. 7(4), 15, 17 and 20 of Directive 2001/18.

they relate to risk on human health or the environment, must be submitted first to the relevant scientific committee advising the Commission. Its opinion is then taken into account in the authorization procedure, in accordance with the relevant comitology procedure. It also appears, from an *a contrario* interpretation of the text in Article 18(1) of the Directive, that "comments" or "objections" of other nature and scope may be raised by the Member States, which are not necessarily of a nature relating strictly to human or environmental risk. Such other "comments" or "objections" are decided by applying, in accordance with Article 30(2) of the Directive, the relevant comitology procedure.

The first point to underline, therefore, with regard to the application of safeguard measures as well as for the resolution of objections raised by the Member States in the authorization process, is that the system laid down by Directive 2001/18 requires that any kind of difference or objection, in the appreciation of the scientific information among the Member States and between one or more of the Member States and the Commission, regarding risks to human health or to the environment should be submitted to the relevant scientific committees advising the Commission. But it is equally important to stress that the mechanism for the resolution of eventual different or diverging scientific opinions between the various national scientific committees and those advising the Commission in this area does *not* necessarily require a unique, harmonized, scientific outcome in all cases, because the scientific opinion of the EFSA in this area has no formal overriding effect on the opinions of the corresponding national scientific committees.[141]

Indeed, Articles 28-30 of Council Regulation 178/2002, which are now applicable in case of divergent scientific opinions in the area of GMOs evaluation, oblige any national and/or Commission bodies and committees,

141. The analysis here is purely descriptive of the system Directive 2001/18 has put in place and is not meant to express any value judgement on the appropriateness or soundness of the mechanism inscribed in its approach. The author has argued elsewhere, however, that such an approach is correct and conforms to generally accepted principles of risk regulation because science alone is neither a neutral nor an objective tool in the resolution of risk-based regulatory disputes in case of divergence of scientific views and uncertainty. The decisional power should rest in such cases not with the experts but with the politically accountable institutions and the public. See Christoforou, "Science, law and precaution in dispute resolution on health and environmental protection: What role for scientific experts", in Bourinet and Maljean-Dubois (Eds.), *Le Commerce International Des Organismes Genetiquement Modifies* (La Documentation Francaise, 2002) p. 213–283. This should be all the more so in the European regulatory system that derives its normative legitimacy from the national level of powers. See e.g. Lindseth, "Delegation is dead, long live delegation – Managing the democratic disconnect in the European market-polity", in Joerges and Dehousse (Eds.), *Good Governance in Europe's Integrated Market* (OUP, 2002), p. 139, 155–156.

whose scientific views on a specific substance or product diverge, only to co-operate "with a view to either resolving the divergence or preparing a joint document clarifying the contentious scientific issues and identifying the relevant uncertainties in the data". But the subsequent opinion of the relevant scientific committee of the EFSA, including the joint document referred to above, is only advisory for the Commission and the Council.[142] The resolution of any remaining scientific differences in the scientific assessment of the GMOs and GM products between a Member State and the Commission (or another Member State) will, therefore, have to be sought ultimately not at the risk assessment phase but in the politically accountable risk management phase at Community level, by applying the relevant comitology procedure.[143]

The above analysis raises inevitably the question whether the Member States are entitled, in their risk management decision on specific applications for marketing authorization, to pursue individually a level of health or environmental protection higher than that contained in the Commission's proposal or when having to decide on a Commission proposal in the Council. The answer to this question needs to be viewed first in the light of Article 95 EC, the legal basis of the Directive 2001/18, but also of Article 37 EC which is one of the legal bases of Regulation 1829/2003 on GM food and feed.

The Amsterdam Treaty, which amended the text of Article 100a EC, entered into force on 1 May 1999. Interestingly, Article 95 EC allows the Member States, under the conditions specified in paragraphs 4, 5 and 6 thereof, to choose a level of protection higher than that deemed appropriate in a Community harmonization measure, such as Directive 2001/18 in this case. But Article 95 EC now makes a distinction in the national measures according to whether the provisions notified are national provisions already in place *prior* to Community harmonization or *new* national provisions which a Member State *now* seeks to introduce.[144] In the former case, under Article 95(4) EC, the maintenance of existing national provisions must be justified on grounds of the major needs referred to in Article 30 EC or relating to the protection of the environment or the working environment.

142. See, by analogy, *Upjohn*, *supra* note 96, at para 47; and Case T-13/99, *Pfizer*, *supra* note 28, at para 196.

143. See Arts. 5 and 7 and Art. 8 of Council Decision 1999/468/EC, of 28 June 1999, laying down the procedures for the exercise of implementing powers conferred on the Commission, O.J. 1999, L 184/23.

144. For a general discussion of national measures based on Art. 95 EC, see De Sadeleer, "Procedures for derogations from the principle of approximation of laws under Article 95", 40 CML Rev., 889–915.

The introduction of *new* national provisions under Article 95(5) EC, however, must be based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State, arising *after* the adoption of the Community harmonization measure.[145] Thus, not all the requirements referred to in Article 30 EC can be taken into account when examining new national measures, in the application of Directive 2001/18.[146] This is because the legal rules laid down by the Amsterdam Treaty amendments in Article 95 now differ from those that were laid down in the former Article 100a EC, on which Directive 90/220, the predecessor of Directive 2001/18, was based.

But Directive 2001/18 repealed Directive 90/220 as from 17 October 2002. According to Article 35 of Directive 2001/18, notifications concerning the placing on the market of GMOs as or in products received pursuant to Directive 90/220, and in respect of which the procedures of that Directive have not been completed by 17 October 2002, shall be subject to the provisions of Directive 2001/18.[147] These transitional provisions are important because some of the applications for placing on the market of GMOs were submitted under Directive 90/220/EEC before the date of entry into force of the Amsterdam Treaty, but the evaluation or the final decision on the application for authorization for some of them was completed only after the Amsterdam Treaty's entry into force.[148] In addition, in some other cases, the evaluation of the application has not been completed even today.[149]

145. For the most recent application of Art. 95(5) and (6) EC in the area of GMOs, see Commission Decision 2003/653/EC of 2 Sept. 2003, relating to national provisions on banning the use of genetically modified organisms in the region of Upper Austria notified by the Republic of Austria pursuant to Art. 95(5) EC Treaty, O.J. 2003, L 230/34. The Commission decision is subject to annulment proceedings in the cases C-492/03, *Austria* v. *Commission*, and T-366/03, *Land Oberösterreich* v. *Commission*, pending.

146. See Case C-512/99, *Germany* v. *Commission*, [2003] ECR I-845, paras. 40–41.

147. This transitional provision reflects established case law according to which new rules apply immediately to the future effects of a situation that arose under the old rules. As long as no final decision – either approval or rejection – was taken under Directive 90/220 for the pending applications, no new legal situation affecting these applications can be said to have been established in the meantime and, hence, they have been correctly submitted to the new legal regime established by Directive 2001/18. See e.g. Case C-512/99, *Germany* v. *Commission*, *supra* note 146 at paras. 45–46.

148. Art. 35(2) of Directive 2001/18 provided to notifiers of pending applications a period up to 17 Jan. 2003 to supplement and update them in accordance with the new requirements of the Directive.

149. The continued handling of the pending applications is commonly referred to as *de facto moratorium* in the authorization of GMOs in the Community. This characterization, however, does not seem to be appropriate. Some of the legal issues raised by the continued handling of the applications for some GMOs and GM products are discussed in section 4 of this article.

As already explained, Regulation 1829/2003 on GM food and feed is not based only on Article 95 EC, but also on Articles 37 and 152(4)(b) EC. Therefore, the possibility for the Member States to invoke also the grounds mentioned in Article 30 EC or other mandatory requirements is, at least with regard to this Regulation, potentially open. As a rule, Article 30 EC allows the maintenance of national restrictions on the free movement of goods, justified *inter alia* on grounds of public morality, public policy or the protection of the health and life of humans, animals or plants or the environment, which constitute mandatory requirements recognized by Community law. However, it is established case law that recourse to Article 30 by a Member State is no longer possible where a Community legal act harmonized the measures necessary to achieve the *specific* objective, which would be furthered by the Member States' reliance upon Article 30 (i.e. the so-called "harmonizing away" of the Member States' powers).[150]

It is also important in this connection to recall that in the *Toolex* case,[151] which involved the notification, classification, packaging and labelling of dangerous substances, the Court of Justice held that the power of the Member States to invoke the exceptions laid down in Article 30 EC and the other defences based on mandatory requirements was *not* pre-empted by the relevant Community legislation applicable at the time.[152] The decisive test, according to the Court of Justice,[153] was to identify whether the Community act provided for the harmonization of the measures necessary to achieve the *specific* objective which would be furthered if the Member State were allowed to rely, in its national measure, upon Article 30 EC. On the other hand, as explained above, the mere adoption of the Community rules does not automatically pre-empt national power, if they are not yet or cannot be effectively implemented.[154] Regulation 1829/2003 on GM food and feed should be interpreted in the light of the above principles and case law. It allows, in the adoption of the risk management measure, to take into account the opinion of the EFSA as well as "any relevant provisions of Community law and other legitimate factors relevant to the matter under consideration."[155] To be sure, a risk management decision based on "other legitimate factors" will

150. See, in particular, Case C-1/96, *The Queen* v. *Minister of Agriculture, Fisheries and Food*, *ex parte Compassion in World Farming Ltd.* [1998] ECR I-1251, at para 47; Case C-5/94, *The Queen* v. *MAFF ex parte Hedley Lomas* [1996] ECR I-2553, at para 18.

151. Case C-473/98, *Kemikalieinspektionen* v. *Toolex Alpha AB*, [2000] ECR I-5681.

152. See *Toolex*, *supra* note 151, paras. 34–49.

153. See *Toolex*, *supra* note 151, paras. 25–33, and Case C-1/96, paras. 47, 64–69.

154. See e.g. Case C-1/00, *supra* note 147, paras. 115 and 124.

155. See Art. 7(1).

normally be decided at Community level by the Commission in the context of the relevant comitology procedure or in some cases by the Council.

To sum up, therefore, primary Community law provisions in the area of common agricultural policy or the general harmonization provisions of the Treaty are in principle capable of conferring power on the Community that is or may become over time exclusive, if the competence conferred has been exercised and the regulatory content of the adopted measure is complete and effectively implemented.[156] This seems to be the case with the four legal acts in the area of GMOs and GM products discussed here. Of course, any persisting disputes in this area will be decided ultimately by the Community courts in the light of the breadth of harmonization achieved and the degree of pre-emption operated by Directive 2001/18 and the other Community legislation in this area.

3.2.3. *Shared responsibility in the implementation of Community legislation in the area of GMOs and GM products*

The above is admittedly a standard, formal way of analysing the scope and breadth of the harmonization pursued by Directive 2001/18. Although the legal basis is undoubtedly important in determining the institutional and decision-making procedures to be followed for the adoption of the Directive, it alone does not say much about the concrete nature of the economic activities that are likely to be affected by the adoption of the legal act nor of the attitude which the Community institutions and the Member States are likely to adopt when actually implementing and applying it.[157]

Another less formalistic and more sophisticated analysis would look closer into the structure (both horizontal and vertical) and the national regulatory discretion (both general and specific) which the Directive can accommodate in the specific field.[158] This exercise must also be examined in the

156. See e.g. Case C-1/00, *supra* note 147, para 124, and Opinion of A.G. Mischo of 20 Sept. 2001, at paras. 133 and 168–169.

157. E.g. in this case, the deliberate release of GMOs both for experimental purposes (e.g. as seeds) and for placing on the market (e.g. as seeds or in food or feed) will affect primarily agriculture and seed production, as distinct sectors of economic activity. As agriculture develops in our natural environment, the latter is also likely to be seriously affected. The Directive also enables economic activities to develop in other sectors of the economy, such as scientific research, the food and feed industry. The consumers will of course also be affected. It should, however, be noted that the potential economic or other kind of impact of the measure is an issue distinct and, from the strict legal point of view, unrelated to the choice of the appropriate legal basis in the Community legal system.

158. For an analysis of the Commission's proposals in the area of GMOs and GM food and feed, see Scott, "European Regulation of GMOs and the WTO", 9 *Columbia Journal of European Law* (2003), 213–239.

broader context of risk regulation in the Community. Such an analysis will not be properly understood, if the specific nature of the Community's quasi-federal structure in general, and risk governance in particular, is not taken into account.

Directive 2001/18, like its predecessor Directive 90/220, established a regulatory system for the authorization of GMOs for deliberate release into the environment or the placing of GMOs on the market, whose structure is not very common in Community law. The authorization system that characterizes Directive 2001/18 is a *decentralized* system that sits in between the early (or old) approach to regulating the authorization of substances in the Community and the new (or advanced) approach that has been developed more recently. A typical example of the early approach from the area of medicinal products is Council Directive 65/65/EEC,[159] which harmonized to a large extent the procedural requirements for the submission of applications but left the substantive power for the evaluation and appreciation of the application with the competent authorities of the Member States when granting the authorization in their territory.[160] The more recent (or advanced) approach in the regulation of medicinal products for human and veterinary use was established by Council Regulation 2309/93,[161] which achieved complete harmonization by means of a system operated at Community level, both as regards the submission of applications, their evaluation by the European Agency for the Evaluation of Medicinal Products (EMEA) and the issuing of authorizations by the Commission that are valid throughout the territory of all the Member States.

But the approach followed in Directive 2001/18 and in Regulation 258/97 is different in the sense that it is a hybrid between the two (old and new) approaches highlighted above. It is a system that consists of two phases – the national and the Community – the smooth functioning of which requires *close cooperation* between the national authorities and the Commission.[162]

159. Council Directive 65/65/EEC of 26 Jan. 1965 on approximation of provisions laid down by law, regulation or administrative action relating to medicinal products, O.J. 1965, L 22/369.

160. Directive 65/65/EEC has been subsequently amended several times and complemented by several other directives, e.g. Council Directive 75/319 of 20 May 1975, O.J. 1975, L 147/13, with the objective of reducing the disparities that remained in order to facilitate the placing of medicinal products in the market of two or more Member States.

161. Council Regulation (EEC) No 2309/93, *supra* note 36.

162. See e.g. *Association Greenpeace France*, *supra* note 136, at para 33, where the ECJ qualified as "close cooperation" the involvement of both the Commission and the competent national authority in the authorization procedure under Directive 90/220/EC. See also para 132 of the judgment in *Monsanto*, *supra* note 55, with regard to the authorization procedure under Regulation 258/97.

The application for a marketing authorization is submitted to a Member State and the evaluation is, in principle, conducted and the authorization is granted by that Member State. But the GMOs, once authorized to be placed on the market, may circulate in the territory of all the other Member States. This result is achieved by means of an advanced, albeit quite complex, system, in which all the Member States may potentially participate in the risk evaluation and risk management process and in the resolution of any dispute, whether of technical, scientific or regulatory nature, initially at national and, where necessary, at Community level. This is the *new era* in the governance of risk regulation in the Community, which, according to Directive 2001/18, must in addition involve the direct consultation of the general public. The authorization procedure used in Regulation 1829/2003 on GM food and feed is still another more recent variant of this new approach, because the marketing authorization can only be granted by the Commission at Community level, even if the applications have to be submitted in the first place to the competent authorities of a Member State. Therefore, to the extent the Community legislative acts in this area have achieved complete harmonization, the Member States still retain in principle implementing powers of administrative nature only in the *decentralized* enforcement system established by the Community measures.[163]

The issue of determining the breadth of harmonization and pre-emptive effect on Member State power seems to be much more broad and complex in the area of risk regulation, and in particular under Directive 2001/18 and Regulation 1829/2003, than in other areas of Community law. This is because, as already explained, Article 95 allows Member States to aim for a higher level of health or environmental protection and may adopt even new measures based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State. Equally, Article 37 EC allows in principle Member States to invoke the exceptions of Article 30 and other imperative reasons, as this has been explained above. Moreover, the implementation of their responsibilities sometimes entails a certain margin of discretion for the Member States, the exercise of which is not always possible to circumscribe neatly in advance.[164] The broad point being made here, therefore, is that Community law in the area of GMOs regulation has essentially given to the national risk assessment and risk management authorities, in the implementation of the

163. See *Association Greenpeace France*, *supra* note 136, at para 54. See also Lindseth, *supra*, note 141, p. 169.

164. For the purpose of the present analysis, account is not taken of the additional margin of discretion that the choice of the Community measure – i.e. whether in the form of a Directive or of a Regulation – may allow to the Member States in the transposition and implementation.

rules, a role that sometimes is not simply executory in nature. Instead, the design of their role is sometimes to involve them more actively and substantively in the *decentralized* implementation and application of the Community regulatory system. This is because the regulatory system in the area of GMOs touches upon supreme values, like human health or the environment (and more recently animal health and welfare), which have been traditionally of immense importance in the governance of risk and the empowerment and legitimacy of politics at national and local level.[165] The question that arises, therefore, is whether the traditional lenses of legal analysis are sufficient to capture the new dynamics that the regulation of GMOs has generated in our democratic system of risk governance. This issue is also intimately linked to the decision-making process, in particular the applicable comitology procedure, which is put in place to resolve different assessments and perceptions of risk and other ethical and legitimate factors between the Member States and the Community institutions.[166] This is discussed shortly in the following sub-section.

3.2.4. *The risk assessment is a necessary but not a sufficient condition to regulate risk; the effect on the distribution of powers in the Community*

Some elements of the mechanism and functioning of the comitology procedure, with particular reference to concrete applications for the authorization of GMOs and GM products, will be dealt with in section 4 of this Article. Before doing so, however, it is important to discuss briefly the view that management decisions about risks which are of direct concern to consumers can be taken on the basis of grounds which may be wider than a strict evaluation of risk in science laboratories. This approach in the governance of risk is obvious to some but is also misconceived and frequently contested by others.[167]

The recent judgment of the Court of First Instance in the *Antibiotics* case is instructive on this point.[168] When the Council prohibited certain antibiotic

165. Needless to say, this regulatory arrangement has also important institutional and constitutional dimensions. See e.g. generally the papers in Joerges, Ladeur and Vos (Eds.), *Integrating Scientific Expertise into Regulatory Decision-Making* (Baden-Baden, 1997).

166. On the nature of problems posed by comitology in the area of risk regulation, see generally Joerges and Vos (Eds.), *EU Committees: Social Regulation, Law and Politics* (OUP, 1999). See also Pedler and Schaefer (Eds.), *Shaping European Law and Policy – The role of committees and comitology in the political process* (European Institute of Public Administration, Maastricht, 1996).

167. For an interesting discussion from a broader perspective see e.g. Weinberg, "Science and trans-science", 10 *Minerva* (1972), 209–222.

168. See Case T-13/99, *Pfizer*, *supra* note 28, and Case T-70/99, *Alpharma*, *supra* note 28.

substances in farming, the potentially affected companies argued that the Commission disregarded the opinion of the Scientific Committee on Animal Nutrition (SCAN) on this subject. In its judgments of 11 September 2002, the Court of First Instance stressed the conditions with which the public regulatory authority in the Community must comply in its risk assessment. It placed particular emphasis on the essential role of scientists in this context and concluded that the view of the competent scientific committees must be obtained, even if their opinion is only advisory or even if this is not specifically provided for by the legislation, unless the public authority can ensure that it is acting on another but equivalent scientific basis. However, the Court pointed out that the decision to ban a product is not a matter for the scientists to decide but rather for the public authority to whom political responsibility has been entrusted and which can claim democratic legitimacy – as opposed to scientific legitimacy – in risk regulation. The Court of First Instance ruled on this point as follows:

> "That finding can also be justified on grounds of principle relating to the political responsibilities and democratic legitimacy of the Commission. Whilst the Commission's exercise of public authority is rendered legitimate, pursuant to Article 155 of the EC Treaty (now Article 211 EC), by the European Parliament's political control, the members of SCAN, although they have scientific legitimacy, have neither democratic legitimacy nor political responsibilities. *Scientific legitimacy is not a sufficient basis for the exercise of public authority.*"[169]

The same basic principle is expressed in equally strong language in recital 32 of Regulation 1829/2003, which states: "It is recognized that, in some cases, scientific risk assessment alone cannot provide all the information on which a risk management decision should be based, and that other legitimate factors relevant to the matter under consideration may be taken into account."

Equally relevant, although from a different legal source, is the following finding by the WTO Appellate Body in the *Hormones* case:

> "It is essential to bear in mind that the risk that is to be evaluated in a risk assessment under Article 5.1 [of the WTO SPS Agreement] is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die."[170]

169. Ibid., at para 201, emphasis added.
170. See Appellate Body Report in *EC Measures Concerning Meat and Meat Products*

Science is, therefore, *a necessary but not a sufficient condition* for risk regulation in the Community and, we would argue, in any democratic system of risk governance.[171] In addition, and more importantly, since Directive 2001/18 mandates in Article 1(1) that "Member States shall, in accordance with the precautionary principle, ensure that all appropriate measures are taken to avoid adverse effects on human health or the environment which might arise from the deliberate release or placing on the market of GMOs", the margin of discretion in situations of scientific uncertainty which managers enjoy in the regulation of risk has to be exercised also in conformity with that principle.[172] The precautionary principle is also enshrined in Regulation 1829/2003 and in Regulation 1830/2003, also by virtue of Regulation 178/2002. Moreover, the precautionary principle, as a general principle of Community law, should be taken into account by the responsible authorities in any area of risk regulation.[173]

Given that Member States are entitled, under Articles 95 and 30 EC, to adopt a level of protection that is even higher than that implied by the phrase "to avoid adverse effects on human health or the environment which might arise" in Article 1(1) of the Directive 2001/18, the conclusion one may draw from a systematic and contextual analysis of all the relevant provisions of Community law is that Member States enjoy – either individually under national law or collectively in the Council – the freedom to strive for the avoidance or elimination of any identified risk in case of scientifically established uncertainty.[174] This conclusion is in perfect harmony also with the relevant

(Hormones), WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 Feb. 1998, at para 187 *in fine*, available at www.wto.org. See also Nowotny, Scott and Gibbons (Eds.), *Re-thinking Science. Knowledge and the public in an age of uncertainty* (Polity Press, Cambridge, 2001).

171. This is a hotly debated issue and many authors have taken varying positions. See e.g. Christoforou, "The precautionary principle, risk assessment, and the comparative role of science in the European Community and the US legal systems", in Vig and Faure (Eds.), *The Green Giants? Environmental Policy of the United States and the European Union* (Cambridge, MIT Press, 2004), pp. 17–51. For a different view, see e.g. Dehousse, "Misfits: EU law and the transformation of European governance", in Joerges and Dehousse, op. cit. *supra* note 141, p. 207–229.

172. See e.g. Christoforou, "The precautionary principle in European Community law and science", in Tickner (Ed.), *Precaution – Environmental Science and Preventive Public Policy* (Island Press, 2002), pp. 241–262.

173. On the precautionary principle in general, see in particular the following seminal judgments: *Association Greenpeace France*, *supra* note 136, paras. 40–45; *Monsanto, supra* note 55, paras. 110–113 and 133; Case C-192/01, *Commission* v. *Denmark*, judgment of 23 Sept. 2003, nyr, paras. 49–52; and Joined Cases T-74, 76, 83–85, 132, 137 & 141/00, *Artegodan GmbH and Others* v. *Commission* [2002] ECR II-4945, paras. 181–195, and in particular 184 where the CFI declared it explicitly for the first time to be a general principle of Community law.

174. Scientifically established uncertainty is one of the basic conditions for the application

principles of international law,[175] in particular with the relevant provisions of the WTO/SPS Agreements relating to risk evaluation and the level of risk a society may consider acceptable.[176]

In addition to the margin for the regulation of risk to human health or the environment which the Member States enjoy when they pursue a level of protection higher than that pursued by the Directive 2001/18, the question remains whether they also retain some *residual* power to take national action by invoking grounds *other than* those laid down in Article 95(5) EC as regards new measures. As already explained above, the answer to this question is in principle negative. However, both Regulation 1829/2003 and Regulation 1830/2003 have objectives wider that those of Directive 2001/18, in so far as Article 1 of the former includes the objectives to protect animal health *and welfare* and consumer *interests*, whilst within the objectives of Regulation 1830/2003 on traceability and labelling of GMOs and GM products is also to protect the environment *and ecosystems.* The pre-emptive effect on Member State power of the references to these additional specific objectives should normally be the same as that described above for the other of their objectives. Yet, to the extent concerns or objections directly related to these additional objectives are not sufficiently catered for in a specific Community implementing measure the power of the Member States to intervene for the purpose of achieving a higher level of protection is likely to remain unaffected.[177]

of the precautionary principle in Community law. See, in general, de Sadeleer, *Environmental Principles – From political slogans to legal rules* (OUP, 2002); and Christoforou, op. cit. *supra* note 35.

175. As I will discuss in the second article in this series, see *supra* note 2.

176. See e.g. the WTO Appellate Body report in *Hormones* case, *supra* note 170, at paras. 172–187. For a useful commentary on the *Hormones* case, see Walker, "Keeping the WTO from becoming the 'World Trans-science Organization': Scientific uncertainty, science policy, and fact-finding in the growth hormones dispute", 31 Cornell Int'l L. J. (1998), 251–320.

177. Specific reference should also be made here to Regulation 258/97, which has Art. 100a as legal base, as it was adopted before entry into force of the Amsterdam Treaty. Whilst the Regulation aims to achieve complete harmonization, certain of its provisions appear to leave still a margin of discretion broader than that left to the Member States under Directive 2001/18. This is evident in particular with regard to the labelling requirements, which are not exhaustively regulated. Thus, the Regulation not only provides for *compulsory* labelling indicating the characteristics or properties of the food or food ingredients modified, together with the method by which these were obtained, but also leaves the possibility open to apply *negative* labelling or labelling that informs the consumers about the possible – but not certain – presence of GMOs in the novel food or food ingredients. See recital 10 of the preamble to the Regulation permitting labelling framed like "this product does not contain, consist of or produced from GMOs". See also recital 9 of the preamble to the Regulation permitting labelling framed like "this product may contain GMOs", especially for bulk consignments.

Finally, it should also be noted in this connection, from a combined reading of Articles 29 and 31(8), in the light of recitals 57 and 58 of the preamble to Directive 2001/18, that the power of the Member States to take into account *ethical* considerations in the authorization process is also not affected.

3.2.5. *Conclusion on the division of powers and extent of preemption between the Community and its Member States in the area of GMOs and GM products regulation*

To sum up on this complex and quite delicate area of Community law, it seems possible, in theory at least, for the Member States when adopting specific implementing measures to take into account broader concerns, pursuant to the specific grounds and the power they have under Articles 37 and 95 of EC, when these concerns are legitimate to the matter under consideration and necessary to achieve a level of protection in their territory that is higher than that pursued in the measure proposed by the Commission or the measure ultimately adopted by the Council. However, it is also true that the possibility of having recourse to such new national measures is in reality extremely limited in this area because of the very high level of protection of no risk that is already pursued by the Community legislation currently in place.

Furthermore, in areas where the level of harmonization under Directive 2001/18, Regulation 1829/2003 and Regulation 1830/2003 is not complete, for instance as regards the rules on ethical concerns or on the co-existence of conventional, organic and GM crops, the Member States will continue to have the power to take national measures,[178] provided that the other conditions laid down in the EC Treaty are also respected.

4. Scientific, economic, social and legal constraints in the regulation of GMOs and GM products in the community

4.1. *General*

The objective of this section is to provide a brief description of the development of the general framework on risk regulation in the Community. Special attention will be paid to the factors and forces that have during the last two decades shaped its policy in this area. The conclusions of this sector will be

178. See e.g. Art. 43(2) of Regulation 1829/2003 on GM food and feed, amending Art. 26a of Directive 2001/18 by introducing measures to avoid the unintended presence of GMOs (the so-called "co-existence" problem). See also Commission Recommendation 2003/556 of 23 July 2003, *supra* note 112.

applied then in the analysis of the Community rules in the area of GMOs and GM products, so as to be able to draw some conclusions on the attitude of the Member States and the Community institutions when the crisis on the application of modern biotechnology in agriculture erupted in Europe, particularly in the period between the years 1996–2001.[179]

4.2. *A brief historical background on the regulation of risk in the Community*

Traditionally, the regulation of the level of acceptable risk in the Member States has varied, sometimes considerably. As a result, the early attempts to harmonize Community legislation in the areas of health and environmental protection inevitably progressed on the basis of the generally accepted average, which sometimes led to agreeing to minimum (lower) standards.

In the 1987 amendment to the EC Treaty by the Single European Act, however, qualified majority voting was established and it was provided that the regulation of risk in the Community will aim to attain a "high level of protection" (Art. 100a(3)). To counter-balance the abolition of unanimity and the introduction of qualified majority voting, the Member States wishing to apply an even higher level of protection (than that to be applied in the Community) were explicitly permitted to do so under certain conditions (Article 100a(4)).[180] As a result, in order to discourage the Member States from continuing to apply disparate national standards that might undermine free movement in the internal market, the Community legislation in the areas of health and environmental protection tended to pre-empt national action by choosing very high levels of protection.[181] By 1992, the abolition of internal controls on free movement made inevitable an upward surge (or drift) in the adoption of levels of health and environmental protection in the Community that are even higher than those previously applied by the Member States, in order to maintain the cohesion and competitiveness of the internal market.[182]

179. For a very useful general discussion, see Gaskell and Bauer (Eds.), *Biotechnology 1996–2000 – The Years of Controversy* (Science Museum, London, 2001).

180. See e.g. Commission Decision 1999/832/EC of 26 Oct. 1999 concerning the national provisions notified by the Netherlands concerning the limitations of the marketing and use of creosote, O.J. 1999, L 329/25, where the European Commission approved the Dutch stricter measures explicitly on the basis of scientific uncertainty and the precautionary principle.

181. See e.g. Case 302/86, *Danish Bottles*, [1988] ECR 4607, and Case C-41/93, *PCP*, [1994] ECR I-1829.

182. Thus, the 1993 Maastricht and the 1997 Amsterdam amendments to the EC Treaty clarified in several places that one of the objectives of the European Community is to aim for a "high level of health protection", e.g. in Arts. 3(1)(p) and 152(1) and (4) on regulation of public health and agriculture; in Art. 153 on consumer protection; in Art. 174(2) on environmental regulation; and in Art. 95(3) on internal harmonization measures.

It should be noted, however, that the Community's success in establishing the single market by 1992 also came at a price: the European institutions (in particular the European Commission) were blamed for excessive regulatory zeal and lack of democratic control and legitimacy (the "democratic deficit"). Consequently, by the early 1990s there was a growing concern that elaborate and detailed Community provisions imposed excessive burdens on the Member States, their industry and people.[183] This concern gave rise to the principle of subsidiarity and its inclusion, together with the principle of proportionality, in Article 3b EC, introduced by the Treaty on European Union in 1993.

During this same period, the political and civic landscape has also been changing rapidly with the appearance of pro-environmental NGOs, with ecology appealing to even wider sections of the population, and the need to achieve sustainable development constantly gaining ground, which was also written into Article 3c of the Treaty.[184] Moreover, the rise of Green parties in some powerful Member States changed politics, with political parties in the centre and left of the political spectrum in many Member States also espousing broad environmental concerns. "Greening" the laws and the trade rules were claims and slogans that caught the attention of many people. These profound societal changes were reflected also in the composition of the European Parliament, whose powers have been constantly increasing in all the successive EC Treaty amendments.[185] In this context, the principle of precaution was then explicitly written into Article 130r EC in 1993 to anticipate regulatory action and halt environmental degradation.[186]

More recently, however, the regulation of risk in the Community is becoming increasingly strict. Two reasons appear to have led to such a regulatory attitude in Europe. First, the positivist view of science, considering it to be a powerful and neutral tool capable of predicting risk and causality almost always, seems to be no longer valid.[187] This view has been demonstrated to

183. See e.g. Breyer and Heyvaert, "Institutions for regulating risk", in Revesz, Sands and Stewart (Eds.), *Environmental Law, the Economy, and Sustainable Development – The United States, the European Union and the International Community* (Cambridge University Press, 2000), p. 283, 331.

184. See Boyle and Freestone (Eds.), *International Law and Sustainable Development – Past Achievements and Future Challenges* (OUP, 1999).

185. See e.g. Vos, *The Institutional Frameworks of Community Health and Safety Regulation – Committees, Agencies and Private Bodies* (Hart Publishing, Oxford, 1999).

186. See de Sadeleer, "Le statut juridique du principe de précaution en droit communautaire: du slogan à la règle", (2001) CDE, 91–132.

187. See e.g. Bourdieu, *Science de la science et réflexivité* (Seuil, Paris, 2001). See also Wynne, "Scientific uncertainty and environmental learning", 3 *Global Environmental Change* (1992), 111.

be wrong in several cases, because the experts' judgments appear to be prone to many of the same mistakes and biases as those of the general public, particularly when experts are forced to go beyond the limits of available information and data and rely on assumptions and intuition.[188] Even if uncertainty and lack of causality normally undercut the ability to prove negligence in litigation, it would be nevertheless legally inappropriate and wrong to require scientific certainty before allowing action to be taken to protect health or the environment.[189] Research has demonstrated that risk means more to people than the expected number of fatalities based on probabilistic quantitative assessments, which is the usual way experts assess risk.[190] If the very content of science is ultimately impersonal, its conduct is nevertheless part of human aptitude and culture. Indeed, the perception people have of risk is wider than that of experts and reflects a number of legitimate concerns, e.g. familiarity with risk, catastrophic potential, irreversibility of harm, threat to future generations, risk control possibilities, voluntariness of exposure, which are frequently omitted from an expert risk assessment.[191]

Second, risk assessment methodologies were found to be inherently biased in favour of avoiding over-inclusive regulatory measures (i.e. the inclination is to avoid false positives) for fear of imposing undue costs on technological progress, industry and on society.[192] Moreover, detailed studies of expressed consumer preferences indicate that people tend to view current levels of risk as unacceptably high for most activities and substances.[193] Studies have also shown that the gap between perceived and desired risk levels suggests that

188. See Fischhoff et al. (Eds.), *Acceptable Risk* (Cambridge University Press, 1981); Slovic, "Risk perception and trust", in Molak (Ed.), *Fundamentals of Risk Perception and Trust* (CRC/Lewis Pub., 1996); Jassanoff, "Contingent knowledge: Implications for implementation and compliance", in Brown and Jacobson (Eds.), *Engaging Countries – Strengthening Compliance with International Environmental Accords* (MIT Press, Cambridge, 1998).

189. See European Environment Agency, *Late Lessons from Early Warnings: The Precautionary Principle 1896–2000* (European Commission, Brussels, 2001).

190. See Fischhoff et al., *supra* note 188; Slovic, *The Perception of Risks* (Earthscan Publications Ltd., 2000); and Renn and Rohrmann (Eds.), *Cross-Cultural Risk Perception – A Survey of Empirical Studies* (Technology, Risk and Society – An International Series in Risk Analysis Volume 13, Kluwer Academic Publishers, 2000).

191. See e.g. Fischhoff et al., *supra* note 188; and Stirling and Mayer, "Precautionary approaches to the appraisal of risk: A case study of a genetically modified crop", 6 Int. J. Occup. Environ. Health (2000), 342.

192. See e.g. Cranor, "Asymmetric information, the precautionary principle, and burdens of proof in environmental health protection", in Raffensperger and Tickner (Eds.), *Protecting Public Health and the Environment: Implementing the Precautionary Principle* (Island Press, Washington D.C. 1999); European Environment Agency, *supra* note 189; and Funtowicz and Ravetz, "Three Types of Risk Assessment and the Emergence of Post-Normal Science", in Krimsky and Golding (Eds.), *Social Theories of Risk* (Praeger, Westport, 1992), pp. 251–273.

193. See, in general, Slovic, op. cit. *supra* note 190.

people are not satisfied with the ways in which the market and regulatory authorities have balanced risks and benefits.[194] Thus, it has been correctly argued that attempts to "educate" the public in order to bring their perceptions of risk in line with those of experts are in most cases unlikely to succeed, especially in cases of risks that are genuinely perceived to be unknown and potentially catastrophic.[195] The preceding analysis suggests that Community risk management measures, instead of trying to patronize consumers scientifically, have increasingly been taking into account their genuine and legitimate concerns.[196] The public's perception of risk should, therefore, be taken into account when evaluating risk management options. Conversely, mere consumer preference or choice, to the extent they can be disentangled from risk, may be addressed by other less trade-restrictive measures, such as providing consumer information and labelling.

Recent surveys on consumer acceptance of GMOs in Europe appear to confirm consistently the above propositions, since they have been reporting that "[T]here was no 'knowledge/education effect', although it is generally observed that the more knowledge people have the more favourable they are to scientific and technological progress.[197] This was not true with GMOs, however, since those ranked as having the greatest knowledge of science based on other evaluations still tended to say they did not want this type of food (65.4%)."[198]

194. See Gaskell and Bauer (Eds.), *supra* note 179. For instance, this appears to be the situation in Europe as regards the use of biotechnology in agriculture. See e.g. Marris, Wynne, Simmons and Weldon, *Public Attitudes to Agricultural Biotechnologies in Europe*, Final Report of Project PABE, 1997–2000, DG Research, European Commission, Brussels, May 2002, available at www.pabe.net. See also European Commission, *Results of the public consultation "Towards a strategic vision of life sciences and biotechnology"*, Commission Staff Working Paper, SEC(2002)630, 29.5.2002.

195. See e.g. Fischhoff et al., "How safe is safe enough? A psychometric study of attitudes towards technological risks and benefits", 9 *Policy Science* (1987), 127. See also Slovic, "Perception of risk", 236 *Science* (1987), 284–285.

196. It is questionable, however, whether more and better information will enhance public confidence and acceptance of the GMOs in the Community. More generally on the public understanding of risk, see Slovic, op. cit. *supra* note 195, 280–285, and Ziman, "Public understanding of science", 16 *Science, Technology and Human Values* (Winter/1991), 99–105. Yet, Habermas argues that, despite today's complex societies, the technocratic variant of paternalism grounded in the monopolization of knowledge entailing a division of labour between experts and laypersons is no longer sufficient in the governance of a society based on deliberative politics. See Habermas, *Between Facts and Norms – Contributions to a Discourse Theory of Law and Democracy* (Polity Press, Oxford, 1996), pp. 315–328.

197. This survey on GMOs' acceptability is part of the Report: "Europeans, Science and Technology", published by the European Commission, DG Research, Eurobarometer No 55.2, December 2001, Brussels.

198. Ibid.

It appears, therefore, that all the above structural, societal and institutional changes have created the dynamics for a regulatory system in Europe that continuously aims for stricter – than national and/or international – standards in health and environmental protection in order to complete the internal market and maintain its cohesion, avoid regulatory failures in the Member States and at Community level and regain democratic legitimacy in the representation and defence of the basic interests of ordinary people in Europe.[199]

4.3. *The so-called de facto moratorium in the handling of applications for the authorization of GMOs and GM products in the Community*

To comprehend properly the nature and scope of the so-called *de facto moratorium* it is necessary to analyse it from several perspectives. Simply observing a fact, that is the application of certain delay in pursuing the various stages of the authorization procedure for some GMOs and GM products, would not provide an accurate picture if no attempt is made to understand the reasons, put in their proper context, that are causing it. Three situations will be examined: first, authorization applications made under Directive 90/220 and its successor Directive 2001/18; second, applications submitted under Regulation 258/97; and third, safeguard measures taken by the Member States under both of the above legal acts.[200]

Since Directive 90/220/EEC entered into force, in October 1991, the commercial release of eighteen GMOs in total has been authorized in the Community, mostly by a Commission decision following a qualified majority vote in the regulatory committee.[201] In two of these cases, however, the Commission decision has not yet been implemented by the Member State concerned.[202]

Around 1996, however, several questions concerning certain scientific aspects of GMOs and GM products, for which an application has been made,

199. See e.g. Vogel, "Risk regulation in Europe and the United States", 3 *Yearbook of European Environmental Law* (OUP, 2003).

200. Obviously, there can be no claim that the so-called *de facto moratorium* arises in the context of the two recently adopted Regulations 1829/2003 and 1830/2003. Certain trade partners of the Community argue that these two Regulations pose different kind of legal problems under the WTO Agreements, which will be discussed in the second part of this article.

201. Of those 18 products, only 3 were approved without objections being raised from the Member States. For the other applications, where objections had been maintained, the Commission followed the authorization procedures under Directive 90/220 and the comitology procedure (regulatory committee) provided therein.

202. These authorizations and the products and uses to which they correspond are explained in Annex 1 of the Commission's Questions and Answers, *supra* note 10, MEMO/02/160/-REV., Brussels, 1 July 2003.

were raised by a number of Member States concerning in particular potential adverse effects on health and the environment. Member States also considered that the regulatory framework was inadequate, particularly with regard to the principles for risk assessment, labelling, and mandatory post-market traceability and monitoring.[203] For those reasons, several Member States started to raise objections to the placing on the market of new GMOs. In addition, concerns started to appear about the total lack of provisions relating to the co-existence of GM crops with conventional and organic farming.

Around the years 1996-1997, it was becoming also apparent that the assessment under Directive 90/220, which dealt essentially with the deliberate release of GMOs into the environment, was limited to possible environmental risks without addressing specifically the use of GMOs in food or feed. Consequently, a serious attempt was made by the Community institutions and the Member States and, as a result, Regulation 258/97 on novel foods and food ingredients, which had been proposed in 1992, was finally adopted.[204]

During the same period, the international negotiations under the auspices of the Biosafety Convention to develop a protocol on biosafety of GM organisms and products commenced.[205] In parallel, work in the context of the OECD[206] and the Codex Alimentarius Commission[207] was also getting under way on several aspects for the regulation of GMOs and GM products. The

203. More labelling provisions were subsequently introduced in 1996/1997 by a technical adaptation of Annex III to Directive 90/220/EEC.

204. The need to propose sector specific legislation on GM seeds and feed was also considered but finally not proposed during that period of time.

205. See e.g. Marquard, Bail and Falkner (Eds.), *The Cartagena Protocol on Biosafety – Reconciling Trade in Biotechnology with Environment and Development?* (Earthscan Earth Summit Book and Royal Institute of International Affairs, 2002). See also Nanda, "Genetically modified food and international law – the Biosafety protocol and Regulations in Europe", 28 Denver J. Inter'l L. & Policy (2000), 235–263.

206. See e.g. OECD, *Safety Evaluation of Foods Derived by Modern Biotechnology – Concepts and Principles* (Paris, 1993). See also OECD, *GM Food Safety: Facts, Uncertainties and Assessment*, OECD Conference, Feb.-March 2000, Edinburgh, (2000). More generally, see Cantley, *The Regulation of Modern Biotechnology: A Historical and European Perspective*, p. 505–681, published in *Biotechnology*, 2nd rev. ed., Vol. 12, *Legal, Economic and Ethical Dimensions* (ed. Brauer) (Weinheim, N.Y., 1995).

207. See e.g. FAO, *Biotechnology and Food Safety*, Report of a Joint FAO/WHO Consultation, FAO Nutrition Paper 61 (1996); FAO/WHO, *Safety Aspects of Genetically Modified Foods of Plant Origin*, Expert Consultation on Food Derived from Biotechnology, May-June 2000. See also FAO/WHO, *Evaluation of Allergenicity of Genetically Modified Foods*, Expert Consultation on Allergenicity of Foods Derived from Biotechnology, 22–25 Jan. 2001; and Codex Alimentarius Commission, *Report of the Codex Ad Hoc Intergovernmental task Force on Foods Derived from Biotechnology*, Alinorm 03/34A, Yokohama, Japan, 11–14 March 2003.

Member States as well as the Commission took a very active role in all these negotiations with the objective, and certainly the expectation, of laying down guidelines for a regulatory framework that would be clear and workable, that would ensure a high level of health and environmental protection whilst providing to the European consumers the right to choose the products they wish to buy in the market place.[208] The benefits of modern biotechnology and, of course, the interests of industry also figured high on the agenda of the Community and its Member States, as all responsible authorities realize the importance of this sector for the European economy and the potential positive effects it can have on the overall wellbeing of consumers world-wide.[209]

Between 1996 and 1998, seven more GMOs were authorized to be placed on the market, after consultation of the relevant scientific committees and approval of the Commission proposal, by qualified majority, in the regulatory committee.[210] However, around 1997–1998 it was becoming all too clear that Directive 90/220 ought to be revised immediately in order to adapt it to the rapid developments on the scientific and regulatory fronts and the international legal framework. This is reflected in the fact that since October 1998, no further authorizations were granted under Directive 90/220/EEC, although at the time of its repeal there were thirteen applications pending, for a number of reasons. They relate essentially to a number of outstanding information requests which the applicants did not provide, the objections raised for the products in question, the ongoing legal and policy developments at Community and the international level, and the reappraisal of the regulatory system relating to biotechnology in general, and bio-engineered products in particular, in the Community and its Member States.

Consequently, in 1998, the Commission submitted a proposal to the Council and Parliament to replace Directive 90/220, taking account of the above

208. Frequently the same regulatory officials participate in all these national, Community and international fora, thus creating network learning effects. The preparatory history of Directive 2001/18, of Regulations 1829/2003 and 1830/2003, of the Cartagena Protocol on Biosafety and of the Codex Alimentarius Commission guidelines on biotechnology, mentioned above, clearly confirms this observation.

209. See e.g. European Commission, Communication on Life Sciences and Biotechnology – A Strategy for Europe, COM(2002)27 final, 23 Jan. 2002, and COM(2003)96 final, 5 March 2003. See also Council Conclusions and Roadmap, of 26 Nov. 2002, for a strategy on life sciences and biotechnology, O.J. 2003, C 39/9.

210. Of these 7 products, the regulatory committee approved 4 in April 1998. Two of these authorizations were issued for all uses and two were restricted to import and processing only. However, the final consent for two oilseed rape products was not issued by a Member State (France) following the Commission's decisions to place them on the market. See Commission Decisions 97/892/EC of 6 June 1997, O.J. 1997, L 164/38, and 97/393/EC, O.J. 1997, L 164/40. See also Commission, Questions and Answers, *supra* note 10, MEMO/03/196, Brussels, 10 Oct. 2003.

scientific and regulatory developments. Directive 2001/18 repealed Directive 90/220 as from 17 October 2002 and the deadline of 17 January 2003 was set for upgrading the applications for which the evaluations were still pending under Directive 90/220/EEC, that is for the applicants to provide the additional information and data now required for the first time by the new provisions of Directive 2001/18. At the time of writing, seven of the thirteen pending applications were re-submitted to the new authorization procedure, the remaining six being withdrawn by the applicants. In addition, since the entry into force of Directive 2001/18, fourteen new applications have been notified to the Commission.[211] The assessment of all these twenty-one applications is now proceeding normally.

As regards the situation of applications under Regulation 257/98, at the time of writing only fourteen applications have been made under Article 4 Regulation 258/97, of which eight are still pending.[212] Of these fourteen applications, five have been withdrawn by the applicants, in most cases because they could not provide the missing or requested additional data or for lack of commercial interest.[213] On four of these fourteen applications, an initial assessment by the Member States is still awaited. On another two of them an additional assessment is being awaited, whilst on two more the authorization is still pending. It appears, therefore, that none of the applications currently pending is unduly delayed, since for a good number of them requests for additional specific information and scientific data have been made by the relevant authorities of the Member States, whilst for some other applications the companies are still expected to provide accurate reference materials and a workable detection method to the Community's Reference Laboratory, in accordance with the provisions of Regulation 258/97 and Article 32 of Regulation 1829/2003.[214]

211. Pending applications for new authorizations can also be viewed at gmoinfo.jrc.it/gmc_browse.asp, with the possibility for the public to submit comments pursuant to Arts. 9 and 24 of Directive 2001/18. Of those pending applications, 21 applications are for placing of GMOs on the market under Part C of the Directive; 68 applications for deliberate release of plants for experimental or field trials; and 4 applications for deliberate release of organisms other than plants for experimental trials. The last two categories of applications have been submitted under Part B of the Directive.

212. Pursuant to Art. 46(1) of Regulation 1829/2003, applications for the authorization of a GM food made under Regulation 258/97 which have received a final risk assessment before the coming into application of Regulation 1829/2003 are still to be processed under the former, notwithstanding Art. 38 of Regulation 1829/2003.

213. See Sheridan, *supra* note 59, p. 152–163.

214. See Joint Research Centre, Action programme No. 1211, available at projects.jrc.cec.eu.int.

In connection to the status of authorizations under Regulation 258/97, it should also be noted that there have been fourteen notifications made under Article 5 of the Regulation for placing products on the market as substantially equivalent. They involve processed foods derived from *inter alia* seven GM oilseed rape, four GM maize and two oil from GM cottonseeds. Finally, there are two GMOs that can already be marketed legally as food in the Community: one GM soy and one GM maize, both approved under Directive 90/220/EEC prior to the entering into force of Regulation 258/97. So in total products from sixteen GMOs can legally be marketed under the novel foods Regulation in the Community until today.

It should also be mentioned that during the period 1997–2001, some Member States have invoked the safeguard clauses provided for in Article 16 of Directive 90/220 and in Article 12 of Regulation 258/97. Article 16 of Directive 90/220 has been invoked on nine separate occasions: three times by Austria, twice by France, and once by Germany, Luxembourg, Greece and the UK.[215] Article 12 of Regulation 258/97 has been invoked only once by Italy in 2000 with regard to food products derived from four varieties of GM maize.[216] The scientific evidence provided as justification by the Member States, in terms of risk to human health or the environment, which was not considered as part of the evidence examined at the time of their original authorization, was submitted to the relevant scientific committees advising the Commission for opinion. It seems that for all of the above safeguard cases, the scientific committees operating at Community level deemed that the new evidence provided was not considered to impact on their original risk assessment.[217]

215. The invocation of safeguards concerns marketing authorizations granted in the period 1996–1998. The reasons advanced by the Member States in almost all cases to justify the safeguard measure relate to potential adverse effects on the environment, human health and on agriculture (pollination problems). Some of them also refer to possible toxic effects on non-target species, including the monarch butterfly. Some of the measures do not prohibit the marketing, but simply require clear isolation from non-GM crops. A most recent study by the UK authorities appears to confirm a number of these adverse effects. See The Royal Society, "The farm scale evaluation of spring-sown genetically modified crops", 358 Phil. Trans. R. Soc. Lond. (2003), 1775–1913 available at www.pubs.royalsoc.ac.uk/phil_bio/news/fse_toc.html.

216. See Commission Decisions 98/292/EC, 98/293/EC, 98/294/EC, and 98/291/EC of 22 April 1998, O.J. 1998, L 131/26–31. This Italian measure gave rise to a reference for a preliminary ruling by an Italian court in *Monsanto*, *supra* note 55, in which Italy advanced as justification potential health problems from the presence of traces of DNA and GM protein, as well as the appropriateness of applying the simplified procedure and the concept of substantial equivalence in such cases.

217. See Commission, Questions and Answers, *supra* note 10, MEMO/03/196, Brussels. But see now the above-mentioned UK studies published in October 2003 by the UK Royal Society, which some consider to relaunch the scientific debate on these issues. Moreover, the

Some of the applicants and certain trade partners of the Community, in particular the USA, Canada and Argentina, claim that the Community authorization system has been excessively long. Some of the applicant companies also claim informally that the Commission and the Council have failed to observe strictly and pursue with the required speed the authorization procedures. It is noteworthy, however, that until today no direct action for failure to act or for damages, in violation of the applicable Community rules, has been brought against the Commission or the Council before the Community courts or the courts of the Member States.[218]

The alleged undue delays, if such delays exist in any of the above cases, could conceivably arise in three different contexts. First, when there is undue delay in the observance of the time limits laid down in Directive 2001/18 and Regulation 258/97 in the handling of the applications by the Member States or in the observance by the Member states of a final favourable decision taken at Community level to grant the marketing authorization. Second, when there is undue delay in the observance of the regulatory committee procedures by the Commission or the Council, especially in cases where the products in question have received the favourable opinion of the relevant Community scientific committees. Third, when there is undue delay in the observance by the Commission of the procedures laid down in case of national safeguard measures, especially for not submitting in time a proposal to the regulatory committee or to the Council, when the grounds invoked to justify the national safeguard measures have been examined and rejected by the relevant Community scientific committees. Therefore, claims about such "undue" delays may relate to either the risk assessment or the risk management phases in the handling of the applications for authorization of GMOs or GM products.

At the *risk assessment* phase, when the responsible national or Community authorities require additional information or scientific evidence and data from the applicant companies, the time limits laid down in the relevant pro-

preliminary results of another study by the European Science and Technology Observatory concerning a number of risk assessments for different products (including GMOs) appear to confirm that significantly more evidence would be required to change policy than to continue with the existing policy, irrespective of the initial direction of those policies. This kind of "policy inertia" seems to be more likely when scientists examine a study showing positive finding of evidence of risk, than a study indicating no evidence of risk, possibly out of a desire to avoid false positive findings, as explained earlier. See European Science and Technology Observatory, *Science in trade disputes related to potential risks: comparative case studies*, Joint Research Centre, Technical Report Series (Wolf, Ibarreta and Sorup (Eds.)), draft 2003.

218. With the exception of the two actions brought before the French and Italian courts that led to *Association Greenpeace France*, *supra* note 136, and *Monsanto*, *supra* note 55.

visions are suspended until effective submission of the information requested.[219] Any delay in the authorization procedure is, therefore, legally justifiable, and this is apparently the situation for nearly all of the pending applications under both Directive 2001/18 (and its predecessor Directive 90/220) and of Regulation 258/97. Therefore, the legal claim of observing or applying delays that are "undue", or the so-called *de facto moratorium*, should be confined essentially to the very few instances at the risk management stage, where the claim is that the regulatory committee procedure is not initiated by the Commission with the appropriate speed or is not pursued before the Council to its end quickly.[220] This specific issue, as described above, is examined in the following sub-section from a more general standpoint of risk governance in Community law.

4.4. *The interplay of scientific complexity, political sensitivity and reasonableness of regulatory action*

Article 18(1) of Directive 2001/18 provides that in case of objections raised and maintained by a Member State or the Commission, in accordance with Articles 15, 17 and 20 thereof, a decision on the authorization "shall be adopted and published within 120 days in accordance with the procedure laid down in Article 30(2)." Article 30(2) of Directive 2001/18 lays down the applicable comitology procedure. The applicable committee is the regulatory committee provided for in Article 5 of Council Decision 1999/468/EC. The corresponding provisions in Regulation 258/97 are Articles 7(1) and 13, respectively.

As the final decision on an application for an authorization will have to be taken within 120 days from the date the objections had been raised and maintained, the Commission should submit the proposal to the regulatory committee soon after receiving them.[221] Article 5(4) of Decision 1999/468 provides that if the management measures proposed by the Commission to be adopted are not in accordance with the opinion of the regulatory commit-

219. See Art. 18(1) of Directive 2001/18.

220. Indeed, with their 7 Aug. 2003 request to the WTO for the establishment of a panel, the USA, Canada and Argentina claim to have identified a number of cases where they allege that undue delays have occurred in the handling of the applications for authorization of GMOs and GM products by the Community and its Member States. As already explained, the Community has approved in total about 34 GM products out of more than 100 applications submitted for *all* kind of authorizations so far, and several of these approved GMOs and GM products are already on the market of the Member States.

221. However, according to Art. 18(1) of Directive 2001/18, the period of time the Council takes to act in the comitology procedure will not be taken into account.

tee or if that committee delivers no opinion, the Commission "shall, *without delay*, submit to the Council a proposal relating to the measures to be taken and shall inform the European Parliament."[222] Article 5(6) of Decision 1999/468 on comitology states that the Council is in that case to act within three months. If on expiry of this three-month period the Council has "neither adopted the proposed implementing act nor indicated its opposition to the proposal for implementing measures, the proposed implementing act shall be adopted by the Commission."[223]

Therefore, for the purposes of our analysis of the so-called *de facto moratorium* it is appropriate to posit the worst-case scenario, that is when either the Commission's first proposal to the regulatory committee had received a negative opinion or no opinion is delivered at all by it within the set time limit. The Commission is then required to make a proposal to the Council "*without delay*". It is also interesting to examine the situation where, at the end of the three-month period, the Council had neither adopted the Commission proposal nor had indicated its opposition to it. Pursuant to Article 5 of Decision 1999/468, the Commission then "*shall adopt*" the implementing measures. Indeed, there may be a few (one or two) such GMO pending applications that could fall within this category and it is, hence, important to examine the precise meaning to be given to the terms "without delay" and "shall adopt", and what is exactly the nature of the Commission's and the Council's obligations and within what time frame do they have to act. These issues will be examined in turn.

According to established case law, in interpreting a provision of Community law, like the terms "without delay", it is necessary to consider the wording of the provision in the appropriate context and take into account its aim.[224] A case in point is the judgment in the *Pharos* case, which concerned a failure to act on an application to set a maximum residue limit for the recombinant somatotrophin (rBST) – a bio-engineered hormonal substance that is meant to increase milk production – in the context of Regulation

222. It is clear that in such a case, once the Commission has proposed to the Council the measures to be taken, the Council regains its full legislative powers, including the right to amend the Commission's proposal by unanimous decision. See e.g. Case C-151/98P, *Pharos SA* v. *Commission*, [1999] ECR I-8159, at para 22.

223. The Council may of course by qualified majority adopt the proposal, or by qualified majority indicate that it opposes the proposal, in which case the Commission should re-examine it. The Commission may then re-submit it, submit an amended proposal, or present a legislative proposal based on the EC Treaty.

224. *Pharos*, *supra* note 222, para 19; Case 337/82, *St. Nikolaus Brennerei* [1984] ECR 1051, at para 10; and Case C-84/95, *Bosphorus* [1996] ECR I-3953, at para 11.

2377/90.[225] This Regulation has a structure and contains time limits that are similar to those laid down in Directive 2001/18. As the first Commission proposal failed to receive the favourable opinion of the regulatory committee, the Commission sought a second opinion from the relevant scientific committee and took some time pondering on the risk management options available. The Court recognized that the words "without delay", whilst requiring the Commission to act swiftly, did allow the Commission "a certain degree of latitude". According to the Court, this means that where the Commission is confronted with a matter, which is *highly complex and sensitive*, the Commission has the right to seek a further opinion from the relevant scientific committee, even though there was no express mention of this possibility in the Regulation at issue there. Accordingly, the amount of time that the Commission has to consider the various courses of action open to it must be appraised in the light of the complexity and sensitivity of the matter concerned. In the circumstances of the *Pharos* case, "a period of 11 months during which the Commission initially considered the file for six months and then sought a second scientific opinion, cannot be considered to be an excessively long period."[226] This approach was confirmed in the *Bergaderm* case, where the Court stated that in "delicate and controversial cases" the Commission had to be accorded "a sufficiently broad discretion and enough time".[227] The underlying rationale in the above case law is also reflected in the statement which the Commission made concerning Article 5 when Council Decision 1999/468 on comitology was adopted, according to which: "In the review of proposals for implementing measures concerning particularly sensitive sectors, the Commission, in order to find a balanced solution, will act in such a way as to avoid going against any predominant position which might emerge within the Council against the appropriateness of an implementing measure."[228]

However, it can be argued that neither the exercise of the margin of discretion available to risk managers nor the time span for taking a decision should

225. Council Regulation (EEC) No 2377/90, of 26 June 1990, laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin, O.J. 1990, L 22/1.

226. See *Pharos*, *supra* note 222, at para 32.

227. See Case C-352/98P, *Bergaderm,* [2000] ECR I-5291, at para 66.

228. O.J. 1999, C 203/1. This is also in line with previous case law which established that the Commission is allowed, in its management functions, to take the time necessary to find a solution that would be acceptable even to Member States that voted against its proposal in the management committee, even though the Commission had the right to adopt the measures immediately. See Case C-244/95, *P. Moskof AE* v. *Ethnikos Organismos Kapnou*, [1997] ECR I-6441, at paras. 33–39.

be unreasonable or abusive. As the Court of Justice clarified in the *France* v. *Monsanto* case,[229] the Commission is required to observe the principle of sound administration[230] and the duty of care, after having weighed the interests of all the parties concerned.

There is little doubt that all the applications for the authorization of GMOs and GM products appear to raise scientifically complex, delicate and controversial issues. The question, therefore, that should be considered next, always within this worst case scenario posited before, is how much time should the Commission or the Council have to reflect and prepare their implementing act so as to be found to be still acting "within a reasonable period of time".

There are other fields of Community law where the Community courts have applied in a number of cases the principle that the Commission must act within a reasonable time.[231] In its recent judgment on the appeals in the *PVC II* cases,[232] the Court found that it was appropriate to examine the reasonableness of the period taken by reference to an examination in different stages, where each of those stages had its own internal logic.[233] One element that can influence an assessment whether the Commission's behaviour is un-

229. Case C-248/99P, *French Republic* v. *Monsanto*, [2002] ECR I-1, at para 92.

230. On the principle of sound or good administration, see Art. 41 of the Charter of Fundamental Rights of the European Union, O.J. 2000, C 364/1, and Art. 6(2) TEU. See also Nehl, *Principles of Administrative Procedure in EC Law* (Hart Publishing, Oxford, 1999).

231. Case C-282/95P, *Guérin Automobiles* v. *Commission*, [1997] ECR I-1503, para 38; Case 120/73, *Lorenz* v. *Germany*, [1973] ECR 1471, para 4; Case 223/85, *RSV* v. *Commission*, [1987] ECR 4617, paras. 12–17; Joined Cases T-213/95 & T-18/96, *SCK* [1997] ECR II-1739; Case T-228/97, *Irish Sugar* v. *Commission*, [1999] ECR II-2969 (holding that the question whether the duration of an administrative proceeding is reasonable must be determined in relation to the particular circumstances of each case and, in particular, its context, the various procedural stages followed by the Commission, the conduct of the parties in the course of the procedure and the complexity of the case).

232. See Joined Cases C-238/99P, *Limburgse Vinyl Maatschappij NV (LVM) et al*, [2002] ECR I-8375.

233. Moreover, the Court held that the reasonableness of the period should be appraised in the light of the circumstances specific to each case and, in particular, the importance of the case for the person concerned, its complexity, and the conduct of the applicant and of the competent authorities. The complexity of the case or the dilatory conduct of the applicant may be deemed to justify a duration which is *prima facie* too long. Conversely, the time taken may be regarded as longer than is reasonable in the light of just one criterion, in particular, where it is the result of the conduct of the competent authorities. As to the question whether there was a precise yardstick by which reasonableness could be assessed, the Court found that it could not be assessed by reference to a precise maximum limit determined in an abstract manner, but instead in the light of the specific circumstances of each case. An initial general examination should be carried out to determine whether the period in question is *prima facie* too long. If it is so found, examination that is more specific is required as to whether there have been actual delays that cannot be justified by the circumstances of the case.

reasonable, or to put it another way, whether the Commission has had enough time to deal with the issue, is whether the Commission has been waiting until it is "fully informed" on the matter in question.[234] Therefore, it appears that the requirement to deal with matters within a reasonable time is but one element of the overall principle to act without undue delay and needs to be interpreted in the light of the other elements of the case at hand. For example, the principle should not be misapplied so as to result in decisions being taken prematurely, that is before the Commission is satisfied that it is in possession of all the necessary elements, for that in itself would infringe the principle of sound administration.

It follows from the judgment in the *Dieckmann* case,[235] that the Court was careful in assessing whether the Commission had infringed the principle of sound administration to take account not only of the individual interests of the trader concerned but also the wider public interests, such as the protection of consumers or the protection of the health and life of humans. In that regard, the CFI noted that the protection of public health should be accorded precedence over economic considerations. That these wider public health responsibilities exist and need to be taken into consideration in assessing the lawfulness of the Commission's conduct is also apparent from the *Denkavit*[236] judgment. The weighing of interests may even include those of the Commission itself.[237]

A preliminary conclusion on this point, therefore, would suggest that one of the constituent parts of the principle of sound administration in Community law is that the Commission should act within a reasonable time and with

234. In *Denkavit,* the Commission waited 21 months before adopting a decision requiring Italy to withdraw a safeguard measure. But the circumstances of that case (a lengthy delay whilst awaiting the definitive scientific position, together with ambiguity in the position of the Standing Committee) meant that "[t]he Commission cannot be blamed for having waited until it was fully informed before adopting a decision on a matter as complex as the presence in feeding-stuffs of substances which might prove to be undesirable from the point of view of human or animal health." See Case 14/78, *Denkavit*, [1978] ECR 2497. In *Usinor*, the delay was not considered excessive, where one of the factors affecting it was the need to carry out a thorough study of actual market trends. See Case 103/83, *Usinor*, [1984] ECR 3483, at para 14. Likewise, in the *Sonasa* case, the Court refrained from criticizing the Commission for infringing the principle of sound administration where it was obliged to await the outcome of an audit. See Case T-126/97, *Sonasa*, [1999] ECR II-2793.

235. See Case T-155/99, *Dieckmann*, [2001] ECR II-3143, at para 76.

236. Case 14/78, *supra* note 234, paras. 23 and 24.

237. See para 92 of the judgment in Case C-248/99P, *Monsanto*, *supra* note 229. The Court recognized the interest of the Commission in not having to follow a highly burdensome decision-making procedure involving reference to the Regulatory Committee, in circumstances where no marketing authorization could yet be issued.

due diligence.[238] It is clear from *PVC II* that an assessment whether the duration of an administrative proceeding is reasonable must be made in relation to the different procedural stages involved, each with its own internal logic. In other words, there is an internal logic to treating the risk assessment stage separately from the risk management stage. This distinction is important in assessing the time it took it to act as a risk manager, where it was either awaiting the outcome of the risk assessment or when it found itself confronted with conflicting scientific advice from various sources at the management stage. However, the Commission is not only entitled but also clearly required, and this is in line with the requirements of the principle of sound administration, to wait until it is in possession of the necessary scientific information from the various risk assessments from credible and reliable sources, both national, Community and international, that could clarify and possibly remove the identified scientific uncertainty. It is also not unreasonable to recognize that, having received the clarification, the Commission should still be given a reasonable period to consider it in the management stage of the decision-making process, always taking into account the circumstances of the case at hand.[239]

Another important point to take into account is that the complexity and sensitivity of each specific case can also affect the scope of judicial review. In the *Norbrook* case the Court of Justice held that:

> "In a sphere in which the Community legislature is called on to undertake complex assessments based on technical and scientific information which is liable to change rapidly, judicial review of the exercise of its powers must be limited to examining whether it has been vitiated by a manifest error of assessment or a misuse of powers or whether the legislature has manifestly exceeded the limits of its discretion."[240]

238. See e.g. Case T-231/97, *Michael P Brown* v. *Commission*, [1999] ECR II-2403. See also the recent judgment of the CFI in Joined Cases T-344/00, *CEVA* v. *Commission*, and T-345/00, *Pharmacia* v. *Commission*, judgment of 26 Feb. 2003, nyr.

239. Of course, *ex post facto* and with the benefit of hindsight, it might be concluded that one risk management approach as opposed to another might have offered a speedier way of resolving the issues on the pending applications. However, for the purposes of assessing compliance with the principle of sound administration, it is the management choices, as they appeared reasonable to the Commission *at the time* it had to make the decisions, which are relevant. See e.g. *Upjohn*, *supra* note 96, at para 34; and Case C-471/00P(R), *Anorectics*, [2001] ECR I-2865, at para 96.

240. Case C-127/95, *Norbrook Laboratories Ltd* v. *Ministry of Agriculture, Fisheries and Food*, [1998] ECR I-1531, at para 90. See also Case C-84/94, *UK* v. *Council*, [1996] ECR I-5755, at para 58.

Equally, in the implementation of legislation, the Court of First Instance held in the *Pfizer* case that the Community judicature "is not entitled to substitute its assessment of the facts for that of the Community institutions".[241] In particular in the area of public health, the Court held in the *Fedesa* case that any measure adopted by the Community institutions should be founded on "a rational and objective basis".[242] Such a basis would be found to exist when divergent scientific and regulatory appraisals are made by the national authorities and when concerns have been expressed by consumers and the public or other Community institutions, even if the restrictive measure is not based "on scientific data alone".[243] Also, the Court held that "under the precautionary principle, the Community institutions are entitled to adopt, on the basis of as yet incomplete scientific knowledge, protective measures which may seriously harm legally protected positions, and they enjoy a broad discretion in that regard".[244]

Furthermore, the Court clarified that measures prohibiting the marketing of certain antibiotics in farming to protect public health were lawful under Community law because "the restoration of consumer confidence can in such circumstances also be an important objective which may justify even substantial economic consequences for certain traders".[245] Finally, the Court held that the rationality of the restrictive measure put in place is not affected even if causal relationship between the risk and harm is not clearly established, by holding 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 become fully apparent".[246]

4.5. *The developing approach to regulating risk from placing GMOs and GM products on the market and transitional justice*

It is now possible to draw some general conclusions about the dynamics of risk regulation of GMOs and GM products in the Community, the attitude of

241. See Case T-13/99, *Pfizer*, *supra* note 28, at para 169. The Court also held that "where a Community authority is required to make complex assessments in the performance of its duties, its discretion also applies, to some extent, to the establishment of the factual basis of its actions", at para 168.

242. See e.g. Case C-331/88, *The Queen* v. *Minister of Agriculture, Fisheris and Food and Secretary of State for Health, ex parte Fedesa and others*, [1990] ECR I-4023, at para 8.

243. Case C-331/88, *supra* note 242, at paras. 9–10.

244. Case T-13/99, *supra* note 28, at para 170.

245. Case T-13/99, *supra* note 28, at para 462.

246. See Case C-180/96, *UK* v. *Commission*, [1998] ECR I-2265, at para 99.

the relevant risk management institutions and the nature and extent of judicial review.

It is generally accepted that defining the level of acceptable risk is a normative decision that belongs to the democratically elected and accountable institutions of a State.[247] Regulation of risk entails making important decisions about how much health and safety people wish and can afford. As this touches upon the basic functions and mission of a democratic system of government, that is to protect *inter alia* the life and health of its people and the environment, decisions about the level of acceptable risk cannot be made only by unaccountable scientific or some other kinds of experts.[248] It follows that in any democratic system of government consumers and the electorate must have an opportunity to express their views, directly or indirectly, on the final decision about which risks they could bear and which benefits they wish to try to obtain. In such a democratic governance of risk, judicial review cannot and should not second-guess Community or national regulatory choices.[249]

Past experience has shown that there are risks that can be caused by multiple, synergistic and confounding factors that sometimes take time to materialize. This poses serious problems for regulatory authorities because it makes causality between authorization of the product and possible harm difficult to establish. For those reasons, lack of evidence in establishing a direct causal link between an activity, process or substance and an identified risk should normally not preclude the adoption of precautionary measures after careful consideration and proper balancing of the values at stake. In view of the deliberative and frequently complex nature of such decisions, their adoption may require considerable time. On the other hand, allowing fears from pure ignorance and indeterminacy or ambiguity about risk to guide any regu-

247. See Case T-13/99, *Pfizer*, *supra* note 28, at paras. 151–152. E.g. in the context of international trade it is accepted that defining the acceptable level of risk is the sovereign or autonomous right or prerogative of each state. See the WTO Appellate Body report in *Hormones* case, *supra* note 170, at para 172; and the Appellate Body report in *Australia – Measures Affecting Importation of Salmon* ("*Australia Salmon*"), WT/DS18/AB/R, adopted 6 Nov. 1998, at para 199.

248. Case T-13/99, *Pfizer*, *supra* note 28, at para 201.

249. See e.g. Gerstenberg and Sabel, "Directly-deliberative polyarchy – An institutional ideal for Europe", in Joerges and Dehousse, op. cit. *supra* note 141, p. 289–341; Poiares Maduro, *We, the Court: the European Court of Justice and the European Economic Constitution* (Hart Publishing, Oxford, 1998), pp. 166, 173. For a similar argument in relation to standard setting in international trade, see Sykes, *Product Standards for Internationally Integrated Goods Markets* (The Brookings Institution, Washington, D.C., 1995).

lation may, if pursued inflexibly, halt technological progress and impose heavy regulatory and budgetary burdens.

It is important to note that the European societies tend in general to be risk-averse. So, they are reluctant to trade a chosen high level of health protection for some uncertain future potential benefit. As a general rule, people and regulatory authorities normally pursue policies that seek to avoid risk to health or the environment unless this becomes clearly a burden too high for them or their society to bear. Pursuing zero risk policies, therefore, is not uncommon in Europe in the area of food law and environmental protection or in many other legal systems. The right to choose a zero level of risk to human health from a particular substance, process or activity that has been found to be potentially harmful has been upheld explicitly both by national and international courts and tribunals.[250]

Equally, the fact that in our technologically complex societies there are multiple sources of risk, including risks to which people voluntarily expose themselves, does not cancel out the legitimate objective to aim, whenever possible, for a zero risk level of health or environmental protection.[251] In addition, the fact that subsequent implementation and enforcement measures cannot always eliminate risk is not as such a reason to refrain from aiming for a zero risk policy. Pursuing a zero risk level of protection, therefore, is not always synonymous with effectively achieving no risk, but with trying to minimize as much as possible an identified risk.[252]

250. See e.g. the WTO Appellate Body report in *Australia Salmon*, *supra*, note 247, at para 125. In the US legal system, this has been explained very pertinently in the Statement for Administrative Action for the WTO Agreements as follows: "The SPS Agreement thus explicitly affirms the right of each government to choose its level of protection, including a 'zero risk' level if it so chooses. A government may establish its levels of protection by any means available under its law, including by referendum. In the end, the choice of the appropriate level of protection is a societal value judgment. The Agreement imposes no requirement to establish a scientific basis for the chosen level of protection because the choice is not a scientific judgement". See *US Statement of Administrative Action for WTO/SPS Agreements (1994):* 103d Congress, 2d Session, H.D. 103–316, p. 745 (27.9.1994).

251. See e.g. Geistfeld, "Implementing the precautionary principle", 31 ELR News & Analysis (2001), 11326.

252. Community law has been applying a zero risk policy in many areas. See e.g. Case C-121/00, *Walter Hahn*, [2002] ECR I-9193, at para 47. Frequently commentators and even the courts state that "'zero risk' does not exist" (e.g. Case T-13/99, *Pfizer*, *supra* note 28, at para 145). It is not clear what the real meaning of such statements is, since national, Community and international law clearly accept that States may set and pursue a zero level of risk as their appropriate level of health or environmental protection. The confusion appears to stem from the fact that the concept of "uncertainty" comprises different and distinct components, the taxonomy of which includes lack of full evidence, inconclusive or contradictory evidence, indeterminacy or ambiguity and ignorance. Uncertainty about the existence or extent of an iden-

It is generally accepted that scientific uncertainty exists when the evidence available is incomplete, inconclusive or conflicting, that is from lack of knowledge or a state of controversy on existing data or lack of some relevant data that render problematic an estimation of the possible adverse effects on health or the environment.[253] It should also be borne in mind that the Court of Justice has held that "in the light of the uncertainty inherent in assessing the public health risks posed by, *inter alia*, the use of food additives, divergent assessments of those risks can legitimately be made, without necessarily being based on new or different scientific evidence."[254] But dealing with scientific uncertainty becomes an issue when it is institutionalized in a democratic decision-making process, because regulators and judges are obliged to make decisions, sometimes within short time limits, even when the scientific evidence in a risk assessment is inconclusive.[255] As already explained, however, the judicial review, in solving a specific legal dispute, only examines whether the authorities have not used in an arbitrary and unjustifiable manner their regulatory discretion, because the courts are not required nor of course are they epistemically capable of resolving the underlying basis of scientific uncertainty.[256] On the other hand, the regulatory authorities' main cause of concern is the potential effects on health and the environment from uncertainty and risk. The difficult decision to make on the acceptability

tified risk can be, however, the object of a restrictive measure in Community law based on the precautionary principle, when a zero risk level of protection is lawfully established and pursued. Conversely, Community law, like many other jurisdictions, does not accept purely theoretical or hypothetical risk, that is perceived risk based on pure ignorance in the risk assessment. See e.g. the judgment in Case C-236/01, *Monsanto*, *supra* note 55, at para 106. See also the WTO Appellate Body report in the *Hormones* case, *supra* note 170, at para 186.

253. See e.g. Commission Communication on the Precautionary Principle, COM(2000)1, *supra* note 34, at para 5.1.3. See also Case T-13/99, *Pfizer*, *supra* note 28, at para 393, and Case C-192/01, *Commission* v. *Denmark*, *supra* note 173, para 52.

254. See Case C-3/00, *Denmark* v. *Commission*, [2003] ECR I-2643, at para 63. See also the judgment in *Toolex*, *supra* note 151, paras. 42–45. It follows that it is of paramount importance for risk assessors to explain in detail any kind of scientific uncertainty they encounter in every step of their analysis and the techniques, assumptions and values they employ to eliminate or reduce it. See Johnson and Slovic, "Presenting uncertainty in health risk assessment: initial studies of its effects on risk perception and trust", 15 *Risk Analysis* (1995), 485.

255. See e.g. Cotterrell, *The Sociology of Law – An Introduction*, 2nd ed. (Butterworths, 1992), p. 51, citing also Levy-Bruhl, *La preuve judiciaire: Etude de la sociologie juridique* (Riviere, Paris, 1964), p. 150–152.

256. See Joined Cases T-74/00 et seq., *Artegodan*, supra, at paras. 199–201. See also Brewer, "Scientific expert testimony and intellectual due process", 107 Yale L. J. (1998), 1535; Jasanoff, *Science at the Bar – Law, Science, and Technology in America* (Harvard University Press, Cambridge, 1995), p. 42–68; and Christoforou, op. cit. *supra* note 141, p. 260–261.

of the identified risk, therefore, must rest ultimately with the regulatory authorities that are accountable to the people, not the courts or the experts alone.[257]

As already explained in section 2 above, the objective of Community legislation in the area of GMOs and GM products is to achieve a "high level" of health or environmental protection and to give consumers real freedom of choice in the market place. One of the means of achieving these objectives when taking implementing measures has been to base the measures or actions on the precautionary principle. This requires that appropriate consideration be given to the interaction between the level of acceptable risk and lack of concluding evidence on risk and causality. It is in this interaction that the precautionary principle functions as a catalyst by enabling the regulatory authorities to err on the side of caution in order to achieve the chosen or desired level of health or environmental protection. It is well known that both risk assessors and risk managers attribute at any given moment in time different subjective values to available scientific data, the risks and the nature of possible adverse effects. Precaution applied by scientists in a risk assessment does not, therefore, eliminate the need to also allow risk managers to apply precaution to the same agent, activity or process when taking regulatory action.[258] Risk assessors' technical precaution, when modelling and interpreting evidence and data, is therefore distinguishable from the risk managers' regulatory precaution, when taking normative regulatory action.[259] Therefore, the precautionary principle in the Community legal system, in particular in the area of GMOs and GM products, plays an important role both for the relevant regulatory authorities and all the potentially affected stakeholders.[260]

257. See e.g. Giddens, *Runaway World – How Globalization is Reshaping our Lives* (Profile Books, London, 2002), p. 20–35.

258. See e.g. Directive 2001/18, Annex II, B., which refers explicitly to the precautionary principle when conducting an environmental risk assessment.

259. It should be recalled that several Member States when discussing in the Council issues concerning the authorization of GMOs and the adoption of new or the revision of existing legislation in this area have invoked explicitly the precautionary principle as a basis of their action. See e.g. the declarations in the 2194 Council meeting, Environment, Luxembourg, 24/25 June 1999; and the statements in the Council on the adoption of Directive 2001/18, doc. 6068/01 ADD 1 REV 2, of 16 Feb. 2001.

260. This is because it provides the means to the regulated or potentially affected natural or legal persons to control, if necessary by means of action before the courts, the way risk management institutions make their normative decisions when evaluating scientific uncertainty and risk, as well as in the way they balance costs and benefits. This entails both *ex ante* and *ex post* control of measures taken to regulate risk. See e.g. Breyer and Heyvaert, *Institutions for Regulating Risk*, *supra* note 183, p. 283–352 (2000). See also Scott and Vos, "The juridification of

As the right to life and health[261] is the most fundamental of all human rights, this implies that no restriction should in principle be placed on this right without proper consideration.[262] Indeed, as a matter of principle and reasons of justice, fairness and morality militate against a balancing exercise based on broad considerations of cost and efficient allocation of resources.[263]

In conclusion on this point, Community law recognizes that in the balancing of interests in the risk management phase, considerations of health take precedence over economic or commercial considerations.[264] There is no general guideline in Community law that obliges the regulatory authorities to analyse systematically the economic impact or cost of risk management measures. However, the regulatory authorities sometimes make, consciously or unconsciously, gross estimates of first level, direct cost and benefits analysis of their decisions, despite the difficulties inherent in such an exercise because of the scientific uncertainty involved. For those reasons, considerations of the level of economic impact or cost from adopting a future

uncertainty: Observations on the ambivalence of the precautionary principle within the EU and the WTO", in Joerges and Dehouse, op. cit. *supra* note 141, p. 253–286; and Fisher, "Precaution, precaution everywhere: Developing a 'Common Understanding' of the precautionary principle in the European Community, 9 MJ (2002), 1.

261. The concept of health is defined in the constitution of the WHO as "a state of complete physical, mental and social well-being that does not consist only in the absence of illness or infirmity". The ECJ referred explicitly to the above definition and concluded that a broad interpretation should be given accordingly to the concept of health in EC law. See Case C-84/94, *UK* v. *Council*, [1996] ECR 5755, at para 15.

262. See Arts. 35 and 37 of the EU Charter on Fundamental Rights, O.J. 2000, C 364/1, and Art. 6(2) TEU. See also Toebes, "The Right to Health", in Eide, Krause and Rosas, *Economic, Social and Cultural Rights*, 2nd. ed. (2001, Nijhoff) pp. 169–190; and Committee on Economic, Social and Cultural Rights, General Comment No. 14: "Right to the highest attainable standard of health" (Art. 12 of the International Covenant on Economic, Social and Cultural Rights), adopted on 11 May 2000, 22nd Session (2000), UN Doc. E/C.12/2000/4, 8 IHRR 1 (2001). As regards in particular the relationship between human rights and the protection of the environment, see Handl, "Human Rights and the Protection of the Environment", in Eide et al., *supra*, pp. 303–328.

263. See e.g. Anderson, *Value in Ethics and Economics* (Harvard University Press, Cambridge, 1993), p. 210–213. See also Geistfeld, *supra* note 251. It is important to note that European consumers normally expect more positive and proactive intervention by state authorities in the regulation of risk than is for example the situation in the USA. See e.g. Vogel, op. cit. *supra* note 199.

264. See e.g. Order in Case C-180/96R, *UK* v. *Commission*, [1996] ECR I-3903, at para 93; Order in Case C-76/96R, *Farmers' Union*, [1996] ECR I-3903, at para 105; Case C-183/95, *Affish*, [1997] ECR I-4315, at para 43; Order in Case T-136/95R, *Industria del Frio Auxiliar Conservera* v. *Commission*, [1998] ECR II-3301, at para 58; Orders in Case T-13/99R, *Pfizer* [1999] ECR II-1961, at para 171, and in Case T-70/99R, *Alpharma* [1999] ECR II-2027, at para 152.

precautionary action do not appear to play a decisive role in the determination whether to adopt a measure, but only in the actual choice or design of the measure to be taken and the acceptable level of risk. In the Community legal order, it is the principle of proportionality and the obligation to give reasons that are used to check the balance between the health or environmental objective pursued and the restrictive effects of the precautionary measure.[265] They require risk management decisions, once their enactment is in principle decided, to be tailored to the chosen level of health or environmental protection and explain adequately the rationale on which they are based in order to allow effective judicial review.[266]

Given the rapidly and substantially changing national, Community and international regulatory framework, and taking also into account the ethical and other societal concerns and the undisputed complexity in regulating modern biotechnology, the questions that courts will have to answer, if they were ever to judge regulatory and administrative choices in this area, is whether justice can be more contextualized in extraordinary periods of political and ethical transition and upheaval,[267] as well as in situations of near civil unrest and disobedience.[268]

In conclusion, it can be argued from a broader institutional point of view that health and safety protection is a goal choice of primary importance, whereas strict law enforcement is a public policy choice. Ethical and moral considerations are also important goal choices. The institutional choice to pursue all these choices at the same time is a complex decision that requires effective co-operation in the political and regulatory process, the market pro-

265. See e.g. Case T-13/99, *Pfizer*, *supra* note 28, at para 410.

266. The ECJ draws the distinction between the obligation to give reasons and the judicial review of the substantive legality of a measure with Community law. See e.g. Case C-265/97P, *VBA* v. *Commission*, [2000] ECR I-2061, at para 114. The most important of the grounds to review the substantive legality of a measure are manifest error of appraisal, misuse of power and violation of the principle of proportionality. See e.g. Case C-157/96, *The Queen* v. *Ministry of Agriculture* (*BSE*), [1998] ECR I-2211, at para 60; Case C-331/88, *Fedesa and others*, *supra* note 242, para 13; and Joined Cases C-133, 300 & 362/93, *Crispoltoni*, [1994] ECR I-4863, at para 41.

267. See e.g. Teitel, *Transitional Justice* (OUP, 2000), arguing that in periods of transitional jurisprudence the conception of justice is partial, contextual, and situated in between at least two legal and political orders; legal norms are decidedly multiple and the idea of justice can be a compromise.

268. See e.g. Rawls, *A Theory of Justice* (OUP, Rev. ed., 1999), p. 337–342, arguing that a civil disobedience action, although strictly speaking it may be contrary to law, is nevertheless a morally correct way of maintaining a constitutional regime, and that courts should take into account the justifiable nature of the action and interpret the applicable law accordingly. See also Dworkin, *Taking Rights Seriously* (Duckworth, London, 1987), p. 215–216, arguing that when the interpretation of the law is uncertain "the path of fairness lies in tolerance".

cess, including all its potentially affected stakeholders, and the adjudicative process.[269] However, if adjudication is seen as having rule-creating, rule-enforcing (deterrence) and compensatory functions, it may be questionable whether strict pursuance of deadlines in the administrative and adjudicative stages would be socially optimum and desirable, in the face of very strong public opposition to the rules whose enforcement is precisely under consideration.[270]

5. Conclusion

Questions about the use of modern biotechnology in agriculture are assuming, in today's context of global markets, important socio-economic dimensions. The public's perception of risk and theories about cultural, social and moral preferences point to substantial differences in risk cognition and consumer reaction to risk between the Member States and countries around the world. Different regulatory approaches about risk reflect also different national priorities about the economic importance of modern biotechnology, compared to other societal values and the ability of science to provide as clear answers as possible about potential harm from modern biotechnology.

The regulation of GMOs and GM products in the European Union has shown to be a daunting task. Its complexity is further increased by the federal structure of risk governance applied in the Community legal system. In the period between 1990 and 2003, the Community's policy on GMOs and GM products has been constantly evolving, in an attempt to follow consumer reaction to possible harm from modern biotechnology and the rapid advances in scientific research. At the same time, it has also been influencing as much as been trying to anticipate international regulatory change.

Broadly speaking, the Community's policy in this area has been driven by three policy goals. First, to lay down a comprehensive, coherent, science-based and, at the same time, precautionary regulatory framework dealing with almost all aspects of placing GMOs and GM products on the market and their deliberate release into the environment. Secondly, to respect free movement in the internal market whilst ensuring a very high level of health

269. See e.g. Komesar, *Imperfect Alternatives – Choosing Institutions in Law, Economics and Public Policy* (University of Chicago Press, 1994), highlighting the need for a complex comparative institutional analysis of goal and public policy choices.

270. See e.g. Habermas, *Between Facts and Norms – Contributions to a Discourse Theory of Law and Democracy* (Polity Press, Oxford, 1996), p. 315–328, arguing that those laws which may claim to have the agreement of citizens in a discursive process equally open to all possibly affected persons are legitimate.

and environmental protection. Thirdly, to balance the interests of the biotechnology industry with those of the consumers, but above all to win the confidence of the latter in the Community regulatory process. With the recent adoption of Directive 2001/18 on deliberate release of GMOs into the environment, and of Regulations 1829/2003 and 1830/2003 on GM food and feed and their traceability and labelling, respectively, the bones and most of the flesh of the Community's legislative framework is now in place.[271]

The success of its implementation and effective application, however, may very well depend on a number of conditions, such as the ability of the responsible national and Community institutions to demonstrate to all stakeholders involved that excellence, independence and transparency are applied, especially in the risk assessment as well as in the risk management and communication phases, and that other legitimate factors that seem to be so dear to consumers today are properly taken into account in the authorization process.

271. Some Member States, however, seem to require the adoption at Community level of binding rules on the co-existence of GM crops with conventional and organic farming, and specific rules on strict liability for environmental damage.