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The EU Regulatory Approach to GM Foods

by

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THE EU REGULATORY APPROACH TO GM FOODS[†]

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I. INTRODUCTION

On April 18, 2004, the core provisions of the current European Union (EU) regulatory framework for genetically-modified (GM) food products entered into force.[1] They supplemented some existing provisions and were fleshed out by some further texts. At present, the framework is more-or-less finalized and the first experiences with it have been made.

A. This Contribution

The aim of this contribution is to present and explain the EU's regulatory approach to GM organisms used as, or in, food products. In this, the first section, I will give some general information on the structure and law of European cooperation. In the second section, I present the background in terms of historical development, and the system, of EU food law. In this context, I will share some personal thoughts on the underlying reasons that may explain the way consumers and politicians react to GM food in the EU. The rest of this article provides an overview of the current regulatory framework.[2] The third section is an introduction. In section four, I will touch briefly upon environmental approval. This subject is outside the scope of this

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[†] The Judge Nelson Timothy Stephens Lecture

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1. *See infra*, Annex.

2. The relevant pieces of legislation are listed in the Annex.

article, but some general information is necessary to provide a context for this article. The biggest section in this article is section five on pre-market approval of GM foods. Section six discusses traceability requirements, section seven, labeling, and section eight, enforcement. In section nine, I will make some observations on experience so far, and in the final section, I will draw some conclusions.

B. EU, EC & Member States

1. Who is Whom?

The EU is a network both of two supra-national organizations[3]—the European Community[4] (EC) and the European Atomic Energy Community (Euratom)[5]—and several intergovernmental policies.[6] Sovereignty lies with the twenty seven member states. The member states cooperate in these policies and have only transferred some more-or-less well-defined parts of their sovereignty to the supra-national organizations.[7] For the average EU citizen, politics is centered at the member state level. The EU is perceived as a distant bureaucracy.

In 1967, the institutions governing these organizations and coordinating these policies merged.[8] Since then, one European Parliament[9] has represented the people in these different fields. One European Commission ("the Commission"), consisting of one independent member from each member state, is responsible for day-to-day administration.[10] Within the Commission, food law is the responsibility of the Commissioner of Health and Consumer Protection.[11] His Directorate-General (the administrative organization) is known by its French acronym: D-G SANCO.[12]

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3. Treaty on European Union (Maastricht Treaty), July 29, 1992, 1992 O.J. (C 191) (EC). A consolidated version has been published in the Official Journal of the European Union, Dec. 24, 2002, 2002 O.J. (C 325(5) (EC); *see also* http://europa.eu.int/eur-lex/en/treaties/dat/EU_treaty.html.

4. *See* Treaty of Rome (1957) (The former European Economic Community (EEC) was established by the Treaty of Rome.). The current name of the Treaty is "Treaty Establishing the European Community." See 2002 O.J. (C 325(33)) (a consolidated version).

5. *See* Second Treaty of Rome, Treaty Establishing The European Atomic Energy Community (1957).

6. For more details, *see* B.M.J. VAN DER MEULEN & MENNO VAN DER VELDE, FOOD SAFETY LAW IN THE EUROPEAN UNION: AN INTRODUCTION Ch. 3 (2004) [hereinafter FSL].

7. Case 26/62, Van Gend en Loos v. Nederlandse Tariefcommissie, 163 C.M.L.R. 105, 129 (1963).

8. *See* Treaty Establishing a Single Council and a Single Commission of the European Communities, July 13, 1967, 1967 O.J. (C 152) (EC). *Cf.* Treaty on European Union (Maastricht Treaty), July 29, 1992, 1992 O.J. (C 191) (EC), tit. I, art. A.

9. *See* Treaty Establishing the European Community, Dec. 24, 2002, 2002 O.J. (C 325) 226, art. 203 189-201 [hereinafter EC Treaty].

10. *See id.* at art. 211-19.

11. Health and Consumer Protection Directorate – General Home Page, http://ec.europa.eu/dgs/health_consumer/index_en.htm.

12. *See* Europa—Food Safety: From the Farm to the Fork, http://ec.europa.eu/food/

Probably the most powerful institution is the Council of Ministers (the Council).[13] Unlike the Commission, the Council is not a permanent body with permanent members. It is a conference of ministers from the governments of the member states. The composition of the Council depends upon the matter at hand. Matters relating to food law are usually discussed by the ministers of public health or the ministers of agriculture.[14]

Through the Council, the member states exercise considerable power in the EU. To compensate for member states' "loss" of power in delegating regulatory power to the Commission, it is often stipulated that the Commission needs approval by a committee of representatives of the member states. The procedures by which the Commission has to cooperate with a committee are colloquially known as "commitology."[15] In food law, the Commission is assisted by the Standing Committee on the Food Chain and Animal Health (SCFCAH).[16]

The EC governs food law, and as the EC is part of the EU, the law is referenced both as EC law and as EU law. In this article, the latter way is chosen. It should be kept in mind, however, that because it is EC law, food law is EU law of a supra-national (member state-binding and overriding) nature.

2. Legislation

EC legislation comes in two major forms: regulations and directives. Regulations are comparable to legislation, like that known in virtually all countries that address their citizens directly in conferring rights and obligations to them. Directives address the legislatures of the member states; directives serve the purpose of harmonizing member states' national legislation. Regulations are immediately applicable in all the member states and, therefore, result in uniform law. Directives result in harmonized national legislation.[17]

EU law has been strongly influenced by the civil law tradition. Generally speaking, civil law approaches are more cautious than common law approaches. For almost a millennium, common law has developed in reaction to problems that arose and has spoken in terms of liability. On the other hand,

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food/biotechnology/index_en.htm (for information on food law and policy and on GM food).

13. *See* Treaty Establishing the European Community art. 202-210 (Dec. 2002), http://europa.eu.int/eur-lex/en/treaties/dat/C_2002325EN.003301.html (last visited Mar. 12, 2007).

14. EC Treaty, art. 203.

15. EC Treaty, art. 202; *see also* FSL, *supra* note 6, § 4.5. A new commitology procedure giving increased power to the European Parliament has been laid down in Council Decision of July 17, 2006 amending Decision 1999/468 (2006 O.J. (L 200) 11).

16. Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, art. 58, 2002 O.J. (L31) 11, *available at* http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_031/l_03120020201en00010024.pdf.

17. *See* Official Journal of the European Union (O.J.), http://eur-lex.europa.eu/en/index.htm (last visited Mar. 12, 2007).

in civil law, legislatures make it their business to foresee and prevent societal problems. In other words, civil law lays down the rules before the game starts where common law makes up the rules while the game is played. Although the distinction between the two legal families is no longer very sharp, I believe that the difference in approach between the EU and the U.S. to food law in general—and GM food in particular—is partially explained by this difference in legal culture.

3. Competent Authority

Part of the sovereignty of the member states is the so-called "principle of institutional autonomy." EU law has little to say about the organization of the public sector in the member states. Usually, obligations are conferred to the national "competent authority." It is for the national legislature to decide which state organ is its "competent authority" in any given matter and to endow it with the powers necessary to fulfill its obligations under EU law. In most member states, food law is in the domain of either the Minister of Agriculture or the Minister of Public Health. Most member states also have a more-or-less independent food safety authority.[18]

II. BACKGROUND

Many accounts of EU food law begin with an historical overview, and most commonly, the Bovine Spongiform Encephalopathy (BSE)[19] crisis of the 1990s serves as the cornerstone. This contribution is no different. To understand the current situation in EU food law, it is necessary to grasp the trauma in reaction to which it has been crafted.

Even taking the historical events into account, it is not easy to come to a full understanding. Trying to make sense of the facts, I have come to the personal conclusion that consumers in the EU show a certain tendency to attach moral and political values to food products and the way they are being produced. Opinions on "good" and "evil" never completely bypass the supermarkets. These opinions may enlarge the way problems are perceived and treated. Popular opposition to the use of nuclear power, for example, included opposition to irradiation of food. Production methods that appear counter-natural (like the use of growth hormones, chemical additives, etc.) are frowned upon. Often, the opposition is expressed or explained in terms of food safety concerns. Perhaps it is a matter of respect, both for the food and for the person consuming it, but I am not entirely convinced that this explanation is

18. *See* INSPECTION REPORTS OF THE FOOD AND VETERINARY OFFICE, http://ec.europa.eu/food/fvo/index_en.htm (this contribution is mainly limited to the common (EU) level. As far as illustrations on the national level are used, I will take them from the experience in my home country, the Netherlands).

19. *See* U.S. Food and Drug Administration, Bovine Spongiform Encephalopathy, http://www.fda.gov/oc/opacom/hottopics/bse.html (last visited Mar. 24, 2007). The common name for BSE is "mad cow disease."

completely adequate.[20]

A. History

1. Crises

The BSE crisis in the late 1990s[21] caused an earthquake in the legal and regulatory landscape of Europe; although several food crises have taken place in the last decades, it is most certainly the BSE crisis that has been a catalyst for the recent developments in the field of EU food legislation.[22] Public awareness of the epidemic—and of the time it took British and European authorities to address it—presented a major challenge to European cooperation in the area of food safety. When the extent of the crisis became public, the EU issued a blanket ban on British beef exports. In response, Great Britain adopted a policy of non-cooperation with the European institutions, and it sought to deny the extent and seriousness of the BSE problem.

The European Parliament played a crucial role in defusing this crisis. A temporary Enquiry Committee was instituted to investigate the actions of the national and European agencies involved in the crisis.[23] The Enquiry Committee presented its report in early 1997, which strongly criticized the British government as well as the Commission. The Committee accused the Commission of wrongly putting industry interests before public health and consumer safety.[24]

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20. *See* Sylvie Bonny, *Why Are Most Europeans Opposed to GMOs? Factors Explaining Rejection in France and Europe*, 6 ELECTRONIC J. OF BIOTECH. 1, (Apr. 15, 2003), http://www.ejbiotechnology.info/content/vol6/issue1/full/4/index.html; *see also, generally*, A. H. Arnout, et al., *Public Acceptance of New Technologies in Food Products and Production, in* RISK AND THE PUBLIC ACCEPTABILITY OF NEW TECHNOLOGIES (R. Flynn & P. Bellaby, eds.) (forthcoming); *see also* FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, VOLUNTARY GUIDELINES TO SUPPORT THE PROGRESSIVE REALIZATION OF THE RIGHT TO ADEQUATE FOOD IN THE CONTEXT OF NATIONAL FOOD SECURITY, *available at* http://www.fao.org/docrep/meeting/009/y9825e/y9825e00.htm (last visited Mar. 25, 2007) (noting that cultural acceptability of food is seen as part of the human right to adequate food); *see also* B.M.J. van der Meulen & F.M.C. Vlemminx, *The Netherlands: Abundant in Food, Wanting in Law*, http://www.cedr.org/english/documents/ roros/commission%201/CI_NED_EN.pdf.

21. *See generally,* Margaret Rosso Grossman, *Animal Identification and Traceability under the United States National Animal Identification System*, to be published in J. FOOD L. & POL'Y (forthcoming 2007).

22. *See* Community Legislation on BSE, *available at* http://ec.europa.eu/food/fs/bse/bse15_en.pdf (last visited Sept. 17, 2007). Ninety-five legal texts have been published on BSE alone, excluding market regulations, financing decisions and rules with respect to cosmetic and medicinal products and medical devices. *Id.*

23. 1996 O.J. (C 261) 132.

24. TEMPORARY COMMITTEE OF INQUIRY INTO BSE, REPORT ON ALLEGED CONTRAVENTIONS OR MALADMINISTRATION IN THE IMPLEMENTATION OF COMMUNITY LAW IN RELATION TO BSE, (1997), *available at* http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+REPORT+A4-1997-0020+0+DOC+XML+V0//EN&language=EN (last visited Mar. 25, 2007); *see also* MINORITY OPINIONS IN BSE, REPORT ON ALLEGED CONTRAVENTIONS OR MALADMINISTRATION IN THE IMPLEMENTATION OF COMMUNITY LAW IN RELATION TO BSE, (1997), *available at* http://www2.europarl.eu.int/omk/sipade2?PUBREF=-

The Enquiry Committee did not confine itself to an analysis and critical comments. The report made concrete recommendations for the improvement of the structure of European food law. This reproachful report provided the Commission with the impetus to restructure European food legislation. The Commission's President, Jacques Santer, undertook a far-reaching commitment to implement the Committee's recommendations.

Progress was made along institutional lines as well as policy lines. The young Directorate General (DG) XXIV was reinforced and renamed "Consumer and Health Protection Policy" and included the scientific advisory committees from the Directorate Generals for Industry and Agriculture.[25] A Scientific Steering Committee was created to bring wider scientific experience and overview to consumer health questions. The internal market "product warning system" was also transferred from DGIII (Agriculture) to DGXXIV. As of 1997, the center of gravity in food legislation moved from DG Agriculture to DGXXIV, now called "SANCO."[26]

As early as May 1997, the Commission published a Green Paper on the general principles of food law in the EU.[27] Consumer protection was made the first and foremost priority. The Commission committed to strengthening its food safety control function. This led directly to the creation of the Food and Veterinary Office (FVO) in Dublin in 1997.[28] The FVO was charged with carrying out the Commission's control responsibilities in the food safety sector, to include controlling animal health and welfare.[29] Furthermore, the Commission established an independent food safety authority.[30] At the European summit in Luxemburg at the end of the same year, the European Council adopted a statement on food safety.[31]

The Commission kept the pressure on beyond 1997, eventually gaining

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25. *See* General Report 1998 - Chapter IV: The Community economic and social area Section 24: Consumer policy and health protection (1/13), *available at* http://europa.eu/generalreport/en/1998/x0634.htm.

26. *See generally*, SANCO (Director General, Health and Consumer Protection, Public Health) official website, http://ec.europa.eu/health/index_en.htm (last visited Sept. 17, 2007).

27. *Commission Green Paper on the General Principles of Food Law in the European Union*, COM (1997) 11176, available at http://www.foodlaw.rdg.ac.uk/eu/green-97.doc (last visited July. 3, 2007).

28. *See generally* European Commission's Health and Consumer Protection DG, *FVO at Home and Away*, 7 CONSUMER VOICE 1 (2002), *available at* http://ec.europa.eu/food/fvo/resources/consumervoice_en.pdf.

29. *Id.*

30. Communication of the European Commission, Consumer Health and Food Safety COM(97) 183 final (April 30, 1997). *See also* Philip James, et al., *A European Food and Public Health Authority: The future of scientific advice in the EU, 1999*, *available at* http://ec.europa.eu/food/fs/sc/future_food_en.pdf (last visited September 16, 2007).

31. December 13, 1997, Conclusions of Luxembourg Summit 1997, No. 57, *available at* http://www.vm.ee/est/euro/aken_prindi/2658.html#environment (last visited September 16, 2007).

the support of the European Court of Justice for the measures that had been taken against Great Britain at the climax of the crisis.[32] Meanwhile, public attention had turned to a new food safety scare: the Belgian dioxin crisis. The Commission proved it had learned a valuable lesson from its experience with BSE, and moved quickly and efficiently to protect consumers from the dioxin crisis. Nonetheless, this second crisis brought to light further shortcomings in European food law.[33]

Despite the resignation of Santer's Commission (which was succeeded by the Commission led by Romano Prodi), food safety remained a priority issue. On January 12, 2000 the Commission published its White Paper on Food Safety.[34]

2. White Paper on Food Safety

The agro-food sector is considered of major importance for the European economy. The European food and drink industry comprises about fifteen percent of the European industrial production. Given the economic importance of food and the essential role of food for human existence, in the opinion of the Commission, food safety is a matter of the utmost importance for society as a whole and for government authorities and food producers in particular. The main goal of the White Paper was to reinstate consumer trust in the food supply, food science, food law and food controls.

The White Paper called for a wide range of measures to improve and otherwise make coherent the corpus of legislation covering all aspects of food products—"from farm to fork." The Commission considered the reconstruction of food safety policy necessary due to wide variations in the manner in which Community legislation had been implemented and enforced in member states. At the status quo, consumers could not be sure of receiving the same level of protection across the Community, thus making it difficult for the effectiveness of national authority measures to be evaluated. The Commission thus identified a wide range of measures necessary to improve food safety standards. It proposed a new legal framework that covered the whole of the food chain—even including animal feed production—to establish a high level of consumer health protection.

Food business operators (FBOs) have the responsibility to comply with legislative provisions, and to provide for adequate risk management. A key issue in food safety policy is the ability to trace products through the entire food chain. A foundational response is the ability to take rapid, effective

32. *See* Case C-157/96, The Queen v. Ministry of Agric., Fisheries and Food, 1998 E.C.R. I-02211; Case C-180/96, U.K. Gr. Brit and N. Ir. v. Comm'n of European Cmty's, 1996 E.C.R. I-03903; Case C-180/96, U.K. Gr. Brit. and N. Ir. v. Comm'n of the European Cmty's, 1996 E.C.R. I-03903; Case C-209/96.

33. *See* B.M.J. VAN DER MEULEN, THE RIGHT TO ADEQUATE FOOD: FOOD LAW BETWEEN THE MARKET AND HUMAN RIGHTS (2004); *see generally*, FSL, *supra* note 6 (explaining the development of European food law).

34. *Commission White Paper on Food Safety*, COM (1999) 719 final (Jan. 12, 2000).

safeguarding measures in response to health emergencies throughout the food chain. Scientific advice must underpin food safety policy, and the precautionary principle[35] shall be used where appropriate. Proposals for the animal feed sector had to ensure that only suitable materials could be used in its manufacture.

In the White Paper, national authorities are held responsible for ensuring that food safety standards are respected by FBOs. Member states need to establish control systems to ensure that Community rules are being respected and, where necessary, enforced. The Commission believed that these systems should be developed at a Community level to ensure that a harmonized approach is followed. To ensure that national control systems are effective, the Commission, through the FVO, carries out a program of audits and inspections to evaluate the performance of national authorities and their ability to deliver and operate effective control systems, supported by visits to individual premises to verify that acceptable standards are actually being met. With regard to GM food, the White Paper calls for clarification of procedures.[36]

3. Legislative Intervention

Annexed to the aforementioned White Paper is the "Action Plan on Food Safety," a list of eighty four legislative steps that the Commission deemed necessary to create a regulatory framework capable of ensuring a high level of protection for consumers and of the public health. The first new regulation took effect in 2002, and, in the past few years, most of the eighty four steps have been taken. The new regulatory framework is based upon regulations rather than directives; in other words, FBOs increasingly face uniform EU legislation instead of more-or-less harmonized national legislation.

Passage of Regulation (EC) No 178/2002—popularly called the General Food Law (GFL)—was the first step in the realization of the reform of food law as planned in the White Paper.[37] To avoid confusion, it should be noted that the GFL is not a code encompassing all food legislation; it is, however, fundamental to the majority of food law. Hundreds of other European and national rules and regulations continue to play their role. The GFL:

> provides the basis for the assurance of a high level of protection of human health and consumers' interest in relation to food, taking into account in particular the diversity in the supply of food including traditional products, whilst ensuring the effective functioning of the internal market. It establishes common principles and responsibilities, the means to provide a strong science base, efficient organizational arrangements and procedures to underpin decision-making in matters of food and feed safety.[38]

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35. *See infra*, section II. C. 3.

36. *White Paper on Food Safety, supra* note 33, at 22, Annex No. XI, 50-52, XV, 72, XVII, 75-78.

37. *See supra*, note 16.

38. Parliament & Council Regulation 178/2002, supra note 16, at art. 1(1).

4. Official Controls and Enforcement

Since the BSE crisis, several layers of controls have been stacked on top of each other to ensure food safety. Self controls take place at the business level and at the level of the food chain. Member states inspect the performance of FBOs, and the FVO inspects the performance of the member states.

The application of HACCP (Hazard Analysis and Critical Control Point)[39] is obligatory for virtually[40] all FBOs in the EU.[41] As a consequence, FBOs have to analyze their processes to establish procedures to ensure hygiene and to exercise self-control in the functioning of these systems. Regulation 852/2004 gives the general requirements for the hygienic production of food.[42] In addition, Regulation 853/2004 lays down the hygiene requirements to be respected by FBOs handling food of animal origin at all stages of the food chain.[43]

The HACCP system applies to the handling of products within the business or businesses under the responsibility of the operator. Hazards may, however, originate earlier in the food chain. For the quality and safety of their products, businesses largely depend upon the reliability of the processes that have been applied upstream. To ensure high quality in all links in the food chain, systems have been set up based on civil law that apply to certification and third party audits. In particular, the big retail chains have elaborated quality and safety standards they impose on the whole chain upstream—among the most well known are the British Retail Consortium (BRC)[44] and EurepGap[45] standards. The audits under these systems form a second layer of controls on top of the self-controls within the businesses required by HACCP.

The holistic approach "from farm to fork" of the new EU regulatory system strongly stimulates the trend toward food chain integration. The requirements that have to be met by individual food businesses are an attempt at a coherent approach *within* the production chain to assure the production of food is safe *throughout* the production chain. Apart from the fact that every FBO has to comply with specific requirements, the GFL requires that food, food ingredients, and food-producing animals be traceable. The intention of this traceability system is to enable food safety problems to be identified at the source and across the food chain. To this end, FBOs must keep comprehensive

39. *See generally*, http://ec.europa.eu/food/index_en.htm (search "HACCP" for links to documents applying this preventative approach to food safety).

40. There are some exceptions. For example, a somewhat less stringent regime of food hygiene applies to primary production.

41. Parliament & Council Regulation 852/2004, 2004 O.J. (L 222) 3, art. 5.

42. Parliament & Council Regulation 852/2004, 2004 O.J. (L 226) 3 (EC). It has become effective as of January 1, 2006.

43. *Id.* at art. 1.

44. *See* BRC Global Standards, *available at* http://www.brc.org.uk/standards/default.asp (last visited Mar. 24, 2007).

45. *See* EurepGap, http://www.eurepgap.org/Languages/English/index_html (last visited Mar. 24, 2007).

records of exactly where their food material originated and where it went.

The relevant provision is within Article 18 of the GFL. Article 18 does not require an intact paper trail to accompany each individual food ingredient from the farm to the fork.[46] The general traceability requirements go only one step up and one step down the food chain.[47] Food and feed business operators must be able to identify their own sources and customers (excepting the final consumer).[48] The burden to reconstruct the whole food chain rests with the authorities, and, to that end, traceability information has to be made available to those authorities on demand.

Article 17 of the GFL establishes the responsibility of the member states for both official controls and enforcement of food law, appropriate to the circumstances, and the duty to monitor and verify that the relevant requirements of food law are fulfilled by FBOs at all stages of production, processing, and distribution.[49] This latter duty encompasses an obligation to communicate with the public concerning food and feed safety and risks, food and feed safety surveillance and other monitoring activities.[50]

Although Article 17 holds the member states responsible for the enforcement of food law, European food law increasingly sets standards for national enforcement and provides for supervision. On April 30, 2004, two Regulations were published in the Official Journal of the European Union: Regulation (EC) No 882/2004[51] and Regulation (EC) No 854/2004.[52] These Regulations are effective as of January 1, 2006.

National inspectors supervise the application of the requirements of feed and food law. The national inspectors have powers under *national* law to inspect premises where animals are kept or where food is handled and to report on irregularities, which may result in sanctions.[53]

Regulation (EC) 882/2004 is concerned with food-related controls in general. Member states are responsible for ensuring that official controls are carried out regularly and with appropriate frequency proportionate to the risk

46. *Compare* Commission Regulation 1830/2003, 2003 O. J. (268) (EC) *available at* http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00240028.pdf; *with* 2003 O.J. (L 268) 24-28 (establishing more stringent traceability requirements for food and feed produced from GMOs).

47. *See infra,* section VI.

48. Communication with the consumer on matters of food safety mainly happens through the media.

49. Parliament & Council Regulation (EC) No. 178/2002, *supra* note 16, at art. 17(2).

50. *Id.*

51. The full title is "Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules."

52. Regulation (EC) No 854/2004 of the European Parliament and of the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption, 2004 O.J. (L 191) 1.

53. Sanctions are a matter of national law of the member states. The GFL requires these to be "effective, proportionate and dissuasive." GFL, supra note 16, at art. 17(2).

for food safety posed by the business operator where the official controls take place.[54] What frequency is appropriate depends, among other things, upon identified risks and past performance. Good past performance by a FBO may lead to a reduced frequency in inspections.

Official controls must cover the whole food chain "from farm to fork." As a rule, they must be carried out without prior warning. Nevertheless, the national competent authority must ensure that they carry out their activities with a high level of transparency. National legislation must ensure that the staff of the competent authorities has access to the premises and documentation kept by FBOs, which are obliged to undergo any inspection and to assist the staff of the competent national authority in the accomplishment of their tasks.[55]

The FVO, instituted in 1997, is not an independent agency (like the European Food Safety Authority (EFSA)),[56] but a part of DG SANCO. It is, however, headquartered in Ireland, at a distance from the other parts of DG SANCO in Brussels.

The Commission, in its role as guardian of the Treaties,[57] being responsible for making sure food safety law is implemented and enforced serves as the foundation for the work of the FVO. The main role of FVO inspectors is to check how national authorities implement and enforce relevant EU legislation. Inspections are primarily focused on evaluating the nature and effectiveness of the national control systems in place and whether they are capable of delivering the required standards. At the same time, FVO inspectors carry out on-the-spot checks on farms, markets, food processing establishments, and other places where food is prepared or handled in order to ensure compliance. Non-compliance by member states may result in infringement proceedings.[58]

Although a FVO is not mentioned as such, the new Regulation 882/2004 provides a further legal basis for its activities in the first paragraph of Article 45.[59]

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54. *See supra*, note 49, at art. 3.

55. Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, 2004 O.J. (L 191) 1 (EC), art. 4(2)(g).

56. *See infra* section II. C. 4.

57. *See generally*, EC Treaty, art. 226.

58. *Id.*

59. Parliament & Council Regulation (EC) No 882/2004, 2004 O.J. (L 191) 1, 28 (EC), art. 45 ("[The] Commission experts shall carry out general and specific audits in Member States. The Commission may appoint experts from Member States to assist its own experts. General and specific audits shall be organised in cooperation with Member States' competent authorities. Audits shall be carried out on a regular basis. Their main purpose shall be to verify that, overall, official controls take place in Member States in accordance with the multi-annual national control plans referred to in Article 41 and in compliance with Community law. For this purpose, and in order to facilitate the efficiency and effectiveness of the audits, the Commission may, in advance of carrying out such audits, request that the Member States provide, as soon as possible, up-to-date copies of national control plans.").

B. Interpretation

The EU is generally regarded as reluctant to embrace GM food. How does the history of EU food law as set out above contribute to understanding the current regulatory approach in the EU toward GM food? Food safety problems are nothing new. In terms of death-toll, the BSE crisis was not the worst.[60] For some reason, however, the BSE crisis and the way it was mismanaged had a tremendous impact. On the one hand, there was the actual health problem; on the other hand, the problem was caused by a production method that raised ethical doubts: turning sheep and cattle into cannibals by feeding them slaughter remains disgusted some consumers.

An attempt made by the British Minister of Agriculture to reassure the public by feeding his young daughter a hamburger on television is symbolic of the way the crisis was mishandled.[61] The British offered scientific proof to support the official position that the problem was insignificant,. As a result, the credibility of the industry, government and science went down the drain.

Consumer distrust bred stereotypes. For many, the industry cared only for money, science was a piper playing the tune it was paid for, and politicians covered it all up. Shortly after the BSE crisis, the resignation of the Commission over a corruption case there dealt a further blow dealt to authorities' credibility (the Cresson Affair).[62]

In the mêlée, authorities lost the legitimacy to decide on the acceptability of food. Even today, when the government communicates that the public health is not at risk in a particular case, it does not reassure the public but instead creates the impression that any existing risk is being downplayed. GM politics in the EU can be understood partially as a defensive strategy of authorities to regain credibility with the public and dissociate themselves from suspect businesses. Even though the reputation of science was tarnished as well, authorities appeared as allies in the attempt to regain consumer trust.

The only actors that have emerged unblemished from these crises seem to

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60. Abaitua Borda I et al., *Toxic Oil Syndrome Mortality: The First Thirteen Years*, 27 INT'L J. EPIDEMIOLOGY 1057 (1998); Emilio Gelpí et al., *The Spanish Toxic Oil Syndrome Twenty Years After Its Onset: A Multidisciplinary Review of Scientific Knowledge*, 110 ENVTL. HEALTH PERSP. 457 (2002) (finding that the toxic oil syndrome (TOS) epidemic that occurred in Spain in the spring of 1981 caused approximately 20,000 cases of a new illness. Researchers identified 1,663 deaths between May 1, 1981 and December 31, 1994 among 19,754 TOS cohort members. Mortality was highest during 1981. The poisoning was caused by fraud, consisting of mixing vehicle oil with consumption oil.).

61. To convince the population that there was nothing wrong with British beef the responsible Secretary, John Gummer, fed his young daughter a hamburger on TV (May 16, 1990 BBC). Text, picture and video available at: http://news.bbc.co.uk/onthisday/hi/dates/stories/may/16/newsid_2913000/2913807.stm.

62. In 1999, a corruption scandal forced the entire European Commission to step down. The affair involved former French Prime Minister Edith Cresson who, as European Commissioner for Research, hired her private dentist as an adviser on HIV/Aids. *See* http://news.bbc.co.uk/1/hi/business/6500011.stm; http://www.abc.net.au/news/newsitems/200607/s1684128.htm.

be NGOs, specifically, Greenpeace. Over the years, Greenpeace has acquired a solid reputation of honesty. Everyone saw the pictures on television of people in small rubber dinghies risking their lives to prevent whalers from hunting the largest mammals on earth to extinction. This seemed to command public respect and trust.

In hindsight, it is easy to conclude that the businesses wanting to win the EU market for GM food products had no idea of the situation.[63] Therefore, they made all the blunders contributing to the current perception that GM food is almost taboo. Monsanto Company, in particular, was easy meat for opponents like Greenpeace. The launch of pesticide-resistant crops implying that farmers could exercise *less* restraint in using pesticides made it easy to brand gene technology as environmentally unfriendly. In the subsequent *Schmeiser* case,[64] Monsanto provided all the ammunition the opposition to GM technology could hope for to brand them to as socially callous. Once Monsanto started out on the wrong foot, all subsequent attempts at environmentally-friendly applications and contributions to food security could be (and were) easily viewed as hypocritical.[65] Scholars and politicians who discarded the fears of consumers as irrational only added insult to injury and, thus, did little for GM food.

C. EU Food Law

1. Concepts of EU Food Legislation

EU food law is based upon general principles set out in the GFL.[66] As EU law does not have a comprehensive system of administrative law, many procedural provisions are set out as well. The EU legislature approaches the subject matter of food from three main angles. First, there are rules concerning the properties of food. These are the rules concerning the use of ingredients and other raw materials. Some raw materials are subject to pre-market approval like additives, and GM and other novel foods. For other foods, only a

63. The first such company was Syngenta, and then later, it was mainly Monsanto.

64. *See* Monsanto Canada Inc. v. Schmeiser, [2004] S.C.R. 902 (The initial judgement that the growing of "Roundup Ready" canola constituted an infringement on Monsanto Company's patent whether Mr. Percy Schmeiser had done so knowingly and willingly may appeal to archbishops of IPR; taken together with Monsanto's apparent willingness to hunt Mr. Schmeiser to bankruptcy on this ground merely served to brand Monsanto as "evil" to the public.).

65. On the impact of GM on food security and the position of third world countries, *see* Jennifer Clapp, *The Political Economy of Food Aid in an Era of Agricultural Biotechnology*, 11 GLOBAL GOVERNANCE 467-85 (2005), 467–485 and Melanie G. Wiber, *Intellectual Property Rights and Food Security: the International Legal Battle Over Patenting Staple Crops*, in B.M.J. VAN DER MEULEN & H. VAN DIJK, FOOD SECURITY (forthcoming).

66. Some principles, however, are explicit. Chapter II section 1 of the General Food Law bears the title "General Principles of Food Law." GFL, *supra* note 16. This chapter sets out the aims of food law (art. 5), the principle of risk analysis (art. 6), the precautionary principle (art. 7) and consumer protection (art. 8). *Id.* Section 2 sets out principles of transparency. Other parts of the GFL set forth notions that are fundamental in nature. Some principles—like the "holistic approach" (see § 3.3)—are implicit. *See generally*, FSL, *supra* note 6.

general safety requirement applies; if the food is regarded as generally safe, then it can be used freely. Some substances are banned for use in food, like BSE-risk material. Further, there are requirements regarding substances whose presence must be avoided as much as possible, like residues of veterinary drugs, pesticides, and other contaminants.[67] The pre-market approval requirement for GM food is discussed in section five. Second, the EU has rules on the handling of food. These legislative requirements address the way food is handled within and between the different stages of production and distribution. HACCP and traceability requirements fall into this category. The traceability requirements for GM food are discussed in section six. Finally, there are rules on communication. These are requirements on the information that must and may not be given about food products, in particular, on the product label. The labeling requirements for GM food are discussed in section seven.

2. General Principles

The GFL takes as a general principle that in order to achieve the general objective of a high level of protection of human health and life, food law shall be based upon risk analysis.[68] Risk analysis is defined as a process consisting of three interconnected components: risk assessment, risk management and risk communication.[69] The work connected with each of these components is further distinguished in terms of scientific research and policy decisions, each of which should be executed independently from the other. To ensure independence, an agency separate from the Commission has been established, the European Food Safety Authority (EFSA),[70] which is responsible for risk assessment, where the Commission retains the initiative in areas of risk management and risk communication.

In general, no pre-market approval of foods and food ingredients is required with a tradition of safe use within the EU. Chemicals not normally consumed as food can be approved as additives. However, foods that have no history of use in Europe prior to 1997 are considered novel and require pre-market approval.[71] GM foods are a special category of novel foods and have been subject to a separate regulatory framework since 2004. GM foods require authorization[72] on the basis of a double safety assessment before they may be brought to market. Under the criteria laid down in Directive 2001/18, one must be specifically authorized to deliberately release a genetically modified

67. Furthermore, statutory limits also apply to many of these substances.

68. 2002 O.J. (L 31) 1, art. 6(1).

69. *Id.* at art 3(10). *See also* Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, art. 5, 2003 O.J. (L 268) 7, *available at* http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00010023.pdf.

70. Parliament & Council Regulation (EC) No. 178/2002, *supra* note 16, at arts. 5, 22-49 (Chapter III).

71. Regulation 258/97; the Novel Foods Regulation.

72. Parliament & Council Regulation (EC) No. 1829/2003, *supra* note 61, at art. 7.

organism (GMO) into the environment, and likewise for the use of a GMO in food or feed under the criteria established in Regulation 1829/2003.[73]

3. Precautionary Principle

Article 174 of the EC Treaty bases EU environmental policy upon the principles of precaution and prevention.[74] The GFL chooses the precautionary principle also as one of the leading principles of European food legislation:

> 1. 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.
>
> 2. Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The

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73. *Id.*; Directive 2001/18 (EC) of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, 2001 O.J. (L 106) 1.

74. Article 174 reads, in part:

1. Community policy on the environment shall contribute to pursuit of the following objectives:
   - preserving, protecting and improving the quality of the environment,
   - protecting human health,
   - prudent and rational utilisation of natural resources,
   - promoting measures at international level to deal with regional or worldwide environmental problems.

2. Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It shall 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.

In this context, harmonisation measures answering environmental protection requirements shall include, where appropriate, a safeguard clause allowing Member States to take provisional measures, for non-economic environmental reasons, subject to a Community inspection procedure.

3. In preparing its policy on the environment, the Community shall take account of:
   - available scientific and technical data,
   - environmental conditions in the various regions of the Community,
   - the potential benefits and costs of action or lack of action,
   - the economic and social development of the Community as a whole and the balanced development of its regions.

4. Within their respective spheres of competence, the Community and the Member States shall cooperate with third countries and with the competent international organisations. The arrangements for Community cooperation may be the subject of agreements between the Community and the third parties concerned, which shall be negotiated and concluded in accordance with Article 300.

The previous subparagraph shall be without prejudice to Member States' competence to negotiate in international bodies and to conclude international agreements.

> measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.[75]

There is a striking difference in wording between Article 174 of the EC Treaty and Article 7 of the GFL.[76] In Article 174, the precautionary principle seems to be seen as an independent notion; the obligation to take into account available scientific and technical data is added almost as an afterthought. By contrast, the GFL places the obligation to conduct a scientific risk assessment at the front, in Article 6. The precautionary principle in Article 7 does little more than answer the question of how to handle risk management if risk assessment is inconclusive.[77]

The full text of each of the relevant articles is included here because the precautionary principle is often seen as the main point of difference between the EU and U.S. approaches to GM food. In my view, the role of Article 7 of the GFL is too limited in relation to Article 6 to sustain this interpretation. I rather believe that the cautious nature of civil law as described at the opening of this article is at the heart of the matter.

4. EFSA

The EFSA was created by the GFL. EFSA is an independent agency responsible for risk assessment. The GFL gives the EFSA—called, colloquially, the "Authority"—the following mission: "The Authority shall provide scientific advice and scientific and technical support for the Community's legislation and policies in all fields which have a direct or indirect impact on food and feed safety. It shall provide independent information on all matters within these fields and communicate on risks."[78] The operation of EFSA as an independent entity is intended to ensure that there is a functional separation of the scientific assessment of risk from risk management decisions. The reason for this separation is that scientific risk assessment should not be swayed by policy or other external considerations[79]; this is designed to guarantee impartiality and objectivity.[80]

5. Novel Foods Regulation

On May 15, 1997, the Novel Foods Regulation became effective.[81] This regulation divided the history of food products in the EU into two periods: prior to and after May 15, 1997. Foods that had a history of safe use in the EU,

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75. Parliament & Council Regulation (EC) No. 178/2002, *supra* note 16, at art. 4(2).

76. On the interpretation of the European Commission of the precautionary principle, *see* Communication from the Commission on the precautionary principle, Brussels 02.02.2000 (COM (2000) 1).

77. This approach seems to be very much in line with Art. 5(7) of the SPS Agreement.

78. Parliament & Council Regulation (EC) No. 178/2002, *supra* note 16, at art. 22.

79. As happened during the BSE crisis. *See supra* notes 19-24 and accompanying text.

80. Simone Gabbi, *The Interaction between Risk Assessors and Risk Managers*, 3 EUR. FOOD & FEED L. REV. 126 (2007).

81. Parliament & Council Regulation 258/97, 1997 O.J. (L 43) 1 (EC).

as of May 15, were to be presumed safe until indications to the contrary presented themselves. All other foods needed to pass a safety clearance on the basis of scientific evidence before they were allowed to enter the market. This system was undoubtedly inspired by the questions that arose in the context of GM foods, but it applied to all novelties, including foods imported for the first time in the EU from other regions of the world where they already had a history of safe use.[82]

Article 3(1) of the Novel Foods Regulation lays down the criteria to judge the marketability of novel foods:

> Foods and food ingredients falling within the scope of this Regulation must not:
>
> - present a danger for the consumer,
> - mislead the consumer,
> - differ from foods or food ingredients which they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous for the consumer.[83]

As discussed further below, criteria similar to these three are commonly used in EU pre-market approval procedures.[84] The Novel Foods Regulation has a simplified procedure for products that are substantially equivalent to existing products. Other products have to pass an extensive safety clearance.

The safety clearance under the Novel Foods Regulation is decentralized. That is to say, member states perform the procedure.[85] In this procedure, all the other member states could file objections against approval of the novel food concerned. Further, there is a safeguard clause giving member states the opportunity to restrict or suspend a food complying with the regulation if they have reason for public health or environmental concerns.

If ever a *de facto* moratorium on GMOs existed—claimed by the U.S. and Canada but denied by the EU[86]—this feature of the Novel Foods Regulation is at its center. Member states have countless opportunities to stall the procedure even after favorable risk assessments. This may have been the motivating factor in taking GMOs out of the scope of the Novel Foods Regulation and providing them their own regulatory framework.[87]

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82. Food additives are outside the scope of the Novel Foods Regulation. *Id.* at art. 2.

83. Parliament & Council Regulation 258/97, *supra* note 70, at art. 3(1).

84. 1989 O.J. (L 40) 27. For the approval of additives for example it is required that (1) a technological need can be demonstrated, (2) they present no health hazard, and (3) they do not mislead the consumer.

85. Parliament & Council Regulation (EC) No. 258/97, *supra* note 61, at art. 4.

86. It is outside the scope of this paper to take a position on this matter.

87. *See* RAYMOND O'ROURKE, EUROPEAN FOOD LAW Ch. 9 (2d ed. 2001); MARI LYYRA, ET AL., LEGISLATION FOR NOVEL FOOD PRODUCTS (2002) (written in German); ALFRED HAGEN MEYER, RECHT NEUARTIGER LEBENSMITTEL (2002) (chronicling the function of the Novel Foods Regulation as framework for GM foods prior to 2004). *See also* MIGUEL ÁNGEL RECUERDA GIRELA, SEGURIDAD ALIMENTARIA Y NUEVOS ALIMENTOS. RÉGIMEN JURÍDICO-ADMINISTRATIVO (2006) (written in Spanish).

III. THE NEW EU REGULATORY FRAMEWORK FOR GM FOOD

A. The GM Package

A GM-centric regulatory framework has been in place since 2004, consisting of the regulations listed in the annex to this article. This article focuses on the content of the package as a whole rather than on commenting the different regulations piece-by-piece.

B. Novel Foods and GMOs

The legislation discussed in this article takes GM foods outside the scope of the Novel Foods Regulation and provides them with their own regulatory framework. GMO's are *lex specialis*, so, as far as they apply, the Novel Foods Regulation no longer applies unless this Regulation applies for another reason.[88] To this effect, recital 11 of Regulation 1829/2003 states, *inter alia*:

> (F)oods covered by an authorisation granted under this Regulation will be exempted from the requirements of Regulation (EC) No 258/97 concerning novel foods and novel food ingredients, except where they fall under one or more of the categories referred to in Article 1(2)(a) of Regulation (EC) No 258/97 in respect of a characteristic which has not been considered for the purpose of the authorisation granted under this Regulation.[89]

C. Holistic Approach

The GFL introduced a so-called "holistic approach" to food law (again, the ambition under the new European food safety legislation to encompass the whole food chain "from farm to fork"). In the new regulatory framework on GMOs, this approach, then, applies to both food and feed products. This article is limited to GM food. Rules concerning feed will only be discussed as far as they are relevant for food.

IV. ENVIRONMENTAL APPROVAL

History has shown that the balance in the natural environment from co-evaluation is vulnerable to alien species. When man started to roam the globe, in his wake he wrought environmental disaster by accidental or intentional introduction of foreign plants and animals into each new environment. Today, protective (sanitary and phytosanitary) measures try to avoid further damage. For instance, travelers from Europe and other continents are not allowed to bring food or plants into the USA. At American airports, this ban is enforced

88. For example, if an exotic food (i.e., a food having a history of use only outside the EU) would be genetically modified, or if a novel technical process (e.g., pressurizing the foodstuff) would be applied to a GMO, then both sets of rules would apply simultaneously.

89. Parliament & Council Regulation (EC) No. 1829/2003, *supra* note 61, at Recital 11.

by the "Beagle Brigade."[90]

To a certain extent, genetic engineering may result in new species to which the environment is vulnerable.[91] Protective measures have been agreed upon on a global level (Cartegena Protocol[92]) and have also been taken in the EU. On May 8, 1990 Council Directive of 23 April 1990 on the deliberate release into the environment of genetically organisms (90/220/EEC) was published in its Official Journal.[93] This Directive was replaced by the current Directive 2001/18.[94]

This, the latter Directive is subdivided in four parts, A through D. Part A contains general provisions. Part B addresses deliberate release of GMOs for any other purpose than for placing on the market. Part C deals with placing GMOs as such or in products on the market. Part D contains final provisions. The Directive takes a "no unless" approach to GMOs. Releases into the environment are prohibited unless specifically approved, under procedures outlined in Part B (commonly used with a view to field trials). Part C of the Directive is the most important part with regard to GM foods.

The regular procedure first requires notification of the competent authority in the member state where the GMO is to be placed on the market for the first time.[95] This authority informs the Commission and the other member states. The competent authority assesses the notification.[96] At this point, the subsequent procedure depends upon whether the assessment report is favorable or not and whether other member states file objections or not. If the competent authority concludes that the GMO must not be placed on the market, the notification is rejected. If the report is favorable and no objections are made, the competent authority gives consent for a renewable maximum period of ten years.

In case of objections, the decision shall be taken in commitology.[97] Member states may not prohibit, restrict, or impede placement of GMOs on the market—as or in products—which comply with the requirements of Council

90. The "Beagle Brigade," the U.S. Department of Agriculture (USDA) "detector dogs," is a tool of the USDA, Animal and Plant Health Inspection Service (APHIS). *See* http://www.aphis.usda.gov/lpa/pubs/detdog3.html.

91. For example, it would be conceivable that resistance to certain natural enemies ('pests') or herbicides provides GMOs with an edge over natural species or human attempts to redress an unwanted situation.

92. Cartagena Protocol, 2002 O.J. (L 201) 50.

93. Council Directive of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (90/220/EEC) 1990 O.J. (L 117) 15.

94. Directive 2001/18/EC of the European Parliament and of the Council of March 12, 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, 2001 O.J. (L 106) 1; *see also* Daniel Lawrence, et al., *New Controls on the Deliberate Release of GMOs*, EUROPEAN ENV. L. REV. 51-56 (Feb. 2002).

95. Council Directive 2001/18, art. 13, 2001 O.J. (L 106) 1, 9 (EC).

96. *Id.* at art. 14.

97. *Id.* at arts. 18, 30.

Directive 2001/18.[98]

V. MARKET APPROVAL

A. General Remarks

Again, the GFL sets out as the applicable general principles science-based regulation and the precautionary principle. Regulation 1829/2003 adds the *procedural* principle of "one door one key."[99]

B. Authorization Requirement

Article 4(2) of Regulation 1829/2003 gives a general prohibition on GMOs on the market for food use unless the particular GMO is covered by an authorization and the conditions to this authorization are satisfied[100]. The whole regulatory framework for pre-market approval is built as a set of exceptions to this prohibition.

C. Scope

The authorization requirements of Regulation 1829/2003 apply to: a) GMOs for food use; b) food containing or consisting of GMOs; and c) food produced from or containing ingredients produced from GMOs.[101]

The first two are straightforward; however, the concept "produced *from*" raises some questions. This concept can be understood to mean highly refined food (ingredients) made from GMOs, but no longer containing proteins or DNA (like soy oil or maize oil).[102] In theory, processing aids fall outside the scope of the Regulation. The Regulation does not apply to food produced *with* GM enzymes.

Recital 16 of Regulation 1829/2003 reads:

> This Regulation should cover food and feed produced 'from' a GMO but not food and feed [produced] 'with' a GMO. The determining criterion is whether or not material derived from the genetically modified source material is present in the food or in the feed. Processing aids which are only used during the food or feed production process are not covered by the definition[103] of food or

98. Council Directive 2001/18, art. 22.

99. Parliament & Council Regulation (EC) No. 1829/2003, *supra* note 61.

100. *Id.* at art. 4.

101. *Id.* at art. 3.

102. This requirement raises some discussion on the question as to what, exactly, a GMO is and if processing can remove this quality from a product. In particular, in the United States, it seems to have been argued that a GMO is no longer a GMO if the genes concerned are no longer present.

103. This assumption is debatable. Article 2 of the GFL defines food as follows: "For the purposes of this Regulation, 'food' (or 'foodstuff') means any substance or product, whether

> feed and, therefore, are not included in the scope of this Regulation. Nor are food and feed which are manufactured with the help of a genetically modified processing aid included in the scope of this Regulation. Thus, products obtained from animals fed with genetically modified feed or treated with genetically modified medicinal products will be subject neither to the authorisation requirements nor to the labelling requirements referred to in this Regulation.[104]

Practice seems to be less clear than theory suggests. Anecdotes relate that companies dealing with the Commission have found the Commission very reluctant to regard enzymes as processing aids falling outside the scope of the Regulation.

The anonymous author of the recital quoted above seems to have had a good sense for the kind of discussions that were to be expected. Currently, in the Netherlands, Greenpeace is campaigning against a dairy business for feeding the cattle with GM feed and advertising the dairy products as natural.[105]

D. Application Procedure

According to Article 5 of Regulation 1829/2003, an authorization is granted exclusively on the basis of an application.[106] Regulation 1829/2003 gives some requirements for the application procedure, which have been further elaborated in Commission Regulation 641/2004.[107]

1. Criteria

The Regulation stipulates that GM food/feed must not: "have adverse effects on human health, animal health, or the environment; mislead the consumer; or differ from the food/feed it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer/animals."[108] The burden of proof is on the applicant.

2. The Applicant

The applicant must define the scope of the application, indicate which parts are confidential,[109] and must include a monitoring plan, a labeling proposal and a detection method for the new GM food or feed.[110] It must

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processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans." *See supra,* note 16. Processing aids are not intended to be ingested by humans, but depending upon the specific processing aid in question, traces or residues may be expected to be ingested. This does not, however, alter the scope of Regulation 1829/2003.

104. Parliament & Council Regulation (EC) No. 1829/2003, *supra* note 61.

105. Gene Crime Investigation, http://www.greenpeace.nl/campaigns/genetische-manipulatie/gene-crime-de-zaak-campina (last visited Sept. 17, 2007) (in Dutch).

106. *Id.* at art. 5.

107. *Id.*

108. *Id.* at art. 4.

109. *Id.* at art. 30.

110. Commission Regulation 641/2004, 2004 O.J. (L 102) 14, arts. 2, 3.

present copies of available studies that have been carried out and any other available material demonstrating that the GM food complies with the mentioned criteria.[111] Applications are to be submitted to the competent authority of the member state where the GM food product will be marketed first.[112]

3. "One Door One Key"

The new regulatory framework is based on the "one door one key" principle. This phrase contains several elements. First, authorization for GM foods is valid throughout the Community.[113] Unlike, for instance, pharmaceutical products, there is no need to acquire authorization from each member state where the product is brought to market. Second, Regulation 1829/2003 makes it possible to file a single application for obtaining both the authorization under Directive 2001/18 for release into the environment and the authorization under Regulation 1829/2003 for placement on the market as a food or feed.[114] However, the applicant may also choose to follow two separate procedures. It may, for instance, want to perform field tests long before an authorization for food use is relevant. Third, this single application is followed by a single risk *assessment* process, for which EFSA is responsible, and a single risk *management* process, involving both the Commission and the member states through a regulatory committee procedure.

Finally, if a product is likely to be used as both a food and a feed, it must be authorized for both or not at all.[115] A single application shall be submitted and shall give rise to a single opinion from EFSA and a single Community decision.[116] A single authorization is given for a GMO and all its possible uses, thus insuring against a repeat of the U.S. experience with Starlink maize.[117]

4. The National Competent Authority

Compared to the Novel Foods Regulation, the role of the national authorities with regard to these applications is very limited. They receive applications[118] and must both acknowledge receipt of applications in writing within fourteen days and inform EFSA.[119] The application, and any supplementary information supplied by the applicant, must be made available to EFSA, which is responsible for a scientific risk assessment covering both environmental risks and a human and animal health safety assessment.

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111. Parliament & Council Regulation (EC) No. 1829/2003, *supra* note 61, at art. 5(3).

112. *Id.* at art. 5.

113. *Id.*

114. *Id.* at arts. 5, 7.

115. *Id.* at arts. 15-26. This contribution does not go into the details of the prescriptions that apply to feed in particular.

116. *Id.* at art. 27.

117. "Starlink" maize (corn) was a GM maize which was only authorized for feed but turned up in food.

118. *Id.* at art. 5(2).

119. *Id.; see also* Commission Regulation 641/2004, 2004 O.J. (L 102) 14, 16, art. 5(2)(a).

EFSA may ask national authorities to carry out risk assessments.[120] EFSA may also ask "a competent authority designated in accordance with Article 4 of Directive 2001/18/EC" to carry out an environmental risk assessment. EFSA is even under an obligation to do so "if the application concerns GMOs to be used as seeds or other plant-propagating material."[121]

5. Opinion of EFSA

EFSA receives the application and any supplementary information supplied by the applicant from the national authorities. EFSA is responsible for a scientific risk assessment, covering both environmental risks and a human and animal health safety assessment. EFSA can conduct the risk assessment itself, or it can ask a national food assessment body to perform this task. EFSA's assessments are subject to a six month time limit, although this may be extended if EFSA requests further information from the applicant.[122]

6. Community Reference Laboratory

In Article 6 (3)(d) of Regulation 1829/2003, EFSA is required to forward to the "Community Reference Laboratory"[123] the particulars necessary to test and validate the method of detection and identification of the GMO proposed by the applicant.[124] It is assisted by a consortium of national reference laboratories—the "European Network of GMO laboratories."

The Community reference laboratory is responsible for:

- reception, preparation, storage, maintenance and distribution to national reference laboratories of the appropriate positive and negative control samples,
- testing and validation of the method for detection, including sampling and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food or feed,
- evaluating the data provided by the applicant for authorization for placing the food or feed on the market, for the purpose of testing and validation of the method for sampling and detection,
- submitting full evaluation reports to EFSA.[125]

7. Publication

EFSA provides a public version[126] of its opinion available to the public.

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120. Parliament & Council Regulation (EC) No. 1829/2003, *supra* note 61, at art. 6.

121. *Id.*

122. *Id.*

123. The Community Reference Laboratory is also referred to as the Community's "Joint Research Centre." *Id.*

124. Regulation 1829/2003 institutes the "Community Reference Laboratory" in Article 32 and in its Annex. *Id.* at art. 32, Annex.

125. Parliament & Council Regulation (EC) No. 1829/2003, *supra* note 61, at Annex.

126. That is to say, EFSA provides the public a text from which confidential information has been deleted.

The public will be allowed to make comments to the Commission within thirty days from the publication.[127]

8. Commission

Within three months of receiving the EFSA's opinion, the Commission will draft a proposal for granting or refusing authorization on the basis of that opinion.[128] The proposal must be approved by a qualified majority of the member states within the Standing Committee on the Food Chain and Animal Health,[129] which is composed of representatives of the member states. If the Committee gives a favorable opinion, the Commission adopts the Decision. If not, the draft Decision is submitted to the Council of Ministers for adoption or rejection by qualified majority. If the Council does not act within three months, the Commission shall adopt the decision. These shifts in competence, depending upon the content of the decision and the amount of consent, seem deplorable from an accountability point of view.

B. Authorization

1. Scope

The authorization lifts the prohibition against bringing a GM food into the market. The decision is addressed to the applicant. As a result, the applicant receives a *de facto* monopoly to bring the authorized product to the GM market until other applicants acquire authorization as well.[130]

Once granted, market authorizations for GM foods are valid for ten years throughout the Community.[131] Conditions and restrictions may be connected to authorizations, and the applicant may be obliged to implement a monitoring plan.[132]

2. Publication and Registration

The applicant is informed without delay of a decision of the Commission. The details of the decision are published in the Official Journal of the European Union.[133] Products authorized shall be entered into a public register of GM food and feed.[134]

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127. Parliament & Council Regulation (EC) No. 1829/2003, *supra* note 61, at arts. 2, 5(2)(b), 6(7), 29-31; Parliament & Council Regulation (EC) No. 178/2002, *supra* note 16, at art. 38(1). *See also* Commission Regulation 65/2004, art. 38(1), 2002 O.J. (31) 18 (EC). The comments received by EFSA are published at http://ec.europa.eu/food/food/biotechnology/autorisation/public_comments_en.htm.

128. Parliament & Council Regulation (EC) No. 1829/2003, *supra* note 61, at art. 7(1).

129. *Id.* at art. 35; Parliament & Council Regulation (EC) No. 178/2002, *supra* note 16, at art. 58.

130. This interpretation departs from the one I expressed in the *New EU Regulatory Framework for GM Food* (Part I), 2 J. OF INT'L BIOTECH. LAW 117-22 (2005).

131. Parliament & Council Regulation (EC) No. 1829/2003, *supra* note 61, at art. 7(5).

132. *Id.* at arts. 5(3)(k), 5(5)(b), (9)(1).

133. *Id.* at art. 7(4).

134. *Id.* at art. 28; GM Food & Feed—Community Register of GM Food and Feed,

C. *Liability*

Article 7 (7) Regulation 1829/2003 states, "The granting of authorisation shall not lessen the general civil and criminal liability of any food operator in respect of the food concerned."[135] Notwithstanding this provision, an authorization certainly has influence on liability. Part of general civil liability law is product liability, as harmonized by Directive 85/374 and Directive 1999/34.[136] An important defense in European product liability law is the "development risk" defense: the producer can disclaim liability if he proves that the state of scientific and technological knowledge at the time the product was put into circulation did not allow the existence of the defect to be discovered.[137] A favorable assessment by the EFSA followed by an authorization would seem to constitute considerable proof that this defense would sustain.

D. *Modification and Renewal*

The authorization-holder can propose to modify the terms of the authorization, by application of the *mutatis mutandis* procedure to the proposal.[138] Authorizations are renewable for ten year periods.[139] Applications must be sent to the Commission one year before the expiration date of the authorization at the latest.

E. *Suspension and Revocation*

An authorization, once granted, is not untouchable during its ten year period of validity. EFSA may, on its own initiative or on request, issue an opinion as to whether an authorization for a product still meets the conditions. The Commission may then decide whether the authorization shall be modified, suspended or revoked.

F. *Administrative Review*

An interesting provision is Article 36 of Regulation 1829/2003, which reads:

Any decision taken under, or failure to exercise, the powers vested in

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available at http://ec.europa.eu/food/dyna/gm_register/index_en.cfm (last visited Mar. 25, 2007).

135. Parliament & Council Regulation (EC) No. 1829/2003, *supra* note 61, at art. 7(7).

136. *See* NICOLE COUTRELIS, PRODUCT LIABILITY IN THE FOOD SECTOR, http://ec.europa.eu/enterprise/regulation/goods/docs/liability/1999-greenpaper-replies/046.pdf (last visited Mar. 25, 2007).

137. Directive 1999/34 of the European Parliament and of the Council of May 10, 1999 amending Council Directive 85/374/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, 1999 O.J. (141) 20-21 (EC), art. 7(3).

138. Parliament & Council Regulation (EC) No. 1829/2003, *supra* note 61, at art. 9(2).

139. *Id.* at art. 11(1).

> the Authority by this Regulation may be reviewed by the Commission on its own initiative or in response to a request from a Member State or from any person directly and individually concerned.
> To this effect a request shall be submitted to the Commission within two months from the day on which the party concerned became aware of the act or omission in question.
> The Commission shall make a decision within two months requiring, if appropriate, the Authority to withdraw its decision or to remedy its failure to act.[140]

Apart from the Treaties, there is no comprehensive body of administrative law in the EU. For this reason, special provisions have had to be made for legal protection and other procedural matters. The Treaties provide an opportunity to challenge decisions of EU institutions—including the Commission—before the European Court of Justice. So far, independent agencies are not subject to the power of this Court.

However, a provision in Article 47 of the GFL brings the EFSA under the jurisdiction of the European Court of Justice for both contractual and non-contractual liability. Against this backdrop, the review clause in Article 36 of Regulation 1829/2003 seems unnecessary; the regulation does not give the EFSA the power to make decisions, so, in this respect, the clause is meaningless.

It is positive that if the EFSA fails to act, the Commission can ensure the progression of an authorization procedure by requesting a risk assessment from some other national authority. The dark side of this provision is that it gives the Commission the power to put its opinion in the place of the EFSA's opinion, seemingly a serious encroachment on the EFSA's independence. The independence of risk assessment from risk management was considered one of the leading principles of the new system of European food law under the GFL.

VI. TRACEABILITY

A. In General

EU Regulation 178/2002 (the GFL) requires that food, feed, food-producing animals, and any other substance intended or expected to be incorporated into a food or feed shall be traceable at all stages of production, processing and distribution.[141] To this end, food and feed business operators must be able to identify any person who has supplied them with a food, feed, food-producing animal, or any substance intended or expected to be incorporated into a food or feed. They must also be able to identify all businesses to which their products have been supplied. In other words,

140. Parliament & Council Regulation (EC) No. 1829/2003, *supra* note 61, at art. 36.
141. Parliament & Council Regulation (EC) No. 178/2002, *supra* note 16, at art. 18.

traceability is required one step up and one step down. Business operators shall have in place systems and procedures that allow this information to be made available to competent authorities on demand.

Food or feed which is or is likely to be placed on the market in the European Community must be adequately labeled or identified to facilitate its traceability through relevant documentation or information in accordance with the relevant requirements of more specific provisions. In a document that provides an interpretation to the most important provisions in the GFL,[142] the Standing Committee of the Food Chain and Animal Health took the position that traceability requirements apply only from entry past the EU border onwards; that is to say, authorities will not demand information regarding the origin of the product in a third country from which it was imported. It is unclear what the basis is for this limited interpretation—the text of the GFL does not provide a foothold. It is even less clear whether this interpretation also applies to the specific traceability regime for GM foods.

This same document also concludes that businesses are not obligated to ensure internal traceability.[143] In other words, they have to know where the ingredients came from and where the products went but not necessarily which ingredients went into which products. This interpretation seems to expose a major flaw in the system. In cases where internal traceability is not assured, it seems highly problematic to reconstruct the entire chain to trace the origins and consequences of a food safety problem.

B. Aim of GM Traceability

Article 1 of Regulation 1830/2003 states that traceability of GM foods has as its objectives: facilitating accurate labeling; monitoring the effects on the environment and, where appropriate, on health; and implementing appropriate risk management measures including, if necessary, withdrawal of products.[144] In practice, traceability schemes play a role in assuring consumers that products indeed possess certain invisible qualities relating to their origin and the way they have been handled (kosher, hallal, organic, et cetera). A new regulation regarding food contact materials has a similar traceability

142. *See Guidance on the Implementation of Articles 11, 12, 16, 17, 18, 19 and 20 of Regulation (EC) No 178/2002 on General Food Law*, CONCLUSIONS OF THE STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH (2004), http://ec.europa.eu/food/food/foodlaw/guidance/guidance_rev_7_en.pdf (last visited Mar. 25, 2007).

143. *See id.*

144. Regulation (EC) No. 1830/2003 of the European Parliament and of the Council 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. (268) (EC), *available at* http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00240028.pdf; *see also* Margaret Rosso Grossman, *Traceability and Labeling of Genetically Modified Crops, Food and Feed in the European Union*, 1 J. FOOD L. & POL'Y 43, 43-85 (2005) (explaining GM traceability).

scheme.[145] This regulation expresses what had been suspected all along: traceability is also meant to facilitate attribution of responsibility (e.g., liability).[146] There is no reason to suppose that this notion applies to food contact materials exclusively.

Whether the possibility of using traceability to establish liability is considered an advantage or a disadvantage depends upon one's point of view. For businesses at the end of the food chain, it seems advantageous for liability to be passed to the companies where the problem originated. Businesses in the latter position would probably see this as a disadvantage.

C. Content of GM Traceability

Regulation 1830/2003 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."[147] Unlike the GFL, Regulation 1830/2003 requires a paper trail to accompany GM food. This paper trail ensures internal traceability. The flaw indicated above, which may exist in the general system of traceability, does not occur with regard to GM food.

At the first stage of placing a product consisting of or containing GMOs on the market, including bulk quantities, operators must ensure that information: (a) that the product contains or consists of GMOs and (b) providing the unique identifier(s) assigned to those GMOs is transmitted in writing to the operator receiving the product. At every following stage, the same information must be passed on for each ingredient or additive that it concerns.[148]

This seems easy on paper, but in practice, it is next to impossible to preserve the identity of each raw material through to the end-products in which they are used. Identity preservation[149] is hard to realize, for instance, in bulk storage, in continuous production processes, and in other cases where failed products re-enter the production chain as raw materials.[150] Additionally, all information must be kept for five years.[151] Small traces—no more than 0.9%—are exempted from the traceability requirements if they are adventitious and unavoidable.[152]

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145. 2004 O.J. (L 338) 1935.

146. *Id.* at art. 17.

147. Parliament & Council Regulation (EC) No. 1830/2003, *supra* note 132.

148. *Id.* at art. 4(1) & (2).

149. Also called "internal traceability."

150. Also called "rework."

151. Parliament & Council Regulation (EC) No. 1830/2003, *supra* note 132, at arts. 4(5) & 5(2).

152. *Id.* at art. 7 (amending art. 21 of 2001 O.J. (L106) 18).

D. Unique Identifiers

In Regulation 65/2004, the Commission devised, as instructed, a system of unique identifiers to be assigned to each GMO.[153] The Annex to this regulation prescribes the format. The Commission follows the formats for unique identifiers that have been established by the Organization for Economic Cooperation and Development (OECD) for use both in the context of its BioTrack product database and in the context of the Biosafety Clearing-House,[154] established by the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.[155] The applicant for an authorization must develop the unique identifier for each GMO concerned.[156]

The Commission specifies the identifier in the authorization decision,[157] records it in the relevant registers,[158] and ensures that it is communicated to the Biosafety Clearing-House as soon as possible.[159]

The unique identifiers consist of nine alphanumeric digits. The first three indicate the businesses concerned. On May 19, 2004, for example, Syngenta Seeds BV received authorization for sweet maize, fresh or canned, with the unique identifier: SYN-BT Ø 11-1. The transformation event (Bt11) is recognizable in the ID.

GMOs will not as yet have a unique identifier if consent for market placement had been granted prior to the entry into force of Regulation 65/2004. The burden to remedy this situation is on the "relevant consent holders or where appropriate the competent authority that has taken the final decision on the original application".[160] Either must consult both the OECD BioTrack product database and the Biosafety Clearing-House to determine whether a unique identifier has already been developed for that GMO.[161] If one has, the details must be communicated to the Commission. If not, the consent holder or authority, again, must develop a unique identifier. Within ninety days following the entry into force of Regulation 65/2004, the consent holder must communicate the details of the identifier to the Commission.[162]

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153. *Id.* at art. 8.

154. *See* Biosafety Clearing House, http://bch.biodiv.org/default.aspx (last visited Mar. 24, 2007).

155. Commission Regulation (EC) No. 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms, at Recital 6, 2004 O.J. (L 10) 65.

156. *Id.* at art. 2.

157. *Id.* at art. 3(a).

158. *Id.* at art. 3(c), 5(3).

159. *Id.* at art. 5(4).

160. Commission Regulation (EC) No. 65/2004, *supra* note 142.

161. *Id.* at art. 4.

162. *Id.* at art. 6.

VII. LABELING

A. In General

One of the principles of modern European food law, as prescribed in the GFL, is that of informed choice. To this effect, Article 8 GFL states:

> Food law shall aim at the protection of the interests of consumers and shall provide a basis for consumers to make informed choices in relation to the foods they consume. It shall aim at the prevention of:
>
> (a) fraudulent or deceptive practices;
>
> (b) the adulteration of food; and
>
> (c) any other practices which may mislead the consumer.

B. Scope

Similar to the scope of the authorization procedure, the scope of the labeling requirements is limited to food and food ingredients consisting of, or produced from, GMOs.[163] "This Section shall apply to foods which are to be delivered as such to the final consumer or mass caterers in the Community and which (a) contain or consist of GMOs; or (b) are produced from or contain ingredients produced from GMOs."[164] Food produced with GMOs fall outside the scope.[165] The use of GM processing aids[166] does not have to be mentioned on the label, nor does the label of animal products have to mention whether the animal concerned was fed with GM feed.

C. GM Labeling

In relation to GM food, the principle of informed choice requires that consumers be informed of the use of gene technology in the production of the food products they buy or consume.[167] Therefore, Regulation 1829/2003 (Article 13) prescribes that "the words 'genetically modified' or 'produced from genetically modified [name of the ingredient]' shall appear in the list of ingredients."[168] This requirement has been elaborated further in Article 4 (6)

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163. *See also* Grossman, *supra* note 132, at 43-71 (explaining GM labelling).

164. Parliament & Council Regulation (EC) No. 1830/2003, *supra* note 132, at art. 12(1).

165. *See id* at Recital 16. In the absence of exhaustive EU provisions, national regulations are possible. In the Netherlands, for instance, it is forbidden to claim on the label that a product was produced without gene-technology if GM-processing aids were used or GM feed was fed to the food (meat, milk, eggs) producing animals concerned.

166. Also in general, processing aids do not need to be labelled. Directive 2000/13 (EC) of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, at art. 6(4)(i),(iv), 2000 O.J. (L 109) 32 (EC).

167. *See also* Peter H. Sand, *Labelling Genetically Modified Food: The Right to Know*, 15 (2) REV. OF EUR. COMMUNITY & INT'L ENVTL. L. J. 185, 185-92 (2006).

168. It should be noted that the word "genetically" must be in the labelling. It may cause some confusion that additives exist that must be labelled as "modified starch." Here the word

of Regulation 1830/2003:

> For products consisting of or containing GMOs, operators shall ensure that:
>
> (a) for pre-packaged products consisting of, or containing GMOs, the words "This product contains genetically modified organisms" or "This product contains genetically modified (name of organism(s))" appear on a label;
>
> (b) for non-pre-packaged products offered to the final consumer the words "This product contains genetically modified organisms" or "This product contains genetically modified (name of organism(s))" shall appear on, or in connection with, the display of the product.[169]

These labeling requirements apply to all products derived from GMOs—even highly refined products. No longer is there an exception for products in which no protein or DNA is present.

However, there are exceptions, albeit very few. As with the traceability requirement, the labeling requirement does not apply to foods containing materials that contain, consist of or are produced from GMOs in a proportion no higher than 0.9 % of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable.[170] The burden of proof is on industry: "In order to establish that the presence of this material is adventitious or technically unavoidable, operators must be in a position to supply evidence to satisfy the competent authorities that they have taken appropriate steps to avoid the presence of such material."[171] To comply with this requirement, FBOs must have detailed information at their disposal concerning the history of the raw materials they use. For example, research has shown that it takes a distance of 24.5 meters between a field of GM-maize and a field of non-GM-maize for the non-GM field to remain below the 0.9% threshold. Other products require even greater distances.[172] This example shows that the labeling standards require complete transparency of the production chain and strict segregation of

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"modified" refers to conventional techniques of modification and not to gene-technology. Consumers do not always understand this distinction. Parliament & Council Regulation (EC) No. 1829/2003, *supra* note 61, at art. 13.

169. Parliament & Council Regulation (EC) No. 1830/2003, *supra* note 132, at art. 4(6).

170. Parliament & Council Regulation (EC) No. 1829/2003, *supra* note 61, at art. 12(2). In case of a GMO that has not yet been authorised, a presence of point five percent maximum is considered not to constitute an infringement provided that this GMO has benefited from a favourable opinion from the Community Scientific Committee(s) or the European Food Safety Authority (EFSA) before the date of application of Council Regulation 1829/2003, art. 47.

171. Parliament & Council Regulation (EC) No. 1829/2003, *supra* note 61, at art. 12(3).

172. Coëxistentie gg-gewassen, conventionele en biologische gewassen, Verslag van een algemeen overleg, vastgesteld 19 januari 2004, kamerstukken II 2003-2004, 29 404, No. 2, at 8 (translated: "Coexistance GM-crops, minutes of the meeting of January 19, 2004") (Proceedings of the Dutch Parliament). On co-existence between conventional and GM crops, *see* the contribution of Margaret Rosso Grossman, this issue; *see also* Sara Poli, *Restrictions on the Cultivation of Genetically Modified Organisms: Issues of EC Law*, in THE REGULATORY CHALLENGE OF BIOTECHNOLOGY 156, 156-73 (Han Somsen, ed., 2007).

the whole GM food chain from the whole conventional food chain for producers on the non-GM side to meet these standards.

The labeling requirements do not apply to products that were in the process of manufacture before the date of application of Regulation 1829/2003. Such products must be labeled in accordance with the legislation applicable before that date. Greenpeace published labels of food products containing GM material on its website, which provides interesting examples of GM-labeling.[173]

VIII. SUPERVISION AND ENFORCEMENT

A. Monitoring

With the authorization, an obligation of post-market monitoring can be imposed upon the authorization-holder. The authorization-holder is obliged to report to the European Commission on monitoring activities; a public version of the monitoring reports must be made accessible to the public.[174] The authorization-holder also must inform the Commission of any new scientific or technical information that might influence the evaluation of the food's safe use.

B. Recall

If an FBO considers, or has reason to believe that, a food it has imported, produced, processed, manufactured or distributed, is not in compliance with the food safety requirements, then it assumes at least four duties.[175] First, there is the duty to immediately initiate procedures to withdraw the food in question from the market. Second, the operator must immediately inform the authorities both that it has reason to believe that an unsafe food has been placed on the market and communicate all actions then taken to deal with the problem. Third, in case the product may have already reached consumers, the operator shall effectively and accurately inform those consumers of the reason for its withdrawal and recall products already supplied when other measures are deemed insufficient to achieve a high level of health protection. Fourth, the FBO has a duty to collaborate with the competent authorities on actions taken to avoid or reduce risks posed by foods, which it supplied.

If the particular FBO has an adequate traceability system, all the information concerning which product to withdraw from which customer should be present in the system. However, it is not required that traceability systems encompass the consumer. Therefore, in most cases, the business

173. *See*, Greenpeace Genetic Engineering Campaign – Map, http://weblog.greenpeace.org/ge/map.html (last visited Mar. 10, 2007).

174. Parliament & Council Regulation (EC) No. 1829/2003, *supra* note 61, at art. 9(1).

175 Parliament & Council Regulation (EC) No. 178/2002, supra note 16, at art. 19.

operator will not have information on the identity of the concerned consumers in his possession. For this reason, recall-actions need to resort to publicity in the media.

The prior authorization of GM food requirement of is a food safety requirement. Accordingly, a GM food that has not yet been authorized falls within the ambit of Article 19 of the GFL. In 2006, unauthorized GM rice appeared on the market in the EU.[176] The manner in which this case has been handled shows that inspection agencies in at least some of the member states—particularly in the UK and the Netherlands—give little priority to enforcing this obligation to recall if no specific indication is available that the unauthorized product actually poses a risk.

C. Official Controls

As usual, responsibility for enforcement is on the member states.[177] They must ensure that inspections and other control measures—including sample checks and testing (both qualitative and quantitative)—are carried out, as appropriate, to ensure compliance.[178] Despite the general principle that the member states are responsible for enforcement, European food law increasingly sets standards for national enforcement and provides for supervision. Regulation 882/2004[179] is the basic text in this regard: member states must ensure that official controls are carried out regularly, with appropriate frequency, and on a risk basis. What frequency is appropriate depends, among other things, upon identified risks and past performance. Good past performance by a FBO may lead to a reduced frequency in inspections. FBOs are obliged to undergo any inspection and to assist the staff of the competent national authority in the accomplishment of their tasks.

D. Second Line Inspections

As discussed above, when the Food and Veterinary Office (FVO) was established in 1997, its two main tasks were to audit the performance of

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176. *See, e.g.,* European Food and Safety Authority, Rapid Alert System for Food and Need, 2006/42, 2006/46 http://ec.europa.eu/food/food/rapidalert/reports/week46-2006_en.pdf; http://ec.europa.eu/food/food/rapidalert/reports/week41-2006_en.pdf. Many other weekly overviews in 2006 provide examples of unauthorized GM foods as well.

177. The EU is a union of law only. No powers to exercise force have been transferred to it by the member States. There is no European army or police force. *See* EU at a Glance, http://europa.eu/abc/index_en.htm (last visited Mar. 25, 2007).

178. Parliament & Council Regulation (EC) No. 1830/2003, *supra* note 132, at art. 9(1); Parliament & Council Regulation (EC) No. 178/2002, *supra* note 16, at art. 17(2).

179. Parliament & Council Regulation (EC) No 882/2004, *supra* note 55; *see also* Parliament & Council Regulation (EC) No 854/2004, *supra* note 50. On the subject of enforcement of EU food law, *see* Marieke Lugt, *Enforcing European and National Food Law in the Netherlands and England*, (1999) (on file with the author); *see also* B.M.J. van der Meulen & Annelies A. Freriks, *Millefeuille: The Emergence of a Multi-Layered Controls System in the European Food Sector*, 2 Utrecht L. R.156 (2006), *available at* http://www.utrechtlawreview.org.

national agencies and to inspect the performance of industry and public authorities in third countries that wish to export food products to the EU.[180] Although the FVO is not mentioned by name, Regulation 882/2004 provides a basis for its activities. Article 45 reads in its first paragraph:

> Commission experts shall carry out general and specific audits in Member States. The Commission may appoint experts from Member States to assist its own experts. General and specific audits shall be organised in cooperation with Member States' competent authorities. Audits shall be carried out on a regular basis. Their main purpose shall be to verify that, overall, official controls take place in Member States in accordance with the multi-annual national control plans referred to in Article 41 and in compliance with Community law. For this purpose, and in order to facilitate the efficiency and effectiveness of the audits, the Commission may, in advance of carrying out such audits, request that the Member States provide, as soon as possible, up-to-date copies of national control plans.[181]

The member states must give all necessary assistance and provide all documentation that the Commission experts—the FVO—request.

E. Emergency Measures

Article 34 of Regulation 1829/2003 indicates that in cases where it is evident that authorized GM products are likely to constitute a serious risk to human health, animal health, or the environment, the Commission can take the measures provided for in Articles 53 and 54 of the GFL. Those measures are connected to the GFL's rapid alert system for feed and food.[182] This system foresees obligatory notification of any direct or indirect risk to human health, animal health or the environment within a network consisting of national competent authorities, the EFSA and the European Commission. The European Commission is entrusted with managing the system and ensuring immediate transmission of information to all contact points.

Participation in the rapid alert system is, in principle, open to candidate countries, third countries and international organizations, subject to negotiated agreements. EFSA's role is to supply scientific and technical information that will be helpful to member states in deciding follow-on steps. If an alert is given through the network, then authorities of the member states must take appropriate steps to inform the public when there are reasonable grounds to suspect a risk.

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180. EUROPEAN UNION, FOOD AND VETERINARY OFFICE – INTRODUCTION, http://ec.europa.eu/food/fvo/index_en.htm (last visited Mar. 25, 2007) (making inspection reports available to the general public).

181. Parliament & Council Regulation (EC) No 882/2004, *supra* note 55, at art. 45.

182. Parliament & Council Regulation (EC) No. 178/2002, *supra* note 16, at arts. 50-52. *See* Rapid Alert System for Food and Feed: Introduction, http://ec.europa.eu/food/food/rapidalert/index_en.htm (last visited Mar. 25, 2007).

The GFL confers special powers on the European Commission to take emergency measures where it is evident that feed or food originating in the EU, or imported from a third country into the EU, is likely to constitute a serious risk to human health, animal health or the environment, and that such a risk cannot be satisfactorily contained by measures taken by the member states. Such action can be initiated by the Commission itself or be requested by a member state. Depending upon the gravity of the situation, emergency measures can include appropriate interim measures restricting the products marketing or use or prescribe other special conditions, including the suspension of a feed or food from the market in the most serious cases.

IV. EXPERIENCE WITH THE FRAMEWORK

The new EU regulatory framework for GM food effectively ended the stalemate situation, labeled by some as a *de facto* moratorium on GM foods in the EU. Since its implementation, a steady flow of GM organisms have been approved for marketing in the EU.[183] Nevertheless, GM foods are only rarely found on the supermarket shelves. According to a Regulatory Impact Assessment carried out by the British Food Standards Agency,[184] the framework has little impact in practice. In response to continued consumer demand for non-GM ingredients, food manufacturers and retailers have continued to seek non-GM supplies and therefore have effectively bypassed the need to comply with the requirements of the regulations. Feed manufacturers, on the other hand, have chosen to label feed as containing GM ingredients, recognizing that certain components of feed are likely to be derived from GM crops. This expectation *ex ante* has been confirmed by the first evaluations executed by the Commission.[185]

The most important conclusion by the Commission seems to be that the difference in market penetration between GM food and feed shows that not the regulatory framework, but consumer preferences, are decisive:

Certain trading partners continue to allege that the Regulation

183. *See* European Union, Food and Feed Safety, *Community Register of GM Food and Feed*, http://ec.europa.eu/food/dyna/gm_register/index_en.cfm (last visited Mar. 25, 2007) (listing authorized products); European Food Safety Authority, *Applications under Regulation (EC) 1829/2003 on Genetically Modified Food and Feed* [GM Food Feed Applications], http://www.efsa.europa.eu/en/science/gmo/gm_ff_applications.html (last visited Mar. 25, 2007) (listing applications that are currently under procedure).

184. FOOD STANDARDS AGENCY, EU REGULATIONS ON GENETICALLY MODIFIED FOOD AND FEED ON TRACEABILITY AND LABELING OF GENETICALLY MODIFIED ORGANISMS, http://www.food.gov.uk/foodindustry/regulation/ria/ria2004/gmria (last visited Mar. 25, 2007).

185. *See* Report from the Commission to the Council and the European Parliament on the implementation of Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products from GM organisms and amending directive 2001/18/EC Brussels, COM (2006) 197 final (May 10, 2006); *see also* Report from the Commission to the Council and the European Parliament on the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council on GM food and feed, Brussels, COM (2006) 626 final (Oct. 25, 2006).

> introduces an excessive administrative burden. Imports of soybean and maize, including their derived products such as soy-meal or corn gluten feed do not appear to have been affected by the Regulation. In practice, consumer and market demand for foodstuffs in particular has certainly had a far greater effect than the provisions of the Regulation in terms of trade in products containing GM material.[186]

I had the pleasure to participate in a research commissioned by the European Commission on competitiveness of the EU food industry.[187] In this context, I conducted several interviews. On the one hand, these interviews show that demand in the EU (and Japan) for non-GM food resulted in price increases for conventional products. Some producers—some in the USA—bear the burden to segregate conventional production from GM production to be able to collect the bonus. Most producers[188] in the USA, however, seem to have given up on European consumers and are focusing on European cattle instead.

The interviews also show that some stakeholders question the hypothesis that *consumers* shy away from GM foods. A powerful supermarket chain presented seventy-three GM food products on their shelves next to conventional products. I have been told that sales were similar. Nevertheless the suppliers insisted on being allowed to deliver from conventional sources, as they did not want their name and reputation to be connected to GM.

Several interviewees expressed the opinion that the burden to acquire market authorization for GM food (and other novel foods) is such that the multi-nationals have a quasi-monopoly; small and medium sized enterprises in the EU feel barred from innovation through genetic modification and novel foods.

In September of 2006, the World Trade Organization (WTO) dispute settlement body ruled that the former policy in the EU on GM foods infringed on WTO law.[189] Some scholars experience this judgment as an infringement on democracy and the European way of life.[190] The majority of consumers, however, does not seem to have noticed; it has not been a big issue in the news. One likely reason is that the ruling relates to a policy that has already been changed. However, it is to be expected that some of the cornerstones of the new approach—traceability and labeling—will be contested next.

It is my personal belief that fundamental changes in the appreciation of

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186. COM (2006) 197 final, *supra* note 185, at 9.

187. COMPETITIVENESS IN THE EUROPEAN FOOD INDUSTRY: AN ECONOMIC AND LEGAL ASSESSMENT, (Jo Wijnands, Bernd van der Meulen, Krijn Poppe eds.), expected publication in late 2007.

188. This information comes from the few with whom we had spoken.

189. World Trade Organization, Reports on Biotech Disputes, http://www.wto.org/english/news_e/news06_e/291r_e.htm (last visited Mar. 24, 2007); *see also* David Wirth, *The Transatlantic GMO Dispute Against the European Communities: Some Preliminary Thoughts*, Boston College Law School Faculty Papers, (2006).

190. *See, e.g.*, Dario Bevilacqua, *The EC-Biotech Case: Global v. Domestic Procedural Rules in Risk Regulation*, 6 EUROPEAN FOOD AND FEED L. REV. 331 (2006).

GM foods in the EU will not be brought about by law, but perhaps by technology. It will take a new generation of GM foods that bring concrete and visible advantages not only to producers but also to consumers to create a market for GM food in the EU. Such new products will have to be marketed by businesses to consumers not viewed as pockets containing money, but instead as people about whom they genuinely care.

X. CONCLUSION

The new regulatory framework for GM foods in the EU sports all the elements that are typical for EU food safety law: pre-market approval requirements for new products, traceability requirements as preparation for dealing with safety issues, and labeling requirements to empower consumers to make informed choices.

The structure of EU food safety law in general—and the strict requirements on GM food in particular—can be understood as resulting from a traumatic history and a need for authorities to dissociate themselves from the market in order to restore their own credibility with consumers who have become very suspicious of the intentions of the different players in the food chain.

ANNEX

OVERVIEW OF RELEVANT LEGISLATION

The EU regulatory framework on GM food falls within the ambit of Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority, and laying down procedures in matters of food safety (2002 O.J. (L 31) 1), the so-called "General Food Law" or "GFL". The GFL gives the general definitions, principles, and procedures for food law and it institutes the European Food Safety Authority (EFSA). The GFL has been amended by Regulation 1642/2003 and Regulation 575/2006. A consolidated version is available on EurLex.[191]

The most important text surviving from the situation prior to 2004, is Directive 2001/18 on the deliberate release into the environment of genetically modified organisms (2001 O.J. (L 106) 1). It regulates experimental releases and the placing on the market of GMOs. This directive has been amended by Decision 2002/623; Regulation 1829/2003 and Regulation 1830/2003. A

191. EurLex is a web-based access service for some European Union law. http://europa.eu.int/eur-lex/.

consolidated version is available on EurLex.

The core of the regulatory framework is Regulation 1829/2003 on GM food and feed (2003 O.J. (L 268) 1). It regulates the placing on the market of food and feed products containing or consisting of GMOs and provides for the labeling of such products to the final consumer.

Regulation 1830/2003 on traceability and labeling of GMOs and the traceability of food and feed products from GMOs (2003 O.J. (L 268) 24) further elaborates the standards set in Regulation 1829/2003 on labeling and adds a specific regime on traceability for GMOs, departing from the general traceability regime in the GFL.

Commission Regulation 65/2004 establishes a system for the development and assignment of unique identifiers for GMOs (2004 O.J. (L 10) 5). This system is used in the traceability regime introduced in Regulation 1830/2003.

Commission Regulation 641/2004 (2004 O.J. (L 102) 14) on the detailed rules for the implementation of Regulation 1829/2003, elaborates the authorization procedure.

For the sake of completeness, one more directive, one more regulation and one recommendation must be mentioned because they are relevant to GMOs, but fall outside the scope of this article. Directive 90/219/EEC, as amended by Directive 98/81/EC, on the contained use of genetically modified micro-organisms (GMMs), regulates research and industrial work activities involving GMMs (such as genetically modified viruses or bacteria) under conditions of containment, that is, in a closed environment in which contact with the population and the environment is avoided, to include work activities in laboratories. Regulation 1946/2003 on transboundary movements of genetically modified organisms, implements the Cartagena Protocol on Biosafety.

Commission Recommendation C (2003) 2624 (2003 O.J. (L 189) 36) on guidelines for national strategies and best practices to ensure coexistence provides Member States with policy options to protect conventional agriculture from GM admixture.

ENTRY INTO FORCE

Regulation 1829/2003 and Regulation 1830/2003 were both published in the Official Journal on October 18, 2003. They entered into force on the twentieth day following its publication (Article 49 Regulation 1829/2003 and Article 13 Regulation 1830/2003). Regulation 1829/2003, the core of the new framework, applies from six months after the date of publication. For this reason, April 18, 2004 is the starting point of the new regime.