ARTICLES

THE REGULATION OF GENETICALLY MODIFIED FOODS IN THE EUROPEAN UNION: AN OVERVIEW

RUTH MACKENZIE*
SILVIA FRANCESCON**

INTRODUCTION

In December 1999, tensions in the European Union (E.U.) over the regulation of activities involving genetically modified organisms (GMOs) were amply illustrated by the apparent disagreement between the E.U. Trade Commissioner and the Member States at the World Trade Organization (WTO) Ministerial Meeting in Seattle. There, the Trade Commissioner apparently initially agreed bilaterally with the United States to the establishment of a Working Group on Biotechnology within the WTO, notwithstanding the E.U. position that issues related to international trade in GMOs should be addressed within the negotiations for a Biosafety Protocol under the Convention on Biological Diversity. The differences within the WTO and within the E.U. itself brought into sharp focus questions involving the proper scope of the regulation of biotechnology.

The 1993 European Commission *White Paper on Growth, Competitiveness and the Environment* highlighted biotechnology as "one of the most promising and crucial technologies for sustainable development in the next century."[1] The 1994 follow-up Communication, *Biotechnology and the White Paper on Growth, Competitiveness and Employment,* noted that biotechnology was a key for the future competitive development of the European Community and would determine the extent to which Commu-

* LL.M., University of London, B.Sc. (Economics), University of London; Programme Director, Foundation for International Environmental Law and Development (FIELD), University of London.

** Laurea (Jurisprudence) Ferrara University; LL.M. Candidate, University of London; Legal Intern, FIELD.

[1] White Paper on Growth, Competitiveness and the Environment: The Challenges and Ways Forward into the 21st Century, COM(93)700 final.

nity industries would remain world leaders in the development of innovative products.[2] Meeting in September 1994, E.U. Industry Ministers recognized the need to "reduce excessive constraints which weigh down European industry compared with its competitors on the world market," and called for changes to European rules regulating the use and release of genetically modified organisms.[3] For the biotechnology industry in Europe, product approval processes were one of the main causes of concern. Therefore, in the early 1990s, a gradual relaxation of existing Community laws on the use and release of GMOs seemed likely, with the prospect of more product-based rather than technology-based regulations.

However, while product legislation has indeed increased, in recent years, public opinion in the E.U. has begun to demand a tightening of the relevant legislation. Member States' concerns about the existence and extent of risks to the environment and human health posed by particular GMOs have further delayed product-marketing approvals under relevant E.U. laws. This shift in public opinion has sparked threats and expectations of a trade war with the United States over delays in processing marketing approvals for GMOs.[4] In 2000, the biotechnology industry remains frustrated by constraints placed on the marketing of its products in the E.U. Countries that have moved ahead with the exploitation of genetic modification technologies, notably the United States, have tended to see E.U. measures, and their application in practice, as thinly disguised protectionism. Within the E.U., by contrast, the European Commission has in some instances been seen as foisting genetically modified (GM) products onto unwilling consumers. Vigorous and effective public awareness campaigns have been conducted by non-governmental organizations in Europe.[5]

E.U. policy-makers have been faced with the challenge of developing and applying GMO legislation in light of continuing

---

[2] Biotechnology and the White Paper on Growth, Competitiveness and Employment, COM(94)219 final.

[3] *Biotechnology: Prospects of Lighter Costs and Regulatory Framework*, EUR. ENV'T, Oct. 11, 1994, § I, at 1.

[4] *See* Paul Jacobs, *Protest May Mow Down Trend to Alter Crops Biotech: Public Outcry Over Genetically Modified Foods Has the U.S. Agricultural Industry Backpedaling*, L.A. TIMES, Oct. 5, 1999, at A1.

[5] *See* David Brough, *Euro Grain-GM Feed Labels Needed to Ease Fears*, Reuters English News Service, Mar. 1, 2000.

scientific uncertainty over potential adverse effects of GMOs on the environment and human health, while at the same time addressing international trade obligations, concerns over competitiveness of the European biotechnology industry, and growing public concern over potential risks posed by GM crops and foods.

This paper provides a brief survey of European Union law on the marketing of GMOs, particularly food produced from GMOs. It attempts to highlight some of the significant recent developments, as well as the multilateral fora that are likely to influence this policy in the years to come. Given the pace of recent activity in this area, it can only provide a snapshot of the existing situation. As indicated below, further significant legislative developments can be expected in the E.U. in the near future.

I
Features of the Regulatory Approach

The E.U. regulatory framework for biotechnology has been designed to ensure adequate protection of human health and the environment while at the same time ensuring a single European market for biotechnological products. The key elements of the regulatory system are therefore twofold: pre-marketing safety assessments and a single "one-stop" authorization procedure. Given the internal market dimension, legislation on GMOs has been adopted under Article 100a/Article 95 of the EC Treaty.[6] This requires the Commission, in its proposals for legislation concerning health, safety, and environmental and consumer protection, to "take as a base a high level of protection."[7] The legal basis in the EC Treaty for legislation on biotechnology affects the extent to which Member States are entitled to adopt more protective measures than those established under E.U. law and determines the relative powers of the European Commission, the Council, and the European Parliament in the decision-making process.[8]

---

[6] Treaty Establishing the European Community, Feb. 7, 1992, O.J. (C 224) 1 (1992), [1992] 1 C.M.L.R. 573 (1992) [hereinafter EC Treaty]. Now, after amendment, Article 100a has become Article 95. The amendment, effected by the Amsterdam Treaty, entered into force on May 1, 1999. The consolidated version of the EC Treaty is reprinted in 37 I.L.M. 79 (1998).

[7] *Id*.

[8] For legislation adopted under Article 95, a co-decision procedure, under Article 251 (ex art. 189b) of the EC Treaty, applies between the Council of

In addition to internal market considerations, the initial horizontal (or technology-based) Community legislation on GMOs[9] was based on the preventive principle and on a step-by-step approach, whereby the containment of a GMO could be reduced, and the scale of its release into the environment could be increased, only gradually after an evaluation of protection of human health and the environment indicated that the next step could safely be taken. Hence, GMOs were to be subject to case-by-case environmental risk assessment and to evaluation at each stage of research, development, and commercialization. While the original 1990 legislation does not mention the precautionary principle, the approach taken in the 1990 Deliberate Release Directive is consistent with a precautionary approach insofar as the Directive as a whole addresses the uncertain nature and the extent of risks to the environment and human health associated with the use and release of GMOs. In the period since the first legislation on biotechnology was adopted in the E.U., the role of the precautionary principle has become more prominent. Indeed, the principle has been explicitly incorporated into the EC Treaty.[10] Although the precautionary principle is only expressly referred to in the Environment title of the Treaty, the Commission has expressed the view that, in practice, its scope is much wider, also encompassing the protection of human health.[11] Indeed, in the WTO, the European Commission has argued in the context of food safety measures that the precautionary principle is "a general customary rule of international law, or at least a general principle of law, the essence of which is that it applies not only in the management of risk, but also in the assessment thereof."[12]

Legislation on GM foods in the E.U. is linked both to horizontal legislation on GMOs and to a broader range of food safety

---

Ministers and the European Parliament. *Id*. This procedure applied to the adoption of the Novel Foods Regulation (*see infra* note 19) and also applies to the ongoing revision of the Directive on the deliberate release of GMOs (*see infra* Part I.A.3).

9 *See* Council Directive 90/220/EEC of 23 April 1990 on the Deliberate Release into the Environment of Genetically Modified Organisms, 1990 O.J. (L 117) 1 [hereinafter Deliberate Release Directive].

10 *See* EC TREATY art. 174 (ex art. 130r), *supra* note 6.

11 *See* Communication from the Commission on the Precautionary Principle, COM(2000)1 at 10.

12 EC Measures Concerning Meat and Meat Products (Hormones), Report of the Appellate Body, AB-1997-4, WT/DS26/AB/R, para. 16 (Jan. 16, 1998).

and labeling rules. The development of food law in the E.U. has been piecemeal to date.[13] In 1997, the European Commission issued a Green Paper on General Principles of Food Law in the E.U.[14] Following consultation on the Green Paper, in January 2000, a White Paper on Food Safety was published.[15] The White Paper sets out principles and aims of EC food safety legislation and policy, as well as proposed legislative initiatives to meet these aims. The White Paper recognizes that food safety needs to be organized in a more rationalized and coordinated way in the E.U., and that legislation must cover all aspects of food safety from "farm to table." Key principles of food policy identified in the White Paper include: the need for a comprehensive, integrated approach; traceability of feed and food and their ingredients; transparency; risk analysis; the use of best available scientific advice; and the application of the precautionary principle in risk management where appropriate.[16]

A raft of new legislative proposals are due from the Commission over the next three years to implement the White Paper, with the most significant proposals scheduled before the end of 2000. A key aspect of the new approach envisaged in the White Paper is the creation of an independent European Food Authority with responsibilities relating, *inter alia*, to providing scientific advice and information to the Commission on food safety issues.[17] Any role for the proposed Authority in market approval procedures for GM foods remains to be seen.

The key issues addressed in the GMO legislation in the E.U. are:

- Regulation of the contained use of genetically modified micro-organisms;[18]
- Authorization of the deliberate release of GMOs into the environment for field-testing and commercial growing;
- Authorization for placing GMOs and products of GMOs on the market; and,

---

[13] *See generally* O'ROURKE, EUROPEAN FOOD LAW (2nd ed. 1999).

[14] Green Paper on General Principles of Food Law in the European Union, COM(97)176 final.

[15] White Paper on Food Safety, COM(99)719 final.

[16] *See id.* at ch. 2.

[17] *See id.* at ch. 4.

[18] *See* Council Directive 90/219/EEC of 23 April 1990 on the Contained Use of Genetically Modified Micro-organisms, as amended by Directive 98/81/EC, 1998 O.J. (L 330) 13. This aspect is not addressed in this article.

• Labeling GMOs and products of GMOs.

Legislation on the marketing and labeling of "GM foods" distinguishes between foods which *consist of* or *contain* GMOs (for example, genetically modified tomatoes or potatoes) and foods *produced (or derived) from, but not containing* GMOs (for example, processed products, such as highly refined oils derived from genetically modified oilseed rape).[19] There is also a distinction drawn between foods produced with (but not containing) GMOs which still contain detectable novel DNA or proteins resulting from genetic modification, and those which do not.[20] These distinctions determine which rules apply to the marketing and labeling of genetically modified food products. For the sake of convenience, this Article uses the term "GM foods" to refer to all of these categories generally, but indicates where different rules apply as a result of these distinctions.

The relevant E.U. legislation consists of both horizontal, technology-based legislation as well as sectoral, product-based rules. At first, horizontal legislation was put in place but, as will be indicated below, there is now a growing range of sectoral rules, such as those governing "novel foods," including GM foods.

A. *Deliberate Release of GMOs into the Environment: Directive 90/220*

The central piece of horizontal legislation in the E.U. is Directive 90/220, which governs the deliberate release of GMOs into the environment and which also addresses the placement on the market of products that consist of or contain GMOs, not including non-viable products of GMOs.[21] The Directive has been the subject of much controversy and its revision is currently under discussion.[22]

The Directive contains a definition of GMOs to which later sectoral legislation refers.[23] Part C of the Directive establishes

---

[19] *See* Council Regulation 258/97 of 27 January 1997 Concerning Novel Foods and Novel Food Ingredients, art. 2(1)(a)-(b), 1997 O.J. (L 043) 1 [hereinafter Novel Foods Regulation].

[20] *See* U.K. MINISTRY OF AGRICULTURE FISHERIES AND FOODS, GUIDANCE NOTES: NOVEL FOODS AND NOVEL FOOD INGREDIENTS LEGISLATION, para. 30 (1999).

[21] *See* Deliberate Release Directive, *supra* note 9.

[22] *See infra* Part I.A.3.

[23] *See* Deliberate Release Directive, art. 2(2), *supra* note 9, at 16.

procedures for the E.U.-wide authorization for the entry of products containing or consisting of GMOs into the market. It also provides a one-stop notification and application procedure for applicants and a harmonized approach to the product throughout the E.U.[24] Articles 11 through 18 of the Directive set out certain environmental risk assessment requirements and authorization procedures for placing GMOs on the market.[25] The Directive provides that these provisions do not apply to products that are the subject of separate sectoral legislation. Nevertheless, such products must be subject to a similar environmental risk assessment as that required under Directive 90/220.[26]

1. *The Marketing Authorization Procedure*

Under the Directive, a manufacturer or importer who wishes to place a GMO on the market in the Community has to notify the competent authority in the Member State where the product will first be marketed.[27] The notification must contain specific information relevant to risk assessment.[28] However, the Directive is vague as to the scope of risk assessment and who should perform it, and it does not contain specific guidelines on the risk assessment criteria to be utilized. This omission has given rise to different approaches to risk assessment by the Member States, and hence to different views on particular market authorization applications. It has also led to problems in the implementation of the Directive and delays in processing market approvals.

The notifier can only proceed to market with the product when he has received final written consent under the Directive.[29] If, having examined the application, the competent authority favors placing the product on the market, it forwards the dossier of information to the Commission with a favorable opinion.[30] The Commission then forwards the dossier to the competent authorities of the other Member States for comment. Other Member States may, and often do, raise objections to the proposed authorization.[31] Where a Member State objects to a proposed au-

---

[24] *See* Deliberate Release Directive, arts. 11-18, *supra* note 9, at 18-20.
[25] *See* Deliberate Release Directive, arts. 11-18, *supra* note 9, at 18-20.
[26] *See* Deliberate Release Directive, art. 10(2), *supra* note 9, at 18.
[27] *See* Deliberate Release Directive, art. 11(1), *supra* note 9, at 18-19.
[28] *See* Deliberate Release Directive, Annex II-III, *supra* note 9.
[29] *See* Deliberate Release Directive, art. 11(5), *supra* note 9, at 19.
[30] *See* Deliberate Release Directive, art. 12(2), *supra* note 9, at 19.
[31] *See* Deliberate Release Directive, art. 13(3), *supra* note 9, at 19.

thorization, it is up to the Commission to make a decision on the authorization in accordance with a procedure established in the Directive.[32] This procedure has itself proven extremely controversial in its application. Like many other examples of technical legislation in the E.U., Directive 90/220 provided for exercise of the Commission's implementing powers through a regulatory committee procedure under which the right to make a decision on authorization may ultimately rest with the Commission.[33]

Once the Commission has made a decision, and if there are no objections to the authorization, the Member State that received the initial application is supposed to give its final written consent.[34] This procedure has led to some interesting difficulties. In July 1999, the Commission indicated that it was pursuing France for failure to provide final marketing consent for two approved varieties of oilseed rape for which France had forwarded initial applications to the Commission.[35] In a recent case on preliminary reference, the European Court of Justice found that, if a Member State forwards a favorable opinion to the Commission for placing a GMO on the market, and either no Member State raises an objection or the Commission takes a favorable decision on the authorization under Article 13(4) of the Directive, then

---

[32] *See* Deliberate Release Directive, art. 13(3), *supra* note 9, at 19.

[33] *See* Deliberate Release Directive, art. 21, *supra* note 9, at 21. Under the procedure, known as the Regulatory Committee procedure, the Commission makes a proposal to the Regulatory Committee, which is composed of representatives from Member States and chaired by a representative of the Commission. The Regulatory Committee has to give an opinion on the proposal by qualified majority. If the Regulatory Committee favors the proposal, then the Commission shall adopt the proposed measures. If there is no qualified majority in favor of the proposed measures, then the matter is referred to the Council of Ministers. The Council may approve the proposed measures by qualified majority, but must act *unanimously* to amend the Commission's proposal. This means, in effect, that if the Commission proposes to authorize a GMO's entry into the market, this decision can be adopted even if there are Member States in the Council that oppose the decision. *See* Council Decision 87/373 Laying down the Procedures for the Exercise of Implementing Powers Conferred on the Commission, 1987 O.J. (L 197) 33. In accordance with Declaration No. 31 annexed to the Final Act of the Intergovernmental Conference (Amsterdam 1997), the comitology decision was reviewed and replaced by Council Decision 1999/468 of 28 June 1999 Laying Down the Procedures for the Exercise of Implementing Powers Conferred on the Commission, 1999 O.J. (L 184) 23.

[34] *See* Deliberate Release Directive, art. 13(4), *supra* note 9, at 20.

[35] *See* European Commission, Press Release, July 7, 1999, GMO's: Commission Moves Against Luxembourg and France (visited April 27, 2000) <http:// europa.eu.int / rapi d/ cg i/ rapcgi.ksh?p_action.gettxt = GT&doc = IP/99/438 | 0 | RAPID&lg=EN>.

the competent authority which forwarded the application to the Commission is *obliged* to issue consent in writing allowing the product to be placed on the market.[36] However, the Member State concerned will not be obliged to give consent if, in the meantime, it has new information which leads it to consider that the product may constitute a risk to human health and the environment. In such circumstances, the Member State must immediately inform the Commission and the other Member States so that a new decision can be made under Article 21 of Directive 90/220.[37]

Once a product has received written consent under the Deliberate Release Directive, it can be used throughout the E.U., in accordance with any conditions attached to its authorization.[38] However, the Directive also contains a "safeguard clause" for Member States in Article 16, which provides that where a Member State has "justifiable reasons" to believe that a product that has received written consent under the Directive constitutes a risk to human health and the environment, it may provisionally restrict or prohibit the use and/or sale of that product in its territory, pending a decision in accordance with the regulatory committee procedures.[39]

It was under Article 16 that Austria and Luxembourg initiated bans on the import and cultivation of a GM insect resistant maize in 1997.[40] The Commission, under the procedure set out in the Directive, had authorized placing the maize on the market (notwithstanding opposition from a majority of Member States),

---

[36] *See* Association Greenpeace France e.a. contre Ministère de l'Agriculture et de la Pêche e.a., Recueil des décisions [arrêts] du Conseil d'Etat, C-6/99 (reference to the court under Article 177 of the EC Treaty, now Article 234 EC, by the Conseil d'Etat, France, for a preliminary ruling in the proceedings pending before that court between Association Greenpeace France and Others and Ministry of Agriculture and Fisheries and Others). The Judgment of the European Court of Justice of March 21, 2000 is available at <http://www.curia.eu.int>.

[37] *See Association Greenpeace France,* C-6/99 para. 47.

[38] *See* Deliberate Release Directive, art. 13(5), *supra* note 9, at 20.

[39] *See* Deliberate Release Directive, art. 16, *supra* note 9, at 20. As of July 2000 there were eight ongoing Article 16 notifications. *See* Commission MEMO/00/43, *Facts on GMOs in the EU*, July 13, 2000, at 4.

[40] *See* Opinion of the Scientific Committee on Plants on the Invocation by Austria of Article 16 ('safeguard' clause) of Council Directive 90/220/EEC with respect to the placing on the market of the Monsanto genetically modified maize (MON810) expressing the Bt *cryia(b)* gene, notification C/F/95/1'2-02 (visited Aug. 22, 2000) <http://europa.eu.int/comm/food/fs/sc/scp/out49_en.html>.

and the relevant national authority had given written consent.[41] The Commission sought to respond by requiring Austria and Luxembourg to lift their bans. However, no formal decision was reached under the Directive as to whether the bans should be allowed to remain in place, and given the controversy surrounding the issue and the ongoing revision of the Directive, the matter has not been pursued so far.[42]

2. *Labeling of GMOs Under Directive 90/220*

Initially, Directive 90/220 said little about the labeling of products authorized under Part C of the Directive. It provided that a notifier should include a proposal for labeling with the application for marketing authorization, to meet the requirements of Annex III to the Directive.[43] However, a notifier could propose not to label a product where it considered that the placement of the product on the market and its use did not pose a risk to human health and the environment.[44] The labeling requirements in Annex III of the Directive were amended in 1997 by Directive 97/35[45] so as to require that products consisting of or containing GMOs be labeled. Where products comprise a mixture of GMOs and non-genetically modified organisms, Annex III, as amended, requires that the *possible* presence of GMOs be indicated.[46] However, Directive 97/35 does not have retroactive

---

[41] *See* Commission Decision 97/98 of 23 January 1997 Concerning the Placing on the Market of Genetically Modified Maize (*Zea mays* L.) with the Combined Modification for Insecticidal Properties Conferred by the Bt-endotoxin Gene and Increased Tolerance to the Herbicide Glufosinate Ammonium Pursuant to Council Directive 90/220, 1997 O.J. (L 31) 69.

[42] Recent reports suggest that these cases are unlikely to be pursued pending the revision of Directive 90/220.

[43] *See* Deliberate Release Directive, art. 11(1), *supra* note 9, at 18-19. Given the scope of the Directive, labeling requirements under Annex III may apply to products consisting of or containing GMOs, but not to non-viable products derived from GMOs.

[44] *See* Deliberate Release Directive, art. 11(1), *supra* note 9, at 18-19.

[45] Commission Directive 97/35 of 18 June 1997 Adapting to Technical Progress for the Second Time Council Directive 90/220/EEC on the Deliberate Release into the Environment of Genetically Modified Organisms, 1997 O.J. (L 169) 72 [hereinafter Directive 97/35].

[46] The provision allowing a "may contain GMOs" label has been subject to criticism. A briefing note prepared by the U.K. competent authority on the ongoing revision of Directive 90/220 (see further below) indicated that most Member States are expected to favor removing the option of labeling products as "may contain GMOs" since this does not provide useful information to the end-user. However, it noted that requiring positive labeling raised difficult is-

effect and therefore does not apply to products that have already been authorized to enter the market under Directive 90/220.[47]

3. *Revision of Directive 90/220*

The Deliberate Release Directive is currently under revision.[48] The upsurge of public concern in many Member States regarding the potential effects of GMOs on the environment and human health has meant that discussions have focused on strengthening the provisions of the Directive. The Council of Ministers reached a political agreement on the revision of the Directive in June 1999 and formally adopted the common position in December 1999.[49]

The common position in the Council suggests a number of significant changes to the Directive. These include:

- GMO marketing authorizations would be subject to a ten year time limit and to post-authorization monitoring.
- The responsibility to carry out environmental risk assessments would be on the applicant or notifier. A new annex with principles for environmental risk assessment would be included in the Directive in order to promote a harmonized approach across the E.U. These would indicate that risk assessment should identify and evaluate direct or indirect and immediate or delayed potential adverse effects of the GMO in question on human health and the environment. The inclusion of a consideration of indirect effects in risk assessment seems especially significant as this could require assessment of changes in agricultural use or management, e.g. herbicide or pesticide spraying practices, where it is the *management* of a GM crop,

---

sues regarding adventitious contamination of non-GMO products with GM material, and with regard to commodities where similar GMO and non-GMO products are mixed together. *See* Department of Environment, Transport and the Regions, Advisory Committee on Releases to the Environment, Proposal for a Directive of the European Parliament and of the Council Amending Directive 90/220/EEC on the Deliberate Release into the Environment of Genetically Modified Organisms: Key Issues and Developments, COM(98)85 final.

47 *See* Directive 97/35, art. 3, *supra* note 47.

48 *See* Wybe Th. Douma & Mariëlle Matthee, *Towards New EC Rules on the Release of Genetically Modified Organisms*, 8 RECIEL 152 (1999).

49 *See* Common Position (EC) 12/2000 adopted by the Council on 9 December 1999 with a view to adopting Directive 2000/. . ./EC of the European Parliament and of the Council of . . . on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, 2000 O.J. (C 64) 1.

rather than the GM crop itself, which may have adverse effects on the environment.

- Notifiers would have to submit information on relevant methods to facilitate post-marketing control and inspection. It is not clear how this would extend to the use of the GMO in processed products, which would clearly have implications for GM food legislation.
- New marketing consents for GMOs would require them to be labeled.
- Authorization procedures, and in particular the applicable committee procedure, would be changed to allow for more influence by Member States.
- New references to the precautionary principle would be explicitly included in the revised Directive.

The Commission's response to the Council's common position notes that to address the growing public concerns about potential adverse effects of GMOs, a more transparent and stringent regulatory system for the deliberate release of GMOs into the environment is now needed.[50] The Commission suggests that the approach taken in the common position will provide for an effective and efficient regulatory system that takes into account both public concerns and the interests of industry.[51]

The European Parliament suggested twenty-nine amendments to the common position, many of which were not acceptable in the view of the Commission.[52] Outstanding differences are due to be resolved through the conciliation process between the Parliament and the Council[53] commencing on September 19, 2000.[54]

The common position does not include provisions on liability for damage caused by GMOs. The much-delayed Commis-

---

[50] *See* European Parliament Legislative Observatory, 1998/0072(COD)-PE2, Position of the European Parliament of 12 April 2000 with a View to the Adoption of European Parliament and Council Directive 2000/. . ./EC on the Deliberate Release into the Environment of Genetically Modified Organisms and Repealing Council Directive 90/220/EC (visited Sept. 6, 2000) <http://www3.europarl.eu.int/dg7/doclegcons/data/word/1998/0072/19980072(COD)-PE2-en.doc>.

[51] *See id.*

[52] *See* Opinion of the Commission, COM(2000)293 final.

[53] *See* EC TREATY art. 251 (ex art. 189b), *supra* note 6.

[54] *See* Joe Kirwin, *European Commission Outlines Plan to Break Moratorium on GMO Licenses,* 23 Int'l Env't Rep. (BNA) No. 15, at 555 (July 19, 2000).

sion White Paper on Liability for Environmental Damage will deal with environmental liability.[55] In addition, it is likely that the revision of the Directive will need to be revisited in light of the adoption in January 2000 of the Cartagena Protocol on Biosafety.[56] The Protocol sets out procedures governing the transboundary movement of certain GMOs.

Pending the entry into force of the revised Directive, there has been a "de facto moratorium" on new authorizations (including those in the pipeline) in place.[57] At the EC Environment Council meeting in June 1999, five member States called for the suspension of new authorizations pending the adoption of rules ensuring labeling and traceability of GMOs and GMO-derived products.[58] Seven other Member States, while not calling for a suspension as such, nonetheless called for a precautionary approach and the application of principles regarding labeling and traceability.[59] In order to advance the authorization process for certain products presently stuck in the pipeline, industry proposed complying in advance with new criteria relating to risk assessment, labeling, and traceability set out in the common position.[60]

In July 2000, the European Commission outlined an initiative to enable resumption of the authorization process before the revised Directive enters into effect.[61] The Commission has proposed applying the key provisions of the revised Directive to all new GMO approvals as soon as agreement has been reached between the Council and the Parliament on its content following the conciliation procedure which begins in September 2000. Es-

---

55 *See* White Paper on Environmental Liability, COM(2000)66 final.

56 *See* Cartagena Protocol on Biosafety to the Convention on Biological Diversity (visited Aug. 23, 2000) <http://www.biodiv.org/biosafe/Protocol/pdf/Cartagena-Protocol-e.pdf> [hereinafter Cartagena Protocol]. Fourteen Member States and the European Community signed the Protocol in May 2000. Luxembourg signed in July 2000.

57 No new authorizations have been granted under Directive 90/220 since October 1998. As of July 2000, fourteen applications were pending. *See* Commission MEMO/00/43, *Facts on GMOs in the E.U.*, July 13, 2000, at 3.

58 *See* Official Minutes of the Environmental Council of the E.U., June 24, 1999 (visited Sept. 6, 2000) <http://www.asser.nl/er/2194.pdf>.

59 *See id*.

60 *See Genetic Engineering: Commission/Industry Initiative to Break Deadlock*, EUR. ENV'T, Nov. 30, 1999, § IV, at 1.

61 *See* Commission Press Release, *Commission Takes Initiative to Restore Confidence in GMO Approval Process* (last modified July 13, 2000) <http://www.asser.nl/EEL/docs/press62_en.htm>.

sentially, companies seeking authorizations would be asked to voluntarily agree to commitments in line with the revised Directive when they submit their notification, and these commitments would become binding once authorization was granted. New authorizations would be time limited. The Commission has also proposed accelerating work on related issues of concern, including labeling and traceability of GMOs, and liability. However, pending a thorough revision and strengthening of the regime, these proposals seem likely to be unacceptable to many in the E.U.

II
Genetically Modified Foods and Food Ingredients

In 1997, a Regulation specifically addressing the marketing and labeling of "novel foods" was adopted in the E.U.[62] The Regulation supercedes the marketing authorization provisions of Directive 90/220 with respect to all GMOs intended for food use. Directive 90/220 continues to apply to the release of GMOs into the environment, for example, governing authorizations for the marketing of GM seeds and for the cultivation of GM crops. Under the Regulation, "novel foods" are those foods or food ingredients which have not hitherto been used for human consumption to a significant degree within the E.U.[63] They include, but are not limited to, foods containing, consisting of, or produced from GMOs. The Regulation does *not* apply to food additives or flavorings addressed within other relevant E.U. food legislation,[64] on which a separate regulation has recently been adopted.[65]

As a general matter, foods and food ingredients falling within the scope of the Regulation must not present a danger for the consumer, mislead the consumer, or differ from foods or food ingredients which they are intended to replace to such an extent that their normal consumption would be nutritionally disadvan-

---

62 *See* Novel Foods Regulation, *supra* note 19.

63 *See* Novel Foods Regulation, art. 1, *supra* note 19, at 2-3.

64 *See* Novel Foods Regulation, art. 1, *supra* note 19, at 2-3.

65 *See* Commission Regulation 50/2000 of 10 January 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, 2000 O.J. (L 6) 15 [hereinafter Labeling Regulation].

tageous for the consumer.[66] The Regulation establishes a pre-market authorization procedure for the placement of foods and food ingredients which fall within the scope of the Regulation on the market in the Community. There are two distinct marketing procedures within the Regulation, depending on (1) the category of novel food concerned; and (2) whether the food or ingredient is deemed "substantially equivalent" to an existing food.[67]

A. *Substantial Equivalence*

"Substantial equivalence" is a concept developed within the World Health Organization and the Organisation for Economic Co-operation and Development (OECD). The use of the concept in relation to GM foods is controversial.[68] As used within the OECD, the concept allows for existing organisms used as food or food sources to serve as the basis of comparison in the assessment of a new or modified food or food component.[69] If the new food is deemed "substantially equivalent" to an existing food or component, then it can be treated in the same manner as the existing food with respect to safety. Levels and variations for characteristics in the novel food must be within the natural range of variation for the same characteristics in the comparator. The establishment of substantial equivalence is not intended as a safety or nutritional assessment in itself, but rather an approach to compare a new food with a conventional counterpart. If the new food or component is not found to be substantially equivalent to an existing food, then its safety must be evaluated on the basis of its unique composition and properties.[70]

---

66 *See* Novel Foods Regulation, art. 3(1), *supra* note 19, at 3.

67 *See* Novel Foods Regulation, arts. 3-4, *supra* note 19, at 3-4.

68 *See e.g.* Erik Millstone et al., *Beyond Substantial Equivalence,* 401 NATURE 525, 525-26 (1999). The need for a more detailed review of the use of the concept was recognized at an OECD Conference on the Scientific and Health Aspects of Genetically Modified Foods in Edinburgh on February 28 – March 1, 2000. See OECD, *Edinburgh Conference Chairman's Report*, para. 13 (visited Sept. 4, 2000) <http://www.oecd.org/subject/biotech/Chairmanreporteng.pdf>.

69 *See* OECD, SAFETY EVALUATION OF FOODS DERIVED BY MODERN BIOTECHNOLOGY: CONCEPTS AND PRINCIPLES (1993).

70 *See* Commission Recommendation 97/618 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, 1997 O.J. (L 253) 1.

Under the Novel Foods Regulation, where the substantial equivalence criterion is met, a simplified procedure applies for placing the novel food or food ingredient on the market. However, with regard to GM foods, only foods or ingredients "produced with, but not containing" GMOs can be assessed for substantial equivalence.[71] Novel foods "consisting of or containing" GMOs must go through the regulation's pre-authorization assessment procedure.[72] Though not stated in the Regulation, it has been accepted by the EC Standing Committee for Foodstuffs that for foods and food ingredients "produced with" GMOs, only those which contain no novel protein or DNA would be suitable for consideration under the substantial equivalence procedure.[73] A full safety assessment is required before authorization for marketing is given for food where novel DNA or protein resulting from genetic modification is present in the final product.

If the substantial equivalence criterion is met, then under the simplified procedure, the applicant may simply notify the Commission of placing the food or food ingredient on the market, and provide relevant information, including the required evidence of substantial equivalence. The Commission forwards the notification to Member States which may request a copy of the relevant details.[74] The labeling provisions of the Regulation contained in Article 8 (see below) continue to apply.[75] An applicant must provide evidence of substantial equivalence either by showing that the food or food ingredient in question is "generally recognized as substantially equivalent on the basis of scientific evidence available" or by obtaining a supportive opinion from a competent authority of a Member State.[76] For example, the U.K. Advisory Committee on Novel Foods and Processes has been called upon to provide an opinion on substantial equivalence in relation to processed oils derived from insect-resistant GM cottonseed.[77]

---

71 Novel Foods Regulation, art. 3(4), *supra* note 19, at 3.

72 Novel Foods Regulation, art. 3(4), *supra* note 19, at 3.

73 *See* U.K. MINISTRY OF AGRICULTURE FISHERIES AND FOODS, para. 30, *supra* note 21.

74 *See* Novel Foods Regulation, art. 5, *supra* note 19, at 4.

75 *See* Novel Foods Regulation, art. 5, *supra* note 19, at 4.

76 Novel Foods Regulation, art. 3(4), *supra* note 19, at 3.

77 *See* MINISTRY OF AGRICULTURE, FISHERIES AND FOOD AND DEPARTMENT OF HEALTH, U.K. ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES, 1998 ANNUAL REPORT (1999).

B. *Assessment and Authorization Process*

If the substantial equivalence criterion does not apply or is not met, then before the novel food or food ingredient may be placed on the market, an application must be made to the competent authority of one of the Member States, which forwards a copy of the request to the Commission.[78] Where the novel food or food ingredient contains or consists of a GMO within the meaning of Directive 90/220, then an applicant must also supply a copy of the written consent, if any, for the deliberate release of the GMO for research and development purposes,[79] as well as related information.[80]

The Member State's food assessment body carries out an initial assessment within three months of receipt of the request, and decides whether the food or food ingredient requires an additional assessment.[81] The Member State must forward the report of its food assessment body to the Commission for transmission to the other Member States, which have sixty days to make comments or present a reasoned objection to the marketing (or proposed presentation or labeling) of the food or ingredient in question. If other Member States raise objections, or where a Member State deems that an additional assessment is required, then the application is referred to the EC Standing Committee for Foodstuffs under Article 13 of the Regulation.[82]

In the case of foods or ingredients containing or consisting of GMOs, the authorization decision must respect environmental

---

[78] Article 4(4) of the Novel Foods Regulation, *supra* note 19, at 4, requires the Commission to publish recommendations concerning scientific aspects of the information necessary to support a marketing application and the presentation of such information as well as the preparation of initial assessment reports under Article 6. The Commission published such guidance in July 1997 in Commission Recommendation 97/618, on the basis of recommendations from the Scientific Committee for Food, established under Commission Decision 97/579, 1997 O.J. (L 237) 18. *See* Commission Recommendation 97/618, *supra* note 70, at 1.

[79] Deliberate release of GMOs into the environment for research and development purposes is addressed under Part B of the Deliberate Release Directive, *supra* note 9, at 17-18.

[80] Additional information includes, for example, results of the release with respect to any risks to human health and the environment, the complete technical dossier of information required under Article 11 of the Deliberate Release Directive (*supra* note 9, at 18-19) and the environmental risk assessment based on this information under Article 9(1) of the Novel Foods Regulation (*supra* note 19, at 5).

[81] *See* Novel Foods Regulation, art. 6, *supra* note 19, at 4.

[82] *See* Novel Foods Regulation, art. 6(4), *supra* note 19, at 4.

safety requirements laid down in Directive 90/220, and consultations must be held between the Commission or Member States with competent authorities established in accordance with Directive 90/220.[83] Like Directive 90/220, the Novel Foods Regulation includes a safeguard provision which allows a Member State to temporarily restrict or suspend trade in or use of an authorized novel food or food ingredient on the basis of new information or a reassessment of existing information.[84]

C. *Labeling Requirements Under Regulation 258/97*

An applicant for marketing of a novel food or food ingredient has to put forward a proposal with regard to labeling of the product.[85] Article 8 of the Regulation provides for specific labeling requirements to apply to foodstuffs under the Regulation, in addition to existing requirements of E.U. law concerning the food labeling.[86] The purpose of the additional labeling is set out in Article 8, which provides for special labeling of novel foods supplied to the final consumer in the following situations:

a) For foods and food ingredients (including those obtained from GMOs) when, on the basis of a scientific assessment, they are judged to be no longer equivalent[87] to an existing food or food ingredient.
b) If a novel food contains material which is not present in an existing equivalent foodstuff and which may have implications for the health of some sections of the population, e.g., allergens.

---

[83] *See* Novel Foods Regulation, art. 9(2), *supra* note 19, at 5. *See also* Deliberate Release Directive, art. 10(2), *supra* note 9, at 18.

[84] *See* Novel Foods Regulation, art. 12, *supra* note 19, at 6.

[85] *See* Novel Foods Regulation, art. 6(1), *supra* note 19, at 4.

[86] The principal E.U. legislation on labeling of foodstuffs is Council Directive 79/112, 1979 O.J. (L 33) 1.

[87] Article 8(1)(a) of the Novel Foods Regulation provides:

> A novel food or food ingredient shall be deemed to be no longer equivalent for the purpose of this Article if scientific assessment, based upon 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.

Novel Foods Regulation, art. 8(1)(a), *supra* note 19, at 5.

In these circumstances, labeling must indicate the characteristic or the properties modified, together with the method by which that characteristic or property was obtained.

c) If a novel food contains material which is not present in an existing equivalent foodstuff and which gives rise to ethical concerns.
d) *All* foods which contain or consist of GMOs within the meaning of Directive 90/220. Thus under the Regulation these foods will always be subject to additional specific labeling, whereas foods or ingredients produced from (but not containing) GMOs may not.

The Regulation does not prescribe specific wording for labeling. Any detailed rules for implementing Article 8 are to be adopted in accordance with the committee procedure set out in Article 13.

III
Additional Specific Labeling of Foods and Food Ingredients Derived from Approved Varieties of GM Maize and Soya

Before the Novel Foods Regulation entered into force, a genetically modified insect resistant maize[88] and a genetically modified herbicide tolerant soya[89] had already received marketing approvals under Directive 90/220 with no mandatory food labeling conditions attached. After the adoption of the Novel Foods Regulation, Regulation 1813/97[90] was adopted so that similar requirements would apply to foods and food ingredients produced from the genetically modified soya and maize. This was subsequently replaced by Regulation 1139/98,[91] which introduced more specific labeling requirements, and indicated wording to be used on labeling. However, Regulation 1139/98 exempts from the additional labeling requirements foodstuffs in which neither protein nor DNA resulting from genetic modification is present.[92] Like the Novel Foods Regulation, Regulation 1139/98 also exempts food additives, flavorings and extraction solvents.[93] The Regulation further provides for the drawing up of a "nega-

[88] *See* Commission Decision 97/98, 1997 O.J. (L 31) 69 (*Zea mays* L.).
[89] *See* Commission Decision 96/281, 1996 O.J. (L 107) 10 (*Glycine max* L.*)*.
[90] Commission Regulation 1813/97, 1997 O.J. (L 257) 7.
[91] Commission Regulation 1139/98 of 26 May 1998, 1998 O.J. (L 159) 4.
[92] *See id.,* art. 2(2), at 6.
[93] *See id.,* art. 1(2), at 6.

tive list" of products not subject to the additional specific labeling requirements.[94]

While the Regulation uses presence in the food or ingredient of DNA or protein resulting from genetic modification as the criterion triggering the additional labeling requirements, it recognizes that adventitious contamination of foodstuffs with DNA or protein resulting from genetic modification cannot be excluded.[95] It envisages that labeling obligations arising from such accidental contamination could be avoided by setting a threshold for the detection of DNA and protein.[96] The Commission has subsequently established such a threshold in Regulation 49/2000, adopted in January 2000.[97] It provides, as before, that the foodstuffs concerned shall not be subject to specific additional labeling requirements where neither protein nor DNA resulting from genetic modification is present in the food ingredients individually or the food comprising a single ingredient.[98] In addition, it exempts from the additional labeling requirements foodstuffs from non-GM sources where material derived from GMOs is present in food ingredients, or in the food as a single ingredient, *in a proportion no higher than one percent, if the presence of the material is adventitious*.[99] In order to benefit from this provision, operators must be able to supply evidence that they have taken appropriate steps to avoid using GMOs (or produce thereof) as a

---

94 *See id.,* art. 2(2), at 6.

95 *See id.*, Preamble(13), at 5.

96 *See id*.

97 *See* Commission Regulation 49/2000 of 10 January 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, 2000 O.J. (L 6) 13. The Regulation entered into force on April 10, 2000. The Regulation also extends the requirements of Regulation 1139/98 to cover foods which are to be delivered to mass caterers. This is in line with the approach used in other E.U. food labeling legislation. Previously, the requirements of Regulation 1139/98 applied only to foods and food ingredients from GM soya and maize which were delivered to the final consumer. The new requirements are designed to make it easier for mass caterers to pass on accurate information to consumers.

98 *See id.*

99 *See id.*

source,[100] possibly through documented and audited "identity preservation" systems.[101]

The Commission rationale for setting a one percent threshold for adventitious contamination was that this is the lowest level which can presently be quantified, and that legal certainty was required. This would seem to suggest, however, that the Commission erred towards the "possible" rather than towards the precautionary. The one percent threshold has been the subject of extensive criticism by E.U. consumer and environmental groups and the European Parliament,[102] which argue that present detection methods would allow for a lower threshold to be set and that, in fact, the threshold in the new Regulation is less stringent than that presently used by some suppliers.[103] The European Parliament insisted that the new Regulation 1139/98 should explicitly provide for a review of the threshold in one year. However, the European Commission gave just a verbal undertaking to review the threshold after a year in the light of DNA detection techniques.[104]

IV
Genetically Modified Food Additives and Flavorings

In January 2000, the Commission moved to address another outstanding issue—the labeling of genetically modified food additives and flavorings.[105] Commission Regulation 50/2000 establishes specific additional labeling requirements for certain food additives and flavorings which are, contain, or are produced from GMOs. The requirements reflect those of Regulation 1139/98. A threshold for adventitious contamination of additives and fla-

---

100 *See id*., art. 1(2), at 14. For example, Cerestar, a starch manufacturing subsidiary of the EBS Franco-Italian Group, has established a traceability system designed to ensure that its products are not derived from GMOs. *See Genetic Engineering: GMO-Free Food is Flavour of the Month,* Eur. Env't, Sept. 21, 1999, § IV, at 4.

101 *See* Ministry of Agriculture, Fisheries and Food Draft Revisions to the Guidance Notes on Labeling of Food Containing Genetically Modified Soya or Maize (PB 4447) (undated).

102 *See EP Condemns Commission Food Labeling Proposal*, Friends of the Earth Eur. Biotech Mailout, Dec. 15, 1999, at 5.

103 *See New Regulation Provides For 1% Tolerance Without Compulsory Labelling*, Eur. Env't, Jan. 25, 2000, § IV, at 13.

104 *See id*.

105 *See* Labeling Regulation, *supra* note 65.

vorings with DNA or protein resulting from genetic modification has yet to be set.

Conclusions and Future Prospects

Within the EU, future developments in this area center upon the revision of Directive 90/220, and the outcome of conciliation procedures due to commence in September 2000, as well as upon proposals put forward by the Commission under the White Paper on Food Safety. The White Paper envisages a raft of new legislative and other proposals over the coming months, including proposals for:[106]

- the establishment of a European Food Authority (September 2000);
- a directive laying down common principles underlying food safety law (September 2000);
- a regulation clarifying the authorization procedure for novel foods and food ingredients (September 2000);
- a report on the implementation of the Novel Foods Regulation (December 2001);
- a regulation on labeling of food containing or derived from GMOs (September 2000);
- revision of the Novel Foods Regulation to adapt it in accordance with the new regulatory framework of Directive 90/220 (December 2001);
- a regulation on novel (including GM) animal feeds (September 2000); and
- a regulation on the labeling of GM-free foodstuffs (September 2000).

Furthermore, additional initiatives may also be expected as part of the Commission's plan to re-start the authorization process under Directive 90/220 pending the entry into effect of the revised Directive on deliberate release.[107]

There remains plenty of scope for disagreement among Member States' food assessment bodies, and between Member States and the Commission, as to the application of Regulation 258/97 and the authorization of specific GM foods and food ingredients in the E.U. To date, no foods have been authorized under the Regulation's procedures, although some authorization

---

[106] *See* Action Plan for Food Safety, Annex to White Paper on Food Safety, *supra* note 15.

[107] *See supra* text accompanying note 57.

applications are in the pipeline.[108] Although time limits for initial safety assessments and for review of the assessments by other Member States are built into the authorization procedures of the Novel Foods Regulation, delays during the consideration of objections within the EC Standing Committee for Foodstuffs remain a likely source of frustration for companies to export new GM foods to the E.U. Delays of this type may seem inevitable where fifteen Member States must be afforded an opportunity to consider potential health and environmental effects of each application. On the other hand, the advantage for the applicant here remains in the one-stop system. However, once product authorizations are issued under Regulation 258/97, the use of the safeguard clause by Member States may prove controversial as under Directive 90/220. As noted in the Food Safety White Paper, the revision of Directive 90/220, in particular the introduction of detailed risk assessment guidelines, is likely to have consequential effects on the application of the Novel Foods Regulation. One aim of the revision of Directive 90/220 has been identified as achieving greater equivalence between the horizontal legislation and product legislation with regard to requirements for risk assessment and risk management.[109] This may facilitate a more consistent approach by Member States.

While labeling is not meant to act as a substitute for proper safety assessment of GM foods within the E.U., it is questionable whether the approach to labeling yet fully accords with the high level of protection "from the farm to the table" mooted in the White Paper on Food Safety. For example, the Commission is under pressure from Member States to bring forward a proposal on GM animal feeds, and in the Food Safety White Paper expresses its intention to do so in September 2000. This is a crucial

---

[108] *See Facts on GMOs in the EU*, European Commission Memo/00/43, July 15, 2000 (visited Sept. 6, 2000) <http://www.asser.nl/EEL/docs/com2000-43.pdf>. For example, in 1998, the U.K. food assessment body forwarded a favorable assessment to the Commission relating to an application for marketing processed tomato products derived from a GM tomato. However, some Member States raised objections to the assessment, and the matter was referred to the Standing Committee for Foodstuffs under the Novel Foods Regulation.

[109] *See* DEPARTMENT OF ENVIRONMENT, TRANSPORT AND THE REGIONS, ADVISORY COMMITTEE ON RELEASES TO THE ENVIRONMENT, PROPOSAL FOR A DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AMENDING DIRECTIVE 90/220/EEC ON THE DELIBERATE RELEASE INTO THE ENVIRONMENT OF GENETICALLY MODIFIED ORGANISMS: KEY ISSUES AND DEVELOPMENTS, para. 15, (Jan. 1999).

element in achieving traceability and transparency. At present more than eighty percent of genetically modified soya apparently goes into animal feeds, yet such feedstuffs are not subject to GMO labeling rules.[110] Under the current approach, even if labeling of animal feeds is introduced, food products from animals given feeds derived from GM soya may not be subject to additional specific labeling if the food products do not themselves contain novel DNA or protein. This outcome seems unlikely to satisfy consumers in Europe who are by now highly sensitized to safety issues through the food chain.

Liability for any damage caused by GMOs will remain a contentious issue in the E.U. during 2000 and beyond. The Commission and the Council have resisted calls to include liability provisions within the revision of Directive 90/220. Instead, the Commission has proposed addressing such damage within a general E.U. liability regime on environmental damage. The White Paper on Environmental Liability,[111] published in February 2000 after several years of delay, suggests that there should be strict liability for environmental damage caused by GMOs regulated under Directive 90/220.[112] However, it is likely to be some time yet before an E.U.-wide regime for environmental liability is in place.

In relation to developments at the multilateral level, in addition to the continuing controversy over addressing biotechnology-related matters and disputes within the WTO, two other fora are likely to be of increasing significance: the Biosafety Protocol and the *Codex Alimentarius*. If the European Community and its Member States become Parties to the Cartagena Protocol on Biosafety, which was adopted at the end of January 2000, E.U. legislation on GMOs will need to be reviewed to ensure consistency with obligations under the Protocol.

---

[110] *See EP Condemns Commission Food Labeling Proposal*, *supra* note 110.

[111] White Paper on Environmental Liability, COM(2000)66 final.

[112] However, the White Paper also suggests that damage to biological diversity will only be covered by the liability regime if it occurs within special protected areas established under other Community legislation. *See id*., para. 4.5.1, at 18-20. In addition, the Environmental Liability White Paper notes that activities involving GMOs are not dangerous *per se*, but have the potential in certain circumstances, to cause damage to health or significant environmental damage. It states that the precise definition of the regime might not be the same for all activities related to GMOs, but may be differentiated according to the relevant legislation and activities concerned. *See id.,* para. 4.2.2, at 15-16.

Although the Protocol does not directly address the issue of foods produced from GMOs, it does contain provisions on trade in genetically modified organisms for direct use for food, feed or for processing of relevance to the ongoing disagreements between the E.U. and the United States and others over imports of GM commodities. In the final hours of negotiation of the Protocol, the United States and others succeeded in having removed from the Protocol provisions which would have required the segregation of shipments of GM and non-GM commodities. For now, it must merely be indicated that such shipments "may contain" living modified organisms,[113] and the Parties to the Protocol are to consider this provision further within two years of the Protocol entering into force.[114] Multilateral solutions to problems of segregation and traceability may therefore well be sought within the institutions established under the Protocol.

Multilateral developments on safety standards and labeling of food derived from GMOs are also being sought within the context of the *Codex Alimentarius*, which has established a special Task Force[115] whose mandate is, *inter alia, to elaborate standards, guidelines or other principles as appropriate for foods derived from biotechnology.*[116] The Task Force met for the first time in Japan in March 2000[117] and is expected to have a four-year life-span.

---

113 *See* Cartagena Protocol, art. 18(2)(a), *supra* note 56. The Protocol refers to "living modified organisms" rather than "GMOs."

114 The Cartagena Protocol will enter into force ninety days after the deposit of the fiftieth instrument of ratification. *See id.,* art. 37. The United States, as a non-party to the Convention on Biological Diversity, is not presently entitled to become a Party to the Protocol on Biosafety. *See* Convention on Biological Diversity, June 5, 1992, 31 I.L.M. 818.

115 The Codex *Ad Hoc* Intergovernmental Task Force on Food Derived from Biotechnology, established at the 23rd Session of the FAO/WHO Codex Alimentarius Commission, June 28-July 3, 1999.

116 Under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), food safety measures which conform to *Codex Alimentarius* standards, guidelines or recommendations shall be deemed to be necessary and presumed consistent with the relevant provisions of the SPS Agreement and of the 1994 General Agreement on Tariffs and Trade. *See* Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, WTO Agreement, Annex 1A, RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS: THE LEGAL TEXTS, art. 3(2), at 69, 1994 WL 761483.

117 Food and Agriculture Organization of the United Nations, Codex Alimentarius Commission, Report of the First Session of the Codex *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology (visited Sept. 5, 2000) <ftp://ftp.fao.org/codex/ALINORM01/Al01_34e.pdf>.

Overall, on the basis of recent experience, it seems likely that consumers will continue to demand a cautious approach to the marketing of GM foods and to the commercial cultivation of GM crops in Europe. Although questions have been raised as to the extent to which the precautionary principle has been applied in practice under biotechnology legislation in the E.U. to date, it now seems certain to be explicitly incorporated into the revision of Directive 90/220 on the deliberate release of GMOs into the environment. The practical application of the precautionary principle in decision-making on GMOs seems likely to remain a contentious issue both within the E.U. and more particularly in relations between the E.U. and the United States.