

From Farm to Fork: The Impact on Global Commerce of the New European Union Biotechnology Regulatory Scheme

MARK MANSOUR AND SARAH KEY*

I. Introduction

On September 22, 2003, the European Parliament and the Council of the European Union (EU) formally adopted two regulations¹ governing the approval, marketing, labeling, traceability, and importation of food and feed produced using modern biotechnology.² The

*Mark Mansour is an FDA/Healthcare Regulation Practice partner, resident in the Washington, D.C. office of Morgan, Lewis & Bockius LLP. His practice focuses on national and international food and drug regulation, and issues relating to pharmaceutical, agribusiness, biotechnology, and consumer products.

Prior to joining Morgan Lewis, Mr. Mansour was partner at a leading regulatory firm. From 1997 to 1998 he served as assistant general counsel and director of global regulatory affairs with the Kellogg Company, where he conceived and implemented the company's global regulatory policies. He was also chairman of a multidisciplinary team that set policies and global strategies in the areas of health and nutrition claims, fortification, packaging, food safety, FDA compliance, and removal of international regulatory and trade barriers.

Mr. Mansour currently serves as a member of several biotechnology-related task forces, including the State Department International Economic Policy Task Force on Biotechnology and the Food Industry Codex Coalition. He is admitted to practice in the District of Columbia, Michigan, and the U.S. District Court, Eastern District of Michigan.

Mr. Mansour is fluent in Arabic and possesses a working knowledge of French. Sarah Key is an associate with the Washington, D.C. law firm of Morgan, Lewis & Bockius LLP.

1. Commission Regulation 1829/2003 of 22 September 2003 on Genetically Modified Food and Feed, 2003 O.J. (L 268) 1, 24 [hereinafter Food and Feed Rule]; Commission Regulation 1830/2003 of 22 September 2003 Concerning the Traceability and Labelling of Genetically Modified Organisms and the Traceability of Food and Feed Products Produced from Genetically Modified Organisms and Amending Directive 2001/18/EC, 2003 O.J. (L 268) 1, 24 [hereinafter Traceability and Labelling Rule]. The regulations were published in the Official Journal of the European Union on October 18, 2003, and entered into force twenty days after publication. They allow a three month transition for the Traceability and Labelling rule (until January 2004) and a six month transition period for the Food and Feed rule (until April 2004) to enable affected parties to achieve compliance with the new rules before they are fully enforced.

2. The popular press typically refers to issues involving bioengineered agricultural commodities and products as concerning genetically modified (GM) foods or genetically modified organisms (GMOs). However, the term genetically modified is technically inaccurate, because, as explained by the U.S. Food and Drug Administration (FDA) in its bioengineering guidance document, most, if not all, cultivated food crops have been genetically modified. See Draft Guidance for Industry, 66 Fed. Reg. 4706 (Jan. 18, 2001), available at <http://vm.cfsan.fda>.

new rules are sweeping in scope and will affect the majority of global food and feed processors that sell in EU markets. More significant, however, are the ramifications of these rules on the trade relationship between the United States and the EU, as well as the international policy issues raised by the rules.

U.S. food and feed companies doing business in Europe will be particularly burdened by the new rules due to the widespread use of agricultural biotechnology in the United States. The United States is the world's leading producer of biotech crops, particularly soybeans and corn,³ and a large percentage of processed foods made in the United States are derived from biotechnology. Aside from the effect the new rules will have on the U.S. agriculture and processed food and feed industry, the rules add another dimension to the ongoing dispute between the United States and the EU over the use of biotechnology in food and feed production. This dispute was raised to a new level when, in May 2003, the Bush administration filed suit with the World Trade Organization (WTO) over the EU's moratorium on the approval of biotech crops and foods. Now many U.S. industry groups are calling on the Administration to file yet another suit with the WTO challenging the EU's new Food and Feed and Traceability and Labelling rules. Although it will be some months before the full impact of these measures is apparent, clearly their implementation will have a profound effect on the multi-billion dollar food, feed, and commodities industries, and perhaps beyond.

This article discusses the new regulations, how they alter the existing EU regulatory framework for genetically modified (GM) food and feed, and some of the problems with the rules from an international legal perspective. In addition, this article sets forth an analysis of the commercial, economic, and trade implications of the new rules and offers suggestions on what steps the United States and industry should take in response to the rules.

II. Changes to the Existing Regulatory Framework

Prior to the adoption of the Food and Feed and Traceability and Labelling rules, the EU employed an extensive patchwork of regulations governing the approval and labeling of genetically modified organisms (GMOs) and of GM food and feed marketed in the EU. Below is an overview of this original regulatory regime, as well as a discussion of how the new rules affect that regulatory framework.

A. EU REGULATORY FRAMEWORK PRIOR TO ENACTMENT OF THE NEW FOOD AND FEED AND TRACEABILITY AND LABELLING RULES

The EU adopted the regulation known as the Novel Foods Law in 1997 to require pre-market authorization for GM food products.⁴ In particular, Regulation 258/97 governs food safety assessments and labeling for most GM foods. More specifically, the regulation requires that consumers be informed of any property that makes a novel food or ingredient

gov/~dms/biolabgu.html [hereinafter Guidance]. Though we believe the term bioengineered is more appropriately used when discussing this issue, for purposes of uniformity with the EU regulations, the terms genetically modified and genetically modified organisms have been used in this paper.

3. According to U.S. Department of Agriculture (USDA) statistics, in 2002, 75 percent of all soy planted in the United States was derived from biotechnology, while 34 percent of all corn was derived from biotechnology.

4. Commission Regulation 258/97 of 27 January 1997 Concerning Novel Foods and Novel Food Ingredients, 1997 O.J. (L 43) 1 [hereinafter Regulation 258/97].

“no longer equivalent” to its conventional counterpart with respect to composition, nutritional value, or intended use.⁵ Products must bear labels informing consumers of (1) “the presence of an organism genetically modified by techniques of genetic modification. . .” or (2) “the presence in the novel food or food ingredient of material which is not present in an existing equivalent foodstuff and which gives rise to ethical concerns.”⁶

Council Directive 2001/18⁷ governs the approval of “living” GMOs prior to their environmental release and commercialization. Directive 2001/18 revised Council Directive 90/220,⁸ which was the original EU regulation governing the environmental release and commercialization of GMOs. Although Directive 2001/18 went into effect on October 17, 2002, many Member States have yet to transform this directive into national law.

Council Regulation 1139/98⁹ was adopted to govern the labeling of the bioengineered corn and soybeans already approved for marketing in the EU prior to the adoption of the Novel Foods Law. This regulation was amended by Regulation No. 49/2000,¹⁰ which establishes a 1 percent threshold for the labeling of bioengineered corn and soybeans to accommodate adventitious contamination of identity-preserved (non-bioengineered) crops with the bioengineered varieties.¹¹ However, Regulation No. 50/2000 removes the threshold to accommodate adventitious contamination. In addition, Regulation No. 50/2000¹² extends the bioengineered labeling requirements to any food product that contains “the presence of an additive or flavouring that is or contains an organism genetically modified by techniques of genetic modification. . .”¹³ This labeling requirement is also triggered if the additive or flavoring contains protein or DNA resulting from the bioengineering process. This analysis does not demand an established *de minimis* threshold or required sensitivity.

B. HOW THE NEW RULES AFFECT THE EXISTING REGULATORY FRAMEWORK

The new Food and Feed and Traceability and Labelling rules will replace three of the four laws currently governing the regulatory review, commercialization, and labeling of GMOs and foods containing or produced with GMOs in the EU. In particular, the new rules will replace Regulations 1139/98, 49/2000, and 50/2000. Although some of its

5. *Id.* art. 8(1)(a).

6. *Id.* art. 8(1)(c)–(d).

7. Council Directive 2001/18 on the Deliberate Release Into the Environment of Genetically Modified Organisms and Repealing Council Directive 90/220/EEC, 2001 O.J. (L 106) 1 [hereinafter Council Directive 2001/18].

8. Council Directive 90/220 of 23 April 1990 on the Deliberate Release Into the Environment of Genetically Modified Organisms, 1990 O.J. (L 117) 15 [hereinafter Council Directive 90/220].

9. Council Regulation 1139/98 of 26 May 1998 Concerning the Compulsory Indication of the Labelling of Certain Foodstuffs Produced from Genetically Modified Organisms Other Than Those Provided for in Directive 79/112/EEC, 1998 O.J. (L 159) 4 [hereinafter Regulation 1139/98].

10. Commission Regulation 49/2000 of 10 January 2000 Amending Council Regulation (EC) No. 1139/98 Concerning the Compulsory Indication on the Labelling of Certain Foodstuffs Produced from Genetically Modified Organisms of Particulars Other Than Those Provided for in Directive 79/112/EEC, 2000 O.J. (L 6) 13 [hereinafter Regulation 49/2000].

11. *Id.* art. 1.

12. Commission Regulation 50/2000 of 10 January 2000 on the Labelling of Foodstuffs and Food Ingredients Containing Additives and Flavourings That Have Been Genetically Modified or Have Been Produced From Genetically Modified Organisms, 2000 O.J. (L 6) 15 [hereinafter Regulation 50/2000].

13. *Id.* art. 2(d).

provisions will be amended by the Food and Feed rule, the Novel Food Law will remain in place for novel foods that are not genetically modified. Finally, both rules will amend Council Directive 2001/18 on the deliberate release of GMOs into the environment.

III. Specifics of the Traceability and Labelling Rule

A. OBJECTIVE

According to the Explanatory Memorandum, the Traceability and Labelling rule was needed because the existing regulatory framework failed to directly address the traceability and labeling of products produced from GMOs, did not provide a definition of traceability for GMOs, did not set forth the objectives of traceability, and did not provide a complete approach for implementation of a traceability system.¹⁴ The Traceability and Labelling rule thus seeks to build upon the foundation of requirements set forth in Directive 2001/18 and establish a harmonized framework for the traceability of products derived from GMOs.

B. SCOPE

The rule applies to the following at all stages of marketing:

- products consisting of or containing GMOs;
- foods and food ingredients, including food additives and flavorings, produced from GMOs; and
- feed materials, compound feedingstuffs, and feed additives produced from GMOs.

C. GENERAL TRACEABILITY REQUIREMENTS

The rule 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.”¹⁵ Tracking the movement of GMOs and products derived from GMOs through the production and distribution chains will be accomplished by traceability requirements. These requirements will be based on information, gathered through all the stages of marketing, regarding such products. The intent is for the traceability system to facilitate the withdrawal of products when a risk to human health or the environment is established, allow for targeted monitoring of the potential effects of products on human health and the environment, and provide control and verification of labeling claims.

To ensure a harmonized system for tracing products through all stages of marketing, operators¹⁶ must enact procedures to carry out the following:

- establish and maintain systems and procedures to identify to whom and from whom products are made available;
- transmit specified information concerning the identity of a product in terms of the individual GMOs it contains or whether it is derived from GMOs;

14. Traceability and Labelling Rule, *supra* note 1, at 2 (Explanatory Memorandum).

15. *Id.* art. 3(3).

16. The Traceability and Labelling Rule defines operator as a “person who places a product on the market or who receives a product that has been placed on the market in the Community...at any stage of the production and distribution chain, but does not include the final consumer.” *Id.* art. 3(5).

- retain all specified information for a period of five years and make it available to the competent authorities on demand.¹⁷

Because many producers already have traceability systems in place, the rule does not specify the means by which this information must be transmitted and retained. Thus, to the extent existing systems are in place to transmit and retain the required information, those existing systems theoretically are sufficient and may be used.

The rule makes a distinction between GMOs and products produced from GMOs, noting that the objectives for the traceability of each group are not identical and that the specified information required to be transmitted and retained for each group differs.¹⁸ In this regard, the rule provides for the traceability of individual GMOs within a product, on the basis of its authorized transformation event; while the traceability of products produced from GMOs do not require identification of the GMOs from which they are produced.

D. TRACEABILITY AND LABELLING FOR GMOs

1. *Specific Requirements for Traceability*

Existing Commission law requires the implementation of measures to ensure the traceability of GMOs at all stages of marketing.¹⁹ However, this requirement does not differentiate between uses of GMOs. In addition, Council Directive 2001/18 requires the implementation of monitoring plans to trace and identify any direct, indirect, immediate, delayed, or unforeseen effects on human health or the environment.²⁰ Because possible effects from GMOs are dependent upon the inherent nature of the GMO or the specific transformation event, the Traceability and Labelling rule calls for the specific identification of each GMO and its associated traits and characteristics in order to facilitate targeted withdrawals and environmental monitoring. As a result, according to the rule, a unique means of identifying each GMO is necessary. To facilitate this identification, operators must transmit the following specified information to the operator receiving the products: (1) that the product contains/consists of GMOs, and (2) the unique codes relating to the GMOs.²¹

2. *Unique Codes*

The Traceability and Labelling rule takes the authorized transformation event²² from which the GMO is developed as its point of departure. The rule requires that the Commission establish a system to develop and assign unique codes²³ to the GMOs.²⁴ In furtherance of this requirement, the rule recommends the establishment of a committee to develop a system for the development and assignment of the unique GMO codes.²⁵

17. *Id.* art. 4(A).

18. *Id.* art. 4(A), art. 5.

19. See generally Council Directive 2001/18, *supra* note 7.

20. *Id.* art. 6. See also generally Annex III.

21. Traceability and Labelling Rule, *supra* note 1, art. 4(A)(1).

22. The Explanatory Memorandum provides that a transformation event is where a conventional organism is transformed through the introduction of modified DNA sequences, resulting in formation of a GMO. The introduction of these sequences ultimately determines the modified characteristics of the GMO (for example, insect resistance or herbicide tolerance). *Id.* at 4 (Explanatory Memorandum).

23. The rule defines unique identifier as a "simple numeric or alphanumeric code which serves to identify a GMO on the basis of the authorised transformation event from which it was developed and providing the means to retrieve specific information pertinent to that GMO." *Id.* art. 3(4).

24. *Id.* art. 8.

25. *Id.* art. 10.

The unique codes must be transmitted and retained from the time the GMOs are first placed on the market through to their final and ultimate use as a food or feed or for processing.²⁶ The purpose of this requirement is to enable the traceback of GMOs through the production and distribution chains. In addition, the unique code information will facilitate labeling, and, in the case of an unforeseen event, post-market withdrawals.

3. *Sampling and Testing*

The rule's Explanatory Memorandum acknowledges that, particularly in the case of imports from third countries (for example, bulk shipments of commodity crops), analytical testing and sampling may be needed if the exporter fails or is unable to supply the importer with information regarding the identity of the products, in particular the GMOs they contain.²⁷ The rule does not require mandatory testing at each stage of marketing. However, the rule does direct the Commission to develop technical guidance on sampling and testing methodologies prior to enactment of the regulation in order to facilitate a coordinated approach for inspection and control by Member States.²⁸

4. *Labelling*

Currently, pursuant to Directive 2001/18, the labeling of GMOs is required at all stages of marketing.²⁹ The Traceability and Labelling rule places a legal obligation on operators to label prepackaged products in accordance with 2001/18.³⁰ Specifically, the rule requires that operators ensure that products are labeled "this product contains genetically modified organisms."³¹ Where labeling is not possible, as with bulk commodities that are not packaged, operators must ensure the appropriate information is transmitted with the product to allow for labeling at a later time.³²

E. TRACEABILITY FOR PRODUCTS PRODUCED FROM GMOs

The new rule builds on existing traceability systems required by other European Community (EC) laws,³³ with the objective of extending those requirements to include information regarding whether a product is produced from GMOs. In particular, the following information must be transmitted to operators receiving products produced from GMOs:

- an indication of each of the food ingredients, including additives and flavorings, derived from GMOs;
- an indication of each of the feed materials or additives produced from GMOs;
- where products do not have an ingredient list, an indication that the product is produced from GMOs.³⁴

26. *Id.* art. 4(A)(1)(b).

27. *Id.* at 6 (Explanatory Memorandum).

28. *Id.* art. 9(2).

29. See Council Directive 2001/18, *supra* note 7.

30. See Traceability and Labelling Rule, *supra* note 1, art. 4(B).

31. *Id.* art. 4(A).

32. *Id.*

33. See, e.g., Council Regulation 1760/2000 of 17 July 2000 Establishing a System for the Identification and Registration of Bovine Animals and Regarding the Labelling of Beef and Beef Products and Repealing Council Regulation (EC) No 820/97, 2000 O.J. (L 204) 1. See also Council Directive 89/396 On Indications or Marks Identifying the Lot to Which a Foodstuff Belongs, 1989 O.J. (L 186) 21.

34. Traceability and Labelling Rule, *supra* note 1, art. 5(1).

Finally, the rule envisions that the traceability requirements will provide the basis for extending current labeling requirements for foods produced from GMOs to cover all foods and food ingredients produced from GMOs.³⁵

IV. Specifics of the Food and Feed Rule

A. OBJECTIVES

The Food and Feed rule has three objectives:

- to ensure the protection of human life and health, animal health and welfare, the environment, and consumers' interest in relation to GM food and feed, while ensuring the effective functioning of the internal market;
- to establish Community procedures for the assessment, authorization, and supervision of genetically modified food and feed; and
- to establish provisions for the labeling of GM food and feed.³⁶

B. SCOPE

The rule covers food and feed containing, consisting of, or produced from GMOs. In addition, the rule extends the scope of existing Community legislation on GMOs to also cover feed produced from GMOs, as well as a specific evaluation of the genetic modification relating to substances such as food additives, flavorings, or feed additives, when produced from GMOs.

Significantly, the rule applies to products produced *from* a GMO, but does not apply to products produced *with* a GMO.³⁷ The rule defines "produced from GMOs" as "derived, in whole or in part, from GMOs, but not containing or consisting of GMOs."³⁸ Produced with GMOs refers to a product that is produced with the assistance of a GMO, but has no material derived from the GMO present in the end product.³⁹ As a result, cheese produced with GM enzymes that are not present in the end product would not be subject to the regulation. The final product obtained from animals fed with GM feed or treated with GM medicinal products would also not be subject to the regulations.

The rule is based on the one door—one key principle, whereby it will be possible to file a single application to obtain authorization for both the (1) deliberate release of a GMO into the environment, pursuant to the criteria set forth in Directive 2001/18 and (2) the use of that GMO in food and/or feed, pursuant to the criteria set forth in this rule.⁴⁰ Authorization will be granted subject to a single risk assessment process, addressing both the environmental risk and risk to human and animal health, to be conducted by the European Food Authority (EFA), as well as a single risk management process involving the Commission and Member States through a regulatory committee procedure.⁴¹

35. *Id.* at 8 (Explanatory Memorandum).

36. Food and Feed Rule, *supra* note 1, art. 1.

37. *Id.* art. 3(1)(c).

38. *Id.* art. 2(10).

39. *See id.* at 4 (Explanatory Memorandum).

40. *Id.* art. 5.

41. *Id.* art. 6.

C. PRINCIPLES OF THE AUTHORIZATION PROCEDURE

The rule sets out the procedures for submitting an application for the approval of GM food and feed.⁴² Applications must be made to the national competent authority who will then inform the EFA.⁴³ The rule allows for public involvement in the authorization process whereby a summary of the application and opinion of the EFA will be made available to the public, which may then comment on the opinion for thirty days.⁴⁴

Products approved under the proposed regulation will be listed in a registry of GM food and feed (the Community Register of Genetically Modified Food and Feed), which includes product specific information, studies demonstrating the safety of the product, and detection methods that must be provided by the applicant to facilitate control.⁴⁵ The initial authorization will be granted for a period of ten years.⁴⁶

Authorizations granted under existing Community law would remain in place under the rule, provided that additional information concerning the risk assessment and the methods for sampling and detection (including samples of the food and feed) are submitted to the EFA within six months of the enactment date of this regulation.⁴⁷ The consequence of failing to comply with this requirement is that food or feed currently approved for marketing in the EU will no longer be viewed as approved.

D. LABELLING

As discussed previously, labeling requirements for GM food are currently set forth in several pieces of Community legislation. In addition, labeling is currently required for GM feed pursuant to Directive 2001/18. However, Directive 2001/18 applies only to live GMOs, not to feed produced from GMOs but no longer containing GMOs.⁴⁸

Labelling is currently triggered by the presence of DNA or protein resulting from genetic modification. However, the new rule extends the current labeling provisions to all GM food and feed *regardless of the detectability of DNA or protein*.⁴⁹ As a result, food that consists of, contains, or is produced from GMOs would have to be labeled as such even in the absence of detectable DNA or protein. This provision is a significant change from the current regulatory regime and will result in the required labeling of numerous products that do not currently require labeling, for example, highly refined oils of GM origin. The Traceability and Labelling rule is intended to facilitate the labeling required under the Food and Feed Rule.

42. See *id.* art. 5.

43. *Id.* art. 5(2).

44. *Id.* art. 6(7).

45. *Id.* art. 7(5), art. 28.

46. *Id.* art. 7(5).

47. *Id.* art. 8(1).

48. The issue of labeling requirements for GM feed is further complicated by the fact that until the second revision of Directive 90/220/EEC, which was the predecessor to 2001/18/EC, there was no requirement for the labeling of GM feed. As a result, currently four authorizations for GM feed require labeling, while four other authorizations do not.

49. Food and Feed Rule, *supra* note 1, arts. 12–13.

E. ADVENTITIOUS CONTAMINATION

To provide for situations where minute traces of GM material may be present in food and feed as a result of adventitious or technically unavoidable contamination, the rule establishes a threshold of 0.9 percent for approved GMOs.⁵⁰ For unapproved GMOs, the threshold is 0.5 percent for three years after the enactment date of the regulations, after which time it will drop to 0 percent.⁵¹

V. The EU's New Rules and the WTO's Agreement on Technical Barriers to Trade

At least some provisions of the new EU rules, the labeling and traceability requirements in particular, are likely violative of international law principles embodied in the WTO's Agreement on Technical Barriers to Trade (TBT Agreement),⁵² and possibly the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement),⁵³ to which all WTO Member nations subscribe as a condition of membership. The EU has argued that the new rules are necessary, not only to protect the health and safety of its citizens but also to facilitate consumer choice. However, the regulatory regime in place prior to enactment of these new rules most certainly achieved these objectives, although they too were arguably violative of WTO agreements.

Article 2.2 of the TBT Agreement provides that technical regulations shall not be "prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade."⁵⁴ To ensure that no unnecessary obstacles are erected, the Agreement requires that any regulations enacted "shall not be more trade-restrictive than necessary to fulfill a legitimate objective."⁵⁵

The labeling and traceability requirements set forth in the EU's new rules are an *obstacle* to trade because they will significantly burden any processor of GM food or feed, as well as any other operator within the supply chain of those products. In addition, EU consumers will not purchase GM food products, and retail stores are increasingly refusing to stock the products on their shelves. Thus, imposing a costly system of traceability on food processors and requiring them to label their products as being derived from a GM source greatly increases the likelihood that those products will go unsold in markets employing mandatory bioengineered labeling.

Second, the labeling requirements are unnecessary, because, as discussed below, other, less restrictive measures are already in place to address safety concerns, and the requirements institute, rather than eradicate, deceptive practices by misleading consumers to

50. *Id.* art. 12(2).

51. *Id.*

52. Agreement on Technical Barriers to Trade, Apr. 12, 1979, 18 I.L.M. 1079 (1979), available at <http://www.wto.org> [hereinafter TBT Agreement].

53. The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), available at <http://www.wto.org> (last visited Jan. 16, 2004). The SPS Agreement requires that WTO member nations "ensure that their sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, [and] is based on scientific principles and is not maintained without sufficient scientific evidence . . ."

54. TBT Agreement, *supra* note 52, art. 2.2.

55. *Id.*

believe that bioengineered food is of a lesser quality than conventional food and that it presents safety risks. Further, the labeling requirements are unnecessary because they are inconsistent with prior approvals of the bioengineered commodity. In essence, by approving a bioengineered agricultural commodity under existing regulations, and then further requiring that the product be labeled as being bioengineered, the initial regulatory approval for the commodity is being withdrawn. On one hand, the commodity or food product is given approval based on science and the law, while on the other hand, a labeling requirement based on fear and political concerns is implemented, which results in a *de facto* sanction against the products. It is certainly unnecessary to require label differentiation of products otherwise equal in safety and quality.

Finally, the labeling and traceability requirements do not *fulfill a legitimate objective* and are more trade restrictive than necessary even if such a legitimate objective exists. For example, voluntary labeling of food products that do not contain ingredients derived from bioengineered sources would address concerns about informing consumers about the nature of their food products without effectively closing entire markets to U.S. bioengineered food products.

A. LABELLING AND TRACEABILITY DO NOT FULFILL A LEGITIMATE OBJECTIVE

Although the TBT Agreement does not expressly define what constitutes a legitimate objective, it does set out examples, such as “protection of human health or safety, animal or plant life or health, or the environment” and “the prevention of deceptive practices.”⁵⁶ Neither of these objectives provides a legitimate basis for the enactment of mandatory bioengineered labeling, particularly with regard to the EU labeling and traceability requirements.

1. *Protection of Health, Safety, and the Environment*

First, any safety concerns the EU could point to as justification for the bioengineered labeling requirements have been addressed through Council Directives 90/220 and 2001/18, which require an assessment to be carried out by the EU’s Scientific Committee on Plants before a bioengineered organism can be placed on the market. The aim of the assessment is to evaluate any risks to human health and to the environment connected with the release of the bioengineered organisms. Any bioengineered organism being reviewed pursuant to these directives must undergo rigorous testing before it is granted approval. In fact, to date the EU has approved only eight bioengineered agricultural commodities, and in 1999, instituted a moratorium on the approval of any new bioengineered organisms.⁵⁷ Furthermore, the EU’s Novel Foods Regulation⁵⁸ requires the approval of all novel foods and food ingredients, including those made from bioengineered agricultural commodities.

The requirements of Directives 90/220, 2001/18, and the Novel Foods Regulation, therefore, provide substantial and sufficient safeguards to ensure that any bioengineered food products marketed in the EU will be safe for the environment and for consumers. Furthermore, as provided by Article 2.2 of the TBT Agreement, when assessing risks pre-

56. *Id.*

57. This moratorium is the subject of the WTO suit filed by the United States and several other nations in May 2003.

58. Commission Regulation 258/97, *supra* note 4.

sented by a legitimate objective (for example, safety concerns) Members implementing technical regulations are to consider, *inter alia*, “available scientific and technical information, related processing technology or intended end-uses of products.”⁵⁹ However, under the EU regulations governing the pre-market approval of bioengineered agricultural commodities and foods, these factors have already been considered.

If bioengineered foods and ingredients are safe enough to be approved for human consumption within the EU, as has been the case, the addition of stigmatizing warnings is unnecessary. This is particularly true when the labeling and traceability requirements are expensive or extremely burdensome for the food industry to follow and when they will only lead to unwarranted consumer fear and rejection of the bioengineered foods.

1. *Prevention of Deceptive Practices*

The EU labeling requirements are also not justified on the ground of prevention of deceptive practices. On the contrary, mandatory bioengineered labeling, if anything, promotes consumer deception. A failure to label the source of a given food ingredient is not deceptive. Indeed, other than bioengineered labeling requirements, no other requirements, of which we are aware, require the source of a food ingredient or the method of its processing to be declared. In the current climate, an unqualified requirement to declare a bioengineered source *is itself* deceptive, because it implies that the food is less safe or of lesser quality than a conventional food. This implication is shown to be false by virtue of the EU’s own scientific pre-market review and approval.

Moreover, the FDA, in a Guidance to the industry on voluntary labeling for biotech foods, discussed how consumers are easily misled by information about the bioengineered status of food products.⁶⁰ The Guidance states the FDA’s view that bioengineered labeling “may be misleading if it fails to disclose facts that are material in light of representations made about a product or facts that are material with respect to the consequences that may result from use of the product.”⁶¹ The Guidance then cites particular examples of bioengineered labeling that might prove misleading or technically inaccurate to the consumer. For example, FDA expressed particular concern that the term “genetically modified” is misleading because terms:

that include the word “modified” are not technically accurate unless they are clearly in a context that refers to bioengineering technology. “Genetic modification” means the alteration of the genotype of a plant using any technique, new or traditional. “Modification” has a broad context that means the alteration in the composition of food that results from adding, deleting, or changing hereditary traits, irrespective of the method. . . . *Most, if not all, cultivated food crops have been genetically modified.*” (emphasis added).⁶²

In lieu of the term “genetically modified,” FDA suggests the use of the terms “bioengineered” or “genetically engineered.” The EU labeling requirements, however, expressly employ the term “genetically modified” which FDA found problematic. The new Traceability and Labelling and Food and Feed Rules also require the use of these terms.⁶³

59. TBT Agreement, *supra* note 52, art. 2.2.

60. See Guidance, *supra* note 2.

61. *Id.* at 4.

62. *Id.* at 5–6.

63. Traceability and Labelling Rule, *supra* note 1, art. 4(B)(6); Food and Feed Rule, *supra* note 1, art. 12.

B. EVEN IF A LEGITIMATE OBJECTIVE EXISTS, THEY COULD BE ADDRESSED THROUGH LESS TRADE-RESTRICTIVE MEASURES

Assuming a legitimate objective of responding to a perceived consumer demand for information exists, the EU could fulfill this objective in a less trade-restrictive manner by providing a framework for voluntary labeling⁶⁴ of food products that did *not* use bioengineered-derived ingredients, as long as statements concerning the absence of such ingredients are not misleading. Under this framework, consumers who prefer to avoid bioengineered ingredients, and who will not object to paying the extra cost of foods not containing them, will have the opportunity to drive such a market. Such an arrangement would be fairer to consumers and makes more economic sense. Consumers would receive an actual choice between bioengineered and non-bioengineered products, as opposed to the dominance of non-bioengineered products encouraged by the current regime. Moreover, the additional costs of non-bioengineered products would be borne by those who desire such products, rather than forced upon the entire population.

VI. Analysis of the Commercial, Economic, and Trade Implications of the Rules

The EU's new biotech rules have the potential to exacerbate the already growing disruptions in trade in commodities and finished food products between the United States and the EU Member States. In addition, a template is now in place for developing countries to take essentially the same action, or some variant. Previously the subject of a protracted dispute between the EU and the United States for several years since the revision of Council Directive 90/220, the rules send an unmistakable signal that the EU is abandoning all traces of substantial equivalence and content-based labeling in favor of process-based labeling, based at least in part on the Precautionary Principle. The rules also rely on so-called other non-scientific factors and the provisions of the Convention on Biological Diversity's Biosafety Protocol. These provisions were never intended to apply to food products but are in fact the basis for the entire EU revision process, including the initial changes to Directive 90/220 that set these directives into motion several years ago.

Although some of the parties in the Commission, with whom U.S. government and industry have negotiated, realized that these rules (if enacted) would do severe damage to the food economy, they were unable to persuade their colleagues of the potential for harm. The assumption that the infeasibility of the rules would ultimately cause their undoing was overly optimistic: those parties who promoted the changes demonstrated little concern for

64. If voluntary labeling were to take place, the EU and other international authorities would need to take care to prevent misleading claims, i.e., an unqualified claim of "contains no ingredients derived from bioengineered sources" is misleading because it implies that the food is safer and of better quality than foods containing bioengineered-sourced ingredients. For example, as noted by the FDA in its voluntary labeling guidance:

A statement that a food was not bioengineered or does not contain bioengineered ingredients may be misleading if it implies that the labeled food is superior to foods that are not so labeled. FDA has concluded that the use or absence of use of bioengineering in the production of a food or ingredient does not, in and of itself, mean that there is a material difference in the food. Therefore, a label statement that expresses or implies that a food is superior (e.g., safer or of higher quality) because it is not bioengineered would be misleading.

Guidance, *supra* note 2, at 6.

whether U.S. industry could comply, and some are probably hoping that it cannot comply. Much of the problem is discernible from the underlying assumptions inherent in the framework. The continued insistence on the use of pejorative descriptors, such as GMO and adventitious contamination, is a signal example. The very use of those words is suggestive more of a regulatory framework for toxic waste than it is for the purpose supposedly intended.

Complicating the problem is that many of the parties in favor of labeling are less concerned with consumer choice and more intent upon securing a trade advantage. This desire is nowhere more evident than in the blatantly discriminatory exemption of enzymes and processing aids from the scope of the labeling provisions. If the concern for the consumer's right to know that the process of recombination was used truly is paramount, regardless of the detectability of protein or DNA, then the rule would have included enzymes used as processing aids in such key exports as wine, beer, and cheese. As it stands, the exclusion is blatantly discriminatory.

The readily predictable effects of implementation of these rules will be several:

- U.S. manufacturers will experience increased costs related to securing, collating, transmitting and maintaining records for each and every product and ingredient that contains or may be derived from biotechnology, regardless of whether protein or DNA is detectable. The adventitious contamination threshold loophole, for labeling purposes, is now closed. Unless a manufacturer knows for certain that its product or ingredient has only been subjected to adventitious contamination (and is prepared to document that fact), rather than having been produced in part or in whole as a result of genetic recombination, labeling is a requirement. Ultimately, the result will be increases in production costs and, inevitably, consumer prices. Any manufacturer that is dependent on transgenically-sourced materials loses a competitive advantage in proportion to that dependence as long as consumer choice is denied.
- The legal penalties for failure to comply are not yet clear, but the commercial penalties will be far more severe. Given the degree of attention this initiative has received, and the lack of acceptance accorded to the old regulatory system, EU member state officials will have little choice but to enforce compliance if they are to maintain their credibility with the public. Activist groups will be watching closely, and taking their own action, in concert with some sectors of the media, to ensure compliance. The consequences of failure to comply are just as, if not more serious, in their effect on relations with distributors and consumers as are the expected fines. The margin for error in the production process will approach zero, and each and every U.S. brand (and eventually some European brands as well) will be placed under a microscope.
- Implementation of these rules will give additional momentum to activist groups and like-minded regulators in a number of developing markets. Many countries are in the process of developing labeling regulations, and the EU rules already have been copied by other countries anxious to avoid seeming to be lax in managing this issue. The results would create large biotech free zones throughout the world in which U.S. farmers, grain handlers, and ingredient suppliers are powerless to provide adequate and legally merchantable product. The resulting demand for GM-free soy, corn, and canola, among other products, will also result in increased raw material prices, with such increases proportionate to the number and size of the countries adopting similar provisions.

The long-term implications are potentially more serious and far more difficult to predict. As onerous as the provisions are, the principles on which the rules are based are even more dangerous. In one series of actions, the EU regulatory, legislative, and political apparatus has:

- rejected the doctrine of substantial equivalence;
- reinterpreted the Biosafety Protocol;
- given additional support to the notion of a Precautionary Principle;
- invoked factors other than science and food safety in making a decision that will affect untold billions of dollars in food exports; and
- undermined thoroughly its credibility by first insisting that the process was sufficient to trigger labeling and then, in the same document, exempting enzymes used as processing aids that might be derived from recombinant sources. Despite promises by EU officials that the exemption for enzymes as processing aids would be removed during the co-decision process, the exemption has remained in the document from its inception.

Moreover, the rules almost certainly violate the TBT Agreement and perhaps the SPS Agreement. They also decidedly undermine the foundations of the WTO. Worse, the rules throw into doubt the credibility, viability, and relevance of such science-based institutions as the Codex Alimentarius Commission, which is in the midst of addressing these issues.

Finally, the precedent is unacceptable. Regardless of the importance to a given manufacturer of biotech labeling regulations, the bases upon which these rules are made are far more critical as a matter of principle. If these justifications are allowed to stand in support of the proposed regulations, they are transferable to virtually any product, ingredient, or technology that may be objectionable to one interest group or another. This action directly affects technological innovation and competitiveness and extends far beyond the realm of food. These principles will be used against American and European industry alike. Both the Precautionary Principle and the doctrine of Other Legitimate Factors are ripe for use across a spectrum of industries, and the consequences are limited only by the imaginations of politically-motivated (or intimidated) risk managers. For these reasons, a challenge should be contemplated at the earliest feasible opportunity, regardless of any speculative notions regarding the possibilities of success. The underlying principles at stake transcend the issue presently under consideration. Nanotechnology and future innovations in a host of other areas and technologies that are today unknown will be governed by the template that emerges from this process. As a consequence, the United States and other affected countries should seek to ensure that the example is a legally, morally, and commercially sustainable one. The regulatory scheme contemplated at present does not fit these essential criteria.

VII. What Should be Done

Industry cooperation from farm to table has always been desirable. The cooperation is now mandatory. In addition, the food chain should be extended to include commodity traders, shippers, freight handlers, insurers, and reinsurers. Many in the Commission and in Parliament have little understanding of the enormous complexity of the U.S. grain handling system. Grain can be warehoused for years at its origin, consolidated with shipments from numerous other locations, shipped to one destination, and converted (or flipped) to yet another destination on the high seas. The grain is often then warehoused by the importer and re-exported.

As a consequence of the new rules, parallel markets for biotech and non-biotech grain are likely to emerge because the costs will be different. For this reason, commodity traders should be brought into immediate discussions with the food and commodities industries so that they might be briefed and their opinions sought. Their response could serve to generate

a more robust debate, encompassing issues of dollars and cents that have thus far been abstractions.

The United States has solid arguments against these rules:

- A convincing argument exists relative to the TBT Agreement, since under Codex, consumers only have the right to know what could harm them, and because voluntary labeling is available for qualities that pertain to consumer preference (such as halal, kosher, and organic). The Commission's rules make the specious claim that failure to label biotech foods would somehow mislead the consumer and that the costs are negligible. Both of these assertions are easily refuted.
- The United States has persuasive arguments in the SPS arena as well, since biotech food is safe and no proof to the contrary has ever been found. The Precautionary Principle, despite protests to the contrary from many in the Commission, appears nowhere in the SPS Agreement. Traceability itself is based on an amorphous, unquantifiable, and unspecified prospective risk to human or environmental health that requires drastic pre-emptive action. Such a philosophical construct was damaging enough when applied to an issue such as bovine spongiform encephalopathy (BSE); it would be even more problematic if and when it is applied to biotech commodities and food products.

The United States also has a compelling argument regarding the relationship between environmental treaties and the WTO. The Preamble of the Biosafety Protocol itself warrants legal challenge, and the WTO is likely to be loath to surrender its prerogatives to the Convention on Biological Diversity.

The ramifications of these rules for the U.S. food and commodity industries are profound, particularly given the potential for the development of similar initiatives in large developing-country markets. Worse, the precedent will have been established that will make each successive instance of non-science based regulation, based instead on ethereal socio-political principles, more easily digestible than the last.

That the Commission has become more and more bold in promoting this regime is surely not a coincidence, as Poland and Hungary, with their considerable grain supplies, have moved ever closer to membership in the EU. Finally, and perhaps most important, the point should be made that the rules are neither consistent nor credible. The basis of the rules is the consumer's fundamental right to know that the process of genetic recombination was used, but the labeling of enzymes used as processing aids was specifically and pointedly exempted. When this inconsistency was pointed out to the Commission two years ago, promises were made that this was unintentional and that the exemption would be removed during the negotiation process. Nearly three years have passed and the exemption remains firmly embedded in the final version of the rules. This exemption is wholly inconsistent with the spirit on which the rules were supposed to have been based and does as much to undermine their credibility as any other single factor. If for no other reason, the rules should be challenged, just as was the beef hormone decision, to set a clear example and prevent the adoption of this framework by other trading partners.

