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**Traceability and Labeling of Genetically Modified
Crops, Food, and Feed in the European Union**

by

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TRACEABILITY AND LABELING OF GENETICALLY MODIFIED CROPS, FOOD, AND FEED IN THE EUROPEAN UNION

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I. INTRODUCTION

In the last several years, European Union (E.U.) policy has encouraged development of biotechnology, including genetically modified (GM) (that is, bioengineered)¹ agricultural crops. The E.U. developed a strategy for life sciences and biotechnology, directed toward improving the competitiveness of the European biotechnology sector and the general situation for European biotechnology.² E.U. documents have acknowledged the potential significance of genetically modified crops—for example, the conclusion in a recent report that “the potential of plant genomics and biotechnology to deliver major advances in our lifestyles and prosperity is enormous. [Biotechnology] can also maintain and enhance the competitiveness of E.U.

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1. Regulatory measures refer to GM crops, though the U.S. Food and Drug Administration (FDA) prefers the more accurate term “bioengineered.” Mark Mansour & Sarah Key, *From Farm to Fork: The Impact on Global Commerce of the New European Union Biotechnology Regulatory Scheme*, 38 INT’L LAW. 55, 65 (2004).

2. See generally Life Sciences and Biotechnology—A Strategy for Europe: Second Progress Report and Future Orientations, COM(2004)250 final.

farmers and food producers.”³ Nonetheless, producers and consumers in the E.U. have been reluctant to grow GM crops or to consume GM foods,⁴ and scientists disagree about the risks and net benefits of GM crops and food products. European Community (E.C.) legislators enacted new regulatory measures only after long deliberation, and some Member States continue to object to the use of GM crops and foods in their territories.

Under the new regulatory measures, the E.C. has started to approve GM products. In July 2004, the European Commission approved the import and processing of Monsanto’s GM maize, NK603, for use in animal feed and for industrial purposes, but not for cultivation or for food.⁵ The maize was approved for ten years under stringent new regulations. A scientific risk assessment ensured that it poses no danger to the environment, and an assessment by the European Food Safety Authority concluded that it is as safe as non-GM corn.⁶ When sold, the corn must be labeled clearly as genetically modified, and its unique identifier will ensure that it can be traced through the process of post-market monitoring.⁷ In October 2004, the Commission authorized the placing on the market of food and food ingredients derived from the same NK603 maize.⁸ Monsanto had submitted its initial request to place NK603 on the market in April 2001, and the regulatory process for authorization of food and feed uses had lasted three and one-half years.⁹

3. EUROPEAN COMMISSION, *PLANTS FOR THE FUTURE—2025: A EUROPEAN VISION FOR PLANT GENOMICS AND BIOTECHNOLOGY* 19 (2004).

4. In 2002, only about 25,000 hectares of GM crops were sown, mostly in Spain. DIRECTORATE-GENERAL FOR AGRICULTURE, *AGRICULTURE IN THE EUROPEAN UNION, STATISTICAL AND ECONOMIC INFORMATION* 2003 at 4.23 (Feb. 2004).

5. Commission Decision 2004/643, 2004 O.J. (L 295) 35. Art. 5 indicates that the Decision does not apply until NK603 has also been approved for food.

6. European Food Safety Authority, *Opinion of the Scientific Panel on Genetically Modified Organisms*, 2003 E.F.S.A. J. 10, 1-13, *available at* http://www.efsa.eu.int/science/gmo/gmo_opinions/176/opinion_gmo_03_final_en1.pdf.

7. *See* Proposal for a Council Decision concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (*Zea mays* L. line NK 603) genetically modified for glyphosate tolerance, COM(2004)193 final.

8. Press Release, European Commission, Genetically modified NK603 maize authorised for both food and feed (IP/04/1305, Oct. 26, 2004). The authorizations do not allow cultivation in the E.U.

9. Proposal for a Council Decision authorizing the placing on the market of foods and food ingredients derived from genetically modified maize line NK 603 as novel foods or novel food ingredients under Regulation (EC) No 258/97, COM (2004)439 final, at 2.

Similarly, in May 2004, the Commission authorized the placing on the market of a GM sweet corn, Syngenta's Bt11.¹⁰ This corn was authorized for import in 1998, and the recent authorization applies to canned corn. The corn will be labeled as genetically modified, can be traced by its unique identifier, and will be entered in the Community Register of Genetically Modified Food and Feed.¹¹ With these approvals, eighteen GM foods and nine GM feeds have been approved for sale in the European Union since 1996.

Approvals of GM crops for cultivation in the E.U. have progressed more slowly. For the first time, in September 2004, the Commission listed genetically modified seeds in the E.U. Common Catalogue of Varieties of Agricultural Plant Species.¹² The seventeen varieties were derived from Monsanto's MON 810 maize, authorized in 1998. Listing in the Common Catalogue allows the maize to be sold and planted in all Member States.¹³

The approval of NK603 corn signaled the end of a *de facto* moratorium on approvals of GM crops for import since 1998. To some extent, the *de facto* moratorium was the result of a perception that regulatory measures were inadequate to govern GM crops, food, and feed. In 2001, after a lengthy regulatory process, the E.C. began to enact new measures to ensure that GMOs are regulated during the experimental stage, when they are placed on the market, and afterwards; that those products can be identified and traced through their life cycle; and that labeling will provide adequate information and consumer choice.

The most important measures directed specifically toward GMOs are

- Directive 90/219 on the contained use of genetically modified microorganisms, as amended.¹⁴

10. Commission Decision 2004/657, 2004 O.J. (L 300) 48.

11. See Proposal for a Council Decision authorising the placing on the market of sweet corn from genetically modified maize line Bt11 as a novel food or novel food ingredients under Regulation (EC) no 258/97, COM(2004)10 final; Press Release, European Commission, Commission authorises import of canned GM-sweet corn under new strict labelling conditions—consumers can choose (IP/04/663, May 19, 2004).

12. The Common Catalog is governed by Council Directive 2002/53, 2002 O.J. (L 193) 1, as amended.

13. Press Release, European Commission, Inscription of MON 810 GM maize varieties in the Common EU Catalogue of Varieties (IP/04/1083, Sept. 8, 2004).

14. Council Directive 90/219, 1990 O.J. (L 117) 1, as amended; consolidated text at CONSLEG 1990L0219–20/11/2003.

- Directive 2001/18 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220, as amended.¹⁵
- Regulation 1829/2003 on genetically modified food and feed.¹⁶
- Regulation 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18.¹⁷

The last two measures replace several Regulations (1139/98,¹⁸ 49/2000,¹⁹ and 50/2000²⁰), as well as the Novel Foods Regulation,²¹ which had governed pre-market authorization and labeling for GM foods, insofar as it applied to GMOs.

The Commission has proposed a Decision to establish minimum thresholds for adventitious or technically unavoidable traces of GM seeds in other products,²² but at a September 2004 meeting, the measure was not agreed. The Food Law, Regulation 178/2002,²³ sets out general principles and establishes the European Food Safety Authority. In addition, the Environmental Liability Directive applies to allocate responsibility for some types of damage for contained use, deliberate release, transport, or placing on the market of GMOs.²⁴ Other measures, mentioned below, also apply.

A. Lawmaking in the E.C.

The European Union, now twenty-five Member States, is governed by primary legislation—its founding Treaties, as amended—and by secondary legislation.

15. Parliament and Council Directive, 2001 O.J. (L 106) 1, as amended; consolidated text at CONSLEG 2001L0018–07/11/2003.

16. Parliament and Council Regulation 1829/2003, 2003 O.J. (L 268) 1.

17. Parliament and Council Regulation 2001/18, 2003 O.J. (L 268) 24.

18. Council Regulation 1139/98, 1998 O.J. (L 159) 4 (labeling of food produced from GMOs).

19. Commission Regulation 49/2000, 2000 O.J. (L 6) 13 (amending Regulation 1139/98).

20. Commission Regulation 50/2000, 2000 O.J. (L 6) 15 (labeling for GM additives and flavorings).

21. Parliament and Council Regulation 258/97, 1997 O.J. (L 43) 1. Parts of the Regulation remain in effect.

22. Draft Commission Decision establishing minimum thresholds for adventitious or technically unavoidable traces of genetically modified seeds in other products, http://www.genfood.at/download/com_draft_seeds_04_2004.pdf.

23. Parliament and Council Regulation 178/2002, 2002 O.J. (L 31) 1.

24. Parliament and Council Directive 2004/35, 2004 O.J. (L 143) 56.

1. Primary Legislation: The Treaties

The Treaties establish the E.C. and many of its institutions, authorize Community activities, and prescribe procedures for decision making. The Treaty of Rome (1958) established the European Economic Community (EEC); the Treaty on European Union (1993) changed the name of the EEC to European Community (EC) and added new cooperation. The Single European Act (1987) helped complete the single market and added the environment title. The Amsterdam Treaty (1999) made further amendments and renumbered the Treaty, and the Treaty of Nice (2003) streamlined procedures for new Member States.²⁵

In June 2004, E.U. leaders agreed on the text of a new Treaty establishing a Constitution for Europe.²⁶ After translation into all official languages, the Constitution was signed by Heads of State and Government of the Member States in Rome, in October 2004. All twenty-five Member States must ratify the Constitution, using their own constitutional procedures, before it can enter into force. If the ratification procedure is successful, the Constitution will enter into force in November 2006.²⁷ The Constitution will create one Union, which will replace the European Communities and European Union, and the Constitution will govern the Union, replacing the E.U. and E.C. Treaties.²⁸

2. Secondary Legislation: Types of Measures

The Treaty entrusts enactment of secondary legislation to the European Parliament acting jointly with the Council, to the Council, and to the Commission. The E.C. enacts secondary legislation under authority of the Treaty, and measures normally identify the source of

25. The various Treaties are available at European Commission, Treaties, http://europa.eu.int/eur-lex/en/search/search_treaties.html.

26. TREATY ESTABLISHING A CONSTITUTION FOR EUROPE, Dec. 16, 2004, 2004 O.J. (C 310) 1 (2004) [hereinafter CONSTITUTION].

27. European Union, Treaty establishing a Constitution for Europe, at http://europa.eu.int/futurum/referendum_en.htm (last visited June 13, 2005). The Heads of State of three candidate countries, Bulgaria, Romania, and Turkey, also signed. In Spring 2005, however, both France and the Netherlands rejected the Constitution in national referenda, raising doubts about its success. See, e.g., Ed Johnson, *Britain Sets Aside Vote on EU Constitution After Defeats in France, Netherlands*, SAN DIEGO UNION-TRIBUNE, June 6, 2005, available at <http://www.signonsandiego.com/news/world/20050606-1638-britain-euconstitution.html>.

28. European Union, *Summary of the Agreement on the Constitutional Treaty* (June 28, 2004) (a non-paper to provide information on the Treaty), at <http://europa.eu.int/futurum> (last visited Mar. 19, 2005).

authority. Measures that govern GMOs and GM food and feed invoke Treaty authority to regulate in the areas of agriculture, the environment, and public health,²⁹ as well as authority for the approximation (or harmonization) of Member State laws that affect the establishment or functioning of the internal market.³⁰

GMOs are governed by several different types of secondary legislation. Most important are regulations and directives. “A regulation shall have general application. It shall be binding in its entirety and directly applicable in all Member States.”³¹ Because regulations apply directly, most need not be transposed into Member State law. Regulations that govern GMOs, however, require cooperation of Member States in the authorization process. “A directive shall be binding, as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and methods.”³² Directives are normally effective after implementation in Member State law, usually by a deadline established in the directive. The Commission may seek enforcement against Member States that fail to enact implementing provisions.³³

Other measures include decisions, recommendations, and opinions. Decisions may be addressed to Member States or private parties, and “a decision shall be binding in its entirety upon those to whom it is addressed.”³⁴ “Recommendations and opinions shall have no binding force.”³⁵

3. Enacting Secondary Legislation

The Treaty prescribes several methods for enacting directives and regulations. Most important is the co-decision procedure,³⁶ a lengthy process that requires agreement of both the European Parliament and the Council. Most recent measures that govern GMOs have been enacted under this procedure. In addition, the Commission or the Council often issues detailed rules to implement measures enacted by Parliament and Council.

29. TREATY ESTABLISHING THE EUROPEAN COMMUNITY, Nov. 10, 1997, O.J. (C 340) 3 (1997) [hereinafter E.C. TREATY].

30. *Id.* art. 95.

31. *Id.* art. 249.

32. *Id.*

33. *Id.* art. 226; *see, e.g.*, Case C-296/01, Commission v. French Rep., 2003 E.C.R. I-0000 (finding that France failed to transpose Directive 90/220, the original measure that governed deliberate release of GMOs).

34. E.C. TREATY art. 249.

35. *Id.*

36. *Id.* art. 251.

The European Court of Justice and Court of First Instance³⁷ ensure that “in the interpretation and application of this Treaty the law is observed.”³⁸ The Commission, national courts, and individuals may refer matters to the courts. The Treaty establishes the jurisdiction of each court.

B. Environmental Principles

The Treaty of Rome did not provide Community competence for environmental matters or even mention the word “environment.” Nonetheless, beginning in 1973, the Commission published a series of Environmental Action Programs, and the Council enacted environmental legislation under authority of more general Treaty articles. In 1987, the Single European Act added a title on the environment and provided a clear legal basis for enacting environmental measures.³⁹

1. Principles

The environmental title of the Treaty, as amended, indicates that community environmental policy should “aim at a high level of protection” and should be based on “the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay.”⁴⁰ The integration principle encourages environmental protection by prescribing that environmental protection must be integrated into the definition and implementation of other Community policies and activities.⁴¹ These principles help to guide E.C. regulation of GMOs; among them, the precautionary principle has received most attention.

37. *Id.* arts. 220-245.

38. *Id.* art. 220.

39. For detail on E.C. environmental authority, see Margaret Rosso Grossman, *Agro-Environmental Measures in the Common Agricultural Policy*, 25 U. MEM. L. REV. 927, 937-53 (1995).

40. E.C. TREATY art. 174(2); CONSTITUTION art. III-233(2) also includes these principles.

41. E.C. TREATY art. 6; CONSTITUTION art. II-97.

2. Precautionary Principle

a) In General

Evolving, perhaps, from the German *Vorsorgeprinzip*,⁴² the precautionary principle (or precautionary approach) has become part of international law, particularly for measures that protect the environment. For example, The Rio Declaration invokes the principle: “In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.”⁴³

Similarly, the Convention on Biological Diversity advocates the precautionary approach, noting that “lack of full scientific certainty should not be used as a reason for postponing measures” to minimize loss of biological diversity.⁴⁴ The Cartagena Protocol on Biosafety to the Convention on Biological Diversity, which entered into force in September 2003 and governs living modified organisms, uses a precautionary approach when importing parties are faced with “[l]ack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism.”⁴⁵

Developed in environmental law, the precautionary principle has also been applied in other fields, including food law and public health measures. The principle has engendered significant controversy, and it is not uniformly accepted, interpreted, or applied.⁴⁶

In the E.C., the precautionary principle is enshrined, though not explained, among the environmental principles in the Treaty; under the integration principle, it should also be incorporated in other E.C.

42. *Vorsorgeprinzip* means “principle of precaution.”

43. U.N. CONFERENCE ON ENVIRONMENT AND DEVELOPMENT, RIO DECLARATION ON ENVIRONMENT AND DEVELOPMENT, Principle 15, U.N. Doc. 4/conf.151/26 (vol. I), U.N. Sales No. E.73.II.A.14 (1992).

44. CONVENTION ON BIOLOGICAL DIVERSITY, pmbl., June 5, 1992, *available at* <http://www.biodiv.org/convention/articles.asp?lg=0&a-cbd-00>.

45. Convention on Biological Diversity, Cartagena Protocol on Biosafety to the Convention on Biological Diversity, art. 11(8) (2000), 39 I.L.M. 1027, *available at* <http://www.biodiv.org/doc/legal/cartagena-protocol-en.pdf>. For more information on the precautionary principle, *see* LUCAS BERGKAMP, EUROPEAN COMMUNITY LAW FOR THE NEW ECONOMY 157-214 (2003); NICOLAS DE SADELEER, ENVIRONMENTAL PRINCIPLES: FROM POLITICAL SLOGANS TO LEGAL RULES 91-223 (2002).

46. *E.g.*, Cass R. Sunstein, *Beyond the Precautionary Principle*, 151 U. PENN. L. REV. 1003, 1004 (“I aim to challenge the precautionary principle . . . because, read for all that it is worth, it leads in no direction at all.”).

policies.⁴⁷ The *Communication from the Commission on the precautionary principle*⁴⁸ provides explanation and guidelines for application. The Commission notes:

Although the precautionary principle is not explicitly mentioned in the Treaty except in the environmental field, its scope is far wider and covers those specific circumstances where scientific evidence is insufficient, inconclusive or uncertain and there are indications through preliminary objective scientific evaluation that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the chosen level of protection.⁴⁹

The principle is used to manage risk, and its use is triggered by unacceptable risk and scientific uncertainty. Measures based on the principle must be proportional, non-discriminatory, consistent with similar measures, based on analysis of costs and benefits, subject to review in light of new scientific data (that is, temporary), and assign responsibility for producing scientific data.⁵⁰

The Council endorsed the broad lines of this Communication and, among other recommendations, called on the Commission to incorporate the principle in legislative proposals and other actions, where appropriate.⁵¹ A European Parliament resolution raised issues about application of the principle.⁵² Parliament noted that the precautionary principle is only one of several tools for risk management and should be “part of an overall policy based on other factors such as, for instance, traceability or labelling.”⁵³

b) GMOs and the Precautionary Principle

Because biotechnology is perceived to pose uncertain risks to health and the environment, GMOs have invited application of the precautionary principle. The principle has influenced the regulation

47. DE SADELEER, *supra* note 45, at 110. For a Court of First Instance decision applying the principle, see Case T-13/99, Pfizer Animal Health SA v. Council, 2002 E.C.R. II-3305.

48. Communication from the Commission on the Precautionary Principle, COM(2000)1 final.

49. *Id.* at 9-10.

50. *Id.* at 16-20.

51. Council Resolution on the Precautionary Principle, ¶¶ 1, 24, Annex III to European Council, Nice, Conclusions of the Presidency (Dec. 2000), http://www.europarl.eu.int/summits/nice2_en.htm.

52. European Parliament Resolution on the Precautionary Principle, 2001 O.J. (C 232) 345.

53. *Id.* at 347.

of GMOs in the E.C., and much commentary has focused on its application to the management of risk from GMOs.⁵⁴

Early E.C. legislation that governed GMOs used a precautionary approach, but without referring directly to the precautionary principle. For example, Directive 90/220 did not cite the principle, though it did invoke the related principle that preventive action should be taken.⁵⁵ Nonetheless, the precautionary approach played a role in implementation of this and other measures, and it was one basis for the *de facto* moratorium on authorizations of GM varieties that began in October 1998.⁵⁶

Directive 2001/18 again mentions the prevention principle and directly invokes the precautionary principle: “The precautionary principle has been taken into account in the drafting of this Directive and must be taken into account when implementing it.”⁵⁷ In addition, “Member States shall, in accordance with the precautionary principle, 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.”⁵⁸ Various provisions of Directive 2001/18, especially for risk assessment and post-approval monitoring, implement the principle.

The 2002 Food Law, which lays down general principles and requirements for food safety, devotes an article to the precautionary principle:

In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.⁵⁹

Measures enacted should be “proportionate and no more restrictive of trade than is required . . . [with] regard being had to technical and economic feasibility and other factors.”⁶⁰

54. E.g., Zeynep Kivilcim Forsman, *Community Regulation of Genetically Modified Organisms: A Difficult Relationship Between Law and Science*, 10 EUR. L.J. 580 (2004).

55. Council Directive 90/220, pmbl., 1990 O.J. (L 117) 15, 15.

56. See Silvia Francescon, *The New Directive 2001/18/EC on the Deliberate Release of Genetically Modified Organisms into the Environment: Changes and Perspectives*, 10 REV. EUR. CMTY. & INT’L ENVTL. L. 309, 311 (2001).

57. Parliament and Council Directive 2001/18, pmbl. (8), 2001 O.J. (L 106) at 1.

58. Directive 2001/18, art. 4(1), 2001 O.J. (L 106) at 5.

59. Parliament and Council Regulation 178/2002, art. 7(1), 2002 O.J. (L 31) 1, 9.

60. Regulation 178/2002, art. 7(2), 2002 O.J. (L 31) at 9.

The 2003 regulation on traceability and labeling, refers to “risk management measures in accordance with the precautionary principle.”⁶¹ The accompanying GM food and feed Regulation refers instead to a “high level of protection of human life and health.”⁶²

II. EUROPEAN COMMUNITY REGULATORY MEASURES

European Community regulation of GMOs and GM food and feed relies on a number of interrelated Directives and Regulations.⁶³ These have been enacted and revised over the past fifteen years,⁶⁴ and the regulatory system is not yet complete. The system for authorizing the use of GMOs is process based, rather than product based. It requires case-by-case authorization of GMOs and follows a step-by-step process of decreasing containment. Traceability and labeling, with thresholds for their applicability, are important components of the most recent E.C. regulation.

Because the focus of these materials is new E.C. measures that govern food and feed and require traceability and labeling, provisions for authorization of GMOs under older measures are treated only briefly, despite the detailed regulatory scheme.

A. *Contained Use—Directive 90/219, as Amended*

Directive 90/219, which continues in force, sets out measures for the contained use of genetically modified micro-organisms (GMMs). Contained use refers to activities in which micro-organisms are genetically modified or in which the GMMs are used in any way, and for which “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.”⁶⁵ The Directive thus governs research, work in

61. Parliament and Council Regulation 1830/2003, pmb. (3), 2003 O.J. (L 268) 24, 24.

62. Parliament and Council Regulation 1829/2003, pmb. (2), 2003 O.J. (L 268) 1, 1.

63. The most important measures are listed in the Introduction, *supra* text accompanying notes 14-24.

64. Measures enacted in 1990 governed the contained use of genetically modified micro-organisms (Council Directive 90/219, 1990 O.J. (L 117) 1) and the deliberate release of genetically modified organisms into the environment (Council Directive 90/220, 1990 O.J. (L 117) 15). Council Directive 90/220 was repealed, effective October 17, 2002, when Directive 2001/18 took effect. Council Directive 90/219, as amended, continues in force.

65. Parliament and Council Directive 90/219, art. 2(c), 1990 O.J. (L 117) 1, as amended; consolidated text at CONSLEG 1990L0219 – 20/11/2003.

laboratories, and industrial work with GMMs. Member States assume responsibility for many aspects of implementation.

Member States designate a competent authority to assume responsibility for implementing the Directive, including inspections and other control measures. Member States must avoid adverse effects on health and environment from contained uses of GMMs. Therefore, users are to carry out risk assessments to determine the class of risk (negligible, low, moderate, or high risk) and the resulting assignment of containment level.⁶⁶ Moderate or high risk contained use of GMMs requires prior written consent of the competent authority.⁶⁷ Users have responsibility to apply the containment and other protective measures that apply to each class of contained use and to notify Member State authorities of activities carried out on their premises.⁶⁸ Member States must report to the Commission when accidents occur and annually (with a summary every three years). They must also notify other States of relevant incidents (e.g., accidents).

Annexes to the Directive describe criteria to be met when establishing safety of GMMs for human health and the environment (Annex II); principles to be applied in the risk assessment (Annex III); measures required for various types of containment—laboratories, growing rooms, animal units, other activities (Annex IV); and information required for notifications required by the Directive (Annex V).⁶⁹

B. *Deliberate Release*

1. In General

The E.C. enacted Directive 2001/18 after a decade of experience with its predecessor, Council Directive 90/220⁷⁰ and a Commission review of its effectiveness.⁷¹ The new Deliberate Release Directive was intended to make the decision making process for authorizing GMOs more efficient and transparent and to control risks that might

66. Directive 90/219, arts. 5, 6, 1990 O.J. (L 117) at 4, 5.

67. Directive 90/219, art. 10, 1990 O.J. (L 117) at 6.

68. Directive 90/219, arts. 7-12, 1990 O.J. (L 117) at 5, 6-7.

69. For more detail on Directives 90/219 and 90/220, see Margaret Rosso Grossman & A. Bryan Endres, *Regulation of Genetically Modified Organisms in the European Union*, 44 AM. BEHAVIORAL SCI. 378, 393-403 (2000).

70. Council Directive 90/220, 1990 O.J. (L 117) 15, as amended (no longer in force).

71. Report of the Commission on the Review of Council Directive 90/220/EEC, cited in Parliament and Council Directive 2001/18, pmbl. (1), 2001 O.J. (L 106) 1.

threaten human health and the environment.⁷² It imposed more stringent measures for environmental risk assessment, added a post-market monitoring requirement, limited the authorization for release of GMOs to ten years, and required Member States to ensure traceability and labeling of GMOs at all stages of placing on the market.

A number of other regulatory measures supplement Directive 2001/18 with detailed guidance notes (e.g., Council Decision 2002/811,⁷³ Commission Decision 2002/623⁷⁴), format instructions for submitting information (e.g., Council Decisions 2002/812, 2002/813;⁷⁵ Commission Decision 2003/701⁷⁶), and arrangements for GMO registers (e.g., Commission Decision 2004/204⁷⁷). Member States were to have implemented Directive 2001/18 in their national laws by 17 October 2002. Not all States have done so. As of August 2004, seven of the fifteen Member States and eight of the ten new States had communicated implementation measures. The Commission filed legal actions against eight of the fifteen Member States for failure to enact national measures.⁷⁸

Under the Directive, a genetically modified organism is “an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.”⁷⁹ General provisions in the Directive—e.g., environmental risk assessment, confidentiality, consultation requirements—apply to all GMOs.

Anyone who plans to seek authorization for release of a GMO must carry out an environmental risk assessment.⁸⁰ The Directive identifies the types of information that might be needed to carry out

72. Directive 2001/18, pmb. (5), (48), 2001 O.J. (L 106) at 3. *See also* Estelle Brosset, *The Prior Authorisation Procedure Adopted for the Deliberate Release into the Environment of Genetically Modified Organisms: the Complexities of Balancing Community and National Competences*, 10 EUR. L.J. 555 (2004).

73. Council Decision 2002/811, 2002 O.J. (L 280) 27.

74. Commission Decision 2002/623, 2002 O.J. (L 200) 22.

75. Council Decision 2002/812, 2002 O.J. (L 280) 37; Council Decision 2002/813, 2002 O.J. (L 280) 62.

76. Commission Decision 2003/701, 2003 O.J. (L 254) 21.

77. Commission Decision 2004/204, 2004 O.J. (L 65) 20.

78. Report from the Commission to the Council and the European Parliament on the experience of member states with GMOs placed on the market under Directive 2001/18/EC and incorporating a specific report on the operation of parts B and C of the Directive, COM(2004)575 final at 4. This document is a report on Member State experience under Directive 2001/18.

79. Directive 2001/18, art. 2(2), 2001 O.J. (L 106) at 4.

80. Directive 2000/18, art. 6, 2001 O.J. (L 106) at 6.

the risk assessment for higher plants and for other organisms.⁸¹ Potential adverse effects of the release on human health and the environment, especially from gene transfer, must be assessed on a case-by-case basis. The Directive establishes “principles” for risk assessment,⁸² and the Commission provided more specific guidance.⁸³

Directive 2001/18 governs deliberate release of GMOs in two circumstances: “any other purpose than for placing on the market” (in Part B) and “placing on the market of GMOs as or in products” (in Part C). These two circumstances are discussed separately.

2. Non-Market Deliberate Releases

Directive 2001/18 implements a step-by-step principle. That is, “the containment of GMOs is reduced and the scale of release increased gradually, step by step, but only if evaluation of the earlier steps in terms of protection of human health and the environment indicates that the next step can be taken.”⁸⁴ GMOs cannot be placed on the market until they have been field tested in appropriate ecosystems; therefore deliberate release at the research stage is one of the steps towards marketing.⁸⁵

Member States, through their competent authorities, play the main role in authorizing non-market deliberate releases, e.g., releases for field testing or other research. The Directive governs the procedure to be followed and the time frames for the various steps in the process.

A notification to the Member State competent authority is required before a deliberate release of a GMO or combination of GMOs. The notification requires a technical dossier, including detailed information prescribed in Annex III,⁸⁶ and the environmental risk assessment.⁸⁷ A summary of each notification must be sent to the Commission, which forwards the summary to other Member States,

81. Directive 2000/18, Annex III, 2001 O.J. (L 106) at 23-31.

82. Directive 2000/18, Annex II, 2001 O.J. (L 106) at 19-22.

83. Commission Decision 2002/623, 2002 O.J. (L 200) 22. Applicants should determine risk by evaluating possible adverse effects, their likelihood, and the magnitude of the consequences, and by identifying management strategies available to reduce risks.

84. Directive 2001/18, pmb. (24), 2001 O.J. (L 106) at 2.

85. Directive 2001/18, pmb. (23), (25), 2001 O.J. (L 106) at 2.

86. *See also* Council Decision 2002/813, art. 1, 2002 O.J. (L 280) 62, 62 (establishing the particular summary notification format that must be used in connection with a non-market deliberate release).

87. Directive 2001/18, art. 6, 2001 O.J. (L 106) at 6.

who may “present observations.”⁸⁸ If appropriate, Member States may consult the public on a proposed release.⁸⁹ The competent authority must give written consent to the release or, if the proposed release does not comply with the Directive, reject the notification.

No release is permitted until the notifier has received written consent from the competent authority. After the release, the notifier must report results, especially concerning risk to health or the environment, to the competent authority.⁹⁰ Member States must make available to the public information on all releases in their territory, but without disclosing confidential information.⁹¹ Commission Decision 2004/204 sets forth detailed guidance for Member States to follow in developing publicly accessible registers.⁹²

C. Placing on the Market

Placing products on the market affects the entire Community. Once a written consent for a GMO has been issued, that GMO may be used “without further notification throughout the community.”⁹³ Member States may not “prohibit, restrict or impede the placing on the market of GMOs, as or in products,” if the GMOs have been authorized.⁹⁴ Therefore the procedures for placing GMOs on the market are more complicated and require more involvement of the Commission and the competent authorities of all Member States.

Directive 2001/18 makes clear that placing on the market also covers imports. That is, products containing or consisting of GMOs cannot be imported into the E.C. if they do not comply with E.C. requirements.⁹⁵

Directive 2001/18 governs the placing on the market of GMOs, and Regulation 1829/2003 governs GM food and feed. Under the latter, the “one door-one key principle” applies; that is, a single au-

88. Directive 2001/18, art. 11, 2001 O.J. (L 106) at 8.

89. Directive 2001/18, art. 9(1), 2001 O.J. (L 106) at 8.

90. Directive 2001/18, art. 10, 2001 O.J. (L 106) at 8; *see also* Decision 2003/701, 2003 O.J. (L 254) 21 (providing the format for reporting results of a non-market deliberate release).

91. Directive 2001/18, arts. 9(2), 25, 2001 O.J. (L 106) at 8, 14.

92. Commission Decision 2004/204, 2004 O.J. (L 65) 20. To protect commercial interests, two sets of data should be maintained, one accessible to the public and the other accessible only to Member States, the Commission, and EFSA.

93. Directive 2001/18, art. 19(1), 2001 O.J. (L 106) at 12.

94. Directive 2001/18, art. 22, 2001 O.J. (L 106) at 13. Article 22 applies without prejudice to the safeguard clause, Article 23.

95. Directive 2001/18, pmbl. (11), 2001 O.J. (L 106) at 1.

thorization can cover the deliberate release of a GMO and its use as food or feed.⁹⁶

1. GMOs—Directive 2001/18

The authorization procedure for GMOs to be placed on the market under Directive 2001/18 begins with notification to the Member State competent authority. That notification must include information about the GMO, the environmental risk assessment, a plan for post-release monitoring, conditions for use and handling of the product, a summary of the dossier, and other information.⁹⁷ The summary dossier must be prepared according to the format prescribed by the Council. Required information includes the nature of the GMO and its predicted behavior, plus information about previous releases and the monitoring plan.⁹⁸

The post-release monitoring plan is an important component of the notification. The Directive describes its contents in general terms,⁹⁹ and guidance notes provide additional details.¹⁰⁰ The objective of the monitoring plan for a GMO is to ensure that the assumptions underlying the environmental risk assessment are correct and to identify unanticipated adverse effects on human health or the environment.¹⁰¹ In light of the unique characteristics of each GMO, monitoring plans must be developed on a case-by-case basis.¹⁰²

The Member State competent authority must examine each notification for compliance with the Directive, then prepare an assessment report. The report should focus particularly on the proposed use, the environmental risk assessment, and the proposed post-release monitoring plan.¹⁰³ A competent authority may decide that a GMO should not be placed on the market and reject the notification. If the competent authority concludes that the GMO should be placed on the market, the authority must send the dossier summary, along with its assessment report on the proposed GMO, to the Commission and to the competent authorities of the other Member States.¹⁰⁴ The

96. Parliament and Council Regulation 1829/2003, 2003 O.J. (L 268) 1.

97. Directive 2001/18, art. 13(2), 2001 O.J. (L 106) at 9.

98. Council Decision 2002/812, Annex, 2002 O.J. (L 280) 37, 38.

99. Directive 2001/18, Annex VII, 2002 O.J. (L 106) at 36.

100. Council Decision 2002/811, Annex, 2002 O.J. (L 280) 27, 27-36.

101. Decision 2002/811, Annex, 2002 O.J. (L 280) at 29.

102. Decision 2002/811, Annex, 2002 O.J. (L 280) at 28.

103. Directive 2001/18, Annex VI, 2001 O.J. (L 106) at 35.

104. Directive 2001/18, art. 4, 2001 O.J. (L 106) at 9-10. If the competent authority concludes that the GMO should not be placed on the market, the procedure differs slightly. *See* Directive 2001/18, art. 15, 2001 O.J. (L 106) at 10.

Commission must make the dossier summary and assessment report available to the public for comment.¹⁰⁵

The Commission and other Member States have the opportunity to ask for information, make comments, or “present reasoned objections” to the placing of a GMO on the market.¹⁰⁶ If no objections are made, or if outstanding issues are resolved, the competent authority that assessed the GMO may give written consent to the notifier and also inform the Commission and the other Member States.¹⁰⁷ Indeed, in a case brought under Directive 90/220, the European Court of Justice held that when no objections are raised, the competent authority is obliged to give consent.¹⁰⁸

Written consent will be explicit and will include specific conditions for use, handling and packaging of the GMO or for protection of the environment, labeling requirements (“This product contains genetically modified organisms.”), and obligations for monitoring.¹⁰⁹ After consent, notifiers must follow the prescribed monitoring plan and report regularly to the Commission and competent authorities; results of monitoring are also available to the public.¹¹⁰ Written consent shall be given for a maximum of ten years, and the Directive prescribes a procedure for renewal.¹¹¹

The standard procedure described above applies unless the Commission or a Member State raises and maintains an objection to consent. In most cases under prior law (that is Directive 90/220), objections have been raised.¹¹² Under Directive 2001/18, when objections are raised, the Commission must consult the competent Scientific Committee, the Scientific Panel on GMOs of the European Food Safety Authority.¹¹³ If the scientific decision is favorable, the Commission will follow the Community inter-agency regulatory procedure to reach a decision.¹¹⁴ The Commission submits a draft of the measure to be taken (i.e., a legislative decision to give consent to a proposed GMO) to a regulatory committee, made up of Member State repre-

105. Directive 2001/18, art. 24(1), 2001 O.J. (L 106) at 14.

106. Directive 2001/18, art. 15(1), 2001 O.J. (L 106) at 10.

107. See Directive 2001/18, art. 15(3), 2001 O.J. (L 106) at 10.

108. Case C-6/99, Association Greenpeace France v. Ministère de l’Agriculture et de la Pêche, [2000] E.C.R. I-1651. See Francescon, *supra* note 56, at 312.

109. Directive 2001/18, art. 19(3), 2001 O.J. (L 106) at 12.

110. Directive 2001/18, art. 20, 2001 O.J. (L 106) at 12-13.

111. Directive 2001/18, arts. 15(4), 17, 2001 O.J. (L 106) at 10-11.

112. See Brosset, *supra* note 72, at 568-71 (outlining Member State failures to cooperate).

113. Directive 2001/18, art. 28, 2001 O.J. (L 106) at 14-15.

114. Directive 2001/18, arts. 18, 30(2), 2001 O.J. (L 106) at 12, 15. That procedure is set out in Council Decision 1999/468, art. 5, 1999 O.J. (L 184) 23, 25.

representatives. If that committee agrees, the Commission will grant consent. If not, the Commission submits the measure to the Council (and informs Parliament). If the Council does not agree or oppose the consent by a qualified majority, the Commission may grant consent. Under this procedure, for example, the Commission granted consent for placing Maize NK603 on the market.¹¹⁵

Even after consent is granted, a safeguard clause protects Member States.¹¹⁶ A Member State may provisionally restrict or prohibit use or sale of a GMO as or in a product on its territory under limited conditions. The Member State must have detailed grounds for considering that the GMO poses a risk to human health or the environment, on the basis of either information made available since the date of consent or a reassessment of existing information using new scientific information.¹¹⁷ The Member State must inform the Commission and other Member States, including its review of environmental risk and other information. The Commission, with assistance of the Scientific Committee, must decide whether the Member State's action is justified. A number of Member States have invoked the safeguard clause in attempted bans of GMOs.¹¹⁸ In July 2004, for example, the European Food Safety Authority (EFSA) published opinions of the Scientific Panel on Genetically Modified Organisms that found no new scientific evidence that would justify prohibition of certain GM crops in Greece or Austria.¹¹⁹

The Treaty offers an additional general safeguard. Article 95(5) permits Member States to introduce national provisions after adoption of a Council or Commission harmonization measure, "based on

115. Commission Decision 2004/643, 2004 O.J. (L 295) 35.

116. Directive 2001/18, art. 23, 2001 O.J. (L 106) at 13.

117. Directive 2001/18, art. 23, 2001 O.J. (L 106) at 13.

118. Six Member States invoked the safeguard clause, art. 16, of Directive 90/220, in nine applications. In each instance, no justification for the state ban was found. European Commission, *Questions and Answers on the Regulation of GMOs in the European Union*, at 8 & Annex 5 (Nov. 2004), http://europa.eu.int/comm/food/food/biotechnology/gmfood/qanda_en.pdf. For a list of Member State invocations of the safeguard clause, see *Invocation of Article 16 under Directive 90/220/EC and Article 23 under Directive 2001/18/EC (Safeguard clause) as of 15 March 2005*, http://europa.eu.int/comm/environment/biotechnology/safeguard_clauses.htm.

119. European Food Safety Authority, Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Austrian invoke of Article 23 of Directive 2001/18/EC, 2004 E.F.S.A. J. 78, 1-13, http://www.efsa.eu.int/science/gmo/gmo_opinions/507_en.html; European Food Safety Authority, Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Greek invoke of Article 23 of Directive 2001/18/EC, 2004 E.F.S.A. J. 79, 1-8, http://www.efsa.eu.int/science/gmo/gmo_opinions/506_en.html.

new scientific evidence relating to the protection of the environment . . . on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure.”¹²⁰ The Member State must notify the Commission of the proposed provisions and the grounds for enacting them; the Commission must ascertain whether the provisions discriminate or restrict trade and whether they interfere with the internal market.¹²¹ Relying on this Treaty provision, Austria proposed a ban on the use of GMOs in Upper Austria, justifying its measure as a means to protect traditional and organic production systems, nature, the environment, and biodiversity.¹²² Austria’s proposed measure, a ban on GMOs, was more restrictive than the case-by-case authorization procedure prescribed in Directive 2001/18.¹²³ To evaluate the scientific justification for the proposed Austrian ban, the Commission asked the advice of EFSA, which consulted the Scientific Panel on Genetically Modified Organisms. EFSA concluded that Austria’s justification did not meet the requirements of Treaty Article 95(5),¹²⁴ and the Commission therefore rejected Austria’s proposed national provisions.¹²⁵

2. Food and Feed—Regulation 1829/2003

a) In General

Regulation 1829/2003 on GM food and feed is designed to ensure a high level of protection of human and animal health and to set out provisions for authorizing, supervising, and labeling GM food and feed.¹²⁶ The Regulation relies on the new principles articulated in Directive 2001/18 and uses the framework for risk assessment established in the 2002 Food Law, Regulation 178/2002.¹²⁷

120. EC TREATY art. 95(5). Article 95(4) includes an analogous provision for existing Member State measures.

121. EC TREATY art. 95(5) (6).

122. Commission Decision 2003/653, 2003 O.J. (L 230) at 36. The difficulties posed by coexistence of organic and GM crops concerned Austria.

123. Decision 2003/653, 2003 O.J. (L 230) at 34, 39. Moreover, Directive 2001/18 permitted widespread circulation of approved GMOs whereas Austria sought to prohibit circulation of an approved GMO.

124. Decision 2003/653, 2003 O.J. (L 230) at 42. Austria did not provide new scientific evidence related to protection of the environment, prove that its concerns about the coexistence of organic and GM crops were environmental, or show that Upper Austria had unique ecosystems.

125. Decision 2003/653, 2003 O.J. (L 230) at 43.

126. Parliament and Council Regulation 1829/2003, art. 1, 2003 O.J. (L 268) at 1-2.

127. Regulation 1829/2003, pmb. (9), 2003 O.J. (L 268) at 2. *See also* Parliament and Council Regulation 178/2002, 2002 O.J. (L 31) 1.

EFSA administrators Regulation 1829/2003, carrying out responsibilities similar to those of the Commission under the Deliberate Release Directive. EFSA assesses the risks of GM food or feed, albeit with assistance from Member State agencies.¹²⁸ The Food Law makes the Scientific Committee and permanent Scientific Panels of independent scientific experts responsible for providing scientific opinions of the EFSA.¹²⁹ A Scientific Panel on Genetically Modified Organisms, established in the Food Law, plays a key role.¹³⁰

Under the one door-one key principle, a single application may cover a GMO and a food or feed containing or consisting of GMOs. In that case, the applicant must provide information normally required under Directive 2001/18: the technical dossier, information and conclusions about the risk assessment, and a monitoring plan for environmental effects.¹³¹

The Regulation sets out separate, but similar, measures for GM food¹³² and feed;¹³³ products likely to be used both as food and feed may be authorized under a single application.¹³⁴ In November 2004, EFSA published a lengthy guidance document for preparation of risk assessments of GM plants and derived food and feed.¹³⁵

b) GM Food

(1) Scope

Regulation 1829/2003 governs GMOs for food use, food containing or consisting of GMOs, and food produced from or containing ingredients produced from GMOs.¹³⁶ “Produced from GMOs” means “derived, in whole or in part, from GMOs, but not containing or consisting of GMOs.”¹³⁷ The Regulation governs GM food additives and flavorings as well.¹³⁸

128. Regulation 1829/2003, art. 6, 2003 O.J. (L 268) at 8-9.

129. Regulation 178/2002, art. 28(1), 2002 O.J. (L 31) at 15.

130. See Regulation 178/2002, art. 28(4)(d), 2002 O.J. (L 31) at 15.

131. Regulation 1829/2003, arts. 5(5), 17(5), 2002 O.J. (L 31) at 8, 13.

132. Regulation 1829/2003, arts. 3-14, 2003 O.J. (L 268) at 6-12.

133. Regulation 1829/2003, arts. 15-26, 2003 O.J. (L 268) at 12-17.

134. Regulation 1829/2003, art. 27, 2003 O.J. (L 268) at 17.

135. See *generally* European Food Safety Authority, Guidance Document of the Scientific Panel on Genetically Modified Organisms for the Risk Assessment of Genetically Modified Plants and Derived Food and Feed, 2004 E.F.S.A. J. 99, 1-94, www.efsa.eu.int/science/gmo/gmo_guidance/660/gmo_guidance_riskassess_en1.pdf.

136. Regulation 1829/2003, art. 3(1), 2003 O.J. (L 268) at 6.

137. Regulation 1829/2003, art. 2(10), 2003 O.J. (L 268) at 6; *see also* Regulation 1830/2003, art. 3(2), 2003 O.J. (L 268) at 24, 25.

138. Regulation 1829/2003, pmb. (12), (13), 2003 O.J. (L 268) at 2.

Products that are produced with a GMO but have no GM material in the end product are excluded from regulation. This includes food made with GM processing or products from animals fed with GM feed.¹³⁹ GMOs to be used as seeds are governed by other measures and generally fall outside the scope of the Regulation.¹⁴⁰ The requirements of Regulation 1829/2003 apply in a “non-discriminatory manner” to Community and imported products,¹⁴¹ and the Regulation purports to take account of commitments to international trade and obligations under the Cartagena Protocol.¹⁴²

(2) Authorization Process

GM food cannot be placed on the market in the E.U. without an authorization granted under Regulation 1829/2003. An authorized GM food must not have adverse effects on health or the environment, mislead the consumer, or differ in a nutritionally adverse way from the food it replaces. The authorization process is intended to ensure that these requirements are met.¹⁴³

Authorization is similar to the process under Directive 2001/18, though the EFSA plays a central role under Regulation 1829/2003. The applicant submits an application, accompanied by scientific studies, a summary dossier, and other information, to the competent authority in a Member State. The Commission, in consultation with EFSA, has enacted detailed rules to guide the preparation of applications.¹⁴⁴ The national competent authority sends the application to EFSA, which informs, and forwards the application to, other Member States and the Commission and makes the summary dossier available to the public.¹⁴⁵

Authorization involves a scientific evaluation followed by a risk management decision.¹⁴⁶ EFSA must prepare its opinion on the basis of scientific analysis and consultation with experts and (for GMOs, under the one door-one key procedure) with Member State competent authorities. EFSA must forward its opinion, along with an assessment report, to the applicant, the Commission, and the Member States. The opinion is made public, and comments may be submitted

139. Regulation 1829/2003, pmb. (16), 2003 O.J. (L 268) at 2-3. *See also* Mansour & Key, *supra* note 1, at 61.

140. Regulation 1829/2003, pmb. (34), art. 6(3)(c), 2003 O.J. (L 268) at 4, 8.

141. Regulation 1829/2003, pmb. (43), 2003 O.J. (L 268) at 5.

142. Regulation 1829/2003, art. 44, 2003 O.J. (L 268) at 21.

143. Regulation 1829/2003, art. 4, 2003 O.J. (L 268) at 7.

144. *See generally* Commission Regulation 641/2004, 2004 O.J. (L 102) 14.

145. Regulation 1829/2003, art. 5, 2003 O.J. (L 268) at 7-8.

146. Regulation 1829/2003, pmb. (9), 2003 O.J. (L 268) at 2.

to the Commission. The Commission then submits a draft decision on the authorization to the Standing Committee on the Food Chain and Animal Health.¹⁴⁷ The inter-agency regulatory procedure, mentioned above,¹⁴⁸ is used to reach final decision on the application. Authorization of GM food is valid throughout the Community for ten years and can be renewed.¹⁴⁹ Authorized GM foods are listed in the Community Register of Genetically Modified Food and Feed.¹⁵⁰

c) GM Feed

(1) Scope

Regulation 1829/2003 also governs GMOs for feed use, feed containing or consisting of GMOs, and feed produced from GMOs.¹⁵¹ GM feed cannot be placed on the market, used, or processed in the E.U. without authorization.¹⁵² Authorized GM feed must not have adverse effects on human or animal health or on the environment, mislead consumers, impair “distinctive features of the animal products,” or differ in a nutritionally adverse way from the feed it is intended to replace.¹⁵³

(2) Authorization Process

The authorization process is similar to the process used for GM food, with the initial application, accompanied by scientific studies and other pertinent information, submitted to the Member State competent authority. That authority informs EFSA, which makes information available to other Member States, the Commission, and the public.¹⁵⁴

An application for authorization will undergo a stringent scientific evaluation, followed by a risk management decision.¹⁵⁵ EFSA prepares an opinion, based on scientific evidence and expert consultation, which is sent to the applicant, the Commission, and the Member States; the public has an opportunity to submit comments to the

147. Regulation 1829/2003, arts. 7, 35, 2003 O.J. (L 268) at 9, 19.

148. Council Decision 1999/468, 1999 O.J. (L 184) at 23.

149. Regulation 1829/2003, arts. 7(5), 11, 2003 O.J. (L 268) at 9, 10-11.

150. Regulation 1829/2003, arts. 7(5), 28, 2003 O.J. (L 268) at 9, 17.

151. Regulation 1829/2003, art. 15(1), 2003 O.J. (L 268) at 12.

152. Regulation 1829/2003, art. 16(2), 2003 O.J. (L 268) at 12. Conditions of the authorization must be satisfied.

153. Regulation 1829/2003, art. 16(1), 2003 O.J. (L 268) at 12.

154. Regulation 1829/2003, art. 17, 2003 O.J. (L 268) at 12-13.

155. Regulation 1829/2003, pmb. (9), 2003 O.J. (L 268) at 2.

Commission.¹⁵⁶ In light of the EFSA opinion, the Commission submits a draft decision on the application to the Standing Committee on the Food Chain and Animal Health.¹⁵⁷ As with GM food, the inter-agency regulatory procedure is used to reach a final decision on the application. A GM feed authorization is valid throughout the Community for ten years and is renewable, and authorized GM feeds are included in the Community Register of Genetically Modified Food and Feed.¹⁵⁸

D. Traceability and Labeling – Regulation 1830/2003 and Regulation 1829/2003

Both traceability and labeling are important components of food safety measures in the E.C. Two regulations enacted in 2003 work together to harmonize these requirements.

1. Traceability and Labeling in Other Measures

The 2002 Food Law defines “traceability” as “the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution.”¹⁵⁹ The Food Law points out the need for a comprehensive system of traceability within food and feed businesses to avoid disruption in case of food safety problems.¹⁶⁰ That Law requires traceability of food, feed, food-producing animals and other substances used in food; it requires food and feed business operators to implement systems and procedures, including labeling, for traceability.¹⁶¹

156. Regulation 1829/2003, art. 18(3), (6)-(7), 2003 O.J. (L 268) at 14.

157. Regulation 1829/2003, arts. 19, 35, 2003 O.J. (L 268) at 14-15, 19.

158. Regulation 1829/2003, arts. 19(5), 28, 2003 O.J. (L 268) at 15, 17.

159. Parliament and Council Regulation 178/2002, art. 3(15), 2002 O.J. (L 31) 1, 8. Compare a narrower definition preferred by U.S. producers and firms: “The efficient and rapid tracking of physical product and traits from and to critical points of origin or destination in the food chain necessary to achieve specific food safety and, or, assurance goals.” FARM FOUNDATION, FOOD TRACEABILITY & ASSURANCE IN THE GLOBAL FOOD SYSTEM 9 (2004), www.farmfoundation.org (last visited June 8, 2005).

160. Regulation 178/2002, pmb. (28), 2002 O.J. (L 31) at 3. The European Rapid Alert System for Food and Feed, authorized by the Food Law, arts. 50-54, was used in November 2004 to trace dioxin-contaminated potato by-products used for animal feed and to block movement of animals on farms that used the feed. Press Release, European Commission, Dioxin Contamination: EU traceability and alert notification systems work well (IP/04/1343, Nov. 5, 2004).

161. Regulation 178/2002, art. 18, 2002 O.J. (L 31) at 11. New guidelines facilitate implementation of traceability requirements in the Food Law. European Commission, Guidance on the Implementation of Articles 11, 12, 16, 17, 18, 19 and 20 of

For GMOs specifically, Directive 2001/18 indicates the importance of ensuring traceability “at all stages of the placing on the market of GMOs as or in products authorized under [the placing on the market provisions] of this Directive.”¹⁶² Directive 2001/18 also requires labeling. For placing a GMO on the market, both the initial notification procedure and the written consent provisions require compliance with labeling requirements and language that “this product contains genetically modified organisms.”¹⁶³ Member States are directed to follow labeling requirements, and minimum thresholds for labeling must be established.¹⁶⁴

While Directive 2001/18 called for a general pre-market traceability system for GMOs, it did not define traceability, articulate its objectives, or prescribe an approach for its implementation. Moreover, labeling provisions in Directive 2001/18 did not apply to operators who placed their GMO products on the open market.¹⁶⁵

2. Traceability Measures

a. Regulation 1830/2003

Regulation 1830/2003, which builds on Directive 2001/18, defines “traceability” as “the ability to trace GMOs and products produced from GMOs at all stages of their placing on the market through the production and distribution chains.”¹⁶⁶ Regulation 1830/2003 establishes a unified system of traceability for GMOs and for food and feed products produced from GMOs. It builds a harmonized framework, with the objectives of “facilitating accurate labelling, monitoring the effects on the environment and, where appropriate, on health, and the implementation of the appropriate risk management mea-

Regulation (EC) No. 178/2002 on General Food Law (Dec. 2004), http://europa.eu.int/comm/food/food/foodlaw/guidance/index_en.htm.

162. Parliament and Council Directive 2001/18, pmb. (42), 2001 O.J. (L 106) at 3.

163. Directive 2001/18, arts. 13(2)(f), 19(3)(e), Annex IV, 2001 O.J. (L 106) at 9, 12, 32.

164. Directive 2001/18, art. 21, 2001 O.J. (L 106) at 13.

165. See Caoimhín MacMaoláin, *The New Genetically Modified Food Labelling Requirements: Finally a Lasting Solution*, 28 EUR. L. REV. 865, 874 (2003); Francescon, *supra* note 56, at 315.

166. Parliament and Council Regulation 1830/2003, art. 3(3), 2003 O.J. (L 268) 24, 25. This definition differs slightly from the Food Law, which defines traceability as “the ability to trace and follow a food, feed, food-producing animal or substance intended to be incorporated into a food or feed, through all stages of production, processing and distribution.” Parliament and Council Regulation 178/2002, art. 15, 2002 O.J. (L 31) 1, 8.

sures including, if necessary, withdrawal of products.”¹⁶⁷ The Regulation applies “at all stages of the placing on the market” to products placed on the market under E.C. legislation. These include products consisting of or containing GMOs, food produced from GMOs, and feed produced from GMOs.¹⁶⁸

(1) Products Consisting of or Containing GMOs

An “operator” is one who places a product on the market or receives a product placed on the market.¹⁶⁹ Operators must ensure that prescribed information is transmitted in writing, at the first stage of placing on the market and at all subsequent stages. Two types of information are required: a statement that the product contains or consists of GMOs, and the unique identifier(s) assigned to the GMOs, under a system developed by the Commission.¹⁷⁰ Operators must have systems and standardized procedures to preserve this information and the identity of the operators by whom and to whom the products were made available for five years from each transaction.

Pre-packaged products must have language on a label (e.g., “This product contains genetically modified organisms.”). The display of bulk products offered to the final consumer must include similar language.¹⁷¹

(2) Food and Feed Produced from GMOs

Requirements are less stringent for food and feed produced from GMOs. When placing the product on the market, the operator must indicate in writing each food ingredient produced from GMOs and each feed material or additive produced from GMOs; if no list of ingredients exists, the operator must indicate that the product is produced from GMOs. The same five-year retention period applies.¹⁷²

b. Unique Identifiers

Before most provisions of Regulation 1830/29 could take effect, the Commission had to establish a system to develop and assign

167. Regulation 1830/2003, art. 1, 2003 O.J. (L 268) at 25.

168. Regulation 1830/2003, art. 2(1), 2003 O.J. (L 268) at 25.

169. Regulation 1830/2003, art. 3(5), 2003 O.J. (L 268) at 25.

170. Regulation 1830/2003, art. 4A(1), 2003 O.J. (L 268) at 26. *See infra* text accompanying notes 172-78.

171. Regulation 1830/2003, art. 4B(6)(b), 2003 O.J. (L 268) at 26.

172. Regulation 1830/2003, art. 5(2), 2003 O.J. (L 268) at 24, 27.

unique identifiers to GMOs. That system was described in Commission Regulation 65/2004 in January 2004.¹⁷³

Under Regulation 65/2004, all GMOs placed on the market are to have a unique identifier, which is to be registered with the Commission and with the Biosafety Clearing-House established in connection with the Cartagena Protocol.¹⁷⁴ The applicant for new GMOs is to develop the unique identifier, and the consent or authorization of the GMO will specify the identifier. Consent holders for GMOs authorized before January 2004 must develop identifiers, unless they already exist.

The annex to the Regulation specifies the formats for unique identifiers, which are to be coordinated with the OECD BioTrack product database.¹⁷⁵ Each identifier will have nine alphanumeric digits, divided into three components separated by hyphens. The first component, two or three digits, identifies the applicant or consent holder. The second, five or six digits, represents the transformation event; a unique number should apply to similar transformation events developed by different organizations or in different organisms. The final component, a single verification digit, is calculated from the numerical values of the other digits.¹⁷⁶

Member States must ensure compliance through control measures, including sample checks and testing (following technical guidelines established by the Commission).¹⁷⁷ The Commission must provide a central register with information about GMOs authorized in the European Union and, where available, other GMOs.¹⁷⁸

3. Labeling

Regulation 1830/2003 imposes labeling requirements for products consisting of or containing GMOs, but is specifically for food or

173. See generally Commission Regulation 65/2004, 2004 O.J. (L 10) 5.

174. Regulation 65/2004, arts. 2-3, 2004 (L 10) at 5-6. For more information, see Biosafety Clearing-House, Welcome to the Central Portal, <http://bch.biodiv.org/>.

175. Regulation 65/2004, Annex, 2004 O.J. (L 10) at 8-10; Organisation for Economic Co-operation and Development, Biotech Database, <http://webdomino1.oecd.org/ehs/bioprod.nsf>. The Cartagena Protocol is discussed *infra* text accompanying notes 243-59.

176. Regulation 65/2004, Annex, 2004 O.J. (L 10) at 8-10.

177. Regulation 1830/2003, art. 9(1)-(2), 2003 O.J. (L 268) at 27. Guidelines for sampling and detection of GM material are in Commission Recommendation 2004/787, 2004 O.J. (L 348) 18.

178. See Commission Decision 2004/204, art. 3, 2004 O.J. (L 65) 20, 21 (enacted under Directive 2001/18, art. 31(2), 2001 O.J. (L 106) at 15).

feed produced from GMOs.¹⁷⁹ For products consisting of or containing GMOs, operators must use the words “This product contains genetically modified organisms” or “This product contains genetically modified [name of the organism(s)].” For pre-packaged products, the words must appear on the label; for non-pre-packaged products, on or in connection with the product display. Labeling applies at all stages of placing on the market. Specific requirements in other E.C. legislation continue to apply.¹⁸⁰

Regulation 1829/2003 has similar labeling requirements for GM foods and feeds.¹⁸¹ The food labeling provisions apply to foods to be delivered to the final consumer or mass caterers in the Community that either contain or consist of GMOs or are produced from or contain ingredients produced from GMOs. Regulation 1829/2003 is more detailed than Regulation 1830/2003 about the content of the label. For example, if food consists of more than one ingredient, the words “genetically modified” shall appear in parentheses following the ingredient concerned. Moreover, if the ingredient is designated by category, the words “contains genetically modified [name of organism]” shall appear in the list of ingredients. Further, if there is no list of ingredients, “genetically modified” shall appear clearly on the label. Labels must mention characteristics or properties of the food if the food is different from its conventional counterpart in composition, nutritional value or effects, intended use, or health implications, or if the food may raise ethical or religious concerns.¹⁸² Detailed rules for implementation may be adopted.

Labeling rules for feed are similar, though not identical. GMOs for feed use and feed containing or consisting of GMOs must indicate “genetically modified [name of organism]” in parenthesis following the name of the feed. Feed produced from GMOs will instead indicate “produced from genetically modified [name of organism].”¹⁸³ The Regulation does not require labeling of products produced with GMOs or products from animals fed with GM feed.¹⁸⁴

179. Regulation 1830/2003, arts. 4B, 5, 2003 O.J. (L 268) at 24, 26-27.

180. Regulation 1830/2003, art. 4A(5), 2003 O.J. (L 268) at 26. For an example of requirements that continue to apply *see* Directive 2000/13, as amended by Commission Directive 2001/101, 2001 O.J. (L 310) 19.

181. Council Regulation 1829/2003, arts. 12-14, 24-26, 2003 O.J. (L 268) at 11-12, 16-17.

182. Regulation 1829/2003, art. 13(2), 2003 O.J. (L 268) at 11-12.

183. Regulation 1829/2003, art. 25(2)(b), 2003 O.J. (L 268) at 17.

184. For criticism of this regulatory omission, *see* MacMaoláin, *supra* note 165.

4. Labeling and Traceability Thresholds

Products that contain “adventitious or technically unavoidable” traces of *authorized* GMOs may not have to be labeled, and some traceability requirements do not apply. To prove that the presence of GM material is adventitious or technically avoidable, operators must be able to supply evidence that they have taken appropriate steps to avoid the presence of GM material.¹⁸⁵ For thresholds, Regulation 1830/2003 refers to Directive 2001/18 and Regulation 1829/2003.

Under Regulation 1830/2003, “traces of GMOs in products” do not trigger traceability and labeling requirements if the traces do not exceed the threshold set in Directive 2001/18.¹⁸⁶ That Directive indicates that, for products intended for direct processing, labeling is not required for adventitious or technically unavoidable traces of authorized GMOs of no more than 0.9%. Lower thresholds can be established.¹⁸⁷

For traces of GMOs in “products intended for direct use as food, feed or for processing,”¹⁸⁸ the traceability and labeling threshold is in Regulation 1829/2003. That Regulation, like Directive 2001/18, sets a threshold of 0.9% of food ingredients considered individually or food consisting of a single ingredient and 0.9% of feed and each feed ingredient.¹⁸⁹

Regulation 1829/2003 applies a three-year transitional threshold for some *unauthorized* GM material, if authorization is pending. If the risk evaluation for a GMO is favorable and the authorization application has not been rejected, the adventitious or technically unavoidable presence of no more than 0.5% of that GM material will not breach the Regulation.¹⁹⁰ The Commission is to provide a list of GMs that have received a favorable opinion from the Scientific Committee.¹⁹¹ This transitional exemption, which lasts until 2007, also applies to the traceability requirements for products for food and feed produced from GMOs.¹⁹² In addition, Directive 2001/18 applies this transi-

185. Regulation 1829/2003, arts. 12(3), 24(3), 2003 O.J. (L 268) at 11, 17.

186. Parliament and Council Regulation 1830/2003, art. 4C(7), 2003 O.J. (L 268) 24, 26; *see also* Parliament and Council Directive 2001/18, 2001 O.J. (L 106) 1.

187. *See* Directive 2001/18, art. 21(3), 2001 O.J. (L 106) 1, as amended by Regulation 1830/2003, art. 7, 2003 O.J. (L 268) 24, 27.

188. Regulation 1830/2003, art. 4C(8), 2003 O.J. (L 268) at 26.

189. Regulation 1829/2003, arts. 12(2), 24(2), 2003 O.J. (L 268) at 11, 16.

190. Regulation 1829/2003, art. 47(1), 2003 O.J. (L 268) at 22.

191. Commission Regulation 641/2004, art. 18(1), 2004 O.J. (L 102) 14, 19.

192. Regulation 1830/2003, art. 5(4), 2003 O.J. (L 268) 24, 27.

tional threshold to GMOs in products intended for direct use as food or feed or for processing.¹⁹³

A threshold for authorized GM seeds, required by Directive 2001/18,¹⁹⁴ has not yet been established. Proposed thresholds were 0.3% for cross-pollinating crops (maize, oilseed rape) and 0.5% for self-pollinating species, calculated to allow harvested material to meet the 0.9% threshold for direct use or direct processing.¹⁹⁵ This proposed measure remains controversial.¹⁹⁶

III. SOME OTHER ISSUES

New regulatory measures in the E.C., especially traceability and labeling requirements, raise several issues. Now that the moratorium on GM crops has ended, with GM varieties added to the Common Catalogue of Varieties of Agricultural Plant Species, producers may plant GM crops in close proximity to traditional or organic crops. Production of GM crops may lead to cross-pollination through pollen drift or commingling of GM and traditional seeds. This situation raises the difficult issue of coexistence and the related question of liability for cross-pollination and other possible damage. Moreover, the transboundary movement of living GM materials is the subject of international agreement and E.C. regulation. E.C. requirements for traceability and labeling, which affect imports as well as E.U.-grown crops, raise questions under international trade regimes. The following materials focus briefly on these important issues.

A. *Coexistence*

1. Background

Coexistence “refers to the ability of farmers to make a practical choice between conventional, organic and GM-crop production, in compliance with the legal obligations for labelling and/or purity standards.”¹⁹⁷ The issue of coexistence “concerns the economic conse-

193. Directive 2001/18, art. 12a, as amended by Regulation 1829/2003, art. 43, 2003 O.J. (L 268) at 20-21.

194. Directive 2001/18, art. 21(2), 2001 O.J. (L 106) at 13.

195. See Draft Commission Decision, *supra* note 22 and accompanying text.

196. The Danish and Austrian delegations were calling for detection levels of 0.1 percent (the detection level for genetically modified seeds). Press Release, European Council, 2578th Council Meeting, Agriculture and Fisheries (IP/8350/04, Apr. 26, 2004).

197. Commission Recommendation 2003/556 on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming, 2003 O.J. (L 189) 36.

quences of adventitious presence” of GM crops in non-GM crops, which can result from “seed impurities, cross-pollination, volunteers harvesting-storage practices and transport.”¹⁹⁸

As Franz Fischler (then agricultural commissioner) indicated, “[c]o-existence is about economic and legal questions, not about risks or food safety, because only authorised GMOs can be cultivated in the E.U.”¹⁹⁹ Issues raised by coexistence are economic aspects of adventitious presence of GMOs (e.g., labeling and the resultant loss of income from conventional crops; contamination of organic crops, which cannot be produced from GMOs under E.C. law) and management measures required to avoid adventitious presence. The probability of “admixture” of GM and non-GM crops and the measures for avoiding it depend on the type of crop and on geographic factors like natural conditions and field sizes.²⁰⁰

Some Member States want to ban GM crops in part or all of their territories, but Mr. Fischler concluded that mandatory GMO-free zones must be excluded. The protection of mere economic interests by strong limits on fundamental liberties cannot be justified legally, and the approach “runs counter to the very principle of co-existence.”²⁰¹

As amended in 2003, Directive 2001/18 notes that “Member States may take appropriate measures to avoid the unintended presence of GMOs in other products.” The Directive directs the Commission to study the issue and then “develop guidelines on the coexistence of genetically modified, conventional and organic crops.”²⁰²

198. Communication from Mr. Fischler to the Commission, Co-existence of Genetically Modified, Conventional and Organic Crops (Feb. 25, 2003), http://www.zs-l.de/gmo/downloads/Communication.Fischler_02_2003.pdf [hereinafter Communication].

199. Press Release, European Commission, GMOs: Commission addresses GM crop co-existence (IP/03/314, Mar. 5, 2003).

200. Communication, *supra* note 198, at 2-5. A practical example of the issue was raised in *Regina v. Secretary of State for the Environment ex parte Watson*, 1998 E.W.C.A. Civ. 1250 (July 21, 1998), <http://bailii.org/ew/cases/EWCA/Civ/1998/1250.html>. Watson, a major organic grower in Britain, feared cross-pollination between his crop and GM trial plantings on a neighboring farm. The court refused to order destruction or detasseling of the GM plants because risk of cross-pollination was slight and the GM producer had the appropriate consent for trial planting. *Id.*

201. Communication, *supra* note 198, at 6.

202. Directive 2001/18, art. 26, as amended by Regulation 1829/2003, art. 43, 2003 O.J. (L268) 1, 21.

2. Commission Recommendation

The Commission issued guidelines in its July 2003 Recommendation. The Commission agreed with Mr. Fischler that “[n]o form of agriculture, be it conventional, organic, or agriculture using [GMOs] should be excluded in the European Union.”²⁰³ Farmers should be allowed to choose the type of crops they grow, but consumer choice should be protected, too.²⁰⁴

Because coexistence measures necessary to protect health and the environment are required when GMOs are authorized under Directive 2001/18, economic loss and management measures are of most concern. Member States, which are diverse, should develop their own measures for coexistence, with guidance from the Commission.²⁰⁵

The Commission guidelines, which are nonbinding recommendations to Member States, address commercial seed and crop production. The guidelines are not measures to be adopted, but instead general principles to apply and factors to consider in designing State-specific measures. Principles include transparency, stakeholder involvement, science-based decision making, a system built on existing means of crop segregation, focus on authorized GM varieties, and consideration of liability rules.²⁰⁶ Factors focus on more practical concerns like sources of admixture, threshold values for labels, and characteristics of specific crops.²⁰⁷ The Commission also provided an “indicative catalogue” of measure, including on-farm measures, that might be part of a Member State’s coexistence strategy.²⁰⁸

Though the Commission rejected the idea of mandatory prohibitions of GM crops, the guidelines indicated that voluntary cooperation of farmers would be appropriate. Farmers could agree to establish zones of a single production type, which would reduce costs of crop segregation. Alternatively, producers could cluster fields with similar crop varieties, plant varieties with different flowering times, use different sowing dates, or coordinate crop rotations.²⁰⁹

Directive 2001/18 and the Commission Recommendation anticipate that each Member State will enact measures to address coexis-

203. Commission Recommendation 2003/556, pmbl. (1), 2003 O.J. (L 189) at 36.

204. Recommendation 2003/556, Annex § 1.1, 2003 O.J. (L 189) at 39.

205. Recommendation 2003/556, pmbl. (4)-(8), 2003 O.J. (L 189) at 36.

206. Recommendation 2003/556, Annex § 2.1, 2003 O.J. (L 189) at 40-42. Twelve principles are listed.

207. Recommendation 2003/556, Annex § 2.2, 2003 O.J. (L 189) at 42-44.

208. Recommendation 2003/556, Annex § 3, 2003 O.J. (L 189) at 44-47.

209. Recommendation 2003/556, Annex § 3.3, 2003 O.J. (L 189) at 46.

tence for its own agricultural conditions. So far, few States have done so. One exception is Denmark, which enacted its Act on the Growing etc. of Genetically Modified Crops (the Act on co-existence) in June 2004.²¹⁰ That law authorizes the Minister for Food, Agriculture and Fisheries to make rules to manage the coexistence of GM and other crops.²¹¹ Rules may require a license for growing, handling and transport of GM crops, issue restrictive authorizations for growing GM crops, and limit sales of GM materials to authorized growers.²¹² The Minister may impose other obligations, including notification of nearby owners and producers of GM crops, prescribed separation distances, and reports on field locations.²¹³ The Minister also has authority to pay compensation, within limits, to farmers who suffer losses from unintended GM material in crops, with funds collected through an annual fee per hectare of GM crops.²¹⁴ Germany's new Genetic Modification Act, passed by the Bundestag 26 November 2004, prescribes coexistence measures. These include a site register accessible to the public and a requirement that those who use GM products take precautionary action (including good farming practices) to avoid adverse effects. Farmers who cultivate GM crops may be liable for material adverse effects, including admixture.²¹⁵ Italy has also enacted a coexistence law, which authorizes framework regulations for coexistence and directs regions to adopt coexistence plans with technical rules.²¹⁶

B. Liability

1. Preliminary Considerations

The assignment of liability for damages that might arise from development or use of GMOs raises difficult issues. Measures enacted to govern GMOs and their products do not address liability comprehensively, and more general measures apply only in limited circumstances.

210. Act No. 436 of 9 June 2004, *available at* <http://www.fvm.dk/file/co-extinse.pdf>.

211. Act No. 436 §§ 3-8.

212. Act No. 436 §§ 3-6.

213. Act No. 436 § 6.

214. Act No. 436 §§ 9-12.

215. Gentechnikgesetz (GenTG), art. 1, §§ 16a, 16b, 36a (Bundestag, 26 Nov. 2004).

216. Decreto-Legge 22 novembre 2004, n.279, *Gazzetta Ufficiale*, serie generale, n. 280; Legge 28 gennaio 2005, n.5, *Gazzetta Ufficiale*, serie generale, n.22. An English translation is available in USDA, Foreign Agricultural Service, Gain Report No. IT5003.

Directive 2001/18 governing deliberate release of GMOs did not address liability. Its preamble indicates that the Directive is without prejudice to national legislation on environmental liability. E.C. regulation of GMOs should be complemented by measures that assign liability for environmental damage, which would be enacted in a more general liability scheme expected to apply to GMOs and other dangerous activities.²¹⁷

The Commission Recommendation on coexistence recognizes that liability for GM crops is an issue for Member States.

The type of instruments adopted may have an impact on the application of national liability rules in the event of economic damage resulting from admixture. Member States are advised to examine their civil liability laws to find out whether the existing national laws offer sufficient and equal possibilities in this regard. Farmers, seed suppliers and other operators should be fully informed about the liability criteria that apply in their country in the case of damage caused by admixture.²¹⁸

The Recommendation suggested that an existing or new insurance scheme might help to compensate damage from admixture of GM and other crops.²¹⁹

The E.C. Products Liability Directive, which applies broadly, prescribes that “The producer shall be liable for damage caused by a defect in his product.”²²⁰ A product is defective when “it does not provide the safety which a person is entitled to expect, taking all circumstances into account.”²²¹ To help restore consumer confidence in safety of agricultural products, the directive was amended in 1999 to include primary agricultural products. So in some instances, limited by the Directive’s definition of damage and the requirement that the product be defective (questionable for GMOs), measures enacted under the Products Liability Directive might be available to redress damage from GMOs.²²²

217. Parliament and Council Directive 2001/18, pmb. (16), 2001 O.J. (C 304) at 2.

218. Commission Recommendation 2003/556, Annex § 2.1.9, 2003 O.J. (L 189) at 42.

219. Recommendation 2003/556, Annex § 2.1.0, 2003 O.J. (L 189) at 42.

220. Council Directive 85/374, art. 1, 1985 O.J. (L 210) 29, as amended by Parliament and Council Directive 1999/34, 1999 O.J. (L 141) 20.

221. Directive 85/374, art. 6, 1985 O.J. (L 210) at 31.

222. Directive 85/374, art. 9, 1985 O.J. (L 210) at 31; Margaret Rosso Grossman, *Genetically modified crops in the United States: Federal regulation and state tort liability*, 5 ENVTL. L. REV. 86, 97 (2003). For more information on this Directive and its limited application to GMOs, see BERGKAMP, EUROPEAN COMMUNITY LAW, *supra* note 45, at 252-58.

Some argue that no special liability regime for GMOs is justified because regulation has reduced risk to “acceptable levels,” and both “scientific knowledge and practical experience” indicate that no significant, unreasonable risk remains.²²³ Even when policy makers agree that a liability scheme might be desired, the design of such a scheme fosters disagreement. For example, negotiations prior to enactment of the Cartagena Biosafety Protocol considered numerous alternative liability regimes for biotechnology, but no agreement could be reached. Instead, the Protocol calls for further study.²²⁴ Nor do other liability regimes (e.g., the Council of Europe’s Lugano Convention) impose liability on agricultural producers. Some national liability regimes provide remedies through laws imposing strict liability for defective goods or substances or through fault-based principles of negligence or nuisance.²²⁵ Specifically for GMOs, the new German Genetic Engineering Act imposes liability on producers whose crops cause a material adverse effect on other property owners,²²⁶ whereas the Danish coexistence law authorizes a compensation system.²²⁷

2. Environmental Liability Directive—Directive 2004/35

The Commission’s *White Paper on Environmental Liability*²²⁸ reflects the concerns of the European public about environmental damage from deliberate release of GMOs. The *White Paper* recommended that liability from GMOs—including both damage to biodiversity and damage to persons and property—be treated in a horizontal measure that would provide a general framework for liability in a number of sectors.

That horizontal measure is Directive 2004/35 on environmental liability with regard to the prevention and remedying of environmental damage, enacted in April 2004.²²⁹ Invoking the polluter pays principle and the principle of sustainable development,²³⁰ the Directive

223. See Lucas Bergkamp, *Allocating unknown risk: Liability for Environmental Damages Caused by Deliberately Released Genetically Modified Organisms*, 2000 TIJDSCHRIFT VOOR MILIEUAANSPRAKELIJKHEID (Part I) 61, (Part II) 104, 110.

224. Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Montreal 2000), art. 27, 39 I.L.M. 1039; Bergkamp, *supra* note 223, Part I, at 66-67.

225. See Bergkamp, *supra* note 218, Part I, at 68-70, Part II, at 104-107. This section was adapted from Grossman, *supra* note 222, at 97.

226. Gentechnikgesetz, *supra* note 215, § 36a.

227. Act on the Growing etc. of Genetically Modified Crops, *supra* note 210.

228. COM(2000)66 final.

229. Parliament and Council Directive 2004/35, 2004 O.J. (L 143) 56.

230. Directive 2004/35, art. 1, 2004 O.J. (L 143) at 59; see also EC TREATY art. 174(2).

on environmental liability governs only environmental damage, rather than traditional damage to persons and property.²³¹

Environmental damage under the Directive includes damage to protected species and natural habitats (generally those protected by the Wild Birds²³² and Habitats Directives²³³ or by national nature conservation legislation). It also includes water damage and land damage.²³⁴ The latter is contamination that creates “a significant risk of human health being adversely affected as a result of the direct or indirect introduction, in, on or under land, of substances, preparations, organisms, or micro-organisms.”²³⁵ The Directive does not give private parties a right to compensation from environmental damage, though it does not prevent Member States from doing so.²³⁶

Member States implement the Directive through a competent authority, and by 30 April 2007 must have national measures to comply with the Directive. The Directive is not retroactive and does not apply to damage caused before that date.²³⁷ Member State measures must require operators (those who carry out the listed activity or hold the authorization for the activity) to take preventive action to avoid environmental damage, to apply measures to remediate the damage, and to bear the costs for preventive and remedial actions.²³⁸

GMOs are one focus of the Directive, which applies to environmental damage, and imminent threat of damage, caused by activities listed in Annex III.²³⁹ Among the listed activities are contained use of GM micro-organisms, as defined by Directive 90/219, and deliberate release and marketing of GMOs, as defined by Directive 2001/18.²⁴⁰ Thus operators have the duty to prevent damage and to remediate damage from GMOs. But Member States may allow the operator not to bear the cost of remedial actions under some conditions—if the operator was not at fault or negligent and the damage was caused by an emission or event expressly authorized and in compliance with national measures that implement E.C. measures (for GMOs, Directives 90/219 and 2001/18) or by an emission or activity that the operator

231. Directive 2004/35, pmb. (14), art 3, 2004 O.J. (L 143) at 57, 60-61.

232. Council Directive 79/409, 1979 O.J. (L 103) 1, as amended.

233. Council Directive 92/43, 1992 O.J. (L 206) 7, as amended.

234. Directive 2004/35, art. 2(1), 2004 O.J. (L 143) at 59.

235. Directive 2004/35, art. 2(1)(c), 2004 O.J. (L 143) at 59.

236. Directive 2004/35, art. 3(3), 2004 O.J. (L 143) at 60-61.

237. Directive 2004/35, arts. 17, 19(1), 2004 O.J. (L 143) at 64-65.

238. Directive 2004/35, arts. 2(6), 6-8, 2004 O.J. (L 143) at 60, 61-63.

239. Directive 2004/35, art. 3(1), Annex III, 2004 O.J. (L 143) at 60, 70.

240. Council Directive 90/219, Annex I, as amended by Council Directive 98/81, 1998 O.J. (L 330) 13, 19; Parliament and Council Directive 2001/18, Annex III, 2001 O.J. (L 106) at 23.

can show was not considered likely to cause environmental damage “according to the state of scientific and technical knowledge” when the emission or activity took place.²⁴¹ This exemption would seem to apply to GMOs that are authorized and used in accordance with their authorizations.

Member States can maintain or adopt more stringent measures to prevent and remedy environmental damage and can identify additional activities and responsible parties.²⁴² Because of the intentionally limited scope of the Directive, Member State legislation will apply to redress traditional damage to persons and property.

C. *Transboundary Movement of GMOs—Directive 1946/2003*

International law has influenced E.C. measures that govern GM crops, especially labeling for transboundary movement. The Cartagena Protocol on Biosafety to the Convention on Biological Diversity²⁴³ adopts a precautionary approach to the “transfer, handling and use of living modified organisms [LMOs] resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.”²⁴⁴

The Protocol establishes an “advance informed agreement procedure” to govern the first intentional movement of LMOs for intentional introduction into the environment of an importing country.²⁴⁵ In brief, the procedure involves notice by the Party of export, acknowledgement by the Party of import, opportunity for a risk assessment, and a decision, in writing, from the Party of import that approves or prohibits the proposed import. The Protocol requires labeling of LMOs intended for direct use as food or feed or for processing, for contained use, or for intentional introduction into the environment.²⁴⁶ The Protocol on Biosafety does not establish liability. Instead it provides for adoption of a process for elaboration of international rules governing liability and redress for damage from transboundary movements of LMOs.²⁴⁷

241. Directive 2004/35, art. 8(4), 2004 O.J. (L 143) at 62-63.

242. Directive 2004/35, art. 16, 2004 O.J. (L 143) at 64.

243. Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Montreal 2000), 39 I.L.M. 1027, *available at* <http://www.biodiv.org/doc/legal/cartagena-protocol-en.pdf>.

244. *Id.* art. 1, at 1027.

245. *Id.* arts. 7-13, at 1030-33.

246. *Id.* art. 18(2), at 1035.

247. *Id.* art. 27, at 1039.

The Protocol creates the Biosafety Clearing-House to facilitate exchange of information and other activities.²⁴⁸ In 2004, the Conference of the Parties to the Cartagena Protocol enacted a Decision that outlines identity requirements for transboundary shipment for LMOs and recommends use of the OECD BioTrack unique identifiers. A technical experts group will develop more detailed guidelines.²⁴⁹

The European Community and its Member States are parties to the Protocol. Directive 2001/18 refers to the Cartagena Protocol and the E.C.'s obligations.²⁵⁰ The Directive invited a Commission proposal with measures to implement the procedures for advance informed agreement and other requirements of the Cartagena Protocol. In addition, Regulation 1829/2003 requires notification of authorizations and other actions concerning GMOs to the Biosafety Clearing-House and other cooperation with the Protocol.²⁵¹

To comply with the Protocol, the E.C. enacted Regulation 1946/2003 on transboundary movements of GMOs.²⁵² That Regulation takes account of the precautionary principle and supplements, but does not interfere with, already-existing E.C. measures, for example, the provisions of Directive 2001/18. The Protocol requires the identification of GMOs exported from or imported into the Community. Because E.C. measures already govern traceability, labeling, and identification of E.C. products and imports, the heart of Regulation 1946/2003 enacts similar rules for exports.²⁵³ Exporters are required to ensure accurate, written notification to the party of import and may not export without express written consent from the importing country.²⁵⁴ No notice is required for contained use. GMOs intended for direct use as food or feed or for processing need no notice and consent for import, but Member States must notify the BioSafety Clearing-House of relevant GM authorizations.²⁵⁵

When GMOs are exported, documentation must indicate that the product contains or consists of GMOs and provide the unique identifi-

248. *Id.* art. 20, at 1036-37.

249. Report of the First Meeting of the Conference of the Parties Serving as the Meeting of the Parties to the Protocol on Biosafety, Apr. 14, 2004, BS-I/6, 85, <http://www.biodiv.org/doc/meetings/bs/mop-01/official/mop-01-15-en.pdf>.

250. Parliament and Council Directive 2001/18, pmbl. (13), art. 32, 2001 O.J. (L 106) at 1-2, 16.

251. Parliament and Council Regulation 1829/2003, art. 44, 2003 O.J. (L 268) at 21. The Biosafety Clearing-House plays a role in the system of unique identifiers; see *supra* note 174.

252. Parliament and Council Regulation 1946/2003, 2003 O.J. (L 287) 1.

253. Regulation 1946/2003, pmbl. (16), arts. 4-13, 2003 O.J. (L 287) at 4-6.

254. Regulation 1946/2003, arts. 4-5, 2003 O.J. (L 287) at 4.

255. Regulation 1946/2003, arts. 8(1), 9, 2003 O.J. (L 287) at 5.

cation codes for those GMOs. Food or feed products must indicate that the GMOs are intended for food, feed, or processing and not for deliberate release into the environment. GMOs exported for deliberate release must include additional information about traits and characteristics.²⁵⁶

Critics have argued that the provisions of the Biosafety Protocol were “never intended to apply to food products but are in fact the basis for the entire E.U. [regulatory] revision process.”²⁵⁷ Indeed, intentional introduction into the environment, for purposes of the advance informed agreement procedure, does not include LMOs intended for direct use as food, feed, or for processing, though parties to the Protocol must receive notice of approval of those products through the BioSafety Clearing-House.²⁵⁸ The Protocol also requires documentation that LMOs intended for direct use as food or feed “may contain” LMOs and are not intended for intentional introduction into the environment.²⁵⁹

D. WTO

E.C. regulation of GMOs affects trading partners, including the United States.²⁶⁰ E.C. measures that govern GMOs apply within the E.C., but those measures also apply to imports. Thus the *de facto* moratorium on authorization of GMOs under Directive 2001/18 had a significant effect on US trade. E.C. measures enacted in 2003 to require traceability and labeling will impose significant burdens on US exporters.

This article has focused only on E.C. regulation of GM crops, food, and feed, but many nations have enacted laws and regulations to govern GMOs. Moreover, international institutions also govern biotechnology for various purposes (e.g., health, trade, environment). Researchers have identified seven international organizations involved with biotechnology (most beyond the scope of this article).²⁶¹ Among international measures are the Biosafety Protocol with its advance informed agreement procedure, international food standards of the *Co-*

256. Regulation 1946/2003, art. 12, 2003 O.J. (L 287) at 6.

257. Mansour & Key, *supra* note 1, at 66.

258. Cartagena Protocol, arts. 7, 11, 39 I.L.M. at 1027, 1030, 1032.

259. *Id.* art. 18, at 1035.

260. *See generally* PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, U.S. vs. EU: AN EXAMINATION OF THE TRADE ISSUES SURROUNDING GENETICALLY MODIFIED FOOD (Aug. 2003), available at <http://pewagbiotech.org/resources/issuebriefs/europe.pdf>.

261. Donald E. Buckingham & Peter W.B. Phillips, *Issues and Options for the Multilateral Regulation of GM Foods*, 2 ESTEY CENTRE J. OF INT'L. L. & TRADE POL'Y 178, 179-80 (2001).

dex Alimentarius Commission, and agreements of the World Trade Organization (WTO).

Most trade disputes focused on GM issues will be directed to the WTO dispute settlement procedure. The WTO relies on scientific knowledge developed by other organizations and is likely to “deliver pro-trade, science- and rules-based decisions,” albeit limited to the cases brought to the dispute resolution body.²⁶²

1. Current Dispute and the SPS Agreement

In response to the E.C.’s long moratorium on authorization of GM products and to individual Member State bans of GM products, the United States, joined by Argentina and Canada, invoked the WTO dispute settlement system. In May 2003, the United States filed a consultation request, and in August 2003 requested establishment of a dispute settlement panel.²⁶³

The United States alleged that the long E.C. moratorium violates numerous obligations under the WTO, including the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). The SPS Agreement applies to measures designed to protect life and health that also affect international trade. The Agreement indicates that Members must ensure that “any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence.”²⁶⁴ Among other alleged violations, the United States noted that the E.C. had failed to use the types of scientific risk assessment required by the SPS Agreement and failed to base its moratorium on risk assessment.²⁶⁵ Moreover, though the establishment of procedures for approval of biotech products does not violate the SPS agreement, the United States argued that the E.C. moratorium violates the requirement that those procedures must be completed “without undue delay.”²⁶⁶

262. *Id.* at 185, 187. The WTO Agreements do not apply neatly to issues concerning biotechnology. See Arthur E. Appleton, *The Labeling of GMO Products Pursuant to International Trade Rules*, 8 N.Y.U. ENVTL. L.J. 566, 570-78 (2000).

263. Case WT/DS291; see also US, Executive Summary of the First Submission of the United States, WT/DS291, 292, 293, 30 April 2004.

264. Agreement on the Application of Sanitary and Phytosanitary Measures, April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, art. 2.2, http://www.wto.org/english/docs_e/legal_e/15-sps.pdf [hereinafter SPS Agreement].

265. *Id.* art. 5.

266. *Id.* art. 8; Annex C, ¶1(a). But see Aaron A. Ostrovsky, *The European Commission’s Regulations for Genetically Modified Organisms and the Current WTO Dispute—Human*

The United States also objects to Member State restrictions on authorized GMOs. Six Member States (Austria, France, Germany, Greece, Italy and Luxembourg) have enacted marketing (five States) or import (Greece) bans on approved GM products, using safeguard provisions under E.C. legislation.²⁶⁷ The safeguard provisions require evidence that the product is a risk to human health or the environment. The E.C. Scientific Committee found no scientific basis for the bans, but the State bans have continued. Therefore, the United States alleges, the measures are not based on risk assessment and also violate the SPS Agreement.²⁶⁸

The dispute settlement panel assigned to the case has agreed to seek expert scientific testimony before deciding the dispute. A panel report is expected sometime in 2005.

2. Other WTO Issues

E.C. reluctance to authorize and import GMOs and their products raises other trade issues. Under the GATT, the national treatment rule requires that products imported from WTO members “be accorded treatment no less favorable than that accorded to like products of national origin in respect of all laws, regulations and requirements”²⁶⁹ One relevant question under this provision is whether GM and conventional crops are “like products.”²⁷⁰ If they are not, the national treatment rule does not apply. If they are like products, GATT article XX provides general exceptions for measures “necessary to protect human, animal or plant life or health.”²⁷¹ The SPS agree-

Health or Environmental Measures? Why the Deliberate Release Directive is More Appropriately Adjudicated in the WTO Under the TBT Agreement, 15 COLO. J. INT’L ENVTL. L. & POL’Y 209 (2004).

267. See *supra* notes 116-121 and accompanying text.

268. SPS Agreement, arts. 2.2, 5.1, and Annex A, ¶4. For more information on the SPS Agreement, see Chris Hilson & Duncan French, *Regulating GM Products in the EU: Risk, Precaution and International Trade*, in AGRICULTURE AND INTERNATIONAL TRADE: LAW, POLICY, AND THE WTO 215, 228-31 (Michael N. Cardwell et al. eds., 2003).

269. General Agreement on Tariffs and Trade, October 1947, art. III. 4, http://www.wto.org/english/docs_e/legal_e/gatt47_e.pdf [hereinafter GATT].

270. See Julian Wong, Note, *Are Biotech Crops and Conventional Crops Like Products? An Analysis under GATT*, 2003 DUKE L. & TECH. REV. 27 (2003).

271. See GATT art. XX, *chapeau* & (b):

Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures (b) necessary to protect human, animal or plant life or health.

ment, with its risk assessment, may provide the standard for determining whether measures are necessary.²⁷²

The E.C. Regulation that governs traceability and labeling may give rise to further claims under the WTO, especially because label requirements apply to imports.²⁷³ The Agreement on Technical Barriers to Trade (TBT Agreement) is intended to ensure that technical regulations made to fulfill a legitimate objective do not create unnecessary obstacles to international trade. Because labeling is a technical regulation, E.C. measures must be compatible with the TBT Agreement. Thus, the measures must fulfill a legitimate objective, which include, e.g., “protection of human health or safety, animal or plant life or health, or the environment.”²⁷⁴ If challenged under the TBT Agreement, E.C. justifications for labeling (environmental protection, consumer choice) must be found to be a legitimate objective. The TBT Agreement also requires non-discriminatory treatment for like products; discrimination triggers application of GATT Article XX.²⁷⁵

The Cartagena Protocol affects trade through its advance informed consent procedure and required labels for imports of LMOs. Its provisions may raise questions under the WTO, especially where Protocol restrictions seem to conflict with WTO goals of free trade. Differences in approach exist; the Protocol, for example, encourages adoption of the precautionary approach in the face of scientific uncertainty,²⁷⁶ while the SPS Agreement allows only a provisional measure, followed by an objective risk assessment within a reasonable time.²⁷⁷ Further, some have questioned whether the label requirement (“may contain LMOs”) under the Cartagena Protocol complies with the SPS or TBT, and whether the E.C. might use its obligations under the Protocol to support its own measures in a WTO dispute.²⁷⁸

272. See Norman W. Thorson, *International Trade in Genetically Altered Agricultural Products: Impact of the Biosafety Protocol*, in AGRICULTURE AND INTERNATIONAL TRADE, *supra* note 268, at 239, 257-61.

273. Appleton, *supra* note 262, at 570.

274. The WTO Agreement on Technical Barriers to Trade (GATT Standards Code), art. 2.2, available at http://www.wto.org/english/tratop_e/tbt_e/tbtagr.htm. For a detailed description see Ostrovsky, *supra* note 266, at 225-31.

275. See Hilson & French, *supra* note 268, at 231-33.

276. Convention on Biological Diversity, Cartagena Protocol on Biosafety to the Convention on Biological Diversity, arts. 10(6), 11(8), 39 I.L.M. 1027, available at <http://www.biodiv.org/doc/legal/cartagena-protocol-en.pdf>.

277. SPS Agreement, art. 5.7.

278. Hilson & French, *supra* note 268, at 235.

The major components of the updated E.C. regulatory system for GM crops, food, and feed are now in effect, and regulators have authorized several new products under these measures. Nonetheless, Member States are divided about GMOs, and fears about their impact on health and the environment continue, even after successful risk assessments. These Member State divisions and fears may help to explain the November 2004 failure of the regulatory committee to approve import of Monsanto's maize, MON 863.²⁷⁹ Moreover, several Member States continue to ban products already approved by the E.C.

The new regulatory system for GMOs exerts significant influence beyond the borders of the E.U. and its now-25 Member States. The E.C. reluctance to approve new products limits trade by preventing the import of non-approved GMs that have been used without incident in the United States and elsewhere. Even when GM crops, food and feed have been approved in the E.C., regulatory requirements impose significant burdens on US food and feed companies, as well as producers.

Regulation 1830/2003, the labeling and traceability measure, is particularly burdensome.²⁸⁰ It imposes obligations and additional costs on agribusiness firms, which must ensure segregation of GM and traditional crops in the complex grain-handling system. Though some firms already have systems for traceability, others must develop and implement them. The Regulation affects United States farmers as well. Some will choose to plant only traditional crops for export; those who grow GM varieties segregate GM from other crops. Production practices that minimize pollen drift and other causes of admixture are important for both traditional and GM varieties. The low threshold for labeling products with adventitious or technically unavoidable presence of GMOs, with an even lower threshold expected for seed, makes the avoidance of admixture critical. Moreover, though labeling facilitates consumer choice, labeling may also stigma-

279. Press Release, European Commission, Midday Express of 2004-11-29, News from the Press and Communication Directorate's Midday Briefing (MEX/04/1129, Nov. 29, 2004). Because the regulatory committee failed to reach a qualified majority, the authorization proposal will go to the Council of Ministers. If the Council neither adopts nor rejects the decision, the Commission can adopt the decision to authorize MON 863.

280. See USDA Advisory Committee on Biotechnology and 21st Century Agriculture, Global Traceability and Labeling Requirements for Agricultural Biotechnology-Derived Products: Impacts and Implications for the United States (May 2005), <http://w3.usda.gov/agencies/biotech/ac21/reports/tlpaperv37final.pdf>.

tize GM products and discourage consumption of foods with no known health risks.²⁸¹

Different attitudes in United States and the E.U. toward GMOs on the part of citizens, the agricultural community, and regulatory agencies help to account for differences in regulatory requirements for GM crops and their products. The European approach, based on process and heavily influenced by the precautionary principle, has limited the market for GM varieties, which are a significant percentage of United States agricultural production. It is to be hoped that incompatibilities in the U.S. and E.C. regulatory systems can be resolved without further damage to trade and to U.S.-E.U. relations.

281. See Mansour & Key, *supra* note 1, at 64-68; Appleton, *supra* note 262.

