Restrictions on Genetically Modified Organisms

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Contents

Argentina

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SUMMARY Argentina is the third largest grower of biotech crops in the world, after the United States and Brazil. GMOs are regulated in Argentina under the Law on Seeds and Phytogenetic Creations and the Law on the Promotion of the Development and Production of Modern Biotechnology, and under administrative regulations issued by the Secretary of Agriculture, Livestock, Fisheries and Food. Argentina has not ratified the Cartagena Protocol on Biosafety.

I. Introduction

Argentina was among the first countries in the world to use genetically modified (GM) crops in agriculture,[1] using GM technologies in the production of soybeans, corn, and cotton. Argentina first started using GM technologies in 1996 with the introduction of soybeans tolerant of the herbicide glyphosate.[2] Since then, Argentina has increased its production of GM crops to become the third largest grower of biotech crops in the world, after the United States and Brazil.[3]

GM technologies applied in agriculture have resulted in economic benefits for Argentina, a commodities exporting country, of about US$72.6 billion through 2011. The introduction of GM technologies in agriculture in Argentina has resulted in the creation of an estimated 1.8 million jobs through 2011.[4]

Of the US$72.6 billion in economic benefit, $65.4 billion is attributable to herbicide-tolerant soybeans. Regarding the distribution of economic benefits from cultivating such soybeans, 72.4% went to farmers, 21.2% to the national government in the form of export taxes and other duties, and the remaining 6.4% to seed and herbicide suppliers.[5]

[1] Rosario Silva Gilli, *Genetically Modified Organisms in Mercosur, in* THE REGULATION OF GENETICALLY MODIFIED ORGANISMS: COMPARATIVE APPROACHES 274, 281 (Luc Bodiguel & Michael Cardwell eds., 2010).

[2] Eduardo J. Trigo, *Fifteen Years of Genetically Modified Crops in Argentine Agriculture* 4 (Consejo Argentino para la Información y el Desarrollo de la Biotecnología, Nov. 2011), http://www.argenbio.org/adc/uploads/15_years_Executive_summary_of_GM_crops_in_Argentina.pdf.

[3] Moises Burachik, *Regulation of GM Crops in Argentina*, 3 GM CROPS & FOOD: BIOTECHNOLOGY AGRIC. & FOOD CHAIN 48 (2012), https://www.landesbioscience.com/journals/gmcrops/2011GMC0034R.pdf.

[4] Trigo, *supra* note 2, at 4.

[5] *Id.*

II. Public and Scholarly Opinion

In general, basic knowledge of the use of biotechnology in agriculture and food is limited.[6] In a 2004 survey, only 39% of the polled population knew that Argentina produced GM soybeans. In the same poll, 51% said they prefer to consume non-GM food, even if it costs more.[7] Only 12% said they believe GM crops benefit the population, while 51% said they believe big corporations, especially foreign ones, are the main beneficiaries.[8]

There have been recent demonstrations against the US company Monsanto in Malvinas, in the Province of Córdoba, near the main entrance of a new seed plant currently under construction.[9] Monsanto is planning to start construction of 240 silos for the storage of GMO corn that is chemically treated. These silos have shafts that need ventilation through fans. The population living close to the future plant opposes the exposure to the chemical dust that those fans would spread throughout the area. Monsanto has been blamed for damage to the health of persons allegedly caused by long-term exposure to the company's Roundup herbicide.[10]

Epidemiological surveys were conducted in 2001–2002 in areas treated with Roundup. Results of those surveys revealed rates of birth defects and malformations in children, cancer, and miscarriages one hundred times higher than the national average, coinciding with the increase of GM soy cultivation and herbicide spraying near populated areas.[11]

III. Structure of Pertinent Legislation

GMOs are regulated in Argentina under the general Law on Seeds and Phytogenetic Creations (Ley de Semillas y Creaciones Fitogéneticas, LS)[12] and the Law on the Promotion of the Development and Production of Modern Biotechnology (Ley de Promoción del Desarrollo y Producción de la Biotecnología Moderna, LB).[13]

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[6] ALICIA DIAMANTE & JUAN IZQUIERDO, MANEJO Y GESTIÓN DE LA BIOTECNOLOGÍA AGRÍCOLA APROPIADA PARA PEQUEÑOS PRODUCTORES: ESTUDIO DE CASO ARGENTINA 59 (Apr. 2004), http://www.argenbio.org/adc/uploads/pdf/manejo_y_gestion.doc.

[7] *Id.* at 60–61.

[8] *Id.*

[9] *Liberaron a los Ambientalistas y Monsanto Suspende la Obra*, LA VOZ (Sept. 30, 2013), http://www.lavoz.com.ar/politica/liberaron-las-ambientalistas-y-monsanto-suspende-la-obra.

[10] *Blockade Against Monsanto in Malvinas Argentinas*, REVOLUTION NEWS (Oct. 15, 2013), http://revolution-news.com/blockade-against-monsanto-in-malvinas-argentina/.

[11] *Id.*

[12] Ley de Semillas y Creaciones Fitogéneticas [L.S.] [Law on Seeds and Phytogenetic Creations], Ley 20247, BOLETIN OFICIAL [B.O.], Mar. 30, 1973, http://www.infoleg.gob.ar/infolegInternet/anexos/30000-34999/34822/texact.htm.

[13] Ley de Promoción del Desarrollo y Producción de la Biotecnología Moderna [L.B.] [Law on the Promotion of the Development and Production of Modern Biotechnology], Ley 20270, B.O., July 25, 2007, http://www.infoleg.gob.ar/infolegInternet/anexos/130000-134999/130522/norma.htm.

The LS is intended to promote the efficient production and marketing of crops by providing farmers with assurances as to the identity and quality of seeds that they acquire while protecting the property of phytogenetic innovations.[14] It provides a definition of seeds that is broad enough to include transgenic crops, since it includes all vegetable matter susceptible to sowing or propagation.[15]

The LS sets forth a general legal framework for the commercialization of crops, including their import and export,[16] as well as seed classification and registration requirements and procedures.[17] It established the National Commission on Seeds within the Ministry of Agriculture and Cattle as the enforcement authority empowered to determine which species will be subject to control and registration under the law.[18] It also provided for the establishment of the National Registry of Cultivars, in which seeds that are open to the public or offered to consumers in any way are identified.[19]

Regarding GM seeds, Resolution 46/2004 on Genetically Modified Plant Organisms (Resolución 46/2004 de Organismos Vegetales Geneticamente Modificandos)[20] requires an additional registration in a specific National Registry of Operators of Genetically Modified Plant Organisms by all those who conduct experiments, import or export, produce or reproduce, or carry out any activity related to GM plants that have not been approved for commercialization in Argentina.[21] Registration is a prerequisite to request authorization for the release of genetically modified organisms (GMOs) for purposes of testing.[22] Registration is also required to obtain authorization for import or export of GM plants.[23]

The LB is intended to promote the development and production of modern biotechnology by granting tax incentives to qualifying research and production projects that meet safety and health standards.[24]

Argentina signed the Cartagena Protocol on Biosafety[25] in 2000, but has not yet ratified it.[26] The Protocol, which regulates transboundary movements of GMOs, adopts the "precautionary

[14] L.S. art. 1.

[15] *Id*. art. 2.

[16] *Id*. arts. 11–15.

[17] *Id*. arts. 16–30.

[18] *Id*. art. 7.

[19] *Id*. arts. 9, 16–18.

[20] Resolución 46/2004 de Organismos Vegetales Geneticamente Modificandos, Jan. 28, 2004, http://www.infoleg.gob.ar/infolegInternet/verNorma.do;jsessionid=578413824CD6FF46DB9979BD5F4EDD86?id=92241.

[21] *Id*. art. 1.

[22] *Id.* art. 3.

[23] *Id*. art. 4.

[24] L.B. arts. 6, 7, 13, 14.

[25] Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Jan. 29, 2000, 39 I.L.M. 1027, *available at* http://bch.cbd.int/protocol/text/.

principle," which entitles the member parties to restrict or prohibit the import of GMOs if there is no sufficient or conclusive information as to its safety.[27] Major world producers of GMOs such as the US, Canada, and Argentina have not ratified it, however, largely due to concerns that the restrictions that it would impose on the free trade of GMOs would be detrimental to their agricultural exports.[28]

IV. Restrictions on Research, Production, and Marketing

A. Responsible Agencies

The Secretary of Agriculture, Livestock, Fisheries and Food (Secretaría de Agricultura, Gandería, Pesca y Alimentación, SAGPA) is in charge of granting permits for the release and commercialization of GMOs. Its permitting decisions are undertaken with the assistance of expert advisory commissions.[29] The review process for granting such permits involves

(1) an assessment to verify that biosafety standards are met with regard to the agricultural ecosystem, with respect to both experiments on GMOs in greenhouses and their release into the environment;

(2) a review of their safety as food additives or ingredients; and

(3) an evaluation of the impact that their commercialization would have on Argentina's international trade. [30]

The first two steps, the environmental and food safety assessments, are based exclusively on scientific data and conducted by expert commissions composed of representatives of both the public and private sectors. The evaluation of environmental safety is assigned to the Biotechnology Directorate (BD) and food safety review is carried out by the National Service on Agricultural Food Health and Quality (Servicio Nacional de Sanidad y Calidad Agroalimentaria, SENASA). The assessment of the impact of the GMO on international commerce is assigned to the Agriculture Market Directorate (AMD), which evaluates whether authorizing commercialization is compatible with the standards of Argentina's trade partners. This is critical because agricultural commodities are Argentina's main exports.[31] In many cases, GMOs that

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[26] MARÍA CRISTINA RODRÍGUEZ, MODERNA BIOTECNOLOGÍA AGRÍCOLA: NORMATIVA Y JURISPRUDENCIA NACIONAL, COMUNITARIA E INTERNACIONAL 21 (2009), bibliographic information available at http://lccn.loc.gov/2010503912.

[27] *Biosafety Protocol*, GREENPEACE, http://www.greenpeace.org/international/en/campaigns/agriculture/solution-ecological-farming/biosafety-protocol/ (last visited Dec. 2, 2013).

[28] *See Posición de ASA con respect a la ratificación del Protocolo de Cartagena sobre Bioseguridad*, ASOCIACIÓN SEMILLEROS ARGENTINOS (July 2006), http://www.asa.org.ar/pdf/posicion_protocolo_06.pdf.

[29] Decreto 1366/2009, B.O., Oct. 2, 2009, Anexo art. 4.20, http://www.infoleg.gob.ar/infolegInternet/anexos/155000-159999/158298/texact.htm.

[30] Moisés Burachik, *Organismos Geneticamente Modificados: Marco Regulatorio en Argentina*, Conferencia Ministerial sobre el Uso de la Ciencia y la Tecnologia para Mejorar la Competitividad en el Sector Agrícola (May 2004), http://www.fas.usda.gov/icd/stconf/event5/MBurachik.pdf.

[31] *Id.*; Burachik, *supra* note 3, at 48–49.

have been proved safe for the agricultural ecosystem and approved for use in the raw components for food are still not permitted to be commercialized until approval is received from the importing country's authorities.[32]

A Biotechnology Office has been created to coordinate seed registration and control and to participate in international negotiations in biotechnology matters. This office has the authority to decide on biosecurity issues, to design and implement guidelines and administrative procedures, and to set biotechnology and agricultural policies.[33]

V. Restrictions on Releasing Organisms into the Environment

Subject to regulatory approval, Argentina allows GMOs to be released into the environment, under either confined or unconfined circumstances. Regulatory approval may be obtained for confined releases in three situations: (1) cultivation in greenhouses, (2) field trials, and (3) production of regulated seeds.[34] Permission for unconfined planting of GM crops is granted only after a comprehensive study assessing whether free planting of the crop would be safe for the agricultural ecosystem.[35]

Regulatory approval requires the applicant to provide pertinent technical information on the crop that is analyzed by the National Advisory Commission on Agricultural Biotechnology (Comisión Nacional Asesora de Biotecnología Agropecuaria, CONABIA). The approval process includes an evaluation of the risks that a GM crop would pose to the agricultural ecosystem.[36]

Authorizations are subject to specific conditions, including appropriate environmental risk management and risk mitigation measures, isolation distances, the availability of specific detection methods, and restrictions on the use of both the harvested material and the field plot in future seasons.[37] Production of regulated seed is permitted only under stringent isolation and seed processing conditions designed to prevent the regulated material from entering the commercial chain.[38]

VI. Restrictions on GMOs in Foodstuffs

SENASA has the authority to evaluate the risks to human and animal health of food derived from GMOs.[39] The risk evaluation includes an assessment of whether such food is harmful, its

[32] Burachik, *supra* note 31.

[33] *Id.*

[34] Burachik, *supra* note 3, at 49.

[35] *Id.*

[36] *Id.*

[37] *Id.*

[38] *Id.*

[39] Resolución 412/2002, sobre Alimentos derivados de Organismos Geneticamente Modificados [On Food Derived from GMOs], B.O., May 17, 2002, http://www.infoleg.gob.ar/infolegInternet/anexos/70000-74999/74376/norma.htm.

nutritional characteristics, and a comparison between the GM-derived food and its conventional counterpart. For a GM-derived food to be approved, it must be as safe and nutritious as conventional food already in the market. As new scientific and technical information becomes available, the food's risk assessment is reevaluated accordingly.[40]

Detailed requirements, forms, and procedures that need to be submitted for approval of GM-derived food are included in Annexes II and III of Resolution 412/2002.[41]

Labelling of food containing GMO material is not required, although several bills requiring the labelling of food with GMO elements for human or animal consumption have been submitted and are pending congressional debate.[42]

The labeling of food and agricultural products with GMOs being imported in the European Union from Argentina and the US, among other countries, was the subject of consultation and a trade dispute before the World Trade Organization in 2003. The exporting countries maintained that the EU required labeling of such imports constituted an undue restriction of agricultural product restrictions.[43]

VII. Liability Regime

Liability for damage to the environment in Argentina is provided for in the General Law on the Environment (Ley General del Ambiente, LGA),[44] which defines environmental damage as any relevant alteration that negatively modifies the environment, its resources, the balance of ecosystems, or collective values or assets.[45]

The LGA establishes a general principle of civil liability that anyone who causes current or future degrading effects to the environment is responsible for the costs of preventive and corrective actions, regardless of other environmental liabilities that may arise.[46] Whoever causes environmental damage is subject to strict liability to restore the environment to its prior condition before the damage occurred.[47] An allegedly responsible party may be exonerated from liability

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[40] RODRIGUEZ, *supra* note 26, at 190.

[41] Resolución 412/2002, *supra* note 39.

[42] *See, e.g.*, Information al Consumidor sobre Etiquetado de Alimentos y Bebidas Transgenicos o que Contengan Organismos Geneticamente Modificados, Proyecto de Ley 2324-D-2013 (2013), HONORABLE CÁMARA DE DIPUTADOS DE LA NACIÓN, http://www1.hcdn.gov.ar/proyxml/ expediente.asp?fundamentos=si&numexp=2324-D-2013, *and* Proyecto de Ley D 8307-D-2010, http://www.diputados.gov.ar/frames.jsp?mActivo=proyectos&p= http://www1.hcdn.gov.ar/proyectos_ search/bp.asp.

[43] Dispute Settlement: Dispute DS291: *European Communities – Measures Affecting the Approval and Marketing of Biotech Products* (Feb. 2010), http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds291_e.htm.

[44] Ley 25675, B.O., Nov. 28, 2002, http://www.infoleg.gob.ar/infolegInternet/anexos/75000-79999/79980/ norma.htm.

[45] *Id*. art. 27.

[46] *Id.* art. 4, ¶ 6.

[47] *Id.* art. 28.

only by proving that all measures aimed at preventing the damage were taken and the damage was caused exclusively by the victim or a third party.[48]

VIII. Prominent Judicial Decisions

On September 4, 2012, a Criminal Court of Appeals of the Córdoba Province rendered a decision convicting a farmer and a crop-spraying pilot for spraying agrochemicals in the suburbs of the provincial capital neighborhood. It appears that the herbicides were applied to a GM soy variety. During the criminal proceeding, it was proved that 114 out of 142 children in the same neighborhood had agrochemicals in their blood. The medical expert in the case testified that he had found children in the area with more than five herbicides and insecticides in their blood. This is an unprecedented decision, since it is the first case in which pollution and harm to public health is treated as a crime and prosecuted in a Criminal court, under the Law 24051 on Hazardous Products[49], which punishes offenders with between five and ten years in prison for polluting soil, water, air, or the environment in a manner that is harmful to health. The ruling points specifically to two agrochemicals: endosulfan and glyphosate.[50] This case may highlight the popular concern about the increased use of herbicides on herbicide-resistant GM crops.

[48] *Id*. art. 29.

[49] Ley 24051de Residuos Peligrosos [on Hazardous Products] B.O. Jan. 17, 1992, arts. 55–58, http://www.infoleg.gob.ar/infolegInternet/anexos/0-4999/450/norma.htm.

[50] Dario Aranda, *Trial Against Use of Agrochemicals in Ituzaingó (Argentina): Spraying is a Crime*, JUICIO A LA FUMIGACIÓN (Sept. 6, 2012), http://www.juicioalafumigacion.com.ar/trial-against-use-of-agrochemicals-in-ituzaingo-argentina-spraying-is-a-crime/.

Belgium

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SUMMARY Belgium is considered to have an intermediate level of restrictions on GMOs, although public opinion tends to generally be hostile to GMOs. Most of Belgium's regulation of GMOs is directly or indirectly derived from European regulations. The fact that Belgium is a federal state has an important impact on the regulatory environment of GMOs, and the applicable rules can exist either at the federal or at the regional level, depending on the specific issue. Overall, regulation of GMOs in Belgium is mostly focused on authorization requirements prior to their production, use, or distribution; on mandatory technical requirements to limit the potential release of GMOs into non-GMO fields; and on information and transparency measures.

I. Introduction

Belgium has been a pioneer in the biotechnology sector, and two Belgian researchers, together with an American scientist, created the first genetically modified plant in 1983.[1] Several Belgian universities are still very active in GMO research.[2] Nonetheless, the use of genetically modified organisms (GMOs) is quite controversial in Belgium. Perhaps because of this dichotomy between an active GMO research agenda and a generally-hostile public opinion, Belgium is considered to have an "intermediate" policy on this topic: less permissive than countries such as the United States, and less restrictive than countries such as Germany.[3]

II. Public and Scholarly Opinion

GMOs are quite controversial in Belgium. A number of consumer rights organizations and environmental groups have voiced their opposition to GMOs, which has led to general concern over the potential risks of GMOs on the part of consumers.[4] A European Union public opinion study from 2007 found that only 22% of Belgians polled were in favor of GMOs, and 55% were against.[5]

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[1] Frédéric Varone & Nathalie Schiffino, *Conflict and Consensus in Belgian Biopolicies: GMO Controversy Versus Biomedical Self-regulation*, *in* THE POLITICS OF BIOTECHNOLOGY IN NORTH AMERICA AND EUROPE 198 (Eric Montpetit, Christine Rothmayr & Frédéric Varone eds., 2007).

[2] *Id.*

[3] *Id.* at 200.

[4] Nathalie Schiffino & Frédéric Varone, *La régulation politique des OGM*, COURRIER HEBDOMADAIRE DU CRISP, 2005/35 N° 1900 (2005), 16.

[5] EUROPEAN COMMISSION DIRECTORATE-GENERAL FOR COMMUNICATION, SPECIAL EUROBAROMETER 295: ATTITUDES OF EUROPEAN CITIZENS TOWARDS THE ENVIRONMENT 65 (Publications Office of the European Union, Mar. 2008), http://ec.europa.eu/public_opinion/archives/ebs/ebs_295_en.pdf.

This placed Belgium near the average for the EU as a whole (in the same study, 21% of EU citizens polled were in favor of GMOs, and 58% were against). Although this and other studies[6] show strong opposition to GMOs in Belgium, this hostility is not quite as strong as it is in some other European countries such as France or Germany.[7] It should also be noted that there seems to be a difference of opinion between the northern and the southern parts of Belgium. Indeed, there is more support for GMOs in Flanders than in Wallonia and Brussels.[8]

III. Structure of Pertinent Legislation

A. EU Regulations

As Belgium is a member of the European Union, its laws and regulations are subordinate to EU regulations regarding consumer and environmental protection.[9] These are issues of shared competence between the EU and Member States, which means that the Belgian government may enact and implement its own laws and regulations at the national level, as long as this does not conflict with EU-level regulations.[10] The main European texts regarding GMOs are Regulation (EC) 1829/2003 of the European Parliament and of the Council on genetically modified food and feed,[11] and Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms.[12] The first, being an EU regulation, automatically became applicable law in the Member States on the date it was published in the European official gazette. The second, being an EU directive, was not automatically and directly applicable, and each Member State is required to transpose the Directive's provisions into its law by passing appropriate legislation at the national level.

B. Domestic Provisions

The main piece of national legislation regarding GMOs in Belgium is a Royal Decree from 2005, which essentially transposed the rules set out in Directive 2001/18/EC of the European

[6] *See also* EUROPEAN COMMISSION DIRECTORATE-GENERAL FOR RESEARCH, EUROPEANS AND BIOTECHNOLOGY IN 2010: WINDS OF CHANGE? 40 (Office for Official Publications of the European Communities, Oct. 2010), http://ec.europa.eu/public_opinion/archives/ebs/ebs_341_winds_en.pdf

[7] SPECIAL EUROBAROMETER 295, *supra* note 5.

[8] Schiffino & Varone, *supra* note 4, at 11.

[9] Consolidated Version of the Treaty on the Functioning of the European Union, arts. 2 & 4, 2012 O.J. (C 326) 50–51, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12012E/TXT:EN:PDF.

[10] *Id.* art. 2.

[11] Regulation (EC) 1829/2003 of the European Parliament and of the Council of 22 September 2003 on Genetically Modified Food and Feed, 2003 O.J. (L 268) 1, http://ec.europa.eu/food/food/animalnutrition/labelling/Reg_1829_2003_en.pdf.

[12] 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, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:106:0001:0038:EN:PDF.

Parliament and of the Council on the deliberate release into the environment of genetically modified organisms.[13]

At the national level, the Belgian federal government (particularly the Ministries for the Environment and for Public Health) is the principal authority with regard to regulating GMOs.[14] Given that Belgium is a federal state, however, the regional authorities of Belgium play a relatively strong role in the regulation of GMOs, mainly within the framework of a 1997 cooperation agreement between the federal government and the regions with regard to administrative and scientific coordination for biosecurity issues.[15]

C. Definition of GMO

The Royal Decree of February 21, 2005, defined a GMO in exactly identical terms as Directive 2001/18/EC of the European Parliament and of the Council: "an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination" ("*Un organisme, à l'exception des êtres humains, dont le matériel génétique a été modifié d'une manière qui ne s'effectue pas naturellement par multiplication et/ou par recombinaison naturelle*").[16]

IV. Restrictions on Research, Production, and Marketing

Belgian law on the research, production, and marketing of GMOs is fractured. As can be seen in the discussion below, certain rules come from the federal level and apply equally over the whole country, but much regulation is done at the regional level.

A. Use of GMOs in Confined Environments

The use of GMOs in confined environments (laboratories) falls under the authority of the regions. All three regions of Belgium (Wallonia, Flanders, and Brussels-Capital) have enacted legislation transposing European norms[17] into their respective regional laws.[18] All three regions

[13] Arrêté royal du 21 février 2005 réglementant la dissémination volontaire dans l'environnement ainsi que la mise sur le marché d'organismes génétiquement modifiés ou de produits en contenant [Royal Executive Order of February 21, 2005, Regulating the Voluntary Release into the Environment as well as the Marketing of Genetically Modified Organisms or Products Containing Genetically Modified Organisms] (Feb. 21, 2005), MONITEUR BELGE [M.B.], Feb. 24, 2005, 7,129; Schiffino & Varone, *supra* note 4, at 5.

[14] Schiffino & Varone, *supra* note 4, at 29.

[15] Accord de coopération entre l'Etat fédéral et les Régions relatif à la coordination administrative et scientifique en matière de biosécurité [Agreement for Cooperation Between the Federal State and the Regions Regarding Administrative and Scientific Coordination for Biosecurity Issues] (Apr. 25, 1997), confirmed by the Loi portant assentiment à l'accord de coopération entre l'Etat fédéral et les Régions relatif à la coordination administrative et scientifique en matière de biosécurité [Law Approving the Agreement for Cooperation Between the Federal State and the Regions Regarding Administrative and Scientific Coordination for Biosecurity Issues] (Mar. 3, 1998), M.B., July 14, 1998, 22,773 .

[16] Royal Executive Order of Feb. 21, 2005, art. 2(2); Directive 2001/18/EC, *supra* note 12.

[17] Council Directive 98/81/EC of 26 October 1998 on the Contained Use of Genetically Modified Micro-organisms, 1998 O.J. (L 330) 13, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1998:330:0013:0031:EN:PDF.

require prior authorization for the use of GMOs in confined environments, and such authorization is based on assessments of risks and how such risks may be mitigated.[19]

B. Deliberate Release of GMOs in Open Environments for Research Purposes

The deliberate release of GMOs in open environments for research purposes is subject to governmental authorization as described in the Royal Decree of February 21, 2005.[20] A person or organization wishing to release GMOs for purposes other than commercialization must submit an application to the Federal Public Service (FPS) for Public Health, Food Chain Safety and Environment, which must evaluate the application's admissibility in coordination with the Biosecurity and Biotechnology Service (BBS).[21] If the application is admissible, the file is sent to the regional ministers that may be concerned, and to the Biosecurity Counsel, which is supposed to give its opinion on the matter.[22] The general public is informed of the application, and its opinion is solicited, through a website.[23]

Once it has reached a decision, the FPS for Public Health, Food Chain Safety and Environment sends it, along with the opinion of the Biosecurity Counsel and the information provided to the public, to the ministers in charge of public health and the environment.[24] These ministers may then approve or reject the application.[25] If any event or new information comes to light that would change the facts upon which an approval was based, the relevant ministers must be informed of it, and they may suspend or revoke their authorization if need be.[26]

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[18] For Wallonia, see Arrêté du Gouvernement wallon déterminant les conditions sectorielles relatives aux utilisations confinées d'organismes génétiquement modifiés ou pathogènes [Executive Decision of the Walloon Government Establishing the Sector-specific Conditions for the Contained Use of Genetically Modified Organisms or Pathogenes] (July 4, 2002), M.B., Sept. 21, 2002, 41,711; for Flanders, see Besluit van de Vlaamse Executieve houdende vaststelling van het Vlaams reglement betreffende de milieuvergunning [Executive Decision of the Flemish Government Establishing the Regulations Regarding Environmental Authorizations] (Feb. 6, 1991), M.B., June 26, 1991, 14,343; for Brussels-Capital, see Arrêté du Gouvernement de la Région de Bruxelles-Capitale relatif à l'utilisation confinée d'organismes génétiquement modifiés et/ou pathogènes et au classement des installations concernées [Executive Decision of the Government of the Brussels-Capital Region Regarding the Contained Use of Genetically Modified Organisms and/or Pathogenes and the Classification of Related Installations] (Nov. 8, 2001), M.B., Feb. 26, 2002, 7,209.

[19] *Id.* (Wallonia, Flanders, and Brussel-Capital Region Executive Decisions).

[20] Royal Executive Order of Feb. 21, 2005, art. 3.

[21] *Id.* art. 15.

[22] *Id.* arts. 15 & 16.

[23] *Id.* art. 17.

[24] *Id.* art. 18.

[25] *Id*.

[26] *Id*. art. 20.

C. Distribution and Release of GMOs for Commercial Purposes

The use or commercial distribution of GMOs or products containing GMOs is subject to governmental authorization as described in the Royal Decree of February 21, 2005.[27] Alternatively, a GMO (or a product containing GMOs) can legally be used or commercially distributed in Belgium if it has another EU Member State's written authorization for the same purposes.[28]

In a procedure generally similar to what is required for the release of GMOs for research purposes (see above), the application to use or market GMOs first goes to the FPS for Public Health, Food Chain Safety and Environment, which evaluates the application's admissibility in cooperation with the BBS, and then sends the file to the competent federal and regional ministers and to the Biosecurity Counsel.[29] The general public is also informed and consulted via a website.[30] The European Commission and other EU member states are informed as well,[31] and they have sixty days from the date of their receipt of the file to voice any objections to the possible authorization of that GMO.[32] Any authorization is subject to periodic renewal,[33] and the authorization may be changed or revoked if new information comes to light that justifies it.[34]

D. Transparency Rules for GM Crops

The Flemish government requires anyone intending to plant GM crops to give official notice to the regional authorities,[35] and also to notify other farmers whose lands are situated within a certain distance from the proposed GM crops.[36] The appropriate governmental authorities are to maintain an online register listing certain information regarding fields of GM crops.[37] Some of the information on this register is made available to the public, including the size of each field, the type of crop grown on it, and the township in which it is located.[38] Some of the more specific

[27] *Id.* art. 4.

[28] *Id.*

[29] *Id.* arts. 6§2, 30 & 31.

[30] *Id.* art. 32.

[31] *Id.* art. 6§2.

[32] *Id*. art. 34§3.

[33] *Id*. art. 36.

[34] *Id*. art. 39.

[35] Besluit van de Vlaamse Regering houdende de vaststelling van algemene maatregelen voor de co-existentie van genetisch gemodificeerde gewassen met conventionele gewassen en biologische gewassen [Executive Order of the Flemish Government Establishing General Measures for the Coexistence of Genetically Modified Crops and Conventional and Organic Crops] (Oct. 15, 2010), art. 3, M.B., Nov. 30, 2010, 73,420.

[36] Flemish Executive Order of Oct. 15, 2010, for the Coexistence of Crops, art. 4; Decreet houdende de organisatie van co-existentie van genetisch gemodificeerde gewassen met conventionele gewassen en biologische gewassen [Decree Organizing the Coexistence of Genetically Modified Cultures and Conventional and Organic Cultures] (Apr. 3, 2009), art. 5, M.B., May 4, 2009, 34, 847.

[37] Decree of Apr. 3, 2009, art. 11.

[38] Flemish Executive Order of Oct. 15, 2010, for the Coexistence of Crops, art. 17.

information, however, such as the name and address of the GM-growing farmer, the exact location of the field, and the precise variety of GMO planted in it, is only made available to certain official bodies and not to the general public.[39]

The Walloon government also requires any farmer wishing to plant GM crops to give official notice to the regional authorities,[40] and to notify other nearby farmers as well as any other farmers who might use the same equipment as the GM farmer.[41] The Walloon authorities may allow the public to have access to certain information regarding GM crops, and contrary to what is the case in Flanders, they can make public the GM farmer's name and business address, as well as the GM field's precise location and time of cultivation.[42]

No analogous regulation seems to exist in the Brussels-Capital region, but this is probably because Brussels-Capital is primarily an urban area, where such rules would have little relevance.

V. Restrictions on Releasing Organisms into the Environment

Rules intended to prevent or limit the release of GMOs into the environment are primarily within the domain of regional authorities. Flanders requires that farmers intending to plant GMOs follow a training course to ensure that they know the best practices to prevent the accidental release of GMOs into the environment.[43] The Flemish government also requires that GM crops be separated from other crops. The specific separation distance differs according to the crops in question: for example, the buffer zone for GM maize must be at least fifty meters,[44] while the minimum buffer zone for sugar beets is only five meters.[45]

Wallonia also mandates that there be a separation zone between GMOs and other crops.[46] It seems that, as of yet, only the separation zone for GM maize has been specifically defined: the

[39] *Id.*

[40] Décret relatif à la coexistence des cultures génétiquement modifiées avec les cultures conventionnelles et les cultures biologiques [Decree on the Coexistence of Genetically Modified Crops and Conventional and Organic Crops] (June 19, 2008), art. 4, M.B., Aug. 8, 2008, 41,481.

[41] *Id.* art. 5.

[42] *Id.* art. 13.

[43] Flemish Executive Order of Oct. 15, 2010, for the Coexistence of Crops, art. 2.

[44] Besluit van de Vlaamse Regering houdende de vaststelling van specifieke maatregelen voor de co-existentie van genetisch gemodificeerde maïsgewassen met conventionele maïsgewassen en biologische maïsgewassen [Executive Order of the Flemish Government Establishing Specific Measures for the Coexistence of Genetically Modified Maize and Conventional and Organic Maize] (Oct. 15, 2010), art. 5, M.B., Nov. 30, 2010, 73,435.

[45] Besluit van de Vlaamse Regering houdende de vaststelling van specifieke maatregelen voor de co-existentie van genetisch gemodificeerde suikerbieten met conventionele suikerbieten en biologische suikerbieten [Executive Order of the Flemish Government Establishing Specific Measures for the Coexistence of Crops of Genetically Modified Sugar Beets and Conventional and Organic Sugar Beets] (Nov. 10, 2011), art. 5, M.B., Dec. 23, 2012, 80,271.

[46] Décret relatif à la coexistence des cultures génétiquement modifiées avec les cultures conventionnelles et les cultures biologiques [Decree on the Coexistence of Genetically Modified Crops and Conventional and Organic Crops] (June 19, 2008), M.B., Aug. 8, 2008, 41,481.

buffer zone must be at least 600 meters if the field does not have a band of non-GM crops at its edges, or it can be of 300 meters if there is a band of non-GM maize around the edges (the non-GM band must be at least six rows wide).[47] Wallonia also mandates certain specific procedures and practices with regard to the seeding of GM crops; their harvest, transportation, and storage; and the handling, cleaning, and maintenance of equipment used for their cultivation.[48]

As with the transparency rules for GM crops discussed in Part IV(D), no analogous regulations seem to exist in the Brussels-Capital region. As mentioned earlier, this is probably because Brussels-Capital is mostly an urban area, where such rules would have little relevance.

VI. Restrictions on GMOs in Foodstuffs

The sale of GMOs is authorized at the European level in accordance with Regulation (EC) 1829/2003 of the European Parliament and of the Council with regard to food for human or animal consumption.[49] Furthermore, the use of GMOs for commercial purposes is subject to authorization under the Royal Decree of February 21, 2005, as described above.[50]

Additionally, rules on traceability and labeling are established through Regulation (EC) 1830/2003 of the European Parliament and of the Council concerning traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.[51]

Contrary to some other EU Member States, Belgium does not provide for specific "no GMO" labels highlighting the absence of GMOs in a product. These types of labels would run against existing Belgian law on advertising, and are therefore not allowed.[52]

VII. Liability Regime

There does not seem to be a specific liability regime for GMOs in Belgium, whether at the federal level or the regional level, beyond the normal rules of civil liability. The regions of Flanders and Wallonia, however, have institutional mechanisms that are indirectly related to the concept of liability for GMO producers.

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[47] Arrêté du Gouvernement wallon relatif à la coexistence des cultures génétiquement modifiées avec les cultures conventionnelles et les cultures biologiques [Executive Decision of the Walloon Government Regarding the Coexistence of Genetically Modified Crops and Conventional and Organic Crops] (Mar. 27, 2009), Annex 1, M.B., May 19, 2009, 37,964.

[48] *Id*. arts. 9–16.

[49] Regulation (EC) 1829/2003, *supra* note 11.

[50] See Part IV(C), "Distribution and Release of GMOs for Commercial Purposes."

[51] Regulation (EC) 1829/2003, *supra* note 11, arts. 12–14.

[52] GUIDE D'APPLICATION DE LA RÉGLEMENTATION RELATIVE AUX OGM [GUIDE ON THE APPLICATION OF REGULATIONS REGARDING GMOS] 22 (June 24, 2010), http://economie.fgov.be/fr/modules/publications/general/guide_ogm.jsp.

Flanders has a sort of mandatory insurance system, by which all farmers are required to pay into a Fund for Agriculture and Fishing, which is to indemnify them if they suffer certain economic losses.[53] Farmers who plant GM crops may be required to pay extra contributions into the fund, in order to make up for the indemnities that this fund may have to pay non-GM farmers due to contamination from GM crops.[54] Furthermore, this fund may require a GM crop farmer to reimburse it when the fund had to pay indemnities to non-GM crop farmers due to the GM crop farmer's failure to follow proper rules and best practices with regard to his/her GM crops.[55]

The situation is very similar in Wallonia. That region has a Budgetary Fund for the Quality of Plant and Animal Products (Fond budgétaire de la qualité des produits animaux et végétaux),[56] which is very similar to the Flemish Fund for Agriculture and Fishing. Like its Flemish equivalent, the Walloon fund is supposed to indemnify farmers for various types of economic damage they may suffer, including contamination from nearby GM crops.[57] If a court finds a GM crop farmer to be liable for the damage to other crops, then the fund may require that farmer to reimburse it for the indemnities that it may have had to pay the farmers of these damaged crops.[58]

VIII. Judicial Decisions / Prominent Cases

The production of GMOs is a very controversial topic in Belgium, and certain anti-GMO activists have resorted to destroying or degrading fields of GM crops.[59] The first such destructions happened in 2000, and became an increasingly frequent occurrence over the next few years.[60] This has led to several well-publicized trials, and some militants were found guilty by the courts.[61] The sentences tended to be very light, such as when thirteen activists were sentenced to pay one symbolic Euro to the Monsanto Corporation in 2004.[62] Some sentences can be heavier, however. For example, a group of militants that destroyed a field of experimental

[53] Decreet betreffende de oprichting en de werking van het Fonds voor Landbouw en Visserij [Decree Regarding the Creation and Functioning of the Fund for Agriculture and Fishing] (May 19, 2006), M.B., July 18, 2006, 35,701.

[54] *Id*. art. 4§1(11); Decree of Apr. 3, 2009, art. 7.

[55] Executive Order of Oct. 15, 2010, art. 10.

[56] Décret-programme du 18 décembre 2003 portant diverses mesures en matière de fiscalité régionale, de trésorerie et de dette, d'organisation des marchés de l'énergie, d'environnement, d'agriculture, de pouvoirs locaux et subordonnés, de patrimoine et de logement et de la fonction publique [Program-Decree of December 18, 2003, Regarding Various Measures on Regional Taxes, Treasury and Debt, Organization of Energy Markets, Environmental Matters, Agricultural Matters, Local and Subordinate Authorities, Patrimony and Housing, and the Public Service] (Dec. 18, 2003), M.B., Feb. 6, 2004, 7,196.

[57] Decree of June 19, 2008, art. 26§1.

[58] *Id*. art. 26§5.

[59] Nathalie Schiffino & Frédéric Varone, *supra* note 4, at 21.

[60] *Id.*

[61] *Id.*

[62] *Id.*

GM crops in 2011 was recently sentenced to pay €25,000 (approximately US$33,400) in damages to the owners of the crops.[63]

[63] *Champ d'OGM saccagé à Wetteren: les auteurs condamnés à 25 000 euros de dédommagements*, RTBF (Feb. 12, 2013), http://www.rtbf.be/info/belgique/detail_champ-d-ogm-saccage-a-wetteren-les-prevenus-devront-verser-25-000-euros-de-dedommagements?id=7926257.

Brazil

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SUMMARY In Brazil, genetically modified organisms (GMOs) are governed by Law No. 11,105 of March 24, 2005, which regulates principles established by the Constitution regarding the preservation of the environment and the country's genetic patrimony, as well as the supervision of entities dedicated to research and manipulation of genetic material.

Scientific advances in the areas of biosafety and biotechnology; the protection of life, human health, and the health of animals and plants; and the observance of the precautionary principle for the protection of the environment were used as guidelines to draft Law No. 11,105. This Law, in turn, led to the creation of general rules on biotechnology research, restructuring of the national technical commission responsible for all regulation of the biotechnology sector, creation of a National Biosafety Council, and establishment of the National Biosafety Policy.

Law No. 11,105 defines the concept of a GMO, and sets rules for the laboratories that work with them. Additionally, it establishes authorization procedures for GMO research, and establishes rules for the production and marketing of GMOs, restrictions on their release into the environment, regimes for their cultivation, requirements for reporting their release, inspections and monitoring of GMO research activities and their commercial release, implementing authorities and authorizing procedures for their release, and restrictions on GMOs in foodstuffs. Finally, it provides for the punishment of administrative violations and criminal offenses.

As for labeling, in 2003 a decree was issued to regulate the right to information, as guaranteed by federal law, regarding food and food ingredients intended for human consumption and animal feed when they contain or are produced from GMOs.

I. Introduction

Brazil's Biosafety Law (Law No. 11,105 of March 24, 2005), passed by the Congress in 2005, put an end to the controversy surrounding genetically modified organisms (GMOs) in the country. In addition to creating general rules on biotechnology research, Law No. 11,105 regulates constitutional principles and establishes safety standards and mechanisms for monitoring activities involving GMOs and their by-products.[1] The guidelines used for drafting this Law were the recognition of scientific advances in the areas of biosafety and biotechnology; the protection of life, human health, and the health of animals and plants; and the observance of the precautionary principle for the protection of the environment.[2]

[1] Lei No. 11.105, de 24 de Março de 2005, art. 1, http://www.planalto.gov.br/ccivil_03/_Ato2004-2006/2005/Lei/L11105.htm#art42.

[2] "The precautionary principle is a legal and policy principle addressing the problem of scientific uncertainty in environmental decision-making. Although numerous formulations have been advanced, the core idea is expressed in the familiar adage, better safe than sorry. The principle has implications for both the timing and substance of

Additionally, Law No. 11,105 created a national technical commission (CTNBio), which became responsible for all regulation of the biotechnology sector. Since then, CTNBio has approved the commercial use of about fifty GMOs, of which thirty-five are plants, including beans, cotton, corn, and soy, the latter of which is the most cultivated GMO in the country. According to the president of CTNBio, the rules for the release of these organisms in the country are among the strictest in the world.[3]

A genetically modified (GM) product must go through five different stages before it can be sold. First, a company must submit the project to CTNBio for approval. The Commission reviews the proposal and makes a site visit to determine whether the conditions exist for carrying out the work safely. Once the proposal is approved, development and testing can begin, and must be performed in a restricted and controlled environment. If the work site is a plant, the Ministry of Agriculture is in charge of supervising the experiment. Then, before the GM product's commercial release, CTNBio evaluates whether the data collected correspond to the Commission's biosecurity criteria.[4]

Prior to its marketing, however, the product is still subject to a political assessment conducted by a council of eleven ministers, who decide whether it is advantageous for the country to launch the new product on the market.[5]

In 2012, Brazil was the second major producer of GMO crops in the world, with an area of thirty million hectares dedicated to the planting of GMOs, which was only behind the United States with an area of 69 million hectares.[6]

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environmental measures: states should anticipate and respond to potential environmental harms, rather than only known or proven harms, and environmental risks should be managed with a margin of error in case they are more serious than originally expected." Daniel Bodansky, *Precautionary Principle*, OXFORD REFERENCE, http://www.oxfordreference.com/view/10.1093/acref/9780195324884.001.0001/acref-9780195324884-e-191 (last visited Dec. 11, 2013).

The most widely cited international formulation of the precautionary principle is Principle 15 of the 1992 Rio Declaration on Environment and Development, which generally viewed the precautionary principle as a protection against as yet unidentified but potential environmental risks. Specifically, Principle 15 states that " [i]n order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." (United Nations Conference on Environment and Development, Rio de Janeiro, Braz., June 3–14, 1992, *Rio Declaration on Environment and Development*, U.N. Doc. A/CONF.151/26/Rev.1 (Vol. 1), Annex I (Aug. 12, 1992), available at http://www.un.org/documents/ga/conf151/aconf15126-1annex1.htm. For further information on the precautionary principle, see the EU survey, *infra* at 65, nn.4, 6.

[3] *Brasil é Vive-Líder em Produção de Transgênicos*, AGÊNCIA CÂMARA DE NOTÍCIAS (Oct. 19, 2012), http://www2.camara.gov.br/camaranoticias/noticias/AGROPECUARIA/428224-BRASIL-E-VICE-LIDER-EM-PRODUCAO-DE-TRANSGENICOS.html.

[4] *Id*.

[5] *Id*.

[6] *Id.* One hectare is equivalent to 10,000 square meters.

II. Public and Scholarly Opinion

A study conducted in 2011 by the Brazilian Agricultural Research Company (Empresa Brasileira de Pesquisa Agropecuária, Embrapa)[7] on the development of strategic communication on GMO biosafety[8] mentioned that surveys of public opinion in several studies have shown that, in general, people are aware of GMOs, but are suspicious of the "ulterior motives" behind the "defense" of GMOs.[9]

The biggest controversy involving GMOs occurred before the enactment of Law No. 11,105 and revolved around conflicting biosafety and environmental laws. This conflict led to a lawsuit (see Part VIII, below) and the subsequent approval of a new legal framework for the regulation of GMOs.

III. Structure of Pertinent Legislation

A. Constitutional Principle

The Brazilian Constitution determines that everyone has the right to an ecologically balanced environment, which is a public good for the people's use and is essential for a healthy life. The government and the community have a duty to defend and preserve the environment for present and future generations.[10] To ensure the effectiveness of this right, it is the government's responsibility to preserve the diversity and integrity of the country's genetic patrimony, and to supervise entities dedicated to research and manipulation of genetic material;[11] to require, as provided by law, a prior environmental impact study, which must be made public, on installation of works or activities that may cause significant degradation of the environment;[12] and to control the production, marketing, and employment of techniques, methods, and substances that carry a risk to life, the quality of life, and the environment.[13]

B. Law No. 11,105 of March 24, 2005

On March 24, 2005, Law No. 11,105 was issued to regulate article 225(§1)(II), (IV), and (V) of the Constitution by establishing safety norms and inspection mechanisms for the construction,

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[7] Embrapa was established on April 26, 1973, as a federal agency under the authority of the Ministry of Agriculture, Livestock and Supply. Its mission is to solve problems of sustainable agriculture using research, development, and innovation in order to benefit Brazilian society. *Missão e Atuação*, EMBRAPA, http://www.embrapa.br/a_embrapa/missao_e_atuacao (last visited Dec. 3, 2013).

[8] Embrapa Meio Ambiente, Desenvolvimento de Comunicação Estratégica sobre Biossegurança de Plantas Geneticamente Modificadas – O Caso do Projeto LAC - Biosafety no Brasil (Aug. 2011), http://www.cnpma.embrapa.br/download/documentos_85.pdf.

[9] *Id*. at 13.

[10] CONSTITUIÇÃO FEDERAL art. 225, http://www.planalto.gov.br/ccivil_03/constituicao/constituicao compilado.htm.

[11] *Id.* art. 225(§1)(II).

[12] *Id.* art. 225(§1)(IV).

[13] *Id.* art. 225(§1)(V).

cultivation, production, manipulation, transport, transfer, import, export, storage, marketing, research, consumption, environmental release, and discharge of GMOs and their by-products.[14]

Educational activities and projects concerning GMO scientific research, technological development, and industrial production are restricted to the public and private entities responsible both for compliance with Law No. 11,105 and its regulation, Decree No. 5,591 of November 22, 2005,[15] and for the eventual consequences resulting from noncompliance.[16] Individuals acting in an autonomous capacity are not allowed to develop activities and projects involving GMOs.[17]

Law No. 11,105 also created the National Biosafety Council (Conselho Nacional de Biossegurança, CNBS),[18] restructured the National Technical Commission on Biosafety (Comissão Técnica Nacional de Biossegurança, CTNBio),[19] and provided for the National Biosafety Policy (Política Nacional de Biossegurança).

Law No. 11,105 defines GMO as an organism whose genetic material (DNA/RNA) has been modified by any genetic engineering technique.[20] It defines a GM by-product as a product obtained from a GMO that has no autonomous replication capacity or that does not contain a viable GM form.[21]

C. Law No. 8,078 of September 11, 1990

Law No. 8,078 of September 11, 1990, establishes the norms for the protection and defense of the consumer, public order, and social interest.[22] Article 6(III) of Law No. 8,078 determines that appropriate and clear information about different products and services; the correct specification of the quantity, characteristics, composition, quality, and price of products; and statements about the risks these products present are basic rights of consumers.[23]

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[14] Lei No. 11.105 art. 1.

[15] Decreto No. 5.591, de 22 de Novembro de 2005, https://www.planalto.gov.br/ccivil_03/_Ato2004-2006/2005/Decreto/D5591.htm.

[16] Lei No. 11.105 art. 2.

[17] *Id.* art. 2(§2).

[18] *Id.* art. 8.

[19] *Id.* art. 10 et seq.

[20] Lei No. 11.105 art. 3(V).

[21] *Id.* art. 3(VI).

[22] Lei No. 8,078, de 11 de Setembro de 1990, art. 1, http://www.planalto.gov.br/ccivil_03/Leis/L8078.htm.

[23] *Id.* art. 6(III).

D. Decree No. 4,680 of April 24, 2003

On April 24, 2003, Decree No. 4,680 was issued to regulate the right to information guaranteed by Law No. 8,078, regarding both food and food ingredients intended for human consumption and animal feed when they contain or are produced from GMOs.[24]

IV. Restrictions on Research, Production, and Marketing

A. Rules for Laboratories

Pursuant to article 14(VI) of Law No. 11,105, CTNBio is responsible for establishing the biosafety requirements for the issuance of permits to operate laboratories, institutions, or companies carrying out activities related to GMOs and their by-products.[25]

To this effect, on November 27, 2006, CTNBio issued Normative Resolution No. 2, which establishes the GMO risk classification and biosafety levels to be applied in containment regimes involving the creation, cultivation, production, handling, storage, quality control, and disposal of GMOs, and the research, technological development, and educational activities related to GMOs. The Resolution provides details on, inter alia, the presentation of proposals for GMO-related projects and activities, GMO risk classification and biosafety levels, laboratory specifications and design, and containment equipment. [26]

B. Rules for Authorizing Research, Production, and Marketing

Those interested in performing the activities provided for in Law No. 11,105 must apply for a permit with CTNBio.[27] For the purposes of Law No. 11,105, research activity is defined as "activity carried out in a laboratory, containment regime, or field as part of the production process of GMOs and their by-products, or of biosafety assessment of GMOs and their by-products, which encompasses, within the experimental ambit, the construction, growing, handling, transportation, transfer, import, export, storage, release into the environment, and disposal of GMOs and their by-products."[28]

An activity that does not fit the criteria for a research activity is considered a commercial use of GMOs and their by-products, which involves the "cultivation, production, handling, transportation, transfer, marketing, import, export, storage, use, release, or disposal of GMOs and their by-products for commercial purposes."[29]

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[24] Decreto No. 4.680, de 24 de Abril de 2003, art. 1, http://www.planalto.gov.br/ccivil_03/decreto/2003/D4680.htm#art8.

[25] Lei No. 11.105 art. 14(VI).

[26] Resolução Normativa No. 2, de 27 de Novembro de 2006, art. 1, available on the website of CTNBio, *at* http://www.ctnbio.gov.br/index.php/content/view/3913.html (last visited Dec. 3, 2013).

[27] Lei No. 11.105 art. 2(§3).

[28] *Id.* art. 1(§1).

[29] *Id.* art. 1(§2).

In addition to a permit, those interested in researching GMOs and producing and marketing them must also follow the rules established in CTNBio Normative Resolution No. 2.

C. Labeling Requirements for Distributed Products

Pursuant to article 2(§1) of Decree No. 4,680, on December 22, 2003, the Ministry of Justice issued Administrative Act (Portaria) No. 2,658, which defines and depicts the "transgenic symbol" (see below) to be used in the marketing of foods and food ingredients intended for human consumption or animal feed containing or produced from GMOs.[30]

Transgenic Symbol

Interministerial Normative Instruction (Instrução Normativa Interministerial) No. 1 of April 1, 2004, defines in Technical Regulations (Regulamento Técnico) the supplemental procedures for the implementation of Decree No. 4,680, which provides for the right to information guaranteed by Law No. 8,078 of September 11, 1990. These Regulations are annexed to the Normative Instruction.[31]

Law No. 11,105 further determines that foods and food ingredients for human consumption or animal feed containing or produced from GMOs or their by-products must contain information to this effect on their labels in accordance with the Law's regulation (Decree No. 5,591).[32]

D. Bodies Involved in Implementation

1. CTNBio

CTNBio, which is part of the Ministry of Science and Technology, is a multidisciplinary collegial body of an advisory and deliberative character designed

> to provide technical support and advice to the federal government in the formulation, implementation, and updating of the National Biosafety Policy on GMOs and their by-products, as well as in establishing technical safety standards and [providing] technical advice regarding the authorization of activities involving research and the commercial use of GMOs and their by-products, based on the assessment of their risk to human health and the environment [*risco zoofitossanitário*].[33]. . .

[30] Portaria No. 2.658, de 22 de Dezembro de 2003, available on the website of the Ministry of Justice, *at* http://portal.mj.gov.br/main.asp?View={4521CE7B-732B-40EB-B529-F9200C365E93} (search by "Tipos: Portarias" or go to Página 2 de 3) (last visited Dec. 3, 2013).

[31] Instrução Normativa Interministerial No. 1, de 1 de Abril de 2004, http://portal.mj.gov.br/main.asp?View={4521CE7B-732B-40EB-B529-F9200C365E93} (last visited Dec. 3, 2013).

[32] Lei No. 11.105 art. 40.

[33] *Id.* art. 10 (translation by the author).

> . . . CTNBio must monitor the development of, and technical and scientific progress in the areas of biosafety, biotechnology, bioethics, and related areas, aiming to increase its capacity to protect human health, animals and plants, and the environment.[34]

CTNBio is composed of members and alternates appointed by the Minister of Science and Technology, and must have twenty-seven Brazilian citizens of recognized technical abilities and outstanding scientific knowledge and performance. The members must have an academic doctoral degree with professional activity in the areas of biosafety, biotechnology, biology, human and animal health, or the environment.[35] The functioning of CTNBio is defined by the regulation of Law No. 11,105.[36]

2. CNBS

The CNBS, which operates under the authority of the Presidency of the Republic, is a superior advisory body to the President for the preparation and implementation of the National Biosafety Policy.[37] Although article 8 of Law No. 11,105 charges the CNBS with the duty of preparing and implementing the National Biosafety Policy, it appears that such a policy has yet to be prepared and implemented.

The Council is charged with establishing principles and guidelines for the administrative actions of federal agencies and entities with jurisdiction on biosafety;[38] analyzing applications for the commercial release of GMOs and their derivatives in matters regarding appropriateness, socioeconomic opportunity, and the national interest, upon the request of CTNBio;[39] and deciding, as the final hearing body, administrative cases relating to the commercial use of GMOs and their by-products.[40]

Decree No. 5,591 further regulates the activities, functioning, and composition of the CNBS, as well as the jurisdiction of the organs and entities in charge of registering, supervising, and authorizing proceedings related to GMOs and their derivatives.[41]

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[34] *Id.* art. 10(sole para.) (translation by the author).

[35] *Id.* art. 11.

[36] *Id.* art. 12. *See also* Decreto No. 5.591 art. 5 et seq.

[37] *Id.* art. 8.

[38] *Id.* art. 8(§1)(I).

[39] *Id.* art. 8(§1)(II).

[40] *Id.* art. 8(§1)(III).

[41] Decreto No. 5,591 arts. 48 et seq.

3. CIBio

Every institution that uses techniques and genetic engineering methods or conducts research on GMOs and their by-products must create an Internal Biosafety Commission (Comissão Interna de Biossegurança, CIBio), besides indicating a technician primarily responsible for each specific project.[42]

V. Restrictions on Releasing Organisms into the Environment

Law No. 11,105 prohibits the release into the environment of GMOs or their by-products

- as part of research activities, without a favorable technical decision issued by CTNBio;
- during trade operations, without a favorable technical opinion issued by CTNBio;
- without a license issued by the appropriate agency or environmental entity when CTNBio considers the activity a potential cause of environmental degradation; or
- without the approval of the CNBS, in accordance with the terms of Law No. 11,105 and its regulations.[43]

The CTNBio is the entity responsible for the establishment of technical standards regarding research and the commercial use of GMOs and their by-products based on the assessment of their risk to human health and the environment (*risco zoofitossanitário*).[44] Accordingly, on November 6, 2008, CTNBio issued Normative Resolution No. 6 with the norms applicable to the planned release into the environment of GM plants and their by-products.[45]

A. Protective Goals

Upon the verification of adverse effects on the environment or on human and animal health, or even upon confirmation of new scientific knowledge, the authorization for the planned release of a GM plant and its by-products may be suspended or revoked at any time by CTNBio.[46]

Any accidental release of a GM plant and its by-products must be immediately reported to the institution's CIBio and to CTNBio. The CIBio has up to five days to send the report of corrective actions taken to CTNBio. The report must include the names of the persons or authorities that have been notified.[47] The report of an accidental release of a GM plant and its

[42] Lei No. 11.105 art. 17.

[43] *Id.* art. 6(VI).

[44] *Id.* art. 10.

[45] Resolução Normativa CTNBio No. 6, de 6 de Novembro de 2008, http://www.ctnbio.gov.br/index.php/content/view/12510.html (last visited Dec. 3, 2013). Article 2(VII) defines "planned release" as "a release into the environment of GM plants or their by-products for experimental evaluations under monitoring, in accordance with the provisions of Normative Resolution No. 6."

[46] *Id.* art. 3.

[47] *Id.* art. 6.

by-products does not exempt the applicant from informing the competent authorities and the people who may be affected, so that they can adopt the appropriate measures in accordance with the laws in force.[48]

B. Regimes for Cultivation

According to Normative Resolution No. 6, the release of GM plants into the environment is subject to previous approval by CTNBio,[49] and the regime of GMO cultivation must be closely monitored and reported.[50]

On August 16, 2007, CTNBio issued Normative Resolution No. 4, which establishes the minimum isolation distances to be observed between genetically modified commercial corn crops and non-genetically modified corn crops to allow the coexistence of different production systems in the field.[51] To allow coexistence, the distance between a genetically modified commercial corn crop and a non-genetically modified corn crop located in a nearby area should be no less than 100 meters (approximately 328 feet) or, alternatively, twenty meters (approximately sixty-five feet) provided that it is surrounded with at least ten rows of conventional corn plants of a similar size and vegetative cycle as the genetically modified corn.[52]

Normative Resolution No. 10 of October 2, 2013, determines that in the planned release of genetically modified citrus plants into the environment, the strategy of pollen competition should be observed by introducing three types of borders, comprising at least six lines of citrus plants, also subject to the conditions established in the Resolution.[53]

C. Reporting Requirements

The applicant (*requerente*)[54] must maintain records of the individual who is monitoring the planned release of GM plants into the environment. These records must include, but are not limited to, information on security measures, agronomic practices, and data collection, as well as on the storage, material transfer, and eventual disposal of the GMOs and their by-products.[55]

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[48] *Id.* art. 6(sole para.).

[49] *Id.* art. 7(I).

[50] *Id.* art. 4.

[51] Resolução Normativa CTNBio No. 4, de 16 de Agosto de 2007, art. 1, http://www.ctnbio.gov.br/index.php/content/view/4687.html.

[52] *Id.* art. 2.

[53] Resolução Normativa CTNBio No. 10, de 2 de Outubro de 2013, art. 1, http://www.ctnbio.gov.br/index.php/content/view/18494.html.

[54] Article 2(IV) of Resolução Normativa CTNBio No. 6 defines "applicant" as "any company that has obtained a legal Biosafety Quality Certificate [*Certificado de Qualidade em Biossegurança*] – CQB [–] that intends to make a planned release, according to the terms of Normative Resolution No. 6."

[55] *Id.* art. 4.

Both the person responsible for the applicant company and its CIBio are charged with ensuring compliance with the provisions of Normative Resolution No. 6 with respect to the planned release of a GM plant and its by-products into the environment.[56] Additionally, the company's technical opinion concerning the planned release must inform CTNBio about any possible breach of the rules set out in Normative Resolution No. 6 and the biosecurity measures established by CTNBio.[57]

D. Inspections

According to article 16 of Law No. 11,105, the registration and inspection bodies of the Ministries of Health, Agriculture, and Environment, and the Special Secretariat for Aquaculture and Fisheries of the Presidency of the Republic are charged, inter alia, within the field of their respective expertise, while observing the technical decisions of CTNBio, the deliberations of the CNBS, and the mechanisms established by Law No. 11,105 and its regulation, with

> I – overseeing the research activities of GMOs and their derivatives;
>
> II – registering and monitoring the commercial release of GMOs and their by-products[.][58]

E. Implementing Authorities and Authorizing Procedures

After the proposal for the planned release of GM plants into the environment is approved by the company's CIBio, the applicant must submit it for approval to CTNBio accompanied by

> I – A request for planned release; information on the institution, dated and signed by the legal representative of the company, according to Annex I of Normative Resolution No. 6;
>
> II – Information on the GMO plant, according to Annex II of Normative Resolution No. 6;
>
> III – Information on the planned release of GMO plants, according to Annex III of Normative Resolution No. 6;
>
> IV – Maps and sketches for the planned release of GMO plants, in accordance with Annex IV of Normative Resolution No. 6; [and]
>
> V – A request for the import of vegetal material, when applicable.[59]

The proposal must be presented in Portuguese, with four copies, and accompanied by a digital file.[60]

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[56] *Id.* art. 5.

[57] *Id.* art. 5(sole para.).

[58] Lei No. 11.105, art. 16 (translation by the author).

[59] Resolução Normativa CTNBio No. 6, art. 7.

[60] *Id.* art. 7(sole para.).

VI. Restrictions on GMOs in Foodstuffs

A. Assessment of Risks

Normative Resolution No. 5 of March 12, 2008, defines assessment of risk as a combination of procedures or methods by which the potential effects of the planned release of GMOs and derived products on the environment and on human and animal health are assessed on a case-by-case basis.[61]

The assessment of risk must identify and evaluate the potential adverse effects of GMOs and their by-products on human and animal health, on the environment, and on plants, while maintaining transparency, the scientific method, and the precautionary principle.[62]

B. Implementing Authorities and Authorizing Procedures

The commercial release of GMOs and their by-products must conform to the standards provided for in Normative Resolution No. 5, as well as the written permission issued by CTNBio in accordance with all the conditions imposed in the permit.[63]

The authorization request for the commercial release of GMOs must be submitted to CTNBio with the information requested in Annexes I, II, III, and IV of Normative Resolution No. 5, which must be duly documented by scientific reports of the results obtained during the planned releases into the environment or other studies, without prejudice to other information deemed relevant by the CTNBio.[64]

C. Fodder for Livestock

The restrictions on GMOs and their by-products on foodstuffs are limited to their approval and authorization for human consumption or animal feed by the competent authorities, as described above.

D. Labeling

Law No. 11,105 determines that food and food ingredients for human consumption or animal feed containing or produced from GMOs or their by-products must provide information to this effect on their labels, in accordance with the regulation.[65]

Consumers must be informed when more than 1% of a product marketed as food for human or animal consumption contains or is produced from GMOs.[66]

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[61] Resolução Normativa CTNBio No. 5, de 12 de Março de 2008, art. 6(I), http://www.ctnbio.gov.br/index.php/content/view/11444.html (last visited Dec. 3, 2013).

[62] *Id.* art. 19.

[63] *Id.* art. 1.

[64] *Id.* art. 20.

[65] Lei No. 11.105 art. 40.

VII. Liability Regime

Without prejudice to the application of the penalties provided for in Law No. 11,105, those responsible for damage to the environment and to third parties are jointly liable for their compensation or full reparation, regardless of fault.[67]

A. Administrative Violations

Any action or omission that violates the rules set forth in Law No. 11,105 and other relevant legislation is considered an administrative violation.[68] Administrative violations must be punished as prescribed in the regulation of Law No. 11,105, regardless of precautionary measures to seize products, suspend the sales of products, and stop prohibited activities. The following sanctions are applicable:

> I – a warning;
>
> II – a fine;
>
> III – seizure of GMOs and their by-products;
>
> IV – suspension of the sale of GMOs and their by-products;
>
> V – halting of the activity;
>
> VI – partial or total interdiction of a business, activity or undertaking;
>
> VII – suspension of registration, license or authorization;
>
> VIII – cancellation of the registration, license or authorization;
>
> IX – loss or restriction on tax incentives and benefits granted by the government;
>
> X – loss or suspension of participation in government financed line of credit;
>
> XI – intervention in the establishment;
>
> XII – ineligibility to enter into contracts with public administration for a period of five years.[69]

It is incumbent upon the registration and inspection agencies and entities referred to in article 16 of Law No. 11,105 to establish "criteria and values," and impose fines ranging from R$2,000 (approximately US$870) to R$1,500,000 (approximately US$652,174), which must be established according to the seriousness of the offense.[70] The fines may be applied cumulatively with other penalties provided for in article 22 of Law No. 11,105.[71] In case of recidivism, the

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[66] Decreto No. 4.680 art. 2.

[67] Lei No. 11.105 art. 20.

[68] *Id.* art. 21.

[69] *Id.* art. 21(sole para.) (translation by the author).

[70] *Id.* art. 22.

[71] *Id.* art. 22(§1).

fine will be doubled.[72] In case of continued violation, characterized by the continuation of the action or omission that was initially punished, the punishment will be applied daily until its cause ceases, without prejudice to the immediate stoppage of the activity or the interdiction of the laboratory, institution, or company responsible.[73]

B. Criminal Offenses

The release or disposal of GMOs into the environment in a way that is contrary to the standards established by CTNBio and by the agencies and entities of registration and inspection is punishable by one to four years in prison and a fine.[74] The punishment is increased by one-sixth to one-third if the offense results in damage to another's property; one-third to one-half if harm is caused to the environment; one-half to two-thirds if the offense results in serious bodily injury to another person; and two-thirds to double if the offense results in death.[75]

The production, storage, transport, sale, import, or export of GMOs or their by-products without authorization or in violation of the standards established by CTNBio and by registration and inspection agencies is punishable by one to two years in prison and a fine.[76]

VIII. Judicial Decisions / Prominent Cases

The passage in 2005 of Brazil's current Biosafety Law, Law No. 11,105, involved a decade-long history of legislative and judicial activity. On January 5, 1995, Brazil issued the first law designed to regulate activities involving GMOs and their by-products. Law No. 8,974 was issued to regulate aspects of biosafety related to the development of GMOs and their by-products in the country.[77] However, conflicts between the biosafety legislation and environmental legislation led to the need for a restructuring of the relevant legislation.[78]

The problems regarding the application of Law No. 8.974 emerged in 1998 when CTNBio issued a technical opinion (*parecer técnico prévio conclusivo*) in which it approved the request for commercial release of a GM soybean tolerant to a glyphosate-based herbicide without requiring the completion of an Environmental Impact Report (Relatório de Impacto Ambiental, EIA/RIMA).

The competence of CTNBio to remove the requirement was immediately challenged in court through a public civil action filed by the Office of Consumer Affairs (Instituto de Defesa do

[72] *Id.* art. 22(§2).

[73] *Id.* art. 22(§3).

[74] *Id.* art. 27.

[75] *Id.* art. 27(§2).

[76] *Id.* art. 29.

[77] Ministério da Saúde, Organização Pan-Americana de Saúd, Marco Legal Brasileiro sobre Organismos Geneticamente Modificados (2010), http://www2.fcfar.unesp.br/Home/CIBio/MarcoLegalBras.pdf.

[78] *Id.*

Consumidor, IDEC), which provoked an extensive and contentious process of discussions about the adoption of this technology in the country.

The discussions involved all of Brazilian civil society and had repercussions within the judiciary, executive, and legislative branches. As a result, several laws were enacted generating a complex regulatory framework with little legal certainty.

In an attempt to address these regulatory weaknesses, in late 2003 the federal government sent the Congress a bill that was the result of discussions with various stakeholders, proposing a new law.

After a year and a half of discussions in the Congress, the bill was approved, and on March 24, 2005, the President of the Republic signed Law No. 11,105, which became Brazil's new Biosafety Law. This Law in conjunction with Decree No. 5,591 of November 22, 2005, which regulated Law No. 11,105, created a new legal framework for biosafety in the country.

Canada

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SUMMARY Canada regulates products derived from biotechnology processes as part of its existing regulatory framework for "novel products." The focus is on the traits expressed in the products and not on the method used to introduce those traits. The Canadian Food Inspection Agency (CFIA) is responsible for regulating genetically modified (GM) plants and approving GM feed for animals. Health Canada is mandated to assess the safety of foods for human consumption, including genetically modified organisms (GMOs) in foodstuff, and for authorizing them to be sold in Canada. Advertising or labeling the presence of GMOs in particular food is voluntary unless there is a health or safety concern.

I. Introduction

Canada is the third largest producer of genetically modified organisms (GMOs) in the world.[1] It is one of the largest producers of GM canola oil and other GM crops include maize, soybean, and beet.[2]

In 1993, the Canadian government established the Federal Regulatory Framework for Biotechnology. This framework resulted from an agreement between "federal regulatory departments on principles for an efficient, effective approach for regulating biotechnology."[3] The Framework established that, rather than creating new regulations, novel products produced through biotechnology will be regulated under existing regulations that cover traditional products.[4] The motive behind the Framework was to avoid the creation of a separate agency and separate legal framework for the regulation of biotechnology and to avoid duplication among regulatory agencies.

In Canada, GMOs used either as food or animal feed must be approved before entering the market.[5] The approval process is based on numerous regulations that are enforced by Health Canada for foods, the Canadian Food Inspection Agency (CFIA) for seeds and livestock

[1] *Genetically Modified Organisms*, ENVIRONMENT CANADA, http://www.ec.gc.ca/inre-nwri/default.asp?lang=En&n=E8A9C49D-1 (last updated July 23, 2013).

[2] *Bio-tech Crop Countries and Mega-Countries, 2010*, *in* CLIVE JAMES, 2010 ISAAA REPORT ON GLOBAL STATUS OF BIOTECH/GM CROPS slide 8, http://www.isaaa.org/resources/publications/briefs/42/pptslides/default.asp.

[3] CANADIAN FOOD INSPECTION AGENCY (CFIA), REGULATION OF AGRICULTURAL BIOTECHNOLOGY IN CANADA: A POST-SECONDARY EDUCATOR'S RESOURCE 13 (2007), http://publications.gc.ca/collections/collection_2007/cfia-acia/A104-24-2007E.pdf.

[4] Sara J MacLaughlin, *Food for the Twenty-First Century: An Analysis of Regulations for Genetically Engineered Food in the United States, Canada, and the European Union* ,14 IND. INT'L & COMP. L. REV. 375, 383 (2003–2004).

[5] *Regulation of Genetically Modified Organisms* (GMOs), FOOD SCIENCE NETWORK, https://www.uoguelph.ca/foodsafetynetwork/regulation-genetically-modified-organisms-gmos (last updated July 31, 2012).

feed, and Environment Canada "for new substances intended for environmental release."[6] Approvals for GMOs are required for both locally produced and imported products. As of 2012, over eighty-one genetically modified foods had been approved by CFIA.[7]

Canada's regulatory approach is essentially to review products rather than processes. In other words, the focus is on the traits expressed in the products and not on the method used to introduce those traits. This approach applies to both traditional breeding methods and genetic engineering. As noted by Professor Eric Montpetit:

> …the principle behind this so called product-based approach entails channelling all products, whether they are genetically modified or not, through a single risk management system. Since existing acts and regulations already provide for effective risk management systems, the product-based approach does not require any major legislative change.[8]

Unlike other countries, "Canada relies on the concept of novelty to trigger regulatory oversight, thereby enabling the regulation of a wider array of novel seeds or foods."[9]

Some scholars also note that Canada generally espouses a permissive attitude[10] towards GMOs and takes a far less precautionary approach to regulating GMOs than European countries.[11]

II. Public and Scholarly Opinion

A. Public Opinion

Public opinion polls have consistently shown that a large majority of Canadians are concerned about GMOs. According to a 1999 Environics poll, 80 percent of Canadians want GM foods to be labeled.[12] However, some assert that the polls are misleading since most consumers do not have a well-developed view of the products. Moreover, as press attention on GMOs has declined so has public opposition to them. According to a 2007 report, "[c]ompared to 29 OECD countries, Canadians see the least amount of media reporting on GMOs."[13] In a more recent poll, it was shown that "76 per cent of respondents said the federal government has not provided

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[6] *Id.*

[7] *Frequently Asked Questions - Biotechnology and Genetically Modified Foods*, HEALTH CANADA, http://www.hc-sc.gc.ca/fn-an/gmf-agm/fs-if/faq_1-eng.php (last updated July 24, 2012).

[8] Eric Montpetit, *A Policy Network Explanation of Biotechnology Policy Differences Between the United States and Canada*, 25(3) J. PUB. POL'Y 339, 341 (Sept.–Dec. 2005), http://www.jstor.org/stable/pdfplus/4007834.pdf.

[9] *Id.* at 346.

[10] *Id.*

[11] Peter Andrée, *An Analysis of Efforts to Improve Genetically Modified Food Regulation in Canada*, 33(5) SCI. & PUB. POL'Y 377, 389 (June 2006), http://spp.oxfordjournals.org/content/33/5/377.full.pdf.

[12] *Genetically Modified Foods: A Primer*, CBCNEWS ONLINE (May 11, 2004), http://www.cbc.ca/news2/background/genetics_modification/.

[13] Lorraine Chan, *GMOs Next Global Lightning Rod Issue*, UBC REPORTS (July 5, 2007), http://www.publicaffairs.ubc.ca/ubcreports/2007/07jul05/gmo.html.

them enough information to make an informed decision on GM foods. Another nine per cent said they'd never even heard of GM foods."[14]

A recent controversy over GM foods related to the development of a genetically modified apple that resists browning by a British Columbia company. The apple has been submitted to the CFIA for approval.[15]

B. Scholarly Opinion

According to one commentator "the official view in government is that transgenic organisms are not really all that different form non-GM food and crops."[16] This view is seen as being based on a "purely scientific assessment, backed by international expert consultations" and it is argued that it "should set the context for any policies dealing with GMOs."[17]

In 2001, the Royal Society of Canada (RSC), a senior national body of pre-eminent scholars, scientists, and artists published a report that contained "substantive critiques of Canadian regulatory processes and scientific capacity and concluded with 53 recommendations to address issues in four areas: fundamental policies and principles; specific regulations and guidelines; the regulatory process itself; and scientific capacity for the regulation of food biotechnology."[18]

In 1999, a Biotechnology Advisory Committee (CBAC), an expert panel advising the Government of Canada, was set up to assess the regulation of GM foods between 1999 and 2003.

Some of the criticisms noted by scholars in respect to Canada's regulatory framework include: "the perception of undue industry influence and the appearance of potential conflicts of interest"[19] of the CFIA; lack of transparency regarding the scientific assessment procedure and the approval and evaluation process; lack of independent "peer reviews and scientific risk assessments;"[20] heavy reliance on data and information provided by the biotech companies

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[14] Joe Fries, *Poll Indicates Lack of Information on Genetically Modified Food*, PENTICTON WESTERN NEWS (July 5, 2012), http://www.pentictonwesternnews.com/news/161480125.html. For the actual poll *see* Leger Marketing, Canadian Public Opinion Poll Arctic Apple Issue, 14522-004 (July 3, 2012), http://www.bcfga.com/files/file/Report%20on%20GE%20survey%20-%20July%203%202012.pdf .

[15] Barb Glen, *GM Apple Variety Submitted to CFIA for Approval*, THE WESTERN PRODUCER (May 31, 2012), http://www.producer.com/daily/gm-apple-variety-submitted-to-cfia-for-approval/.

[16] Peter Andrée, *The Biopolitics of Genetically Modified Organisms in Canada*, 37(3) J. CAN. STUD. 163 (Fall 2002), http://www.ask-force.org/web/Regulation/Andree-Biopolitics--GMO-Canada.pdf.

[17] *Id.*

[18] *Id.* at 379.

[19] Moran et al., *A Cause of Action for Regulatory Negligence? The Regulatory Framework for Genetically Modified Crops in Canada and the Potential for Regulator Liability*, 6 UNIV. OTTAWA L. & TECH. J. 10 (2009), http://www.uoltj.ca/articles/vol6.1-2/2009.6.1-2.uoltj.Moran%20.1-23.pdf.

[20] Scott Prudham & Angela Morris, *Making The Market "Safe" for GM Foods: The Case of the Canadian Biotechnology Advisory Committee*, 78 STUD. POL. ECON. 148, http://spe.library.utoronto.ca/index.php/spe/article/view/5216/2108.

themselves "in making its scientific assessment;"[21] and concerns about the application of the substantial equivalence standard by CFIA and Health Canada "for evaluating new products derived from biotechnology."[22]

III. Structure of Pertinent Legislation

Health Canada and the CFIA are both mandated to evaluate the safety and nutritional value of genetically modified foods released in Canada.

Genetically modified (GM) or genetically engineered (GE) foods are primarily regulated by the Food and Drugs Act[23] and its subordinate regulations.[24] Health Canada is responsible, under the above legal framework:

> for provisions related to public health, food safety and nutrition. Through science-based regulation, guidelines and public health policy, as well as health risk assessments concerning chemical, physical and microbiological contaminants, toxicants and allergens in the food supply, Health Canada works to protect the health and safety of Canadians. Health Canada also conducts pre-market evaluations to assess the safety and nutritional adequacy of novel foods proposed for sale in Canada, including foods derived from biotechnology.[25]

Under Canada's regulations, GE and GM foods are classified as one class of "novel foods." Health Canada "regulates the sale of novel foods in Canada through a pre-market notification requirement which is specified under Division 28 of Part B of the *Food and Drugs Regulations*."[26]

The CFIA "is responsible for regulating the environmental release of a plant with a novel trait (PNTs)."[27] This mandate is authorized through the following laws and regulations: the Plant

[21] Jane Matthews Glen, *The Coexistence of Genetically Modified and Non-genetically Modified Agriculture in Canada: A Courtroom Drama*, *in* THE REGULATION OF GENETICALLY MODIFIED ORGANISMS: COMPARATIVE APPROACHES 267 (Luc Bodiguel & Michael Cardwell eds., 2010).

[22] Moran et al., *supra* note 19, at 7.

[23] Food and Drugs Act, R.S.C., 1985, c. F-27, http://laws-lois.justice.gc.ca/eng/acts/F-27/index.html.

[24] Food and Drug Regulations, C.R.C., c. 870, http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.%2C_c._870/.

[25] *The Regulation of Genetically Modified Food*, HEALTH CANADA, http://www.hc-sc.gc.ca/sr-sr/pubs/biotech/reg_gen_mod-eng.php (last updated Dec. 12, 2012).

[26] *Id.*

[27] *Plants with Novel Traits*, CANADIAN FOOD INSPECTION AGENCY (CFIA), http://www.inspection.gc.ca/plants/plants-with-novel-traits/eng/1300137887237/1300137939635 (last updated Sept. 8, 2012).

Protection Act[28], Plant Protection Regulations[29], the Seeds Act[30] and Seed Regulations (Part V).[31]

IV. Restrictions on Research, Production, and Marketing

The development and planting of PNTs for research purposes is overseen by the CFIA's Plant Biosafety Office (PBO). The PBO evaluates applications for confined research field trials and sets out the rules[32] and conditions for how they are to be conducted.[33] These confined research field trials of PNTs are assessed by government scientists to ensure that the trials do not endanger the environment.[34] Stringent conditions are placed prior to conducting a confined research trial and developers are required to provide the government evaluators with "information about the plants (such as where they are being grown and the procedures being used) and must also work with the CFIA both during the field trial and after harvest."[35]

Before a GMO can be released into the environment more generally or sold for human consumption it must go through an authorization process as outlined below. The CFIA is mandated to assess GM plants and authorize their release into the environment. Health Canada, on the other hand, authorizes the sale of GM foods for human consumption.

V. Restrictions on Releasing Organisms into the Environment

As noted above, the CFIA is responsible for regulating GM plants and approving GM feed for animals.[36] Therefore, the CFIA is largely responsible for the regulation of the environmental release of PNTs. This oversight is conducted under the authority of the Plant Protection Act, Plant Protection Regulations, the Seeds Act, and Seed Regulations (Part V).[37]

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[28] Plant Protection Act, S.C. 1990, c. 22, http://laws-lois.justice.gc.ca/eng/acts/P-14.8/.

[29] Plant Protection Regulations, SOR/95-212, http://laws-lois.justice.gc.ca/eng/regulations/SOR-95-212/.

[30] Seeds Act, R.S.C., 1985, c. S-8, http://laws-lois.justice.gc.ca/eng/acts/S-8/.

[31] Seeds Regulations, C.R.C., c. 1400, http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._1400/index.html.

[32] CFIA, Directive Dir2000-07: Conducting Confined Research Field Trials of Plant with Novel Traits in Canada, http://www.inspection.gc.ca/plants/plants-with-novel-traits/applicants/directive-dir2000-07/eng/1304474667559/1304474738697 (last updated May 3, 2011).

[33] *Confined Research Field Trials for Plants With Novel Traits (PNTs),* CFIA http://www.inspection.gc.ca/plants/plants-with-novel-traits/general-public/field-trials/eng/1338138305622/1338138377239 (last updated May 27, 2012).

[34] *Id.*

[35] *Id.*

[36] Alexander Singh, *Proceed with Precaution: The Statutory, Legal, and Consumer Influence on Genetically Modified Foods in Canada*, 14(3) CAN. J.L. & TECH. 182, http://cjlt.dal.ca/vol4_no3/pdfarticles/singh.pdf.

[37] *Plants with Novel Traits*, *supra* note 27.

The CFIA's responsibilities are performed through "an assessment of the GM plants' impact on the environment and biodiversity, including assessing the possibility for gene flow and impact on non-target organisms, as well as ensuring the safety of livestock feed."[38]

The first step in the approval process requires the applicant to provide scientific data which includes information on the "nature of the novel trait, its stability in the plant, all test data pertinent to environmental and human risk assessment; and protocols that address preventing the establishment and spread into the environment of the genetic material, as well as monitoring and contingency plans to minimize any adverse effect of an accidental movement outside the confined release site."[39]

As stated by Thomas Moran, Nola M Ries and David Castle, in assessing a plant with a novel trait,

> the regulations require consideration of "all relevant matters, including […] the potential impact on and risk to the environment, including the potential impact on and risk to human health, posed by the proposed release" of a seed, including a seed with novel traits. The environmental and human health risks associated with release (ranging from minimal to unacceptable risk) must be assessed, which requires evaluation of scientific data and specialized knowledge. The regulations give authority to reject, approve and impose conditions on the release of seeds.[40]

The CFIA applies the principle of substantial equivalence when comparing the characteristics in the novel food with its "conventional counterpart" in respect to its "molecular, compositional, toxicological and nutritional makeup"[41] In other words, a product will be approved if it is substantially equivalent to its conventional counterpart. This has caused significant controversy since some critics believe the standard is a "decision-threshold standard in the decision-making process, rather than as a safety standard."[42]

Canada does not have a biosafety framework to track GMOs released into the environment or the food production system.[43]

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[38] Singh, *supra* note 36, at 182.

[39] *Id.*

[40] Moran et al., *supra* note 19, at 6.

[41] Singh, *supra* note 36, at 182.

[42] *Id.*

[43] John Fagan, *Monitoring GMOs Released into the Environment and the Food Production System*, *in* BIOSAFETY FIRST 1 (T. Traavik & L.C. Lim eds., 2007), http://genok.no/wp-content/uploads/2013/04/Chapter-33.pdf.

VI. Restrictions on GMOs in Foodstuffs

A. Safety Assessment

Health Canada has the mandate to assess the safety of foods for human consumption, including GMOs in foodstuff, and for authorizing them to be sold in Canada. It does so in accordance with the Food and Drugs Act and its regulations. Health Canada's process for assessing the safety of GM foods follows a "similar pattern" to the CFIA's assessment process explained above.[44] According to Division 28 of Part B of the Food and Drugs Regulations (Novel Foods), manufacturers and importers "who wish to sell or advertise a GM food in Canada, must submit data to Health Canada for a pre-market safety assessment."[45] This safety assessment "provides assurance that the food is safe when prepared or consumed according to its intended use."[46]

The safety reviews are based on the concepts of "familiarity" and "substantial equivalence." Familiarity is defined as "our knowledge of the characteristics of a plant species and experience with the use of that species in Canada."[47] Substantial equivalence is defined as "the equivalence of a novel trait within a particular plant species, in terms of its specific use and safety to the environment and human health, to those in that same species, that are in use and generally considered as safe in Canada, based on valid scientific rationale."[48]

According to Health Canada, it is a "seven to ten year process to research, develop, test and assess the safety of a new GM food" before it can be approved.[49]

Since the government relies on scientific data provided by corporations there does not appear to be requirements for independent testing to be conducted. There is also no long-term testing or monitoring of approved products. The assessment and testing process is described by Health Canada as follows:

> 1. **Pre-submission consultation**
> Health Canada encourages proponents to consult with the Novel Foods Section of the Food Directorate in advance of notifying a GM food to Health Canada for safety assessment. This provides the opportunity for regulatory process requirements to be clarified and for any specific safety issues to be raised.
>
> 2. **Pre-market notification**
> When the product's proponent believes it has sufficient information about the safety of a GM food to address Health Canada's criteria, a submission is made to the Novel Foods Section. This office coordinates a full safety assessment of the product, which

[44] Andrée, *supra* note 16.

[45] *The Regulation of Genetically Modified Food*, *supra* note 25.

[46] *Id.*

[47] *Id.*

[48] *Id.*

[49] *Id.*

involves a rigorous scientific evaluation by Health Canada scientific evaluators. These criteria are described in Health Canada's Guidelines for the Safety Assessment of Novel Foods.

3. **Scientific Assessment**
   Scientific evaluators, with individual expertise in molecular biology, toxicology, chemistry, nutritional sciences and microbiology, assess the following:

   - development of the modified organism, including the molecular biological data that characterizes the genetic change;
   - composition of and nutritional information about the GM food compared to a non-modified counterpart food;
   - the potential for production of new toxins in the food;
   - the potential for causing allergic reactions;
   - microbiological and chemical safety of the food;
   - the potential for any unintended or secondary effects;
   - key nutrients and toxicants; and,
   - major constituents (for example, fats, proteins, carbohydrates) and minor constituents (for example, minerals and vitamins).

4. **Requests for additional information**
   If Health Canada evaluators find that any of the information provided about a GM food is insufficient, further documentation is requested from the proponent of the submission. Health Canada does not give any further consideration to the submission until all requested material is provided and deemed to be scientifically valid.

5. **Summary report of findings**
   Once evaluators have completed their assessments, they summarize their findings and recommendations in a report.

6. **Preparation of food rulings proposal**
   Once the evaluation of the product is completed, a Health Canada Food Rulings Proposal is prepared. This proposal is reviewed by senior staff (Directors and Director General) in the Food Directorate to ensure that all issues have been addressed. Once this has been done, a decision is made whether or not to approve the product.

7. **Letter of no objection**
   If a product has successfully completed the evaluation process, and the other regulatory approvals such as environmental and feed safety are in place, a "Letter of No Objection" is sent to the product proponent. This letter indicates that the product can be sold in Canada for the intended uses, as listed in the submission, and whether there are any restrictions or requirements associated with the Health Canada decision.

8. **Decision document on Health Canada Web site**
   A decision document, describing the novel food and summarizing the safety information used to determine its safety as a food, is posted on the *Novel Foods and Ingredients page* of Health Canada's Web site.[50]

[50] *Id.*

B. Labeling

Health Canada and the CFIA have a joint mandate for federal food labeling policies under the Food and Drugs Act.[51] Health Canada is "responsible for setting food labelling policies with respect to health and safety matters (i.e., nutritional content, special dietary needs, etc.). This applies to all foods, including foods that have been derived through genetic engineering."[52] The CFIA, on the other hand, "is responsible for the development of non-health and safety food labelling regulations and policies and enforcement of all food labelling legislation. The CFIA sets standards for Canadian food labels so that they will be truthful and not misleading."[53]

Advertising or labeling of products containing GMOs or derived through GE processes is largely voluntary in Canada. There have been three major public consultation processes since 1993 in Canada on the labeling of novel foods derived from genetic engineering. Based on these consultations, a set of guidelines for food importers and manufacturers was developed. The guidelines reflect a general consensus to

- require mandatory labelling if there is a health or safety concern, i.e., from allergens or a significant nutrient or compositional change (these decisions will be made by Health Canada), in order to inform consumers of the allergen or change;
- ensure labeling is understandable, truthful, and not misleading;
- permit voluntary positive labeling on the condition that the claim is not misleading or deceptive and the claim itself is factual; and
- permit voluntary negative labeling on the condition that the claim is not misleading or deceptive and the claim itself is factual.[54]

Therefore, in Canada labeling is required "if there is a health or safety issue with the food which might be mitigated through labeling"[55] (e.g., if the "nutritional value or composition has been changed or if an allergen is present"[56]). This rule applies to all novel foods, whether GM or not. In respect to the labeling of the majority of GMOs, there is only "a national standard for the voluntary labelling of foods derived through biotechnology."[57]

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[51] *Labelling of Genetically Engineered Foods in Canada*, CFIA, http://www.inspection.gc.ca/food/labelling/other-requirements/method-of-production/ge-factsheet/eng/1333373177199/1333373638071 (last updated Nov. 19, 2012).

[52] *Id.*

[53] *Id.*

[54] *Id.*

[55] *The Regulation of Genetically Modified Food*, *supra* note 25.

[56] Maria Lusser & Emilio Rodríguez Cerezo, *Comparative Regulatory Approaches for New Plant Breeding Techniques: Workshop Proceedings*, EUR 25237 EN 7 (JRC Scientific & Technical Reports, 2012), ftp://ftp.jrc.es/pub/EURdoc/JRC68986.pdf.

[57] *Id.*

VII. Liability Regime

According to health law experts Thomas Moran, Nola M Ries, and David Castle "Canadian jurisdictions have not enacted statutory compensation regimes for harms associated with GM crops, so liability flowing from GM activities must be assessed through the common law of torts."[58]

VIII. Judicial Decisions / Prominent Cases

One of the most well-known recent cases involving GMOs is *Monsanto Canada Inc. v. Schmeiser*,[59] which largely involved property or patent rights in respect to GMOs. This case was a "patent infringement claim brought by [the agricultural biotech company] Monsanto against an arable farmer whose rapeseed crop had acquired its patented RT73 gene, either by wind drift and crosspollination or by any of a number of other unproved means."[60]

[58] Moran et al., *supra* note 19, at 4.

[59] Monsanto Canada Inc. v. Schmeiser, 2004 S.C.C. 34, http://scc.lexum.org/decisia-scc-csc/scc-csc/scc-csc/en/item/2147/index.do.

[60] Christopher P. Rodgers, *Liability for the Release of GMOS into the Environment: Exploring the Boundaries of Nuisance*, 62(2) CAMBRIDGE L.J. 375 (July 2003).

People's Republic of China

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SUMMARY In China, restrictions on genetically modified organisms (GMOs) are primarily provided by the agricultural GMO regulations enacted by the State Council in 2001 and relevant administrative rules. The agricultural GMO regulations regulate not only crops, but also animals, microorganisms, and products derived from these sources.

The testing, production, and marketing of GMOs in China are subject to government approval. Foreign companies that export GMOs to the PRC, including GMOs as raw materials, must apply to the Ministry of Agriculture and obtain GMO Safety Certificates.

I. Introduction

A. Policy Issues

The agriculture biotech industry is supported by the central government of the People's Republic of China (PRC or China) as an emerging sector of strategic importance.[1] According to China's *12th Five-Year Plan on National Economic and Social Development* for 2011–2015 (12th Five-year Plan), the country will "speed up the innovation and application of biotechnology breeding in agriculture," "develop new biological variety with important application value and independent intellectual property rights," and "foster a large and strong modern seed industry."[2]

Based on the 12th Five-year Plan and other plans supplementing it, the Ministry of Agriculture (MOA) released the *12th Five-Year Plan for Development of Agricultural Science and Technology* (Agricultural S&T Plan), which provides more details on the development of agricultural science and technology. In this Plan, the MOA proposes to strengthen research involving genetically modified organisms (GMOs).[3] Major research projects on breeding new varieties of GMOs will continue to be carried out in the 2011–2015 period, according to the

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[*] This report was prepared with the assistance of Law Library intern Bing Jia. An earlier version of the report was prepared in 2003 by the then Chief of the Eastern Law Division, Tao-tai Hsia, and Legal Research Analyst Wendy Zeldin.

[1] JOSHUA E. LAGOS & MA JIE, USDA FOREIGN AGRICULTURAL SERVICE, CHINA – PEOPLES REPUBLIC OF: AGRICULTURAL BIOTECHNOLOGY ANNUAL 2013, GAIN Report No. CH13033 (July 15, 2013), http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Beijing_China%20-%20Peoples%20Republic%20of_8-12-2013.pdf.

[2] 中华人民共和国国民经济和社会发展第十二个五年规划纲要 [12th Five-Year Plan], Central Government of the People's Republic of China website (Mar. 16, 2011), http://www.gov.cn/2011lh/content_1825838.htm (in Chinese). *Excerpt of China's 12th Five-Year Plan—Agriculture Part*, Ministry of Agriculture website (Apr. 28, 2012), http://english.agri.gov.cn/hottopics/five/201301/t20130115_9545.htm.

[3] For the purpose of this report, *zhuan ji yin* in the Chinese context is translated as "genetically modified," which literally means "transgenic."

Agricultural S&T Plan.[4] The plans also incorporate biosafety assessment and management as focus areas of biotech industry development.[5]

B. Legislative Purposes

The country's legislation attempts to balance the promotion of agricultural GMOs with concern for consumers and environmental safety. As early as 2002, the PRC Agriculture Law incorporated safety controls over the research, testing, production, processing, marketing, and other applications of agricultural GMOs.[6]

When formulating the Regulations on Administration of Agricultural Genetically Modified Organisms Safety (GMO Regulations), currently China's primary legislation on GMOs, the State Council outlined the purposes of the Regulations in article 1, as

- strengthening the safety management of agricultural GMOs;
- safeguarding the health of human bodies and the safety of animals, plants, and microorganisms;
- protecting the ecological environment; and
- promoting research into technologies of agricultural GMOs.[7]

China is a party to the Convention on Biological Diversity, which became effective to China in 1993.[8] China is also a party to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, which entered in force in 2005.[9]

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[4] 农业科技发展十二五规划 [12th Five-year Plan for Development of Agricultural Science and Technology] (issued by the MOA Dec. 30, 2011), http://www.moa.gov.cn/zwllm/zcfg/nybgz/201112/t20111231_2449779.htm, *translated in* National Modern Agriculture Development Plan (2011–2015) (Apr. 21, 2013), http://english.agri.gov.cn/hottopics/five/201304/t20130421_19483.htm.

[5] *Id. See also* 生物产业发展规划 [Plan for Development of Biology Industry] (issued by the State Council, Dec. 29, 2012), http://www.gov.cn/zwgk/2013-01/06/content_2305639.htm.

[6] 中华人民共和国农业法 [PRC Agriculture Law] (promulgated by the Standing Committee of the NPC, July 2, 1993, rev'd Dec. 28, 2002, last amended Dec. 28, 2012), art. 64, 2013 XIN FAGUI HUIBIAN, 62.

[7] 农业转基因生物安全管理条例 [Regulations on Administration of Agricultural Genetically Modified Organisms Safety (hereinafter GMO Regulations)] (promulgated by State Council May 23, 2001, revised Jan. 8, 2011), 2001 FAGUI HUIBIAN 1072, English translations *available at* http://english.agri.gov.cn/hottopics/bt/201301/t20130115_9551.htm; and http://www.fas.usda.gov/gainfiles/200106/110681034.pdf.

[8] Convention on Biological Diversity (signed by China June 11, 1992, ratified Jan. 5, 1993, effective Dec. 29, 1993), http://www.cbd.int/information/parties.shtml.

[9] Cartagena Protocol on Biosafety to the Convention on Biological Diversity (signed by China Aug. 8, 2000, approved June 8, 2005, effective Sept. 6, 2005), http://bch.cbd.int/protocol/parties/.

C. Approved GMOs

According to the data published by the MOA on April 27, 2013, China has issued GMO Safety Certificates to seven domestically developed, genetically modified (GM) crops, including a varieties of tomato (1997), cotton (1997), petunia (1999), sweet pepper and chili pepper (1999), papaya (2006), rice (2009), and corn (2009). Among them, the approved cotton has been broadly cultivated in China. As of 2010, China grew 3.3 million hectares of the approved cotton and a few hectares of the papaya, while the other GM crops had not been cultivated broadly, according to the MOA.[10]

An International Service for the Acquisition of Agri-Biotech Applications brief, *Global Status of Commercialized Biotech/GM Crops: 2012*, indicates that China grew 4.0 million hectares of GM crops, including cotton, papaya, poplar, tomato, and sweet pepper, as of 2012, which constituted the largest biotech crop area among developing countries, and the sixth largest around the world.[11]

Licenses have been granted for the import into China of four foreign GM crops: cotton, soybean, corn, and rape. Among them, only the cotton is permitted to be grown in China; the other crops can only be used as raw materials, according to the MOA.[12] In 2011, imported GM soybeans constituted two-thirds of the soybeans consumed domestically.[13]

II. Public and Scholarly Opinion

A. Public Opinion

The safety of GMOs is hotly debated in China through traditional media and the emerging online social media, where the public expresses deep concerns about the safety of GMO foodstuffs. A study of a GM grain carried out in China in 2012 caused great concern to the public. In the study, a US researcher and her team were accused of feeding Chinese children a GM grain, golden rice, and measuring the effects without telling their parents. The incident was widely reported in the Chinese media, and the public is reportedly "furious" about the study using children for tests.[14] As a result, the Chinese government rapidly punished three Chinese

[10] *我国发放了哪些转基因作物生产应用安全证书？其种植情况如何？* [*Which GM Crops are Granted GMO Safety Certificates? How is Their Cultivation?*] (Apr. 27, 2013), http://www.moa.gov.cn/ztzl/zjyqwgz/zswd/201304/t20130427_3446853.htm.

[11] *ISAAA Brief No. 44 (2012): Executive Summary*, ISAAA, http://isaaa.org/resources/publications/briefs/44/executivesummary/default.asp (last visited Nov. 26, 2013).

[12] *我国已批准进口用做加工原料的转基因作物有哪些？可以在国内种植吗？* [*Which Genetically Modified Agricultural Plants are Permitted to Import to be Used as Raw Materials? Are They Permitted to Cultivate Domestically?*] (Apr. 27, 2013), http://www.moa.gov.cn/ztzl/zjyqwgz/zswd/201304/t20130427_3446861.htm.

[13] DEPARTMENT OF HIGH-TECH INDUSTRY OF NATIONAL DEVELOPMENT AND REFORM COMMISSION OF PRC & CHINESE SOCIETY OF BIOTECHNOLOGY, ANNUAL REPORT ON BIOINDUSTRY IN CHINA: 2011, 235 (Ma Youzhi et al. eds., Huaxue Gongye Chubanshe, 2012).

[14] Dan Charles, *In A Grain Of Golden Rice, A World Of Controversy Over GMO Foods*, NPR (Mar. 7, 2013), http://www.npr.org/blogs/thesalt/2013/03/07/173611461/in-a-grain-of-golden-rice-a-world-of-controversy-over-gmo-foods.

coauthors of the study by removing them from their jobs. A year later, in September 2013, the home institute of the American researcher, Tufts University, announced that the researcher broke ethical rules while carrying out the study of GM golden rice in China.[15]

Some nonprofit organizations have also alleged that GMOs generate food safety concerns and environmental dangers. Greenpeace China, for example, particularly focuses on GM rice sold in China. It has released multiple reports warning the public about the danger of GMOs and illegal sales of GM rice in China.[16]

B. Scholarly Opinion

Mainstream research institutes in China appear to share the government's view in promoting GMO research. Major research institutes contribute funds and laboratory facilities to GMO research. Among them, the Chinese Academy of Agricultural Sciences has established a Biotechnology Research Institute. The Institute not only supports GMO safety evaluations, but also carries out projects on GM plant research and production.[17]

Some recent discussions have raised new concerns over GMOs other than threats to human health and the environment, suggesting GMOs may endanger the country's food security. In September, a conference on "GMOs and National Security" was held in Beijing, where scholars warned that the issues relating to GMOs were not just about science or technology, but also about food security, ecological security, and even national security.[18]

III. Structure of Pertinent Legislation

A. GMO Regulations and Rules

China has not passed a national law specifically regulating GMOs. Restrictions are primarily on agricultural GMOs, which are provided by the GMO Regulations enacted by the State Council in 2001 and the administrative rules implementing the GMO Regulations. The GMO Regulations are designed to regulate not only crops, but also animals, microorganisms, and their products. [19]

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[15] Dan Charles, *Golden Rice Study Violated Ethical Rules, Tufts Says*, NPR (Sept. 17, 2013), http://www.npr.org/blogs/thesalt/2013/09/17/223382375/golden-rice-study-violated-ethical-rules-tufts-says; Elizabeth Renter, *Potentially Dangerous GMO 'Golden Rice' Fed to Chinese Children Without Warning*, NATION OF CHANGE(Oct. 20, 2013), http://www.nationofchange.org/potentially-dangerous-gmo-golden-rice-fed-chinese-children-without-warning-1382281851.

[16] *See Safeguarding Food & Agriculture*, http://www.greenpeace.org/eastasia/campaigns/food-agriculture/ (last visited Nov.26, 2013). *See* also *Genetically Engineered Rice: Illegal and Unwanted in China*, GREENPEACE (Apr. 2005), http://www.greenpeace.org/eastasia/publications/reports/food-agriculture/2005/genetically-engineered-rice-i/.

[17] *本所简介* [*Institute Introduction*], CAAS, http://bri.caas.net.cn/bsgk/index.aspx (last visited Nov. 26, 2013).

[18] *高度重视转基因问题，粮食安全要靠自己* [*GMO Issues Need High Attention, Food Security Relies on Ourselves*], XINHUANET (Sept. 30, 2013), http://news.xinhuanet.com/world/2013-09/30/c_125474948.htm.

[19] GMO Regulations, *supra* note 7, art. 3.

Agricultural GMO research, testing, production, processing, business operations, and import/export activities within the PRC's territory are subject to the GMO Regulations.[20]

The MOA and the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) have issued the following administrative rules implementing the GMO Regulations, which regulate, respectively, safety evaluations, processing, labeling, import, and entry and exit inspections and quarantine:

- Administrative Measures for Safety Evaluations of Agricultural GMOs (Safety Evaluation Measures)[21]
- Measures for Examination and Approval of the Processing of Agricultural GMOs[22]
- Administrative Measures for Labeling Agricultural GMO Marks (Labeling Measures)[23]
- Administrative Measures for Safety Control for Importing Agricultural GMO Products[24]
- Administrative Measures on the Entry and Exit Agricultural GMO Products Inspection and Quarantine[25]

In addition, the Ministry of Forestry has issued a separate document regulating gene-altered engineering of trees in forests (Forestry Measures).[26]

B. Rules on GMO Foodstuffs

The Ministry of Health (MOH) issued the Administrative Measures for Genetically Modified Food Hygiene in 2002,[27] but those measures were abolished in 2007.[28] GMO foodstuffs are now

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[20] *Id.* art. 2.

[21] 农业转基因生物安全评价管理办法 [Administrative Measures for Safety Evaluation Agricultural GMO] (hereinafter Safety Evaluation Measures) (issued by MOA Jan. 5, 2002, effective Mar. 20, 2002, revised July 1, 2004), http://www.moa.gov.cn/ztzl/zjyqwgz/zcfg/ 201007/t20100717_1601305.htm.

[22] 农业转基因生物加工审批办法 [Measures for Examination and Approval of Processing Agricultural GMO] (issued by MOA Jan.16, 2006, effective July 1, 2006), http://www.gov.cn/flfg/2006-03/02/content_215830.htm.

[23] 农业转基因生物标识管理办法 [Administrative Measures for Labeling Agricultural Genetically Modified Organisms Marks] (hereinafter Labeling Measures) (issued by MOA Jan. 5, 2002, effective Mar. 20, 2002, revised July 1, 2004), 2002 JAN-JUNE FALÜ QÜANSHU 1689. For an unofficial English translation of the above three sets of Measures, *see* USDA FOREIGN AGRICULTURAL SERVICE GAIN REPORT #CH2002 (Jan. 14, 2012), http://www.fas.usda.gov/gainfiles/200201/135683205.pdf.

[24] 农业转基因生物进口安全管理办法 [Administrative Measures for Safety Control of Importing Agricultural GMO Products] (issued by MOA Jan. 5, 2002, effective Mar. 20, 2002, revised July 1, 2004), http://www.moa.gov.cn/ztzl/zjyqwgz/zcfg/201007/t20100717_1601304.htm.

[25] 进出境转基因产品检验检疫管理办法 [Administrative Measures on the Entry and Exit Agricultural GMO Products Inspection and Quarantine] (issued by AQSIQ Sept. 5, 2001), http://www.moa.gov.cn/ztzl/zjyqwgz/zcfg/201007/t20100717_1601300.htm.

[26] 国家林业局开展林木转基因工程活动审批管理办法 [Administrative Measures for Gene-altered Engineering over Forestry] (issued by MOF May 11, 2006, effective July 1, 2006), art. 6, 6 2006 XIN FAGUI HUIBIAN 201.

subject to the Agricultural GMO Safety Regulations. There is no separate legislation specifically regulating GMO foodstuffs today.

C. Other GMO Provisions

Apart from the aforementioned legislation, the PRC Law on Seeds,[29] PRC Law on Fisheries,[30] PRC Law on the Environment,[31] and the Administrative Measures for Safety Control over Genetic Engineering[32] contain provisions relating to GMOs.

D. Local Rules

Zhangye City in China's Gansu Province recently issued a ban on growing, selling, or using any GM seeds. This is the first local ban on GM seeds in China.[33] In a document released on October 25, 2013, the city government ordered that no organizations or companies may grow, trade, or use any GM seeds in the area.[34]

E. Definition of Agricultural GMO

Under the GMO Regulations, "agricultural GMO" refers to any plant, animal, or microorganism whose genome constitution has been changed by using genetic engineering technology, and their products, which includes

- GM animals, plants (planting seeds, breed livestock, breed fowl, aquatic seedlings), and microorganisms;
- GM animal, plant, and microorganism products;
- products directly processed from GM agricultural products; and

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[27] 转基因食品卫生管理办法 [Administrative Measures for Genetically Modified Food Hygiene] (promulgated by MOH Apr. 8, 2002, effective July 1, 2002, repealed July 2, 2007), 2002 JAN-JUNE FALÜ QÜANSHU 626.

[28] 新资源食品管理办法 [Administrative Measures for Novel Food] (promulgated by MOH July 2, 2007, effective Dec. 1, 2007, repealed May 31, 2013), arts. 27–28, 2007 MAY-AUG. FALÜ QÜANSHU 560.

[29] 中华人民共和国种子法 [Law on Seeds of the People's Republic of China] (promulgated by Standing Committee of NPC July 8, 2000, effective Dec. 1, 2000, amended June 29, 2013), 2013 XIN FAGUI HUIBIAN Vol. 7, 149.

[30] 中华人民共和国渔业法 [Law on Fishery of the People's Republic of China] (promulgated by Standing Committee of NPC Jan. 20, 1986, effective July 1, 1986, amended Aug. 28, 2004), 2004 FAGUI HUIBIAN 1068.

[31] 中华人民共和国环境保护法 [Law on Environment of the People's Republic of China] (promulgated by Standing Committee of NPC Dec. 26, 1989), 1989 FAGUI HUIBIAN 419.

[32] 基因工程安全管理办法 [Administrative Measures for Safety Control over Genetic Engineering] (promulgated by Ministry of Science and Technology (MOST) Dec. 24, 1993), http://www.gene.gov.cn/news/7643809.html (in Chinese) (last visited Nov. 18, 2013).

[33] Chen Ximeng, *Gansu City China's first to Ban GM Seed*s (Oct. 31, 2013), http://www.globaltimes.cn/content/821781.shtml#.UpPWV3Lh-So.

[34] *Id.*

- planting seeds, breed livestock, breed fowl, aquatic seedlings, pesticides, veterinary medicines, fertilizers, and additives that contain GM animal, plant, or microorganism ingredients.[35]

IV. Restrictions on Research, Production, and Marketing

Under the GMO Regulations, testing, production, and marketing of GMOs in China are subject to government approval. Research involving Class III and IV GMOs must be reported to the MOA.

A. Responsible Agencies

1. MOA

The MOA is the primarily responsible agency for biosafety management of GMOs in China. Agricultural administrative departments of subnational governments above the county level are also responsible for biosafety management in their own jurisdictions.[36]

2. GMO Biosafety Committee

A national agricultural GMO Biosafety Committee was established in accordance with the GMO Regulations to evaluate applications for GMO Safety Certificates.[37] The Committee consists of experts in GMO research, production, processing, inspection, quarantine, health, and environmental protection. The committee members serve three-year terms.[38]

B. Research and Testing

All institutes engaged in agricultural GMO research and testing are required to have facilities and measures commensurate with their GMO safety class to ensure safety.[39] Research into agricultural GMOs classified as Class III and IV need to report to the MOA before the research is carried out.[40]

Under the GMO Regulations, testing is chronologically subdivided into three stages: medium testing (small-scale tests, also referred to as "restricted field tests"), environmental release, and product testing.[41] After completing research in the laboratory, if the testing organization needs to

[35] GMO Regulations, *supra* note 7, art. 3(1).

[36] *Id.* art. 4.

[37] Safety Evaluation Measures, *supra* note 21, art. 5.

[38] *Id.*

[39] GMO Regulations, *supra* note 7, art. 11.

[40] *Id.* art. 12.

[41] *Id.* art. 13.

proceed to medium testing, the testing organization must report to the MOA.[42] Moving from one testing stage to the next requires approval from the MOA.[43]

C. Production

Upon the completion of the three testing stages, researchers may apply for a GMO Safety Certificate from the MOA.[44] According to the GMO Regulations, organizations or individuals engaged in the production and processing of agricultural GMOs must obtain approval from the MOA or a provincial agricultural administrative department.[45]

The production of GM planting seed, breed livestock, breed fowl, or aquatic seedlings requires a production license from the MOA.[46]

D. Marketing

1. Licenses and Permits

Marketing GM planting seeds, breed livestock, breed fowl, and aquatic seedlings requires a marketing license from the MOA.[47] Advertising agricultural GMOs requires a permit from the MOA as well.[48]

Any foreign company that exports to the PRC GM planting seeds, breed livestock, breed fowl, and aquatic seedlings, or any of these items plus other products (pesticides, veterinary medicines, fertilizers, or additives) using GMOs or containing GM ingredients must submit an application to the MOA and obtain a GMO Safety Certificate.[49]

Those who export GMOs as raw materials to the PRC must go through a similar process and obtain a GMO Safety Certificate.[50]

2. Labeling

GMO products on the GMO list published by the state must be clearly labeled when sold within the PRC territory; unlabeled products may not be sold.[51] The label should indicate the name of

[42] *Id.* art. 14.

[43] *Id.* art. 15.

[44] *Id*. art. 16.

[45] *Id.* art. 21.

[46] *Id*. art. 19.

[47] *Id.* art. 26.

[48] *Id*. art. 30.

[49] *Id*. art. 32.

[50] *Id.* art. 33.

[51] *Id.* art. 28.

the GM materials and, if there are special restrictions on where it may be sold, the area in which it will be sold.[52]

The list of the first group of GMO products to be included under the labeling system was published along with the Labeling Measures, and it appears that no additional products have been added to the list since the first group was published. The first group of products included soybean seeds, soybeans, soybean powder, soybean oil, and soybean meal; seed corn, corn, corn oil, and corn powder; planting seed of rape, rapeseed, rapeseed oil, rapeseed meal; cotton seed; and tomato seed, fresh tomatoes, and tomato paste.[53]

V. Restrictions on Releasing Organisms into the Environment

The purposes of regulating GMOs in China, according to the GMO Regulations, include safeguarding the health of human bodies; safeguarding animals, plants, and microorganisms; and protecting the ecological environment. The classification of GMOs is also based on the nature of their potential danger to humans, animals, plants, microorganisms, and the ecological environment.

A. Environmental Release

Environmental release under the GMO Regulations refers to the medium-scale testing conducted under natural conditions with appropriate safety measures—the second testing stage after the restricted field tests and before the product testing.[54]

Upon completion of the restricted field tests, an application must be submitted to the MOA in order to release the tested GMO into the environment. Only after the application passes a safety evaluation conducted by the GMO Biosafety Committee will the MOA approve product testing.[55] When making the application, the applicant must also submit

- a designation of the safety class of the GMO and the justifications for that designation,
- a copy of the inspection report issued by a technical inspection body of agricultural GMOs,
- a list of appropriate safety administration and precautionary measures, and
- a summary report of the previous testing stage.[56]

[52] *Id.* art. 29.

[53] Labeling Measures, *supra* note 23, App. *See also 我国目前规定对哪些转基因产品进行标识?* [*Which GMOs are Required to Be Labelled in China?*], MOA (Apr. 27, 2013), http://www.moa.gov.cn/ztzl/zjyqwgz/zswd/201304/t20130427_3446072.htm.

[54] GMO Regulations, *supra* note 7, art. 13.

[55] *Id*. art. 15.

[56] *Id.*

B. Reporting Requirements

Individuals or organizations engaged in GMO production and processing must arrange their production in accordance with the approved varieties, scope, safety control requirements, and relevant technical standards. They are also required by the GMO Regulations to regularly report their production, processing, safety controls, and the products' whereabouts to their local agricultural administrative department.[57] Entities engaging in GMO tests and production are required to regularly report to the MOA and local agricultural administrative departments.[58]

VI. Restrictions on GMOs in Foodstuffs

GMO foodstuffs are regulated by the GMO Regulations as "GMO products." Therefore, the restrictions mentioned in Part IV, above, apply to GMO foodstuffs. In addition to the MOA, the local governments above the county level are responsible for the safety management of GMO foodstuffs.[59]

Fodder for livestock is also subject to the GMO Regulations.[60]

VII. Liability Regime

The GMO Regulations provide a chapter with thirteen articles on the penalties to be imposed for violations of those Regulations.[61] Violators are mainly subject to administrative penalties, while civil or criminal penalties may also apply under certain circumstances (discussed below).

A. Administrative Penalties

Importing GMOs without a permit, or producing or processing GMOs without a permit, or with a permit but not in accordance with its terms concerning the permitted varieties, scope, safety control requirements, and technical standards, is punishable with a fine of up to RMB200,000 (about US$33,000), or up to five times the illegal gain if the gain is over RMB100,000.[62]

Researching, testing, storing, or transporting agricultural GMOs without approval may also result in administrative penalties, such as suspension of activities, a demand to correct the problem, confiscation of illegal gains, or fines.[63]

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[57] *Id*. art. 23.

[58] Safety Evaluation Measures, *supra* note 21, art. 34.

[59] GMO Regulations, *supra* note 7, art. 4; 国务院关于废止和修改部分行政法规的决定 [Decision of the State Council on Abolishing and Amending Some Administrative Regulations] (State Council Decree [2011] No. 588, Jan. 8, 2011), item 94, http://www.gov.cn/flfg/2011-01/17/content_1786304.htm.

[60] *Id*. art. 3.

[61] *Id.* arts. 43–55.

[62] *Id.* arts. 47 & 50.

[63] *Id.* ch. 7.

B. Civil Penalties

Any damages caused by GMO accidents in the course of research, testing, production, processing, storage, transportation, sales, or import and export must be compensated, according to the GMO Regulations.[64]

C. Criminal Penalties

Under the GMO Regulations, whoever forges, falsifies, transfers, sells, or purchases GMO certifying documents may be criminally punished if such offense violates the Criminal Law.[65] Government officials may also be criminally punished for issuing GMO certifying documents in violation of the Regulations, or for failing to perform their oversight duties.[66]

VIII. Judicial Decisions / Prominent Cases

The Chinese courts do not systematically report their judgments, and court decisions do not have precedential effect as in common law jurisdictions. Court decisions that have significantly influenced GMO regulations in China were not located.

[64] *Id.* art. 54.

[65] *Id*. art. 53.

[66] *Id.* art. 55.

Egypt

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SUMMARY Egypt takes a permissive approach to genetically modified organisms (GMOs), and its public policy does not oppose growing, importing, and exporting genetically modified crops. Egyptian activists have voiced their rejection of this policy. Egyptian laws do not contain restrictions on researching, producing, or marketing genetically modified crops and food products. The country also has no restrictions on releasing genetically modified organisms into the environment. A draft law on biosafety was not approved by the Egyptian Parliament.

I. Introduction

In spite of Egypt's announcement in 2009 that any agricultural import must have a certificate from the country of origin stating that the product is not genetically modified,[1] the country takes a permissive approach to genetically modified organisms (GMOs), and its public policy does not oppose growing, importing, and exporting genetically modified crops. According to recent news reports, Egypt ranks third in Africa in planting and importing genetically modified crops.[2] Since December 2010, genetically modified crops have been planted without restrictions in ten different Egyptian provinces,[3] including one thousand hectares of genetically modified maize in 2012. In 2008, Egypt became the first North African country to grow genetically modified crops,[4] and it is now one of the five countries worldwide to introduce biotech crops to other countries.[5]

Egypt not only engages in growing and trading genetically modified crops, but also provides training to other countries to develop their capacity to produce such crops, one example being Tanzania, to which Egypt agreed to provide technical assistance in 2004.[6]

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[1] Maha El Dahan, *Egypt Says No GM Food Exports or Imports*, REUTERS (Aug. 12, 2009), http://www.reuters.com/article/2009/08/12/us-egypt-food-idUSTRE57B3VS20090812.

[2] Louise Sarant, *Biotechnology Report: 1000 Hectares of Genetically Modified Maize Grows in Egypt*, EGYPT INDEPENDENT (Mar. 14, 2013), http://www.egyptindependent.com/news/biotechnology-report-1000-hectares-genetically-modified-maize-grows-egypt.

[3] Louise Sarant, *Tests on Rats Suggest Genetically Modified Foods Pose Health Hazards*, EGYPT INDEPENDENT (Aug. 12, 2012), http://www.egyptindependent.com/news/tests-rats-suggest-genetically-modified-foods-pose-health-hazards.

[4] ADEMOLA A. ADENLE, BMC RESEARCH NOTES – RESPONSE TO ISSUES ON GM AGRICULTURE IN AFRICA: ARE TRANSGENIC CROPS SAFE? (2011), http://www.biomedcentral.com/content/pdf/1756-0500-4-388.pdf.

[5] CLIVE JAMES, ISAAA BRIEF 39 – GLOBAL STATUS OF COMMERCIALIZED BIOTECH/GM CROPS: 2008 (2008), http://isaaa.org/resources/publications/briefs/39/download/isaaa-brief-39-2008.pdf.

[6] Deodatus Balile, *Egypt Will Help Tanzania with "Inevitable" GM Crops*, SCIDEVNET (June 18, 2004), http://www.scidev.net/global/gm/news/egypt-will-help-tanzania-with-inevitable-gm-crop.html.

II. Public and Scholarly Opinion

Egyptian activists have voiced their rejection of the country's policies of growing, importing, and exporting genetically modified crops. In May 2013, around one hundred activists protested in front of the Ministry of Agriculture to condemn the use of genetically modified food products.[7] The protest was a result of news reports stating that genetically modified food products cause cancer.[8] Previously, in August 2012, Egyptian scientists from Cairo University had announced that genetically modified crops planted in Egypt cause health hazards, including organ failure.[9]

III. Structure of Pertinent Legislation

In an attempt to curb the proliferation of genetically modified crops and food products, activists have collaborated with the Nature Protection Section of the Ministry of Environment to draft legislation, titled the Biosafety Law, that would regulate genetically modified crops and food products in Egyptian markets. In November 2011, the draft legislation was approved by the Council of Ministers. However, neither the People's Assembly (the lower chamber of Egypt's Parliament) nor the Shura Council (the upper chamber of the Parliament) has approved the measure.[10]

IV. Restrictions on Research, Production, and Marketing

Egypt does not have any restriction on researching, producing, or marketing genetically modified crops and food products. To the contrary, in 2011, Egypt commercialized genetically modified cotton.[11] This initiative followed a research phase, which had begun in May 2007.[12]

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[7] Marwa Hussein, *Egyptian Activists Launch First Protest Against Genetically Modified Food*, AHRAMONLINE (May 26, 2013), http://english.ahram.org.eg/NewsContent/3/12/72305/Business/Economy/Egyptian-activists-launch-first-protest-against-ge.aspx.

[8] *American Company Exports Carcinogenic Genetically Modified Crops to Egypt*, AL-NAHAR (May 26, 2013), http://www.alnaharegypt.com/t127804 (in Arabic).

[9] Louise Sarant, *Tests on Rats Suggest Genetically Modified Foods Pose Health Hazards*, EGYPT INDEPENDENT (Aug. 12, 2012), http://www.egyptindependent.com/news/tests-rats-suggest-genetically-modified-foods-pose-health-hazards.

[10] Haytham Khayri, *Biosafety Law Protecting Citizens from Chaos Caused by Genetically Modified Food Products*, AL-SHOROUK (Oct. 8, 2011), http://www.shorouknews.com/news/view.aspx?cdate=08102011&id=49170ffe-e4f9-420f-9ecf-479b41a34f23.

[11] Phillip De Wet, *The Tide Turns in Favor of Biotech Foods*, MAIL&GUARDIAN (May 2, 2012), http://mg.co.za/article/2012-05-02-the-tide-turns-in-favour-of-biotech-foods.

[12] USDA FOREIGN AGRICULTURAL SERVICE, EGYPT: FOOD AND AGRICULTURAL IMPORT REGULATIONS AND STANDARDS NARRATIVE – FAIRS COUNTRY REPORT (July 28, 2009), http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Food%20and%20Agricultural%20Import%20Regulations%20and%20Standards%20-%20Narrative_Cairo_Egypt_7-28-2009.pdf.

V. Restrictions on Releasing Organisms into the Environment

Egypt has no restrictions on releasing genetically modified organisms into the environment. In March 2008, the Ministry of Agriculture approved the domestic cultivation of genetically modified corn, and the Egyptian Ministry of Agriculture allowed the importation of twenty-eight tons of genetically modified corn seeds into Egyptian markets. However, in the spring of 2009, genetically modified corn seed imports were halted so that the National Biosafety Committee (NBC) could complete the country's National Biosafety Framework (though the NBC continued to permit the planting of locally produced biotech seeds in newly reclaimed areas).[13]

VI. Restrictions on GMOs in Foodstuffs

Ministerial Resolution 770-2005, issued by the Minister of Foreign Trade, bans canned tuna that is packed in genetically modified oil.[14] It appears, however, that there are no other restrictions on GMOs in foodstuffs under Egyptian law.

VII. Liability Regime

Egyptian law provides for no liability or damages for the use of genetically modified crops or food products.

VIII. Judicial Decisions / Prominent Cases

No judicial decisions or prominent cases on this topic have been located.

[13] *Id*.

[14] Ministerial Resolution 770-2005, Al-Waqa'a Al-Masriyyah (supp.), vol. 234, p. 2, available in English on the official website of the Ministry of Foreign Trade and Industry, at http://www.mfti.gov.eg/english/laws.htm (click on Executive Regulation to Implement Import and Export Law).

England and Wales

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SUMMARY The growth and sale of genetically modified organisms (GMOs) are permitted in England and Wales, subject to an intensive authorization process that occurs primarily at the European Union (EU) level. Most legislation in England and Wales that applies to GMOs is implementing legislation for EU law. The general attitude in England is averse to genetically modified (GM) products; however, a slight shift in attitude towards GM products has recently been reported, and the UK government's policy indicates a more receptive attitude towards these products.

I. Introduction

The UK is generally viewed as having a restrictive approach towards genetically modified organisms (GMOs) and crops; however, recently there appears to have been a slow shift toward greater acceptance of them.[1] Genetically modified (GM) crops are currently not grown commercially in the UK, but they are imported. These crops are primarily used in animal feed and a few food products.[2] There is no general prohibition on the planting of GM crops, but planting them is only permitted "if a robust risk assessment indicates that it is safe for people and the environment."[3] The government has stated that if GM crops are commercially grown in the UK, it will implement "pragmatic and proportionate measures to segregate these from conventional and organic crops, so that choice can be exercised and economic interests appropriately protected."[4] In the past, there have been protests when GM crops have been planted, and anti-GM groups frequently destroy such areas. There are strict labeling rules in place that require the disclosure of GM products if they have been used.

The primary purpose of the UK's legislation and policy approach is the protection of people and the environment. Specifically, the government states that it will "only agree to the planting of GM crops, the release of other types of GM organism, or the marketing of GM food or feed products, if a robust risk assessment indicates that it is safe for people and the environment."[5] Each application for GM products is determined on a case-by-case basis, and includes

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[1] *See*, *e.g.*, Adam Vaughn, *Public Concern over GM Food Has Lessened, Survey Shows*, THE GUARDIAN (Mar. 9, 2012), http://www.theguardian.com/environment/2012/mar/09/gm-food-public-concern; Martin Robbins, *Hulk Smash GM Crops*, THE GUARDIAN (May 30, 2012) (accessed via Lexis).

[2] Department for Environment, Food & Rural Affairs (DEFRA), *Making the Food and Farming Industry More Competitive While Protecting the Environment: Genetic Modification*, GOV.UK (July 24, 2013), https://www.gov.uk/government/ policies/making-the-food-and-farming-industry-more-competitive-while-protecting-the-environment/supporting-pages/genetic-modification.

[3] *Id.*

[4] *Id.*

[5] *Id.*

consideration of all scientific information available, with the protection of public health and the environment being overriding priorities.

II. Public and Scholarly Opinion

Newspaper reports generally depict the British public as averse to the use of genetically modified crops and food products, with newspapers describing Britain as a country that is impenetrable by biotech companies interested in developing and selling GM products.[6] This strong resistance developed in the late 1990s when there was a move to introduce GM crops into the country. The public was not receptive to these crops and, over fears of cross pollination, staged demonstrations, and even pulled up known GM crops out of the ground to stop work.[7] GM crops became widely known as "frankenfoods," and the British public was strongly opposed to their growth, sale, and consumption.[8] A newspaper report reflecting on this time noted that the opposition was largely aimed at the large multinational companies that were seen as heavy-handed in their approach to the public's concern as to the safety of consuming such crops.[9] Some newspaper reports even refer to this time as the "GM wars," as activists, led on at least one occasion by a government minister, armed themselves with lawnmowers to shred crops while farmers fought back by using their tractors as battering rams.[10] 2007 and 2008 saw similar moves, when two fields planted with GM crops were subsequently raided overnight by activists, who pulled out the plants despite twenty-four-hour security guards, fencing, and court injunctions.[11] More recent GM crop cultivation has been met with some resistance, but not quite the outrage that was seen in the 1990s.[12] When anti-GM groups in 2012 threatened to pull up the experimental GM crops of public-sector scientists, the scientists recorded a video plea to the protesters, asking them not to not destroy their work. In this instance, the media were sympathetic to the scientists and condemned the activists' threat to pull up the crops as an act of vandalism.[13] Because public opinion in both Britain and the EU remains generally opposed to GM crops, giant biotech seed producer Monsanto announced that it was withdrawing all

[6] Ian Sample, *Special Report: The Return of GM: Biotech Firm Mans Barricades as Campaigners Vow to Stop Trials*, THE GUARDIAN, Feb. 16, 2008, at 6 (accessed via Lexis).

[7] Ian Sample, *The 'Frankenfood' Experiments,* THE GUARDIAN (May 28, 2012) (accessed via Lexis).

[8] Michael Cardwell, *The Release of Genetically Modified Organisms into the Environment: Public Concerns and Regulatory Responses*, 4 ENVTL. L. REV. 156–58 (2002) (accessed via Lexis).

[9] Phil Angell, Director of Corporate Communications for Monsanto, was quoted in the *New York Times* on October 25, 1998, as stating that "Monsanto should not have to vouchsafe the safety of biotech food. . . . Our interest is in selling as much of it as possible. Assuring its safety is the FDA's job." Press Release, Michael F. Jacobson, Ph.D., Executive Director, Center for Science in the Public Interest (Nov. 18, 1999), http://cspinet.org/new/genetics_fda.html .

[10] Sample, *supra* note 6.

[11] *Id*.

[12] Ian Sample, *Scientists Send Video Plea to Anti-GM Crop Campaigners*, THE GUARDIAN, May 2, 2012, at 11 (accessed via Lexis).

[13] Sample, *supra* note 7.

applications for European Union (EU) approval for its GM crops as "the EU today is effectively a conventional seed market."[14]

The resistance of the UK to GM crops has been criticized by the government's former chief science adviser, who estimated that Britain has lost around £4 billion (approximately US$7.2 billion) worth of revenue.[15] The current government, led by the Environment Secretary and Science Minister, is reportedly moving to push the UK towards eating more GM foods,[16] with the current policy statement on GM foods indicating support. Government policy states that, provided it is used safely, GM foods could be a tool with which to address global food security and climate change, and help with sustainable agricultural protection.[17]

III. Structure of Pertinent Legislation

Legislation in England and Wales governing GMOs serves to implement EU law. The Environmental Protection Act 1990 is the primary piece of legislation that addresses GMOs and provides the Secretary of State with the authority and responsibility to control the deliberate release of GMOs in England.[18]

A. Definition of GMO

Part IV, section 6 of the Environmental Protection Act 1990 defines an organism as genetically modified if

> (4) . . . any of the genes or other genetic material in the organism—
>
> **[**F4(a) have been artificially modified, or**]**
>
> (b) are inherited or otherwise derived, through any number of replications, from genes or other genetic material (from any source) which were so modified.
>
> **[**F5(4A) Genes or other genetic material in an organism are "artificially modified" for the purposes of subsection (4) above if they are altered otherwise than by a process which occurs naturally in mating or natural recombination.[19]

B. Environmental Laws

The laws that govern the environment and the use of GMOs are primarily based on EU law. As stated above, the main piece of national legislation that regulates the environment is the Environmental Protection Act, which provides the Secretary of State with the power and responsibility to control the deliberate release of GMOs in England. At the EU level, the main

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[14] Christopher Hope, *Major GM Food Company Monsanto Pulls Out of Europe*, THE TELEGRAPH, July 18, 2013, at 13 (accessed via Lexis); Sample, *supra* note7.

[15] Sample, *supra* note 6.

[16] Hope, *supra* note 14; Sample, *supra* note 7.

[17] DEFRA, *supra* note 2.

[18] Environmental Protection Act 1990, c. 43, http://www.legislation.gov.uk/ukpga/1990/43/contents.

[19] *Id*. pt. VI.

EU directive that regulates the release of GMOs across Member States is Directive 2001/18.[20] This was implemented in the national law of England through the Genetically Modified (Deliberate Release) Regulations 2002.[21]

The Department for Environment, Food and Rural Affairs (DEFRA) is the lead government department in England for protecting the environment. How it conducts these responsibilities with regard to GMOs is detailed in Part V, below.

C. Food Laws

The laws that govern the use and labeling of GMOs in food are extensive, and are again primarily based upon EU law. The EU Regulations that govern the use of GMOs in food products across Member States are Regulations 1829/2003 and 1830/2003.[22] These are implemented in England by the Genetically Modified Food (England) Regulations 2004,[23] the Genetically Modified Animal Feed (England) Regulations,[24] and the Genetically Modified Organisms (Traceability and Labelling) (England) Regulation.[25] These laws are discussed further in Part VI, below.

IV. Restrictions on Research, Production, and Marketing

Any person who wishes to release a GMO into the environment must get formal authorization to do so. Whether the decision is made at the EU or national level depends upon the purpose of the release. The EU has the authority to approve the marketing of products (including crop seeds or food), while the national government has the authority to approve the release of GMOs for research and development purposes.[26] The assessment of applications for marketing GMO products is discussed in Part VI, below.

The regulatory regime that governs GMO research is extensive. According to the government, the "strict legislation controlling the deliberate release into the environment of genetically modified organisms (GMOs)" is based on the need "to protect human health and the environment

[20] Directive 2001/18/EC of the European Parliament and of the Council art. 2(2), 2001 O.J. (L 106) 1, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:106:0001:0038:EN:PDF.

[21] Genetically Modified (Deliberate Release) Regulations 2002, SI 2002/2443, http://www.legislation.gov.uk/uksi/2002/2443/introduction/made#f00003.

[22] Regulation (EC) 1829/2003 of the European Parliament and of the Council, 2003 O.J. (L 268) 1, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:268:0001:0023:EN:PDF; Regulation (EC) 1830/2003 of the European Parliament and of the Council, 2003 O.J. (L 268) 24, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:268:0024:0028:EN:PDF.

[23] Genetically Modified Food (England) Regulations 2004, SI 2004/2335, http://www.legislation.gov.uk/uksi/2004/2335/contents/made.

[24] Genetically Modified Animal Feed (England) Regulations 2004, SI 2004/2334, http://www.legislation.gov.uk/uksi/2004/2334/contents/made.

[25] Genetically Modified Organisms (Traceability and Labelling) (England) Regulations 2004, SI 2004/2412, http://www.legislation.gov.uk/uksi/2004/2412/contents/made.

[26] DEFRA, *supra* note 2.

and ensure consumer choice."[27] To obtain consent to release GMOs into the environment for research and development, an application must be made in writing to the Secretary of State.[28] Within ten days of submitting the application, applicants must publish information in a national newspaper that includes their contact information, the description of the GMO that will be released, and the location, date, and purpose of the release.[29] The assessment process for research or release of GMOs is the responsibility of DEFRA, and undertaken by the Advisory Committee on the Release to the Environment (ACRE), an independent statutory advisory committee of experts appointed under the Environmental Protection Act.[30] The Committee advises government ministers on the "risks to human health and the environment from the release and marketing of genetically modified organisms."[31] The Committee considers a number of factors when assessing applications for GMO release or marketing, including safety factors such as toxicity, potential allergens, or the transfer of new genes to other organisms.[32]

Prior to granting an application for research involving the deliberate release of a GMO, the Committee ensures that

- the crops produced as a result of the research will not be put into the human food chain,
- a barrier of crops will be planted around the GMO crops to prevent the transfer of any GMO crops,
- any workers or farm machinery will be sanitized after handling the GMO crops, and
- the field will be left fallow for one year after the research period.[33]

V. Restrictions on Releasing Organisms into the Environment

As noted above, any person who wishes to release a GMO into the environment must get formal authorization to do so, at the EU level for marketing products, and at the national level for research and development purposes.[34] The Genetically Modified Organisms (Deliberate Release) Regulations 2002 implemented in the national law of England EU Directive

[27] DEFRA, *Genetically Modified Organisms: Applications and Consents*, GOV.UK (updated Nov. 22, 2013), https://www.gov.uk/genetically-modified-organisms-applications-and-consents.

[28] Genetically Modified (Deliberate Release) Regulations 2002, 2002/2443, ¶ 10(1), http://www.legislation.gov.uk/uksi/2002/2443/introduction/made#f00003.

[29] *Id*. ¶ 12.

[30] Environmental Protection Act 1990, c. 43, § 124, http://www.legislation.gov.uk/ukpga/1990/43/part/VI. *See also Advisory Committee on Releases to the Environment*, DEFRA, http://www.defra.gov.uk/acre/ (last visited Oct. 30, 2013).

[31] *Advisory Committee on Releases to the Environment*, DEFRA, *supra* note 30.

[32] *Id*.

[33] Advisory Committee on Releases to the Environment, Advice on an Application for Deliberate Release of a GMO for Research and Development Purposes: Advice of the Advisory Committee on Releases to the Environment to the Secretary of State Under Section 124 of the Environmental Protection Act 1990 (Sept. 5, 2011), http://www.defra.gov.uk/acre/files/acre-advice-11r801.pdf.

[34] DEFRA, *supra* note 2.

2001/18/EC regulating the release of GMOs into the environment.[35] The release of GMOs into the environment in England and Wales is subject to any conditions that the Secretary of State wishes to impose that are necessary "for the purpose of ensuring that all appropriate measures are taken to avoid damage to the environment which may arise from the activity permitted by the consent."[36]

A. Reporting Requirements

The regulations that govern GMOs require a great degree of transparency. As noted above, the application requires publishing in a national newspaper the applicant's name and address, and the location and dates of the GM crop's introduction. Any trials of GM crops require publishing in a register[37] information that essentially reveals the locations of the crops. Many biotech corporations have expressed frustration at this regulation, as they consider that to be a "gift to the activists," who learn exactly where the crops are planted and then come and destroy them. Farmers have also been intimidated by these activists and have pulled out of trials because of the fear of vandalism to the crops or concern from neighboring farmers about cross-pollination/ contamination. The requirement to provide the location of a GM crop is based on EU Directive 2001/18/EC; however, the manner in which the directive was implemented in the UK has reportedly been described by biotech firms as being "introduced in the most draconian way possibly by Michael Meacher, Tony Blair's anti-GM former environment minister. Elsewhere in Europe, fields are not pinpointed so clearly, with companies giving only the region in which a trial will take place, or submitting the details to a tightly-controlled public register."[38]

B. Inspections

The Food and Environment Research Agency (FERA), an agency of DEFRA, is responsible under Part IV of the Environmental Protection Act for enforcing legislation in cases where GMOs have been deliberately released.[39] FERA undertakes this responsibility through a program of inspections and audits of companies that have authorization to release GMOs into the environment. This Agency is also responsible for investigating any suspected unauthorized release of GMOs.[40]

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[35] Genetically Modified Organisms (Deliberate Release) Regulations 2002, SI 2002/2443, http://www.legislation.gov.uk/uksi/2002/2443/contents/made.

[36] Environmental Protection Act 1990, c. 43, § 112, http://www.legislation.gov.uk/ukpga/1990/43/section/112.

[37] The latest register, dated April 20, 2013, details the grid sites of GMO crop sites. *Sites with Consent for Part B Release of GMOs*, GOV.UK, https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/200516/partb-consent-sites-list-20130420.pdf.

[38] Sample, *supra* note 6.

[39] *GM Inspectorate*, THE FOOD & ENVIRONMENT RESEARCH AGENCY (FERA), http://www.gm-inspectorate.gov.uk/index.cfm (last visited Nov. 19, 2013).

[40] FERA, *GMO Risk Assessment and Regulation*, DEFRA, http://www.fera.defra.gov.uk/landUseSustainability/gmCrops.cfm (last visited Nov. 19, 2013).

VI. Restrictions on GMOs in Foodstuffs

A. Approval for the Sale of GM Foods

The approval regime for the evaluation and authorization of GM foods moved to the EU in 2003.[41] Safety assessments are now conducted by the European Food Safety Authority (EFSA). The EFSA provides a case-by-case review of each GM food, and assesses their safety for human consumption to ensure that the foods do "not present a risk to health, [do] not . . . mislead consumers, and [are] not of less nutritional value than the foods they are intended to replace."[42] During any investigation into the safety of GM foods, the EFSA may consult the relevant body in each Member State. In the UK, the body responsible for food safety assessment is the Food Standards Agency.[43] If the consultation in the UK also includes issues of cultivating GM crops, DEFRA must also be included.[44]

B. Labeling GM Foods

Foods containing or consisting of GMOs must comply with EU regulations that require any approved GM products to be clearly labeled.[45] This requirement includes foods derived from GM crops, even if they do not have a detectable GM content. The labeling rules are extensive and require the disclosure of the presence of any GM material in the final product.[46] This brings such products as flour and oils under the labeling requirements, as any product from a GM source must be labeled as GM. However, foods produced with GM technology, such as cheese made with GM enzymes, are not required to be labeled, nor are products from animals that have been fed with GM products, such as milk or meat from cows fed with feed containing GM products.[47]

Any intentional use of GM ingredients in foods must be labeled as GM; however, there is a threshold of 0.9% for the accidental presence of GM foods. This threshold only applies to GM food that has been approved for sale by the EU. Thus, foods that contain any GM ingredients that are not approved by the EU may not be sold in the EU.[48]

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[41] Regulation (EC) 1829/2003 of the European Parliament and of the Council, 2003 O.J. (L 268) 1, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:268:0001:0023:EN:PDF.

[42] *Evaluating GM Goods*, FOOD STANDARDS AGENCY, http://www.food.gov.uk/policy-advice/gm/evaluating (last visited Oct. 23, 2013).

[43] *Id.*

[44] *Id.*

[45] Regulation (EC) 1829/2003 of the European Parliament and of the Council, 2003 O.J. (L 268) 1, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:268:0001:0023:EN:PDF.

[46] *Id.*

[47] *Id.*

[48] *Id.*

C. Livestock Feed

The assessment and authorization of GMOs in livestock feed is the same process as for human food (discussed above in Part VI(A)) and is governed at the EU level.[49]

VII. Liability Regime

Legislation in England that governs environmental damage is largely based on EU regulations and the principal that the "polluter pays."[50] Liability for environmental damage in England is, in part, provided for by the Environmental Damage (Prevention and Remediation) Regulations.[51] These regulations place the responsibility on the "operator of an activity" that poses an environmental threat, or that has caused environmental damage, to identify when there is an imminent threat, or that damage has been caused, and to act immediately to prevent or rectify this damage.[52] Environmental liability is thus frequently described as a "backstop," with emphasis on measures to prevent pollution, and to stop threats and damage from arising.[53]

The regulations apply only to serious cases of environmental damage. Such cases include where the integrity of a site of special scientific interest has been adversely affected, surface or ground water has been adversely affected, or land has been contaminated, resulting in an adverse effect on human health.[54]

Strict liability (liability without the need to show fault) applies in cases where GMOs are used and released, including during transportation.[55] In the case of actual or imminent environmental damage, the operator is required to take steps to prevent damage, or any further damage, and notify the relevant authority,[56] which in the majority of cases is the Environment Agency. The authority then determines whether the damage is environmental damage within the terms of the regulations and identifies the operator responsible. The authority then serves a remediation notice on the operator, who must then undertake the steps specified and pay any costs claimed by the authority for the environmental damage.[57]

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[49] *Id*.

[50] DEFRA, THE ENVIRONMENTAL DAMAGE REGULATIONS, PREVENTING AND REMEDYING ENVIRONMENTAL DAMAGE (May 2009), *available at* http://webarchive.nationalarchives.gov.uk/20130321224818/http://archive.defra.gov.uk/environment/policy/liability/pdf/quick-guide-regs09.pdf.

[51] The Environmental Damage (Prevention and Remediation) Regulations 2009, SI 2009/153, http://www.legislation.gov.uk/uksi/2009/153/made.

[52] *Id*. pt. 2. *See also* DEFRA, *supra* note 50, at 2.

[53] DEFRA, *supra* note 50, at 4.

[54] Environmental Damage (Prevention and Remediation) Regulations 2009, SI 2009/153, ¶ 4, http://www.legislation.gov.uk/uksi/2009/153/made.

[55] *Id*. sched. 2. *See also* DEFRA, *supra* note 50, at 3.

[56] Environmental Damage (Prevention and Remediation) Regulations 2009, SI 2009/153, ¶¶ 4, http://www.legislation.gov.uk/uksi/2009/153/made.

[57] DEFRA, *supra* note 50, at 4.

Operators have rights of appeal that arise if they believe that

- the activity did not cause the damage
- the authority has unreasonably decided that the damage is 'environmental damage'
- the damage was the result of an act of a third party
- the operator was not at fault or negligent and the emission or event was: authorized and in accordance with a permit, or in accordance with the state of scientific knowledge (this ground for appeal is not available in Wales for damage caused by GMOs).

> Operators may also appeal against are [*sic*] mediation notice on the grounds that the contents of the remediation notice are unreasonable.[58]

General civil liability rules may also come into play, such as the laws of negligence and nuisance. There do not appear to be any reported cases that involve GMOs and civil liability in England. A law review article from 2005 notes that liability for negligence is "of limited use in the field of genetic contamination" because

> it will be difficult to prove the absence of reasonable care for preventing cross-pollination or other gene transfer. Moreover, liability is for damage to land and other property. While 'failed' crops or propagation of wild relatives of GM plants as weeds may be considered as property damage, gene flow that affects only commerciability of crops does normally not constitute an actionable damage. Pure pecuniary damage is not covered in most common law jurisdictions.[59]

VIII. Judicial Decisions / Prominent Cases

The majority of judicial decisions concerning GMOs that affect England are at the EU level and involve other countries. There appear to be no reported cases involving GMOs in England.

[58] *Id.* at 8 (referring to Environmental Damage (Prevention and Remediation) Regulations 2009, ¶ 19(3), SI 2009/153, http://www.legislation.gov.uk/uksi/2009/153/regulation/19/made).

[59] International Court of Environmental Arbitration and Conciliation, *Consultative Opinion on Liability of Public and Private Actors for Genetic Contamination of Non-GM Crops*, 7 ENVTL L. REV. 253, 253–56 (2005) (accessed via Lexis).

European Union

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SUMMARY The European Union (EU) has in place a comprehensive and strict legal regime on genetically modified organisms (GMOs), food and feed made from GMOs, and food/feed consisting or containing GMOs. The EU's legislation and policy on GMOs, based on the precautionary principle enshrined in EU and international legislation, is designed to prevent any adverse effects on the environment and the health and safety of humans and animals, and it reflects concerns expressed by skeptical consumers, farmers, and environmentalists.

GMOs and food or feed made from GMOs can be marketed in or imported into the EU, provided that they are authorized after passing strict evaluation and safety assessment requirements that are imposed on a case-by-case basis. Authorizations are granted for a ten-year period by the European Commission through a centralized procedure, as provided for in Regulation No. 1829/2003, or by national competent authorities under Directive 2001/18/EC, which regulates the intentional release of GMOs into the environment. At the EU level, the European Food and Safety Authority (EFSA) conducts the required risk assessments. GMOs, or food and feed consisting of or containing GMOs, are assigned a unique identifier and are labeled as such to ensure traceability and enable consumers to make informed choices.

Since 2001 the EU has had a de facto moratorium on GMO approvals. However, a September 2013 decision of the General Court of the EU, which requires the Commission to push forward a pending (since 2001) authorization proposal for marketing maize 1507, may put an end to the moratorium.

While marketing and importing GMOs and food and feed produced with GMOs are regulated at the EU level, the cultivation of GMOs is an area left to the EU Members. EU Members have the right to prohibit or restrict the sale or cultivation of approved GMOs based on adverse effects on health and the environment. A pending Commission proposal, as amended by the European Parliament, will give EU Members more flexibility to invoke socioeconomic grounds and impacts on local or regional environments when imposing such measures.

Liability issues and compensation schemes for individuals fall primarily within the domain of the EU Member States. In general, the EU espouses the principle that the polluter pays. The EU court system is used mainly for preliminary rulings regarding the interpretation of EU legislation on GMOs.

I. Introduction

European Union (EU) legislation defines a genetically modified organism (GMO) as "an organism, with the exception of human beings, in which the genetic material has been altered in

a way that does not occur naturally by mating and/or natural recombination."[1] The EU was prompted to adopt legislation on GMOs for two key reasons: (1) to protect human and animal health and welfare, consumer interests, and the environment, as required by articles 168 (public health), 169 (consumer protection), and 191 (environment) of the Treaty on the Functioning of the European Union (TFEU);[2] and (2) to ensure that authorized GMOs, or genetically modified (GM) products derived from a GMO may circulate freely within the EU and the European Economic Area to ensure their effective functioning.[3] Based on the precautionary principle, which is embodied in EU legislation,[4] the Cartagena Protocol on Biosafety to the Convention on Biological Diversity,[5] and other international instruments,[6] the EU and its Members are required to take measures to prevent adverse effects on human health and the environment that may occur

[1] 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, art. 2(2), 2001 O.J. (L 106) 1, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:106:0001:0038:EN:PDF. Directive 2001/18/EC was amended by Directive 2008/27/EC, 2008 O.J. (L 81) 45/EC, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:081:0045:0047:EN:PDF.

[2] Treaty on the Functioning of the European Union (TFEU), 2012 O.J. (C 326) 47, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2012:326:0047:0200:EN:PDF.

[3] Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003 on Genetically Modified Food and Feed, art. 1, 2003 O.J. (L 268) 1, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:268:0001:0023:EN:PDF.

[4] Article 191 of the TFEU, *supra* note 2, which refers to the precautionary principle without defining it, aims to safeguard the environment. The principle also applies to areas related to food, human and animal health, and consumer interests. A 2000 Communication from the Commission provides common guidelines on the precautionary principle's application, stating that it applies "where scientific evidence is insufficient, inconclusive or uncertain and there are indications through preliminary objective scientific evaluation that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the chosen level of protection." *Communication from the Commission on the Precautionary Principle*, COM (2000) 0001 final, para. 3 (Feb. 2, 2000), http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52000DC0001:EN:NOT.

[5] Cartagena Protocol on Biosafety to the Convention on Biological Diversity Concerning the Safe Transfer, Handling and Use of Living Modified Organisms Resulting from Modern Biotechnology, art. 10, Jan. 29, 2000, http://www.cbd.int/doc/legal/cartagena-protocol-en.pdf. The Cartagena Protocol on Biosafety to the Convention on Biological Diversity was signed by the Community and its Member States in 2000. The Council concluded the Protocol on behalf of the Community through the adoption of Decision 2002/628/EC: Council Decision of 25 June 2002 Concerning the Conclusion, on behalf of the European Community, of the Cartagena Protocol on Biosafety, 2002 O.J. (L 201) 48, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002D0628:EN:HTML.

[6] The precautionary principle has been consolidated in international law and the EU and its Members are bound by it. It was first recognized in Principle No. 15 of the Rio Declaration adopted at the 1992 UN Conference on the Human Environment and Development. Rio Declaration on Environment and Development, Annex I, princ. 15, UN Doc. A/CONF.151/5/Rev.1, June 3–14, 1992, 31 I.L.M. 874, http://www.unep.org/Documents.Multilingual/Default.asp? documentid=78&articleid=1163. In addition, article 3 of the 1992 UN Framework Convention on Climate Change refers to the precautionary principle. United Nations Framework Convention on Climate Change, May 9, 1992, 1771 U.N.T.S. 107, http://treaties.un.org/pages/ViewDetailsIII.aspx?&src=TREATY&mtdsg_no=XXVII~7&chapter=27&Temp=mtdsg3&lang=en. It was also referenced in the Preamble to the 1992 Convention of Biological Diversity. UN Convention on Biological Diversity, June 5, 1992, 1760 U.N.T.S. 79, http://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=XXVII-8&chapter=27&lang=en. The precautionary principle is also indirectly recognized in article 5.7 of the WTO Sanitary and Phytosanitary Agreement. WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), Apr. 15, 1994, http://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm.

owing to the intentional release of GMOs into the environment or the marketing of and import into the EU of GMOs or products made from GMOs.

Since 2001, the EU has placed a de facto moratorium on approvals of GMOs.[7] An official list of authorized GM plants is available at the EU public register of GM food and feed.[8] The United States, Canada, and Argentina have in the past challenged before the World Trade Organization (WTO) the moratorium itself; the lack of action with respect to certain products; and the practice by EU Members of resorting to a safeguard clause, which allows them to restrict or ban the cultivation of GMOs in their territories. In 2006, the EC-Biotech Panel of the WTO found against the EU for violating the Sanitary and Phytosanitary Agreement.[9] Following the September 2013 decision of the General Court, which held that the Commission failed to act on a GM cultivation request for maize 1507, the Commission complied with the Court's ruling in November 2013 by forwarding a proposal for approval of maize 1507 to the Council.[10] The application for cultivation for maize 1507 was submitted initially in 2001 by Pioneer Hi-Bred International, Inc. under Directive 2001/18/EC on the Deliberate Release of GMOs into the Environment. Maize 1507 is currently approved in the EU only for food and feed uses. A number of EU Members, such as France, Austria, and Poland are expected to oppose the proposal, while Britain, Spain, and Sweden are expected to vote in favor.[11]

GMO cultivation in the EU is limited because of concerns expressed by stakeholders about adverse effects on the environment, farmlands, and biodiversity.[12] Under the current legal regime, EU Members may restrict or totally ban cultivation in their territories of those GMOs already authorized in the EU by resorting to the safeguard clause of Directive 2001/18/EC, or by using the notification procedures under the rules on internal markets.[13]

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[7] MARIA LEE, EU REGULATION OF GMOS: LAW AND DECISION MAKING FOR A NEW TECHNOLOGY 3 (2006).

[8] As of today, the list of forty-nine authorized GMOs for food and feed use includes twenty-seven maizes, eight cottons, seven soybeans, three oilseed rapes, one sugar beet, one potato, and two microorganisms. Press Release, European Commission, Memo, Questions and Answers on EU's Policies on Cultivation and Imports of GMOs (Nov. 6, 2013), http://europa.eu/rapid/press-release_MEMO-13-952_en.htm (citing *EU Register of Authorized GMOs*, EUROPEAN COMMISSION, HEALTH AND CONSUMERS, http://ec.europa.eu/food/dyna/gm_register/index_en.cfm (last visited Dec. 11, 2013).

[9] LEE, *supra* note 7, at 189.

[10] Charlie Dunmore, *EU Prepares New GMO Maize Cultivation Approval: Draft*, REUTERS (Oct. 31, 2013), http://www.reuters.com/article/2013/10/31/us-eu-gmo-cultivation-idUSBRE99U0W820131031.

[11] *Id*.

[12] Within the EU, a number of countries—the Czech Republic, Germany, Poland, Portugal, Romania, Slovakia, and Spain—planted MON810, a genetically modified maize variety sold by Monsanto, on a commercial basis in 2008. The total acreage for the seven countries increased from 88,673 hectares in 2007 to 107,719 hectares in 2008. Spain planted more than others. However, in 2009, the EU acreage decreased by 9% compared to 2008 because of Germany's prohibition on MON810. TIMO KAPHENGST ET AL., ASSESSMENT OF THE ECONOMIC PERFORMANCE OF GM CROPS WORLDWIDE 1 (Ecologic Institute Mar. 2011), http://ec.europa.eu/food/plant/gmo/reports_studies/docs/economic_performance_report_en.pdf.

[13] *Proposal for a Regulation of the European Parliament and of the Council Amending Directive 2001/18/EC as Regards the Possibility for the Member States to Restrict or Prohibit the Cultivation of GMOs in Their Territory*, at 3, COM (2010) 375 final (July 13, 2010), http://ec.europa.eu/food/food/biotechnology/docs/proposal_en.pdf.

II. Public and Scholarly Opinion

At the request of the European Commission, a 217-page report was commissioned to evaluate the effectiveness of the legal framework on authorization of GMOs in the EU,[14] as provided for in Regulation (EC) Nos. 1829/2003[15] and 1830/2003.[16] The report was based on a questionnaire, interviews, and surveys sent to stakeholders and competent authorities.[17]

The report found that the EU authorization procedure is generally considered to achieve the objectives of the protection of human and animal health through the use of science-based risk assessment, and that there were no cases of animal or human health problems resulting from GMOs to date. Concerns were expressed that the authorization procedure may not facilitate the effective functioning of the internal market as well as it could, because of different interpretations of the tolerance level for the adventitious and technically unavoidable presence of GMOs in food and feed.[18]

On the question of whether EU GMO legislation promotes or inhibits the development of the agricultural biotechnology sector, given the fact that the main objective is to protect the environment and human health, 50% of respondents stated that the legislation is not adequate because potential benefits are not taken into account.[19]

With regard to existing labeling rules, in general farmers and retailers were satisfied. In addition, nongovernmental organizations (NGOs) and consumer organizations were in favor of the rules, which allow the general public to make an informed choice. They stated that the mandatory labeling rules should also be expanded to include livestock products and products from microorganism fermentation, which are currently excluded. NGOs expressed the need to clarify even further that the 0.9% labeling threshold is not a tolerance level but applies only to the adventitious and technically unavoidable presence of GMOs.[20]

The study also noted that, due to the lack of availability of GM-labeled products in the EU markets, it was not easy to evaluate public acceptance of GMOs.[21] However, many respondents

[14] EUROPEAN COMMISSION DIRECTORATE GENERAL FOR HEALTH AND CONSUMERS, EVALUATION OF THE EU LEGISLATIVE FRAMEWORK IN THE FIELD OF GM FOOD AND FEED (FINAL REPORT) (July 12, 2010), http://ec.europa.eu/food/food/biotechnology/evaluation/docs/evaluation_gm_report_en.pdf.

[15] Regulation (EC) No 1829/2003, *supra* note 3.

[16] Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 Concerning the Traceability and Labeling of Genetically Modified Organisms and the Traceability of Food and Feed Products Produced from Genetically Modified Organisms and Amending Directive 2001/18/EC, 2003, O.J. (L 268) 24, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:268:0024:0028:EN:PDF.

[17] EUROPEAN COMMISSION DIRECTORATE GENERAL FOR HEALTH AND CONSUMERS, *supra* note 14, at XIV.

[18] *Id*. at XV.

[19] *Id*. at 76.

[20] *Id*. at 105.

[21] *Id*. at 144.

cited the general negative public attitude and suggested that consumers should be made more aware of the scientific risk assessment that GMOs undergo under the authorization procedure.[22]

A US Council on Foreign Relations paper, *The Regulation of GMOs in Europe and the United States: A Case-Study of Contemporary European Regulatory Politics*, provides a comparison of the EU and US approaches to GMOs.[23] The authors opine that the EU's current regulatory approach on GMOs is more restrictive than that of the US, which in general was more stringent until the mid-1980s. The authors examine the divergent approaches between the two partners from the perspective of the cultural approach to GMOs and on economic grounds. They cite the case of Monsanto's introduction of nonlabeled GM food in the EU and its purchase of a large number of seeds as an influential factor that to a large extent shaped the negative attitude of EU consumers and farmers against GMOs. The authors conclude that the EU's adoption of strict rules on GMOs have less to do with culture or economic reasons and more with a different overall approach to risk management during the last decade and more reliance on the precautionary principle.[24]

Finally, a study prepared for the European Commission by the Swiss Federal Institute of Technology and the University of Reading, titled *Assessment of the Economic Performance of GM Crops Worldwide*, provides an overview of financial and other benefits from growing GMOs.[25] The study provides an overview of the economic performance of GM crops worldwide based on the current state of knowledge; it also examines the direct economic and other effects of growing GM crops that influence farmers' income, as represented by the following economic parameters: crop yields, seed costs, pesticide and herbicide costs, labor costs, and gross margins.[26]

III. Structure of Pertinent Legislation

The EU and its twenty-eight Members share competence in the areas related or affected by the use of GMOs—that is, the environment, consumer protection, and public health matters.[27]

At the EU level, two basic and comprehensive pieces of legislation regulate various aspects of GMOs: Regulation No. 1829/2003 on Genetically Modified Food and Feed,[28] and Directive 2001/18/EC on the Deliberate Release into the Environment of Genetically Modified Organisms

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[22] *Id*. at 52.

[23] DIAHANNA LYNCH & DAVID VOGEL, THE REGULATION OF GMOS IN EUROPE AND THE UNITED STATES: A CASE-STUDY OF CONTEMPORARY EUROPEAN REGULATORY POLITICS (Council on Foreign Relations Apr. 5, 2001), http://www.cfr.org/ agricultural-policy/regulation-gmos-europe-united-states-case-study-contemporary-european-regulatory-politics/p8688.

[24] *Id*.

[25] KAPHENGST ET AL., *supra* note 12, at II.

[26] *Id*.

[27] TFEU, *supra* note 2, art. 4.

[28] Regulation (EC) No. 1829/2003, *supra* note 3, art. 1.

and Repealing Council Directive 90/220/EEC.[29] Directive 2001/18/EC was amended by Directive 2008/27/EC.[30] Implementation of Directive 2001/18/EC is also closely linked with Directive 91/414/EEC on the Placing of Plant Protection Products on the Market, as amended.[31] In addition, Regulation (EC) No 1830/2003 governs traceability and labeling requirements of GMOs and amends Directive 2001/18/EC[32] concerning the traceability and labeling of GMOs and the traceability of food and feed products produced from GMOs and amending Directive 2001/18/EC.

Both Regulations No. 1829/2003 and 1830/2003 are directly applicable in the legal systems of the twenty-eight EU Member States. Concerning Directive 2001/18/EC, EU Members are required to comply with the requirements contained therein, but are free to choose the method of implementation. Exports of GMOs in general are governed by Regulation (EC) No. 1946/2003 on Transboundary Movements of Genetically Modified Organisms.[33]

Moreover, in 2010, the Commission prepared its Guidelines for the Development of National Co-existence Measures to Avoid the Unintended Presence of GMOs in Conventional and Organic Crops.[34] The guidelines urge EU Members to develop their own national measures based on their specific local and regional conditions in order to avoid the unintended presence of GMOs in conventional and organic crops.[35] Another recommendation is the possibility for EU Members to exclude GMO cultivation from large areas of their territory (GM-free areas) to avoid the unintended presence of GMOs in conventional and organic crops. In such a case, EU Members should show that purity from GMO contamination cannot be achieved through other methods.[36]

[29] Directive 2001/18/EC, *supra* note 1.

[30] Directive 2008/27/EC of the European Parliament and of the Council of 11 March 2008 Amending Directive 2001/18/EC on the Deliberate Release into the Environment of Genetically Modified Organisms, as Regards the Implementing Powers Conferred on the Commission, 2008 O.J. (L 81) 45, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:081:0045:0047:EN:PDF.

[31] Directive 91/414/EEC on the Placing of Plant Protection Products on the Market, 1991 O.J. (L 230) 1, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1991:230:0001:0032:EN:PDF, *as amended by* Commission Directive 1999/80/EC, O.J. (L 210) 13, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1999:210:0013:0015:EN:PDF.

[32] Regulation (EC) No. 1830/2003, *supra* note 16.

[33] Regulation (EC) No. 1946/2003 of the European Parliament and of the Council of 15 July 2003 on Transboundary Movements of Genetically Modified Organisms, 2003 O.J. (L 287) 1, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:287:0001:0010:EN:PDF.

[34] Commission Recommendation of 13 July 2010 on Guidelines for the Development of National Co-existence Measures to Avoid the Unintended Presence of GMOs in Conventional and Organic Crops, 2010 O.J. (C 200) 1, http://ecob.jrc.ec.europa.eu/documents/CoexRecommendation.pdf.

[35] *Id*. at 4.

[36] *Id*. at 5.

IV. Restrictions on Research, Production, and Marketing

A. Research

Directive 2001/18/EC requires EU Members and the Commission to ensure that research on GMOs is conducted prior to their being released into the environment or placed on the market.[37] Each EU Member must allocate appropriate funding for such research, in compliance with budgetary procedures. Researchers must be granted access to all pertinent materials, provided that intellectual property rights are fully respected.[38]

At the EU level, in 2010 the Commission published a compendium titled *A Decade of EU-Funded GMO Research*, which summarizes the results of fifty research projects assessing the safety of GMOs for the environment and for animal and human health between 2001 and 2010. The projects were funded to the amount of €200 million (approximately US$ 273 million) from the EU.[39]

B. Cultivation

Member States have the right to invoke the safeguard clause, as provided for in article 23 of Directive 2001/18/EC, and to temporarily ban the cultivation or use of a GMO in their territory.[40] Members have to substantiate their actions with new or additional information that an authorized GMO can pose a threat to the environment or human health. The Commission may ask EFSA to provide a scientific opinion on the information provided by Member States. In these cases, the GMO Panel of EFSA assesses the new evidence provided by the Member State in the form of a scientific opinion. A number of EU Members have prohibited individual authorized GMOs or GM seeds, including Austria, Hungary, France, Greece, Germany, and Luxembourg, all of which ban the cultivation of the GM maize MON810. Poland has enacted legislation that prohibits the marketing of all GM seeds. Since 2002 the Commission has repeatedly proposed that national safeguard measures on GMO cultivation be repealed, with no success.

In addition, Austria, Hungary, and Luxembourg have notified the Commission of their ban on the cultivation of the approved Amflora potato.[41] The company BASF Plant Science GmbH had submitted two authorization procedures for the Amflora potato that were subsequently adopted by the Commission in March 2010: (a) a procedure based on Directive 2001/18/EC for cultivation and use for industrial purposes, and (b) a procedure based on Regulation 1829/2003 for the production of animal feed. On December 13, 2013, the General Court (GC)—based on a legal action instituted by Hungary in 2010 and assisted by Austria, France, Luxembourg, and

[37] Directive 2001/18/EC, *supra* note 1, Recital 21.

[38] *Id*.

[39] EUROPEAN COMMISSION, EUROPEAN RESEARCH AREA, FOOD, AGRICULTURE & FISHERIES & BIOTECHNOLOGY, A DECADE OF EU-FUNDED GMO RESEARCH (2001–2010), http://ec.europa.eu/research/biosociety/pdf/a_decade_of_eu-funded_gmo_research.pdf.

[40] Directive 2001/18/EC, *supra* note 1, art. 23, para. 1.

[41] Press Release, European Commission, *supra* note 8.

Poland—annulled the Amflora authorization decisions adopted by the Commission. The GC held that the Commission had failed to comply with the authorization procedures by not requesting the opinion of the competent committees composed of representatives of the Member States.[42] In this regard, the GC concluded that "if the Commission had complied with those rules, the result of the procedure or the content of the contested decisions could have been substantially different."[43]

In July 2010, at the request of a number of EU Members, the Commission introduced a proposal for a Regulation to amend the safeguard clause of Directive 2001/18/EC and to expand the legal grounds on GMO cultivation. When adopted, EU Member States will be able to restrict or prohibit GMO cultivation in part or all of their territory without recourse to the safeguard clause. While this proposal was approved by the Parliament in 2011, no agreement could be reached in the Council. The Parliament's amendment includes grounds related to local and regional environments, such as the prevention of the development of pesticide resistance among weeds and pests, the prevention of negative impacts on the local environment due to changes in agricultural practices connected with the cultivation of GMOs, and the maintenance of local biodiversity. It also includes grounds relating to socioeconomic impacts, such as the need to preserve seed purity and to protect the diversity of agricultural production. These measures will stay in force for a period of five years.[44]

C. Authorization Under Directive 2001/18/EC

The general objective of Directive 2001/18/EC is to harmonize the national legislation on GMOs in the twenty-eight EU Member States in compliance with the precautionary principle and to ensure that individuals and companies take necessary measures to safeguard the environment and human health prior to intentionally releasing into the environment a GMO or placing in the EU market a GMO or GM products.

The procedure for authorization for a GMO to be placed on the market is similar to that provided under Regulation No. 1829/2003. An individual or a company must notify the competent authority of a Member State where the GMO will be marketed for the first time. In turn, the competent authority will send the dossier with necessary documentation to the competent authorities of the EU Members and the Commission.[45] The notification will contain (a) the information required in Annexes III and IV and results obtained from research on the potential impact on the environment and human health; (b) an environmental risk assessment pursuant to Annex II, section D, which must take into account the direct and indirect effects and immediate and delayed effects on human health and the environment, as prescribed in Annex II; (c)

[42] Press Release No. 160/13 of the General Court, The General Court Has Annulled the Commission's Decisions Concerning Authorisation to Place on the Market the Genetically Modified Potato Amflora (Dec. 13, 2013), http://europa.eu/rapid/press-release_CJE-13-160_en.htm.

[43] *Id.*

[44] *See* Article 26b added by the European Parliament to the Proposal for a Regulation of the European Parliament and of the Council Amending Directive 2001/18/EC as Regards the Possibility of the Member States to Restrict or Prohibit the Cultivation of GMOs in Their Territory, 2013 O.J. (C 33) E/350.

[45] Directive No. 2001/18/EC, *supra* note 1, art. 13, para. 1.

conditions for placing the item on the market; (d) consent for a period of up to ten years; (e) a monitoring plan; and (f) a proposal for labeling and packaging, and a summary of the dossier.[46]

The Directive requires that the EU Members designate the competent authority or authorities to be in charge of monitoring the implementation of its provisions.[47] The role of the national authorities is to examine notifications and carry out control and other measures.[48] The competent authority is required to prepare an assessment report within ninety days after receiving the notification, which will indicate whether or not the GMO is to be placed on the market and the conditions thereof.[49]

V. Restrictions on Releasing GMOs into the Environment

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 requires EU Members to ensure that the intentional release of GMOs into the environment is possible only if it is in compliance with part B of Directive 2001/18/EC. "Deliberate release" is defined as "any intentional introduction into the environment of a GMO or a combination of GMOs for which no specific containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment."[50] In 2012, the Court of Justice held that the "location of release" of genetically modified organisms is determined by all the information relating to the location of the release submitted by the notifier to the competent authorities of the Member State on whose territory the release will occur.[51]

Intentional release into the environment may occur, provided that prior to the release of a GMO or GMOs an individual in charge submits a notification to the national competent authority of the Member State where the release will take place. In addition, the following items must be prepared or obtained:

- A dossier containing information, as provided for in Annex III of the Directive
- An environmental risk assessment consistent with the requirements of Annex II of the Directive
- Explicit consent prior to release

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[46] *Id*. art. 13, para. 2.

[47] *Id*. art. 4, para. 4.

[48] *Id*. art. 4, paras. 4 & 5.

[49] *Id*. art. 14, paras. 1–3.

[50] Directive 2001/18/EC, *supra* note 1, art. 2(3).

[51] Case C-552/07, 2001/18 Judgment of the Court (Fourth Chamber) of 17 February 2009 (reference for a preliminary ruling from the Conseil d'État (France))—Commune de Sausheim v. Pierre Azelvandre, http://curia.europa.eu/juris/document/document.jsf;jsessionid=9ea7d2dc30dbc3b29977a1134bcfb724c51ba52915a8.e34KaxiLc3qMb40Rch0SaxuMaNb0?text=&docid=72933&pageIndex=0&doclang=en&mode=lst&dir=&occ=first&part=1&cid=929369.

- A monitoring plan pursuant to the requirements of Annex III designed to detect the adverse effects of the GMO(s) on human health and the environment [52]
- Disclosure of information to the public on the release and results of the release and provide a reasonable time frame for the public to respond.[53]

If there are modifications or unintended changes to the release of a GMO into the environment, or additional information emerges on new risks that could potentially affect human health after the competent authority has granted its consent, the individual in charge must take measures to avert such risks and must notify the competent national authorities.[54]

VI. Restrictions on GMOs in Foodstuffs

Regulation No. 1829/2003 prohibits placing on the EU market a GMO for food use, or a food containing or consisting of GMOs or food products produced "from" GMOs, unless an authorization is granted. Food and feed produced "with" a GMO are excluded from the scope of this Regulation. The critical determining factor is whether material derived from a GMO is present in the food or feed; thus, if a GMO is not present in the food or feed, then such food or feed does not fall within the purview of Regulation 1829/2003.[55]

To be marketed in or imported into the EU, any food or feed produced from a GMO, or food or feed that contains or consists of GMOs, must be previously authorized and must not cause any adverse effects on human and animal health and the environment, mislead consumers, or differ from the food it intends to replace to the extent that nutritionally it does not offer any advantage to consumers.[56]

A. Authorization Under Regulation No. 1829/2003

An application for authorization, which is sent to the national competent authority, must include the name and address of the applicant, designate the food and its specifications, and meet inter alia the following requirements:

- Comply with Annex II to the Cartagena Protocol on Biosafety, if applicable
- Describe in detail the method of production and manufacturing
- Include a copy of independent peer-reviewed studies
- State that the food will not raise ethical or religious concerns of consumers

[52] Directive 2001/18/EC, *supra* note 1, art. 6.

[53] *Id*. art. 9.

[54] *Id*. art. 8, para. 1.

[55] Reg. (EC) No. 1829/2003, *supra* note 3, Recital 16.

[56] *Id*. art. 4, para. 1.

- Indicate conditions for placing the GMO food or feed on the market
- Provide for post-market monitoring, if the food is intended for human consumption[57]

The application must also include the required technical dossiers in compliance with Annexes III and IV of Directive 2001/18/EC, a copy of the authorization decision if the GMO was approved under Part C of Directive 2001/18/EC, and a monitoring plan to evaluate environmental effects in compliance with this Directive.[58]

Within fourteen days the national competent authority must inform the applicant that it received the application and forward all information to the EFSA. It must also inform the Commission and the EU Members of the application. The EFSA must then provide its opinion within a six-month deadline. The Commission, within three months after receiving the opinion, must submit to the Standing Committee on the Food Chain and Animal Health a draft of its decision. The draft must include all the appropriate and relevant information, including the name of the authorization holder and the unique identifier that is given to each GMO approved in the EU.

The Commission's decision is published in the *Official Journal of the European Union*.

B. Labeling and Traceability Requirements

The right of consumers to information is recognized in article 169 of the TFEU. Based on this article, the EU is obliged to promote this right in legislation affecting consumers.[59]

Labeling requirements apply to foods delivered to the final consumers or mass caterers in the EU that either contain or consist of GMOs, or are produced from or contain ingredients produced from GMOs. Regulation No. 1829/2003 requires that the phrase "genetically modified" or "produced from genetically modified [name of the organism]" must appear clearly next to the ingredient list.[60] When there is no list of ingredients the same phrase must appear on the label. In the case of nonpackaged food, the same labeling must appear on the food display or next to it.[61] When GMOs are found in minute amounts in conventional food due to their adventitious or technically unavoidable presence during cultivation, harvest, or transport, the food is not subject to labeling provided that the amount present is less than 0.9%.[62] Similar labeling requirements are contained in Directive 2001/18/EC.[63]

[57] *Id*. art. 5, paras. 1–3.

[58] *Id*. art. 5, para. 5(a), (b).

[59] TFEU, *supra* note 2.

[60] Reg. No. 1829/2003, *supra* note 3, art. 13, para. 1(a).

[61] *Id*. art. 13, para. 1(c).

[62] *Id*. art. 12, para. 2.

[63] Directive 2001/18/EC, *supra* note 1, arts. 21 & 26.

The traceability and labeling of GMOs and the traceability of food and feed products produced from GMOs are governed by Regulation (EC) No. 1830/2003.[64] Directive 2001/18/EC introduced a general traceability requirement, which obliges EU Members to ensure traceability at all stages of marketing for GMOs.

When placing on the market a product consisting of or containing GMOs, operators (individuals or legal entities) are required to provide in writing two important items: (a) a statement that the product contains or consists of GMOs, and (b) the unique identifier assigned to each GMO (a numeric or alphanumeric code) in order to facilitate the identification of the GMO. This type of information must be forwarded from one operator to the next.[65]

When placing on the market a product for food and feed produced from GMOs, operators must forward to those who will receive them, the following:

- Each food ingredient produced from GMOs
- Each of the feed materials or additives produced from GMOs
- If there is no list of ingredients, an indication that the product is produced from GMOs[66]

Operators must ensure that prepackaged products consisting of or containing GMOs carry a label with the words, "[t]his product contains genetically modified organisms" or "this product contains genetically modified [name of the organism]."[67] For non-prepackaged products offered to consumers, the same phrase must appear on the product or where the product is displayed.[68]

The traceability or labeling requirements do not apply when there are traces of GMOs of no higher than 0.9%, and the traces of GMOs are "adventitious or technically unavoidable."[69]

VII. Liability Issues

In general, liability issues arising from the use of food or feed produced from GMOs or consisting of or containing GMOs fall within the legal systems of the EU Member States, where producers and importers of GMOs may be subject to the general rules of civil liability.[70] The specific question of liability and compensation schemes for damage due to the presence of

[64] Regulation (EC) No. 1830/2003, *supra* note 16.

[65] *Id*. arts. 1, 6, 8.

[66] *Id*. art. 6, para. 1.

[67] *Id*. art. 4, para. 6(a).

[68] *Id*. art. 4, para. 6(b).

[69] *Id*. art. 7 (amending Directive 2001/18/EC art. 21).

[70] *See also* para. 2.5 of Commission Recommendation of 13 July 2010 on Guidelines for the Development of National Co-existence Measures to Avoid the Unintended Presence of GMOs in Conventional and Organic Crops, 2010 O.J. (C 200) 1, at 5, http://ecob.jrc.ec.europa.eu/documents/CoexRecommendation.pdf.

GMOs in non-GM crops is the subject of a lengthy study by the European Centre of Tort and Insurance Law, which provides information on the individual EU Member States.[71]

At the EU level, the scope of Directive 2004/35/EC on Environmental Liability with Regard to the Prevention and Remedying of Environmental Damage[72] may be relevant to this discussion. The general EU principle is that the polluter pays for environmental damage. Directive 2004/35/EC extends the damage or imminent threats of damage to the environment—including protected species and their natural habitats, water, and land—due to a number of activities, including any deliberate release into the environment, transport, or placing on the market of GMOs, as defined by Directive 2001/18/EC.[73] The scope appears to be limited, however, since biodiversity found in farmlands appears to fall outside its scope, unless such farmland is located within a protected area.[74]

In 2011, the Court of Justice of the EU rendered a preliminary ruling in a case that could be influential in paving the way for biotech companies to be held accountable for GMOs released into the environment that cause damage to individuals. In this case, the Court upheld the right to compensation of a German beekeeper who instituted legal proceedings against the State of Bavaria when Monsanto's GM corn (MON810), which was cultivated for research purposes in plots owned by the State of Bavaria, contaminated his honey. The Court found that the beekeeper suffered an economic loss by not being able to sell his product and that he ought to be compensated.[75]

In 2013, the Parliament, in amending the Commission's proposal on restrictions to the cultivation of GMOs, added a new article 26c related to liability requirements. This new article requires EU Members to establish a general mandatory system of financial liability and financial guarantees, such as through insurance. Such a liability and insurance scheme will be applicable to all operators and will ensure that the polluter pays for the unintended effects of damage that may occur due to the deliberate release or marketing of GMOs.[76]

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[71] EUROPEAN CENTRE OF TORT AND INSURANCE LAW, LIABILITY AND COMPENSATION SCHEMES FOR DAMAGE RESULTING FROM THE PRESENCE OF GENETICALLY MODIFIED ORGANISMS IN NON-GM CROPS REPORTS (Bernhard A. Koch ed., Apr. 2007).

[72] Directive 2004/35/CE of the European Parliament and of the Council of 21 April 2004 on Environmental Liability with Regard to the Prevention and Remedying of Environmental Damage, 2004 O.J. (L 143) 56, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:143:0056:0075:EN:PDF.

[73] *Id*. Annex III(11).

[74] CANADIAN INSTITUTE FOR ENVIRONMENTAL LAW AND POLICY, GMO STATUTORY LIABILITY REGIMES: AN INTERNATIONAL REVIEW 11 (2004).

[75] Rady Ananda, *EU High Court Rules on GMO Contamination; Opens Door to Biotech Liability*, FOOD FREEDOM (Sept. 6, 2011), http://foodfreedom.wordpress.com/2011/09/06/eu-court-rules-on-gmo-contamination/.

[76] Article 26c, Position of the European Parliament Adopted at First Reading on July 5, 2011, with a View to the Adoption of Regulation (EU) No. …/2011 of the European Parliament and of the Council Amending Directive 2001/18/EC as Regards the Possibility for the Member States to Restrict or Prohibit the Cultivation of GMOs in Their Territory, 2013 O.J. (C 33) E/350.

At the international level, the purpose of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity is to ensure protection during the transfer, handling, and use of living modified organisms that may adversely affect the conservation of natural habitats or species. However, its application is limited to the transboundary movement of GMOs.[77] In the implementation of article 27 of the Cartagena Protocol, the Nagoya-Kuala Lumpur Supplementary Protocol was adopted. It establishes international rules and procedures for liability and a means of redress in case of damage to biological diversity as a result of living modified organisms.[78] The Supplementary Protocol applies to damage resulting from living modified organisms that originate in transboundary movement and extends to the following:

- Direct use as food or feed, or for processing
- Contained use
- Intentional release into the environment[79]
- Damage resulting from any authorized use of the living modified organisms[80]

The EU ratified the Supplementary Protocol on March 21, 2013, by depositing the instruments of approval.[81]

VIII. Judicial Decisions / Prominent Cases

The EU court system has played a significant role in the area of GMOs, by interpreting provisions of EU legislation on GMOs and by ensuring effective implementation when the Commission initiates action against certain EU Members for failing to comply with its requirements. The most recent judgment delivered in September 2013 terminates the EU's de facto moratorium by requiring the Commission to take further action in a long-pending application for authorization.

[77] Cartagena Protocol, *supra* note 5.

[78] Nagoya–Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety, Oct. 15, 2010, http://bch.cbd.int/protocol/NKL_text.shtml.

[79] 1999/468/EC: Council Decision of 28 June 1999 laying down the Procedures for the Exercise of Implementing Powers Conferred on the Commission, 1999 O.J. (L 184) 23, http://eur-lex.europa.eu/Notice.do?val=329852:cs&lang=en&list=335859:cs,329853:cs,329852:cs,&pos=3&page=1&nbl=3&pgs=10&hwords=&checktexte=checkbox&visu=#texte. Article 2, para. (b) and article 5 of this decision specify that when the Commission adopts implementing legislation concerning the health and safety of humans, animals, and plants it has to do so with the assistance of a regulatory committee, composed of representatives of the EU Members and chaired by a representative of the Commission. The representative prepares a draft, which is voted on by the representatives of the Member States.

[80] *Id*. art. 3(1) & (2).

[81] Press Release, United Nations Decade on Biodiversity, Convention on Biological Diversity Communique, European Union Approves Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress Montreal (Mar. 26, 2013), http://www.cbd.int/doc/press/2013/pr-2013-03-26-eu-en.pdf.

A. Case T-164/10: Pioneer Hi-Bred International, Inc.

On September 26, 2013, the General Court issued a judgment in Case T-164/10 and found against the Commission for failing to act under Directive 2001/18/EC by not submitting to the Council a proposal under article 5(4) of the Comitology Decision 1999/468/EC.[82] The facts of this case involve the 2001 application for authorization of maize 1507 for cultivation by Pioneer Hi-Bred International, Inc. under Directive 2001/18/EC on the deliberate release of GMOs into the environment.

In 2007, Pioneer Hi-Bred International initiated a first action before the General Court of the European Union against the Commission for its failure to present a decision of authorization of that maize for vote to the Regulatory Committee. The General Court closed the case when the Commission presented a proposal for a draft authorization decision to the Regulatory Committee in February 2009. The Committee, however, failed to deliver an opinion. In 2010, following the absence of an opinion by the Regulatory Committee, Pioneer Hi-Bred International launched a second action for failure to act (Case T-164/10) against the Commission for not having referred to the Council a proposal for an authorization decision, in compliance with the comitology procedure applicable at the time. In November 2013 the Commission complied with the General Court's decision.[83]

B. Judgment in Case C-442/09: Karl Heinz Bablok and Others v. Freistaat Bayern

In 1998 Monsanto received authorization for marketing the genetically modified MON810 maize. As noted in Part VII, above, a beekeeper in the State of Bavaria, Germany, claimed that his honey and the pollen that he produced for sale as a food supplement on land close to public land where MON810 maize was being cultivated for research purposes became contaminated by MON810 and therefore he could not sell his honey and pollen. He instituted a legal action before the Bavarian Higher Administrative Court. The latter requested that the EU Court of Justice issue a preliminary ruling as to whether the mere presence of genetically modified maize pollen that has lost its ability to reproduce prohibited the beekeeper from placing his products on the market without authorization.[84]

The EU Court determined that products such as honey and food supplements containing GMO pollen constitute foodstuffs containing ingredients produced from GMOs within the meaning of the regulation. Therefore, it concluded that the pollen in question was "produced from GMOs" and that it constituted an "ingredient" of the honey and pollen-based food supplements. The Court also noted that foodstuffs containing ingredients produced from GMOs are subject to the

[82] Case T‑164/10, Pioneer Hi-Bred International, Inc., Judgment of the General Court (Seventh Chamber), Sept. 26, 2013, http://curia.europa.eu/juris/document/document_print.jsf?doclang=EN&text=&pageIndex=0&part=1&mode=lst&docid=142241&occ=first&dir=&cid=127901.

[83] *See* Dunmore, *supra* note 10.

[84] Case C-442/09, Karl Heinz Bablok and Others v. Freistaat Bayern, Judgment of the Court (Grand Chamber), Sept. 6, 2011, http://curia.europa.eu/juris/document/document.jsf?text=&docid=109143&pageIndex=0&doclang=en&mode=lst&dir=&occ=first&part=1&cid=780715.

authorization procedure, irrespective of whether the GMO is introduced intentionally or adventitiously.[85]

[85] *Id*. para. 109.

France

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SUMMARY The production and sale of certain genetically modified organisms (GMOs) are legal in France, but are subject to very restrictive rules. French legislation regarding GMOs falls within the broader framework of European regulation, but France has supplementary national rules that provide additional restrictions. These rules are particularly focused on the potential release of GMOs in the environment, and on labeling requirements for GM products. French legislation also requires that the location of GM crops be public information, and establishes strict liability rules regarding the possible release of GM crops into non-GM fields. As a result of both public hostility to GMOs and these legal restrictions, there are currently no GM crops grown in France, even though France imports substantial amounts of GMOs from abroad.

I. Introduction

France is considered to be very restrictive on genetically modified organisms (GMOs).[1] Though some aspects of French legislation ostensibly promote a balanced approach to GMOs by guaranteeing the "freedom to consume and produce with or without genetically modified organisms,"[2] French authorities have generally not been favorable to agricultural biotechnology.[3] Although France remains very active in GMO laboratory research,[4] and imports large amounts of GM crops to feed its livestock,[5] there is a complete absence of commercially grown GMOs in French agriculture,[6] and the last French open-field GMO research project ended in July 2013.[7]

II. Public and Scholarly Opinion

French opinion is quite divided on the issue of genetically modified organisms. The U.S. Department of Agriculture notes that "[m]arket acceptance of plant biotech products is high among stakeholders that need the products, i.e., importers, animal feed compounders, as well as poultry/swine/cattle ranchers who all depend upon largely imported soybean products."[8]

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[1] USDA FOREIGN AGRICULTURAL SERVICE, GAIN REPORT: FRANCE: AGRICULTURAL BIOTECHNOLOGY ANNUAL 2, 14–15 (June 10, 2013).

[2] CODE DE L'ENVIRONNEMENT art. L531-2-1.

[3] FRANCE: AGRICULTURAL BIOTECHNOLOGY ANNUAL, *supra* note 1, at 14–15.

[4] *Id.* at 5.

[5] *Id.* at 8–11.

[6] *Id.* at 8.

[7] Marc Mennessier, *Fin de la recherche sur les OGM en France*, LE FIGARO (July 15, 2013), http://www.lefigaro.fr/environnement/2013/07/15/01029-20130715ARTFIG00419-il-n-y-a-plus-de-recherche-sur-les-ogm-en-france.php.

[8] FRANCE: AGRICULTURAL BIOTECHNOLOGY ANNUAL, *supra* note 1, at 23–24.

Furthermore, many French scientists are favorable to continued biotechnology research.[9] However, anti-GMO nongovernmental organizations are very active in France,[10] and a strong majority of consumers are hostile to GMOs. Indeed, a 2012 poll found that 79% of respondents said they were worried about the presence of GMOs in foodstuffs,[11] and a 2011 poll found that 80% opposed the cultivation of GMO crops in open fields.[12]

III. Structure of Pertinent Legislation

A. EU Regulations

As France is a member of the European Union, its laws and regulations regarding genetically modified organisms are strongly affected by EU-level rules.[13] As is the case for other members of the EU, France's national legislation is subordinate to EU regulation regarding consumer and environmental protection.[14] However, as these are issues of shared competence between the EU and Member States, the French government has some latitude to enact and implement its own laws and regulations, as long as these are consistent with EU-level regulations.[15] Furthermore, the European authority in charge of approving GMOs may seek advice from national food safety agencies.[16] In the case of France, the food safety agency is the Agence nationale de sécurité sanitaire, de l'alimentation, de l'environnement et du travail (National Agency on Sanitary, Food, Environmental, and Workplace Safety).[17]

B. Domestic Provisions

In France, at the national level, GMOs are principally regulated under a comprehensive 2008 law on this matter.[18] The provisions of this law were inserted in the French legal codes.[19] Most of the provisions of the 2008 law were incorporated into the Code de l'environnement (Environmental Code), but several were inserted in the Code rural (Rural Code) and a couple of

[9] *Pour un débat raisonné sur les OGM*, LE MONDE (Sept. 27, 2012), http://www.lemonde.fr/idees/article/2012/09/27/pour-un-debat-raisonne-sur-les-ogm_1766673_3232.html.

[10] FRANCE: AGRICULTURAL BIOTECHNOLOGY ANNUAL, *supra* note 1, at 15.

[11] IFOP, *Les Francais et les OGM* (Sept. 2012), http://www.ifop.com/media/poll/1989-1-study_file.pdf.

[12] IFOP, *Les Francais et les OGM* (Dec. 2011), http://www.ifop.com/media/poll/1697-1-study_file.pdf.

[13] FRANCE: AGRICULTURAL BIOTECHNOLOGY ANNUAL, *supra* note 1, at 13.

[14] Consolidated Version of the Treaty on the Functioning of the European Union, arts. 2 & 4, 2012 O.J. (C 326), 50–51, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12012E/TXT:EN:PDF.

[15] *Id.* art. 2.

[16] Regulation (EC) 1829/2003 of the European Parliament and of the Council, arts. 6(2)(b) & 18(3)(b), 2003 O.J. (L 268) 8, 14, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:268:0001:0023:EN:PDF.

[17] CODE DE LA SANTE art. 1313-1.

[18] Loi 2008-595 du 25 juin 2008 relative aux organismes génétiquement modifiés [Law 2008-595 of June 25, 2008, regarding genetically modified organisms], JOURNAL OFFICIEL DE LA REPUBLIQUE FRANÇAISE [J.O.] [OFFICIAL GAZETTE OF THE REPUBLIC OF FRANCE], June 26, 2008, p. 10218.

[19] *Id.*

provisions were inserted in the Code de la santé publique (Public Health Code) and the Code de la recherche (Research Code).[20] Most of the substance of the 2008 law was put in the Environmental Code, but certain provisions dealing with the production, transportation, and sale of agricultural products were placed in the Rural Code. The provisions that were inserted in the Public Health Code have to do with GMOs in medication, and the article modifying the Research Code (art. 16 of the 2008 law) has to do with the evaluation of research and higher education.[21] For greater ease of reference, the present report will cite to relevant provisions in these codes rather than to the 2008 law.

One of the key elements of French legislation on GMOs is the establishment of a special high council called the Haut Conseil des biotechnologies (High Council for Biotechnologies).[22] This high council is comprised of a number of experts and representatives from the political sphere, from community organizations, and from relevant advocacy and professional groups. It is divided into a scientific committee, and an economic, ethical, and social committee.[23] As will be seen below, many French legislative provisions require the governmental authorities to seek advice from the Haut Conseil des biotechnologies on the topic of GMOs.

At the local level, many mayors and town councils have tried to issue regulations prohibiting the cultivation of genetically modified organisms within their jurisdictions, but such measures have been systematically challenged by the prefects and struck down by administrative courts.[24]

C. Definition of GMO

The French Code de l'environnement (Environmental Code) defines a genetically modified organism as an "organism, the genetic material of which has been modified in a manner other than by natural reproduction or recombination [*organisme dont le matériel génétique a été modifié autrement que par multiplication ou recombinaison naturelles*]."[25] This definition is essentially identical to the one given at the European level by Directive 2001/18/EC of the European Parliament and of the Council, according to which a genetically modified organism "means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination."[26]

IV. Restrictions on Research, Production, and Marketing

French law requires that GMOs only be grown, sold, or used "in a manner that respects the environment and public health, agricultural structures, local ecosystems, production and

[20] *Id.*

[21] *Id.*

[22] CODE DE L'ENVIRONNEMENT art. L531-3.

[23] *Id.*

[24] BIRGIT MÜLLER, LA BATAILLE DES OGM, COMBAT VITAL OU D'ARRIÈRE-GARDE? 88 (Ellipses, 2008).

[25] CODE DE L'ENVIRONNEMENT art. L531-1.

[26] Directive 2001/18/EC of the European Parliament and of the Council, art. 2(2), 2001 O.J. (L 106) 4, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:106:0001:0038:EN:PDF.

commercial channels labeled as 'without genetically modified organisms,' and with full transparency."[27] To further these goals, French law subjects the research, production, and sale of GMOs to prior governmental authorization, and subjects the cultivation of GM crops to transparency rules.

A. The Use of GMOs in Confined Environments

The use of genetically modified organisms in confined spaces for research and educational purposes is subject to prior authorization from the ministry in charge of research.[28] The ministry must receive the opinion of the Haut Conseil des biotechnologies before giving its authorization.[29] Prior authorization is not necessary if potential risks for public health or the environment are inexistent or negligible, but the use of genetically modified organisms must be declared to the government even in such circumstances.[30] The use of genetically modified organisms in confined environments for industrial purposes is subject to the same rules, except that the competent authority is the local prefect rather than the ministry in charge of research.[31]

B. Deliberate Release of GMOs in Open Environments for Research Purposes

The deliberate release of genetically modified organisms in open environments for research purposes is also subject to prior approval by the government (usually through the ministry in charge of the environment, although other executive bodies may be competent with regard to certain specific products).[32] The government must receive the opinion of the Haut Conseil des biotechnologies regarding possible risks for public health and the environment before granting an authorization.[33] The government must also consult the public at large through a website.[34] Furthermore, the government must provide advance notice to the local authorities of areas where genetically modified organisms are to be disseminated.[35] The authorization to disseminate genetically modified organisms may be amended or suspended if new information justifies it.[36]

C. Distribution and Release of GMOs for Commercial Purposes

The marketing and release of genetically modified organisms for commercial purposes are subject to prior approval by the government (generally through the ministry in charge of the environment, although other government bodies may be competent with regard to certain

[27] CODE DE L'ENVIRONNEMENT art. L531-2-1.

[28] *Id.* arts. L532-3 & R532-5.

[29] *Id.*

[30] *Id.*

[31] *Id.* art. L532-25.

[32] *Id.* arts. L533-3 & R533-1.

[33] *Id.* art. L533-3-3.

[34] *Id.* art. L533-3-2.

[35] *Id.* art. L533-3-4.

[36] *Id.* art. L533-3-5.

specific products).[37] Before granting its approval, the government must evaluate potential risks for the environment and for public health, and obtain the opinion of the Haut Conseil des biotechnologies.[38] Article L533-6 of the Code de l'environnement states that an authorization issued by another EU Member State or by the competent EU authority in compliance with EU regulations is equivalent to a French governmental approval.[39] However, even after an authorization has been issued, the government can suspend or prohibit the use or sale of a genetically modified product if new or additional information brings to light risks to the environment or public health.[40]

D. Transparency Rules for GM Crops

In addition to the authorization requirements described above, French legislation requires that the location where genetically modified crops are being grown be declared to the government.[41] The government authorities then enter this information into a national register, which is made available online.[42] This rule has been controversial, as the availability of this information can be used by anti-GMO activists seeking to destroy the crops in question.[43] French lawmakers therefore attempted to establish a compromise: on the one hand, failure to declare the location of genetically modified crops is punishable by a €30,000 fine (approximately US$41,000) and six months of incarceration,[44] and on the other hand, the destruction or degradation of authorized GM crops is punishable by a €75,000 fine (approximately US$102,600) and two years of incarceration.[45] The destruction or degradation of GM crops that were planted for research purposes is punished even more severely, by a €150,000 fine (approximately US$205,000) and three years of incarceration.[46]

In addition to informing the government authorities, a GM farmer is required to notify the farmers of surrounding land of his intention to plant GM crops, prior to sowing.[47]

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[37] *Id.* arts. L533-5 & R533-25.

[38] *Id.* arts. L533-5 & L533-5-1.

[39] *Id.* art. L533-6.

[40] *Id.* art. 533-8.

[41] CODE RURAL [RURAL CODE] art. L663-1.

[42] *Id.* art. L663-1.

[43] Luc Bodiguel et al., *Coexistence of Genetically Modified, Conventional, and Organic Crops in the European Union: National Implementation*, *in* THE REGULATION OF GENETICALLY MODIFIED ORGANISMS: COMPARATIVE APPROACHES 172 (Luc Bodiguel & Michael Cardwell eds., Oxford University Press, 2010).

[44] CODE RURAL art. L671-14.

[45] *Id.* art. L671-15.

[46] *Id.*

[47] *Id.* art. L663-1.

V. Restrictions on Releasing Organisms into the Environment

Given the potential for GMOs to spread through the environment, the coexistence of genetically modified, conventional, and organic crops has become an important focus of regulation in Europe.[48] The use and sale of GMOs are authorized at the EU level in accordance with Directive 2001/18/EC of the European Parliament and of the Council with regards to deliberate release of GMOs into the environment.[49] European regulations prevent Member States from outright prohibiting the cultivation or sale of GMOs.[50] However, Member States are allowed to take "appropriate measures to avoid the unintended presence of GMOs in other products."[51] France has therefore enacted certain measures towards that purpose.

As mentioned earlier, article 531-2-1 of the Environmental Code requires that GMOs only be grown, sold, or used "in a manner that respects the environment and public health, agricultural structures, local ecosystems, production and commercial channels labeled as 'without genetically modified organisms,' and with full transparency."[52] The same article guarantees the "freedom to consume and produce with or without genetically modified organisms."[53] In order to promote these goals, French legislation aims to limit the spread of GMOs to areas outside of their intended fields. Article L663-2 of the Code rural thus states that the cultivation, harvest, storage, and transportation of genetically modified crops are subject to certain technical rules.[54] These rules are established by the minister in charge of agriculture, after consultation with the Haut Conseil des biotechnologies and the minister in charge of the environment.[55] Article L663-2 highlights rules governing distances between genetically modified crops and other fields as being particularly important to avoid the accidental presence of GMOs in other crops.[56] Violations of these technical rules on separation distances can be punished by particularly serious penalties: article L671-15 of the Code rural states that the penalty for non-compliance is a fine of €75,000 and two years of incarceration.[57] However, it is important to note that these distance rules, which are supposed to be set by the Minister of Agriculture, have not yet been defined.[58]

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[48] Margaret Rosso Grossman, *Coexistence of Genetically Modified, Conventional, and Organic Crops in the European Union: The Community Framework*, *in* THE REGULATION OF GENETICALLY MODIFIED ORGANISMS: COMPARATIVE APPROACHES, *supra* note 43, at 122–62.

[49] Directive 2001/18/EC of the European Parliament and of the Council, art. 2(2), 2001 O.J. (L 106) 1, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:106:0001:0038:EN:PDF.

[50] Grossman, *supra* note 48, at 131.

[51] *Id.* (citing the 2001/18/EC Deliberate Release Directive, art. 26a(1), as amended by the (EC) 1829/2003 Food and Feed Regulation).

[52] CODE DE L'ENVIRONNEMENT art. L531-2-1.

[53] *Id.*

[54] CODE RURAL art. L663-2.

[55] *Id.*

[56] *Id.*

[57] *Id.* art. L671-15.

[58] Bodiguel et al., *supra* note 43, at 173.

In addition to the rules discussed above, French legislation provides for "biological monitoring" of French territory, to observe the health of plant life and watch for possible unforeseen consequences of agricultural practices, including the use of GMOs.[59] This is coordinated by the Comité de surveillance biologique du territoire (Committee for Biological Monitoring of the Territory), which was created for that purpose by the 2008 law on GMOs.[60] This body gives an annual report to both houses of the French Parliament (the Senate and the National Assembly), and can alert the government if it finds that certain unintended consequences require special measures to be taken.[61]

VI. Restrictions on GMOs in Foodstuffs

The sale of GMOs is authorized at the European level in accordance with Regulation (EC) 1829/2003 of the European Parliament and of the Council with regards to food for human or animal consumption.[62] Additionally, rules on traceability and labeling are established through Regulation (EC) 1830/2003 of the European Parliament and of the Council concerning traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.[63]

Beyond those EU-level regulations, some restrictions exist at the national level as well. Specifically, the marketing of foodstuffs containing genetically modified organisms is subject to prior governmental approval, as explained earlier.[64] Furthermore, genetically modified products are subject to specific labeling rules. Some of these rules are set at the European level, as mentioned above. Specifically, food containing more than 0.9% of GMO per ingredient must be labeled as containing GMOs (food containing less that 0.9% of GMO per ingredient is only exempt from labeling to the extent that the GMO presence is adventitious or technically unavoidable).[65] Similar rules apply to feed meant for livestock.[66] In addition to these European rules, a 2012 French decree provides for a special, optional label for GMO-free products.[67] The "GMO-free" label can only be placed on the front of a product's packaging when the GMO-free

[59] CODE RURAL art. L251-1.

[60] Loi 2008-595 du 25 juin 2008 relative aux organismes génétiquement modifiés [Law 2008-595 of June 25, 2008, Regarding Genetically Modified Organisms] art. 9, J.O., June 26, 2008, p. 10221.

[61] CODE RURAL art. L251-1; *see also* the webpage of the Ministry of Agriculture regarding the Comité de surveillance biologique du territoire, http://agriculture.gouv.fr/CSBT-missions-et-avis,1645 (last visited Sept. 27, 2013).

[62] Regulation (EC) 1829/2003 of the European Parliament and of the Council, 2003 O.J. (L 268) 1, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:268:0001:0023:EN:PDF.

[63] *Id.* at 24 Grossman, *supra* note 48, at 129.

[64] *See* Part IV, "Restrictions on Research, Production, and Marketing," *supra*.

[65] Grossman, *supra* note 48, at 129; Regulation (EC) 1829/2003, *supra* note 62, arts. 12–13.

[66] Regulation (EC) 1829/2003, *supra* note 62, arts. 24–25.

[67] Décret n° 2012-128 du 30 janvier 2012 relatif à l'étiquetage des denrées alimentaires issues de filières qualifiées « sans organismes génétiquement modifiés » [Decree No. 2012-128 of January 30, 2012, Regarding the Labeling of Food Products Emanating from Channels Deemed "Without Genetically Modified Organisms"], J.O., Jan. 31, 2012, p. 1770.

ingredient makes up 95% of the product. Otherwise, the "GMO-free" label can only be placed in the ingredients list at the back of the packaging, and must be written in the same size, color and font as the ingredients list.[68] This labeling is separate from other, voluntary labeling initiatives that were previously put in place by the food industry and supermarket chains,[69] but these voluntary private initiatives must now comply with the 2012 decree on "GMO-free" labeling.[70]

VII. Liability Regime

The Code rural provides that a GMO cultivator will be automatically liable when the accidental spread of his or her GMO causes economic harm to a non-GMO cultivator.[71] This liability arises even if the accidental spread occurred through no fault of the GMO cultivator.[72] Under this law, if a non-GMO cultivator ends up having to label his or her crops as GM because of contamination from a nearby field, he or she can seek compensation for the resulting depreciation of his or her crop's value.[73] The Code rural also makes it mandatory for any cultivator who uses GMOs to obtain liability insurance coverage.[74] In practice, this severely limits the use of GMOs in agriculture, as insurance companies have been unwilling to cover GM crops in France.[75]

Furthermore, though this scenario has not happened yet, it may be possible for someone whose property was adversely affected by another's use of GMOs to sue for damages through an "abnormal neighborhood disturbance" theory under European law.[76]

VIII. Judicial Decisions / Prominent Cases

As GMOs are highly controversial in France, they have been at the heart of several judicial cases over the last several years. Some of the most publicized cases have involved the trials of anti-GMO activists charged with the destruction or degradation of GM crops. The first incident of GM crop destruction by a group of *faucheurs volontaires* (volunteer reapers), as these activists call themselves, happened in 1997.[77] Many more similar incidents happened in the following years, to the point where these activists could claim to have destroyed 70% of GM research fields in 2004.[78] Many of these incidents have led to arrests and criminal charges against some

[68] *Id.* arts. 8–13.

[69] FRANCE: AGRICULTURAL BIOTECHNOLOGY ANNUAL, *supra* note 1, at 19–20.

[70] Décret n° 2012-128 du 30 janvier 2012 art. 2.

[71] CODE RURAL art. L663-4.-I.

[72] *Id.*

[73] *Id.*

[74] *Id.* art. L663-4.-III.

[75] MÜLLER, *supra* note 24, at 124.

[76] BROU AKPOUÉ, DROIT PRIVÉ DE L'ENVIRONNEMENT 46–50 (Atelier National de Reproduction des Theses, 2009).

[77] MÜLLER, *supra* note 24, at 116.

[78] *Id.* at 117.

of these anti-GMO activists, but courts have been very inconsistent in their treatment of such cases, with results ranging from acquittals to prison sentences.[79] Despite these inconsistencies, however, and despite the fact that such trials have been used by activists to publicize their cause, defending against these criminal charges has also proven quite costly for anti-GMO groups over the long run. This has lead many of them to conduct their destructions of GM crops at night in order to avoid detection and arrest.[80]

Aside from these trials, there have been other judicial decisions that have had a significant impact on the regulation of GMOs in France. The most recent case is a decision from the French Conseil d'Etat (Council of State, France's highest court for administrative matters) of August 1, 2013.[81] In this case, the Conseil d'Etat was asked to rule on the legality of a French governmental decree prohibiting the use of a GM maize called MON 810. Although the MON 810 maize had been approved by the European Commission, the French government had the authority to ban it in case of a situation of emergency or a "serious risk to human health, animal health, or the environment" under article 34 of European Regulation 1829/2003.[82] However, the Conseil d'Etat ruled that neither a serious risk, nor a situation of emergency, existed with regard to MON 810, and that the government therefore exceeded its authority in banning it. Thus, this decision essentially legalized that particular GMO in France. This result was received quite negatively by the French public, and the government expressed its intention to seek other ways to maintain the moratorium on MON 810 maize.[83]

[79] *Id.* at 121.

[80] *Id.* at 121–23.

[81] CE, Aug. 1, 2013, *Association génerale des producteurs de maïs (AGPM) et autres*, http://www.conseil-etat.fr/fr/selection-de-decisions-du-conseil-d-etat/ce_1er_aout_2013_association_generale-producteurs_mais_agpm_et_autres.html.

[82] Regulation (EC) 1829/2003 of the European Parliament and of the Council, 2003 O.J. (L 268) 19, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:268:0001:0023:EN:PDF.

[83] Sophie Louet, *Le Conseil d'Etat suspend l'interdiction du maïs MON810* [*The Conseil d'Etat Suspends the Ban on MON810 Maize*], REUTERS (Aug. 1, 2013), http://fr.reuters.com/article/topNews/idFRPAE97004F20130801?pageNumber=2&virtualBrandChannel=0&sp=true.

Germany

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SUMMARY Germany discourages the cultivation of genetically modified (GM) crops to the extent possible within the already stringent European Union (EU) legislation on genetically modified organisms (GMOs). Germany imposes strict liability for accidental contamination with GMOs, and has tough and methodically enforced controls over the release of GMOs. In 2009 Germany banned MON810 maize from cultivation for agricultural purposes, even though the EU has approved it for release into the environment. The only other GM plant that the EU has approved for release, the Amphora potato, is currently not being grown as a crop in Germany. Since 2013 the experimental planting of GM plants has also been abandoned owing to persistent vandalism.

German public opinion is averse to food that contains GMOs, and German scholarly councils have stressed the environmental risks emanating from the release of GMOs. German scientists, on the other hand, would like to continue researching GMOs. In 2010 the German Federal Constitutional Court held that the restrictive German legislation is compatible with German constitutional principles.

I. Introduction

German legislation on genetically modified organisms (GMOs) operates within the framework of European Union (EU) law. Germany transposed EU Directive 18/2001 on the release of GMOs into the environment[1] in 2004 by reforming the German Act on Genetic Engineering,[2] while EU Regulation 1829/2003 on GMOs in foodstuffs took effect in Germany with its enactment at the EU level in 2003.[3] Within the limits of EU law, the German laws and regulations on GMOs are characterized by restrictiveness, complexity, and rigorous requirements that allow for effective governmental oversight and enforcement and hold polluters responsible through civil liabilities. As a result of these stringencies and of the banning of MON810 maize in 2009,[4] no genetically modified (GM) plants have been cultivated in Germany in recent years as agricultural crops.[5] Even the number of plantings for research purposes has dwindled from about five hundred in the

[1] *See* EU report.

[2] Gesetz zur Neuordnung des Gentechnikrechts [Act Restructuring the Genetic Engineering Act], Dec. 21, 2004, BUNDESGESETZBLATT [BGBL.] 2005 I at 186.

[3] *See* EU Report.

[4] Verwaltungsgericht [Regional Administrative Court] Braunschweig, May 4, 2009, docket no. 2 B 111/09, *available at* https://www.juris.de (by subscription).

[5] INES HÄRTEL, HANDBUCH DES FACHANWALTS AGRARRECHT 726 (2012).

year 2000 to seventy-five in 2012.[6] In 2013 no experimental planting was carried out owing to persistent sabotage by anti-GMO activists.[7]

II. Public and Scholarly Opinion

The German position on GMOs is characterized by a population that is averse to GM plants in foodstuffs and apprehensive of the release of GMOs into the environment on the one hand, and a scientific community that does not want to lose its ability to research GMOs[8] on the other. Some farmers also would find GM planting useful, in particular planting of the banned MON810 maize.[9] The German Farmer's Association, on the other hand, advises against the cultivation of GM crops in response to the popular aversion to foods containing GMOs.[10]

The German debate on GMOs has been robust, with the adversaries of GMOs invoking the precautionary principle of protecting the environment against unforeseeable risks,[11] while proponents of GMO research and GM plant cultivation stress economic advantages, particularly for the third world,[12] and the lack of substantiated harm from GMOs[13] after decades of intensive research.[14] In 2008 a Council of Environmental Scholars weighed in on this debate, holding that a total avoidance of pollution from GM planting is technically not feasible.[15] The Council sees the risks of GMOs as a threat not so much to human health as to the environment, citing the risks

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[6] BERLIN-BRANDENBURGISCHE AKADEMIE DER WISSCHENSCHAFTEN, GRÜNE GENTECHNOLOGIE. AKTUELLE WISSENSCHAFTLICHE WIRTSCHAFTLICHE UND GESELLSCHAFTLICHE ENTWICKLUNGEN – THEMENBAND DER INTERDISZIPLINÄREN ARBEITSGRUPPE "GENTECHNOLGIEBERICHT": KURZFASSUNG 11 (2013), *available at* http://www.gentech nologiebericht.de/bilder/Kurzfassung_Internet.pdf; AGRICULTURAL BIOTECHNOLOGY. CURRENT SCIENTIFIC, ECONOMIC AND SOCIETAL DEVELOPMENTS – SUPPLEMENT OF THE INTERDISCIPLINARY RESEARCH GROUP "GENE TECHNOLOGY REPORT": SUMMARY 27 (2013), *available at* http://www.gentech nologiebericht.de/bilder/Kurzfassung_Internet.pdf.

[7] Justus Bender, *Regenwürmer würden reichen,* FRANKFURTER ALLGEMEINE ZEITUNG, at 3 (Feb. 15, 2014).

[8] BERLIN-BRANDENBURGISCHE AKADEMIE DER WISSCHENSCHAFTEN, SUPPLEMENT "GM PLANTS" (2007): SUMMARY AND CORE STATEMENTS 3 (Oct. 2008), *available at* http://www.gentechnologiebericht.de/gen/bilder/Summary_GM%20plants_2007.pdf.

[9] Jost Maurin, "*Die Technik wird verteufelt*," TAZ, DIE TAGESZEITUNG, Feb. 19, 2014, at 4, *available at* http://www.taz.de/Landwirt-ueber-den-Anbau-von-Gen-Mais-/!133307/.

[10] HÄRTEL, *supra* note 5, at 726.

[11] Bundesverfassungsgericht [Federal Constitutional Court], Nov. 24, 2010, ENTSCHEIDUNGEN DES BUNDESVERFASSUNGSGERICHTS [BVerfGE] 128 /1 [hereafter BVerfGE 128/1] ¶ 135, https://www.bundesverfassungsgericht.de/entscheidungen/2010/11/24; *see also* Press Release, Federal Constitutional Court, Application for Judicial Review in the Matter of the Genetic Engineering Act is Unsuccessful (Nov. 24, 2010), https://www.bundesverfassungsgericht.de/pressemitteilungen/bvg10-108en.html.

[12] BERLIN-BRANDENBURGISCHE AKADEMIE, *supra* note 6.

[13] *Grüne Gentechnik*, BUNDESMINISTERIUM FÜR ERNÄHRUNG UND LANDWIRTSCHAFT, http://www.bmel.de/DE/Landwirtschaft/Pflanze/Gentechnik/gentechnik_node.html (last visited Mar. 4, 2014).

[14] HÄRTEl, *supra* note 5, at 759.

[15] SACHVERSTÄNDIGENRAT FÜR UMWELTFRAGEN, UMWELTGUTACHTEN 2008, at 502 (2008), http://www.umweltrat.de/SharedDocs/Downloads/DE/01_Umweltgutachten/2008_Umweltgutachten_BTD.pdf?__blob=publicationFile.

of contaminating natural areas and non-GM crops, dissemination through vertical and horizontal gene transfers, toxic effects on nontargeted organisms, and effects possibly resulting from changes in agricultural practices.[16]

III. Structure of Pertinent Legislation

In Germany the research, production, marketing, and release of GM plants are governed by the Genetic Engineering Act.[17] The Act deals with GMOs in both plants and animals but does not deal with food or feed containing GMOs. The latter are governed by directly applicable EU regulations, primarily Regulations 1829/2003 on GMOs in food or feed and 1830/2003 on the traceability and labeling of GMOs and foods containing them,[18] with German legislation limited to the implementation of the EU rules.[19] Nor does the German Genetic Engineering Act deal with GMOs in pharmaceutical products. The Act on Pharmaceutical Drugs[20] and various best-practice guidelines for producing pharmaceutical drugs apply to these.[21]

Germany first enacted the Genetic Engineering Act in 1990, yet with respect to GM plants the current version is based on a reform of 2005[22] that transposes EU law, particularly Directive 2001/18, which deals with the release of GMOs into the environment. Germany had delayed transposition until the European Court of Justice declared Germany to be tardy in the discharge of its obligation.[23] In compliance with the European mandate, the 2005 version of the Act became somewhat less restrictive than it formerly had been.[24] Yet after the 2005 reform, Germany had to reform the Act again in 2006 and 2008 to live up to EU requirements.[25]

The purposes of the Genetic Engineering Act are threefold. First, the Act aims to protect the environment and human and animal health from risks emanating from GMOs. Second, the Act aims to guarantee that genetically modified, conventionally produced, and organically grown

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[16] *Id*. at 489.

[17] Gentechnikgesetz [Genetic Engineering Act], repromulgated Dec. 16, 1993, BGBL. I at 2066, http://www.gesetze-im-internet.de/gentg/index.html.

[18] *See* EU Report.

[19] EG-Gentechnik-Durchführungsgesetz [EC Genetic Engineering Implementation Act], June 22 2004, BGBL. I S. 1244, http://www.gesetze-im-internet.de/eggentdurchfg/BJNR124410004.html.

[20] Arzneimittelgesetz [Act on Pharmaceutical Drugs], repromulgated Dec. 12, 2005, BGBL. I at 3394, *as amended*, translation at http://www.gesetze-im-internet.de/englisch_amg/index.html.

[21] ARZNEIMITTELRECHT 1022 (Stefan Furhmann & Andreas Fleischfresser eds., 2010).

[22] Gesetz zur Neuordnung des Gentechnikrechts [Act Restructuring the Genetic Engineering Act], Dec. 21, 2004, BGBL. 2005 I at 186.

[23] Case C-420/03, Commission v. Germany, July 15, 2004, *available at* http://curia.europa.eu/juris/documents.jsf?pro=&lgrec=en&nat=or&oqp=&lg=&dates=&language=en&jur=C%2CT%2CF&cit=none%252CC%252CCJ%252CR%252C2008E%252C%252C%252C%252C%252C%252C%252C%252C%252C%252Ctrue%252Cfalse%252Cfalse&num=C-420%252F03&td=ALL&pcs=Oor&avg=&page=1&mat= or&jge=&for=&cid=548564 (click on "Curia" to select language).

[24] 128 BVerfGE 1 ¶ 25.

[25] SACHVERSTÄNDIGENRAT, *supra* note 15, at 496.

products, particularly food and feed, can be grown, produced, and marketed in coexistence with each other. Third, the Act creates the legal framework for research on and the development and economic use of GMOs.[26]

Germany introduced the goal of coexistence between GM, non-GM, and organic plantings in 2005, in compliance with the common-market orientation of Directive 18/2001. At the same time, Germany changed the definition of a GMO to protect against environmental pollution through GM plants. Since then the German Act has defined a GMO not only as an organism whose genetic material has been altered in a way that does not occur naturally by mating or natural recombination, but also as one that has come into existence through mating or natural recombination between a GMO and a non-GM organism.[27] Accordingly, plants that were accidentally bred through recombination with GMOs also fall under the restrictions of the Genetic Engineering Act, such as requiring a permit to be marketed or released. [28] Rulings in German court cases based on this expanded definition have led to the destruction of many contaminated plantings.[29]

The Genetic Engineering Act has a chapter on working with GMOs in enclosed spaces and another on marketing GMOs and releasing them into the environment. In addition, administrative procedural rules are provided, as are a civil liability regime and penal provisions. Given the preeminence of EU law in authorizing GM plants for release and marketing, the German Law focuses primarily on safety rules that must be observed in lab work or individual releases, particularly plantings, both experimental and agricultural.[30] Yet in banning MON810 Germany has set aside the EU prerogative to approve GMOs[31] under the German justification that this GMO poses a risk to health and the environment.[32]

The Genetic Engineering Act is implemented by the German states[33] and, at the federal level, by the Federal Office of Consumer Protection and Food Safety.[34] The latter acts as an advisory and at times supervisory agency for the state agencies, and together they carry out the numerous approval processes that are required in researching, producing, and using GMOs. The Federal Office also acts as a liaison in consultations with and notification of EU authorities and the other

[26] Genetic Engineering Act § 1.

[27] *Id.* § 3 no. 3.

[28] *Id*. § 3 no. 6; BVerfGE 128/1 ¶ 8.

[29] Martin Brandt, *Vernichtung gentechnisch veränderter Pflanzen*, JURIS-PR (2012), *available at* http://www.juris.de (by subscription); Bayerischer Verwaltungsgerichtshof [Bavarian Higher Administrative Court], Nov. 14, 2013, http://www.gesetze-bayern.de/jportal/portal/page/bsbayprod.psml?doc.id=MWRE130003444&st=ent&showdoccase=1&paramfromHL=true#focuspoint.

[30] *Grüne Gentechnik*, *supra* note 13.

[31] Verwaltungsgericht [Regional Administrative Court] Braunschweig, May 4, 2009, docket no. 2 B 111/09, *available at* http://www.juris.de (by subscription).

[32] Genetic Engineering Act § 16(1).

[33] *Id.* § 31.

[34] BUNDESAMT FÜR VERBRAUCHERSCHUTZ [FEDERAL OFFICE OF CONSUMER PROTECTION AND FOOD SAFETY], http://www.bvl.bund.de/DE/Home/homepage_node.html (last visited Mar. 4, 2014).

EU member states, and thereby carries out the German part of these intertwined responsibilities.[35]

Germany also has a Central Committee for Biological Safety, which is composed of scientists from various disciplines. The Committee participates in approval proceedings, advises the government on policy, monitors safety, and issues annual reports.[36]

Even though genetic engineering law is federal in Germany, the states still have some possibilities of implementing their own policies, be it through strict enforcement of the federal laws, protection of state parks and forests, or state-wide quality labels of origin. The State of Baden-Württemberg, for instance, uses all these techniques to discourage GM planting and prides itself on being a GMO-free region.[37]

IV. Restrictions on Research, Production, and Marketing

Germany has a dense regulatory regime for the research and production of GMOs in enclosed spaces. The operator of the installation is responsible for proper risk assessment and adequate containment measures, and there is tight governmental oversight. The rules for handling GMOs in laboratories or production facilities differ, depending on the riskiness of the activity. Compliance is ensured through numerous reporting duties and the appointment of an internal monitoring official.[38] In addition, permits are required for all installations and processes, and these are awarded only to properly qualified operators.[39] If GMOs are released into the environment in the course of experimental plantings, the general rules on the release of GMOs apply (see Part V, below).[40]

The rules for marketing GMOs fall largely into the domain of EU law, in that a GMO or a product containing GMOs must be approved at the EU level before being marketed throughout the EU. The approval process is governed by Directive 2001/18, and if the GMO or GMO product concerns food or feed, by Regulation 1829/2003. At times an applicant may ask for approval under both regimes if the GMO is to be used for crop cultivation as well as food or

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[35] *See* EU report.

[36] ACTIVITY REPORT OF THE CENTRAL COMMITTEE ON BIOLOGICAL SAFETY 2010, GERMAN FEDERAL OFFICE OF CONSUMER PROTECTION AND FOOD SAFETY (Aug. 18, 2011), http:www.bvl.bund.de/EN/06_Genetic_Engineering/ZKBS/05_Taetigkeitsberichte/Ordner_Taetigkeitsberichte/Taet_2010.html?nn=1414304 (click on the link to access the report).

[37] Press Release, Baden-Wuerttemberg, Ministerium für Ländlichen Raum und Verbraucherschutz, Bonde begrüßt Ablehnung von Gen-Mais durch Europaparlament und Bundesländer (Jan. 17, 2014), http://www.baden-wuerttemberg.de/de/service/presse/pressemitteilung/pid/bonde-begruesst-ablehnung-von-gen-mais-durch-europaparlament-und-bundeslaender/.

[38] Genetic Engineering Act § 6.

[39] *Id.* §§ 7–14.

[40] GENTECHNIK UND LEBENSMITTEL: DIE WICHTIGSTEN FAKTEN, BUNDESMINISTERIUM FÜR ERNÄHRUNG, LANDWIRTSCHAFT UND VERBRAUCHERSCHUTZ, http://www.bmelv.de/SharedDocs/Downloads/Landwirtschaft/Pflanze/GrueneGentechnik/OhneGTSiegel/HintergrundInformationenOhneGTSiegel.pdf?__blob=publicationFile (last visited Mar. 7, 2014).

feed.[41] In compliance with the EU common-market principles, Germany permits the importation of the approximately fifty GMOs that the EU has approved as food or feed.[42] Of the two EU-approved GMOs for release into the environment, Germany allows the marketing of only the Amphora potato, having banned MON810 maize in 2009, as explained above (see Part I).

V. Restrictions on Releasing Organisms into the Environment

Although the approval of GMOs for release into the environment is primarily governed by EU law, the Member States still have much discretion over fashioning the regulatory systems to protect the environment from undue risk when GM plants are cultivated, and Germany has made use of this discretionary power to create a very stringent system to control any GMO releases.

Releases are permitted only after governmental approval is obtained, and the permit criteria are as strict as those for the operator of a GMO-processing installation in that they insist on highly qualified operators and observance of state of the art techniques. Moreover, the law requires that approval be granted only after balancing and weighing the benefits of a release with any potential risks,[43] and this statutory criterion is subject to conflicting interpretations.[44]

The locations register for GM plantings is an important tool for transparency and governmental oversight, yet it also allows anti-GMO activists to locate plantings for the purpose of destroying them.[45] Growers of GMO crops must notify the authorities three months prior to seeding or planting, and again three days prior to each release. The information must include a description of the GMO and the exact location of its release.[46] Portions of the register are available to the public on the Internet, whereas personal data are released only if the requester has a justifiable interest. The published portion of the register specifies the exact location of each planting,[47] and researchers who conduct experimental plantings hold this publicity responsible for the destruction of virtually all research plantings since 2004.[48]

To avoid contamination of adjacent plantings or the environment at large, various best practices must be observed in the cultivation of GM plants, among them separation zones for GM maize. The distance of a field of GM maize from a planting of conventional maize must be at least one hundred fifty meters, and from an organic planting of maize, three hundred meters.[49] These are

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[41] Felix Sinn & Thomas Gross, *Schwerpunktbereich: Einführung in das Gentechnikrecht*, JURISTISCHE SCHULUNG 797 (2011).

[42] GENTECHNIK UND LEBENSMITTEL, *supra* note 40.

[43] Genetic Engineering Act § 16(1).

[44] Sinn & Gross, *supra* note 41, at 797.

[45] Bender, *supra* note 7.

[46] Genetic Engineering Act § 16a.

[47] *Id.*

[48] Bender, *supra* note 7.

[49] Gentechnik-Pflanzenerzeugungsverordnung [GM Crop Production Regulation], Apr.7, 2008, BGBL. I at 655, Anhang [Appendix].

the only prescribed separation zones, yet there has been discussion on the need for a ten-kilometer zone to protect the beehives of beekeepers (see Part VIII, below, for the EU honey decision and its impact), and the State of Baden-Württemberg may be in the process of requiring a one-kilometer zone to protect nature preserves.[50]

The authorities of the states enforce the laws and regulations on the release of GMOs so as to avoid accidental contamination of adjacent fields and harvested crops.[51] For this purpose, the authorities may prohibit plantings[52] and destroy contaminated plantings (see Part VIII, below). Some states pride themselves on the thoroughness of their oversight. The State of Baden-Württemberg, for instance, tests crops methodically for contamination.[53]

VI. Restrictions on GMOs in Foodstuffs

In compliance with the EU common-market principles, Germany permits the importation of the approximately fifty GMOs that the EU has approved for food or feed.[54] Currently, GMOs are mostly used in Germany in feed for livestock. Little food labeled as containing GMOs is marketed for human consumption in Germany, yet given the EU labeling rules, the ingredients of such foods may still contain GMOs below the threshold level of 0.9%. In addition, dietary supplements and additives in such foods may contain GMOs, since these are not subject to the requirements of Regulations 1829/2003 on GMOs in food or feed and Regulation 1830/2003 on the traceability and labeling of GMOs and foods containing them.[55]

To market food that is free of even traces of GMOs, Germany allows the use of a label indicating "No Genetic Engineering" (*Ohne Gentechnik*). Under the auspices of the German authorities, this label is administered by an association that supports GMO-free food.[56] In order to qualify for this label, a food must be free of traces of GMOs, and the additives and dietary supplements in such foods must also be free of GMOs. For meat and meat products to qualify for the label, the animals must have been fed a GMO-free diet for lengthy periods before slaughter.[57]

VII. Liability Regime

The Act on Genetic Engineering contains a strict liability regime for damage caused by GMOs.[58] Damages are capped at €85 million (about US$117,050,000), and the operators of research or

[50] Press Release, *supra* note 37.

[51] Sinn & Gross, *supra* note 41, at 800.

[52] Genetic Engineering Act § 26(4).

[53] Press Release, *supra* note 37.

[54] GENTECHNIK UND LEBENSMITTEL, *supra* note 40.

[55] *See* EU Report.

[56] VERBAND LEBENSMITTEL OHNE GENTECHNIKE, http://www.ohnegentechnik.org/.

[57] EG-Gentechnik-Durchführungsgesetz [EC Genetic Engineering Implementation Act], June 22, 2004, BGBl. I S. 1244, *as amended*, § 3a, http://www.gesetze-im-internet.de/eggentdurchfg/BJNR124410004.html.

[58] Genetic Engineering Act §§ 32–36a.

production facilities must obtain liability insurance or coverage through governmental guarantees. Injunctive relief is also available.

This liability regime also applies to the accidental pollution of adjacent properties. If a grower of GM plants contaminates a neighbor's field and the neighbor's planting must therefore be destroyed (owing to the unauthorized release of GMOs), then the grower of the GM plants is presumed to have caused this damage and is fully liable. Likewise, if food is produced from GMO-contaminated plants and therefore must be labeled as containing GMOs owing to the level of contamination, or can no longer qualify for the "No Genetic Engineering" label, then the grower presumed to have caused this contamination is fully liable for the reduction in marketability and value of the contaminated food.[59] Damages can be considerable, considering the German preference for foods without GMOs. In fact, this liability regime has proven to be the biggest deterrent to the cultivation of GM crops in Germany, and has caused the German Farmer's Association to advise against the cultivation of GM plants.[60]

VIII. Judicial Decisions / Prominent Cases

German judicial decisions have touched on many aspects of GMO legislation, both domestic and European. In 2009 the Administrative Court of Munich referred the *Bablok* case (honey case)[61] to the European Court of Justice (ECJ).[62] In 2010 the Federal Constitutional Court (FCC) upheld the Genetic Engineering Act.[63] In 2012 and 2013 administrative courts upheld destruction orders for GMO-contaminated plantings,[64] while at various times anti-GMO activists have been tried in the criminal courts.[65]

The FCC decision of 2010 balances and weighs the potential risks of GMO releases with the interests of researchers and users of GMOs. A constitutional challenge had been brought by the government of the German State of Sachsen Anhalt, which objected to the publication of location register data (see Part V, above) on the grounds that this could invite vandalism by anti-GMO activists. The State also objected to the strict liability regime for contamination of neighboring properties. The Court held that the Act on Genetic Engineering struck an appropriate balance between the purpose of protecting against GMO risks on the one hand, and the enhancement of research on and the development and proper use of GMOs on the other. The Court also pointed out that the data on the German locations of GM plantings could be viewed in

[59] *Id.* § 36a.

[60] HÄRTEL, *supra* note 5, at 726.

[61] Case C-442/09, Karl Heinz Bablok and Others v. Freistaat Bayern, Judgment of the Court (Grand Chamber), Sept. 6, 2011, http://curia.europa.eu/juris/document/document.jsf?text=&docid=109143&pageIndex=0&doclang=en&mode=lst&dir=&occ=first&part=1&cid=780715 (click on "Curia" to select language); *see also* EU report.

[62] *See* EU Report.

[63] BVerfGE 128/1, *supra* note 11.

[64] Brandt, *supra* note 29; Bayerischer Verwaltungsgerichtshof, *supra* note 29.

[65] OLG [Oberlandesgericht, Higher Regional Court] Naumburg, May 8, 2013, docket no. 2Ss58/12, *available at* http://www.juris.de (by subscription).

Internet registers according to the Cartagena Protocol[66] and in the EU's Register of Genetically Modified Foodstuff and Animal Feed.[67] With respect to the liability provisions contained in the Genetic Engineering Act regarding the contamination of neighboring properties, the Court held that the Act merely exemplified and clarified liabilities already existing in the German law of nuisance.

The *Bablok* decision of the ECJ continues to generate follow-up decisions and legislative proposals in Germany. In *Bablok,* the EJC had held that GMO-contaminated honey and pollen fell under the restrictions of Regulation 1829/2003. In March 2012 the Bavarian Higher Administrative Court rejected in part claims of a beekeeper for additional measures to protect his bees from the risk of contamination by GMO plantings.[68] In June 2012 a parliamentary minority party submitted a legislative draft calling for the introduction of ten-kilometer separation zones between GM plantings and the location of beehives.[69]

Acts of vandalism against GMO crops also generate court decisions that touch on various aspects of the law on GMOs. In May 2013 a Higher Regional Court rescinded and remanded a lower court's conviction of destroyers of GM plantings because the lower court had failed to examine whether the permit for the planting had been given in violation of the law. The perpetrators had used the justification (defense) of necessity and had claimed that the permit had been in violation of the law.[70]

[66] *See* Report on the Cartagena Protocol.

[67] EU Regulation 1829/2003 art. 28.

[68] Bayerischer Verwaltungsgerichtshof [Bavarian Higher Administrative Court], Mar. 27, 2012, docket no. 22 BV 11.2175, http://www.gesetze-bayern.de/jportal/portal/page/bsbayprod.psml?doc.id=JURE120008921&st=ent&showdoccase=1&paramfromHL=true#focuspoint.

[69] Deutscher Bundestag, Drucksachen und Protokolle, Imkerei vor der Agro-Gentechnik schützen, June 13, 2012, http://dipbt.bundestag.de/dip21/btd/17/099/1709985.pdf.

[70] OLG Naumburg, *supra* note 65.

Israel

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SUMMARY Israeli law permits the development and growth of genetically modified organisms (GMOs) for research purposes in accordance with requirements established by subsidiary legislation. Although GMO growth is not permitted for commercial purposes, GMO products may be imported, sold, and used in the production of food and pharmaceuticals in Israel. While Israeli scientists usually support the development of GMOs, environmental activists have expressed concerns regarding what they see as potential harm resulting from their use. Israel's religious *kashrut* authority has determined that the use of GMO ingredients in food does not affect its kosher status because GMOs are only used in "microscopic" proportions. This determination has been contested by some Jewish groups in Israel and the United States. All new food, including food that was genetically engineered, goes through a risk assessment process before being approved. Such assessment includes an evaluation of aspects related to its safety, nutrition, and consumption. To date, legislation specifically regulating the labeling of GMO components in food does not appear to have been passed.

I. Introduction

Israel is considered "an international center for studying genetically modified organisms."[1] Research involving genetically modified organisms (GMOs) concentrates on the development of seeds and is conducted in Israeli universities, in government research institutions,[2] and by the private sector.[3] Funding for GMO research and testing in Israel derives from Israeli and foreign sources, including the United States.[4]

Israeli subsidiary legislation defines a GMO as "[a]n organism, including a microorganism, virus, viroid, and any single-celled or multi-celled entity, that has undergone a modification by

[1] Marlene-Aviva Grunpeter, *GMOs, A Global Debate: Israel a Center for Study, Kosher Concerns*, EPOCH TIMES (Aug. 5, 2013), http://www.theepochtimes.com/n3/229556-gmos-a-global-debate-israel-a-center-for-study-kosher-concerns/.

[2] *See Agricultural Research Organization (ARO), Volcani Center: Plant Pathology and Weed Research*, MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT (MARD), http://www.agri.gov.il/en/departments/12.aspx (last visited Sept. 12, 2013).

[3] *See*, *e.g.*, Hagai Amit, *Homegrown Israeli Idea for Conquering the World Food Shortage*, HAARETZ (Apr. 12, 2012), http://www.haaretz.com/weekend/week-s-end/homegrown-israeli-idea-for-conquering-the-world-food-shortage-1.423959.

[4] *Id.* (stating, for example, that the US government was helping to fund pre-field trial tests conducted by an Israeli startup company). For general information on life sciences research in Israel, *see* Tova Cohen & Steven Scheer, *Analysis: After Tech Success, Israel Seeks Life Sciences Growth*, REUTERS (June 6, 2013), http://www.reuters.com/article/2013/06/06/us-israel-biomed-idUSBRE9550IU20130606.

genetic engineering and is involved with plants in any way during its life cycle."[5] A commentator has noted that while GMO research in Israel has focused on "developing and improving plants' resistance to pests, diseases, and herbicides[,] . . . the research can only reach the 'proof of concept' stage, because of regulations."[6]

Accordingly, although the growth of GMOs is generally permitted in Israel for research purposes, subject to conditions enumerated by law, it is not authorized for commercial purposes.[7] Ingredients derived from GMOs may, however, be imported, sold, and used in the production of food in Israel.[8] GMO products are also "widely used in the pharmaceutical industry"[9] in Israel. There are currently no requirements for the labeling of GMOs in Israel.[10]

II. Public and Scholarly Opinion

A. Government Policies

In a December 2011 hearing of the 18th Knesset (Israel's Parliament) Science and Technology Committee, experts testified in favor of research and development (R&D) involving genetic engineering in agriculture. Projecting a rise in global population and food shortages, Professor Yoram Kapolnik, head of agricultural research at the Ministry of Agriculture and Rural Development (MARD), testified on the need for Israel to prepare for 2050, by which time he expects central food components to be depleted.[11] Professor Amnon Lars, a researcher at the Agriculture Research Organization's Volcani Center,[12] also testified that genetic engineering proposed alternatives to the use of pesticides by developing vegetables that would be resistant to various viruses.[13]

The hearing concluded with a call by Ronit Tirosh, the Committee's Chair, to remove "the stigmas regarding the low level of safety [associated with] genetically engineered products;

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[5] Seed Regulations (Genetically Modified Plants and Organisms) 5765-2005, KOVETZ HATAKANOT [KT] [Subsidiary Legislation] No. 6391 p. 782. An unofficial translation of the regulations is available on the MARD website at http://www.ppiseng.moag.gov.il/PPISENG/GeneticallyModifiedPlants/LicensingandanalysisofGMplants/

[6] Grunpeter, *supra* note 1.

[7] *Id.*

[8] *Genetically Engineered Food*, MINISTRY OF HEALTH, http://www.health.gov.il/unitsoffice/hd/ph/fcs/novelfood/pages/engfood.aspx (last visited Sept. 12, 2012).

[9] Grunpeter, *supra* note 1.

[10] *Id.*

[11] THE KNESSET COMMITTEE FOR SCIENCE AND TECHNOLOGY, THE 18TH KNESSET, USE OF GENETIC ENGINEERING IN AGRICULTURAL RESEARCH IN ISRAEL (Hearing in the Committee, Protocol No. 112: Summary of the Committee's Activity, Part B, p. 50 (Aug. 2011–Nov. 2012), http://www.knesset.gov.il/committees/heb/docs/ mada_18b.pdf (in Hebrew).

[12] For information on the Center's research activities, see *Agriculture Research Organization (ARO) Volcani Center*, MARD, http://www.agri.gov.il/units/institutes/default.aspx (last visited Sept. 16, 2013).

[13] THE KNESSET COMMITTEE FOR SCIENCE AND TECHNOLOGY, *supra* note 11, at 51.

because it was proved that they are unjustified."[14] Calling on MARD to allocate funding "for marketing and for educating the public" on this issue, Ms. Tirosh stressed the need for closer cooperation between the Ministry of Health and MARD's research institutions. Such cooperation is necessary, she stated, "so that regulations and directives that are issued by the Ministry of Health will be considered in connection with every research project that is conducted, when the goal at the completion of the research is to open the products for wide distribution and trade."[15] Ms. Tirosh called for the introduction of a bill that would regulate the labeling of genetically engineered products and increase the number of inspectors to ensure compliance with quality standards.[16]

A search for legislative developments since the December 2011 hearing has disclosed an amendment delaying the enforcement date of the Public Health (Food) (Nutritional Labeling) (Amendment) 5771-2011 Regulations to January 31, 2014. The text of these regulations, however, does not include reference to the labeling of GMO products.[17] The absence of labeling requirements for GMO food components was criticized at a hearing conducted by the Knesset Committee for Labor, Welfare and Health on July 3, 2013.[18]

B. Public Environmental Concerns

Environmental activists have expressed concerns regarding the quality and the potential harm that they believe would result from the use of GMOs. Activists argue that "GM seeds produce sterile crops, so cross-pollination with wild plants could bring rapid extinction to those wild varieties. . . . GM plants are very weak and 'spoiled'."[19] They have also expressed concerns about the long-term ecological effects of GMOs breeding with other plants.[20]

Israeli scientists, however, have generally support the development of GMOs.[21] According to Professor Gad Galili of the Weizmann Institute of Science in Rehovot, the development of genetically engineered crops can address "the global shortage of staple foods." In response to concerns regarding the long-term impact of GMO use he opined that

> [a]lthough scientists do not know the long-term effects of genetically modified organisms' consumption . . . they were safer than conventionally interbred ones because

[14] *Id.* (translated by author, R.L.).

[15] *Id.*

[16] *Id.*

[17] Public Health (Food) (Nutritional Labeling) (Amendment) 5771-2011 Regulations, KT No. 7019, p. 1198 (July 31, 2011), *as amended by* KT No. 7160, p. 1661 (Aug. 30, 2012).

[18] *See* The 19th Knesset Committee for Labor, Welfare and Health Meeting (Protocol No. 47, July 3, 2013) pp. 18–21, http://www.knesset.gov.il/protocols/data/rtf/avoda/2013-07-03.rtf (in Hebrew).

[19] Grunpeter, *supra* note 1.

[20] Gal Tziperman Lotan, *Scientists, Activists Debate if Genetically Modified Foods are Panacea or Plague*, THE JERUSALEM POST (Apr. 30, 2008), http://www.jpost.com/Health-and-Sci-Tech/Science-And-Environment/Scientists-activists-debate-if-genetically-modified-foods-are-panacea-or-plague.

[21] *Id.*

> scientists had full control over all the variables in the gene transfer. As for the risk of contamination . . . [i]f you put a virus into GMO, it will spread. But we safeguard it, there are expert committees that approve GMO, and one thing is certain: If someone wanted to insert a virus genome, or there was a contamination risk, it would not be approved.[22]

C. Religious Concerns

Concerns have been raised both in Israel and among Jewish communities around the world[23] regarding whether products that include GMO components are Kosher and thus fulfill strict Jewish dietary standards. The *Epoch Times* has reported that

> [t]he religious kashrut authority [which certifies products as Kosher] in Israel had ruled that genetic engineering "does not affect kosher status" because genetic material is "microscopic." But there are Jewish groups that dispute this decision and consider GMOs a violation of the biblical prohibition against "kilayim," mixed breeding both in crops and in livestock. Those believing GM products cannot be labeled kosher quote the well-respected 13th century Kabbalist Rabbi Moshe ben Nachman (known as "the Ramban"), who said mankind should not disturb the fundamental nature of creation.[24]

In the United States, the Natural Food Certifiers (NFC) Organization, announced that its Apple K Kosher Certification Program would no longer accept applications for products that contain GMOs.[25]

According to a press release issued by the NFC:

> While according to the strict letter of Kosher food law a GMO food ingredient is not prohibited, in our view it is not natural. Additionally, there is a Torah (religious)-based law to 'guard your health'. GMOs are the number-one growing concern among health-conscious consumers and for businesses in the natural and organic food market, as well as in the conventional food industry. . . ."[26]

III. Structure of Pertinent Legislation

Israeli law currently does not include any primary legislation on GMOs. Responsibilities for GMO research, development, and use are shared by MARD and the Ministry of Health in accordance with regulations established by these ministries based on their respective authorities.

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[22] *Id.*

[23] *See Natural Food Certifiers*, GREENERCHOICES, http://www.greenerchoices.org/eco-labels/label.cfm?LabelID=198 (last visited Sept. 16, 2013).

[24] Grunpeter, *supra* note 1.

[25] The NFC has been certifying products as organic since 2002 and is accredited as an organic certifier by the USDA. *See* GREENERCHOICES, *supra* note 23.

[26] Daisy Luther, *Kosher Certification Program Bans All GMO Ingredients*, THE ORGANIC PREPPER (Apr. 25, 2013), http://www.theorganicprepper.ca/kosher-certification-program-bans-all-gmo-ingredients-04252013.

A. Regulation of GMO Research

The Seed Regulations (Genetically Modified Plants and Organisms) 5765– 2005[27] were issued in 2005 by the Minister of Agriculture and Rural Development based on general authorities provided under the Seeds Law, 5716-1956,[28] and the Plant Protection Law, 5716-1956.[29]

MARD oversees all experimentation with transgenic plants and organisms that are involved in the life cycle of plants in accordance with the regulations. In addition, MARD handles the importation and exportation, handling and commercialization of genetically modified propagation material.[30]

MARD's activities in these areas are managed by the following bodies:

1. The Plant Protection and Inspection Service (PPIS);
2. The National Committee for Transgenic Plants (NCTP); and
3. The Authorized Institutional Representative.[31]

B. Regulation of GMO Use in Food

According to information posted on the Ministry of Health website,

> [l]egislation regulating the rules regarding new food, including genetically engineered food and its labeling, is going through the final legislative steps. Every new food (including food that was genetically engineered) before being approved goes through risk assessment that includes aspects related to its safety, nutrition and consumption … With the entry into force of the new food regulations a labeling requirement will apply to genetically engineered food components, in addition to the safety assessment that has been done until now.[32]

Legislation specifically regulating labeling of GMO components in food does not appear to have been passed to date.

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[27] Seed Regulations (Genetically Modified Plants and Organisms) 5765–2005, KT No. 6391, p. 728.

[28] Seeds Law, 5716-1956, 10 LAWS OF THE STATE OF ISRAEL [LSI] 99 (5716-1955/56), *as amended*.

[29] Plant Protection Law, 5716-1956, 10 LSI 75, *as amended*.

[30] *Genetically Modified Plants & Organisms*, MARD PLANT PROTECTION AND INSPECTION SERVICES, http://www.ppiseng.moag.gov.il/PPISENG/GeneticallyModifiedPlants/LicensingandanalysisofGMplants/ (click on "[l]earn more about the service . . . "; last visited Nov. 1, 2013).

[31] *Id.*

[32] *Genetically Engineered Food*, MINISTRY OF HEALTH, http://www.health.gov.il/unitsoffice/hd/ph/fcs/novelfood/pages/engfood.aspx (last visited Sept. 18, 2012) (translated by author, R.L.).

IV. Restrictions on Research, Production, and Marketing

A. Rules for Authorizing Research and for Research Laboratories

The Seed Regulations prohibit any experimentation with plants that have undergone a change by means of genetic modification without a permit issued by the Director of the PPIS.[33] The regulations authorize the Director to grant experiment permits and to stipulate conditions and restrictions for their issue; including conditions for destroying plant material, organisms or regulated articles used during the experiment and requiring that testing be conducted in laboratories that have been approved by the Director. The Director may refuse to issue a permit for experiments that are to be carried out in a

> (1) Containment facility, unless the applicant had proven that the containment facility is appropriate for its function and that all necessary means have been taken to prevent all risk to humans, animals and to plants; and to prevent unacceptable negative impacts on the environment;
>
> (2) Field trial only, after consultation with the National Committee for Transgenic Plants.[34]

The regulations authorize the Director to exempt applicants from needing to obtain an experiment permit if he or she is satisfied that the experiment will be conducted in a laboratory equipped with an autoclave facility and its operator and safety officer have ensured that "all experiment residues are destroyed in an incinerator or sterilized with material that the Director has approved."[35]

B. Marketing Rules

The sale of transgenic plants requires permission from the Director in consultation with the NCTP and compliance with all the conditions enumerated in the experiment permit.[36] The sale or export of transgenic propagation material or organism similarly requires a valid registration certificate or an approved label.[37]

The regulations require an applicant who requests authorization to sell transgenic propagation material or transgenic organisms to submit a registration application that includes the following information:

> (1) A description of the genetic modification and its characteristics, including complete data pertaining to the effects and potential effects on humans, animals, plants and the environment;

[33] Seed Regulations (Genetically Modified Plants and Organisms) 5765-2005, § 3.

[34] The National Committee for Transgenic Plants is a committee appointed by the Minister of Agriculture and Rural Development for matters concerning experiments with transgenic plants and organisms and their sale. *See id.* § 2(a).

[35] *Id.* § 2(b)–(c).

[36] *Id.* § 7(a).

[37] *Id.* § 7(b)–(c).

(2) Scientific publications on the results of experiments with the transgenic propagation material or the transgenic organism and their international use, including approved labels and translations to Hebrew (excluding English);

(3) A report of the results of experiments with transgenic propagation material or the transgenic organism under local conditions and the proposed utilization of the material;

(4) Examples of proposed labels for transgenic propagation material as regulated for in the Seed Law, with the addition of the words "Genetically Modified Material";

(5) For transgenic organisms – the words "Genetically Modified Material" must appear on the label;

(6) Imported transgenic propagation material or imported transgenic organisms – Import permit;

(7) Additional information as may be required by the Director, including a testing laboratory approved by him.[38]

The Director is authorized to reject, restrict, or cancel a registration of transgenic propagation material or organisms for sale based on evidence that the plant material or organism may endanger plants, humans, or animals or have unacceptable negative impacts on the environment, or based on noncompliance with labeling requirements that have been authorized by the Director or deviation from the trait description that has been supplied at the time of registration application.[39]

C. Labeling Requirements for Distributed Products

As discussed above, labeling requirements apply to the marketing of transgenic plants, propagation material, and organisms. Labeling requirements for distribution of processed food products containing GMO components do not apply at this time.

D. Agencies Involved in Implementation

According to the regulations, the role of the NCTP is to advise the Director, in accordance with the instructions prescribed by the regulations, and "to determine if genetically modified plants or organisms or their sale, pose any risk to humans or animals or have unacceptable negative impacts on the environment."[40]

The thirteen committee members are appointed by the Minister of Agriculture and Rural Development and include the following persons:

(1) Two representatives from the Ministry; one of whom will act as chairman of the committee, and the second as deputy chairman;

[38] *Id.* § 8(b).

[39] *Id.* §§ 9–15.

[40] *Id.* § 2(b).

(2) One representative from a list submitted by the Minister of the Environment;

(3) One representative from a list submitted by the Minister of Health;

(4) One representative from a list submitted by the Minister for Science, Culture and Sport;

(5) Eight representatives of the public from among the scientific and research community who have backgrounds in life sciences, nature or environmental protection, and from seed producers and variety breeders. [41]

V. Restrictions on Releasing Organisms into the Environment

As explained above, GMOs may be produced in Israel only for research purposes subject to conditions enumerated by the relevant regulations. GMO growth is not authorized for commercial purposes.[42]

VI. Restrictions on GMOs in Foodstuff

GMO products may be imported, sold, and used in the production of food in Israel,[43] and are not required to be labeled in a way that identifies their GMO components.[44]

VII. Liability Regime

Israeli law does not contain a special liability regime in relation to the development, use, or release of GMOs.

VIII. Judicial Decisions / Prominent Cases

A search for case law concerning GMO research and use unconnected to patent rights has not identified any relevant court decisions.

[41] *Id.* § 2(a).

[42] *Id.*

[43] MINISTRY OF HEALTH, *supra* note 32.

[44] *See* discussion, Part II(A), above.

Italy

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SUMMARY As a member of the European Union, Italy has been implementing European directives concerning genetically modified organisms (GMOs) over the last two decades, but at a rather reluctant pace. In fact, as reflected by GMO legislation in Italy, Italian public opinion has shifted from a decidedly general opposition to the introduction of GMOs into a more recent open acceptance of them. Italy's political and administrative structure relies on the powers of the central government and the governments of its twenty regions, which enjoy certain autonomy in the regulation of agriculture and crops, and in experimentation with GMOs. As a consequence, some regions have enacted slightly more permissive regimes than others. In addition, the Italian Constitutional Court has ruled that the national government is constrained from encroaching on the power of regional governments to establish their own regimes on GMOs. This factor, in conjunction with the more permissive regulations to which Italy is bound at the European level, creates a scenario where the decentralized and spontaneous growth of GMOs in agriculture will probably increase in the near future.

I. Introduction

Early regulations concerning genetically modified organisms (GMOs) in Italy were aimed at deterring their development in the country. However, the flow of European regulations from the late 1990s onward changed the legal framework for regulating GMOs. Pursuant to European Union (EU) Directive Nos. 219 and 220 of 1990, and 259 of 1997, Italy cannot limit the importation of GMOs, which are already approved at the European level. In 2000, Italy for the first time enacted legislation to ban the use of certain GMOs used in foods for human consumption (see discussion, Part III(C), below). Two years later legislation imposed a moratorium on the mixture of GMO and non-GMO products. Finally, several pieces of legislation enacted since early 2003 have sought to more strictly regulate GMO experimentation, use, mixtures, and release into the environment, particularly concerning GMOs used for food crops. Thus, at this point, GMO cultivation is currently permitted in Italy, but subject to stringent regulations concerning the assessment of its impacts on human and animal health, and the environment.

II. Public and Scholarly Opinion

GMOs have received a mixed reception by the general public in Italy. For some observers, the incorporation of new technologies altering the genetic code of plants and animals has represented a success in the quest for maximization of food alternatives.[1] For others, the introduction of GMOs in Italy has generated serious concerns related to food safety and consumer protection.

[1] *OGM: una nuova tecnologia che ha avuto troppo successo* [*GMO: A New Technology That Has Had Much Success*], CONFAGRICOLTURA ROVIGO, http://www.salmone.org/ogm-cosa-sono/ (last visited Nov. 20, 2013).

For instance, the introduction of proteins and genes into GMOs that have not previously been consumed by animals or humans (e.g., scorpion genes in potatoes or bacteria in maize), and their subsequent impact on the food chain is a very controversial matter.[2] Another common objection to GMOs arises over the dangers of GMOs escaping from their confined environments and mixing with populations living under natural conditions.[3]

Overall, despite the European GMO regulations, the general public has strongly opposed the introduction of GMOs into Italy, and this opposition has had an impact on Italian legislation since at least 2000.[4]

Only recently, on July 12, 2013, the Italian government banned the cultivation of Monsanto Corn 810 (Mon810), as the first of a series of measures designed to define a new more restrictive framework for the cultivation of GMOs in Italy.[5] However, fresh opinion polls indicate that the Italian public is now adopting a slightly more pro-GMO stance.[6]

III. Structure of Pertinent Legislation

A. Definition of "GMO"

In Italy, GMOs (*Organismi Geneticamente Modificati*) are defined as "organisms whose genetic material has been altered in a way that does not occur naturally for fertilization and/or natural recombination. GMOs can be plants, animals, or microorganisms, such as bacteria, parasites and fungi."[7] GMOs from both plants and animals are used in food, agriculture, animal husbandry, and medicine.[8] Nonetheless, the scientific community uses the terminology "GMO" mainly to

[2] *OGM: Organismi geneticamente modificati: una definizione* [*GMO: Genetically Modified Organisms: A Definition*], MINERVA OSSERVATORIO SULL'INDUSTRIA ALIMENTARE, http://www.minerva.unito.it/Alimentare/OGM/OGMdef.htm (last visited Nov. 20, 2013).

[3] *OGM*, TRECCANI.IT: L'ENCICLOPEDIA ITALIANA [ITALIAN ENCYCLOPEDIA], http://www.treccani.it/enciclopedia/ogm/ (last visited, Nov. 20, 2013).

[4] *Il Paradosso della sfiducia negli OGM* [*The Paradox of the Distrust of GMOs*], LE SCIENZE (EDIZIONE ITALIANA DI SCIENTIFIC AMERICAN) (Sept. 11, 2013), http://www.lescienze.it/news/2013/09/11/news/ogm_sicurezza_controlli_percezione_rischio-1804408/.

[5] Press Release, Ministero delle politiche agricole, alimentari e forestali [Ministry of Agricultural, Food, and Forestry Policies], Ogm, De Girolamo: firmato decreto che vieta la coltivazione del mais MON810 in Italia [GM, De Girolamo: Signed Decree Prohibiting the Cultivation of MON810 Corn in Italy] (July 12, 2013), http://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/6560.

[6] *Pro o contro: sugli Ogm è facile cambiare opinione* [*For or Against: It is Easy to Change Opinions About GMOs*], CORRIERE DELLA SERA.IT AMBIENTE (Sept. 13, 2013), http://www.corriere.it/ambiente/13_settembre_13/ogm-facile-cambiare-opinione_bce7ca28-1c49-11e3-8df2-24a872f62c06.shtml.

[7] *Organismi Geneticamente Modificati* [*Genetically Modified Organisms*], AUTORITÀ EUROPEA PER LA SICUREZZA ALIMENTARE [EUROPEAN AUTHORITY FOR FOOD SAFETY], http://www.efsa.europa.eu/it/topics/topic/gmo.htm (last visited Nov. 20, 2013).

[8] TRECCANI.IT, *supra* note 3.

describe plants whose hereditary patrimony has been altered by receiving genes, thereby transforming their cells or tissues.[9]

Specifically, Legislative Decree (L.D.) No. 224 of 2003 defines a GMO as "an organism, different from a human being, whose genetic material has been altered in a way that does not occur in nature through coupling or intersection or natural recombination."[10]

B. EU Law

The complexity of the ethical and economic questions involved in the production of GMOs has caused the EU to regulate this field through Directive Nos. 90/219, 259/97, and 2001/18, which replaced Directive 90/220[11] As a consequence of these directives, Italy may neither limit the importation of GMOs authorized at the European level nor prohibit their cultivation for reasons other than those scientifically supported.

European GMO legislation, which rests on the precautionary principle,[12] comprises the following instruments:

- Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed
- Regulation (EC) No. 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC
- Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 (amended by Regulation (EC) No. 1830/2003) on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (which had required producers to demonstrate to authorities that a new product abided by certain security standards)

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[9] *Id*.

[10] Decreto Legislativo 8 luglio 2003, n. 224, Attuazione della direttiva 2001/18/CE concernente l'emissione deliberata nell'ambiente di organismi geneticamente modificati [Legislative Decree No. 224 of July 8, 2003, Implementing Directive 2001/18/CE Concerning the Deliberate Release of Genetically Modified Organisms into the Environment] [L.D. No. 224 of 2003] art. 1(b), Gazzetta Ufficiale della Repubblica Italiana [G.U.] [OFFICIAL JOURNAL OF THE REPUBLIC OF ITALY], No. 194, Aug. 22, 2003, http://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:decreto.legislativo:2003;224.

[11] 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, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:106:0001:0038:EN:PDF.

[12] For a discussion of the precautionary principle, which generally allows for preventative decision making in the face of environmental risk, see *The Precautionary Principle*, EUROPA: SUMMARIES OF EU LEGISLATION, http://europa.eu/legislation_summaries/consumers/consumer_safety/l32042_en.htm (last visited Nov. 20, 2013).

- Commission Recommendation 2003/556/EC of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming[13]

C. Domestic Legislation

The first attempt to block the entry of GMOs into Italy took place in 2000 with the issuance by the President of the Council of Ministers of the Decreto Amato,[14] which banned the use of foods derived from GMO Corn 4. This provision was adopted pursuant to a safeguard clause included in European Regulation 258/97, which had authorized the use of GMO Corn 4 at the European level. The Decreto Amato was repealed, however, by a court in 2004 for lack of evidence that GMO Corn 4 caused a health hazard. In consequence, this GMO may now be freely cultivated and used in Italy.

The debate over transgenic products continued in Italy when in 2000 a group of more than 1,500 Italian scientists—including Nobel Prize recipients—signed a letter opposing a total ban on scientific research on GMOs.[15] The Decreto Alemanno, adopted in 2002, contained rules for the coexistence of GMO, conventional, and organic agriculture. This instrument established a moratorium on mixing GMO and conventional seeds, with severe penalties for violators, and suspended the GMO experimentation that the government was conducting in accordance with regulations of the Ministry of Agricultural, Food, and Forestry Policies.[16]

As already stated, Italy had for many years adopted a zero-tolerance policy concerning GMO seeds. In fact, in 2003, there was an incident in the Piedmont Region where the local government ordered the destruction of areas destined for GMO-crop cultivation based on the fact that the ratio of GMO seeds to conventional seeds exceeded the maximum ratio allowed by European and Italian regulations. This decision was not echoed at the national level or in other regions of the country, however.

In addition, European Directive 2001/18/EC was implemented in Italy by Legislative Decree No. 224 of 2003.[17] Along with the existing required standards and evaluations for conducting experiments with GMOs, this Decree mandated the prior assessment of, among other activities,

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[13] *Id.*

[14] Decreto del Presidente del Consiglio dei Ministri 4 agosto 2000 Sospensione cautelativa della commercializzazione e dell'utilizzazione di taluni prodotti transgenici sul territorio nazionale, a norma dell'art. 12 del regolamento (CE) n. 258/97 [Decree of the President of the Council of Ministers of August 4, 2000, Concerning the Precautionary Suspension of the Commercialization and Use of Certain Transgenic Products on the National Territory, in Accordance with Article 12 of Regulations (EC) No. 258/97], http://www.arpa.emr.it/cms3/documenti/alimenti/normativa/DPCM_04ago2000.pdf.

[15] *Pusztai Rebuttal to "GM Myths"; Italian Scientists Blast*, AGBIOWORLD, http://www.agbioworld.org/newsletter_wm/index.php?caseid=archive&newsid=886 (last visited Nov. 20, 2013).

[16] *Ogm, il decreto Alemanno è legge "Mai più commistioni nei campi,"* LA REPUBBLICA.IT (Jan. 25, 2005), http://www.repubblica.it/2004/j/sezioni/politica/ogmo/okogm/okogm.html.

[17] Decreto Legislativo 8 luglio 2003, n. 224 Attuazione della direttiva 2001/18/CE concernente l'emissione deliberata nell'ambiente di organismi geneticamente modificati [Legislative Decree No. 224 of July 8, 2003,

(a) the abandonment or replacement of crops that, owing to the impact of GMOs, have become no longer appropriate or economically convenient, particularly regarding local varieties;

(b) damage to the image of local products and/or the release area and the costs involved to defend the image;

(c) a change of market patterns caused by products originating in the release area due to the impossibility of purchasing GMO-free products, or other commercial impacts;

(d) modifications of the landscape with negative impacts on agro-tourism activities; and

(e) abandonment or marginalization of the release area caused by the impairment of agricultural practices in the area that have become less profitable owing to GMO impacts.[18]

Decree-Law No. 279 of 2004,[19] which was amended and enacted as legislation by Law No. 5 of 2005,[20] provided for equality between different types of agriculture but imposed on the regions and autonomous provinces a "plan of coexistence" to prevent the commingling of GMO products and non-GMO products. Before its conversion into law in 2005, Decree-Law No. 279 was declared partially unconstitutional with regard to the coexistence of crops and the jurisdiction of the Italian regions (see the analysis of this decision in Part VIII, below). As a consequence, the twenty regions (political-administrative divisions) of the country are now free to determine their own policies concerning the coexistence of GMO and non-GMO agriculture, but to conform with European regulations they may not prohibit GMO crops altogether. Currently, thirteen of the regions have issued provisions imposing de facto restrictions on the cultivation of GMOs in their territories.

In sum, GMO cultivation in Italy is taking place at an experimental level only. At the same time, most of the fodder used on Italian farms is produced from genetically modified soy and corn imported from the United States, Canada, and Latin America.

IV. Restrictions on Research, Production, and Marketing

L.D. No. 224 of 2003 provided that information about GMOs must be made available to the general public on a transparent and continuous basis,[21] with some exceptions related to the

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Implementing Directive 2001/18/EC on the Deliberate Release of Genetically Modified Organisms], G.U., No. 194, Aug. 22, 2003, http://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:decreto.legislativo:2003;224.

[18] *Id*. arts. 8, 15, 19 & 22.

[19] Decreto-Legge 22 novembre 2004, n. 279, Disposizioni urgenti per assicurare la coesistenza tra le forme di agricoltura transgenica, convenzionale e biologica [Decree-Law No. 279 of November 22, 2004, Containing Urgent Measures to Ensure the Coexistence Between Transgenic, Conventional, and Biological Forms of Agriculture], G.U., No. 280, Nov. 29, 2004, http://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:decreto-legge:2004;279.

[20] Legge 28 gennaio 2005, n. 5 Conversione in legge, con modificazioni, del decreto-legge 22 novembre 2004, n. 279, recante disposizioni urgenti per assicurare la coesistenza tra le forme di agricoltura transgenica, convenzionale e biologica [Law No. 5 of January 28, 2005, Converting into Law, with Amendments, Decree-Law No. 279 of November 22, 2004, Containing Urgent Measures to Ensure the Coexistence Between Transgenic, Conventional, and Biological Forms of Agriculture], G.U., No. 22, Jan. 28, 2005, http://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:legge:2005;5.

[21] L.D. No. 224 of 2003 art. 26.

confidentiality of the concerned information.[22] L.D. No. 70 of 2005[23] established a three-year moratorium on including GMOs in foods or feeds in a ratio greater than 0.5% of the non-GMO content.[24] In addition, L.D. No. 224 of 2003 mandated that companies authorized to release GMOs engage in post-release monitoring and research activities,[25] and created a digital public registry to inventory the localization of authorized GMOs released around the country.[26] Finally, L.D. No. 224 of 2003 established a procedure for the exchange of information on GMOs with the European Commission and other EU member states.[27]

These statutory authorities are complemented by Presidential Decree No. 433 of 2001,[28] which contains provisions related to data protection relevant for GMO cultivation.[29]

V. Restrictions on Releasing Organisms into the Environment

L.D. No. 124 of June 25, 2010[30] (L.D. No. 124) sets forth mandatory criteria concerning the release of GMOs into the stream of commerce; that is, notification, environmental impact assessment, and public consultation requirements.[31] L.D. No. 124 charges the Ministry of Agricultural, Food, and Forestry Policies with the main responsibility for determining national policies on agriculture, food security, and forests.[32] L.D. No. 124 also permits the release of materials into the food chain that will cause the multiplication of fruit plants designed to

[22] *Id*. art. 27.

[23] Decreto Legislativo 21 marzo 2005, n. 70, Disposizioni sanzionatorie per le violazioni dei regolamenti (CE) numeri 1829/2003 e 1830/2003, relativi agli alimenti ed ai mangimi geneticamente modificati [Legislative Decree No. 70 of March 21, 2005, Penalties for the Violation of Regulation (EC) Nos. 1829/2003 and 1830/2003, Related to Genetically-Modified Food and Feed] [L.D. No. 70 of 2005], G.U., No. 98, Mar. 21, 2005, http://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:decreto.legislativo:2005;070 (implementing Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of September 22, 2003, on Genetically Modified Food and Feed).

[24] *Id*. art. 9.

[25] *Id*. art. 22.

[26] *Id*. art. 30.

[27] *Id*. art. 14.

[28] Decreto del Presidente della Repubblica 2 novembre 2001, n. 433, Regolamento di attuazione delle direttive 96/51/CE, 98/51/CE e 1999/20/CE in materia di additivi nell'alimentazione degli animali [Presidential Decree No. 433 of November 2, 2001, Implementing Regulations of Directives 96/51/CE, 98/51/CE and 1999/20/CE Concerning Additives to Animal Feeds] [Presidential Decree No. 433 of 2001], G.U., No. 291, Dec. 15, 2001, http://www.normattiva.it/atto/caricaDettaglio Atto?atto.dataPubblicazioneGazzetta=2001-12-15&atto.codiceRedazionale=001G0484.

[29] *Id*. art. 7.

[30] Decreto Legislativo 25 giugno 2010, n. 124 Attuazione della direttiva 2008/90 relativa alla commercializzazione dei materiali di moltiplicazione delle piante da frutto destinate alla produzione di frutti (refusione) [Legislative Decree No. 124 of June 25, 2010, Implementing Directive 2008/90 Related to the Commercialization of Propagating Materials of Fruit Plants Intended for Fruit Production (Reimbursement)], G.U., No. 180, Aug. 4, 2010, http://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:decreto.legislativo:2010;124.

[31] *Id*. art. 3(c)–(i).

[32] *Id*. art. 3.

contribute to genetic diversity.[33] In addition, L.D. No. 124 provides that labeling for GM fruit plants must clearly indicate that the variety has been genetically modified and must specify the organism that has been genetically modified.[34] Moreover, L.D. No. 124, which does not apply to the transportation of GMOs over railroads, streets, internal navigable waters, or by sea or air,[35] creates an interministerial commission charged with reviewing GMO authorizations.[36]

Complementing L.D. No. 124, Presidential Decree No. 433 of 2001 provides that no additives may be released without the previous appropriate authorizations,[37] and that such authorizations must include the pertinent permits issued by EU authorities.[38]

VI. Restrictions on GMOs in Foodstuffs

L.D. No. 224 of 2003,[39] (L.D. No. 224) which does not apply to GM substances and medicinal preparations for human use, reinforces compliance with labeling and packaging requirements for GMOs that have been authorized for marketing and distribution.[40] L.D. No. 224 authorizes the Ministries of the Environment, of Health, and of Agricultural, Food, and Forestry Policies to limit or temporarily suspend the commercialization of GMOs based on new scientific information concerning risks to humans, animals, or the environment.[41]

Complementing L.D. No. 224, Presidential Decree No. 433 of 2001 includes other norms related to the labeling, packaging, and commercial distribution of GMO additives,[42] and regulates their monitoring and control.[43]

VII. Liability Regime and Criminal Penalties

The civil liability regime for damages arising from GMO-related activities in Italy is that set forth in the Civil Code, and therefore reflects the negligence-based liability structure that applies to torts.[44]

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[33] *Id*. art. 4(5)(c).

[34] *Id*. art. 8.

[35] *Id*. art. 4.

[36] *Id*. art. 6.

[37] Presidential Decree No. 433 of 2001 art. 3, G.U., No. 291, Dec. 15, 2001, http://www.normattiva.it/atto/caricaDettaglioAtto?atto.dataPubblicazioneGazzetta=2001-12-15&atto.codiceRedazionale=001G0484.

[38] *Id*. art. 6.

[39] L.D. No. 224 of 2003 art. 7, G.U., No. 194, Aug. 22, 2003, http://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:decreto.legislativo:2003;224.

[40] *Id*. art. 24.

[41] *Id*. art. 25.

[42] Presidential Decree No. 433 of 2001 arts. 14–19, G.U., No. 291, Dec. 15, 2001, http://www.normattiva.it/atto/carica DettaglioAtto?atto.dataPubblicazioneGazzetta=2001-12-15&atto.codiceRedazionale=001G0484.

[43] *Id*. art. 20.

[44] CODICE CIVILE [CIVIL CODE] art. 2043.

In particular, L.D. No. 224 contains provisions for damage to human health and the environment, environmental remediation and restoration, and compensation for environmental damage. L.D. No. 224 specifically provides that anyone who by an act or omission, in violation of L.D. No. 224, causes damage to water, soil, subsoil, or other environmental resources that leads to a real and present danger of environmental pollution must, at their own expense, implement measures for safety and for the remediation and environmental restoration of the polluted areas.[45]

In turn, L.D. No. 70 of 2005[46] establishes penalties for those who, without the proper government authorizations, commercially distribute a GMO designed for human nutrition or a food that contains or has been produced with GMOs. Those who fail to take the appropriate measures to monitor the performance of the GMO, or who do not inform the authorities about ensuing developments affecting the security of the GMO, are also subject to penalties.[47]

L.D. No. 70 of 2005 also provides additional penalties for those who release GMOs into the market without complying with labeling requirements, or who release food that contains a higher concentration of GMOs than that authorized by law or the authorities.[48] Furthermore, penalties are imposed on those who release GMOs designed as animal food or feed without complying with the Law's specified authorizations and labeling requirements.[49]

VIII. Judicial Decisions / Prominent Cases

Perhaps the most important judicial decision concerning GMOs in Italy is that issued by the Constitutional Court in 2006[50] on the constitutionality of Decree-Law No. 279 of 2004. The Court partially annulled this Decree-Law based on procedural irregularities in the legislative process that led to its enactment, and considered its powers as an encroachment by the national government on the powers of the regions. Furthermore, the Court held that the executive branch did not hold "consultation and wide debate" prior to adopting the measure as required by the Constitution. In addition, the Court considered arguments concerning the alleged irreversibility of the potential damage posited by the admixture of GMO products and non-GMO products. The effect of this decision was to allow for a decentralization of the national government's policy-making powers concerning GMOs and an increase in regional power. The practical result has been a lack of uniform national policies concerning GMOs in Italy.

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[45] L.D. No. 224 of 2003 art. 36(2), G.U., No. 194, Aug. 22, 2003, http://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:decreto.legislativo:2003;224.

[46] L.D. No. 70 of 2005 art. 1, G.U., No. 98, Mar. 21, 2005, http://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:decreto.legislativo:2005;070 (implementing Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of September 22, 2003, on Genetically Modified Food and Feed).

[47] *Id*. art. 3.

[48] *Id*. art. 4.

[49] *Id*. art. 5.

[50] Corte Costituzionale, 8 marzo 2006, sentenza n. 116 [Constitutional Court, March 8, 2006, Decision No. 116], http://www.cortecostituzionale.it/actionSchedaPronuncia.do?anno=2006&numero=116.

Japan

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SUMMARY Japan enacted the Cartagena Act in 2003 to implement the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. The Act classifies genetically modified organisms (GMOs) according to two types of uses: use with containment measures and use in open space. Both uses are regulated by the Act, but the latter use is the more regulated of the two.

Although it is legal to plant genetically modified (GM) crops in Japan if certain procedures are followed, no commercial planting of GM crops (aside from ornamental flowers) is occurring in Japan at this time, mainly because the general public is skeptical about the safety of GM crops. Nevertheless, Japan is one of largest importers of GMO foods, though labeling is required if GM crops are used in food in certain cases.

I. Introduction

Japan enacted the Act on the Conservation and Sustainable Use of Biological Diversity Through Regulations on the Use of Genetically Modified Organisms (Cartagena Act) in 2003.[1] This Act aims to ensure the precise and smooth implementation of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Cartagena Protocol).[2] A person who follows the procedures under the Act and, if necessary, obtains approval from the government is permitted to create, import, or use a genetically modified organism (GMO).

However, because of the general public's negative views on GMOs, genetically modified (GM) crops are not commercially planted in Japan (see Part II, below). Some prefectures have enacted ordinances that place restrictions on planting GM crops within their jurisdictions (see Part III, below). The only exception is the blue rose, which was genetically engineered by a Japanese company together with an Australian company, and is allowed to be planted and sold in Japan.[3]

[1] Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Cartagena Act), Act No. 97 of June 18, 2003. An English translation of this Law is available on a website managed by the Ministry of Justice, at http://www.japaneselawtranslation.go.jp/law/detail_main?re=02&vm=02&id=132 (last visited Oct. 22, 2013).

[2] *Id*. art. 1 (citing the Cartagena Protocol, Jan. 29, 2000, http://treaties.un.org/doc/Treaties/2000/01/20000129%2008-44%20PM/Ch_XXVII_08_ap.pdf).

[3] *Shokubutsu: Sekai hatsu! baiotekunorogi de "aoi bara" no kaihatsu ni seikou!* [*Plants: First in the World! Success of Development of "Blue Rose" by Biotechnology!*], SUNTORY, http://www.suntory.co.jp/company/research/hightech/blue-rose/history.html (last visited Nov. 18, 2013).

Despite the public's disapproval of GMOs, the government has conducted safety tests and approved 238 foods and food additives that are derived from GMOs.[4] Japan has become one of the world's biggest GM crop importers.[5]

II. Public and Scholarly Opinion

The general public's skepticism about the safety of GM crops and foods has found expression in a number of social forums. In a written request to the government regarding the "promotion of knowledge based on science among Japanese people," the Japanese Society of Plant Physiologists, in conjunction with other organizations, provided an analysis of why consumers persist in their negative views on GM crops.[6] There are many blog sites and websites of private groups that post negative information on GMOs and warn of the dangers of using them.[7] In some quarters there is suspicion that the government is hiding information on GMOs,[8] and newspapers sometimes publish articles that introduce negative views on GMOs.[9]

III. Structure of Pertinent Legislation

As stated in Part I, the Cartagena Act implements the Cartagena Protocol. Domestic food laws regulate the safety of GM food crops (see Part VI, below). Additionally, the Pharmaceutical Affairs Act regulates the assessment of pharmaceuticals that use GMOs.

GMOs are defined in the laws and regulations in slightly different ways, depending on the purpose of the laws and regulations. The definition of a GMO under the Cartagena Act is as follows:

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[4] Ministry of Health, Labour and Welfare, Pharmaceutical and Food Dept., Food Safety Sec., Chart of GM Foods and Food Additives that Went Through Safety Examinations (Oct. 17, 2013), http://www.mhlw.go.jp/topics/idenshi/dl/list.pdf.

[5] Tony C. Dreibus & Rudy Ruitenberg, *Wheat Falls as Japan Suspends U.S. Imports on Biotech Crop Find,* BLOOMBERG (May 30, 2013), http://www.bloomberg.com/news/2013-05-30/wheat-drops-as-global-crop-outlook-counters-u-s-planting-delays.html.

[6] Japanese Society of Plant Physiologists, Teigen: "idenshi kumikae shokubutsu no shakai ni okeru tekisetsu na juyō o susumeru taisei o motomu" [Proposal: "Requesting System to Support Adequate Acceptance of GM Food by the Society"] at 3, http://www.s.affrc.go.jp/docs/commitee/gm/4kai/pdf/siryo1.pdf (last visited Oct. 18, 2013).

[7] Blogs are very popular in Japan. *See* Chris Salzberg, *Japan: Number 1 Language of Bloggers Worldwide*, GLOBAL VOICES (Apr. 16, 2007), http://globalvoicesonline.org/2007/04/16/japan-number-1-language-of-bloggers-worldwide/.

[8] *See GM shokuhin, shohisha no "shiru kenri" ni dou kotaeruka* [*GM Foods, How to Respond to Consumers' "Right to Know"*], JAPAN AGRICULTURAL COMMUNICATIONS (June 11, 2013), http://www.jacom.or.jp/news/2013/06/news130611-21193.php.

[9] Yoshiyuki Ashida, *Mainichi shinbun no rensai shokutaku doko e: idenshi kumikae* [*How Foods on Table at Home Change According to Mainichi Newspaper: Genetically Modified Food*], YASASHII BAIO TEKUNOROJI [EASY BIOTECHNOLOGY] (Nov. 10, 2009), http://yoshibero.at.webry.info/200911/article_23.html. The author, Yoshiyuki Ashida, is a professor who comments on articles from the *Mainichi Newspaper* on his blog site.

> (2) In this Act, "living modified organism" shall mean an organism that possesses nucleic acid, or a replicated product thereof, obtained through use of the any of the following technologies.
>
> (i) Those technologies, as stipulated by the ordinance of the competent ministries, for the processing of nucleic acid extracellularly.
>
> (ii) Those technologies, as stipulated by the ordinance of the competent ministries, for fusing of the cells of organisms belonging to different taxonomical families.[10]

The Act obligates the government to adopt general measures (known as "Basic Matters") that are designed to prevent adverse effects caused by the use of GMOs and ensure their proper use.[11] The government established these Basic Matters in the form of an ordinance in 2003.[12]

In addition to national legislation, there are local ordinances that regulate GM crops. Eleven prefectures and three municipalities have enacted ordinances or issued guidelines for restrictions on the planting of genetically modified crops within their jurisdictions that go beyond the restrictions established in the Cartagena Act.[13] Local residents' groups concerned about the safety of GM crops have demanded that such ordinances be passed by their local governments.[14]

Although it is legal to grow government-approved GM crops commercially so long as procedures under the Act and local ordinances are followed, no GM crops (aside from ornamental flowers) are commercially grown in Japan at this time.[15]

IV. Restrictions on Research, Production, and Marketing

The intended use of GMOs dictates the level of restrictions imposed on them under the Cartagena Act. Uses undertaken with the intention of preventing "the dispersal of GMOs into the air, water or soil outside facilities, equipment or other structures" that can prevent such dispersal

[10] Cartagena Act, Act No. 97 of June 18, 2003, art. 2, para. 2, http://www.japaneselawtranslation.go.jp/law/detail_main?re=02&vm=02&id=132.

[11] *Id*. art. 3.

[12] Basic Matters Under the Provisions of Article 3 of the Law Concerning the Conservation and Sustainable Use of Biological Diversity Through Regulations on the Use of GMOs (Basic Matters), MOF, MEXT, MHLW, MAFF & MOE Ordinance No. 1 of 2003, http://www.bch.biodic.go.jp/english/law.html (click "Word" icon next to the title).

[13] Yoshiko Sasaki, Idenshi kumikae gijutsu to shoku no anzen / anshin [Safety and Feeling of Safety on GM Technology and Foods], 1st and 2nd Meetings for Food Safety and Feeling of Safety, Yamanashi Pref. (Nov. 15 & Dec. 20, 2012), at 25, http://www.pref.yamanashi.jp/shoku-portal/communication/documents/tudoikouen-sassa_1.pdf.

[14] Many resident groups'activity reports are available through general Internet searches. *See*, *e.g.*, Jiro Urushihara, Jorei de chiiki no anzen/anzhin o kakuho suru—idenshi kumikae o meguru ho (5) [Securing Safety/Feeling of Safety of Residents by Local Ordinances—Laws Concerning GM (5)], Kagaku gijutsu no anekudoto [Anecdote of Science and Technology] (June 11, 2012), http://sci-tech.jugem.jp/?eid=2416.

[15] *Idenshi kumikae sakumotsu wa nihon de jissai ni saibai sarete iru no desu ka?* [*Are GM Crops Actually Grown in Japan?*], MONSANTO JAPAN, http://www.monsanto.co.jp/question/03/03/ (last visited Nov. 1, 2013).

of GMOs are classified as Type 2 uses and are subject to fewer restrictions.[16] Type 2 uses may include research activities in a laboratory.

For Type 2 uses, the government ministries with jurisdiction over the use of GMOs might issue ordinances that establish containment measures for the GMOs during their use. The nature of the use dictates which ministry has jurisdiction. When such ordinances have been issued, the users must implement any containment measures during the period of use.[17] Thus far, two such ordinances have been issued, one that establishes containment measures for industrial use,[18] and one that pertains to the research and development of GMOs.[19] The following examples illustrate which government entities are in charge of Type 2 uses:

Improvements to crops conducted within facilities, development of live vaccines for animals, etc.	Ministry of Agriculture, Forestry and Fisheries (MAFF)
Viruses for gene therapy, etc.	Ministry of Health, Labour and Welfare (MHLW)
Uses in the experiments of gene recombination in University, etc.	Ministry of Education, Culture, Sports, Science and Technology (MEXT)
Uses in the process of production of industrial enzymes, etc.	Ministry of Economy, Trade and Industry (METI)
Yeast used in the production of alcoholic beverages, etc.	National Tax Agency

Source: MINISTRY OF THE ENVIRONMENT (MOE), BIOSAFETY REGULATIONS IN JAPAN 5 (2010), http://www. bch.biodic.go.jp/english/cartagena/images/e_cartagena.pdf.

If an intended use does not fall within the purview of an existing ordinance, the user must draft containment measures and obtain confirmation, in advance, from the competent minister.[20]

In order to make sure that the containment measures are properly followed, the Basic Matters obligate Type 2 users of GMOs to endeavor to set up a committee to consider the safe handling of the GMOs in their place of use, according to the characteristics and mode of their use, so that

[16] Cartagena Act, Act No. 97 of June 18, 2003, art. 2, paras. 5 & 6, arts. 4 & 12, http://www.japaneselawtranslation.go.jp/law/detail_main?re=02&vm=02&id=132.

[17] *Id*. art. 12.

[18] Ordinance to Designate Measures to Prevent Dispersal of GMOs During Their Industrial Use Among Type 2 Use, Ministry of Finance, MHLW, MAFF, METI & MOE Ordinance No. 1 of 2004.

[19] Ordinance to Designate Measures to Prevent Dispersal of GMOs During Their Type 2 Use for Research and Development Purposes, MEXT & MOE Ordinance No. 1 of 2004.

[20] Cartagena Act art. 13.

measures for the prevention of adverse effects on biological diversity are appropriately carried out.[21]

If an accident occurs and the Type 2 user cannot take containment measures, the user must immediately take emergency measures and promptly notify the competent minister about the accident and outline the measures taken. The competent minister may then order the user to take emergency measures if they have not as yet been taken.[22]

V. Restrictions on Releasing Organisms into the Environment

The use of a GMO in a field or other open space (Type 1 use) is approved only when the competent minister decides the GMO will not cause any adverse effects on biological diversity. The competent ministries (depending on the purpose and use of GMOs) and the Ministry of the Environment (MOE) jointly manage Type 1 use cases. The MOE is in charge of Type 1 use in all fields because it has the responsibility of deciding whether the uses in an open system will affect biological diversity or not. A Type 1 use applicant must submit a biological diversity risk assessment report that evaluates the extent that the GMO may affect biological diversity.[23] If there is a native species that could be affected, the evaluation examines the possible effects and to what extent the species will be affected. In the case of crops, the possibilities of the GMO's competition with native wild species, hybridization with native wild species, and production of harmful substances are examined.[24]

A person who wishes to create, import, or use GMOs for Type 1 use must devise a Type 1 Use Rule—that is, draft rules for the use of each type of GMO—and obtain the approval of the competent minister. However, if the GMO is designated by the competent minister as an organism that clearly causes no adverse effect on biological diversity through Type 1 use, the user is not required to draft rules of use.[25] The competent minister must approve the applicant's Type 1 Use Rule if the minister determines, after consultation with experts, that there would be no unacceptable risks to the preservation of species or populations of wild fauna or flora, or any other adverse effect on biological diversity.[26]

In order to appropriately carry out measures for the prevention of adverse effects on biological diversity, the Type 1 user, like the Type 2 user, must endeavor to set up a committee to consider the safe handling of the GMOs in their place of use, according to the characteristics and mode of their use.[27]

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[21] Basic Matters, *supra* note 12, § II, 2.

[22] Cartagena Act art. 15.

[23] *Id*. art. 4, para. 2.

[24] MINISTRY OF THE ENVIRONMENT (MOE), BIOSAFETY REGULATIONS IN JAPAN 9–10 (2010), http://www.bch.biodic.go.jp/english/cartagena/images/e_cartagena.pdf.

[25] Cartagena Act art. 4, para. 1.

[26] *Id*. art. 4, para. 5.

[27] Basic Matters, *supra* note 12, § II, 2.

If a person engages in a Type 1 use without a proper Type 1 Use Rule, the competent minister may order the person to take steps to recall the GMOs or take other necessary measures to prevent adverse effects on biological diversity.[28] If an accident occurs and the Type 1 user cannot comply with the Type 1 Use Rule, and an adverse effect on biological diversity could arise, the user must immediately take emergency measures to prevent such an adverse effect. The user must also promptly notify the competent minister of the accident and outline the measures taken. The competent minister may then order the user to take additional emergency measures, if necessary.[29]

When there is a high likelihood that unapproved GMOs have been inadvertently imported, in view of the situation of the producing area or other circumstances, an importer must notify the competent minister to that effect on each occasion.[30] The competent minister may then order the importer to have these organisms tested by a registered inspector.[31]

The Cartagena Act obligates the government to collect, arrange, and analyze information on GMOs, as well as research the effects of their use on biological diversity.[32] The Ministry of Agriculture, Forestry, and Fisheries (MAFF) has annually monitored the spread of escaped imported GM seeds (canola and soy) and their contamination of domestic plants around major shipping ports and roads nearby. In the most recent report (2012), GM canola and soy were observed around the ports, but no contamination of domestic plants was found.[33]

VI. Restrictions on GMOs in Foodstuffs

A. Safety

The safety evaluation standards and production standards of new GM crops to be used for food or food additives are under the jurisdiction of the Ministry of Health, Labour and Welfare (MHLW). The relevant standards are stipulated in MHLW circulars and notifications based on the Food Sanitation Law.[34] Once the MHLW receives an application for the use of a GMO food, the Food Safety Commission (FSC) evaluates the safety of the GM food in terms of human health based on the Food Safety Basic Law.[35] The Expert Committee on Genetically Modified

[28] Cartagena Act art. 10, para. 1.

[29] *Id*. art. 11.

[30] *Id*. art. 16.

[31] *Id*. art. 17.

[32] *Id*. art. 34.

[33] Press Release, MAFF, "Heisei 24 nendo idenshi kumikae shokubutsu jittai chōsa" no kekka ni tsuite [Regarding the Result of "Research on GM Plants in Fields in Fiscal Year 2012"] (Sept. 24, 2013), http://www.maff.go.jp/j/press/syouan/nouan/130924.html.

[34] Food Sanitation Law, Act No. 233 of 1947, *last amended by* Act No. 70 of 2013, art. 7, para. 1; Standards of Foods and Food Additives, Ministry of Health and Welfare Notification No. 370 of 1959, *amended by* MHLW Notification No. 232 of 2000, http://www.mhlw.go.jp/topics/idenshi/anzen/kokuji.html.

[35] Food Safety Basic Law, Act No. 48 of 2003, *last amended by* Act No. 74 of 2011, arts. 11 & 23, English translation *available at* http://www.fsc.go.jp/english/basic_act/fs_basic_act.pdf.

Foods within the FSC conducts safety assessments based on the following standards and policies:[36]

(1) Standards for the Safety Assessment of Genetically Modified Foods (Seed Plants);

(2) Policies Regarding the Safety Assessment of Stacked Varieties of Genetically Modified Plants

(3) Standards for the Safety Assessment of Food Additives Produced Using Genetically Modified Microorganisms

(4) Policies Regarding the Safety Assessment of Highly Purified Nonprotein Food Additives, Including Amino Acids Produced Using Genetically Modified Microorganisms

According to the Food Sanitation Law, "[i]n order to prevent distribution of GM foods that have not been assessed in Japan, food products are analyzed at quarantines."[37] The Food Sanitation Law obligates importers of foods, food additives, "apparatuses," or containers/packages for sale or for use in business to notify the Minister of Health, Labour, and Welfare on each occasion.[38] When such notification is submitted, the food sanitation inspector at the quarantine station inspects the product to examine whether the item meets the regulations under the Food Sanitation Law.[39]

The MAFF is responsible for approving new GM crops for feed use in order to keep livestock safe. The safety test is conducted in accordance with the Act on Feed Safety and Improvement of Quality.[40] The safety of food derived from livestock that are fed GM crops is examined by the FSC.[41]

B. Labeling

As a part of the legal safety assessment system under the Food Sanitation Law, there is a labeling system for GM foods and two corresponding laws that include provisions on labeling: the Japanese Agricultural Standards Law (JAS Law)[42] and the Food Sanitation Law.[43] The two

[36] *Procedure for Safety Assessment*, MHLW, http://www.mhlw.go.jp/english/topics/foodsafety/dna/01.html (last visited Oct. 23, 2013).

[37] *Foods Produced by Recombinant DNA Techniques*, MHLW, http://www.mhlw.go.jp/english/topics/foodsafety/dna/index.html (last visited Oct. 25, 2013).

[38] Food Sanitation Law art. 27.

[39] *Id*. art. 28. *See* Development of Imported Foods Monitoring and Guidance Plan for FY 2013, MHLW Notice No. 0318 Article 1 of the Department of Food Safety (Mar. 18, 2013), http://www.mhlw.go.jp/topics/yunyu/keikaku/13_en.html.

[40] Act on Feed Safety and Improvement of Quality, Act No. 35 of 1953, *last amended by* Act No. 8 of 2007, art. 3. Ordinance on Act on Feed Safety and Improvement of Quality, MAFF Ordinance No. 35 of 1976, *last amended by* MAFF Ordinance No. 60 of 2013, Tables 1, 1(1)(shi)(su) & (2)(ko), 2 & 3(8).

[41] Ideas for Safety Evaluations of Feed and Feed Additives That Are or Include GMOs, Food Safety Commission Decision (May 6, 2004), http://www.fsc.go.jp/senmon/idensi/gm_siryoukijyun.pdf.

[42] Law Concerning Standardization and Proper Labeling of Agricultural and Forestry Products (JAS Law), Act No. 175 of 1950, *last amended by* Act No. 70 of 2013, art. 19-13, *translated by* MAFF at http://www.maff.go.jp/e/jas/

labeling systems are almost the same, and only one label is required.[44] Eight crops/vegetables/fruits (soy, corn, potato, canola, cotton seed, alfalfa, beet, and papaya) and thirty-three processed foods[45] that include more than 5% of these eight foods in weight are subject to labeling.[46] The 5% tolerance applies only to GM varieties that have been approved in Japan. A summary of the labeling system follows.[47]

1. Mandatory Labeling

GM products whose compositions or nutritional values are the same as their conventional counterparts, and processed food in which genetically modified DNA or proteins derived from the DNA can be detected even after processing of GM products, are subject to mandatory GM labeling. There are two types of cases:

(a) GM products that have been handled to preserve their identity by segregating them from non-GM products ("IP handling")

(b) Products for which IP handling has not been conducted (e.g., in the case of voluntary labeling, discussed below, soybeans are labeled "GM Ingredients," "GM Ingredients Not Segregated," or "Non-GM")[48]

In addition, food items that are considerably different in composition or nutritional value from their conventional counterparts and the processed foods made from them, which require labeling

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pdf/jaslaw01.pdf; Processed Food Quality Labeling Standards, MAFF Notification No. 513 of 2000, *last amended by* Consumer Affairs Agency Notification No. 5 of 2012, art. 7, para. 1; Fresh Produce Quality Labeling Standards, MAFF Notification No. 514 of 2000, *last amended by* MAFF Notification No. 126 of 2008, art. 7, para. 1; Labeling Standards on GM Food Set by Minister of MAFF Based on Article 7, Paragraph 1 of Processed Food Quality Labeling Standards and Article 7, Paragraph 1 of Fresh Produce Quality Labeling Standards (Labeling Standards on GM Food Set by Minister of MAFF), MAFF Notification No. 517 of 2000, *last amended by* MAFF Notification No. 9 of 2011, http://www.caa.go.jp/jas/hyoji/pdf/kijun_03.pdf, available in English translation (as last amended by MAFF Notification No. 1173 of October 1, 2007), *at* http://www.maff.go.jp/e/jas/labeling/pdf/ modi01.pdf.

[43] Food Sanitation Law, art. 19, para. 1, Cabinet Office Ordinance on Labeling Standards Based on Food Sanitation Law (Cabinet Office Ordinance on Labeling Standards), art. 19, para. 1, Cabinet Office Ordinance No. 45 of 2011, art. 1, para. 1, item 12 & Table 1, http://www.cao.go.jp/consumer/history/02/kabusoshiki/syokuhinhyouji/doc/130530_shiryou2-1.pdf.

[44] Consumer Affairs Agency, Food Labeling Sec., Shokuhin hyōji ni kansuru kyōtsū Q&A (dai 3 shū: idenshi kumikae shokuhin ni kansuru hyōji ni tsuite) [Common Q&A on Food Labeling (Part 3: Regarding Labeling of GM Food)] (Dec. 2003, *amended* Oct. 2007 & Mar. 2010), http://www.caa.go.jp/foods/pdf/syokuhin244.pdf.

[45] Labeling Standards on GM Food Set by Minister of MAFF Based on Article 7, Paragraph 1 of Processed Food Quality Labeling Standards and Article 7, Paragraph 1 of Fresh Produce Quality Labeling Standards (Labeling Standards on GM Food Set by Minister of MAFF), MAFF Notification No. 517 of 2000, *last amended by* MAFF Notification No. 9 of 2011; Cabinet Office Ordinance on Labeling Standards, *supra* note 43.

[46] Cabinet Office Ordinance on Labeling Standards, *supra* note 45, art. 14, item 1.

[47] *See Labeling Scheme for Genetically Modified Foods in Japan*, MAFF, http://www.maff.go.jp/e/jas/labeling/pdf/modi02.pdf (last visited Oct. 30, 2013).

[48] Labeling Standards on GM Food Set by Minister of MAFF, *supra* note 45, art. 3, para. 1(1) & para. 2(1); Cabinet Office Ordinance on Labeling Standards, *supra* note 45, art. 1, para. 2, item 40.

(e.g., soybeans with high oleic acid, labeled "soybeans (High Oleic Acid/GMO)," and corn with a high lysine content)[49]

2. Voluntary Labeling

Food in which genetically modified DNA or proteins derived from such DNA cannot be detected after processing, such as oil and soy sources, are not subject to mandatory GM labeling and can be labeled as not containing GM products. In addition, products certified as being free of GM products through IP handling can be labeled as not containing GM products.[50]

3. Prohibited Labeling

Agricultural products that have no variety developed by recombinant DNA techniques, and foods processed from such products, cannot have a term on their labels that suggests they are non-GM.[51] The reason is that if such labeling were allowed, consumers might think that GM versions of such products exist in Japan and that they are thus buying a non-GM version. In such cases, it is possible to add a description about the product to prevent misunderstandings. For example, it is permissible to add a description to a bag of rice, next to the legally required labeling, stating that "[a]t present, there is no GM rice on the market."[52]

VII. Liability Regime

There is no special civil liability regime in relation to the development, use, or release of GMOs. The Cartagena Act provides administrative and criminal sanctions against violators of the Act.

VIII. Judicial Decisions / Prominent Cases

There was a case in 2005 in which farmers in a city sued a research institution that owned lands in the same city to stop the experimental planting of genetically modified rice outside a building on that land. The institution was planting rice, in conformity with Cartagena Act regulations, that is supposed to create a protein to kill a rice pathogen. The plaintiffs claimed that a pathogen that is immune to the protein may be created and thereby endanger humans and the environment. However, the courts held that the plaintiffs had not successfully proved their claims and dismissed the case.[53]

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[49] Labeling Standards on GM Food Set by Minister of MAFF, *supra* note 45, art. 3, para. 1(2) & para. 2(2).

[50] *Id*. arts. 3 & 4; Cabinet Office Ordinance on Labeling Standards, *supra* note 45, art. 1, para. 7.

[51] Labeling Standards on GM Food Set by Minister of MAFF, *supra* note 49, art. 5.

[52] Consumer Affairs Agency, Food Labeling Sec., Shokuhin hyōji ni kansuru kyōtsū Q&A (dai 3 shū: idenshi kumikae shokuhin ni kansuru hyōji ni tsuite) [Common Q&A on Food Labeling (Part 3: Regarding Labeling of GM Food)] (Dec. 2003, *amended* Oct. 2007 & Mar. 2010), at 42.

[53] *Ine jikken chushi, baisho mitomezu: idenshi kumikae sosho* [*Injunction of Rice Experiment and Damages Were Not Awarded: Genetically Modified Rice Case*], 47NEWS (Oct. 1, 2009), http://www.47news.jp/CN/200910/CN2009100101000504.html. *See also* KINDAN NO KAGAKU SAIBAN [TRIAL OF FORBIDDEN SCIENCE], http://ine-saiban.com/ (last visited Oct. 23, 2013).

Lebanon

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SUMMARY Although Lebanon ratified the Convention on Biological Diversity in 1994 and the Cartagena Protocol in 2008, it has not yet adopted policies dealing with genetically modified organisms. While there are some existing laws that are indirectly relevant to this subject matter it is fair to say that no comprehensive legal regime on this issue exists at this time.

I. Introduction

Lebanon is a small country but has a lot of biodiversity due to its geography, which includes mountains, plains, and seashores, with at least three different climates. However, Lebanon appears to have not yet adopted any policies or legislation, either restrictive or permissive, on genetically modified organisms (GMOs), despite having ratified the Convention on Biological Diversity by Law No. 360 of 1994[1] and the Cartagena Protocol on Biosafety to the Convention on Biological Diversity by Law No. 31 of 2008.[2]

II. Public and Scholarly Opinion

The public in Lebanon has apparently not been seriously engaged on issues of national biosafety. When the Ministry of Environment collaborated with the United Nations Development Program (UNDP) on a project for the development of a National Biosafety Framework for Lebanon in 2004/2005 they conducted, as stated in the final report on the project, awareness-raising activities in universities, government agencies, and nongovernmental organizations in order to ensure public participation.[3] However, no information is available regarding public views on the development or use of GMOs.

There has also not been much discussion of the subject matter in scholarly literature produced in Lebanon. A search for such materials located reference to one recent paper, which was prepared by a professor of the faculty of Agricultural Sciences at the Lebanese University and presented at the Conference on Biosecurity and Biosafety Strategy in Case of Biological, Chemical or Nuclear Crisis held in Beirut from January 22 to 26, 2013.[4]

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[1] Law No. 360 of 1994, http://www.moe.gov.lb/getattachment/2270bcc2-d961-426b-b780-8055b1a6dd18/رقم-قرار-360-ابرام-اتفاقية-الامم-المتحدة-للتنوع-ال.aspx (in Arabic).

[2] Law No. 31 of 2008, AL-JARIDAH AL-RASMIYAH [OFFICIAL GAZETTE] No. 44 of 2008, http://www.pcm.gov.lb/Cultures/ar-LB/Menu/الجريدة الرسمية/الإصدارات السابقة/Pages/jolist.aspx (in Arabic; select relevant date and volume number).

[3] E.J. SATTOUT, D. JAMALI & W. NASSER, NATIONAL BIOSAFETY FRAMEWORK 7 (2005), http://www.unep.org/biosafety/files/LBNBFrep.pdf.

[4] Lamis Chalak Soukarie, Genetically Modified Organisms and Biosafety: Current Status in Lebanon, Presentation at the Conference on Biosecurity & Biosafety Strategy in Case of a Biological, Chemical or Nuclear Crisis, Beirut

A similar paper by the same author was included in a 2010 report prepared in conjunction with a Food and Agriculture Organization (FAO) regional project entitled "Strengthening capacities towards the establishment of a regional platform for the detection of genetically modified organisms." In this paper the author confirms that "there is no official policy or strategy for biotechnology in Lebanon"[5] and identifies the main gaps affecting the development of genetic engineering as follows:

- The absence of a national strategy addressing the use of biotechnology in the agricultural sector.
- The lack of cooperation between academia, research, industry and government.
- The absence of biosafety legislations.
- The absence of appropriate infrastructure (glasshouses and others) to pursue the studies on GM plants after the first laboratory tests vis-à-vis transgenes.
- The deficiency of human skills specialized in genetic engineering.
- The lack of funds.[6]

III. Structure of Pertinent Legislation

As mentioned above, Lebanon has not yet adopted a comprehensive national policy on GMOs. However, there are laws that may be indirectly related to the subject matter. For example, the National Biosafety Framework report identifies the following legislative instruments as relevant to biosafety:[7]

- Ordinance No. 3044 of 1925, which authorizes control of insects and diseases affecting plants;
- Decree No. 4396 of 1939, which provides for the compulsory fight against insects and diseases affecting citrus fruits;
- A law dated June 10, 1948 and Ministerial Ordinance No. 283/1 of 1998 related to agricultural quarantine; and
- Ministerial Ordinance No. 18/1 of 1997 concerning the vaccination of imported live animals.

(Jan. 2013), http://www.bbic-network.org/Uploads/Document/Genetically%20Modified%20Organisms%20(GMOs)%20and%20Biosafety%20Current%20Status%20in%20Lebanon.pdf.

[5] Lamis Chalak, *Lebanon*, *in* MAGDY MADKOUR, STATUS AND OPTIONS FOR REGIONAL GMOS DETECTION PLATFORM: A BENCHMARK FOR THE REGION 47 (2010), http://www.fao.org/docrep/012/al310e/al310e00.htm.

[6] *Id.* at 57.

[7] SATTOUT ET AL., *supra* note 3, at 34; *see also* Chalak, *supra* note 5, at 59–62, listing various existing laws related to agriculture and animal health, environment and biodiversity, health protection, food safety, and trade and customs the implementation of which "could have beneficial repercussions on biosafety in Lebanon." *Id.* at 59.

IV. Restrictions on Research, Production, and Marketing

There are apparently not yet any specific restrictions on the research, production, or marketing of food, feed, or medicines containing GMOs. A presentation about Lebanon at the 1st International Workshop on Harmonisation of GMO Detection and Analysis in MENA Region, held in Jordan on June 4 and 5, 2012, asserted that "[p]resently there is no laws or decrees against the consumption of food or feed containing GMOs or the use of medicines containing GMOs."[8]

V. Restrictions on Releasing Organisms into the Environment

As mentioned above, it does not appear that Lebanon has specific legislative instruments related to the releasing of GMOs into the environment. However, the Environmental Protection Law No. 444 of 2002 has provisions that may be relied upon to order such restrictions. For example, chapter 8 of that Law requires the protection of biodiversity, nature and genetic heritage from any influencing activity.[9]

VI. Restrictions on GMOs in Foodstuff

The only restriction located on GMOs in foodstuff is provided for in paragraph 4 of article 14 of the Law on Plant Quarantine and Phytosanitary Measures No. 778 of 2006.[10] This instrument prohibits the importation of genetically modified plants or their derivative products if such modifications endanger or cause damage to humans, animals, or plants.

VII. Liability Regime

Lebanon does not have a special liability regime to compensate for damages caused by GMOs. Any such damages are to be addressed through tort law as contained in the Obligations and Contracts Code, articles 121 to 139.[11]

VIII. Judicial Decisions

No relevant judicial decisions were located in the limited number of court reports available as a part of the Lebanese collection at the Law Library of Congress.

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[8] Gretta Abou Sleymane & Lamis Chalak, Status and Experiences Related to the Implementation of GMO Legislation in Lebanon, Presentation at the 1st International Workshop on Harmonisation of GMO Detection and Analysis in MENA Region, Dead Sea, Jordan (June 2012), http://gmo-crl.jrc.ec.europa.eu/capacitybuilding/docsworkshops/Jordan-2012/LEBANON.pdf.

[9] SATTOUT ET AL., *supra* note 3, at 34.

[10] Law on Plant Quarantine and Phytosanitary Measures No. 778 of 2006, OFFICIAL GAZETTE No. 58 of 2008, p. 6577, http://www.pcm.gov.lb/Cultures/ar-LB/Menu/الجريدة الرسمية/الإصدارات السابقة/Pages/jolist.aspx (in Arabic; select relevant date and volume number).

[11] Obligations and Contracts Code, *available at* http://www.aproarab.org/Down/Lebanon/24.doc (in Arabic).

Mexico

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SUMMARY Mexico's Law on Biosecurity of Genetically Modified Organisms (GMO Law) is the main federal statute pertaining to these organisms. It provides rules on research concerning, and the release, commercialization, exportation, and importation of, GMOs, and is aimed at preventing, avoiding, or reducing the risks that these activities may cause to human health, the environment, biological diversity, or the health of plants and animals. It also provides that the policy pertaining to biosecurity of GMOs is to ensure that these organisms are released, commercialized, exported, and imported with an adequate level of safety. Approval of GMOs for human consumption requires a study of the possible risks that consumption of the GMO may present for human health. Prior to their release, GMOs must be subject to risk studies and successful approval of experimental releases. Authorization for release may be denied if it is determined that the risks posed by a GMO may negatively affect human health; biological diversity; or the health of animal, plants, or water organisms by causing them grave or irreversible harm. The GMO Law provides that violations of its provisions or its regulations are punishable with civil penalties. Mexico's Federal Criminal Code provides that an individual who, in contravention of applicable law, commercializes, transports, stores, or releases into the environment a GMO that negatively alters or may alter the components, structure, or functioning of natural ecosystems is punishable with imprisonment of one to nine years and a fine.

I. Introduction

Mexico's Law on Biosecurity of Genetically Modified Organisms (GMO Law) provides rules on research concerning, and the release, commercialization, exportation, and importation of, Genetically Modified Organisms (GMOs), and is aimed at preventing, avoiding, or reducing the risks that these activities may cause to human health, the environment, biological diversity, or the health of plants and animals.[1]

Furthermore, the GMO Law provides that the purpose of, and the policy pertaining to, biosecurity of GMOs, is to ensure that these organisms are released, commercialized, exported, and imported with an adequate level of safety, which requires an evaluation of risks prior to their release and oversight of their effects after release.[2] Mexico's Department of Health has approved approximately 130 GMOs for human consumption.[3]

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[1] Ley de Bioseguridad de Organismos Genéticamente Modificados [Law on Biosecurity of Genetically Modified Organisms (hereinafter GMO Law)], art. 1, DIARIO OFICIAL DE LA FEDERACIÓN [D.O.], Mar. 18, 2005, http://www.diputados.gob.mx/LeyesBiblio/pdf/LBOGM.pdf.

[2] *Id.* art. 9(III), (V).

[3] *Cuales son los principales cultivos utilizados en la generación de OMGs/* [*What are the Main Crops Utilized in the Production of GMOs?*], COMISIÓN FEDERAL PARA LA PROTECCIÓN CONTRA RIESGOS SANITARIOS (COFEPRIS) [FEDERAL COMMISSION FOR THE PROTECTION AGAINST SANITARY RISKS], http://www.cofepris.gob.mx/AZ/Paginas/OGMS/Cultivos.aspx (last visited Nov. 19, 2013). *See also Preguntas Frecuentes* [*Frequently Asked*

II. Public and Scholarly Opinion

A. Public Opinion

While reliable public opinion data on GMOs in Mexico were not located, the fact that some Mexicans have expressed concern with respect to some aspects of GMOs can be inferred from a "Frequently Asked Questions" section on the website of Mexico's Commission on Biosecurity of GMOs.[4] A number of these questions, including the following, reflect concern about issues related to GMOs:

- Whether national producers have support from the government in order to compete with transnational companies, and whether these companies are the sole beneficiaries from GMOs in Mexico.[5]
- Whether GMOs will adversely affect human and animal health, as well as the genetics of native crops.[6]
- Whether Mexico's environmental authorities are taking measures to prevent GMOs from damaging the environment.[7]

B. Scholarly Opinion

The Mexican Academy of Science (MAS) has published a number of studies that explain technical aspects and the generally positive effects of GMOs and biotechnology.[8] For example, one of the studies published by MAS argues that GMOs currently utilized as foodstuffs have been subject to several evaluations that have proved that they do not harm human health.[9] Studies conducted by the MAS reportedly were instrumental in the approval and enactment of the GMO Law.[10] Conversely, the Mexican organization Semillas de Vida (Seeds of Life) has produced studies criticizing GMOs in Mexico.[11]

Questions on GMOs], COMISIÓN INTERSECRETARIAL DE BIOSEGURIDAD DE LOS ORGANISMOS GENÉTICAMENTE MODIFICADOS (CIBIOGEM) [COMMISSION ON BIOSECURITY OF GMOS] questions 34, 37, http://www.cibiogem.gob.mx/Paginas/FAQs.aspx (last visited Nov. 15, 2013).

[4] CIBIOGEM, *supra* note 3.

[5] *Id.* questions 9 & 20.

[6] *Id.* questions 30 & 15.

[7] *Id.* question 29.

[8] ACADEMIA MEXICANA DE CIENCIAS [MEXICAN ACADEMY OF SCIENCES], http://www.amc.mx/ (click on "Publicaciones"; last visited Nov. 20, 2013). Please cite a couple of studies by name.

[9] ACADEMIA MEXICANA DE CIENCIAS [MEXICAN ACADEMY OF SCIENCES], POR UN USO RESPONSABLE DE LOS ORGANISMOS GENÉTICAMENTE MODIFICADOS, 2011, at 12, 100, http://www.amc.mx/.

[10] FAUSTO KUBLI-GARCÍA, Capítulo Quinto, *Bioseguridad de los Organismos Genéticamente Modificados en México, in* RÉGIMEN JURÍDICO DE LA BIOSEGURIDAD DE LOS ORGANISMOS GENÉTICAMENTE MODIFICADOS 197, 199, 200, 204 (Institute of Legal Research, National Autonomous University, 2009), http://biblio.juridicas.unam.mx/libros/6/ 2637/9.pdf.

[11] SEMILLAS DE VIDA, http://www.semillasdevida.org.mx/index.php/documentos (last visited Nov. 20, 2013).

III. Structure of Pertinent Legislation

The GMO Law is the main federal statute pertaining to these organisms. It provides rules on research, releases into the environment, commercialization, exportation, and importation of GMOs, and is concerned with preventing, avoiding, or reducing the risks that these activities may cause to human health, the environment, biological diversity, or the health of plants and animals.[12] It provides that one of the principles that guides the policy pertaining to biosecurity of GMOs is to ensure that these organisms are released, commercialized, exported, and imported with an adequate level of protection for human health, biodiversity and the environment, which requires an evaluation of risks prior to their release.[13]

The GMO Law defines GMOs as any living organism (except human beings) that has acquired a novel genetic combination generated through the use of modern biotechnology techniques, so long as such techniques are recognized by the GMO Law or its regulations.[14]

IV. Restrictions on Research, Production, and Marketing

A. General

The GMO Law provides that protection of human health, the environment, and biological diversity requires the control of possible risks derived from activities related to GMOs through an evaluation of such risks prior to their release.[15]

The Mexican government has established a National Network of Laboratories for the Detection, Identification and Quantification of GMOs.[16] This network conducts research on GMOs in order to provide Mexican authorities with technical information necessary to determine whether these organisms pose risks to Mexico's biosecurity.[17]

B. Labeling Requirements for Distributed Products

Labels of genetically modified seeds or plants for agricultural production must indicate that these products are GMOs, and must describe their genetically acquired characteristics, special requirements for their cultivation, and changes in reproductive capabilities.[18]

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[12] Ley de Bioseguridad de Organismos Genéticamente Modificados art. 1.

[13] *Id.* art. 9(III), (V).

[14] *Id.* art. 3(XXI).

[15] *Id.* art. 9(V).

[16] *Red Nacional de Laboratorios de Detección, Identificación y Cuantificación de Organismos Genéticamente Modificados* [*National Network of Laboratories for the Detection, Identification and Quantification of GMOs*], CIBIOGEM, http://www.cibiogem.gob.mx/redes/RNLD-OGM/Paginas/default.aspx (last visited Nov. 19, 2013).

[17] *Id.*

[18] GMO Law art. 101, D.O., Mar. 18, 2005, http://www.diputados.gob.mx/LeyesBiblio/pdf/LBOGM.pdf.

V. Restrictions on Releasing Organisms into the Environment

The GMO Law provides that the purpose of, and the policy pertaining to, biosecurity of GMOs are to ensure that these organisms are released with an adequate level of safety.[19] Prior to their release, GMOs must be subject to risk studies and successful approval of experimental releases.[20] The basic steps to be followed in the study and evaluation of risks include the following:

- Identification of new characteristics of a particular GMO that may put biological diversity at risk
- Evaluation of the consequences if potential risks materialize
- An estimate of the potential global risk that the GMO poses, based on the evaluation of the probability that the possible risks and identified consequences may occur
- A conclusion indicating whether or not the possible risks are acceptable or manageable, including strategies to handle those risks[21]

Risk analysis is conducted primarily by Mexico's Departments of Environment and Agriculture.[22] Authorization for the release of a GMO may be denied if these agencies determine that the risks posed may negatively affect human health or biological diversity, or cause grave or irreversible harm to the health of animals, plants, or water organisms.[23] In order to ensure compliance with the GMO Law, the Mexican government has the authority to conduct inspections as deemed necessary.[24]

The Mexican government also has the authority to take a number of measures in order to manage the accidental release of unauthorized or prohibited GMOs, including the following:

- Temporary closure of places and/or facilities where the organisms are stored or processed
- Precautionary seizure of GMOs and the property, vehicles, utensils, and instruments directly related to the unauthorized release
- Repatriation of GMOs to their country of origin
- Destruction of GMOs[25]

[19] *Id.* art. 9(III), (V).

[20] *Id.* art. 9(IX).

[21] *Id.* art. 62.

[22] *Id.* arts. 11–15, 66.

[23] *Id.* art. 34(II)(C).

[24] *Id.* art. 113.

[25] *Id.* art. 115(III).

VI. Restrictions on GMOs in Foodstuffs

An application for approval of GMOs for human consumption (which includes fodder for livestock where such livestock may be consumed by human beings) requires a study of the possible risks that consumption of the GMO may represent for human health.[26] Such a study must include scientific and technical information pertaining to the harmlessness of the GMO.[27] The application and study must be presented to Mexico's Department of Health (DOH) (Secretaría de Salud) for its analysis and review.[28] If the review finds no evidence of risks to human health, the GMO may be approved by the DOH for commercialization and importation.[29]

GMOs or products that contain GMOs authorized for human consumption by Mexico's Department of Health must display on their labels information on their nutritional value and ingredients, in those cases where these characteristics are significantly different from conventional products.[30] This information must be objective, clear, useful for the consumer, and based on scientific and technical information.[31]

VII. Liability Regime

The GMO Law provides that violations of its provisions or its regulations are punishable with the following civil penalties:

- Temporary or permanent closure of the facilities where the infraction took place if the violation causes possible risks or adverse effects to human health; biological diversity; or the health of animals, plants, or aquatic organisms
- Seizure of instruments, organisms, or other products obtained as a direct result of the violation
- Suspension or revocation of permits and authorizations granted by the government
- Arrest of up to thirty-six hours
- Fines[32]

In addition, the GMO Law provides that any person who causes damage to third parties as a result of the illegal uses of GMOs may be held responsible and forced to repair the damage under

[26] *Id.* arts. 91, 92.

[27] *Id.* art. 92(I).

[28] *Id.* arts. 16(II), 94.

[29] *Id.* arts. 96, 97. *See also Evaluación de la Inocuidad de un OMG* [*Evaluation of Harmlessness of a GMO*], COFEPRIS, http://www.cofepris.gob.mx/AZ/Paginas/OGMS/Evaluacion-ogms.aspx (last visited Nov. 19, 2013).

[30] GMO Law art. 101, D.O., Mar. 18, 2005, http://www.diputados.gob.mx/LeyesBiblio/pdf/LBOGM.pdf.

[31] *Id.*

[32] *Id.* art. 120.

federal tort law.[33] Furthermore, Mexico's Federal Criminal Code provides that an individual who, in contravention of applicable law, commercializes, transports, stores, or releases into the environment a GMO that negatively alters or may alter the components, structure, or the functioning of natural ecosystems is punishable with imprisonment of one to nine years and a fine.[34]

VIII. Judicial Decisions / Prominent Cases

In October 2013, a federal judge in Mexico City issued a preliminary injunction whereby Mexico's Departments of Agriculture and Environment were ordered to temporarily stop authorizations for releasing any genetically modified species of corn.[35] This measure was ordered in legal proceedings derived from a lawsuit filed earlier in the year by a group of activists who want to stop the proliferation of transgenic corn in Mexico on health and environmental grounds.[36] In December 2013, this lawsuit was reportedly dismissed on a number of grounds, including lack of standing of the plaintiffs.[37] News reports indicate that the plaintiffs have appealed the dismissal.[38]

[33] *Id.* art. 121.

[34] CÓDIGO PENAL FEDERAL [FEDERAL PENAL CODE] *as amended*, art. 420 ter, Aug. 14, 1931, http://www.diputados.gob.mx/LeyesBiblio/pdf/9.pdf.

[35] Press Release, Semillas de Vida, Tribunal Federal suspende toda la siembra de maíz transgénico (Oct. 10, 2013), http://www.semillasdevida.org.mx/index.php/documentos/articulos/93-boletines-de-prensa/86-articulo-2-muestra.

[36] *Id.*

[37] María del Pilar Martínez, *Juez rechaza demanda contra transgénicos*, EL ECONOMISTA (Dec. 19, 2013), http://eleconomista.com.mx/sociedad/2013/12/19/juez-rechaza-demanda-contra-transgenicos.

[38] Press Release, Semillas de Vida, Se mantiene la suspensión de emisión de permisos para la siembra de transgénico en México (Dec. 20, 2013), http://www.semillasdevida.org.mx/index.php/documentos/articulos/93-boletines-de-prensa/143-boletin-de-prensa-10-oct-13 (last visited Jan. 27, 2014).

Netherlands

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SUMMARY Although the Netherlands was the first European Union Member State to have legal coexistence guidelines on genetically engineered (GE) crops, commercial production of genetically modified (GM) crops has not yet taken place there, and there are no GE livestock. While the government and the agriculture sector take a pragmatic approach toward the import and use of GM products, public opinion is divided as to whether GM foods pose health risks, and the complex regulatory environment and effective pressure from environmental groups have worked to hamper the commercial manufacture of genetically modified organisms (GMOs).

Activities involving GMOs are for research purposes in laboratories or field trials, and are tightly regulated, in particular through EU Directives made applicable in the Netherlands. The Ministry of Infrastructure and Environment oversees the GMO-related activities in the Netherlands; its Bureau for Genetically Modified Organisms carries out licensing. Prior risk assessment and subsequent monitoring and reporting are necessary for all GMO-related activities. Criminal penalties and administrative sanctions may be applied to violations of licensing requirements.

The Netherlands Food and Consumer Product Safety Authority and the Institute of Food Safety are responsible for determining the safety of GMO food and feed, respectively. Labeling of pre-packaged food products for sale in the Netherlands requires conformity with the Food Labeling (Commodities Act) Decree and the relevant EU Regulation on food and feed. Contained-use license holders must ensure, if making GMOs available to another party, that the GMO packaging label or the document accompanying the GMOs clearly indicates the presence of GMOs.

I. Introduction

Commercial production of genetically modified (GM) crops has not yet occurred in the Netherlands.[1] According to a report on biotechnology in the Netherlands issued by the US Department of Agriculture (USDA) in June 2013, "there are no genetically engineered (GE) crops under development that will be on the market in the next five years."[2] However, the

[*] This report was prepared chiefly on the basis of materials available in English in the Law Library collection and online. At present the Law Library does not have staff with Dutch language skills.

[1] *Country Reports: GMOs in EU Member States: The Netherlands*, GMO COMPASS (Mar. 23, 2007), http://www.gmo-compass.org/eng/news/country_reports.

[2] BOB FLACH, NETHERLANDS: AGRICULTURAL BIOTECHNOLOGY ANNUAL 1 (June 12, 2013), http://gain.fas.usda.gov/Recent%20GAIN%20Publications?Agricultural%20Biotechnology%20Annual_The%Hague_Netherlands_6-12-2013.pdf (or conduct search using "GAIN Report NL3019" on Mozilla Firefox) (copy on file with author). The report notes that Wageningen University was slated to start a trial in 2013 with a GE potato whose market introduction was unlikely to be within five years. Three groups—public research institutes, biotechnology firms,

Netherlands does import large quantities of GE crops and derived products.[3] It also transships such imported crops and products to other European Union (EU) countries, or exports them to non-EU countries, using the requisite documentation and labeling required under EU law.[4] Because cultivation of GE crops is not permitted, GE seed is not imported.[5] Additionally, because GE products for consumers must be labeled, imported quantities of the products are small.[6] The main imported GE crops and derived products are soybeans from Brazil and the United States and soybean meal from Brazil and Argentina.[7] In accordance with EU legislation, the Netherlands has a Low Level Presence policy for unapproved GE varieties in feed.[8] According to the USDA report, "the Dutch livestock sector depends on feed imports from third countries [that consist] mainly of GE soybean meal. The livestock sector does not include any GE animals nor do Dutch agricultural research institutes have them for research purposes."[9]

II. Public and Scholarly Opinion

The Dutch government and parliament view GM crop varieties as "a very important field of development for the economy and civil society at large."[10] While the government and the agricultural sector have been characterized as taking a pragmatic approach towards the import and use of GE agricultural products, because of "cumbersome regulations" and the specter of protests from environmental groups, crop trials and the cultivation of biotech crops for commercial purposes are viewed as being effectively blocked.[11] There are other considerations as well. According to a 2008 report published by the Commission on Genetic Modification (Commissie Genetische Modificatie, COGEM), an independent scientific advisory committee[12] on the environmental and economic impact of GM crops on Dutch agriculture,[13] "given the small

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and potato breeding companies—have been directly involved in breeding a GE potato in the Netherlands. W.J. Bijman, *The Development and Introduction of Genetically Modified Potatoes in the Netherlands*, http://www.accessexcellence.org/RC/AB/BA/Potatos_in_Netherlands.php (last visited Nov. 13, 2013).

[3] FLACH, *supra* note 2.

[4] *Id*.

[5] *Id*.

[6] *Id*.

[7] *Id*.

[8] *Id*. at 5.

[9] *Id*. at 1.

[10] Hubert P.J.M. Noteborn & Freija H. van Duijne, *The Dutch Approach to Safety in Agriculture*, *in* GOVERNING RISK IN GM AGRICULTURE 88 (Michael Baram & Mathilde Bourrier eds., Cambridge University Press 2011); Maggie Delano, *Key Players: Farmers – Monsanto – Government – Non-Government Organizations*, ROUNDUP READY CROPS (Spring 2009), http://web.mit.edu/demoscience/Monsanto/players.html.

[11] FLACH, *supra* note 2.

[12] *COGEM*, COMMISSIE GENETISCHE MODIFICATIE: COGEM, http://www.cogem.net/index.cfm/en/cogem/ (last visited Nov. 5, 2013).

[13] COGEM, SOCIO-ECONOMIC ASPECTS OF GMOS: BUILDING BLOCKS FOR AN EU SUSTAINABILITY ASSESSMENT OF GENETICALLY MODIFIED CROPS 34 (Jan. 5, 2010), http://www.rijksoverheid. nl/documenten-en-publicaties/kamerstukken/2010/01/15/sociaal-economische-aspecten-van-genetisch-gemodificeerde-gewassen-rapport-engels.html.

area of land used for agriculture in the Netherlands, the GM crops currently available are not particularly attractive for Dutch farming," and properties added thus far "offer few advantages to [a Dutch farmer of arable land]."[14]

Awareness of GM foods and of animal cloning is relatively high in the Netherlands; it was reported in 2010 that some 93% of the Dutch public had heard of the GM foods and 87% were aware of animal cloning.[15] Public opinion is divided as to whether GM foods are good for people, with 43% of persons surveyed of the view that such foods are not good, 44% disagreeing with that view, and 13% not sure.[16] Although the majority of respondents believed that GMO foods were not safe for future generations, a higher proportion of the Dutch (34%) compared to other Europeans held that the products would be safe.[17] On the whole, in the view of one study, the Dutch general public's perceptions on conventional crop and food safety "are grounded more in culture and tradition than in scientific safety testing."[18]

Among political parties, it appears that the Party for the Animals has recently been active against the use of GMOs. In January 2013, it put forward a proposal to make Amsterdam a GMO-free zone.[19] Some of the other organizations and institutions active on GMO issues (chiefly against GMOs) in the Netherlands are Gentech-NL – ASEED (which called for a march against MonsantoS on October 30, 2013);[20] Milieudefensie (Friends of the Earth Netherlands); Greenpeace Netherlands; Nederlands Platform Genetechnologie; De Gentechvrije Burgers; GoedeWaar.nl; and Burgers voor gentechvrij voedsel.[21]

III. Structure of Pertinent Legislation

A. Definition of GMOs

Under the Decree on Genetically Modified Organisms in the Environment (hereinafter GMO Decree),[22] "genetically modified organisms" (*genetisch gemodificeerde organismen*) are defined

[14] *Id*.

[15] TNS OPINION & SOCIAL, EUROBAROMETER: BIOTECHNOLOGY REPORT 13 & 52 (Oct. 2010), http://ec.europa.eu/public_opinion/archives/ebs/ebs_341_en.pdf.

[16] *Id*. at 20–21.

[17] *Id*. at 23.

[18] Noteborn & van Duijne, *supra* note 10, at 86.

[19] *Netherlands*, GMO-FREE EUROPE 2012, http://www.gmo-free-regions.org/gmo-free-regions/netherlands.html (last visited Oct. 25, 2013). For the text of the proposal, *see* PARTIJ VOOR DE DIEREN, AMSTERDAM GENTECHVRIJ (Jan. 28, 2013), http://amsterdam.partijvoordedieren.nl/downloads/amsterdam/2013/01/1359384683_Initiatiefvoorstel_Amsterdam_gentechvrij_Partij_voor_de_Dieren_-_28012013.pdf.

[20] *30 October 2013: March Against MonsantoS*, ASEED, http://aseed.net/en/topic/gmos-2/ (last visited Nov. 6, 2013).

[21] *Netherlands*, GMO-FREE EUROPE 2012, *supra* note 19.

[22] Besluit genetisch gemodificeerde organismen milieubeheer [hereinafter GMO Decree] (Jan. 25, 1990, as last amended June 24, 2010, in force on Oct. 1, 2010), http://wetten.overheid.nl/BWBR0004703/geldigheidsdatum_25-10-2013.

as organisms, with the exception of human beings, in which the genetic material has been altered in a way that is not possible in nature through mating or through natural recombination.[23] Genetic material is defined as DNA and RNA; genetic modification, as the alteration of genetic material in a way that is not possible in nature through reproduction or recombination; and organisms, as microorganisms and other biological entities with the capacity for multiplication or transmission of genetic material.[24]

B. Regulation of GMOs

GMOs in the Netherlands are regulated at the international, European Union, national, and local levels. The Netherlands is a party to the Convention on Biological Diversity,[25] the Cartagena (Biosafety) Protocol,[26] and the Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters.[27] The Netherlands signed The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety on March 7, 2011.[28]

In the case of EU regulation, Directive 90/219/EEC on the contained use of GM microorganisms as amended by Directive 98/81/EC (the Contained Use Directive)[29] and Directive 2001/18 on the

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[23] *Id*. art. 1(f). This is essentially the same definition as in EU Directive 2001/18/EC; for the citation *see* note 30 below.

[24] *Id*. art. 1(b, c, & e).

[25] Convention on Biological Diversity (opened for signature June 5, 1993, in force from Dec. 29, 1993), http://www.cbd.int/doc/legal/cbd-en.pdf (English text). The Netherlands signed the treaty on June 5, 1992; the treaty entered into force for the country on July 12, 1994. *List of Parties*, CONVENTION ON BIOLOGICAL DIVERSITY, http://www.cbd.int/convention/parties/list/default.shtml (last visited Nov. 5, 2013).

[26] The Cartagena Protocol on Biosafety (Jan. 29, 2000; in force from Sept. 11 2003), http://bch.cbd.int/protocol/ (click on left-side column for text of protocol). The Netherlands deposited its instrument of acceptance of the Protocol on January 8, 2002; the Protocol entered into force in the Netherlands on September 11, 2003. *Parties to the Protocol and Signature and Ratification of the Supplementary Protocol*, CONVENTION ON BIOLOGICAL DIVERSITY, http://bch.cbd.int/protocol/parties/ (last visited Sept. 19, 2013). The Netherlands has not yet ratified the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (Oct. 15, 2010). For the English text of the Supplementary Protocol, *see* http://bch.cbd.int/protocol/nkl_text.shtml (last visited Nov. 5, 2013).

[27] Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (done at Aarhus, Denmark, June 25, 1998), http://www.unece.org/fileadmin/DAM/env/pp/documents/cep43e.pdf. The Netherlands signed the Convention on June 25, 1998, and deposited its instrument of acceptance on December 29, 2004. *Chapter XXVII: Environment, Status as at 05-11-2013*, UNITED NATIONS TREATY COLLECTION, http://treaties.un.org/ Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=XXVII-13&chapter=27&lang=en (last visited Nov. 25, 2013).

[28] Press Release, United Nations, Press Conference on Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to Cartagena Protocol on Biosafety (Mar. 7, 2011), http://www.un.org/News/briefings/docs/2011/110307_Biosafety.doc.htm; Press Release, The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (Oct. 16, 2010), http://bch.cbd.int/protocol/nkl_pressrelease.shtml; for the text of the Supplementary Protocol, *see* http://bch.cbd.int/protocol/nkl_text.shtml (last visited Nov. 5, 2013).

[29] Council Directive 90/219/EEC of 23 April 1990 on the Contained Use of Genetically Modified Micro-Organisms, 1990 O.J. (L 117), http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31990L0219:EN:HTML; Council Directive 98/81/EC of 26 October 1998 Amending Directive 90/219/EEC on the Contained Use of

deliberate release of GMOs into the environment (the Deliberate Release Directive)[30] have been implemented in Dutch law by the GMO Decree. Other key EU legislation includes Directive 2009/41/EC on the framework for laboratory experiments using GM microorganisms,[31] Regulation EC No. 178/2002 on general principles and requirements of food law and procedures for food safety,[32] Regulation EC No. 258/97 on novel foods and novel food ingredients,[33] Regulation EC No. 1829/2003 on GM food and feed,[34] and Regulation EC No. 1830/2003 on the traceability and labeling of GMOs and traceability of GMO derived food products.[35] Regulation 1946/2003 applies to transboundary movements of GMOs.[36]

The basic purpose of current Dutch legislation on GMOs is to implement European Union directives on the subject, which seek to balance the promotion of scientific progress with protection of the environment and consumer safety. This is mainly accomplished in the GMO Decree. The overarching national law on which the GMO Decree is based is the Environmentally Hazardous Substances Act.[37] In addition to the GMO Decree, key items of legislation implementing the EU law in the Netherlands are the Regulation on GMOs,[38] the

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Genetically Modified Micro-Organisms, 1998 O.J. (L 330), http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0081:EN:HTML.

[30] 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 – Commission Declaration, 2001 O.J. (L 106), http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32001L0018:EN:HTML. Art. 2(2) of the Directive defines "genetically modified organism (GMO)" as "an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination."

[31] Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the Contained Use of Genetically Modified Micro-Organisms (Recast) Text with EEA Relevance, 2009 O.J. (L 125), http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:125:0075:01:EN:HTML.

[32] 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), http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:EN:PDF.

[33] Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 Concerning Novel Foods and Novel Food Ingredients, 1997 O.J. (L 43), http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31997R0258&model=guichett.

[34] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on Genetically Modified Food and Feed (Text with EEA Relevance), 2003 O.J. (L 268), http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32003R1829:EN:HTML.

[35] 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, 2009 O.J. (L 268), http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32003R1830:EN:HTML.

[36] Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on Transboundary Movements of Genetically Modified Organisms, 2003 O.J. (L 287), http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:287:0001:0010:EN:PDF.

[37] Wet milieugevaarlijke stoffen (Dec. 5, 1985, as last amended effective Oct. 17, 2007), http://wetten.overheid.nl/BWBR0003892/geldigheidsdatum_31-05-2008.

[38] Regeling Genetisch Gemodificeerde Organismen [Regulation on GMOs] (May 28, 1998, as last amended effective Oct.1, 2010), http://wetten.overheid.nl/BWBR0009653/Hoofdstuk1/geldigheidsdatum_05-11-2013.

Environmental Management Act,[39] the Food and Commodities Act,[40] and the Decree on Novel Foods.[41]

At the local level, cities and provinces have taken action against GMOs. For example, on January 26, 2011, Friesland Province became the first GMO-free region in the Netherlands, and in July of that year the Community Council of Nijmegen declared the city to be GMO-free.[42]

IV. Restrictions on Research, Production, and Marketing

A. Licenses and Risk Assessments

Prior risk assessment and authorization is required in order to engage in activities involving GMOs. The Dutch Environment Management Act provides that anyone who by virtue of his profession manufactures a substance, preparation, or genetically modified organism; imports it into or administers, prepares, processes, or makes it available to others in the Netherlands; and who knows or reasonably could have guessed that by his actions the substance, preparation, or organism may pose a threat to human health or the environment, must take all measures that can reasonably be demanded of him to avoid or reduce the risks as far as possible.[43] Under Dutch law, as part of the permit process for such activities, COGEM is responsible for assessing the risks they might pose to health and the environment[44] and reporting its findings to the Minister of Infrastructure and the Environment.[45]

GMOs are classified into three groups under Dutch law. Group I comprises GM microorganisms that meet the rules for GMO classification laid down by the Minister of Infrastructure and Environment, as well as such microorganisms manufactured using organisms and vectors not designated as suitable for the production of Group I organisms but that, upon application to the

[39] Wet milieubeheer (June 13, 1979, as last amended effective July 1, 2013), http://wetten.overheid.nl/BWBR0003245/geldigheidsdatum_05-11-2013; Environmental Management Act (English translation as of May 1, 2004), http://www.asser.nl/upload/eel-webroot/www/documents/national/netherlands/EMA052004.pdf.

[40] Warenwet (Dec. 28, 1935, as last amended Dec. 20, 2012, in force on Jan. 1, 2013), http://wetten.overheid.nl/BWBR0001969/geldigheidsdatum_13-11-2013; *see also* Charles-Emmanuel Côté, European Commission: Health and Consumer Protection Directorate-General, The Practical Application of Council Directive 92/59/EEC on General Product Safety: The Netherlands (Feb. 2000), http://ec.europa.eu/dgs/health_consumer/library/surveys/sur13_13_en.pdf.

[41] Besluit van 29 april 1997, houdende regels voor nieuwe voedingsmiddelen en nieuwe voedselingrediënten (Warenwetbesluit Nieuwe voedingsmiddelen) (as last amended Jan. 17, 2007, in force on Feb. 7, 2007), http://wetten.overheid.nl/BWBR0008643/geldigheidsdatum_13-11-2013.

[42] *Netherlands,* GMO-FREE EUROPE 2012, *supra* note 19.

[43] Wet milieubeheer art. 9.2.1.2.

[44] A recent example of COGEM advice on the importation of a GMO into the Netherlands is available on the COGEM website, at *28.10.2013: Additional Advice on Import of T25 Maize (CGM/131028-01)*, COGEM, http://www.cogem.net/index.cfm/nl/publicaties/publicatie/additional-advice-on-import-of-t25-maize.

[45] Noteborn & van Duijne, *supra* note 10, at 89. The Ministry of Infrastructure and Environment (Ministerie van Infrastructuur en Milieu) was formerly the Ministry of Housing, Spatial Planning, and the Environment (Ministerie van Volkshuisvesting, Ruimtelijke Ordening en Milieu, VROM).

Minister, are found to meet the classification criteria. Group II is other GM microorganisms, and Group III is GMOs other than microorganisms.[46]

The GMO Decree requires that a license be obtained for the genetic modification of plants and microorganisms.[47] The Decree allows for various types of licenses, which may be roughly divided into the three categories of contained use, market introduction, and other purposes such as field trials.[48] In general, the GMO permit is to include the following information: the purpose of the genetic modification; the name of the host(s), vector(s), and insert(s); the safety level; and the exact place of the work.[49] The specific kinds of information required for each type of permit are set forth in Annex 4 of the GMO Decree.

The Bureau for Genetically Modified Organisms (Bureau Genetisch Gemodificeerde Organismen, or Bureau GGO), on behalf of the Ministry of Infrastructure and the Environment, handles the granting of licenses (*vergunningverlening*) to work with GMOs.[50] The government maintains a database of licenses that have been granted as well as those that are pending. In addition, the database website includes information from 2008 on the locations of field trials in the Netherlands and the registration of GM crops.[51]

B. Contained Use (*Ingeperkt Gebruik*)

Anyone who intends to engage in the contained use of GMOs must conduct an analysis beforehand of possible risks to humans or the environment and keep available a summary report for the Minister of Infrastructure and the Environment, and for the authority that has jurisdiction over the establishment where the activities in question take place.[52] It is prohibited to carry out contained use of GMOs without a permit issued in response to an application for a license.[53]

For purposes of standard laboratory research or manufacturing involving procedures on a small scale (generally up to ten liters of culture fluid per unit), a Group I Class A permit is required.[54]

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[46] GMO Decree arts. 2(1) & 2(4).

[47] Han Somsen, *GMO Regulation in the Netherlands*, *in* UNCERTAIN RISKS REGULATED 195 (Michelle Everson & Ellen Vos eds., Routledge-Cavendish 2009).

[48] *Id.*

[49] Piet de Wildt, Enforcement and Inspections: "Contained Use"/"Field Trails" [sic]: Dutch Case, Workshop on Biosafety, Kiev (Apr. 2012), *available at* http://ec.europa.eu/enlargement/taiex/dyn/taiex-events/library/detail_en.jsp?EventID=46779 (click on "Enforcement and Inspections" under "Mr Petrus Jacobus de Wildt").

[50] BUREAU GGO, http://www.ggo-vergunningverlening.nl/ (last visited Nov. 25, 2013).

[51] *Vergunningendatabase* [*Permit Database*], BUREAU GGO, http://www.ggo-vergunningverlening.nl/Vergunningendatabase (last visited Nov. 15, 2013). Click on *vergunningdatabase biotechnologie* hyperlink to view the granted and pending licenses.

[52] GMO Decree art. 5.

[53] *Id*. art. 17(1). Articles 8–11 are on different types of permit applications.

[54] *Groep I Categorie A (IA) Aanvraag* [*Group I Class A (IA) Application*], BUREAU GGO, http://ggo-vergunningverlening.nl/Vergunningverlening/Ingeperkt_gebruik/Groep_I_categorie_A_IA_aanvraag (last visited Nov. 15, 2013).

Class A covers laboratories, animal housing, storage rooms, or greenhouses intended for (1) genetic modification of organisms or (2) education, research, development or the non-industrial-purpose reproduction, storage, use, possession, transport, disposal, or destruction of GMOs.[55] Group I Class A permit holders must prepare a report before June 1 every year on the previous year's activities and keep it for five years, at the disposal of the Minister.[56] There is also a Group I Class B permit, for "other operations" involving Group I organisms.[57] Such permits might involve procedures on a large scale (use of more than ten liters)[58] or work not covered by small-scale or large-scale operations.[59]

All work carried out under a contained use license is to be monitored by a Biological Safety Officer (Biologische-veiligheidsfunctionaris, BVF). The BVF must be authorized by the State Secretary of Infrastructure and the Environment.[60] The license holder charges the BVF with such tasks as drafting and modifying detailed internal procedures and rules for the safe handling of GMOs, and conducting internal monitoring of compliance with the relevant legal provisions as well as those procedures and rules.[61]

V. Restrictions on Releasing Organisms into the Environment

A. Conditions for Deliberate Release into the Environment

For activities involving the release of GMOs into the environment, adherence to procedures set forth under EU Directive 2001/18/EC (the Deliberate Release Directive) is required.[62] An application for a license to place GMOs on the market must contain, among other material, information required by the Directive, an environmental risk assessment, the desired duration of the license, and a monitoring plan.[63] In general, a marketing license is granted for up to ten years.[64] An application for a permit for deliberate release of GMOs into the environment for other purposes (e.g., for field trials) must include information needed to carry out an

[55] GMO Decree art. 3.1(a).

[56] *Id*. art. 8(3).

[57] *Id*. art. 3.1(b).

[58] *Ingeperkt gebruik* [*Contained Use*], BUREAU GGO, http://ggo-vergunningverlening.nl/Vergunningverlening/Ingeperkt_gebruik (last visited Nov. 15, 2013).

[59] *Id*.

[60] *Toelating BVF* [*BVF Admission*], BUREAU GGO, http://www.ggo-vergunningverlening.nl/Vergunningverlening/Ingeperkt_gebruik/Toelating_BVF (last visited Nov. 25, 2013).

[61] Regulation on GMOs art. 4 (on "Internal Organization").

[62] *Wetten en Regels*, COGEM, http://www.cogem.net/index.cfm/nl/genetische-modificatie/wetten-en-regels/ (last visited Nov. 5, 2013).

[63] GMO Decree art. 28(1).

[64] *Id*. art. 31.

environmental risk assessment, in accordance with Annex III of the Directive as well as the environmental risk assessment itself.[65]

It is prohibited without a license to produce GMOs to use, hold, or be made available to another party, to introduce or discard them in the Netherlands, or to transport GMOs that are not microorganisms.[66] Exceptions to this ban include, for example, GMOs for contained use;[67] the transport of GMOs, other than microorganisms, for other purposes in accordance with ministerial rules;[68] operations for other purposes involving medicinal substances and preparations for human use that consist of or contain GMOs, if certain conditions are met;[69] GMOs as or in products or marketed products, or insofar as they meet certain conditions;[70] GMOs as or in marketed products if the competent authority of another Member State has provided for their market placement or otherwise been granted prior written permission;[71] and traces of a GMO in products marketed and intended for direct use as food or feed, or for processing.[72]

Material derived from GMOs for which a permit or written permission has been granted by a competent authority of another EU Member state is prohibited from placement on the market unless a license or written consent has been granted for such a purpose.[73]

Violation of the GMO Decree's licensing requirements is deemed a criminal offense in conformity with article 1a of the Dutch Act on Economic Offenses, with maximum penalties ranging from imprisonment for six years for intentional acts and fines up to €78,000 (approximately US$106,018).[74] The Minister for Infrastructure and the Environment may also apply certain "standard" administrative sanctions, such as revocation of the license.[75]

B. Reporting and Transparency

Licensees are responsible for providing various types of reports. Before a licensee begins work, he or she should provide a description of the proposed work (*Beschrijving van Voorgenomen*

[65] *Id*. art. 24(1)(a) & (b).

[66] *Id*. art. 23(1); exceptions are listed in art. 23(2).

[67] *Id*. art. 23(2)(a).

[68] *Id*. art. 23(2)(c).

[69] *Id*. art. 23(2)(d).

[70] *Id*. art. 23(2)(e) & (f).

[71] *Id*. art. 23(2)(g).

[72] *Id*. art. 23(2)(h).

[73] *Id*. art. 23(3).

[74] J. H. Jans, GMO Regulation in the Netherlands, Avosetta Meeting, Siena (Sept. 2006), at 3, http://www-user.uni-bremen.de/~avosetta/netherlands_06.pdf; *Wet op de economische delicten* (June 22, 1950, as last amended Nov. 6, 2013), art. 1a(1) & art. 6, http://wetten.overheid.nl/BWBR0002063/geldigheidsdatum_25-11-2013; Wetboek van Strafrecht [Criminal Code] (Mar. 3, 1881, as last amended Nov. 6, 2013, in force on Nov. 15, 2013), art. 23(4), http://wetten.overheid.nl/BWBR0001854/EersteBoek/TitelII/geldigheidsdatum_25-11-2013.

[75] Jans, *supra* note 74.

Werkzaamheden) for the coming year.[76] The report must be approved, with written confirmation, by the Bureau GGO.[77] As was noted above in connection with contained use licensees, at the end of the work year, a report of work performed (*Verslag van Verrichte Werkzaamheden*) must be submitted.[78] Once a field trial is terminated, a final report must be prepared, in conformity with the fixed format required by the European Commission.[79]

If the applicant or the holder of a license for placing GMOs on the market or for other purposes becomes aware of new information on the risks that the GMO or the operations involving it may pose to humans or the environment, or if there is a modification or unintended change in the deliberate release of GMOs into the environment, the person must immediately notify the Minister of Infrastructure and the Environment, take any measures needed to protect humans and the environment from the risks, and revise the relevant information in the authorization application and submit it to the Minister.[80] If a significant potential risk is involved, the Minister must publicize the new information,[81] as is also required if the Minister becomes aware of the release without a license of GMOs into the environment.[82]

An authorization that has been obtained for GMO-related activities also applies when there is a change in the location of those activities, if the change does not lead to different or greater risks to humans or the environment than those posed by the licensed activities.[83] Among other conditions for granting such authorization, the Minister of Infrastructure and the Environment, in concert with the Minister of Agriculture, Nature Management and Fisheries, must state in writing to the licensee that the proposed change meets the necessary criteria and there is no reason to amend the license.[84] The Minister of Infrastructure and Environment is to issue a notice, containing all the key relevant information, in one or more daily newspapers, or at least the *Government Gazette* (*Staatscourant*).[85]

C. Monitoring

All work carried out under a permit for GMO release into the environment must be monitored by an Environmental Safety Officer (*Milieuveiligheidsfunctionaris*), who must be authorized by the

[76] *Verplichtingen op afgegeven vergunningen* [*Obligations of Permits Issued*], BUREAU GGO, http://ggo-vergunningverlening.nl/Vergunningverlening/Introductie_in_het_milieu/Verplichtingen_op_afgegeven_vergunningen (last visited Nov. 15, 2013).

[77] *Id*.

[78] *Id*.; GMO Decree art. 23c.

[79] *Verplichtingen op afgegeven vergunningen*, *supra* note 76.

[80] GMO Decree art. 23a(1).

[81] *Id*. art. 23a(2).

[82] *Id*. art. 23b.

[83] *Id*. art. 24a.

[84] *Id*. art. 24a(1).

[85] *Id*. art. 24b(3).

Minister of Infrastructure and the Environment.[86] In conformity with the GMO Decree, a register of the location of GMOs must be maintained.[87]

D. Coexistence

The Netherlands was the first country in the EU to have legal coexistence guidelines, the stakeholders having reached a consensus in 2005.[88] In agriculture, coexistence "refers to the possibility of cultivating GM crops alongside conventional and organic farming without one excluding the other."[89] On July 13, 2010, the European Commission decided on new rules for coexistence that now permit Member States to enforce their own conception of the term.[90] In the past, the Member States could only arrange for gene technology-free zones on the basis of voluntary agreements; under the new rules, they can prohibit the cultivation of certain GM plants.[91] Previously, a Member State's mandatory measures were required to be "appropriate" to maintain the admixture of GMOs in conventional crops under the EU-wide threshold value of 0.9%. With the adoption of the new guidelines, "national cultivation regulations can be so constructed to prevent much lower GMO proportions."[92]

VI. Restrictions on GMOs in Foodstuffs

A. Regulatory Agencies and Risk Assessments

EC Regulations 1829/2003 on GM food and feed, 1830/2003 on the traceability and labeling of GMOs, and 1946/2003 on the transboundary movement of GMOs set rules at the EU level for the use of GMOs in foodstuffs. The European Food Safety Agency (EFSA) is responsible for providing "objective scientific advice on all matters with a direct or indirect impact on food and feed safety in the EU,"[93] and it has issued guidance documents for risk assessment of GM plants and derived food and feed.[94] The Ministry of Health, Welfare and Sports and the Ministry of Economic Affairs, Agriculture and Innovation are responsible for the implementation of Directives 1829/2003 and 1830/2004 in the Netherlands.

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[86] *Toelating MVF* [*MVF Admission*], BUREAU GGO, http://ggo-vergunningverlening.nl/Vergunningverlening/Introductie_in_het_milieu/Toelating_MVF (last visited Nov. 15, 2013); Regulation on GMOs art. 11.

[87] Regulation on GMOs art. 12.

[88] *Country Reports*, *supra* note 1.

[89] Somsen, *supra* note 47, at 201.

[90] *New Coexistence – Guidelines in the EU: Cultivation Bans Are Now Permitted*, GMO SAFETY (July 27, 2010), http://www.gmo-safety.eu/news/1205.coexistence-guidelines-cultivation-bans-permitted.html.

[91] *Id*.

[92] *Id*.

[93] *GMOs in a Nutshell*, EUROPEAN COMMISSION, http://ec.europa.eu/food/food/biotechnology/qanda/a3_en.htm#a (last visited Nov. 18, 2013).

[94] *Id*. For a detailed description of the EFSA, with charts and diagrams, *see* Yi Liu, GMO Food Safety Assessment in the European Union, Workshop on GMOs in Global Perspective, Wageningen (May 16, 2013), http://www.selamat.net/en/show/Workshop-on-GMOs-in-global-perspective-safety-assessment-and-traceability-1.htm.

In addition, Regulation 882/2004[95] provides for institutes within EU Member States to serve as National Reference Laboratories for purposes of GMO analysis. In the Netherlands, there are two Routine Field Laboratories that conduct GMO sample analysis for the government: the Netherlands Food and Consumer Product Safety Authority (Nederlandse Voedsel-en Warenautoriteit, NVWA) for food, and the Institute of Food Safety (RIKILT) for feed.[96] The NVWA is "an independent agency in the Ministry of Economic Affairs and a delivery agency for the Ministry of Health, Welfare and Sport."[97] The NVWA's Office for Risk Assessment "identifies early warning signs of troubling aspects of innovations in GM agriculture, screens potential threats to human and animal health, evaluates public perceptions, and commissions necessary research."[98] The Office is said to have become the "front office" for GMO regulation, even though it "confines its duties to weighing the risks and benefits of a particular GM crop and does not engage in policy enactment, decision making, or food law enforcement."[99]

B. Labeling

In general, labeling of prepackaged food products for sale in the Netherlands requires conformity with the Food Labeling (Commodities Act) Decree (Warenwetbesluit Etikettering van levensmiddelen). It is obligatory under the Decree to provide, among other information, the product name; the net quantity; the minimum best-before date or latest consumption date; and information on the manufacturer, packager, or seller.[100] If a foodstuff product makes any claims as to its nutritional value, benefit to health, or medical advantages, the producer must comply with certain rules that differ according to the claim and the product.[101] The Decree on Novel Foods (Warenwetbesluit Nieuwe Voedingsmiddelen)[102] may also apply to GMOs.

For GM foods, Dutch labeling requirements are also based on articles 12–13 of EU Regulation 1829/2003. The requirements are applicable to foods that are "to be delivered as such to the final

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[95] 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 165), http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004R0882:en:NOT.

[96] I.M.J. SCHOLTENS-TOMA ET AL., GENETICALLY MODIFIED ORGANISMS IN FOOD AND FEED: ANNUAL REPORT OF THE DUTCH NATIONAL REFERENCE LABORATORY 7–8 (May 2012), http://edepot.wur.nl/217728. *See also*, in connection with RIKILT, *GMOs*, WAGENINGENUR, http://www.wageningenur.nl/en/Expertise-Services/Research-Institutes/rikilt/Research/GMOs.htm (last visited Nov. 19, 2013).

[97] *About the Netherlands Food and Consumer Product Safety Authority*, NEDERLANDSE VOEDSEL- EN VARENAUTORITEIT, http://www.vwa.nl/english/about-the-netherlands-food-and-consumer-product-safety-authority (last visited Nov. 19, 2013).

[98] Noteborn & van Duijne, *supra* note 10, at 106.

[99] *Id.*

[100] *Labelling of Food*, ANSWERS FOR BUSINESS (official Dutch government website) http://www.answersforbusiness.nl/regulation/labelling-food (last visited Dec. 5, 2013); Food Labeling (Commodities Act) Decree [Warenwetbesluit Etikettering van levensmiddelen] arts. 3–5.

[101] *Labelling of Food*, *supra* note 100.

[102] Warenwetbesluit Nieuwe Voedingsmiddelen (Apr. 29, 1997, as last amended effective Feb. 7, 2007), http://wetten.overheid.nl/BWBR0008643/geldigheidsdatum_18-11-2013.

consumer or mass caterers" and that contain or consist of GMOs or that are "produced from or contain ingredients produced from GMOs."[103] They are not applicable to foods with material that "contains, consists of or is produced from GMOs in a proportion no higher than 0,9 per cent of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable."[104] In addition, the labeling must mention any characteristic or property where (a) a food differs from its conventional counterpart in terms of its composition, nutritional value or effects, intended use, or health implications for certain population groups, and/or (b) ethical or religious concerns may arise from the food.[105] For those foods that lack a conventional counterpart, the labeling must contain appropriate information about their nature and characteristics.[106] There are also labeling requirements for contained-use license holders that make GMOs available to another party.[107] According to a USDA report, "since the Netherlands follows EU legislation, standard U.S. labels fail to comply with Netherlands labeling requirements."[108]

The Decree on Novel Foods states that the reference "made without genetic engineering" is used only for food or drink that (1) does not consist of or is not derived from GMOs; (2) is not prepared with the aid of substances that consist of or are derived from GMOs or produced using technical processing aids derived from GMOs; and (3) is not derived from animals that are fed with GM feed or feed with GM additives; produced using modern biotechnology, with certain exceptions; or that contain traces of GM DNA, except when unintentional and unavoidable.[109]

It may be noted that new EU food labeling rules will generally apply from December 13, 2014, but with some requirements to apply from January 1, 2014, or December 13, 2016.[110] The new EU Regulation 1169/2011[111] will repeal Directive 2000/13/EC,[112] article 3 of which sets forth general requirements for the labeling of foodstuffs.[113]

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[103] Regulation (EC) 1829/2003 art. 12(1).

[104] *Id*. art. 12(2).

[105] *Id*. art. 13(2).

[106] *Id*. art. 13(3).

[107] GMO Decree art. 22a, in accordance with Annex 4 of Directive 2001/18.

[108] MARCEL HENDRIKUS PINCKAERS, NETHERLANDS: FOOD AND AGRICULTURAL IMPORT REGULATIONS AND STANDARDS – NARRATIVE: FAIRS COUNTRY REPORT (Mar. 8, 2013), http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Food%20and%20Agricultural%20Import%20Regulations%20and%20Standards%20-%20Narrative_The%20Hague_Netherlands_3-8-2013.pdf.

[109] Warenwetbesluit Nieuwe voedingsmiddelen art. 3a.

[110] PINCKAERS, *supra* note 108.

[111] Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the Provision of Food Information to Consumers, Amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and Repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004, 2011 O.J. (L 304), http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:304:0018:0063:EN:PDF.

[112] 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, 2000 O.J. (L 109), http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2000:109:0029:0042:EN:PDF.

VII. Liability Regime

The Netherlands apparently has no special regime for liability or compensation for damage in connection with GMO crops.[114] Under Dutch law, there is a distinction between strict liability and fault-based liability for wrong acts.[115] Strict liability falls into the two main categories of strict liability for unlawful acts of other individuals and strict liability for defective objects and substances, with possibility two relevant sources: vicarious liability (Civil Code art. 6:170, on tortious acts by employees) and strict liability for hazardous substances (Civil Code art. 6:175).[116] The Civil Code covers fault-based liability in article 6:162.[117]

To establish a causal link between alleged damage and the presence of a GM crop, Dutch law is said to rely on a two-stage test: the condition sine qua non ("but for") test, whereby the GMO's presence is a necessary condition for the existence of the damage, and the imputation test.[118] This test is based on the Civil Code, Book 6, article 98, which states that compensation can only be claimed insofar as the damage related to the event creating liability can be imputed to the debtor as a result of the event.[119] Dutch case law had further developed the imputation test to include the requirement of "reasonable imputability" now codified in article 98.[120]

VIII. Judicial Decisions / Prominent Cases

No key judicial decisions or prominent cases were found.

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[113] PINCKAERS, *supra* note 108.

[114] Melissa Moncada Castillo & Willem H. van Boom, *Netherlands*, *in* LIABILITY AND COMPENSATION SCHEMES FOR DAMAGE RESULTING FROM THE PRESENCE OF GENETICALLY MODIFIED ORGANISMS IN NON-GM CROPS: ANNEX I: COUNTRY REPORTS 306 (Bernhard A. Koch ed., European Centre of Tort and Insurance Law Apr. 2007), http://ec.europa.eu/agriculture/analysis/external/liability_gmo/annex1.pdf. *See also* Ingrid Greveling & Willem H. van Boom, *Damage Caused by GMOs Under Dutch Law*, *in* DAMAGE CAUSED BY GENETICALLY MODIFIED ORGANISMS (Bernard A. Koch ed., De Gruyter 2010), http://www.professorvanboom.eu/pdf_files/2010_Greveling_VanBoom_GMO_Netherlands.pdf.

[115] Castillo & van Boom, *supra* note 114.

[116] *Id*. at 312. Burgerlijk Wetboek [Civil Code], Book 6: General Part of the Law of Obligations, Title 3: Torts § 2: Liability for Persons and Things arts. 170 & 175, http://wetten.overheid.nl/BWBR0005289/Boek6/geldigheidsdatum_19-11-2013. For an English translation of the Civil Code as of 2009, *see* HANS WARENDORF, RICHARD THOMAS & IAN CURRY-SUMNER, THE CIVIL CODE OF THE NETHERLANDS 679–80, 681–82 (Kluwer Law International 2009).

[117] Castillo & van Boom, *supra* note 114, at 306–07; Burgerlijk Wetboek, Book 6, Title 3, § 1: General Provisions art. 162, *supra* note 116; WARENDORF, THOMAS & CURRY-SUMNER, *supra* note 116, at 677.

[118] Castillo & van Boom, *supra* note 114, at 308.

[119] *Id*.; Burgerlijk Wetboek, Book 6, Title 1, art. 98, http://wetten.overheid.nl/BWBR0005289/Boek6/Titel1/Afdeling10/Artikel98/geldigheidsdatum_19-11-2013; WARENDORF, THOMAS & CURRY-SUMNER, *supra* note 116, at 660.

[120] Castillo & van Boom, *supra* note 114, at 308.

New Zealand

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SUMMARY The importation, development, testing, and release of genetically modified organisms are strictly regulated in New Zealand. Such activities must be approved by the Environmental Protection Authority, which is required to take into account various factors related to the potential risks and benefits of the proposal. These include environmental, economic, social, cultural, and public health considerations. Public notification of applications is generally required under the legislation.

Genetic modification techniques have been approved for use in research involving both plants and animals. These projects are subject to various controls and are conducted in contained research facilities. The relevant legislation provides for inspections to be conducted as well as including other enforcement powers. Criminal and civil penalties may be applied in relation to breaches of the legislation, and offenders may be ordered to mitigate or remedy any adverse effect on people or the environment.

There are currently no genetically modified commercial crops in New Zealand, and no fresh produce or meat sold that has been genetically modified. Imported food and ingredients derived from GMOs must be approved by a food safety authority and those that are approved for use must be clearly labeled on food packaging.

The development and use of GMOs is a topic that has generated considerable debate and controversy in New Zealand. The current regulatory approach is largely based on the findings and recommendations of the Royal Commission on Genetic Modification that were released in 2001. The government's decision to proceed cautiously with allowing for genetic modification was met with public demonstrations and there continue to be challenges to various proposals and calls for New Zealand to be "GM free."

I. Introduction

According to the United States Department of Agriculture, New Zealand "maintains one of the most comprehensive and rigorous approval regimes for genetically modified organisms in the world."[1] Genetic modification techniques have been approved for use in specific field research in contained outdoor environments, for example in relation to pest control, pharmaceutical research, and the enhancement of the production capacity of crops and animals.[2] However, there

[1] USDA FOREIGN AGRICULTURAL SERVICE, GAIN REPORT: NEW ZEALAND – BIOTECHNOLOGY – GE PLANTS AND ANIMALS (July 15, 2010), http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Biotechnology%20-%20GE%20Plants%20and%20Animals_Wellington_New%20Zealand_7-15-2010.pdf.

[2] *About GM in New Zealand*, MINISTRY FOR THE ENVIRONMENT (MFE), http://www.mfe.govt.nz/issues/managing-environmental-risks/organisms/gm-in-nz/about.html (last updated May 17, 2013). *See also Field Tests and Outdoor Developments of Genetically Modified Organisms,* ENVIRONMENTAL PROTECTION AUTHORITY (EPA), http://epa.govt.nz/new-organisms/popular-no-topics/Pages/GM-field-tests-in-NZ.aspx (last visited Oct. 25, 2013).

have not yet been any applications for the release of resulting products. An imported, genetically engineered equine influenza vaccination is currently the only product containing live modified organisms that has been approved for use in the country.[3] There are no genetically modified commercial crops being grown in New Zealand at this time, and no fresh produce or meat sold that is genetically modified.[4] Processed food containing imported, genetically modified ingredients are assessed for safety and must comply with labeling requirements.[5]

The importation, development, field testing, and release of "new organisms," including genetically modified organisms (GMOs), are regulated by the Hazardous Substances and New Organisms Act 1996 (HSNO Act).[6] Various aspects of the HSNO Act relating to GMOs were incorporated through amending legislation that was passed in 2003, including provisions relating to the conditional release of new organisms, a civil liability and pecuniary penalties regime, as well as a requirement to establish an advisory committee to inform decision makers about matters of concern to the Māori people.[7] The amendments resulted from the government's response[8] to the report of a Royal Commission on Genetic Modification, which was established in 2000 and completed its report in July 2001.[9] The major conclusion of the Royal Commission was that New Zealand should proceed cautiously with genetic modification, but not completely "close the door" to it.[10]

Although there is also some discussion in the country about the potential impact of the strict controls on GMOs on scientific and economic development,[11] "there have been no official

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[3] USDA FOREIGN AGRICULTURAL SERVICE, GAIN REPORT: NEW ZEALAND BIOTECHNOLOGY ENVIRONMENT (July 15, 2013), http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Wellington_New%20Zealand_7-15-2013.pdf; *New Microorganisms in New Zealand*, EPA, http://www.epa.govt.nz/new-organisms/popular-no-topics/Pages/GM-EI-vaccine.aspx (last visited Oct. 25, 2013).

[4] *See Labelling & Safety – Questions & Answers*, MINISTRY FOR PRIMARY INDUSTRIES (MPI), http://www.foodsmart.govt.nz/whats-in-our-food/genetically-modifed-food/labelling/questions-answers.htm (last visited Oct. 25, 2013).

[5] *About GM in New Zealand*, *supra* note 2.

[6] Hazardous Substances and New Organisms Act 1996, http://www.legislation.govt.nz/act/public/1996/0030/latest/DLM381222.html. "New organism" is defined in section 2A to include genetically modified organisms.

[7] *See 2003 Law Changes in Response to the Royal Commission on Genetic Modification*, MFE, http://www.mfe.govt.nz/issues/managing-environmental-risks/organisms/regulation/hsno-law-changes/2003.html (last updated May 21, 2013).

[8] *See Government Response to the Royal Commission's Report*, MFE, http://www.mfe.govt.nz/issues/managing-environmental-risks/organisms/gm-in-nz/commission/government-response.html (last updated May 17, 2013).

[9] REPORT OF THE ROYAL COMMISSION ON GENETIC MODIFICATION (2002), *available at* http://www.mfe.govt.nz/publications/organisms/royal-commission-gm/index.html.

[10] *About the Royal Commission on Genetic Modification*, MFE, http://www.mfe.govt.nz/issues/managing-environmental-risks/organisms/gm-in-nz/commission/about.html (last updated May 17, 2013). *See also* Allan Coukell, *A Step Forward for Genetic Engineering in New Zealand*, N.Y. TIMES (Aug. 21, 2001), http://www.nytimes.com/2001/08/21/science/a-step-forward-for-genetic-engineering-in-new-zealand.html.

[11] *See, e.g.*, Paul Gorman, *GM Trials' Failure 'Not Law's Fault'*, STUFF.CO.NZ (Apr. 12, 2012), http://www.stuff.co.nz/business/farming/6732484/GM-trials-failure-not-laws-fault; David Fisher, *GE Law Probe a Big Surprise*, NEW ZEALAND HERALD (Nov. 20, 2011), http://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=10767413; Press Release, McGuinness Institute, Time for New Zealand to Revisit the Genetic

changes to the heavily regulated and cautious policy settings operated by the New Zealand Government in relation to products derived from biotechnology."[12]

II. Public and Scholarly Opinion

More than 10,000 written submissions from organizations and members of the public were received as part of the Royal Commission process in the early 2000s.[13] During the process, a two-year moratorium on applications to release GMOs was in effect.[14] The moratorium expired on October 29, 2003, when the HSNO Act amendments relating to GMOs came into force.[15] Protesters held marches and rallies against the lifting of the moratorium, while the biotechnology industry and farmers welcomed the move.[16]

The Royal Commission recommended the establishment of a Bioethics Council to "provide advice and promote ongoing dialogue among New Zealanders" regarding the cultural, ethical, and spiritual aspects of biotechnology.[17] This body began work in 2002 and was disestablished in March 2009.[18]

There remains a relatively high level of controversy in New Zealand relating to the development and use of GMOs in the context of crops and farm animals.[19] The debate includes public opinion and political stances regarding the economic benefits[20] of genetic engineering as opposed to those gained from protecting New Zealand's "clean, green image,"[21] as well as questions about

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Modification Debate (Aug. 29, 2013), http://www.mcguinnessinstitute.org/site/publications/media_releases/media_release_29_august_2013.aspx.

[12] GAIN REPORT: NEW ZEALAND BIOTECHNOLOGY ENVIRONMENT, *supra* note 3.

[13] *About the Royal Commission on Genetic Modification*, *supra* note 10.

[14] *See* Press Release, Hon. Pete Hodgson, GM Research Moratorium Keeps NZ's Options Open (Apr. 17, 2000), http://www.beehive.govt.nz/release/gm-research-moratorium-keeps-nz039s-options-open.

[15] Press Release, Hon. Marian Hobbs, New GM Legislation in Force as Moratorium Expires (Oct. 29, 2003), http://www.beehive.govt.nz/node/18221.

[16] *See* Kevin Taylor, *Government Opens Door to GE Despite Protests, Polls and Threats*, NEW ZEALAND HERALD (Oct. 29, 2003), http://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=3531306.

[17] *Spiritual, Cultural and Ethical Issues in Genetic Modification, in* MFE, GENETIC MODIFICATION – THE NEW ZEALAND APPROACH (June 2004), http://www.mfe.govt.nz/publications/organisms/gm-nz-approach-jun04/html/page5.html.

[18] *See Toi Te Taiao: The Bioethics Council*, MFE, http://www.mfe.govt.nz/website/closed-sites/bioethics.html (last updated Jan. 14, 2010).

[19] *See, e.g.*, *GM Fight Still Rages 20 Years On*, TVNZ (Nov. 29, 2008), http://tvnz.co.nz/health-news/gm-fight-still-rages-20-years-2340450; Editorial, *The Genetic Modification Debate*, OTAGO DAILY TIMES (Sept. 27, 2013), http://www.odt.co.nz/opinion/editorial/227675/genetic-modification-debate.

[20] *See* THE TREASURY, ECONOMIC RISKS AND OPPORTUNITIES FROM THE RELEASE OF GENETICALLY MODIFIED ORGANISMS IN NEW ZEALAND (Apr. 17, 2003), http://www.treasury.govt.nz/economy/reports/gmo.

[21] *See* Joanna Gamble, *Genetic Engineering: The New Zealand Public's Point of View*, THE UNIVERSITY OF AUCKLAND (2001), https://researchspace.auckland.ac.nz/handle/2292/863; Doug Ashwell & Su Olsson, *"To Be or Not To Be": An Analysis of Political Rhetoric in the New Zealand Debate on Genetic Modification*, AUSTRALIA AND NEW ZEALAND COMMUNICATION ASSOCIATION ONLINE JOURNAL (2002), http://www.hss.bond.edu.au/ANZCA/

the environmental risks from genetic modification, the impact on human health, and consideration of spiritual and cultural values, particularly the perspectives of Māori.[22] As a result of this discussion, and the regulatory approaches that have been developed in an attempt to address and balance the various concerns and interests, there is a large amount of information and analysis available on the subject of genetic modification, ethics, and the law in New Zealand.[23] This includes information produced by governmental bodies, academics, and NGOs, as well as reporting and commentary in the media.

III. Structure of Pertinent Legislation

Matters related to the regulation of GMOs are governed by national legislation. There has recently been controversy regarding the ability for local authorities to impose a more restrictive approach on the release of GMOs under their official planning documents, which are developed under the rules set out in the Resource Management Act 1991 (RMA).[24] The RMA is currently under review and the government has stated that it may seek to amend the legislation to clarify that such authorities cannot establish their own rules regarding GMOs.[25]

As with the RMA, which is New Zealand's core environmental legislation, the preliminary provisions in the HSNO Act are of central importance in its interpretation and application. Section 4 states that the purpose of the legislation is "to protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms."[26]

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papers/SOlssonDAshwellPaper-.pdf; Pauline Hamilton, *GE or Not GE: The Genetic Engineering Debate in New Zealand*, 31(12) CHEMICAL INNOVATION 59 (Dec. 2001), http://pubs.acs.org/subscribe/archive/ci/31/i12/html/12vp.html.

[22] *See generally* Parliamentary Library, Background Note: Genetic Modification (Feb. 21, 2002), http://www.parliament.nz/NR/rdonlyres/42B8A108-0670-4C7E-B242-5D430E6BC1AF/370/0201Geneticmodification1.pdf; Dana Rachelle Peterson, Genetic Modification: A Resource Document for MPs (Parliamentary Library Background Paper No. 26, Feb. 2002), http://www.parliament.nz/NR/rdonlyres/4CA0C507-3047-486B-8E6C-DFEBE9AB761E/416/BP26_GeneticModification3.pdf.

[23] For general background information, *see* MFE, GENETIC MODIFICATION: THE NEW ZEALAND APPROACH (June 2004), http://www.mfe.govt.nz/publications/organisms/gm-nz-approach-jun04/genetic-modification-nz-approach.pdf. A list of government publications on new and genetically modified organisms is available on the MFE website at http://www.mfe.govt.nz/publications/organisms/ (last visited Oct. 25, 2013).

[24] *See, e.g.*, Keri Molloy, *Genetic Modification a Hot Topic*, NORTHERN NEWS (May 22, 2013), http://www.stuff.co.nz/auckland/local-news/northland/northern-news/8699303/Genetic-modification-a-hot-topic; Julie Moffett & Felix Marwick, *Tighter Rules on Genetic Modification in Auckland*, NEWSTALKZB (Sept. 24, 2013), http://www.newstalkzb.co.nz/auckland/news/nbnat/1571363499-tighter-rules-on-genetic-modification-in-auckland. For information on GMOs and the RMA, see *Genetic Modification (GM) and Local Government*, MFE, http://www.mfe.govt.nz/issues/managing-environmental-risks/organisms/regulation/gm-local-govt.html (last updated May 17, 2013).

[25] [2013] 691 NZPD 11175 (Questions to Ministers, No. 10.), http://www.parliament.nz/en-nz/pb/business/qoa/50HansQ_20130625_00000010/10-genetically-modified-organisms%E2%80%94regulation-of-release; Marty Sharpe, *Minister's GM Move Dismays Opponents*, THE DOMINION POST (June 27, 2013), http://www.stuff.co.nz/dominion-post/news/hawkes-bay/8846254/Ministers-GM-move-dismays-opponents.

[26] Hazardous Substances and New Organisms Act 1996, s 4.

Other preliminary provisions set out key principles and relevant matters that must be taken into account in the exercise of decision-making functions under the Act. The wording of these provisions reflects the various societal interests and concerns associated with new and genetically modified organisms, and requires a detailed assessment of risks and benefits. For example, "the maintenance and enhancement of the capacity of people and communities to provide for their own economic, social, and cultural well-being and for the reasonably foreseeable needs of future generations" is a matter that must be taken into account in achieving the purpose of the Act.[27] Section 6 of the Act lists several other considerations, including sustainability; "the intrinsic value of ecosystems"; public health; the relationship of Maori with their ancestral lands, water, valued flora and fauna, etc.; and the economic costs and benefits of a particular new organism.[28] In addition, the legislation states that "[a]ll persons exercising powers and functions under this Act shall take into account the principles of the Treaty of Waitangi (Te Tiriti o Waitangi)."[29]

Furthermore, section 7 of the Act explicitly requires persons exercising functions and powers under the Act to take a precautionary approach, stating that they must "take into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects."[30] Different parts of the Act regarding application and approval procedures for the importation, development in containment, field testing, and release of GMOs contain additional considerations relating to the potential risks, costs, and benefits of the activity.

The HSNO Act is administered by the Ministry for the Environment, while the Environmental Protection Authority (EPA) is responsible for implementing the provisions relating to the application and assessment process for new organisms.[31] The Ministry for Primary Industries has a range of responsibilities related to HSNO Act enforcement and compliance as well as food safety regulations.[32]

Apart from the HSNO Act and associated regulatory instruments, other legislation that relates to the control of genetically modified organisms includes the following:[33]

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[27] *Id.* s 5(b).

[28] *Id.* s 6.

[29] *Id.* s 8. Similar "Treaty clauses" are included in various pieces of legislation in New Zealand and have both legal and symbolic meaning. The clause prevents the Crown and its representatives from acting inconsistently with obligations to Māori and related principles that have been interpreted as applying under the Treaty of Waitangi signed between Māori tribes and the British Crown in 1840. *See Principles of the Treaty*, WAITANGI TRIBUNAL, http://www.waitangi-tribunal.govt.nz/treaty/principles.asp (last visited Oct. 25, 2013).

[30] Hazardous Substances and New Organisms Act 1996, s 7.

[31] *New Organisms and the HSNO Act*, MFE, http://www.mfe.govt.nz/issues/managing-environmental-risks/organisms/regulation/hsno.html (last updated May 17, 2013); *What We Do: Hazardous Substances and New Organisms*, EPA, http://www.epa.govt.nz/about-us/what/Pages/Hazardous-substances-and-new-organisms.aspx (last visited Oct. 25, 2013).

[32] *See New Organisms and the HSNO Act*, *supra* note 31; *About Us – Our Organisation*, MPI, http://www.biosecurity.govt.nz/biosec/org (last updated May 8, 2012); *Our Role in Enforcement*, EPA, http://www.epa.govt.nz/about-us/what/Pages/EPA-role-enforcement.aspx (last visited Oct. 25, 2013).

[33] *NZ Laws Regulating New Organisms*, MFE, http://www.mfe.govt.nz/issues/managing-environmental-risks/organisms/regulation/nz-laws.html (last updated May 17, 2013).

- The Biosecurity Act 1993,[34] which provides for the exclusion, eradication and management of pests and other unwanted organisms in New Zealand, and includes provisions relating to import and border controls and various powers of relevance to the release of GMOs.[35] In addition to the inspection and clearance procedures in this law, relevant provisions on importation[36] are also contained in the Imports and Exports (Living Modified Organisms) Prohibition Order 2005.[37]
- The Australia New Zealand Food Safety Code[38] (applicable in New Zealand under the Food Act 1981[39]), which requires that any food that is genetically modified or contains genetically modified material must be approved by Food Standards Australia New Zealand[40] and be clearly labeled.
- The Animal Welfare Act 1999,[41] which regulates the use of animals in research and testing, requires that every project be approved and monitored by an animal ethics committee and only be conducted by organizations that follow an approved ethical code of conduct.[42]
- The Agricultural Compounds and Veterinary Medicines Act 1997[43] and Medicines Act 1981,[44] which also contain restrictions relevant to the importation, manufacture, sale, and use of medicines and compounds containing genetically modified organisms.

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[34] Biosecurity Act 1993, http://www.legislation.govt.nz/act/public/1993/0095/latest/DLM314623.html.

[35] *See Biosecurity Act 1993*, MPI, http://www.biosecurity.govt.nz/biosec/pol/bio-act (last updated Oct. 19, 2012).

[36] *See generally, Importing Genetically Modified Organisms*, MPI, http://www.biosecurity.govt.nz/regs/imports/plants/gmo (last updated Oct. 10, 2012).

[37] Imports and Exports (Living Modified Organisms) Prohibition Order 2005, http://www.legislation.govt.nz/regulation/public/2005/0012/latest/DLM311538.html.

[38] New Zealand (Australia New Zealand Food Standards Code) Food Standards 2002, *available at* http://www.foodsafety.govt.nz/elibrary/industry/zealand-australia-zealand-food-standards/ (last visited Oct. 25, 2013).

[39] Food Act 1981, http://www.legislation.govt.nz/act/public/1981/0045/latest/DLM48687.html. *See New Zealand Food Legislation*, MPI, http://www.foodsafety.govt.nz/policy-law/food-regulation/nz-food-legislation/ (last visited Oct. 25, 2013).

[40] FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ), http://www.foodstandards.gov.au/Pages/default.aspx. *See Australia-New Zealand Co-operation*, MPI, http://www.foodsafety.govt.nz/policy-law/food-regulation/australia-nz-cooperation/ (last visited Oct. 25, 2013).

[41] Animal Welfare Act 1999, pt 6, http://www.legislation.govt.nz/act/public/1999/0142/latest/DLM49664.html.

[42] *Animals in Research,* MPI, http://www.biosecurity.govt.nz/regs/animal-welfare/research (last updated Sept. 13, 2013).

[43] Agricultural Compounds and Veterinary Medicines Act 1997, http://www.legislation.govt.nz/act/public/1997/0087/latest/DLM414577.html.

[44] Medicines Act 1981, http://www.legislation.govt.nz/act/public/1981/0118/latest/DLM53790.html.

IV. Restrictions on Research, Production, and Marketing

Section 25 of the HSNO Act states that no new organism shall be imported, developed, field tested, or released unless approval is granted under the Act. Section 27 sets out the types of approval that may be granted by the EPA, including for the import for release or release from containment of any new organism, and for the import of any new organism into containment, or to field test or develop any new organism in containment.

Section 39 allows the EPA to approve the importation, development, or field testing of any new organism in containment. Applications for such approval must cover a number of matters, including providing information on "all the possible adverse effects of the organism on the environment."[45] In making determinations on applications to develop or field test genetically modified organisms in containment, in addition to the considerations discussed above, the EPA must take into account any adverse effects on "human health and safety" and "the environment, in particular ecosystems and their constituent parts," as well as alternative methods for achieving the research objective and "any effects resulting from the transfer of any genetic elements to other organisms in or around the site of the development or field test."[46]

Procedures relating to notification and public submissions apply to applications to import, field test, or release of GMOs, and public hearings may be held on an application.[47] However, a rapid assessment process is available for research activities in indoor containment that are considered to be low risk. This process can be delegated to a lower-level body and does not involve public notification of the application.[48]

V. Restrictions on Releasing Organisms into the Environment

Any approval to develop or field test new organisms must include controls that address particular matters set out in Schedule 3 of the HSNO Act,[49] including facility and access requirements aimed at limiting the likelihood of any accidental release, monitoring and phytosanitary requirements, eradication plans for escaped organisms, and inspection and monitoring of facilities.[50] In addition, an approval must include controls to ensure that the genetically modified organism and any heritable material is removed or destroyed at the end of the development or field test.[51] Part 7 of the HSNO Act contains detailed provisions relating to inspections and other

[45] Hazardous Substances and New Organisms Act 1996, s 40(2)(a)(v) & 40(2)(b)(v).

[46] *Id.* s 44A.

[47] *Id.* ss 53–54, 60–61; *What Types of New Organism Applications are Publicly Notified and Open for Submission?*, EPA, http://www.epa.govt.nz/about-us/have-your-say/Pages/notified-applications.aspx (last visited Oct. 25, 2013).

[48] *Id.* ss 41–42B; Hazardous Substances and New Organisms (Low-risk Genetic Modification) Regulations 2003, http://www.legislation.govt.nz/regulation/public/2003/0152/latest/DLM195215.html. *See generally, Are you Importing, Developing, Regenerating or Fermenting Low Risk Genetically Modified Organisms in an Indoor Containment Facility in New Zealand?*, EPA, http://www.epa.govt.nz/new-organisms/find-application-form/application-finder/Pages/low-risk-applications.aspx (last visited Oct. 25, 2013).

[49] Hazardous Substances and New Organisms Act 1996, s 45(2).

[50] *Id.* sch 3.

[51] *Id.* s 45A.

enforcement powers with respect to activities involving the importation, development, field testing, or release of new organisms.

Applications can be made for approval to release new organisms (either from containment or through importation).[52] The HSNO Act lists minimum standards that allow the EPA to decline such an application where the new organism is likely to

> (a) cause any significant displacement of any native species within its natural habitat; or
> (b) cause any significant deterioration of natural habitats; or
> (c) cause any significant adverse effects on human health and safety; or
> (d) cause any significant adverse effect to New Zealand's inherent genetic diversity; or
> (e) cause disease, be parasitic, or become a vector for human, animal, or plant disease, unless the purpose of that importation or release is to import or release an organism to cause disease, be a parasite, or a vector for disease.[53]

In addition, the EPA must take into account "the ability of the organism to establish an undesirable self-sustaining population" and the ease with which the organism could be eradicated if such a population was established.[54]

As a result of the 2003 changes to the HSNO Act, the EPA may grant approval for "conditional release" with controls.[55] The various controls that can apply to any approval include controlling the "extent or purposes for which organisms could be used"; imposing requirements for monitoring, record-keeping, and reporting; "requiring contingency plans to be developed to manage potential incidents"; limiting the proximity of the organism to other organisms; and imposing obligations on those that hold approvals, such as compliance with relevant codes of practice or standards and requiring certain levels of training or knowledge.[56]

VI. Restrictions on GMOs in Foodstuffs

New Zealand currently imports more than fifty varieties of genetically modified food ingredients, including ingredients derived from GM crops such as corn and soybeans.[57] In order to be sold in the country, each GM food or ingredient must be evaluated by Food Standards Australia New Zealand (FSANZ) and determined to be safe for consumption, then approved by the FSANZ Board and by all Australian and New Zealand ministers responsible for food regulation.[58] A particular standard, Standard 1.5.2 – Food Produced Using Gene Technology,[59]

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[52] *Id.* ss 34 & 38.

[53] *Id.* s 36.

[54] *Id.* s 37.

[55] *Id.* ss 38A & 38B.

[56] *Id.* s 38D.

[57] *See GM Current Applications and Approvals*, FSANZ, http://www.foodstandards.govt.nz/consumer/gmfood/applications/pages/default.aspx (last updated Sept. 2013).

[58] For general information on the rules and requirements, see *Genetically Modified Food – Overview*, MPI, http://www.foodsmart.govt.nz/whats-in-our-food/genetically-modifed-food/overview/ (last visited Oct. 25, 2013); *Genetically Modified Food – Labelling & Safety – Questions and Answers*, MPI, http://www.foodsmart.govt.nz/

which is part of the Australian New Zealand Food Standards Code,[60] contains the regulations for food containing GMOs and lists the ingredients that have been given approval.

Standard 1.5.2 also contains rules relating to the labeling of foods, ingredients, additives, or processing aids that contain novel DNA or protein, or where genetic modification has resulted in an altered characteristic in the food. These labeling requirements have been in place since 2001. Such products or ingredients must be labeled with the words "genetically modified" either next to the name of the food or in the ingredient list.[61] Labeling is not required where "there is no more than 1% (per ingredient) of an approved GM food unintentionally present as an ingredient or processing aid in a non-GM food."[62] The requirements do not apply to food prepared in restaurants.[63]

Animal feed containing genetically modified ingredients is not subject to the same labeling requirements, and meat and dairy products from animals fed such feed also does not need to be labeled under the food regulations.[64]

VII. Liability Regime

Various criminal offenses are set out in section 109 of the HSNO Act, including, in contravention of the Act, developing or field testing a new organism; knowingly importing or releasing a new organism; knowingly, recklessly, or negligently possessing or disposing of a new organism illegally imported, manufactured, developed, or released; failing to comply with any controls imposed by any approval granted under the Act; and failing to report any new information of any adverse effect of a new organism.[65] The penalties for such offenses are set out in section 114 and include fines ranging from up to NZ$5,000 (about US$4,100) to up to NZ$500,000 (about US$414,000), depending on the offense. The court can also order a person to mitigate or remedy any adverse effect on people or the environment or pay the costs of doing so and may order the destruction of any new organism.[66]

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whats-in-our-food/genetically-modifed-food/labelling/questions-answers.htm; MPI, GENETICALLY MODIFIED FOOD AND INGREDIENTS (updated Apr. 2013), http://www.foodsafety.govt.nz/elibrary/industry/Genetically_Modified-Expectations_Importers.pdf.

[59] Australia New Zealand Food Standards Code - Standard 1.5.2 - Food Produced Using Gene Technology, http://www.comlaw.gov.au/Details/F2013C00199.

[60] *See Food Standards Code*, FSANZ, http://www.foodstandards.govt.nz/code/Pages/default.aspx (last visited Oct. 25, 2013).

[61] *See GM Food Labelling*, FSANZ (Aug. 2013), http://www.foodstandards.govt.nz/consumer/gmfood/labelling/Pages/default.aspx.

[62] *Id.*

[63] *Id.*

[64] GAIN REPORT: NEW ZEALAND BIOTECHNOLOGY ENVIRONMENT, *supra* note 3.

[65] Hazardous Substances and New Organisms Act 1996, s 109.

[66] *Id.* s 114(5) & (6).

The Act specifies that some of the offenses listed in section 109 are strict-liability offenses where it is not necessary to prove that the defendant intended to commit the offense.[67] However, several defenses are available.

Part 7A of the HSNO Act, which was inserted by the 2003 amendments, provides for pecuniary penalty orders and civil liability for breaches relating to new organisms. Pecuniary penalty orders may be granted by the High Court where it is satisfied that the person

> (a) developed, field tested, imported, or released a new organism in breach of this Act; or
> (b) possessed or disposed of any new organism imported, developed, or released in breach of this Act; or
> (c) failed to comply with any controls relating to a new organism—
> (i) imposed by any approval granted under this Act; or
> (ii) specified in regulations made under this Act.[68]

The standard of proof that applies under this part is that which applies in civil proceedings. Under the Act, an individual may be ordered to pay a pecuniary penalty of up to NZ$500,000, while a company may be required to pay up to NZ$10 million (about US$8.3 million). Alternatively, a company may be ordered to pay three times the commercial gain resulting from the contravention, or 10% of the company's turnover. The court can take various considerations into account in determining the level of the penalty.[69] It can also order that a person mitigate the adverse effects on people or the environment.[70]

The Act also provides that a person is liable in damages for any loss or damage caused by an act or omission while, for example, developing, field testing, importing, or releasing a new organism in breach of the Act. Liability may be incurred regardless of whether a person intended the act, omission, or breach, or was taking reasonable care. Civil proceedings for damages are in addition to any other action.[71] A defendant can prove one or more listed defenses in order to avoid liability under these provisions.[72]

VIII. Judicial Decisions / Prominent Cases

Since the completion of the Royal Commission process, there have been various controversies relating to the development and potential release of genetically modified organisms. For example, there has been public debate and legal proceedings related to research involving farm animals,[73] including in 2009–2010 in relation to approvals granted for trials involving putting

[67] *Id.* s 117(1).

[68] *Id.* s 124B.

[69] *Id.* s 124C.

[70] *Id.* s 124D.

[71] *Id.* s 124G.

[72] *Id.* s 124H.

[73] Branwen Morgan, *New Zealand's GM Cattle Under Fire*, NATURE (Mar. 27, 2010), http://www.nature.com/news/2010/100327/full/news.2010.155.html; Jeff Neems, *Anti-GE Backers File Appeal Against Trials*, WAIKATO TIMES (June 25, 2010), http://www.stuff.co.nz/waikato-times/news/3853353/Anti-GE-backers-file-appeal-against-trials.

synthetic human genes into goats, sheep, and cows to see if they would produce human proteins in their milk.[74]

In terms of plants and other organisms, during the mid-2000s, authorities investigated the importation and possible planting of certain seeds (particularly maize and corn) that potentially contained genetically modified material.[75] Other incidents that have generated some controversy have involved containment breaches. For example, in March 2013 it was reported that a genetically modified fungus had been discovered outside containment facilities at a university.[76] Some groups raised concerns, but government authorities investigating the incident indicated that it presented very low biological risks.[77] There have also been reports of various activities by anti-GM protestors. For example, genetically modified pine trees that had been contained at a research center were destroyed by protesters in 2012.[78]

Most recently, an environmental group has initiated court proceedings seeking to overturn an exemption from HSNO Act rules that was granted to a research institute in relation to a new DNA manipulation technique. The case will be heard by the High Court in November 2013.[79]

[74] Eloise Gibson, *Human Genes to be Injected into Goats, Cows, and Sheep*, NEW ZEALAND HERALD (Apr. 16, 2010), http://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=10638717; Eloise Gibson, *Mutant Cows Die in GM Trial*, NEW ZEALAND HERALD (May 1, 2010), http://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=10642031.

[75] *See, e.g.*, Press Release, MPI (previously Ministry of Agriculture and Forestry (MAF)), MAF Releases Imported Corn Seed Report (Feb. 1, 2007), http://www.biosecurity.govt.nz/media/01-02-07/gm-corn.htm; Press Release, MAF, MAF Investigation into GM Maize Nears Completion (May 28, 2004), http://www.biosecurity.govt.nz/media/28-05-06/gm-maize.

[76] Thomas Mead, *Genetically Modified Fungus Leaked*, 3NEWS (Mar. 20, 2013), http://www.3news.co.nz/Genetically-modified-fungus-leaked/tabid/423/articleID/291058/Default.aspx.

[77] Press Release, MPI, MPI Investigates GM Breach at Lincoln University (Mar. 19, 2013), http://www.mpi.govt.nz/news-resources/news/mpi-investigates-gm-breach.

[78] *Hundreds of GM Trees Destroyed*, STUFF.CO.NZ (Apr. 13, 2012), http://www.stuff.co.nz/national/6735584/Hundreds-of-GM-trees-destroyed.

[79] Isaac Davison, *American Chemical Giant out of NZ Court Case*, THE NEW ZEALAND HERALD (Oct. 10, 2013), http://www.nzherald.co.nz/business/news/article.cfm?c_id=3&objectid=11137661.

Norway

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SUMMARY Norway is one of the most restrictive importers of GM products and does not produce GMOs. As Norway is only part of the European Economic Area and not a full European Union Member it is not bound by EU Directives but generally implements EU Directives nonetheless. There are several EU-approved GMOs that are specifically illegal in Norway. Following a recent regime shift in Norway it is yet unclear whether Norway's position on GMOs might change.

I. Introduction

Norway is one of the most restrictive countries with regard to the importation of genetically modified organisms (GMOs) and does not allow for GMO production. It has yet to approve an application for the import of foodstuffs that include GMOs.[1] Norway applies the precautionary principle[2] when vetting GMOs and in addition requires any user or importer of a GMO to show that the use is ethically and socially justifiable, requiring proof both that the GMO is not harmful and that its use will benefit society.[3]

The industry that is most concerned by GMOs is the fishing industry, and salmon producers in particular. Yet, four fisheries have been exempted from applying for a license for genetically modified (GM) fodder, which was not subject to the application process until a more strict application process also made EU-approved GMOs subject to application in 2005.[4]

II. Public and Scholarly Opinion

The public is generally very averse to GMOs and Norwegians are considered, together with the Swiss, the most GMO skeptical in Europe.[5]

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[1] *See* generally MATTILSYNET, http://www.mattilsynet.no (Norwegian Food Safety Authority website; last visited Nov. 13, 2013).

[2] For a discussion of the precautionary principle, which generally allows for preventative decision making in the face of environmental risk, see *The Precautionary Principle*, EUROPA: SUMMARIES OF EU LEGISLATION, http://europa.eu/legislation_summaries/consumers/consumer_safety/l32042_en.htm (last visited Nov. 20, 2013); *see also* discussion in EU survey, *supra* at 65, nn. 4, 6.

[3] GENTEKNOLOGILOVEN [GENE TECHNOLOGY ACT], LOV APRIL 2, 1993 NO. 38 OM FRAMSTILLING OG BRUK AV GENMODIFISERTE ORGANISMER M.M., ch. 1:1 §, http://lovdata.no/dokument/NL/lov/1993-04-02-38.

[4] *See Faar norske produksjondyr genmodifisert for?*, MATTILSYNET (Nov. 27, 2012), http://www.mattilsynet.no/planter_og_dyrking/genmodifisering/faar_norske_produksjonsdyr_genmodifisert_for.4024.

[5] Pressmeddelande SLU, *EU-konsumenter mindre negativa till GMO än man trott*, FORSKNING.SE (Sept. 11, 2013), http://www.forskning.se/nyheterfakta/nyheter/pressmeddelanden/eukonsumentermindrenegativatillgmoanmantrott.5.14577fce1410af7f17532.html.

A. Government Position

Norway had a change in government following the September 9, 2013, elections. On October 16, 2013, Høyre and Fremskrittpartiet formed a government with Erna Solberg from Høyre as the prime minister. Høyre has been regarded as holding the most GMO-friendly position of all the political parties in Norway, in particular, by advocating for more research on GMOs.[6] It is too soon to tell whether this will affect Norway's GMO policy.

B. Position of the Opposition

The current opposition parties—Arbeiderpartiet, Sosialistisk Venstreparti, and Senterpartiet—were in government between October 2005 and October 2013.[7] During this time no GMO was approved for food consumption.

C. Scholarly Opinion

Some scholars argue that it is better to genetically modify a plant than to use pesticides,[8] especially as high volumes of pesticides have been proven to cause cancer.[9] Yet, the Norwegian population at large is reluctant to change the laws, causing researchers to claim, "we cannot get [the research] financed, the farmers don't want it and the consumers don't want it."[10] Other GMO-related negative research that has received more traction includes a study on rats, which found that rats who eat GM corn are fatter than rats fed with normal corn.[11] Another study in pigs showed that "GMO-fed" pigs were less healthy than pigs fed with non-GMO fodder.[12]

D. Position of Industry

Norwegian fishermen were critical of the US decision in 2010 to allow GM salmon.[13] Still, fisheries are unsatisfied with how Norway has handled the GMO issue previously, arguing that the fear of GMOs is not proportional to other risks connected to food and human health.[14]

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[6] *Hoyre mest positive till genmodifiserte mat*, DAGEN.NO, http://www.dagen.no/Default.aspx?ModuleId=62582&articleView=true&tabId=248 (last visited Oct. 26, 2013); *see also GMO – hva svarar partiene*?, OIKOS (Aug. 20, 2009), http://www.renmat.no/newsread/page.aspx?docid=11328.

[7] REGJERINGEN, http://www.regjeringen.no/nb/om_regjeringen/tidligere/oversikt/ministerier_regjeringer/nyere_tid/regjeringer/jens-stoltenbergs-andre-regjering.html?id=449424 (last visited Nov. 22, 2013).

[8] *Bedre å sette inn et gen enn å sprøyte*, NRK (Oct. 2, 2012), http://www.nrk.no/fordypning/forskere-positive-til-gmo-mat-1.8333629.

[9] *Id*.

[10] *Id*.

[11] *Rotter fetere av genmat*, FORSKNING.NO (July 11, 2012), http://www.forskning.no/artikler/2012/juli/327547.

[12] *Griser far darligere helse med genmodifisert mat*, NHI.NO (June 13, 2013), http://nhi.no/forside/griser-far-darligere-helse-med-genmodifisert-mat-40051.html.

[13] *Nå kommer den genmodifiserte laksen*, NRK.NO (Nov. 19, 2010), http://www.nrk.no/nordnytt/na-kommer-den-genmodifiserte-laksen-1.7388437.

E. NGO Positions

1. Norsk Landbrukssamvirke

The Norwegian NGO Norsk Landbrukssamvirke, representing sixteen producers on the Norwegian food market, also favors the precautionary principle.[15]

2. Norges Bygdekvinnelag

Prior to the 2013 election there was a move by NGOs, including Norges Bygdekvinnelag (Norway's Rural Women), a women's association that advocates a strong rural community and local sourcing,[16] to push the then Stoltenberg government to deny the new GM corn applications that Norway had received.[17]

III. Structure of Pertinent Legislation

Norway is not part of the European Union but has a strong record of implementing legislation based on EU directives and regulations, including EU Regulation 1829/2003. It has, however, adopted a much stronger stance against GMOs than the European Union, specifically making imports of certain EU-approved GMOs illegal.[18]

A. Genteknologiloven

Norway has chosen to issue a stand-alone act for its GMO regulation. The Norwegian Gene Technology Act (Genteknologiloven),[19] adopted in 1993, covers the following issues: contained use of GMOs (ch. 2), release of genetically modified organisms (ch. 3), and cloning (ch. 3a).

The goal of the legislation is to ensure that all production and use of GMOs is ethically and socially justifiable, taking into account the goal of sustainable development without harm to health or the environment.[20] By requiring that GMOs be both safe *and* contribute to the

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[14] *Advarer mot en ensidig negative holdning till GMO*, DAGEN (July 19, 2013), http://www.dagen.no/Default.aspx?ModuleId=62582&articleView=true&tabId=248.

[15] *Genmodifisering i landbruket*, NORSK LANDBRUKSSAMVIRKE, http://www.landbruk.no/Naeringspolitikk/Internasjonalt/Genmodifisering-i-landbruket (last visited Oct. 21, 2013).

[16] *Bygdekvinnelaget – en modern møtesplass*, BYGDEKVINNELAGET, http://bygdekvinnelaget.no/om-bygdekvinnelaget (last visited Dec. 1, 2013).

[17] *GMO-forbudet må på plass nå*, BONDEBLADET (Oct. 4, 2012), http://www.bondebladet.no/rammebetingelser/2012/10/04/gmo-forbudet-maa-paa-plass-naa.aspx.

[18] *See* FOR 2000-12-15 1268, FORSKRIFT OM FORBUD MOT OMSETNING I NORGE AV BESTEMTE GENMODIFISERTE PRODUKTER [REGULATION ON THE PROHIBITION ON USE IN NORWAY OF SPECIFIED GENETICALLY MODIFIED (GM) PRODUCTS], http://www.lovdata.no/for/sf/md/xd-20001215-1268.html.

[19] GENE TECHNOLOGY ACT, *supra* note 3. An overview of pertinent legislation is available at Norsk regelverk om GMO, MILJODIREKTORATET (Feb. 19, 2010; rev'd June 14, 2013), http://www.miljodirektoratet.no/no/Regelverk/Lov/Genteknologiloven/Norsk-regelverk-om-GMO/.

[20] *Id*.

community, the legislation ensures that GMOs will face an uphill battle to enter the Norwegian market.

B. Definition of GMO

"Genetically modified organisms" are defined in section 4(b) of the Gene Technology Act as "organisms altered through the use of gene technology or cell technology [cellteknologi]."[21]

C. National Food Act

In addition to the Gene Technology Act, Norway also has a national Food Act (Matloven) regulating the use of GMOs in food.[22]

D. Special Instructions/Ordinances

Norway has also adopted six instructions on the topic of GMO use issued by the Ministry for the Environment (FOR 2000-12-15 1268, 2001-12-21 1600, 2001-12-21-1602, 2001-12-21-1603, FOR 2005-09-02 1609) as well as a number of GMO regulations, which are listed on the Environment Agency website.[23] These instructions focus on labeling, transportation, import, export, production, fodder use, and contained use of GMs, as well as impact reports and internal controls.

Certain EU-approved GMO products are specifically illegal in Norway and cannot be given an import license.[24] All other GMOs are subject to a case-by-case application process whereby the pertinent license is granted by either the Food Safety Authority or the government.

IV. Restrictions on Research, Production, and Marketing

A. Research

The contained use of GMOs is regulated in FOR 2001-12-21-1600.[25] For use in laboratories, the use as well as the laboratory itself must be approved prior to commencing the use.[26] The relevant oversight agency is the Ministry of Health and Social Affairs unless otherwise specified.

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[21] *Id*. 4 § (translation by the author).

[22] LOV 19 DES 2003 NR 124 OM MATPRODUKSJON OG MATTRYGGHET MV. (MATLOVEN [FOOD ACT]), http://lovdata.no/dokument/NL/lov/2003-12-19-124?q=matloven.

[23] *Nasjonale forskrifter*, MILJODIREKTORATET (Feb. 19, 2010; rev'd June 14, 2013), http://www.miljodirektoratet.no/no/Regelverk/Lov/Genteknologiloven/Norsk-regelverk-om-GMO/Nasjonale-forskrifter/.

[24] REGULATION ON THE PROHIBITION ON USE OF SPECIFIED GM PRODUCTS, *supra* note 18.

[25] FOR 2001-12-21-1600 FORSKRIFT OM INNESLUTTET BRUK AV GENMODIFISERTE MIKROORGANISMER [REGULATION ON THE CONTAINED USE OF GENETICALLY MODIFIED MICROORGANISMS], http://www.lovdata.no/for/sf/ho/xo-20011221-1600.html.

[26] *Id*. 7 § st. 1. Note that not all uses need prior approval. The use of GMOs in Risk Classes 1 and 2 only requires notification. *Id*. 10 §.

B. Labeling Requirements

Products that include GMOs must be labeled unless the GMO content is less than 0.9%.[27]

C. Relevant Agencies

1. Bioteknologinemnda

The Norwegian Biotechnology Advisory Board (Bioteknologinemnda)[28] oversees the use of biotechnology in general and issues statements and gives advice on the use of biotechnology (including GMOs).[29] The Norwegian Biotechnology Advisory Board is an independent body with members appointed by the Norwegian government.[30] It includes biotechnology experts and representatives from affected industries. It currently has no outright political representatives.[31]

In a recent communication with an applicant seeking to import GM soy, the board made a list of queries to the importer indicating that Norway is very restrictive towards GMOs and that approval of an application requires a showing of the effects of the import both short term (five years) and long term (twenty years).[32] This is a showing that goes beyond that which the EU calls for, thus requiring applicants to make a separate application for Norway.

The Board has published a report in English on how it conducts its interpretation of the Gene Technology Act.[33] In June 2013, a majority of members of the Board argued that Norway generally ought to deny applications for the import of GM corn into Norway.[34] The overarching reason was that there was no justifiable benefit to society associated with the import that would outweigh the potential risks.[35] Thus, the Board relies heavily on the precautionary principle.

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[27] GENE TECHNOLOGY ACT, *supra* note 3, 4:14 §; FOR 1993-12-21 NR 1385: FORSKRIFT OM MERKING MV AV NÆRINGSMIDLER [REGULATION ON FOOD LABELING] ch. III:10c, http://www.lovdata.no/cgi-wift/ldles?doc=/sf/sf/sf-19931221-1385.html#10c; FOR 2002-11-07 NR 1290 FORSKRIFT OM FÔRVARER [REGULATION RELATING TO FODDER] ch. III:4b §, http://www.lovdata.no/cgi-wift/ldles?doc=/sf/sf/sf-20021107-1290.html#4b.

[28] BIOTEKNOLOGINEMNDA, http://www.bion.no (last visited Nov. 22, 2013).

[29] GENE TECHNOLOGY ACT, *supra* note 3, ch. 5:26 §.

[30] *Id*.

[31] A list of members can be found on the Board's website, http://www.bion.no/om-oss/nemndsmedlemmer/ (last visited Nov. 22, 2013).

[32] 2013/110, Genmodifisert, sprøytemiddelresistent soya DAS-444 ø6-6, June 21, 2013, http://www.bion.no/filarkiv/2013/06/Hoeringssvar-EFSA_GMO_NL_2012_106-soya-DAS-444%C3%986-6-21.06.13.pdf.

[33] BIOTEKNOLOGINEMNDA, SUSTAINABILITY, BENEFIT TO THE COMMUNITY AND ETHICS IN THE ASSESSMENT OF GENETICALLY MODIFIED ORGANISMS: IMPLEMENTATION OF THE CONCEPTS SET OUT IN SECTIONS 1 AND 10 OF THE NORWEGIAN GENE TECHNOLOGY ACT (2d rev. ed. 2009), http://www.bion.no/filarkiv/2010/07/2009_11_18_diskusjonsnotat_baerekraft_engelsk.pdf. For more on this subject, see G. KRISTIN ROSENDAL, COMPETING KNOWLEDGE CLAIMS AND GMO ASSESSMENT BY THE NORWEGIAN BIOTECHNOLOGY ADVISORY BOARD, FNI Report 5/2007 (Aug. 2007), http://www.fni.no/doc&pdf/FNI-R0507.pdf.

[34] Press Release, Bioteknologinemnda, Noreg bør avslå 27 søknader om å få godkjent genmodifisert mais til import, vidareforedling og bruk i mat og fôr, tilrår eit fleirtal i Bioteknologinemnda (Sept. 10, 2013), http://www.bion.no/2013/07/nei-til-genmodifisert-mais/.

Although the Board leaves the final decision to the government, which also consults the Norwegian Scientific Committee for Food Safety, the Food Safety Authority, the Norwegian Environment Agency, and the Ministry of the Environment, the Board's position clearly reflects some reluctance with regard to GMOs.

2. Norwegian Food Safety Authority

The Norwegian Food Safety Authority[36] is the inspection agency for both GM food and GM fodder (*see* Part VI(B)(1), below).

3. Norwegian Scientific Committee for Food Safety

According to its website, "[t]he Norwegian Scientific Committee for Food Safety (VKM)[37] carries out independent risk assessments for the Norwegian Food Safety Authority (Mattilsynet) across the Authority's field of responsibility as well as environmental risk assessments of genetically modified organisms for the Norwegian Environment Agency."[38]

V. Restrictions on Releasing Organisms into the Environment

The release of organisms into the environment is regulated by the Gene Technology Act, which requires a permit and an impact analysis.[39]

The Norwegian Directorate for Nature Management (part of the Norwegian Environment Agency) is responsible for the administrative aspects and coordination of applications for release of GMOs into the environment.[40]

Prior approval is required for the transport of most GM material.[41] Examples of GMOs that do not require approval for transport are genetically altered animals that do not have wild relatives with whom cross-fertilization may occur.[42] Records must be kept of all transports of GMOs.[43] The Norwegian Environment Agency should be informed and if the GMO is classified as a

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[35] *Id*.

[36] MATTILSYNET, http://www.mattilsynet.no (last visited Nov. 22, 2013).

[37] VITENSKAPSKOMITEEN FOR MATTRYGGHET (VKM), http://www.vkm.no (last visited Nov. 22, 2013).

[38] VKM, http://www.english.vkm.no/; *see also* GMO overview at http://www.vkm.no/dav/adfb158238.pdf (both last visited Nov. 22, 2013).

[39] GENE TECHNOLOGY ACT, *supra* note 3, 10 & 11 §§.

[40] FOR 2005-12-16-1495, FORSKRIFT OM KONSEKVENSUTREDNING ETTER GENTEKNOLOGILOVEN [REGULATION ON IMPACT ASSESSMENT ACCORDING THE GENE TECHNOLOGY ACT] § 3.

[41] FOR 2005-09-02-1009 § 7, FORSKRIFT OM MERKING, TRANSPORT, IMPORT OG EKSPORT AV GENMODIFISERTE ORGANISMER [REGULATION ON LABELING, TRANSPORT, IMPORT AND EXPORT OF GENETICALLY MODIFIED ORGANISMS], http://www.lovdata.no/for/sf/md/xd-20050902-1009.html#map004.

[42] *Id*.

[43] *Id*. § 9.

hazardous good the local fire department must also be informed.[44] In addition the transporter of the GMO must ensure that all handling of the GMO is done without risks to health or the environment.[45]

VI. Restrictions on GMOs in Foodstuffs

A. Assessment of Risks

Because Norway adheres to the precautionary principle,[46] the assessment of risk is central to the granting of GMO licenses in the country.[47] The applicant for a GMO license must show that its intended use is consistent with the legal requirement, "ethically and socially justifiable, taking into account the goal of sustainable development without harm to health or the environment."[48]

B. The Role of the Norwegian Food Safety Authority

Each application for a GMO license requires that an environmental impact report be sent to the Norwegian Food Safety Authority.[49] The Food Safety Authority is the authority on both GMOs in foodstuffs and in fodder. In addition to the general Gene Technology Act, GMOs in food are also regulated by Lov 19 des 2003 nr 124 om matproduksjon og mattrygghet mv. (Matloven). So far the Food Safety Authority has not approved any use of GMO in fodder or food. It has, however, granted the fishing industry an exemption from GMO-related permit requirements (see Part VI(D), below).

C. Fodder for Livestock

Fodder for livestock is regulated under FOR 2002-11-07 nr 1290: Forskrift om fôrvarer (Regulation Relating to Fodder).[50] GM fodder must be labeled and approved by the National Food Safety Authority.[51] Currently, there is no fodder that has gained approval for use with livestock.[52]

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[44] *Id*. § 20.

[45] *Id*. § 4.

[46] *Id*. (referencing the legislative history of the Norwegian Gene Technology Act).

[47] BIOTEKNOLOGINEMNDA [THE NORWEGIAN BIOTECHNOLOGY ADVISORY BOARD], SUSTAINABILITY, BENEFIT TO THE COMMUNITY AND ETHICS IN THE ASSESSMENT OF GENETICALLY MODIFIED ORGANISMS: IMPLEMENTATION OF THE CONCEPTS SET OUT IN SECTIONS 1 AND 10 OF THE NORWEGIAN GENE TECHNOLOGY ACT 8 (2d rev. ed. 2009), http://www.bion.no/filarkiv/2010/07/2009_11_18_diskusjonsnotat_baerekraft_engelsk.pdf.

[48] GENE TECHNOLOGY ACT, *supra* note 3, 1 § (translation by author).

[49] *See* FORSKRIFT OM KONSEKVENSUTREDNING ETTER GENTEKNOLOGILOVEN, *supra* note 40; LOV 19 DES 2003 NR 124 OM MATPRODUKSJON OG MATTRYGGHET MV. (MATLOVEN), http://lovdata.no/dokument/NL/lov/2003-12-19-124?q=matloven; FORSKRIFT OM FÔRVARER, *supra* note 27. More information on the Norwegian Food Safety Authority (Mattilsynet) is available on its website, http://www.mattilsynet.no (last visited Nov. 22, 2013).

[50] FORSKRIFT OM FÔRVARER, *supra* note 27.

[51] *Id*. 4a & 4b §§.

[52] *See* MATTILSYNET, http://www.mattilsynet.no/planter_og_dyrking/genmodifisering/ (last visited Nov. 22, 2013).

D. Fodder for Fish

Although Norwegian salmon were not fed GM fodder when the rules for fodder changed in September of 2005, they may well be in the future.[53] In 2008, the Fiskeri og Havsbruksnaeringens Landsforening (FNL) acknowledged it was becoming more difficult to find GMO-free fodder.[54]

Prior to 2005 Norway had less stringent rules on the importation of EU-approved GMOs that were processed and used as fodder for fish; however, through recent legislation Norway no longer accepts these blanket imports, but instead requires permits for each GMO imported. Because some players on the fishing market may find it impossible to find GMO-free fodder Norway granted an exemption until 2008, which has now been extended into 2014.[55] The exemption only applies to the need to apply for a permit, not to the requirement to label such imports. A list of the GM products (corn and soy) that the fisheries may use as of September 15, 2013, is available on the Food Safety Authority website.[56]

E. Labeling

All products containing GMOs must be labeled "contains genetically modified ['organisms' or name of product]" in either Norwegian or English.[57] The information should be stated on the packaging if the product is packaged, or in accompanying documentation if it is not.[58] The information must be accompanied by information to the distributor, as well as information that identifies which GMOs it includes.[59] For those products that it is impossible to adequately label as GM, directly or through supporting documentation, prior approval is needed.[60]

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[53] *Laks kan få genmodifisert mat*, NRK.NO (Aug. 1, 2006), http://www.nrk.no/nordland/laks-kan-fa-genmodifisert-mat-1.792575.

[54] Henrik Stenwig, Op-ed., *Oppgjør med bonde-topp*, FHL.NO (Mar. 27, 2008), http://fhl.no/oppgjor-med-bonde-topp/.

[55] Press Release, Mattilsynet, Fire virksomheter har fått dispensasjon fra kravet om godkjenning av genmodifisert fiskefôr (Sept. 17, 2013), http://www.mattilsynet.no/planter_og_dyrking/genmodifisering/fire_virksomheter_har_faatt_dispensasjon_fra_kravet_om_godkjenning_av_genmodifisert_fiskefor.10951.

[56] *Genmodifiserte fôrprodukter som fiskefôrvirksomhetene Biomar, Ewos, Skretting og Polarfeed kan omsette på det norske markedet inntil 15. september 2014, forutsatt at de er merket "genmodifisert,"* MATTILSYNET, http://www.mattilsynet.no/planter_og_dyrking/genmodifisering/oversikt_over_tillatte_gmproduktgrupper_pr_15_september_2013.10952/BINARY/Oversikt%20over%20tillatte%20GM-produktgrupper%20pr%2015%20september%202013.

[57] FORSKRIFT OM MERKING, TRANSPORT, IMPORT OG EKSPORT AV GENMODIFISERTE ORGANISMER, *supra* note 41, § 19.

[58] *Id.*

[59] *Id.* § 19 st. 2–3.

[60] *Id.* § 7e.

F. Inspections

Inspections of GMOs in plants are conducted by the Food Safety Authority.[61] As of 2012 there were few illegal GMOs reported in foodstuffs.[62] However, a genetically modified aquarium fish, the so-called zebra fish (Danio Rerio), was found in Norway in 2012.[63]

VII. Liability Regime

Damages and liability for GMO are regulated in chapter 4, section 23 of the Gene Technology Act.[64] A person (legal or physical) who releases a GMO is responsible for any damage, inconvenience, or loss that it may cause, regardless of his or her own culpability. In addition, violations of the Gene Technology Act may result in a fine or imprisonment for up to one year.[65]

VIII. Judicial Decisions / Prominent Cases

There are no prominent court cases in Norway on GMOs. In 2013 the Food Safety Authority discovered that GM corn was illegally imported and distributed as popcorn.[66] The Food Safety Authority had previously stopped the sale of popcorn containing GMOs.[67]

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[61] FORSKRIFT OM FÔRVARER, *supra* note 27, § 18.

[62] *Faa funn av ulovlig genmodifisert materiale paa det norske markedet*, MATTILSYNET (Apr. 29, 2013), http://www.mattilsynet.no/planter_og_dyrking/genmodifisering/faa_funn_av_ulovlig_genmodifisert_materiale_paa_det_norske_markedet.9246.

[63] *Fant ulovlig genmodifisert fisk*, MILJODIREKTORATET.NO (Nov. 30, 2012; rev'd May 23, 2013), http://www.miljodirektoratet.no/no/Nyheter/Nyheter/Nyhetsarkiv/2012/11/Fant-ulovlig-genmodifisert-fisk/.

[64] GENE TECHNOLOGY ACT, *supra* note 3, 4:23 §.

[65] *Id*. ch. 4:25 §.

[66] *Mattilsynet stanser salg av genmodifisert mais ti popcorn*, MATTILSYNET.NO (Sept. 18, 2013), http://www.mattilsynet.no/planter_og_dyrking/genmodifisering/mattilsynet_stanser_salg_av_genmodifisert_mais_til_popcorn.10901.

[67] *Mattilsynet stanser salg av genmodifisert popcorn*, MATTILSYNET.NO (June 18, 2013), http://www.mattilsynet.no/planter_og_dyrking/genmodifisering/mattilsynet_stanser_salg_av_genmodifisert_popcorn.9920.

Russian Federation

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SUMMARY Cultivation of transgenic plants for commercial use is not allowed in the Russian Federation. However, several types of genetically modified (GM) food and feed lines that have passed the procedure of state registration and control are allowed to be imported, processed, and used for food or feed production. Research on genetically engineered animals is not supported by the government. Russia recently adopted an approval procedure for release of genetically modified organisms (GMOs) into the environment, which brings the country closer to possible cultivation of GM plants. Currently, eighteen GM food lines and fourteen GM feed lines are approved and registered in Russia.

I. Introduction

Recently, the Russian Federation initiated legislative attempts to frame the policy of modernization and innovation in the field of genetic engineering. The Comprehensive Program for Development of Biotechnology in the Russian Federation through 2020 was approved in 2012. This document acknowledges that Russia is falling behind of many other countries and demonstrates that the Russian Government is interested in promoting the further development of agricultural biotechnology.[1] The government-approved Plan of Measures for the Development of Biotechnology and Genetic Engineering[2] proposes substantial measures that should be implemented within the next two or three years in biomedicine and industrial and agricultural biotechnology.[3]

Neither the Cartagena Protocol on Biosafety, nor the Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters have been ratified by Russia. However, after joining the WTO in 2012, Russia took some steps to develop a legislative framework for the cultivation of biotech crops and use of GMOs, including a procedure for the state registration of GMOs for release into the environment. In June 2012, the main Russian authority responsible for the state control over

[*] This report was prepared with the assistance of Foreign Law Consultant Svitlana Vodyanyk.

[1] Comprehensive Program for Development of Biotechnology in the Russian Federation through 2020, Adopted by the Resolution of the Government of the Russian Federation No. 1853p-P8 of April 24, 2012, *available at* the RF Ministry of the Economy website, http://www.economy.gov.ru/minec/activity/sections/innovations/development/doc20120427_06 (in Russian; last visited Nov. 4, 2013).

[2] Action Plan for Development of Biotechnologies and Genetic Engineering ("Roadmap"), approved by the Order of the Government of the Russian Federation No. 1247-p of July 18, 2013, http://government.ru/media/files/41d47b5e0ae078ee508b.pdf (official government portal; in Russian).

[3] *Id.*

genetically engineered foods, Rospotrebnadzor, expressed its intention to promote a positive image of GMO products in Russian society.[4]

On November 19, 2006, the Russian Federation and the United States signed an exchange letter on agricultural biotechnology during the course of the bilateral negotiations on Russia's Accession to the WTO. According to the letter, Russia agreed to maintain an approval and registration system for products of modern biotechnology used for cultivation, food, feed, processing, and import, which will enable the use and trade of such products within the WTO framework. The letter also provided that Russia must grant the US the opportunity to comment on issues related to biotechnology regulation and will take those comments into account.[5] After the letter was signed, some anti-GMO activists in Russia called it a lobbying mechanism that virtually guarantees the US the right to directly influence decision making in the field of consumer rights and biosafety in Russia.[6]

In 2012, Russia was among the thirteen states endorsing an International Statement on Low Level Presence (LLP) in order to avoid the disruption of global trade due to national restrictions on the import of agricultural commodities with traces of GMOs. By signing this international statement, Russia committed to continue to work collaboratively with other signatory countries to address the overarching problem of asynchronous approvals of biotech products, while trying to mitigate the impact of LLP situations in food and feed.[7]

Following instructions from the Russian President, the government entrusted responsible agencies with determining whether to ban imports of products containing GMOs into the country.[8] Russian agencies responsible for the policy in this field were expected to report to Russian Prime Minister Dmitry Medvedev by October 15, 2013.[9] Previously, products that contained Monsanto's genetically engineered corn NK603 were banned from importation into Russia.[10]

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[4] *Rospotrebnadzor Will Save the Image of GMO*, BUSINESS FM.RU (June 7, 2012), http://www.bfm.ru/news/183095?doctype=news (in Russian; last visited Nov. 4, 2013).

[5] Agreement on Trade and Agricultural Biotechnology, U.S.-Russ., Nov. 19, 2006, T.I.A.S. No. 06-1119.1, *available at* http://www.state.gov/documents/organization/189168.pdf.

[6] *Russia Adopted Mechanism for Direct Lobbying of the U.S. Interests in GMO Regulation*, TECHEXPERT, http://www.cntd.ru/458201982.html (in Russian; last visited Nov. 20, 2013).

[7] *Thirteen Countries Endorse International Statement on Low Level Presence*, INTERNATIONAL SERVICE FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATIONS, http://www.isaaa.org/kc/cropbiotechupdate/article/default.asp?ID=10370 (last visited Nov. 4, 2013).

[8] Instruction of the Prime Minister of the Russian Federation on Enforcement of the Orders of the President of the Russian Federation Made During the Meeting on Social and Economic Development of Rostov Region (Sept. 18, 2013), http://government.ru/orders/6131 (in Russian).

[9] As of the date this report, no information on further developments regarding this issue was available.

[10] LEVIN FLAKE & YELENA VASSILIEVA, USDA FOREIGN AGRIC. SERV., GAIN REP. NO. RS1345, RUSSIAN FEDERATION: AGRICULTURAL BIOTECHNOLOGY ANNUAL 14 (2013), http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Moscow_Russian%20Federation_7-15-2013.pdf.

II. Public and Scholarly Opinion

Agricultural producers and scientists generally support GMO production in Russia and advocate for pro-GMO legislation.[11] On the other hand, some environmentalists claim that the penetration of agricultural biotechnology and GMO-oriented production is dangerous for the environment, public health, and national food security. In their opinion, Russia should use its huge potential for the domestic production of organic food, which they argue has higher demand and is more environmentally friendly.[12]

Surveys indicate that Russian consumers prefer to buy GMO-free food products. According to analytical surveys of food markets, the number of people concerned with the quality of their food choices has been steadily growing. Around 80% of survey respondents who bought food in Moscow stated that they would not purchase a product if it contained GM components.[13] However, the actual purchasing behavior of the Russian population is affected by the price of products.[14]

III. Structure of Pertinent Legislation

The Russian legal framework governing the safety of GMO products and the control over their circulation on the market consists mainly of several federal laws and government resolutions that regulate agricultural biotech policy. These include the Federal Law on State Regulation in the Field of Genetic Engineering Activities (amended in 2010),[15] Federal Law on the Sanitary-Epidemiological Well-Being of the Population,[16] Federal Law on the Quality and Safety of Food Products,[17] and Federal Law on Consumer Rights Protection.[18]

In 2010, Russia entered into a Customs Union with Belarus and Kazakhstan. The Union formed the basis of the Eurasian Economic Commission, a trilateral government authority in charge of harmonizing trade tariffs. Russian trade legislation is now subordinated to norms and procedures of the Customs Union and regulations issued by the Commission.[19] The Customs Union has

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[11] Anna Skripka, *Farmers Ask for Permission to Produce Genetically Modified Products*, ROSSIYSKAYA GAZETA [ROS. GAZ.], Mar. 26, 2013, *at* http://www.rg.ru/2013/03/26/reg-cfo/zerno.html (in Russian).

[12] LEGALIZED MUTANTS *(IN RUSSIAN), EKOREPORTER.RU, HTTP://ECOREPORTER.RU/NODE/1966 (LAST VISITED NOV. 4, 2013).*

[13] Sergey Golubchikov et al., *GMO Problem in Russia*, GMO.RU (Nov. 19, 2006), http://www.gmo.ru/sections/15 (in Russian).

[14] USDA FOREIGN AGRIC. SERV., GAIN REP. NO. RS1345, *supra* note 10, at 20.

[15] Federal Law No. 86-FZ on State Regulation in the Field of Genetic Engineering Activities, SOBRANIE ZAKONODATELSTVA ROSSIISKOI FEDERATSII [SZ RF] [COLLECTION OF RUSSIAN FEDERATION LEGISLATION (official gazette)] 1996, No. 28 (in Russian).

[16] Federal Law No 52-FZ on Sanitary-Epidemiological Well-Being of the Population, SZ RF 1999, No. 14.

[17] Federal Law No. 29-FZ on Quality and Safety of Food Products, SZ RF 2000, No. 2.

[18] Federal Law No. 2300-I on Consumer Rights Protection, ROS. GAZ., Apr. 7, 1992 (official publication).

[19] For information on the Eurasian Economic Commission, see http://www.eurasiancommission.org/ru/Pages/default.aspx (last visited Nov. 20, 2013).

adopted Technical Regulations on Food Safety (TR TS 021/2011), on Food Labeling (TR TS 022/2011), and on the Safety of Grain (TR TS 015/2011).[20] These regulations came into force on July 1, 2013.

The Technical Regulation on Food Safety is a key Customs Union umbrella regulation covering standards and requirements for all food products and their processing. The Technical Regulation on Food Product Labeling is designed to establish uniform requirements for food products labeling to ensure the free movement of food products released for circulation in the territory of the Customs Union member states. The Technical Regulation on the Safety of Grain covers standards and requirements for grain and oilseeds produced and traded in the territory of the Customs Union, including imported and exported grains and oilseeds.[21] A Technical Regulation on Feed, which will address genetically engineered feed, is under consideration.[22]

In September 2013, the government approved the Resolution on the State Registration of Genetically Engineered/Modified Organisms Intended for Release into the Environment and Products Derived from the Use of Such Organisms or Containing Such Organisms (the Resolution).[23] The Resolution established a registration process for GMOs released into the environment for such purposes as the production of raw food materials and foodstuffs; feed and feed additives for animals; and breeding and growing modified plants, animals, and microorganisms for agricultural use in the territory of the Russian Federation.[24]

The Rules approved by the Resolution define the functions of different government agencies in the registration and oversight of GMOs. For example, the Federal Service for Surveillance of Consumer Rights Protection will register modified organisms used for the production of raw food materials, while modified plants and animals intended for breeding in Russia and modified agricultural microorganisms will be registered and monitored by the Federal Service for Veterinary and Phytosanitary Surveillance.[25] Consolidated registration of all GMOs and GM products will be maintained by the Ministry of Health.[26] Registration will require a positive assessment of the environmental impact of the released organisms and products conducted by the

[20] Technical Regulations of the Customs Union in Force (Dec. 9, 2011), http://www.eurasiancommission.org/ru/act/texnreg/ deptexreg/tr/Pages/TRVsily.aspx (in Russian).

[21] CHRISTOPHER RIKER ET AL., USDA FOREIGN AGRIC. SERV., GAIN REP. NO. RS1343, CUSTOMS UNION FOOD TECHNICAL REGULATIONS IN FORCE AS OF 1 JULY 2013 (July 5, 2013), http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Customs%20Union%20Food%20Technical%20Regulations%20in%20Force%20as%20of%201%20July%202013_Moscow_Russian%20Federation_7-5-2013.pdf.

[22] USDA FOREIGN AGRIC. SERV., GAIN REP. NO. RS1345, *supra* note 10, at 7.

[23] Resolution of the Russian Federation Government No. 839 on State Registration of Genetically Engineered/Modified Organisms Intended for Release into the Environment and Products Derived from the Use of Such Organisms or Containing Such Organisms, http://government.ru/docs/6128 (in Russian).

[24] *Id*., Rules art. 11.

[25] *Id*., Rules art. 3.

[26] *Id*., Rules art. 22.

Federal Service for Surveillance in the Sphere of Environmental Management.[27] The Rules will come into effect on July 1, 2014.[28]

According to a US Department of Agriculture report, before this Resolution was adopted, Russia did not have a procedure for the release of GM plants into the environment, which amounted to a de facto ban on the cultivation of any such crop. The Resolution lifts this ban, and while it will not have any immediate effect on the cultivation of biotech crops in Russia, it creates an approval process to make cultivation of such crops possible.[29]

IV. Restrictions on Research, Production, and Marketing

A. Regulation of Research

Laboratory research on genetically engineered crops has not reached the stage of field trials. While field trials are not specifically prohibited, special permission is required from the Variety Testing Commission at the Ministry of Agriculture,[30] and some companies report that such permission is no longer granted.[31] Reportedly, research on genetically engineered animals was conducted at the Russian Academy of Agricultural Sciences. No information on the continuation of this research since 2012 is available.[32]

B. Labeling Requirements

In accordance with the Federal Law of the Russian Federation on Consumers Rights Protection, all organizations that import to, produce in, or trade food and foodstuffs with Russia must inform consumers about the presence of GM components in their products if each individual biotech element exceeds 0.9% of product composition.[33] This legal provision is in line with the Technical Regulations of the Customs Union that came into effect on July 1, 2013.[34]

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[27] *Id*., Rules art. 12("c").

[28] *Id*., Resolution.

[29] LEVIN FLAKE & YELENA VASSILIEVA, USDA FOREIGN AGRIC. SERV., GAIN REP. NO. RS1366, RUSSIAN FEDERATION: GOVERNMENT RESOLUTION ON GMO REGISTRATION FOR ENVIRONMENTAL RELEASE 1–2 (2013), http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Government%20Resolution%20on%20GMO%20Registration%20for%20Environmental%20Release_Moscow_Russian%20Federation_9-25-2013.pdf.

[30] Information about the Commission is available at the Russian Ministry of Agriculture official website, http://www.mcx.ru/.

[31] USDA FOREIGN AGRIC. SERV., GAIN REP. NO. RS1345, *supra* note 10, at 3.

[32] *Id*. at 20.

[33] Federal Law on Consumers Rights Protection, *supra* note 18, art. 10.

[34] Uniform Sanitary, Epidemiological, and Hygienic Requirements for Goods Subject to Sanitary and Epidemiological Control § 1, "Safety Requirements and Nutritional Value of Foods," approved by the decision of the Commission of the Customs Union No. 299, May 28, 2010, http://www.tsouz.ru/KTS/KTS17/Pages/P2_299.aspx (in Russian).

Several Russian regions and producers have implemented voluntary labeling showing that their products are GMO free. However, such voluntary labeling is in some cases viewed by Russian authorities as contrary to rules of competition.[35] For example, in 2007 GMO-free labeling requirements were introduced by the Moscow City Government that allowed food producers to test their products for the absence of GMO ingredients at the city government's laboratories and receive a special, green label issued by the City Government stating that the product "Does not Contain GMO!" Following a request from the Federal Antimonopoly Service, the Moscow City Government abolished this program.[36]

Labeling of GMOs in animal feed is not required. Information on GMOs in grain and oilseeds and their products must be included in the accompanying shipping documents.[37]

C. Responsible Agencies

There is no single unified authority competent to make decisions on matters relating to the security of growing GM crops and the use of GMOs in food and animal feed. Currently, several Russian government agencies are responsible for the development of Russian biotechnology policy and controlling the use of genetically engineered crops and foodstuffs. They include the Ministry of Agriculture, the Ministry of Healthcare, the Federal Service for Surveillance of Consumer Rights Protection, the Federal Service for Veterinary and Phytosanitary Surveillance, and some others.

The Ministry of Agriculture is the country's leading agency in charge of regulating the veterinary and phytosanitary sphere. It is responsible for mitigating any negative effects of GMOs on agricultural animals, plants, and the environment. Starting July 1, 2014, the Ministry of Healthcare will be responsible for the maintenance of the consolidated register of all GMOs and GM products intended for release into the environment. The Federal Service for Surveillance of Consumer Rights Protection (Rospotrebnadzor) surveys and controls the turnover of GM food products. It also conducts state registration of new food products containing GMOs, including imports, and keeps a state register of GM food products authorized for sale and production in, and import into, Russia. The Federal Service for Veterinary and Phytosanitary Surveillance (VPSS) is subordinated to the Ministry of Agriculture of the Russian Federation. With regard to GMOs, it controls the safety of feed and feed additives derived from GMOs.[38]

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[35] Marina Sheina et al., *Economic and Social Impact on Treatment of Food Products Containing GMOs, an Example of the Russian Market*, Materials of International Scientific Practical Conference on Economy and Management: Theoretical and Practical Aspects (Russia, Novosibirsk, Aug. 22, 2011), http://sibac.info/konferentsii-uchenykh-2/ekonomika-i-menedzhment/203-203 (in Russian).

[36] LEVIN FLAKE & YELENA VASSILIEVA, USDA FOREIGN AGRIC. SERV., GAIN REP. NO. RS1230, RUSSIAN FEDERATION: MOSCOW GOVERNMENT STOPS REQUIRING GMO-FREE LABELING OF FOOD PRODUCTS (2012), http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Moscow%20Government%20Stops%20Requiring%20GMO-Free%20Labeling%20of%20%20Food%20%20Produc_Moscow_Russian%20Federation_5-7-2012.pdf.

[37] USDA FOREIGN AGRIC. SERV., GAIN REP. NO. RS1345, *supra* note 10, at 18.

[38] For more information on the structure and functions of the government institutions dealing with GMO issues, see USDA FOREIGN AGRIC. SERV., GAIN REP. NO. RS1345, *supra* note 10, at 6–7, *and* USDA FOREIGN AGRIC. SERV., GAIN REP. NO. RS1366, *supra* note 29, at 2.

V. Restrictions on Releasing Organisms into the Environment

GMOs designed for release into the environment and the products obtained from or containing such organisms are subject to state registration.[39] In accordance with the newly adopted Rules on State Registration of GMOs and GMO-Containing Products for Release into the Environment that will come into effect on July 1, 2014, the registering authorities will issue certificates on the state registration of GMO and GMO-containing products on the basis of an application from a legal entity. GMOs used for research work are exempt from registration if they are produced in accord with the existing sanitary norms and procedures. Similarly exempt from registration are the products obtained by the combination or processing of registered GMO-containing products if the genetic material of these products is not changed.[40]

Registration of GMOs and GMO-containing products will have no expiration date. However, in the case of a negative impact of a registered GMO product on human or animal health and/or the environment, the registration certificate may be revoked or special conditions for its use may be imposed.[41]

VI. Restrictions on GMOs in Foodstuffs

A. General Requirements

According to the Federal Law on State Regulation in the Field of Genetic Engineering, those working in the field of GMOs are responsible for the safety of the public and of the environment, accessibility of information on the safety of genetic engineering activities, certification of products containing the results of genetic engineering, state registration of GMOs intended for release into the environment, and state registration of products derived from the use of such organisms or containing such organisms.[42] The Law requires that certificates provide full details regarding the methods of obtaining the product in question and its properties. It also states that products and services developed by means of genetic engineering must meet the requirements of environmental safety, public health, and pharmacopoeia provisions.[43]

Certain types of new food products, materials, and articles manufactured and intended for sale in the territory of the Russian Federation or imported for the first time into the territory of the Russian Federation are subject to state registration.[44] A special export control procedure with regard to genetically modified microorganisms (GMMs) has been established by the government.[45] Following this procedure, the periodically updated list of GMMs and genetic

[39] Federal Law on State Regulation in the Field of Genetic Engineering Activities, *supra* note 15, art. 5.

[40] Resolution of the Russian Federation Government No. 839, *supra* note 23.

[41] *Id*.

[42] Federal Law on State Regulation in the Field of Genetic Engineering Activities, *supra* note 15, art. 5.

[43] *Id*. art. 11.

[44] Federal Law on Quality and Safety of Food Products, *supra* note 17, art. 10.

[45] Regulation of the Russian Federation Government No. 634 on Control over Microorganisms, Toxins, Equipment and Technologies in the Course of Foreign Economic Activity, SZ RF 2001, No. 37 (in Russian).

elements allowed for export from Russia was approved by the President of the Russian Federation in 2007.[46] The most recent updates to the list were made in July 2013.[47]

The list of foodstuffs containing GMOs subject to sanitary and epidemiological monitoring and state registration was approved by the Decision of the Customs Union Commission on the Application of Sanitary Measures within the Customs Union.[48]

As of September 2012, Russia approved and registered eighteen GM food lines (four soybean lines, ten lines of corn, two types of potatoes, one line of rice and one line of beet) and fourteen GM feed lines (four lines of soybean and ten lines of corn).[49]

B. Risk Assessment

Food and foodstuffs derived from GM sources are subject to a safety assessment procedure, which includes a 180-day toxicity study in animals and the application of modern methods of analysis.[50] Products with properties that do not differ from counterparts obtained by traditional methods and that pass medical and biological assessments are deemed safe for human health and are authorized for sale to the public and use in the food industry without restrictions.[51]

C. Fodder for Livestock

Feed derived from GMOs is subject to compulsory state registration.[52] Plant-origin feed imports require a letter stating that the feed is biotech free. Feed may be classified as biotech free if the presence in such feed of each nonregistered biotech line does not exceed 0.5% and the presence of each registered biotech line does not exceed 0.9%. If the feed contains genetically engineered ingredients and is not declared as biotech free, the shipment must include a copy of the certificate indicating that the biotech components in the feed are registered with the Federal

[46] Decree of the Russian Federation President No. 1087 on Approval of the List of Microorganisms, Toxins, Equipment and Technologies Subject to Export Control, SZ RF 2007, No. 35 (in Russian).

[47] Decree of the Russian Federation President No. 612 on Amendments to the List of Microorganisms, Toxins, Equipment and Technologies Subject to Export Control approved by the Decree of President of the Russian Federation No. 1087 of August 20, 2007, SZ RF 2013, No. 28 (in Russian).

[48] Resolution No. 299 of the Customs Union Commission on Application of Sanitary Measures in the Customs Union Member States (May 28, 2010), http://www.tsouz.ru/KTS/KTS17/Pages/R_299.aspx (in Russian).

[49] Recommendations No. 15-3.5 of the Parliamentary Hearings on Legal Regulation of GMO Circulation in the Russian Federation, approved by the State Duma Science and Technology Committee, Sept. 17, 2012, http://komitet2-8.km.duma.gov.ru/site.xp/052053124052055054.html (in Russian).

[50] *Id*.

[51] Letter of Rospotrebnadzor No. 0100/3572-06-32 on Improving the Supervision of Food Products Containing GMOs, Apr. 3, 2006, http://89.rospotrebnadzor.ru/documents/ros/103/print/ (in Russian).

[52] Decree of the Russian Federation Government No. 26 on State Registration of Feed Derived from Genetically Modified Organisms, http://www.fsvps.ru/fsvps/laws/243.html.

Service for Veterinary and Phytosanitary Surveillance. Feed registration is issued for five years with the possibility of renewal.[53]

VII. Liability Regime

In Russia, while administrative liability for violations of the requirements related to GMOs has been established, the amount of financial penalties is rather insignificant. Individuals, officials, and legal entities that do not comply with the requirements of law with respect to sanitary and epidemiological standards are punishable by a fine in the amount up to 20,000 rubles (approximately US$620) or administrative suspension of operations for up to ninety days (in the case of legal entities).[54]

The sale of products in the absence of required information or proper GMO labeling entails a warning or a fine in an amount of up to 40,000 rubles (approximately US$1,240).[55]

Violations of rules related to the transportation, sale, or release of products with GMOs are punishable by a fine in an amount of up to 300,000 rubles (approximately US$9,400). Violations that cause harm to the lives or health of people, property, or the environment, or that pose a threat of such harm, entail a larger fine in an amount of up to 600,000 rubles (approximately US$19,000), and may be accompanied by confiscation of the product in question.[56]

VIII. Judicial Decisions / Prominent Cases

Russia does not have significant court decisions that have influenced the application of law or the practice of law enforcement in the field of GMO regulation.

[53] Administrative Regulation on the State Function of the Federal Service for Veterinary and Phytosanitary Surveillance for State Registration of Feed Produced from GMOs, approved by the Order of the Ministry of Agriculture of the Russian Federation No. 466 of October 6, 2009, http://www.mcx.ru/documents/document/v7_show/11682.285.htm (in Russian).

[54] Code of Administrative Violations of the Russian Federation, SZ RF 2001, No. 1, art. 6.3.

[55] *Id.* arts. 14.5, 14.8.

[56] *Id*. art. 14.43.

South Africa

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SUMMARY: The primary legislation in South Africa dealing with genetically modified organisms (GMOs), including their contained use, trial release, commercial release, and import and export is the Genetically Modified Organisms Act of 1997 (GMO Act) and its subsidiary legislation. This Act established three regulatory authorities—an Executive Council, Registrar, and an Advisory Committee—for effective implementation of its objectives.

The GMO Act places various restrictions on the research, production, and marketing of GMOs. For instance, it requires a permit for conducting most GMO-related activities, and conducting such activities entails putting in place scientifically-based risk assessment measures and notifying the public before the release of GMOs into the environment. If the EC deems it fit to do so, an applicant for a permit for a GMO-related activity may also be required to conduct an environmental risk assessment. The Act also requires the registration of all facilities where GMO-related activities take place. It further requires that safety to the environment be demonstrated before GMOs can be approved for release.

The GMO Act imposes civil liability on people who conduct GMO-related activities for damage they cause and criminalizes various acts, including violations of its provisions or refusing to cooperate with the regulatory bodies.

In addition to the primary legislation and regulatory institutions, South Africa also has in place other laws and institutions regulating specific issues relating to GMOs. The Department of Health, specifically the Food Control Section, tasked with the responsibility to ensure food safety in the country, has issued regulations requiring that foodstuffs obtained through certain genetic modification techniques be labeled as such before being offered for sale in the marketplace. Further labeling requirements are imposed by the Consumer Protection Act and its subsidiary legislation.

I. Introduction

Relative to other African countries, South Africa embraced biotechnology early on. The first field trials of genetically modified crops in the country were conducted in 1989.[1] South Africa first approved the commercial release of genetically modified, insect-resistant cotton and maize in 1997.[2] Today, South Africa is the world's eighth largest producer of GMO crops. The statistics for the 2011–12 maize production season illustrate the scale of GMO penetration in the

[*] This report was prepared with the assistance of Law Library intern Antoinette Ofosu-Kwakye.

[1] Rosemary A. Wolson, *Assessing the Prospects for the Adoption of Biofortified Crops in South Africa*, 10(3) AGBIOFORUM 184 (2007), *available at* https://mospace.umsystem.edu/xmlui/bitstream/handle/10355/57/Biofortified %20Crops%20in%20South%20Africa.pdf?sequence=1.

[2] *Id*. at 185.

country. During this period, genetically modified maize accounted for 79% (2.1 million hectares) of the commercial land planted with maize, with white maize accounting for 78% (1.3 million hectares) and yellow maize accounting for 81% (863,277 hectares) of the total maize planted in their respective classes.[3]

South Africa has a fairly vigorous regulatory regime governing various aspects of GMO use, including contained use, trial release, commercial release, and transboundary movement. The primary legislation governing the issue is the Genetically Modified Organisms Act of 1997 (GMO Act)[4] and its subsidiary legislation (GMO Regulations).[5] The GMO Act was amended in 2006 (although the amendment did not take effect until 2010) in part to give effect to the Cartagena Protocol on Biosafety, which South Africa ratified in 2003.[6] There are also a number of other laws imposing additional rules on GMO-related activities, including the National Environmental Management: Biodiversity Act (NEMBA),[7] the Consumer Protection Act,[8] and the Foodstuffs, Cosmetics and Disinfectants Act.[9]

This report briefly discusses key aspects of the GMO regulatory regime, including relevant legislation, regulatory bodies, and available case law on the subject.

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[3] DEPARTMENT OF AGRICULTURE, FORESTRY AND FISHERIES, TRENDS IN THE AGRICULTURAL SECTOR – 2012 at 11 (2013), http://www.nda.agric.za/docs/statsinfo/Trends2012.pdf.

[4] Genetically Modified Organisms Act (GMO Act) No. 15 of 1997, *as amended*, 2 BUTTERWORTHS STATUTES OF THE REPUBLIC OF SOUTH AFRICA [BSRSA] (rev. ed. 2012). The 1997 GMO Act is available on the Department of Agriculture, Forestry and Fisheries (DAFF) website, at http://www.daff.gov.za/doaDev/sideMenu/acts/15%20 GMOs%20No15%20% 281997%29.pdf. The Genetically Modified Organisms Amendment Act No. 23 of 2006 (Apr. 17, 2007) is available on the South Africa government portal, at http://www.info.gov.za/view/DownloadFileAction?id=67850.

[5] Genetically Modified Organisms Act, 1997, Regulations, 2010, GOVERNMENT NOTICES [GN] No. 32966 (Feb. 26, 2010), http://www.info.gov.za/view/117972; Genetically Modified Organisms Act, 1997, Regulations Amendments, 2010, GN No. 33007 (Mar. 12, 2010), http://www.info.gov.za/view/123130; Genetically Modified Organisms Act, 1997, Regulations Amendments, 2011, GN No. 34020 (Feb. 18, 2011), http://www.info.gov.za /view/142060; Genetically Modified Organisms Act, 1997, Regulations Amendments, 2011, GN No. 35007 (Feb. 10, 2012), http://www.info.gov.za/view/159582; Genetically Modified Organisms Act, 1997, Regulations Amendments, 2011, GN No. 36124 (Feb. 8, 2013), http://www.info.gov.za/view/183647 (hereinafter collectively referred to as GMO Regulations, *as amended*).

[6] Genetically Modified Organisms Amendment Act No. 23 of 2006, Preamble; *Country Profile – South Africa*, BIOSAFETY CLEARING HOUSE, CONVENTION ON BIOLOGICAL DIVERSITY, http://bch.cbd.int/about/countryprofile .shtml?country=za (last visited Oct. 30, 2013).

[7] National Environmental Management: Biodiversity Act No. 10 of 2004 [NEMBA], 20 BSRSA (rev'd through 2012).

[8] Consumer Protection Act No. 68 of 2008, 526 GOVERNMENT GAZETTE [GG], No. 467 (Apr. 29, 2009), http://www .info.gov.za/view/DownloadFileAction?id=99961.

[9] Foodstuffs, Cosmetics and Disinfectants Act No. 54 of 1972 (May 19, 1972), available on the South African Department of Health website, *at* http://www.doh.gov.za/docs/legislation/acts/2011/Act-541972.pdf.

II. Public and Scholarly Opinion

The most recent statistical data located regarding public sentiment toward GMOs in South Africa is contained in a 2005 study, which found that only a small segment of South Africa's public had an understanding of and held an opinion about GMOs.[10] The study found that eighty percent of those surveyed had limited understanding of biotechnology, and more than two-thirds had never heard of GMOs before.[11]

However, various key organizations have shown interest in the process of overhauling the GMO regulatory regime. In 2006, during the public hearings it conducted on the GMO Amendment Bill, the Agriculture and Land Affairs Portfolio Committee of South Africa's Parliament received over ten submissions from a range of pro- and anti-GMO activists, including farmers unions, nongovernmental organizations, governmental agencies, and academics.[12] For example, the African Centre for Biosafety, as part of its submission, demanded that biotech companies assume liability for any adverse impact of a GMO-related activity on human health and the environment, a demand that was later incorporated into the GMO Act as part of the 2006 amendment (see the Liability Regime section below).[13] Similarly, one of the farmers unions called for the introduction of labeling requirements for foods containing GMOs.[14]

Despite the recognition of the risks involved, GMO-related activities appear to enjoy support within scientific and academic circles, with supporters believing that the risks are manageable. Nevertheless, opposition and skepticism persists among various groups, including rights groups, trade unions, and religious organizations.[15]

III. Structure of Pertinent Legislation

The GMO Act, which is administered by the Department of Agriculture, Forestry and Fisheries (DAFF), and three institutions established under its provisions (the Registrar, the Executive Council (EC), and the Advisory Council (AC)), has a number of objectives. These include promoting responsible GMO-related activities; limiting harm to the environment as well as to human and animal health; and establishing standards for conducting risk assessments for GMO-related activities.[16]

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[10] Wolson, *supra* note 1, at 3.

[11] *Id.*

[12] Parliamentary Monitoring Group (PMG), Genetically Modified Organisms Amendments Bill: Hearings (Jan. 17, 2006), http://www.pmg.org.za/minutes/20060116-genetically-modified-organisms-gmo-amendment-bill-hearings.

[13] *Id.*, Submission by African Centre for Biosafety; GMO Act § 17.

[14] PMG, Genetically Modified Organisms Amendments Bill: Hearings, Submission by Kwangwanase Farmers Union, *supra* note 12.

[15] Wolson, *supra* note 1, at 188.

[16] *Legislation*, DAFF, http://www.daff.gov.za/# (click on "Agricultural Production, Health & Food Safety Branch," then "Biosafety," then "Legislation") (last visited Oct. 30, 2013); GMO Act, Preamble.

The Act defines a GMO as "[a]n organism the genes or genetic material of which has been modified in a way that does not occur naturally through mating or natural recombination or both. . . ."[17] The application of the GMO Act is limited to

a) the genetic modification of organisms;

b) the development, production, release, use and application of genetically modified organisms (including viruses and bacteriophages); and

c) the use of gene therapy.[18]

As noted above, the GMO Act established three regulatory bodies with specific functions: the EC, the Registrar, and the AC. The EC, a juristic person, has a number of key functions in the application and approval process for GMO-related activities.[19] Some of its functions include

- advising the Minister of Agriculture, Forestry and Fisheries on GMO-related activities and monitoring these activities to ensure that they follow the rules and procedures set under the GMO Act;
- determining whether an applicant should submit an environmental assessment report; and
- approving applications for the use of facilities for conducting GMO-related activities in consultation with the AC.[20]

The EC may have up to ten members, who are appointed by the Minister of Agriculture, Forestry and Fisheries.[21] Members must include representatives from various departments listed in the GMO Act, including the Department of Science and Technology and the Department of Environmental Affairs and Tourism, who are well versed on the impact of GMOs in their respective fields/sectors and applicable law and policy.[22] All decisions of the EC require unanimous support of its members, and anything short of that amounts to rejection.[23]

The Registrar is appointed by the Minister of Agriculture, Forestry and Fisheries in consultation with the EC. He or she is in charge of administering the GMO Act and exercises the powers delegated and duties assigned to the position by the GMO Act or the EC.[24] Among the Registrar's functions are

[17] GMO Act § 1.

[18] *Id*. § 2. The GMO Act also provides a list of activities to which it does not apply, including techniques involving human gene therapy. *Id.*

[19] *Id*. §§ 3 & 5.

[20] *Id*. §§ 4 & 5.

[21] *Id* § 3.

[22] *Id*.

[23] *Id*. § 7.

[24] *Id*. § 8.

- examining applications for GMO-related activity;
- issuing permits or extensions;
- amending or withdrawing permits;
- ensuring that all users take the necessary measures to protect the environment as well as human and animal health; and
- addressing any matter related to GMO-related activities.[25]

The Registrar is required by law to keep a register of all facilities used for the contained use of GMOs, all trial release sites, and the names and addresses of all users (individuals involved in GMO-related activities).[26] The Registrar is also required to arrange for inspection of facilities where GMO-related activities take place and order the cessation of an activity that he or she has established or reasonably suspects is in violation of the GMO Act or a condition set under a permit.[27]

Inspections are conducted by inspectors appointed by the Registrar. The GMO Act authorizes the inspectors to investigate and, among other things, seek and obtain warrants to search for and seize various items, including GMOs and documents, whenever the inspectors have reason to believe that the GMO Act has been violated.[28] In addition, inspectors have the power to conduct routine, unannounced, and warrantless inspections of facilities registered for conducting GMO-related activities, and take samples of GMOs.[29]

The AC is a national advisory body on all matters having to do with GMO-related activities, including the introduction of GMOs into the environment, contained use, transboundary movement, and drafting of GMO-related laws and guidelines.[30] It is also mandated to liaise with international bodies concerned with biosafety through relevant national departments.[31] It consists of up to ten members appointed by the Minister of Agriculture, Forestry and Fisheries, eight of whom must be knowledgeable in the field of science applicable to GMO-related activities.[32] Two of the members must be from the public sector. One of these members must be knowledgeable on ecological matters and GMOs, while the other must be well versed on the effects of GMOs on human and animal health.[33]

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[25] *Id*. § 9.

[26] *Id*.

[27] *Id*. § 8.

[28] *Id*. § 15.

[29] *Id.* § 16.

[30] *Id*. § 11.

[31] *Id.*

[32] *Id*. § 10.

[33] *Id.*

IV. Restrictions on Research, Production, and Marketing

A GMO-related activity may not be conducted in South Africa without a permit.[34] This includes "activity with genetically modified organisms but it is not limited to the importation, exportation, transit, development, production, release, distribution, use, storage and application of genetically modified organisms only."[35] However, a permit is not required for organisms under conditions of contained use at containment level 1 or 2 in a registered facility.[36]

A person interested in carrying out a GMO-related activity may make an application to the Registrar, and the application must include

- a scientifically-based risk assessment;
- proposed risk assessment measures;
- a copy of public notices as required under the GMO Regulations; and
- if the EC deems it appropriate, an environmental risk assessment.[37]

There are strict rules on how a scientifically-based risk assessment is to be conducted. The assessment should take into account current national, regional, and international risk-assessment methods.[38] The steps of the assessment should include the following:

> a) Identification of any potential adverse effect resulting from the novel genotypic and/or phenotypic characteristics of the genetically modified organism.
>
> b) An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the potential receiving environment to the genetically modified organism.
>
> c) An evaluation of the consequences should these adverse effects be realized.
>
> d) An estimate of the overall risk proposed by the genetically modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized.[39]

Once an application is submitted, the EC may approve the application, reject it, or request that the applicant provide additional information; the EC must provide reasons for every decision.[40]

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[34] GMO Regulations § 2, *as amended.*

[35] GMO Act § 1.

[36] GMO Regulations § 2, *as amended.*

[37] *Id*. § 3.

[38] *Id*. § 4.

[39] *Id.*

[40] *Id*. § 3.

If the EC approves an application, it must include all applicable terms and conditions that the Registrar may then attach to a permit.[41]

All facilities (any place where contained use of a GMO takes place) must be registered with the Registrar.[42] The application for registration must include the name of the person taking responsibility for the facility; a map of the facility showing the different units within the facility; a locality map that includes geographic coordinates; a science-based risk assessment of the activity within the facility; and the proposed risk-management mechanism, measures, and strategies.[43]

Any applicant aggrieved by a decision or action of the EC, the Registrar, or an inspector may appeal before the Minister of Agriculture, Forestry and Fisheries within thirty days of the issuance of the decision or action in question.[44]

V. Restrictions on Releasing Organisms into the Environment

There is a strict application and approval process for the release of GMOs, including a trial release and a general release.[45] If the release of a GMO "may pose a threat to an indigenous species or the environment no permit for such a release may be issued unless an environmental impact assessment has been conducted" under the terms of the relevant law.[46] In effect, a GMO would not be approved for any form of release if "safety to the environment cannot be demonstrated."[47]

The law also imposes a public notification requirement for the release of GMOs. An applicant who seeks to undertake a general or commodity release must publish a notice in at least three national newspapers; a proposed trial release requires publication of a notice in at least two local newspapers and one national newspaper.[48] Where there are no newspapers circulating in the immediate area in which the proposed trial release will take place, the applicant has to inform the public through other means of effective communication, document the means of communication employed, and submit it to the Registrar as proof.[49] The notice must include, among other

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[41] *Id*.

[42] *Id*. § 8.

[43] *Id*.

[44] GMO Act § 19; GMO Regulations § 11, *as amended*.

[45] Department of Agriculture, Application for Intentional Introduction (Conduct a Trial Release) of a Genetically Modified Organism into the Environment of South Africa, http://www.services.gov.za /services/webdav/Documents /Agriculture/trial_release.pdf (last visited Oct. 30, 2013).

[46] NEMBA § 78. Release means "release into the environment and includes a trial release, conditional release and general release." GMO Act § 1.

[47] *Understanding Genetically Modified Organisms: What Are the Issues of Concern for the Environment?*, DAFF, http://www.nda.agric.za/doaDev/sideMenu/biosafety/doc/understandingGMOs.pdf (last visited Oct. 30, 2013).

[48] GMO Regulations § 9, *as amended*.

[49] *Id*. § 9.

things, information about the applicant, the objective of the application, the general description of the GMOs, and the place of release.[50]

If there is an accident involving unintentional environmental release or transboundary movement of GMOs, the user must notify the Registrar both verbally and in writing by providing relevant information, including the estimated quantities, date of the release, and possible adverse effect on the environment and on human and animal health and safety.[51]

Once released, the impact of GMOs on the environment is monitored by a separate institution, the South African National Biodiversity Institute, a juristic person established under NEMBA.[52] One of the functions of this institution is to "monitor and report regularly" to the Minister of Water and Environmental Affairs on the effects of any released GMO, including the impact on "non-target organisms and ecological processes, indigenous biological resources and biological diversity of species used for agriculture."[53] (For information on cleanup costs and liability when damage occurs, see the Liability Regime section below.)

VI. Restrictions on GMOs in Foodstuffs

The task of ensuring food safety in South Africa is under the jurisdiction of the Department of Health (DoH), specifically the Food Control Section.[54] As part of its functions, this section oversees the administration of food legislation, which includes publicizing regulations for food safety, labeling food, and evaluating risk assessments for DAFF that are related to agricultural chemicals and food produced through biotechnology.[55]

South Africa requires that foodstuffs obtained through certain techniques of genetic modification be labeled as such before they are offered for sale in the marketplace.[56] The law imposes this requirement if the composition, nutritional value, mode of storage, preparation, or cooking "of the foodstuff differs significantly from the characteristic composition of the corresponding existing foodstuff. . . ."[57]

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[50] *Id*.

[51] *Id.* § 10.

[52] NEMBA § 10.

[53] *Id*. § 11.

[54] *Food Control*, DEPARTMENT OF HEALTH, http://www.doh.gov.za/healthtopics .php?t=FoodControl (click on "Food Control" under "Health Topics") (last visited Oct. 30, 2013).

[55] *Id*.

[56] Regulations Relating to the Labelling of Foodstuffs Obtained Through Certain Techniques of Genetic Modification, GG No. 25908 (Feb. 26, 2010), http://www.doh.gov.za/docs/foodcontrol/advertising/2004/fcr25.pdf.

[57] *Id*. § 2. The term "significantly different" means "in respect of a foodstuff obtained through certain techniques of genetic modification, that characteristics scientifically assessed through an appropriate analysis of data are different from those of a corresponding existing foodstuff, taking into account accepted limits on natural variation of that foodstuff." *Id*.

A different law imposes additional, specific labeling requirements. The Consumer Protection Act requires that "[a]ny person who produces, supplies, imports or packages any prescribed goods must display on, or in association with the package or those goods, a notice in the prescribed manner and form that that discloses the presence of any genetically modified ingredients or components of those in accordance with applicable regulations."[58] Goods covered by this requirement are all goods approved for consumption by the EC and containing at least 5% GMOs.[59]

VII. Liability Regime

The GMO Act imposes two forms of liability: civil and criminal liability. Under the GMO Act, users have a duty to take appropriate measures to avoid an adverse impact on the environment and on human and animal health from the use of GMOs.[60] When damage occurs, users are responsible for cleanup costs. They are required to take a number of actions, including ceasing the act causing the damage, containing/minimizing the spread of the GMOs, eliminating the source of the damage, and remedying the damage caused.[61] If the user fails to take any such measures, the EC may step in and take all the necessary actions at the user's expense.[62] In addition, users are subject to liability for damage caused by GMO-related activity, unless the GMO was in the possession of an inspector and the user could not have foreseen or prevented the damage.[63]

The GMO Act and its subsidiary legislation also impose criminal liability for certain actions. A person commits an offense if he contravenes any of the GMO Act's provisions or any condition, restriction, ban, or instruction imposed under its provisions.[64] A person also commits a crime if he refuses to cooperate with or provides false or misleading information to an inspector, the Registrar, the EC, or the AC.[65] A person who impersonates any officer appointed under the GMO Act also commits a crime.[66] In addition, a person who violates any of the GMO Regulations commits an offense.[67] A conviction for any of these crimes is punishable by a fine or up to two years imprisonment; a second or subsequent conviction may result in up to four years imprisonment.[68]

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[58] Consumer Protection Act No. 68 of 2008, § 24, 526 GG No. 467 (Apr. 29, 2009), http://www.info.gov.za/view/DownloadFileAction?id=99961.

[59] The Consumer Protection Act Regulations, No. 293, § 7, GN No. 34180 (Apr. 1, 2011), http://www.info.gov.za/view/DynamicAction?pageid=623&myID=292342.

[60] GMO Act § 17.

[61] *Id*.

[62] *Id*.

[63] *Id*.

[64] *Id*. § 21.

[65] *Id*.

[66] *Id.*

[67] GMO Regulations § 13, *as amended*.

[68] GMO Act § 21.

The Consumer Protection Act, which imposes labeling requirements on food items containing a certain level of GMOs, also criminalizes certain acts. It makes it an offense for anyone to "alter, obscure, falsify, remove or omit . . . labeling . . . without authority."[69] This offense is, on conviction, punishable by a fine and/or up to one year imprisonment.[70] In addition, a violation under the Consumer Protection Act may result in a civil action and/or administrative fines.[71]

VIII. Judicial Decisions / Prominent Cases

In 2005, questions regarding access to information on GMO-related activities were litigated in court.[72] Biowatch Trust, a nongovernmental organization engaged in monitoring and publicizing issues of genetic modification, made a number of requests for information regarding the use of GMOs in South Africa, including locations of GMO field trials and risk-assessment data.[73] When the Registrar refused to release information on the grounds that the request was too broad and that part of the information sought was proprietary in nature, Biowatch instituted a legal action before the High Court against the Registrar, the EC, and others.[74] The court, in its decision, noted that access to information in South Africa is not an absolute right and that it should be weighed against justifiable governmental and private concerns for maintaining confidentiality of certain information.[75] However, the Court held that Biowatch was entitled to access some information and that the Registrar's refusal to grant access to such information violated Biowatch's constitutional rights.[76] The Court also found unacceptable the Registrar's claim that Biowatch's request was too broad, noting that the Registrar had a legal obligation to work with Biowatch to identify the relevant information sought.[77]

Matters pertaining to cost were litigated further on appeal and settled by the Constitutional Court.[78]

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[69] Consumer Protection Act No. 68 of 2008, § 110, 526 GG No. 467 (Apr. 29, 2009), http://www.info.gov.za/view/DownloadFileAction?id=99961.

[70] *Id*.

[71] *Id.* §§ 112 & 113.

[72] *Trustees, Biowatch v. Registrar: Genetic Resources, and Others* 2005 (4) SA 111 (T), available on the Southern Africa Legal Information Institute (SAFLII) website, *at* http://www.saflii.org/za/cases/ZAGPHC/2005/135.html.

[73] *Id.* at 113; *About Us*, BIOWATCH SOUTH AFRICA, http://www.biowatch.org.za/main.asp?include=about/about.html (last visited Oct. 30, 2013).

[74] *Trustees, Biowatch v. Registrar: Genetic Resources, and Others*, at 119–26. *See also* a summary of the case at *Trustees For the Time Being of the Biowatch Trust v. Registrar Genetic Resources and Others*, RIGHT2INFO, http://www.right2info.org/cases/r2i-trustees-for-the-time-being-of-the-biowatch-trust-v.-registrar-genetic-resources-and-others (last visited Oct 30, 2013).

[75] *Trustees, Biowatch v. Registrar: Genetic Resources, and Others* at 137.

[76] *Id*. at 145–46.

[77] *Id*.

[78] *Biowatch Trust v Registrar Genetic Resources and Others* 2009 (6) SA 232 (CC), *available at* http://www.saflii.org/za/cases/ZACC/2009/14.pdf.

South Korea

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SUMMARY Korea signed the Cartagena Protocol on Biosafety in 2000 and enacted implementing legislation, the Act on Transboundary Movements of Living Modified Organisms and Other Related Matters (LMO Act), the following year. The LMO Act regulates overall issues concerning genetically modified organisms (GMOs). Importing, cultivating, researching, and developing GMOs are permitted under the LMO Act, as long as applicable procedures are observed. However, even though more and more research on GMOs is being performed, people are still concerned about undiscovered side effects and unanticipated adverse effects on the environment. As yet, there has been no authorized GMO cultivation within Korea.

Restrictions on GMO food include a safety assessment under the Food Sanitation Act in addition to a risk assessment and approval procedure under the LMO Act. Sellers of genetically modified food must follow labeling requirements under the Food Sanitation Act.

I. Introduction

South Korea signed the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Cartagena Protocol) in 2000 and ratified it in 2007.[1] The Cartagena Protocol became effective for Korea at the beginning of 2008. To implement the Protocol, Korea enacted the Act on Transboundary Movements of Living Modified Organisms and Other Related Matters (LMO Act) in 2001 and it became effective when the Protocol became effective in Korea.[2] The LMO Act aims to improve the living conditions of people by protecting public health and the conservation and sustainable use of biodiversity from any adverse effects posed by genetically modified organisms (GMOs).[3] As of today, while research and development related to GMOs is actively conducted, there has been no authorized GMO cultivation within Korea.[4] There is no social or political consensus regarding the safety of GMOs for cultivation or consumption in Korea. However, stopping the importation of genetically modified (GM) grains, such as soybeans and corn, is nearly impossible because Korea has a low level of self-sufficiency with

[*] This report was prepared with the assistance of Law Library intern Sojin Park.

[1] *Country Profile: Republic of Korea*, BIOSAFETY CLEARING-HOUSE, CONVENTION ON BIOLOGICAL DIVERSITY, http://bch.cbd.int/about/countryprofile.shtml?country=kr (last visited Dec. 9, 2013).

[2] Yujeonja Byunhyung Saengmulchae-ui Kookakan Idongdeung-e Kwanhan Beobryul [Act on Trans-boundary Movements of Living Modified Organisms and Other Related Matters (LMO Act)], Act No. 6448, Mar. 28, 2001, *last amended by* Act No. 11536, Dec.11, 2012. The last amendment of the LMO Act became effective on December 12, 2013.

[3] *Id*. art. 1.

[4] *Domestic Data*, KOREA BIOSAFETY CLEARING HOUSE, http://www.biosafety.or.kr/01_basic/sub0301.asp (last visited Dec. 9, 2013).

regard to grains and non-GM grains are becoming less available. As of 2012, for example, GM soybeans occupied 81% of the total soybean cultivation area in the world.[5]

II. Public and Scholarly Opinion

Public awareness of GMOs has generally been high in South Korea. The Korea Biosafety Clearing House (KBCH) has issued annual statistical analyses on public perception and knowledge levels of GMOs since 2004.[6] The KBCH was established as a legal institute for the management and exchange of information on GMOs and promoting international coordination.[7] According to a statistical analysis conducted in 2013, 80.2% of the general public in Korea is aware of GMOs and they learn and acquire knowledge and information mainly from television, the Internet, newspapers, and friends and acquaintances. However, the level of understanding of the current status of domestic distribution and risk assessment procedures for GMOs, among other issues, is low.[8]

The public sentiment trends against GMOs. Generally, people are more tolerant of the pharmaceutical or medical use of GMOs, but unwilling to accept GMOs in food or livestock, according to the KBCH's 2012 survey.[9] In terms of the necessity of restricting GMOs, more than 83% of the survey respondents said it was necessary to impose strict regulations on GMO handling, storage, distribution, and labeling.[10]

III. Structure of Pertinent Legislation

The Biotechnology Support Act, which was enacted to promote biotechnology in 1983,[11] was the first law in Korea that required implementing measures to prevent potential risks involved in the development of biotechnology. In September 2000, Korea signed the Cartagena Protocol and in March 2001 enacted the LMO Act as a general law to establish the legal basis for domestic implementation of the Protocol.[12] However, the LMO Act does not apply to GMOs used as medicines for the human body.[13] The Enforcement Decree of the LMO Act[14] and ministerial

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[5] KOREA BIOSAFETY CLEARING HOUSE, YUJEONJA BYUNHYUNG SAENGMULCHAE KWALYUN JUYO TONGYE (YO-YAK) [STATISTICS ON GENETICALLY MODIFIED ORGANISMS (SUMMARY)] 13 (Apr. 9, 2013), http://www.biosafety.or.kr/bbs/mboard.asp?exec=view&strBoardID=bsn_064&intPage=1&intCategory=0&strSearchCategory=|s_name|s_subject|&strSearchWord=&intSeq=69104 (click the pdf file name next to a floppy disk mark).

[6] *Current Status of Public Awareness*, KOREA BIOSAFETY CLEARING HOUSE, http://www.biosafety.or.kr/03_data/sub0501.asp (last visited Dec. 2, 2013) (in Korean).

[7] LMO Act art. 32.

[8] KOREA BIOSAFETY CLEARING HOUSE, *supra* note 5, at 16.

[9] *Id*.

[10] *Id*. at 18.

[11] Biotechnology Support Act, Act No. 3718, Dec. 31, 1983, *last amended by* Act No. 11683, Mar. 23, 2013.

[12] LMO Act art. 4.

[13] *Id*. art. 3.

ordinances[15] provide detailed provisions for the effective enforcement of the LMO Act. The Unified Enforcement Regulation of the LMO Act (Unified Enforcement Regulation) was prepared in 2007 in order to provide detailed and technical measures to implement the LMO Act.[16] The Unified Enforcement Regulation regulates different areas such as GMO use in food, medicine, agriculture, and intentional introduction of GMOs into the environment.

The LMO Act designates a competent national authority, a national focal point, and relevant central administrative agencies. The Ministry of Trade, Industry and Energy (MOTIE) is the designated competent national authority and is in charge of GMO regulations in the industrial sector. The Ministry of Foreign Affairs (MOFA) is the national focal point.[17] Jurisdictions of the ministries designated as relevant central authorities are as follows:

Ministry	Jurisdictional Area Under the LMO Act
Ministry of Science, Information, Communication, Technology & Future Planning (MSIP)	GMOs used in research and development
Ministry of Health & Welfare (MW)	GMO research facilities related to health, medical sectors
Ministry of Environment (ME)	Environmental issues related to GMOs
Ministry of Agricultural, Food & Rural Affairs (MAFRA)	GMOs in agricultural, forestry, livestock sectors, and in animal health improvement
Ministry of Oceans & Fisheries (MOF)	GMOs in oceans, inland bodies of water
Ministry of Food and Drug Safety (MFDS)	GMOs in food, medicine, medical devices

Source: LMO Act art. 2, para. 5; Enforcement Decree art. 2, para. 1.

[14] Yujeonja Byunhyung Saengmulchae-ui Kookakan Idongdeung-e Kwanhan Beob Sihaengryung [Enforcement Decree of the Act on Trans-boundary Movements of Living Modified Organisms and Other Related Matters (Enforcement Decree)], Presidential Decree No. 19062, Sept. 30, 2005, *as amended by* Presidential Decree No. 24442, Mar. 23, 2013.

[15] Yujeonja Byunhyung Saengmulchae-ui Kookakan Idongdeung-e Kwanhan Beob Sihaengyuchick [Ministerial Ordinance of the Act on Trans-boundary Movements of Living Modified Organisms and Other Related Matters], Ministry of Commerce, Industry & Energy Ordinance No. 327, Mar. 10, 2006, *last amended by* Ordinance of Ministry of Trade, Industry & Energy (MOTIE) No. 5, Apr. 30, 2013.

[16] Yujeonja Byunhyung Saengmulchae-ui Kookakan Idongdeung-e Kwanhan Tonghap Goshi [Unified Enforcement Regulation of the Act on Trans-boundary Movements of Living Modified Organisms and Other Related Matters (Unified Enforcement Regulation)], Enforcement Regulation of Ministry of Science, Information, Communication, Technology & Future Planning No. 2007-19, Enforcement Regulation of Ministry of Agricultural, Food & Rural Affairs No. 2007-80, Enforcement Regulation of MOTIE No. 2007-153, Enforcement Regulation of Ministry of Health & Welfare No. 2007-105, Enforcement Regulation of Ministry of Environment No. 2007-189, Enforcement Regulation of Ministry of Oceans & Fisheries No. 2007-115, Enforcement Regulation of Ministry of Food and Drug Safety No. 2007-78, Dec. 27, 2007.

[17] LMO Act art. 6, para. 1.

MOTIE established the Biosafety Committee based on the LMO Act.[18] The vice-minister of each relevant central authority is a member of the Committee.[19] The Committee deliberates on matters concerning implementation of the Cartagena Protocol, establishment and implementation of risk management plans, reassessment of risks for previously denied GMOs, prevention, and plans for countering any damage caused by GMOs, among other things.[20]

The LMO Act obligates relevant central authorities to establish and enforce risk management plans. The plans include basic policies of safety management concerning the import and export of GMOs, matters on safety management for employees and facilities that deal with GMOs, and matters on GMO technology development and related support measures. Such risk management plans should be approved in advance by the Biosafety Committee.[21]

The LMO Act has a definition of GMOs, which is substantially the same as definitions appearing in other acts:

> Living modified organisms means any organism that possesses a novel combination of genetic material obtained through the use of the following modern biotechnology(ies) ;
> (1) technologies for artificially recombining genetic materials or directly injecting nucleic acid constituting genetic materials into cells or organelles;
> (2) technologies for cell fusion which is beyond the family under taxonomy.[22]

A GM agricultural or marine product is defined in the Agricultural Act as an agricultural or marine product that possesses targeted features made through the artificial separation or recombination of genes.[23] Under the Food Sanitation Act, genetically modified food is any food or food additive produced or processed with raw ingredients that are cultivated with the technologies for recombining genetic materials.[24]

IV. Restrictions on Research, Production, and Marketing

Research on and the development of GMOs must meet the requirements and permission procedures under the LMO Act and accord with social values, as discussed below.

[18] LMO Act art. 31, para. 1.

[19] *Id*. art. 31, para. 3.

[20] *Id*. art. 31, para. 1.

[21] *Id*. art. 7.

[22] *Id*. art. 2, para. 2.

[23] Nongsusanmul Poomjil Kwali Beob [Agricultural and Marine Products Quality Control Act (Agricultural Act)], Act No. 5667, Jan. 21, 1999, *last amended by* Act No. 12064, Aug. 13, 2013, art. 2, para. 1(11).

[24] Sikpoon Weesaeng Beob [Food Sanitation Act], Act No. 1007, Jan. 20, 1962, *last amended by* Act No. 11819, May 22, 2013, art. 12-2.

A. Risk Assessment

A person who intends to import, produce, use, or develop GMOs must follow the risk assessment procedure through the relevant central authority before the person applies for permission to import, produce, or use a GMO.[25] The risk assessment process is designed to identify and evaluate the possible adverse effects of GMOs on the conservation and sustainable use of biodiversity, taking into account risks to human health.[26] The minister of the relevant central authority should establish the criteria for the assessment and publicize it.[27] A minister of the relevant central authority must consult with the Ministry of Health and Welfare (MW) when risks to human health are examined. When the GMOs are to be released into the environment, other ministers are involved in addition to the relevant central authority, as described in Part V, below.[28] The applicant and the general public are notified of the results of the risk assessment.[29] If the risk is too high, the import, production, use, or development of the GMO may be restricted.

B. Prior Approval for Production, Import, or Export of GMOs

A person who intends to import GMOs must obtain the approval of the minister of the related central authority.[30] When the sole purpose of importing GMOs is for experimentation on, research into, or exhibition of GMOs, only reports to the relevant central authorities are required.[31] However, approval is required if the GMOs fall into one of the following categories:

- GMOs obtained using microorganisms for which the human pathogenic capability is unknown and the taxonomic name is not specified
- GMOs with the ability to produce toxins against vertebrates, as determined and published by the Minister of MW
- GMOs intentionally introduced with a drug-resistant gene, excluding ones with drug-resistant genes that the Minister of MW publishes
- GMOs obtained using pathogenic micro-organisms that the Minister of MW publishes because management by the state is necessary in view of public health concerns.[32]

A person who intends to produce GMOs must also obtain approval from the related central authority.[33] As of September 2013, one GM microorganism had been approved for production.[34]

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[25] LMO Act art. 7-2, para. 1.

[26] *Id*. art. 7-2, para. 3.

[27] *Id*. art. 7-2, para. 4; Unified Enforcement Regulation, Annex 1-3: General Principles and Method of Risk Assessment Under Annex II of the Protocol *and* Annex 10-1: Criteria and Required Materials for Risk Assessment.

[28] LMO Act art. 7-2, para. 3.

[29] *Id*. art. 7-2, para. 7.

[30] *Id*. art. 8, para. 1.

[31] *Id*. art. 9, para. 1.

[32] *Id*.

[33] *Id*. art. 12.

The minister of the relevant central authority may prohibit or restrict the importation or production of GMOs if he or she determines that such GMOs have adverse effects on public health or the preservation of biodiversity and sustainable use, and also if he or she determines that such GMOs have or may have negative effects on social or economic values with regard to domestic biodiversity.[35]

A person who intends to export GMOs must notify the relevant central authority of the items, quantity, importing country, and other required information under Annex II of the Protocol.[36] Anyone who intends to unload and export GMOs via a domestic port or airport must give a transit report to the relevant central authority.[37]

C. Laboratory Permission

A person who intends to establish a laboratory that conducts GMO research or conduct such research at an existing laboratory must acquire an approval for laboratory use from, or report the laboratory use to, the relevant central authorities in accordance with the level of safety of the research.[38] Levels of safety are classified from 1 (safest) to 4 (highest risk).[39] A person who establishes or runs a laboratory that carries out research that falls under levels 3 or 4 must obtain permission from the Minister of Science, Information, Communication, Technology & Future Planning in terms of environmental risk assessment or from the Minister of MW in terms of the risk assessment for the human body.[40] Level 3 research is research or experimentation involving GMOs that may cause serious but curable disease to the human body or serious but curable danger to the environment. Level 4 research is research or experimentation involving GMOs that may cause fatal disease to the human body or irreparable danger to the environment.[41] Laboratories that conduct level 1 and 2 research must only submit a report to the Minister of Science, Information, Communication, Technology & Future Planning.[42] As of July 2013, reported and permitted research facilities numbered 2,608 in total and of that number 1,985 were schools.[43]

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[34] *Kuknae Weehaesung Simsa Hyunhwang* [*Domestic Risk Assessment Status*], KOREA BIOSAFETY CLEARING HOUSE, http://www.biosafety.or.kr/bbs/mboard.asp?exec=view&strBoardID=bsn_065&intPage=1&intCategory=0&strSearchCategory=|s_name|s_subject|&strSearchWord=&intSeq=71872 (last visited Dec. 4, 2013).

[35] LMO Act art. 14, para. 1.

[36] *Id.* art. 20; Enforcement Decree art. 21.

[37] LMO Act art. 21.

[38] *Id.* art. 22.

[39] Enforcement Decree art. 23, para. 1 & table 1.

[40] *Id*. art. 23, para. 2 & table 1.

[41] *Id.* art. 23, para. 1 & table 1.

[42] *Id.* art. 23, para. 4 & table 1.

[43] *Status of Approval and Registration*, KOREA BIOSAFETY CLEARING HOUSE, http://www.biosafety.or.kr/03_data/sub0304.asp (last visited Dec. 4, 2013) (in Korean).

D. Laboratory Research Approval

Separate from research laboratory permission, a laboratory must obtain approval to conduct experiments from the relevant central authority if the GMOs that are developed or used in the experiments are considered highly dangerous.[44] Experiments that fall within this category include the following:

- Experiments involving GMOs obtained using microorganisms for which the human pathogenic potential is unknown and the taxonomic name is not specified
- Experiments using GMOs that have the ability to produce toxins against vertebrates, as determined and published by the Minister of MW
- Experiments using GMOs intentionally introduced with a drug-resistant gene, excluding ones with drug-resistant genes that the Minister of MW publishes
- Experiments involving GMOs obtained using pathogenic micro-organisms that the Minister of MW publishes because management by the state is necessary in view of public health concerns
- Experiments related to releasing GMOs into the environment
- Experiments involving, or the development of, GMOs classified as highly dangerous by the minister of the relevant central authority through deliberation of the relevant committee[45]

E. Labeling Requirements for GMOs

The LMO Act imposes labeling obligations upon anyone who develops, imports, exports, or produces GMOs. A person who develops, imports, exports, or produces GMOs must label the GMOs, the package containing GMOs, or the import invoice concerning the GMOs with the following information:

- Name, type, use, and character of the GMOs
- Precautions on the safe handling of the GMOs
- Name, address, and phone number of the GMO developer, producer, exporter, and importer
- The fact that such product is GM
- Whether such GMOs are to be released into the environment[46]

A person who fails to label GMOs according to these guidelines, or who falsely labels or intentionally changes or removes a GMO label is subject to imprisonment not exceeding one year or a fine not exceeding 20,000,000 Korean won (KRW) (about US$20,000).[47]

[44] LMO Act art. 22-2.

[45] *Id*.; Enforcement Decree art. 23, para. 6.

[46] LMO Act art. 24; Enforcement Decree art. 24.

[47] LMO Act art. 42.

When there is a special labeling regulation, the labeling regulation under the LMO Act does not apply. For example, there is a special labeling regulation for GMO food. (See Part VI, below, for a discussion of approved GMOs for food and feed.)

V. Restrictions on Releasing Organisms into the Environment

A person who intends to import GMOs for discharge into the environment must obtain approval from the minister of the relevant central authority through the Minister of MOTIE.[48] The minister of the relevant central authority must consult with the Minister of MW when potential risks to human health are examined. When the GMOs are to be released into the environment, other ministers are involved in addition to the relevant central authority: MAFRA for risks to the cultivation of crops, ME for risks to the ecosystem, and MOF for risks to the marine environment and marine ecosystem.[49] The minister of the relevant central authority considers any potential social and economic effect upon the value of domestic biodiversity resulting from approval.[50] Necessary documentation for applications includes the following:[51]

- A consent form on the import of GMOs for the purpose of intentional release into the environment issued by the Minister of MOTIE upon request from the importer
- An importing agreement, handling agreement, or self-handling schedule
- A safety management policy addressing the handling of, professional manpower for, and facility where the GMO is to be used/processed

Once the minister of the relevant central authority completes the evaluation, he or she notifies the Minister of the MOTIE. The Minister of MOTIE, via the Korea Biosafety Clearing House, announces the results to the exporting nation and to the Biosafety Clearing House under the Protocol.[52]

The cultivation of GM crops in a field is allowable under the LMO Act if it is approved by the relevant central authority.[53] However, there has been no authorized GMO cultivation within Korea thus far.[54]

[48] *Id*. art. 8, para.2; Enforcement Decree arts. 8 & 9; Unified Enforcement Regulation ch. 2.

[49] LMO Act art. 7-2, para. 3.

[50] *Id*. art. 8, para. 4.

[51] *Id*. art. 8, para. 2; Enforcement Decree arts. 8 & 9; Unified Enforcement Regulation ch. 2.

[52] LMO Act art. 8, para. 5; Enforcement Decree art. 9, para. 5.

[53] LMO Act art. 12.

[54] *Domestic Laws*, KOREA BIOSAFETY CLEARING HOUSE, http://www.biosafety.or.kr/03_data/sub0102_3.asp%20 (last visited Dec. 9, 2013) (in Korean).

VI. Restrictions on GMOs in Foodstuffs

A. Food

The safety of GM food is assessed under the Food Sanitation Act, in addition to the risk assessment and approval procedure under the LMO Act.[55] MFDS established the Safety Assessment Committee to review materials submitted for assessment.[56] The committee performs risk assessments of the effect of GMOs on the human body, upon request. Once the committee reaches a conclusion, MFDS must announce that conclusion via the Internet and gather opinions from the public. If a reasonable opinion with scientific support is received, MFDS may reflect that opinion in its conclusion. MFDS notifies the applicants of the final conclusion and publicizes it via the Internet and the official gazette.[57] As of September 2013, ninety-six GMOs had been approved for food and food additives, including soybean, maize, cotton, canola, potato, alfalfa, sugar beet, and one microorganism.[58]

B. Fodder for Livestock

A person who wants to import or produce GMO feed may apply for the environmental risk assessment separately before he applies for an approval to import.[59] MAFRA is the designated ministry for this risk assessment and approval. MAFRA has established the Environmental Risk Expert Committee, and that Committee has in turn established a risk assessment procedure.[60] Once the Committee issues the results of a risk assessment, the Minister of MAFRA must announce it and gather opinions via the Internet or the official gazette.[61] When making a decision on importing or producing GMO feed, the Minister may, if necessary, consult with an advisory committee that evaluates the socio-economic effects of GMOs.[62] As of September 2013, eighty-eight GMO feeds had been approved, including soybean, maize, cotton, canola, and alfalfa.[63]

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[55] Food Sanitation Act art. 18, para. 2.

[56] Sikpoom Weesaeng Beob Sihaengryung [Enforcement Decree of the Food Sanitation Act], Cabinet Order No. 811, June 12, 1962, *last amended by* Presidential Decree No. 24800, Oct. 16, 2013, art. 10.

[57] Yujeonja Jaejohab Sikpoom Deung-ui Anjeonseong Pyungga Simsa Deung-e Gwanhan Gyujeong [Regulation on Risk Assessment for Genetically Modified Food], Enforcement Regulation of Ministry of Food and Drug Safety, No. 2007-60, Aug. 30, 2007, *last amended by* No. 2013-80, Apr. 5, 2013, art. 9.

[58] KOREA BIOSAFETY CLEARING HOUSE, *supra* note 34.

[59] Unified Enforcement Regulation art. 4-1, para. 2.

[60] *Id.* art. 4-11.

[61] *Id.* art. 4-8, para. 9.

[62] *Id.* art. 4-6.

[63] KOREA BIOSAFETY CLEARING HOUSE, *supra* note 34.

C. Labeling

To share information and guarantee the public's right to know and the right of choice, GM food (including agricultural products and processed foods) and GM feed may have to be labeled in accordance with all the relevant laws: the LMO Act,[64] the Food Sanitation Act,[65] the Agricultural and Marine Products Quality Control Act,[66] and the Control of Livestock and Fish Feed Act.[67] Food is subject to labeling as follows:

	Agricultural Products	Processed Foods
Subject to labeling	Every GM agricultural product approved for importation by MFDS	1. Food containing GM ingredients derived from agricultural products that are subject to labeling 2. Food containing GM ingredient(s) as main ingredient(s)[68] 3. Processed food that tests positive for foreign heterologous proteins
Not subject to labeling	1. Agricultural products separately handled from non-GMOs 2. GMO content of less than 3% (considered as unintentional inclusion)	1. Using agricultural products separately handled from non-GMOs 2. GMO content of less than 3% (considered as unintentional inclusion)

Source: Labeling Guideline for Agricultural Products art. 3, paras. 2 & 3 (agricultural products); Yujeonja Jaejohab Sikpoom Deung-ui Pyoshi Kijoon [Labeling Guideline for Genetically Modified Food by Ministry of Food and Drug Safety (Labeling Guideline for Processed Food)], Enforcement Regulation, No. 2000-43, Aug. 30, 2000, amended by Enforcement Regulation, No. 2013-165, Apr. 5, 2013 (processed foods).

[64] LMO Act art. 24.

[65] Food Sanitation Act art. 12-2; Sikyakcheo Goshi Yujeonja Byunhyung Nongsusanmul Pyoshiyoryung [Labeling Guideline for Genetically Modified Agricultural and Marine Product by Ministry of Food and Drug Safety (Labeling Guideline for Agricultural Products)], Enforcement Regulation of Ministry for Food, Agriculture, Forestry and Fisheries, No. 2012-75, July 22, 2012, *amended by* Enforcement Regulation of Ministry of Food and Drug Safety No. 2013-143, Apr. 5, 2013.

[66] Agricultural Act art. 56; Enforcement Decree of the Food Sanitation Act art. 20; Labeling Guideline for Agricultural Products, *supra* note 65.

[67] Saryo Kwali Beob [Control of Livestock and Fish Feed Act], Act No. 1393, Aug. 14, 1963, *last amended by* Act No. 11690, Mar. 23, 2013.

[68] A "main ingredient" is defined as one of the top five ingredients contained in the processed food or food additive. Yujeonja Jaejohab Sikpoom Deung-ui Pyoshi Kijoon [Labeling Guideline for Genetically Modified Food by Ministry of Food and Drug Safety (Labeling Guideline for Processed Food)] art. 2, para. 4, Enforcement Regulation, No. 2000-43, Aug. 30, 2000, *amended by* Enforcement Regulation, No. 2013-165, Apr. 5, 2013.

When labeling is required for agricultural products, the label should be one of following:

- "Genetically modified [name of agricultural product]"
- "Partially contains genetically modified organism"
- "Possibly contains genetically modified organisms"[69]

The label for the GM agricultural product should be on the package, the container, or the storage facility of the product. The label must be eye-catching, with a different color from the background color.[70]

When labeling is required for processed food, the label should be one of followings:

- "Genetically modified food"
- "Partially contains genetically modified organism"
- "Possibly contains genetically modified organisms"

The label for processed food should be created with a non-erasable ink in an eye-catching form on the package or container of GM food.[71]

A person who sells, displays, transfers, or imports GM food without a label or with a false label is subject to cancellation of approval, suspension from producing such item, and imprisonment not exceeding three years or a fine not exceeding 30,000,000 KRW (about US$30,000).[72]

VII. Liability Regime

There is no existing law or regulation that specifically regulates liability issues with regard to damage caused by GMOs. Academics have been actively discussing the necessity of creating a liability scheme through amendments to existing laws or supplemental laws. There have been several attempts to apply other existing legal principles, such as the product liability regime or the no-fault liability regime, or reversing/easing the burden of proof.[73] However, the question of liability with regard to GMOs remains unsettled.

VIII. Judicial Decisions / Prominent Cases

No court decision that directly deals with GMOs has yet been issued by the Supreme Court or the Constitutional Court.

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[69] Labeling Guideline for Agricultural Products, *supra* note 65, art. 3, para. 2.

[70] *Id*. art. 4.

[71] Labeling Guideline for Processed Food, *supra* note 68, art. 5.

[72] Food Sanitation Act art. 12-2, para. 2, arts. 75, 76 & 97.

[73] Sang Hyuk Moon, A Study of Regulation and Liability Relating to Genetically Modified Organisms 101 (Feb. 2010) (unpublished PhD thesis, Sung Kyun Kwan University) (on file with National Assembly Library).

Sweden

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SUMMARY Swedes, both consumers and producers, are very conscious of genetically modified organisms (GMOs). GMO use is limited and almost exclusively used in animal fodder products. The use of GMOs in food is a sensitive topic that generates strong public opinion. A majority of Swedes consider it important or very important that their milk is GMO free, and dairy farmers therefore avoid GMOs in their fodder. Sweden, as a European Union Member, has adopted a case-by-case analysis for each GMO. One GM potato for industrial use has been approved for cultivation in Sweden, but currently no GMOs are being produced.

I. Introduction

Sweden is generally seen as being reluctant to use genetically modified organisms (GMOs). Only one genetically modified (GM) product, the GM Amflora potato, has been specifically approved for commercial production in Sweden. The potato is currently not being cultivated. Adhering to European Union (EU) regulations, two types of corn are also approved for cultivation although no application or notification for production of GM corn has been received in Sweden. While the Swedish government has adopted a case-by-case approach guided by the precautionary principle in accordance with the EU position, several local municipalities have taken a hard stance against GMOs and declared themselves "GMO free." Imported GMOs are used almost exclusively in fodder.

II. Public and Scholarly Opinion

A. Public Opinion and Its Effect on the Market

Swedes are generally very wary of GM products, especially in food. In a study conducted by milk farmers, 63% of the respondent consumers held that it was important or very important for the milk they consumed to be GMO free.[1] Another study conducted by the National Food Agency found that the big players in the Swedish agricultural market try to avoid GMOs and any association of GMOs with their brands. The National Food Agency study also showed that one corporation was willing to sell GMOs, but only if it could do so under a brand not associated with its own.[2] The perception that GMOs are dangerous or at least commercially undesirable is further evidenced by the small number of GM products available for human consumption on the Swedish market. In a 2006 survey the National Food Agency found only one item (out of the ninety-six surveyed products) that contained GMOs and was so labeled, whereas ten products

[1] *Frågor och svar om GMO-fritt foder*, LANTBRUKARNAS RIKSFÖRBUND, http://www.lrf.se/PageFiles/137196/20130913_fos_gmofritt_foder.pdf (revised Sept. 13, 2013).

[2] LIVSMEDELSVERKET, UNDERSÖKNING AV TILLÄMPNING AV LAGSTIFTNINGEN RÖRANDE GENETISKT MODIFIERADE LIVSMEDEL (GMO) [INVESTIGATION OF THE APPLICATION OF LEGISLATION ON GMOS] (Feb. 14, 2007), http://www.slv.se/upload/dokument/rapporter/genteknik/gmorapport_tillynsavdelningen_20070214.pdf.

were labeled as free from GMOs.[3] As part of its environmental policy the Swedish Food Industry continues to strive to reduce and eliminate GMOs.[4] The GMO Project conducted by the National Food Agency continued into 2009 and is still ongoing.

Public opinion against GMOs is powerful in Sweden. In 2011, market forces compelled Scan, the largest Swedish meat retailer, to go back to its GMO-free standard for fodder.[5]

B. Position of the Government and the Opposition

The official position of the government is that it is neither in favor of nor opposed to GMOs, and the government has implemented a system whereby every use of a GMO should be judged on its own risks and merits.[6] However, the official policy on GMOs also varies between different governmental agencies as they have a different focuses (promoting research, protecting the environment, etc.).[7]

The opposition (comprised of the Social Democrats, Leftist Party, and Green Party) holds a more restrictive view of GMOs than the center-right coalition government.[8] The Swedish Green Party in particular strongly opposes the use of GMOs.[9]

A slight shift in public opinion may be deduced from the language describing GMOs, as GMOs during the 1990s were commonly referred to as "manipulated foods" and are now referred to as "genetically modified foods."[10] This change could be related to the change of government that occurred in 2006. There are also vocal members of the public who favor GMOs.[11]

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[3] *Id*.

[4] *Id*. at 11.

[5] *Enbart GMO-fritt foder till Scans grisar*, CISION.COM (Mar. 23, 2011), http://news.cision.com/se/scan-ab/r/enbart-gmo-fritt-foder-till-scans-grisar,c556350.

[6] *Genetiskt modifierade organismer*, REGERINGSKANSLIET, http://www.regeringen.se/sb/d/6421/a/58280 (last updated July 1, 2013).

[7] For one view, see a study by the Environmental Protection Agency (Naturvårdsverket). EKOLOGISKA EFFEKTER AV GMO, NATURVÅRDSVERKET (Sept. 2006), *available at* http://www.popgen.su.se/pdf/GMO620-5597-6.pdf.

[8] The largest coalition party, the Moderaterna, does not specifically mention GMOs in its manifesto, which is available at MODERATERNA.SE, http://www.moderat.se/jordbruk/mat. The Green Party position is available at MILJOPARTIET, http://www.mp.se/sala/just-nu/sala-gmo-fri-kommun. The Social Democrats want the EU Member States to have the opportunity to ban the cultivation of GMO plants and oppose their use for health reasons. *See* SOCIALDEMOKRATERNA, http://www.socialdemokraterna.se/Webben-for-alla/EU/EU/Ledamoterna-/maritaulvskog/Mediany/Nyheter/GMO-grodor-ar-upp-till-medlemslanderna/ (last visited Oct. 18, 2013).

[9] *See*, *e.g.*, Carl Schlyter, Op-Ed., *Genmanipulation ger inte ett uthålligt jordbruk*, SVENSKA DAGBLADET (Mar. 26, 2012), http://www.svd.se/opinion/brannpunkt/genmanipulation-ger-inte-ett-uthalligt-jordbruk_6951821.svd, *and* Kew Nordqvist's voting record on the Board, Addendum 1 of each of the following: 040/2013-4.1.1., 034/2013-4.1.1., 007/2013-4.1.1., 007/2013-4.1.1., 005/2013-4.1.1., 004/2013-4.1.1., 104/2012-4.1.1, 103/2012-4.1.1., *available at* GENTEKNIKNÄMNDEN, http://www.genteknik.se/sv/2013---yttranden (last visited Oct. 18, 2013).

[10] *Genmanipulerade* vs. *Genmodifierade* (translation by author).

[11] *See*, *e.g.*, *Nyttig genmanipulerad mat stoppas av skräckpropaganda*, DAGENS NYHETER (Mar. 11, 2009), http://www.dn.se/debatt/nyttig-genmanipulerad-mat-stoppas-av-skrackpropaganda/.

C. Scholars and NGOs

Swedish scientists have not agreed on a firm conclusion concerning the effects GMOs have on health and the environment.[12] Therefore, in accordance with the general policy of Sweden, the precautionary principle is applied on a case-by-case basis.

Some NGOs favor and some oppose GMOs. The greatest opponents of GMO use are environmental activists (such as those belonging to the Green Party and Greenpeace), while the strongest supporters are farmers, who want to use the cheaper GMO fodder. Even the agricultural community is divided. The industry organization Federation of Swedish Farmers favors GMOs.[13] However, in 2003 LRF Dairy Sweden (which is part of the Federation of Swedish Farmers) decided to continue to exclusively use non-GM fodder for its milk-producing cows.[14] The reason was a fear of losing the public's trust, as most milk consumers consider that it is important or very important for their milk to be GMO free.[15]

III. Structure of Pertinent Legislation

An overview in English of the pertinent Swedish legislation and responsible government agencies can be found at a government-run webpage called GMO.nu.[16] Relevant information is summarized below.

A. European Union Law

As a member of the European Union, Sweden is bound by the EU Directives on GMOs. Sweden has implemented Directives 2009/41/EG and 2001/18/EG, as well as Regulations 1829/2003, 1830/2003, 1946/2003, and 726/2004, through amendments to the Environmental Act and stand-alone legislation.[17]

B. National Legislation and Definition of GMO

The overarching Swedish legislation on GMOs is found in chapter 13 of the Environmental Code and its accompanying regulations. Where so designated in the Code, certain government agencies or authorities may also issue instructions that regulate GMOs.

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[12] Lars Brander, *Kan genmanipulerad föda ge skador?*, ALLTOMVETENSKAP MAGAZINE (May 4, 2010), http://www.alltomvetenskap.se/nyheter/kan-genmanipulerad-foda-ge-skador.

[13] *LRFs genpolicy*, LANTBRUKARNAS RIKSFÖRBUND, http://www.lrf.se/Medlem/Politik--Paverkan/Miljo--vatten/Genteknik/LRFs-genpolicy/ (last visited Nov. 15, 2013).

[14] *Fortsatt GMO-fritt till svenska mjölkkor*, LANTBRUKARNAS RIKSFÖRBUND, http://www.lrf.se/Om-LRF/Kontakta-LRF/Press/Pressmeddelanden/2013/Fortsatt-GMO-fritt-till-svenska-mjolkkor/ (last visited Sept. 25, 2013).

[15] *Frågor och svar om GMO-fritt foder*, LANTBRUKARNAS RIKSFÖRBUND, *supra* note 1.

[16] *Welcome Page*, GMO REGULATIONS IN SWEDEN, http://www.gmo.nu/gmoenglish.4.778a5d1001f29869a7fff935.html (last visited Sept. 25, 2012).

[17] MILJÖBALK [MB] [ENVIRONMENTAL CODE] (Svensk författningssamling [SFS] 1998:808) 13:4. For a more detailed discussion of EU law, see the survey of EU law included in this report at page ***.

A genetically modified organism is defined as "an organism where the genetic material has been altered in a way that does not happen naturally through mating or natural recombination."[18]

There is special GMO legislation for food, fodder, medical use, release into water, and release into the general environment. There are also instructions on the protection of workers handling GMOs, contingency plans for hazardous GMOs, etc. There are in total ten different pieces of legislation and thirteen agency instructions addressing GMOs.[19] The government agencies that issue the instructions are the same as the enforcing government agencies.

C. Local Municipality Instructions and "GMO-Free Zones"

A county or municipality cannot issue a local GMO instruction for its municipality. Thus, any municipality that desires to be "GMO free" must come to an agreement with the farmers in the region, and entry into such an agreement must be voluntary. A municipality cannot prevent a farmer from cultivating or using an otherwise allowed GMO.

IV. Restrictions on Research, Production, and Marketing

A. General Provisions

All use of GMOs is regulated by chapter 13 of the Swedish Environmental Code, and all use, whether in a contained laboratory setting or in nature, must receive prior approval from the relevant government authority.[20] The inspection and oversight required by the Environmental Code is regulated in a special oversight regulation.[21] The Environmental Code also includes area-specific legislation with more strenuous provisions for GMO use, such as their use in water (chapter 2) and chemicals (chapter 14).[22]

B. Licensing and Oversight Agencies

Several authorities are part of the process of granting mandatory permits for the use, release, or production of GM products, as well as the oversight and inspections of pertinent GMO use.[23]

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[18] ENVIRONMENTAL CODE 13:4.

[19] *See also* Part IV(B), below. For a list of GMO legislation see the official website of the Swedish gene technology authorities, at http://www.gmo.nu/toppmeny/lagstiftning.4.1d07c3f108381dd74480001062.html (last visited Nov. 12, 2013).

[20] *See* Part IX(B), below.

[21] MILJÖTILLSYNSFÖRORDNING [REGULATION ON ENVIRONMENTAL OVERSIGHT] (SFS 2011:13), issued with delegation through ch. 26 of the Environmental Code, http://www.notisum.se/rnp/sls/lag/20110013.htm.

[22] MILJÖTILLSYNSFÖRORDNING [REGULATION ON ENVIRONMENTAL OVERSIGHT] (SFS 2011:13) chs. 2, 14.

[23] *Id*. 2 ch. 12–18 §§.

1. Swedish Gene Technology Advisory Board

A special Gene Technology Advisory Board has been set up to "monitor developments in the field of gene technology, oversee ethical issues, and give advice on use of gene technology."[24] It receives copies of and recommends decisions for all applications for the use of new GMOs.[25] The government controls the composition of the Board.[26] Currently, the composition includes lawyers, political representatives, and experts.[27]

2. National Environmental Protection Agency

The National Environmental Protection Agency is responsible for field studies of GMOs. It focuses on the need for increased research on GMOs and their long-term effects on the environment.[28]

3. Swedish Agency for Marine and Water Management

The Swedish Agency for Marine and Water Management is responsible for the use of GMOs in waterliving organisms, the deliberate placement of waterliving GM organisms, and the release of products that contain waterliving GM organisms.[29]

4. Swedish Board of Agriculture

The Swedish Board of Agriculture is responsible for the approval and oversight of the intentional release of GMOs into the environment through GM plants, land-based organisms not covered by the Swedish Chemicals Agency, and GM fodder.[30]

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[24] *The Swedish Gene Technology Advisory Board*, GENTEKNIKNÄMNDEN, http://www.genteknik.se/sv/in-english (last visited Nov. 12, 2013).

[25] FÖRORDNING OM UTSÄTTNING AV GENETISKT MODIFIERADE ORGANISMER I MILJÖN [REGULATION ON THE RELEASE OF GENETICALLY MODIFIED ORGANISMS INTO THE ENVIRONMENT] (SFS 2002:1086) ch. 2:11st2.

[26] ENVIRONMENTAL ACT ch. 13:19 §.

[27] *Gentekniknämndens ledamöter och personliga ersättare*, GENTEKNIKNÄMNDEN, http://www.genteknik.se/sv/ledamoter (last visited Oct. 23, 2013).

[28] *Genetiskt modifierade organismer i Sverige*, NATURVÅRDSVERKET, http://www.naturvardsverket.se/Miljoarbete-i-samhallet/Miljoarbete-i-Sverige/Uppdelat-efter-omrade/Naturvard/Genetiskt-modifierade-organismer/GMO-i-Sverige/ (last updated Feb. 4, 2013).

[29] FISKERIVERKETS FÖRESKRIFTEROM GENETISKT MODIFIERADE VATTENLEVANDE ORGANISMER [FISHERY MINISTRIES REGULATIONS ON GENETICALLY MODIFIED ORGANISMS LIVING IN WATER] (Fiskeriverkets föreskrifter [FIFS] 2004:2), *amended by* Havs- och vattenmyndighetens författningssamling [HVMFS] 2011:3, *available at* https://www.havochvatten.se/download/18.312592e0130 1d753523800017708/1348912773023/ HVMFS+-+FIFS+ +2004-2-keu-1107...pdf.

[30] JORDBRUKSVERKET, http://www.jordbruksverket.se/amnesomraden/odling/genteknikgmo.4.373db8e013d4008b3a18000378.html (last visited Nov. 15, 2013).

5. The National Board of Forestry

The National Board of Forestry is responsible for the intentional release of GM forest trees intended for timber production.[31]

6. Swedish Chemicals Agency

The Swedish Chemicals Agency processes applications for approval for studies deliberately releasing GM microorganisms, nematodes, arachnids, and insects into the environment. The Swedish Chemicals Agency lists one approved study for cultivation of a GM product on its webpage.[32] The Swedish Chemicals Agency also preapproves the use of biological pesticides.[33]

7. Swedish Civil Contingency Agency

The Swedish Civil Contingency Agency is responsible for the transportation of such GM material that is classified as "dangerous goods."[34]

8. The National Food Agency

The National Food Agency is responsible for "the GMO project," through which producers are tested concerning GMO use and educated on GMO rules.[35]

9. Medical Products Agency

The Medical Products Agency is responsible for the intentional release of drugs that contain GMOs as well as the release into the environment of GMOs.[36] There is currently no medical GMO on the market. Clinical testing in humans is generally considered as a release of GMOs into the environment.[37] Tests that do not necessitate a release into the environment, such as certain animal tests, require GMO approval from the Swedish Work Environment Authority

[31] MILJÖTILLSYNSFÖRORDNING [REGULATION ON ENVIRONMENTAL OVERSIGHT] (SFS 2011:13), ch. 2:17 §; SKOGSSTYRELSEN, http://www.svo.se (last visited Nov. 12, 2013).

[32] *Genmodifierade organismer, GMO*, KEMIKALIEINSPEKTIONEN, http://www.kemi.se/Innehall/Bekampningsmedel/Genmodifierade-organismer-GMO/ (last visited Nov. 12, 2013).

[33] *Id*.

[34] SWEDISH CIVIL CONTINGENCY AGENCY, https://www.msb.se/en/ (last visited Nov. 12, 2013).

[35] *See* annual reports on the GMO project in Swedish at LIVSMEDELSVERKET, http://www.slv.se/sv/grupp3/Rapporter/Genteknik/ (last visited Oct. 23, 2013).

[36] Governed by SFS 2011:13, ch. 2:16 §, which implements 2001/18/EG.

[37] LÄKEMEDELSVERKETS FÖRESKRIFTER OCH ALLMÄNNA RÅD OM AVSIKTLIG UTSÄTTNING VID KLINISK PRÖVNING AV LÄKEMEDEL SOM INNEHÅLLER ELLER BESTÅR AV GENETISKT MODIFIERADE ORGANISMER [MEDICAL PRODUCTS AGENCY'S REGULATION ON ADVICE ON INTENTIONAL RELEASE DURING CLINICAL TRIALS OF DRUGS CONTAINING GENETICALLY MODIFIED ORGANISMS] (Livsmedelsverkets föreskrifter [LVFS] 2004:10) 4 § 3p, *available at* http://www.lakemedelsverket.se/upload/lvfs/LVFS_2004-10.pdf.

rather than the Medical Products Agency.[38] All medical products containing GMOs must be labeled "This product contains genetically modified organisms."[39]

10. Swedish Work Environment Authority

The Swedish Work Environment Authority oversees the issuance of permits and the registration of use of GMOs in a contained setting (such as laboratory use), and the work conditions for all workers handling GMOs. Based on the classification of harm to the people working with the product the use will require registration or a permit from the user.[40]

C. Labels

Fodder, food, and pharmaceuticals that include GMOs must be labeled.[41] Products from livestock that have been fed GMO fodder need not be labeled.

V. Restrictions on Releasing Organisms into the Environment

A. General Provisions

The release of GMOs into the environment is regulated by EU Directive 2001/18/EG as implemented through Regulation SFS 2002:1086. Release is restricted and requires a license.[42] Agencies must apply the precautionary principle and ensure that appropriate measures are taken to avoid negative effects on human health or the environment that may result from the intentional release of GMOs into the environment.[43] Additional guidelines may be issued by the relevant agency, and the release must be ethically justifiable to be granted a permit.[44] Before an application for use of GMO is approved, the public is offered an opportunity to comment on the application.[45] The agency must also send a copy of the application to the European Commission, the National Environmental Protection Agency, and the Gene Technology Advisory Board.[46] Once a release is approved and has commenced, it must be followed by a report by the GMO

[38] *Id*. at 4 §. Läkemedelsverket still requires a general application for all medical testing, but does not oversee the GMO aspect of the testing.

[39] Translation by author of "Denna produkt innehåller genetiskt modifierade organismer." LVFS 2004:10 12 §.

[40] INNESLUTEN ANVÄNDNING AV GENETISKT MODIFIERADE MIKROORGANISMER [CONTAINED USE OF GENETICALLY MODIFIED ORGANISMS] (Arbetsmiljöverkets Föeskrifter [AFS] 2011:2) at 14–16 §§.

[41] *See* Instruction LVFS 2004:10 12 §, *and* The National Food Agency Instruction, both issued under the delegation in ENVIRONMENTAL CODE ch. 13:18 §.

[42] ENVIRONMENTAL CODE ch. 13:12–14 §§, FÖRORDNING OM UTSÄTTNING AV GENETISKT MODIFIERADE ORGANISMER I MILJÖN (SFS 2002:1086) ch. 2:2 and 3:2.

[43] FÖRORDNING OM UTSÄTTNING AV GENETISKT MODIFIERADE ORGANISMER I MILJÖN [REGULATION ON RELEASE OF GENETICALLY MODIFIED ORGANISMS INTO THE ENVIRONMENT] ch.1:3 §.

[44] ENVIRONMENTAL CODE ch. 13:13 §, http://www.riksdagen.se/sv/Dokument-Lagar/Lagar/Svenskforfattningssamling/Miljobalk-1998808_sfs-1998-808/.

[45] FÖRORDNING OM UTSÄTTNING AV GENETISKT MODIFIERADE ORGANISMER I MILJÖN ch. 2:10 §.

[46] *Id*. chs. 2:9, 2:11, 2:11 st2.

user describing the effects of the release and all other requirements dictated by the relevant authority.[47] All GMO studies conducted in Sweden can be found on the EU website, according to which there has been a total of forty-eight studies with plants[48] and nine studies with nonplants.[49]

B. Reporting Requirements and Inspections

Inspections are carried out by the relevant authority as specified in the Environmental Oversight Regulation.[50] Each authority issues its own instructions for the inspections but they must be in compliance with the Environmental Code.

C. Protection of Neighboring Cultivation

EU Member States set their own policies and regulations for cultivating GMOs in the proximity of another non-GM product. In Sweden a farmer must maintain a distance of fifty meters between GM and non-GM corn and three meters between GM and non-GM potatoes.[51] As mentioned above, only the GM Amflora potato has been approved for cultivation in Sweden, but is currently not being produced. The Swedish Board of Agriculture regulates the distance required between GM and non-GM products.[52] The Swedish Board of Agriculture has issued an instruction as a guide for application of the precautionary principle in the cultivation of GMOs.[53]

D. Development of "GMO Free Zones"

Although there are restrictions on releasing and cultivating GM products, there is no legal basis for a Swedish municipality to proclaim itself to be GMO free.[54] A municipality may reach an agreement with its farmers not to produce GMOs, provided these agreements are voluntary. Several Swedish municipalities and one county have declared themselves "GMO free."[55]

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[47] *Id*. ch. 2:17.

[48] *Deliberate Release and Placing on the EU Market of GMOs – GMO Register*, EUROPEAN COMMISSION, http://gmoinfo.jrc.ec.europa.eu/gmp_browse.aspx (last visited Oct. 23, 2013).

[49] *Id*.

[50] MILJÖTILLSYNSFÖRORDNING (SFS 2011:13) ch. 2:11–18 §§, http://www.notisum.se/rnp/sls/lag/20110013.htm.

[51] 4 § FÖRSIKTIGHETSÅTGÄRDER VID ODLING AV GENETISKT MODIFIERADE GRÖDOR [PRECAUTIONARY MEASURES FOR CULTIVATION OF GENETICALLY MODIFIED PLANTS] (Statens jordbruksverks föreskrifter [SJVFS] 2008:34).

[52] 9 § FÖRSIKTIGHETSÅTGÄRDER VID ODLING OCH TRANSPORT M.M. AV GENETISKT MODIFIERADE GRÖDOR (SFS 2007:273).

[53] FÖRSIKTIGHETSÅTGÄRDER VID ODLING AV GENETISKT MODIFIERADE GRÖDOR (SJVFS 2008:34), http://www.jordbruksverket.se/download/18.26424bf71212ecc74b080001053/1242046883569/2008-034.pdf.

[54] Compare with Latvia, which allows its municipalities to decide about GMO use. *GMO i nordisk perspektiv*, BYGDEKVINNELAGET (Nov. 6, 2012), http://bygdekvinnelaget.no/gmo-i-nordisk-perspektiv.

[55] *See*, *e.g.*, *Östersunds kommun är Sveriges första GMO-fria kommun*, HEJ DÅ GMO! (Mar. 30, 2009), http://hejdagmo.se/2009/03/30/ostersunds-kommun-ar-sveriges-forsta-gmo-fria-kommun/; NORDANSTIG, http://www.nordanstig.se/Kommunen/Kost-och-stad/Kost/GMO-fri-kommun.html (last visited Nov. 11, 2013); GREENPEACE, http://www.greenpeace.org/sweden/se/nyheter/nyheter/aennu-en-kommun-blir-gmo-fri/ (last visited Nov. 11, 2013). Jämtland County has declared itself GMO free as a benchmark, hoping that farmers will follow

Other municipalities source locally and organically without calling themselves GMO-free zones because they deemed it "practically impossible" to rid an area of GM organisms.[56] Regardless of the municipality's approach to GMOs, the granting of GMO licenses for agriculture is still carried out by the Swedish Board of Agriculture on a national level. Municipalities can thus not prevent local farmers from producing or using EU-approved GMOs.

VI. Restrictions on GMOs in Foodstuffs

A. The Precautionary Principle

As mentioned above, Sweden together with the EU previously relied on the precautionary principle when restricting GMOs in food and animal fodder.[57] Although GMOs are now allowed in the EU, the principle is applied to each application on a case-by-case basis.[58]

B. Implementing Authorities and Authorizing Procedures

The Swedish Board of Agriculture oversees the use of GMOs in fodder, and the National Food Agency oversees GMOs in food intended for human consumption.[59]

C. GMOs in Food for Human Consumption

GMOs in food is regulated in Livsmedelslagen[60] and Livsmedelsförordningen,[61] implementing EU Regulations 852/2004, 178/2002, and 853/2004.[62] Foods that contain GMOs need to be labeled.[63] However, animal products intended for human consumption originating from animals raised on GM fodder need not be labeled (such as eggs from hens, beef, etc.). Swedish honey is not tested for GMOs.[64] GMOs that have not been approved by the EU may not be used in food products. It is the European Food Safety Agency that decides which GMOs are fit for human

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suit. So far no GMO has been produced in Jämtland. *Jämtland vill vara GMO-fri zon*, ATL (May 7, 2009), http://www.atl.nu/lantbruk/jamtland-vill-vara-gmo-fri-zon.

[56] *E.g.*, *Meeting Minutes, City Council,* GOTLAND (Apr. 24, 2006), http://www.gotland.se/25174.

[57] *Ordlistan, försiktighetsprincipen*, EUROPA, http://europa.eu/legislation_summaries/glossary/precautionary_principle_sv.htm (last visited Nov. 12, 2013).

[58] *GMO-potatis och försiktighetsprincipen*, RIKSDAGEN (June 22, 2011), http://www.riksdagen.se/sv/Dokument-Lagar/Fragor-och-anmalningar/Svar-pa-skriftliga-fragor/GMO-potatis-och-forsiktighetsp_GY12585/.

[59] MILJÖTILLSYNSFÖRORDNING (SFS 2011:13) at 15, 18 §§.

[60] LIVSMEDELSLAG [FOOD ACT] (SFS 2006:804), http://www.riksdagen.se/sv/Dokument-Lagar/Lagar/Svenskforfattningssamling/Livsmedelslag-2006804_sfs-2006-804/.

[61] LIVSMEDELSFÖRORDNING [FOOD REGULATION] (SFS 2006:813), http://www.riksdagen.se/sv/Dokument-Lagar/Lagar/Svenskforfattningssamling/Livs medelsforordning-2006813_sfs-2006-813/

[62] FOOD ACT (SFS 2006:804); FOOD REGULATION (SFS 2006:813).

[63] *See* Instruction by the Livsmedelsverket, issued after specific designation in SFS 2006:804 ch.1:6 § st1. p2, *and* ENVIRONMENTAL CODE ch. 13:18 §.

[64] *Honung med pollen från GMO*, LIVSMEDELSVERKET, http://www.slv.se/sv/grupp1/Marknin-av-mat/Genmodifierad-mat-GMO/Honung-med-pollen-fran-GMO/ (last updated Apr. 29, 2013).

consumption and which are not. The Swedish National Food Agency merely implements the European Food Safety Agency's decision.

D. Fodder for Livestock

GMOs are mainly used for fodder for livestock in Sweden, as evidenced by the applications for the use of GMOs.[65] A list of GMOs approved to be used in fodder can be found at the Swedish Board of Agriculture website.[66] The rules governing fodder can also be found there.[67] The approved GMOs include eight strands of cotton, twenty-seven types of corn, three strands of colza, one sugar beet, seven types of soybeans, and one potato.[68] For a fee, a survey of the Swedish GM fodder market can be accessed at the Swedish Board of Agriculture's website.[69]

E. "GMO Free" and Commonly Used Labels Indicating Green Products

GMO-free labels are technically not allowed in Sweden but are common.[70] Following an inspection by the National Food Agency they have been replaced by other labels such as "organically grown" and "KRAV" (indicating approval by a special labeling organization by the same name).[71] Products do not live up to the labeling standard if they contain genetically modified products.[72] As mentioned above, animal products from animals fed with GM produce do not require a special label.[73] The Leftist and Green Parties argue that this makes it impossible for consumers who want to avoid GMO products to do so, and therefore these parties want to limit all imports of GM colza.[74] The use of the Svenskt Sigill (Swedish Seal) requires the use of GMO-free fodder.[75]

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[65] *See* Gene Technology Board applications, *Yttranden 2013*, http://www.genteknik.se/sv/2013---yttranden, *and* LIVSMEDELSVERKET, UNDERSÖKNING AV TILLÄMPNING AV LAGSTIFTNINGEN RÖRANDE GENETISKT MODIFIERADE LIVSMEDEL (GMO) [INVESTIGATION OF THE APPLICATION OF LEGISLATION ON GMOS] (Feb. 14, 2007), http://www.slv.se/upload/dokument/rapporter/genteknik/gmorapport_tillynsavdelningen_20070214.pdf.

[66] For a list of all approved GMOs, *see Godkända genetiskt modifierade växter*, JORDBRUKSVERKET, http://www.jordbruksverket.se/amnesomraden/djur/foder/genteknikgmo/godkandagenetisktmodifieradevaxter.106.7c4ce2e813deda4d30780001930.html (last updated Apr. 15, 2013).

[67] *Genteknik och foder*, JORDBRUKSVERKET, http://www.jordbruksverket.se/amnesomraden/djur/foder/genteknikgmo.4.207049b811dd8a513dc80004212.html (last modified Apr. 16, 2013).

[68] *Godkända genetiskt modifierade växter*, JORDBRUKSVERKET, *supra* note 66.

[69] JORDBRUKSVERKET, GMO PÅ FODERMARKNADEN, Rapport 2009:17, http://webbutiken.jordbruksverket.se/sv/artiklar/gmo-pa-fodermarknaden.html.

[70] *See* Annual GMO project reports, *available at* http://www.slv.se/sv/grupp3/Rapporter/Genteknik/ (last visited Nov. 12, 2013).

[71] *Id*.

[72] *See Svenskt Sigill och gentekniken*, SVENSKT SIGILL (Mar. 26, 2013), http://www.svensktsigill.se/Om-Sigill/Intressenter/Svenskt-Sigill-och-gentekniken/; KRAV, http://www.krav.se/ar-krav-certifierad-mat-fri-fran-gmo.

[73] GENTEKNIKNÄMNDEN, *Yttrande 2013-0417*, Diarienr 034/2013-4.1.1 Bilaga 1, http://www.genteknik.se/Uploads/Files/034_2013_raps_MS8xRF3xGT73.pdf.

[74] *Id*.

[75] *See* SVENSKT SIGILL, *supra* note 72.

F. Recent Licenses for GMO Use

Despite public resistance to GMOs, all of the most recent (seven out of seven) applications for import licenses for GM products have been approved by the Swedish Gene Technology Advisory Board.[76] The Board's general position on GMOs can be found in its annual GMO reports.[77]

The Swedish Board of Agriculture lists all approved GM products.[78] Out of forty-eight products only the GM Amflora potato is approved for cultivation.[79] Note that this potato is not suitable nor intended for human consumption.[80] Forty-five of the other forty-seven products are suitable only for fodder. All but eight are suitable for import.[81] Current field studies of GM plants in Sweden include oil cabbage, potato, aspen, cress, and apple and pear trees.[82]

VII. Liability Regime

Breaches of the Environmental Code are regulated in its chapter 29. Beginning November 5, 2013, violations of the stipulated precautions in relation to the release of GMOs into the environment are subject to a fine and up to two years of imprisonment.[83] Also, obstructions of environmental inspections may result in fines or imprisonment for up to two years.[84] Fines may also be issued for failure to comply with GMO-specific legislation, such as observing the mandatory distance between GM and non-GM products; failing to label products as GM when required to do so; and failing to inform, identify, and document the transport of GMOs.[85] There

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[76] Decision Nos. 040/2013-4.1.1, 034/2013-4.1.1, 007/2013-4.1.1, 007/2013-4.1.1, 005/2013-4.1.1, 004/2013-4.1.1, 104/2012-4.1.1, and 103/2012-4.1.1, *available at* http://www.genteknik.se/sv/2013---yttranden.

[77] *Genteknikens utveckling 2007-2012*, GENTEKNIKNÄMNDEN, http://www.genteknik.se/sv/--2012 (last visited Nov. 12, 2013).

[78] *Godkända genetiskt modifierade växter*, JORDBRUKSVERKET, http://www.jordbruksverket.se/amnesomraden/odling/genteknikgmo/kommersiellanvandning/godkanda.4.300b18bd13d103e79ef80002529.html (last updated July 31, 2013).

[79] For more information on the potato, see *Stärkelsepotatisen Amflora*, JORDBRUKSVERKET, http://www.jordbruksverket.se/amnesomraden/odling/genteknikgmo/kommersiellanvandning/starkelspotatisenamflora.4.300b18bd13d103e79ef80002589.html (last updated May 16, 2013).

[80] *Id*.

[81] *Godkända genetiskt modifierade växter*, JORDBRUKSVERKET, http://www.jordbruksverket.se/amnesomraden/djur/foder/genteknikgmo/godkandagenetisktmodifieradevaxter.106.7c4ce2e813deda4d30780001930.html (last updated Apr. 15, 2013).

[82] *See* List of 2013 field studies of GMO plants, *Försök med genetiskt modifierade växter*, JORDBRUKSVERKET, http://www.jordbruksverket.se/amnesomraden/odling/genteknikgmo/faltforsok/2013arsforsok.4.300b18bd13d103e79ef80002609.html (last updated July 8, 2013). A list of all EU-approved GMOs can be found on the EU Register of Authorised GMOs, EUROPEAN COMMISSION, http://ec.europa.eu/food/dyna/gm_register/index_en.cfm (last visited Nov. 12, 2013).

[83] ENVIRONMENTAL CODE ch. 29:4 § 1st h & i.

[84] *Id*. ch. 29:5 § 4.

[85] *Id*. ch. 29:9 §§ 5–8.

is no liability for minor breaches.[86] Animals, plants, etc. used in these violations can be confiscated.[87] There is currently no special legislation granting a private cause of action for others' GMO violations. Thus, the general culpability rules for torts apply.[88]

VIII. Judicial Decisions / Prominent Cases

There are no prominent cases on the national level that directly control the use of GMOs. The most prominent EU case applicable also to Sweden is the EU honey case.[89]

A. Misleading Advertisement ("GMO Free")

In 2004 the Market Court found that an advertisement for chicken stating, among other things, that it was GMO free was improper and misleading as the chicken included up to 2% GMO, whereas Swedish custom at the time defined "free from GMO" as including less than 1% GMO.[90] The advertisement was therefore banned.

B. Municipalities' Control over Leased Land

In a January 15, 2013, decision the Göta Court of Appeals found that a municipality could generally change the terms of a lease for land only if the change in terms did not lead to unreasonable burdens on the lessee (farmer).[91] However, in this case the Court found that the desired change into an ecological, GMO-free type of agriculture would be unreasonably burdensome for the farmer and therefore prevented the municipality from placing such a burden on the farmer. The lessee terms could therefore not be changed and the farmer was not required to farm ecologically.

[86] *Id*. ch. 29:11.

[87] *Id*. ch. 29:12.

[88] *See* SKADESTÅNDSLAGEN [TORTS LIABILITY ACT] (SFS 1972:207). For a full discussion of the liability issue with regard to cultivation of GMO plants, see Statens Offentliga Utredningar [SOU] 2007: 46 Ansvarsfrågan vid odling av genmodifierade grödor [government report series].

[89] Case C-442/09, Karl Heinz Bablok and Others v. Freistaat Bayern (Sept. 6, 2011), http://curia.europa.eu/juris/document/document.jsf?text=&docid=109143&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=809490, case summary available at http://ec.europa.eu/dgs/legal_service/arrets/09c442_en.pdf. *See also* case discussion in EU survey, *supra* at 78.

[90] Marknadsdomstolen [Market Court], MD 2004:8, Mar. 24, 2004 (on file with author).

[91] Decision from Göta Court of Appeals, Jan. 15, 2013, No. ÖÄ 2956-12 (on file with author).

United States

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SUMMARY GMOs are regulated in the United States under the Coordinated Framework for Regulation of Biotechnology, published in 1986, pursuant to previously existing statutory authority regulating conventional products, with a focus on the nature of the products rather than the process in which they are produced.

Plant GMOs are regulated by the US Department of Agriculture's Animal and Plant Health Inspection Service under the Plant Protection Act. GMOs in food, drugs, and biological products are regulated by the Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act. GMO pesticides and microorganisms are regulated by the Environmental Protection Agency pursuant to the Federal Insecticide, Fungicide and Rodenticide Act and the Toxic Substances Control Act. The form of regulation varies depending on the type of GMO involved.

I. Introduction

The United States does not have any federal legislation that is specific to genetically modified organisms (GMOs). Rather, GMOs are regulated pursuant to health, safety, and environmental legislation governing conventional products. The US approach to regulating GMOs is premised on the assumption that regulation should focus on the nature of the products, rather than the process in which they were produced.[1]

Compared to other countries, regulation of GMOs in the US is relatively favorable to their development. GMOs are an economically important component of the biotechnology industry, which now plays a significant role in the US economy.[2] For example, the US is the world's leading producer of genetically modified (GM) crops. In 2012, of the 170.3 million hectares of biotech crops globally, the United States accounted for 69.5 million, over 40% of the total.[3] For several crops grown in the US, genetically engineered varieties now make up the vast majority of

[1] PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, GUIDE TO U.S. REGULATION OF GENETICALLY MODIFIED FOOD AND AGRICULTURAL BIOTECHNOLOGY PRODUCTS 6 (Sept. 2001), http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food_and_Biotechnology/hhs_biotech_0901.pdf.

[2] *The Biotechnology Industry in the United States*, SELECT USA, http://selectusa.commerce.gov/print/industry-snapshots/biotechnology-industry-united-states (last visited Nov. 5, 2013) (stating there are 1300 firms and 1.3 million employees in biosciences in the US, and 5.8 million employees in related industry sectors).

[3] INT'L SERV. FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATIONS, ISAAA BRIEF NO. 44-2012, GLOBAL STATUS OF COMMERCIAL BIOTECH/GM CROPS, Executive Summary, http://www.isaaa.org/resources/publications/briefs/44/executivesummary/default.asp (last visited Nov. 5, 2013).

the crop. In 2013, 93% of the soybeans, 90% of the cotton, and 90% of the corn grown in the US were genetically engineered for either herbicide tolerance or insect resistance.[4]

The US is not a party to the Cartagena Protocol on Biosafety.[5] As a signatory but a nonparty to the parent Convention on Biological Diversity, it cannot become a party to the Protocol.[6] It has participated in meetings as a nonparty observer, however.[7]

II. Public and Scholarly Opinion

A. Public Opinion

Public opinion on GMOs in the US is mixed. A series of polls conducted over five years, from 2001 to 2006, found that public understanding of biotechnology was relatively low, and that consumers were relatively unaware of the extent to which their foods included genetically modified ingredients.[8] Support for the introduction of genetically modified foods into the food supply held steady at 26 to 27% of respondents in favor over that time period, while opposition to the introduction of such foods fell from 58 to 46% over the period.[9]

Polls indicate strong support for labeling of GMO foods; one recent poll found 93% of respondents supporting mandatory labeling.[10] The same poll found three-fourths of Americans expressing concern regarding GMOs in food; nearly half indicating they were aware that many processed or packaged foods contain genetically modified ingredients; around half saying they would not eat genetically modified vegetables, fruits, and grains; three-quarters stating they would not eat genetically modified fish; and two-thirds saying they would not eat genetically modified meat.[11]

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[4] Economic Research Service, *Adoption of Genetically Engineered Crops in the US, Recent Trends in GE Adoption*, UNITED STATES DEPARTMENT OF AGRICULTURE, http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/recent-trends-in-ge-adoption.aspx#.UobvBXL92Dk (July 9, 2013).

[5] Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Jan. 29, 2000, 39 I.L.M. 1027, http://bch.cbd.int/protocol/text/; *Parties to the Protocol and Signature and Ratification of the Supplementary Protocol*, CONVENTION ON BIOLOGICAL DIVERSITY, http://bch.cbd.int/protocol/parties/ (last updated Sept. 10, 2012).

[6] Bureau of Oceans and International Environmental and Scientific Affairs, *Frequently Asked Questions on the Cartagena Protocol on Biosafety (CPB),* U.S. DEPARTMENT OF STATE (Feb. 23, 2004), http://2001-2009.state.gov/g/oes/rls/or/2004/29751.htm.

[7] *See, e.g., id.* (noting participation as nonparty in first Meeting of the Parties to the Protocol).

[8] Memorandum from the Mellman Group to the Pew Initiative on Food and Biotechnology, Review of Public Opinion Research 1 (Nov. 16, 2006), http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Public_Opinion/Food_and_Biotechnology/2006summary.pdf.

[9] *Id.* at 3.

[10] Allison Kopicki, *Strong Support for Labeling Modified Foods,* N.Y. TIMES (July 27, 2013), http://www.nytimes.com/2013/07/28/science/strong-support-for-labeling-modified-foods.html; *see also U.S. Polls on GE Food Labeling*, CENTER FOR FOOD SAFETY, http://www.centerforfoodsafety.org/issues/976/ge-food-labeling/us-polls-on-ge-food-labeling# (last visited Nov. 12, 2013) (citing multiple polls showing support for mandatory labeling ranging from 93 to 96% percent).

[11] Kopicki, *Strong Support for Labeling Modified Foods, supra* note 10.

B. Scholarly Opinion

Several scientific organizations in the US have issued studies or statements regarding the safety of GMOs indicating that there is no evidence that GMOs present unique safety risks compared to conventionally bred products. These include the National Research Council,[12] the American Association for the Advancement of Science,[13] and the American Medical Association.[14]

Groups in the US opposed to GMOs include some environmental organizations,[15] organic farming organizations,[16] and consumer organizations.[17] A substantial number of legal academics have criticized the US's approach to regulating GMOs.[18]

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[12] COMMITTEE ON IDENTIFYING AND ASSESSING UNINTENDED EFFECTS OF GENETICALLY ENGINEERED FOODS ON HUMAN HEALTH, NATIONAL RESEARCH COUNCIL, SAFETY OF GENETICALLY ENGINEERED FOODS: APPROACHES TO ASSESSING UNINTENDED HEALTH EFFECTS 180 (2004), http://www.nap.edu/openbook.php?isbn=0309092094 ("[N]o adverse health effects attributed to genetic engineering have been documented in the human population."); COMMITTEE ON ENVIRONMENTAL IMPACTS ASSOCIATED WITH COMMERCIALIZATION OF TRANSGENIC PLANTS, BOARD ON AGRICULTURE AND NATURAL RESOURCES, NATIONAL RESEARCH COUNCIL, ENVIRONMENTAL EFFECTS OF TRANSGENIC PLANTS: THE SCOPE AND ADEQUACY OF REGULATION 49 (2002), http://www.nap.edu/openbook.php?isbn=0309082633 ("The transgenic process presents no new categories of risk compared to conventional methods of crop improvement, but specific traits introduced by both approaches can pose unique risks.")

[13] *AAAS Issues Statement on Labeling of Genetically Modified Foods*, CALIFORNIA COUNCIL ON SCIENCE AND TECHNOLOGY (Nov. 1, 2012), http://www.ccst.us/news/2012/1101aaas.php. **(**"[C]rop improvement by the modern molecular techniques of biotechnology is safe. . . . [C]onsuming foods containing ingredients derived from GM crops is no riskier than consuming the same foods containing ingredients from crop plants modified by conventional plant improvement techniques.")

[14] American Medical Association, *Policy No. H-480.958, Bioengineered (Genetically Engineered) Crops and Foods*, http://www. ama-assn.org/resources/doc/PolicyFinder/policyfiles/HnE/H-480.958.HTM (last visited Nov. 10, 2013) (reaffirming prior conclusion that "no evidence that unique hazards exist either in the use of rDNA techniques or in the movement of genes between unrelated organisms").

[15] *See, e.g.*, *Support Sustainable Agriculture*, GREENPEACE USA, http://www.greenpeace.org/usa/en/campaigns/genetic-engineering/ (last visited Nov. 12, 2013); *Genetic Engineering*, SIERRA CLUB, http://www.sierraclub.org/biotech/ (last visited Nov. 12, 2013).

[16] *See*, *e.g.*, *Policy*, ORGANIC SEED GROWERS & TRADE ASSOCIATION, http://www.osgata.org/policy/ (last visited Nov. 12, 2013).

[17] *See*, *e.g.*, *Genetic Engineering and Biotechnology*, ORGANIC CONSUMERS ASSOCIATION, http://www.organicconsumers. org/gelink.cfm (last visited Nov. 12, 2013); *GE Foods*, CENTER FOR FOOD SAFETY, http://www.centerforfoodsafety.org/issues/311/ge-foods (last visited Nov. 12, 2013).

[18] *See*, *e.g.*, Gregory N. Mandel, *Toward Rational Regulation of Genetically Modified Food*, 4 SANTA CLARA J. INT'L L. 21 (2006), http://digitalcommons.law.scu.edu/cgi/viewcontent.cgi?article=1015&context=scujil; Maria R. Lee-Muramoto, *Reforming the "Uncoordinated" Framework for the Regulation of Biotechnology,* 17 DRAKE J. AGRIC. L. 311 (2013), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2175622; Debra M. Strauss, *Defying Nature: The Ethical Implications of Genetically Modified Plants*, 3 J. FOOD L. & POL'Y 1 (2007), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1302506; Sheryl Lawrence, *What Would You Do With a Fluorescent Green Pig?: How Novel Transgenic Products Reveal Flaws in the Foundational Assumptions for the Regulation of Biotechnology,* 34 ECOLOGY L.Q. 201 (2007), http://www.boalt.org/elq/documents/elq34-1-05-lawrence-2007-0430.pdf.

III. Structure of Pertinent Legislation

There is no comprehensive federal legislation specifically addressing GMOs. GMOs are regulated under the general statutory authority of environmental, health, and safety laws.

A policy statement published in 1986 by the Executive Office of the President, Office of Science and Technology Policy (OSTP) entitled the Coordinated Framework for Regulation of Biotechnology (Coordinated Framework)[19] sets forth the basic approach to the regulation of GMOs in the US. The Coordinated Framework was the outgrowth of efforts by an interagency working group formed in 1984 to address whether the regulatory framework that pertained to conventional products was adequate for products derived from biotechnology. The working group concluded that existing laws as then implemented, supplemented with new regulations, were adequate to address regulatory needs.[20] A proposed notice was published and comments were requested.[21] The final Coordinated Framework policy notice confirmed that the regulatory jurisdiction over biotechnology products would be allocated in the same manner as conventional products, using existing laws governing conventional products.[22]

The three main agencies involved in regulating GMOs are the US Department of Agriculture's Animal and Plant Health Inspection Service (APHIS), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA).

A. Animal and Plant Health Inspection Service

APHIS regulates the planting, importation, or transportation of GM plants pursuant to its authority under the Plant Protection Act (PPA),[23] which authorizes the Secretary of Agriculture to "prohibit or restrict the importation, entry, exportation, or movement in interstate commerce of any plant, plant product [etc.] if the Secretary determines [it] is necessary to prevent the introduction . . . of a plant pest or noxious weed within the United States."[24] By regulation, APHIS classifies most GM plants as plant pests or potential plant pests and as "regulated

[19] Coordinated Framework, 51 FED. REG. 23,302 (June 26, 1986), *available in manuscript format at* http://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf.

[20] *Id*. at 3 (PDF manuscript pagination).

[21] OSTP, Proposal for a Coordinated Framework for Regulation of Biotechnology, 49 FED. REG. 50,856 (Dec. 31, 1984).

[22] Coordinated Framework, *supra* note 19, at 6–8.

[23] 7 U.S.C. §§ 7701–7786 (2012), http://uscode.house.gov/view.xhtml?path=/prelim@title7/chapter104&edition=prelim.

[24] 7 U.S.C. § 7712(a) (2012), http://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title7-section7712&num=0&edition=prelim.

articles."[25] Under the PPA, a regulated article must receive prior approval from APHIS before it is introduced.[26]

APHIS grants authorization to use GM plants in three ways: through a notification process, a permitting process, or a determination of nonregulated status.

1. Notification Procedure

The notification procedure is available to plants that are not classified as noxious weeds, or weeds in the release area, if certain criteria and performance standards are met.[27] The criteria include that the plant must be a species that APHIS has determined may be safely introduced; the genetic material must be stably integrated; the expression of the genetic material must not result in plant disease; etc.[28] The performance standards govern shipment, storage, planting, and testing, and are intended to prevent the plant from being released from containment.[29] When the applicant sends a notification to APHIS, APHIS will respond within a prescribed time with an acknowledgement or a denial.[30] If the notification is denied, the applicant may apply for a permit.[31]

2. Permit Procedure

The permit procedure requires an applicant to submit information concerning, among other things, the donor organism, the recipient organism, the composition of the regulated article; the expression of altered genetic material in the regulated article and the molecular biology of the system used to produce the article; the locality where the donor and recipient organisms and the regulated article were developed; the purpose of the regulated article; the quantity to be introduced; processes to prevent release; the intended destination, use, and distribution; and the final disposition of the regulated article.[32] If APHIS grants the permit, it is subject to conditions designed to ensure both that the regulated article remains contained and that APHIS can maintain

[25] 7 C.F.R. § 340.1 (2013), http://www.gpo.gov/fdsys/pkg/CFR-2013-title7-vol5/pdf/CFR-2013-title7-vol5-sec340-1.pdf.

[26] 7 U.S.C. § 7711(a) (2012), http://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title7-section7711&num=0&edition=prelim; 7 C.F.R. § 340.0 (2013), http://www.gpo.gov/fdsys/pkg/CFR-2013-title7-vol5/pdf/CFR-2013-title7-vol5-sec340-0.pdf.

[27] 7 C.F.R. § 340.3 (2013), http://www.gpo.gov/fdsys/pkg/CFR-2013-title7-vol5/pdf/CFR-2013-title7-vol5-sec340-3.pdf.

[28] 7 C.F.R. § 340.3(b).

[29] 7 C.F.R. § 340.3(c).

[30] 7 C.F.R. § 340.3(e).

[31] 7 C.F.R. § 340.3(e)(5).

[32] 7 C.F.R. § 340.4(b) (2013), http://www.gpo.gov/fdsys/pkg/CFR-2013-title7-vol5/pdf/CFR-2013-title7-vol5-sec340-4.pdf.

regulatory oversight.[33] Failure to comply with the conditions can result in withdrawal of the permit.[34]

3. Determination of Nonregulated Status

GM plants that have been tested and have been shown not to pose a risk may be eligible for a determination of nonregulated status.[35] A petition for determination of nonregulated status must include detailed biological information on the regulated article and the recipient organism, published and unpublished scientific studies, data from field tests, and other information designed to assist APHIS in determining whether the plant constitutes a pest.[36] Upon receipt of a petition, APHIS publishes a notice in the *Federal Register* and allows sixty days for public comment.[37] APHIS has 180 days to approve in whole or part or deny the petition.[38]

B. Food and Drug Administration

The FDA regulates the safety of all human and animal food products in the US (other than meat, poultry, and eggs), as well as drugs and biological products.

1. Food

The FDA's primary statutory authority is the Federal Food, Drug, and Cosmetic Act (FFDCA),[39] which authorizes the agency to regulate, among other things, "adulterated food,"[40] defined as food that "contains any poisonous or deleterious substance that may render it deleterious to health,"[41] and "food additives,"[42] which include "any substance [that may] becom[e] a component or otherwise affect[] the characteristics of any food."[43] The FFDCA prohibits the sale of adulterated or misbranded food.[44]

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[33] 7 C.F.R. § 340.4(f).

[34] 7 C.F.R. § 340.4(g).

[35] 7 C.F.R. § 340.6 (2013), http://www.gpo.gov/fdsys/pkg/CFR-2013-title7-vol5/pdf/CFR-2013-title7-vol5-sec340-6.pdf.

[36] 7 C.F.R. § 340.6(c).

[37] 7 C.F.R. § 340.6(d).

[38] *Id.*

[39] 21 U.S.C. §§ 301–399f (2012), http://uscode.house.gov/view.xhtml?path=/prelim@title21/chapter9&edition=prelim.

[40] 21 U.S.C. § 342 (2012), http://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title21-section342&num=0&edition=prelim.

[41] 21 U.S.C. § 342(a).

[42] 21 U.S.C. § 348 (2012), http://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title21-section348&num=0&edition=prelim.

[43] 21 U.S.C. § 321(s) (2012), http://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title21-section321&num=0&edition=prelim.

[44] 21 U.S.C. § 331 (2012), http://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title21-section331&num=0&edition=prelim.

Under the FFDCA, substances added to food can be classified either as "food additives," which require approval from the FDA that they are safe before they can be marketed,[45] and substances added to food classified as "generally recognized as safe" (GRAS), as to which preapproval is not needed.[46]

In a 1992 policy statement, the FDA reaffirmed that in most cases it would treat foods derived from GMOs like those derived from conventionally bred plants, and that most foods derived from GM plants would be presumptively GRAS. However, with respect to a GMO product "that differs significantly in structure, function, or composition from substances found currently in food," premarket approval of the substance as a food additive would be required.[47]

The FDA encourages developers of new plant varieties intended for food use, including GMOs, to engage in a consultation procedure with the FDA, in order "to ensure that human food and animal feed safety issues or other regulatory issues (e.g. labeling) are resolved prior to commercial distribution."[48] The consultation procedure is meant to enable the FDA to determine if regulatory action is needed with respect to food derived from the new variety such as "significantly increased levels of plant toxicants or anti-nutrients, reduction of important nutrients, new allergens, or the presence in the food of an unapproved food additive."[49] Among the issues subject to consultation is the food safety of new proteins in new plant varieties, including those developed through genetic engineering.[50] The FDA makes detailed information regarding completed consultations publicly available.[51]

2. Animals

The FDA also asserts jurisdiction over genetically engineered animals, pursuant to its authority to regulate "new animal drugs" (NADs) under the FFDCA.[52] Under the FFDCA, NADs are

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[45] 21 U.S.C. § 348 (2012), http://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title21-section348&num=0&edition=prelim.

[46] 21 U.S.C. § 321(s) (excluding substances from definition of "food additive" that are "generally recognized . . . to be safe.").

[47] FDA, Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984 (May 29, 1992), *available at* http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096095.htm.

[48] FDA, Guidance on Consultation Procedures: Foods Derived from New Plant Varieties (rev. Oct. 1997), http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096126.htm.

[49] *Id.*

[50] FDA, Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use (June 2006), http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096156.htm.

[51] FDA, Completed Consultations on Bioengineered Foods, http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=bioListing (last updated May 31, 2013).

[52] FDA, Guidance for Industry: Regulation of Genetically Engineered Animals Containing Heritable rDNA Constructs (rev. May 17, 2011), http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM113903.pdf (hereinafter GE Animals Guidance). The FFDCA definition of "new animal drug" includes articles "intended to affect the structure or function of the body of . . . animals." 21

deemed generally unsafe unless the FDA has approved a New Animal Drug Application (NADA) for the particular use of the drug.[53] Except in cases in which the FDA exercises discretion to decline to require compliance,[54] or where the drug is only for investigational use and thus need only conform to specified exemptions,[55] the FDA requires a genetically engineered (GE) animal to be the subject of an approved NADA based on a demonstration that it is safe and effective for its intended use.[56] A NADA for a GE animal must include information on the animal's identification; chemistry; clinical purpose; labeling; components and composition; manufacturing methods, facilities, and controls; safety and effectiveness; environmental impact; and other information.[57]

3. Drugs

The FDA also has regulatory authority over drugs generally. Companies interested in introducing a new drug into the US market in most cases must submit a New Drug Application (NDA) to the FDA, which must include extensive information and data on the drug's safety and effectiveness, such as the drug's chemistry, manufacture, animal and in vitro studies, clinical data, and the like.[58] Drugs developed through genetic engineering must go through the same NDA process as other types of drugs.

4. Biological Products

The FDA also regulates medical products classified as "biological products," which includes vaccines, serums, blood products, and the like, under relevant provisions of the Public Health Service Act (PHSA).[59] Biological products, whether involving genetic modification or not, must be licensed by the FDA before they can be introduced. The licensing procedure for biological products requires submission to the FDA of detailed information on laboratory and clinical studies, manufacturing methods, and other information relevant to whether they are safe and effective for their intended purpose.[60]

U.S.C. § 321(v). The FDA reasons that the "rDNA construct in a GE animal that is intended to affect the structure or function of the body of the GE animal, regardless of the intended use of products that may be produced by the GE animal," and thus all GE animals are NADs for purposes of regulation. GE Animals Guidance at 6. While the FDA could regulate all GE animals, it has determined it will decline to regulate those that are under the jurisdiction of other agencies. *Id*. at 7.

[53] 21 U.S.C. § 360b(a) (2012), http://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title21-section360b&num=0&edition=prelim.

[54] GE Animals Guidance, *supra* note 52, at 7–9.

[55] *Id*. at 9–12.

[56] *Id*. at 12–13.

[57] *Id*. at 14–20.

[58] 21 C.F.R. § 314.50 (2013), http://www.gpo.gov/fdsys/pkg/CFR-2013-title21-vol5/pdf/CFR-2013-title21-vol5-sec314-50.pdf.

[59] 42 U.S.C. §§ 262 to 263a-7 (2012), http://uscode.house.gov/view.xhtml?path=/prelim@title42/chapter6A/subchapter2/partF&edition=prelim.

[60] 21 C.F.R. § 601.2 (2013), http://www.gpo.gov/fdsys/pkg/CFR-2013-title21-vol7/pdf/CFR-2013-title21-vol7-part601-subpartA.pdf.

C. Environmental Protection Agency

The EPA regulates pesticides and microorganisms developed through genetic engineering.

1. Pesticides

The EPA regulates the manufacture, sale and use of pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).[61] Under FIFRA, pesticides must not cause "unreasonable adverse effects on the environment,"[62] which is defined to include both safety to the environment and safety in food for consumption.[63] FIFRA requires all pesticides to be registered with the EPA before they can be distributed commercially.[64] Pesticides must be tested and shown to be safe before they can be registered.[65] A registration application must include information regarding testing, identity of the product, draft labeling, information on tolerance of residues, and other safety-related information.[66]

Pursuant to its authority under FIFRA, the EPA regulates plants that are genetically modified to produce substances intended to control pests as to both their environmental safety and their safety in food, termed plant-incorporated protectants (PIPs).[67] The standard registration procedures for pesticides apply to PIPs, unless they are made exempt by regulation.[68] PIPs are exempt from FIFRA registration if the PIP is used in a crop used in food and its residues are exempt from regulation under the FFDCA,[69] if the PIP is an inert ingredient listed as exempt by the EPA,[70] or if the PIP is from a plant that is sexually compatible with the recipient plant.[71] With respect to those PIPs that are exempt, if the producer of the PIP obtains information

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[61] 7 U.S.C. §§ 136–136y (2012), http://uscode.house.gov/view.xhtml?path=/prelim@title7/chapter6/subchapter2&edition=prelim.

[62] 7 U.S.C. § 136a(c)(5) (2012), http://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title7-section136a&num=0&edition=prelim.

[63] 7 U.S.C. § 136(bb) (2012), http://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title7-section136&num=0&edition=prelim.

[64] 7 U.S.C. § 136a(a) (2012).

[65] 7 U.S.C. § 136a(c)(5) (2012).

[66] 40 C.F.R. § 152.50 (2013), http://www.ecfr.gov/cgi-bin/text-idx?SID=9f032ce863baf7cb8c325ee059e49510&node=40:25.0.1.1.3&rgn=div5#40:25.0.1.1.3.3.1.6.

[67] 40 C.F.R. pt. 174 (2013), http://www.ecfr.gov/cgi-bin/text-idx?SID=9f032ce863baf7cb8c325ee059e49510&node=40:25.0.1.1.23&rgn=div5.

[68] 40 C.F.R. § 174.1 (2013), http://www.ecfr.gov/cgi-bin/text-idx?SID=c72e2a2a61e1ad7b08706bfe11c90051&node=40:25.0.1.1.23&rgn=div5#40:25.0.1.1.23.1.19.1 ("Unless otherwise superseded by this part, the regulations in parts 150 to 180 of this chapter apply to plant-incorporated protectants.").

[69] 40 C.F.R. § 174.21(b) (2013), http://www.ecfr.gov/cgi-bin/text-idx?SID=8263e366359fd60abf234c5e03b502f5&node=40:25.0.1.1.23&rgn=div5#40:25.0.1.1.23.2.19.1.

[70] 40 C.F.R. § 174.21(c) (2013).

[71] 40 C.F.R. § 174.25 (2013), http://www.ecfr.gov/cgi-bin/text-idx?SID=8263e366359fd60abf234c5e03b502f5&node=40:25.0.1.1.23&rgn=div5#40:25.0.1.1.23.2.19.2.

regarding adverse effects from the PIP on human health or the environment, it must share it with the EPA.[72]

2. Microorganisms

The EPA also has authority to regulate GMOs under the Toxic Substances Control Act (TSCA).[73] The TSCA authorizes the EPA to regulate chemical substances that may present an unreasonable risk of injury to health or the environment.[74] Manufacturers of covered substances must submit a premanufacture notification to the EPA.[75] The EPA has determined that GMO microorganisms are chemical substances subject to regulation under the TSCA.[76] The EPA has established regulations specifically for microorganisms that require submission of a Microbial Commercial Activity Notice (MCAN) before they are used for commercial purposes.[77] The Notice must include information describing the microorganism's characteristics and genetic construction; byproducts of its manufacture, use, and disposal; health and environmental effects data; and other information.[78]

D. National Environmental Policy Act

The National Environmental Policy Act (NEPA)[79] requires federal agencies in some cases to prepare Environmental Assessments (EAs) of federal actions, such as adopting a policy or approving a permit, to determine if they are likely to significantly impact the environment.[80] If a federal action is likely to have a significant impact, the agency must prepare a more detailed

[72] 40 C.F.R. § 174.71 (2013), http://www.ecfr.gov/cgi-bin/text-idx?SID=8263e366359fd60abf234c5e03b502f5&node=40:25.0.1.1.23&rgn=div5#40:25.0.1.1.23.4.19.1.

[73] 15 U.S.C. §§ 2601–2695d (2012), http://uscode.house.gov/view.xhtml?path=/prelim@title15/chapter53&edition=prelim.

[74] 15 U.S.C. § 2605(a) (2012), http://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title15-section2605&num=0&edition=prelim.

[75] 15 U.S.C. § 2604 (2012), http://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title15-section2604&num=0&edition=prelim.

[76] 40 C.F.R. § 725.1(a) (2013), http://www.ecfr.gov/cgi-bin/text-idx?SID=7c33b229782bc824885546d25f6cf057&node=40:32.0.1.1.13&rgn=div5#40:32.0.1.1.13.1.1.1.

[77] 40 C.F.R. § 725.100 (2013), http://www.ecfr.gov/cgi-bin/text-idx?SID=7c33b229782bc824885546d25f6cf057&node=40:32.0.1.1.13&rgn=div5#40:32.0.1.1.13.4.1.1.

[78] 40 C.F.R. §§ 725.155, 725.160 (2013), http://www.ecfr.gov/cgi-bin/text-idx?SID=7c33b229782bc824885546d25f6cf057&node=40:32.0.1.1.13&rgn=div5#40:32.0.1.1.13.4.1.5.

[79] 42 U.S.C. §§ 4321–4370h (2012), http://uscode.house.gov/view.xhtml?path=/prelim@title42/chapter55&edition=prelim.

[80] 40 C.F.R. § 1508.9 (2013), http://www.ecfr.gov/cgi-bin/text-idx?SID=d1401a6ba0ae88ac9dc35920b0670960&node=40:34.0.3.3.9&rgn=div5#40:34.0.3.3.9.0.29.9.

evaluation called an Environmental Impact Statement (EIS).[81] Federal agency approvals of GMOs may require an EA or an EIS in some circumstances.[82]

E. State Law

State law generally plays little role in the regulation of GMOs in the US. The federal preemption doctrine, which bars conflicting state regulation when Congress intends federal regulation to occupy a particular field, precludes many aspects of state regulation of GMOs.[83]

A rare example in which one state's law is more stringent than federal law on GMOs involves a bioengineered tropical aquarium fish known as the GloFish, which is unregulated at the federal level,[84] but has been banned by the California Fish and Game Commission.[85]

Some municipal governments in the US have banned GMO crops. For example, in California, the counties of Marin and Mendocino have enacted ordinances forbidding the cultivation of GMOs.[86] In Hawaii, Kauai County and Hawaii County similarly have banned the cultivation of most GMO crops.[87]

IV. Restrictions on Research, Production, and Marketing

The nature of restrictions on GMOs with respect to research, production and marketing in the US vary with the different regulatory regimes that cover various aspects of genetic modification.

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[81] 40 C.F.R. §§ 1502.1–1502.25 (2013), http://www.ecfr.gov/cgi-bin/text-idx?SID=d1401a6ba0ae88ac9dc35920b0670960&node=40:34.0.3.3.3&rgn=div5.

[82] *See*, *e.g.*, GE Animals Guidance, *supra* note 52, at 19 (describing EA requirement in New Animal Drug Application to enable FDA to either prepare an EIS or make a finding of no significant impact).

[83] Doug Farquhar & Liz Meyer, *State Authority to Regulate Biotechnology Under the Federal Coordinated Framework*, 12 DRAKE J. AGRIC. L. 439, 461–71 (2007), http://students.law.drake.edu/aglawjournal/docs/agVol12No3-Farquhar.pdf.

[84] FDA Statement Regarding GloFish (Dec. 9, 2003), http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm161437.htm ("In the absence of a clear risk to the public health, FDA finds no reason to regulate these particular fish.").

[85] Kenneth R. Weiss, *State Takes Dim View of GloFish, Bans Sale,* L.A. TIMES (Dec. 4, 2003), http://articles.latimes.com/2003/dec/04/local/me-glofish4.

[86] MARIN COUNTY, CAL. CODE ch. 6.92 (2013), *available at* http://library.municode.com/index.aspx?clientID=16476 (select title 6, then select chapter 6.92); MENDOCINO COUNTY, CAL. CODE ch. 10A.15 (2013), *available at* http://library.municode.com/index.aspx?clientId=16484 (select title 10A, then select chapter 10A.15).

[87] Andrew Pollack, *Limits Approved for Genetically Modified Crops in Kauai, Hawaii,* N.Y. TIMES (Oct. 16, 2013), http://www.nytimes.com/2013/10/17/business/limits-approved-for-genetically-modified-crops-in-kauai-hawaii.html?_r=0; Christopher D'Angelo, *Hawaiian Islands Take More Steps to Limit Spread of GMO Crops*, REUTERS (Dec. 6, 2013), http://www.reuters.com/article/2013/12/07/usa-gmos-hawaii-idUSL2N0JL1RL20131207. The Hawaii County ordinance permits GM papaya to be grown on the island. *Id.*

A. Animal and Plant Health Inspection Service

The introduction of GM plants requires prior approval from APHIS, by means of a notification, permitting, or a determination of nonregulated status procedure. (See Part III(A), above.)

B. Food and Drug Administration

1. Foods

The FDA regards most GMO foods as presumptively falling within the category of "generally regarded as safe," thus not needing premarket approval, but a GMO product "that differs significantly in structure, function, or composition from substances found currently in food" requires premarket approval as a food additive. (See Part III(B)(1), above.)

2. Animals

In most cases, the FDA requires a genetically engineered animal to be approved by means of a New Animal Drug Application based on a demonstration that it is safe and effective for its intended use. (See Part III(B)(2), above.)

3. Drugs

FDA requires those wishing to introduce a new drug into the US market, whether it involves genetic modification or not, to submit a New Drug Application (NDA) to the FDA, with detailed information on the drug's safety and effectiveness. **(**See Part III(B)(3), above.)

4. Biological Products

The FDA requires all biological products, regardless of whether or not they are developed by genetic modification, to be licensed by FDA before they can be introduced, with detailed information on whether they are safe and effective for their intended purpose. (See Part III(B)(4), above.)

C. Environmental Protection Agency

Under FIFRA, the EPA requires all pesticides to be registered prior to commercial distribution, and the registration must include information on their safety. The EPA also requires PIPs to comply with the pesticide registration procedures, unless they meet the criteria for exemption from these procedures. (See Part III(C)(1), above.)

Under TSCA, the EPA requires those wishing to use microorganisms for commercial purposes to submit a Microbial Commercial Activity Notice (MCAN). (See Part III(C)(2), above.)

D. Labeling of GMOs

There is no law in the US requiring that GMO foods or foods with GMO ingredients be labeled to so indicate. Proposed federal legislation, the Genetically Engineered Food Right-to-Know Act,[88] which would mandate labeling of any GMO food or food with a genetically modified ingredient, has been introduced in the last several Congresses, but has never advanced beyond the committee stage in either chamber. At the state level, a 2012 California initiative mandating labeling of GMO foods, and a similar 2013 Washington State initiative, both failed.[89]

The FDA has regulatory authority to prevent false and misleading labeling of foods and drugs. With respect to genetically engineered foods, the FDA has stated in policy documents that if a GM food product is not materially different from its traditional counterpart, there is no need to label or change the name of the product, but name changes are appropriate when a food from a GM plant is so different from its traditional counterpart that the usual name no longer adequately describes the new food, or if there is a safety issue to which consumers should be alerted, such as the presence of allergens.[90]

V. Restrictions on Releasing Organisms into the Environment

Because US regulation of GMOs focuses on the nature of the products, rather than the process in which they were produced, the extent to which there are restrictions on releases of GMOs into the environment depends on the GMOs in question. (See the discussion of the different regulatory regimes for different types of GMOs, Part III, above.)

VI. Restrictions on GMOs in Foodstuffs

GMOs are not restricted categorically from the US food supply. As discussed above, the FDA treats foods derived from GMOs like those derived from conventionally bred plants, and therefore most foods derived from GM plants are classified as presumptively "generally recognized as safe." However, with respect to a GMO product "that differs significantly in structure, function, or composition from substances found currently in food," premarket approval of the product is required. (See Part III(B)(1), above.)

VII. Liability Regime

All of the various statutory schemes under which GMOs are regulated in the US provide for civil and criminal penalties. For example, violations of the PPA are subject to substantial civil or

[88] S. 809, 113th Cong. (2013), http://www.gpo.gov/fdsys/pkg/BILLS-113 s809is/pdf/BILLS-113s809is.pdf.

[89] Mark Lifsher, *Prop. 37 Backers Vow to Continue Food Regulation Efforts*, L.A. TIMES (Nov. 7, 2012), http://articles.latimes.com/2012/nov/07/business/la-fi-prop37-genetic-food-labeling-20121108; Stephanie Strom, *Food Companies Claim Victory Against Labeling Initiative in Washington State*, N.Y. TIMES (Nov. 6, 2013), http://www.nytimes.com/2013/11/07/us/politics/food-companies-claim-victory-against-labeling-initiative-in-washington-state.html.

[90] FDA, Statement of Policy: Foods Derived from New Plant Varieties, *supra* note 47, § VI, Labeling.

criminal penalties;[91] knowingly importing or moving any regulated article for sale or distribution in violation of the PPA is punishable by a fine, imprisonment up to five years, or both.[92] The liability provisions of the FFDCA list several practices that can lead to significant civil or criminal penalties, including imprisonment.[93] Violations of FIFRA and TSCA similarly are subject to civil or criminal penalties.[94]

VIII. Judicial Decisions / Prominent Cases

A landmark case of significance in the early development of the US biotechnology industry was the US Supreme Court's 1980 decision in *Diamond v. Chakrabarty*,[95] holding that genetically engineered microorganisms can be patented. This decision "contributed to a revolution in biotechnology that has resulted in the issuance of thousands of patents, the formation of hundreds of new companies, and the development of thousands of bioengineered plants and food products."[96]

Outside of patent law, however, the role of the US courts in shaping regulatory policy with respect to GMOs has been limited. A common theme among many court decisions on GMOs has been the judiciary's deference to agency expertise in determining how to regulate them.

The Supreme Court's decision in *Monsanto Co. v. Geertson Seed Farms*[97] involved a challenge under NEPA to APHIS's decision to issue a determination of nonregulated status to Monsanto's Roundup Ready Alfalfa (RRA), a genetically engineered variety of alfalfa, after making a "finding of no significant impact" determination instead of preparing an environmental impact statement (EIS). The district court ruled that an EIS was required, and as a remedy enjoined APHIS from deregulating RRA, in whole or in part, pending completion of the EIS, and also enjoining almost all planting of RRA nationwide.[98] The Supreme Court reversed, ruling that the district court exceeded its authority in enjoining APHIS from partially deregulating RRA and

[91] 7 U.S.C. § 7734 (2012), http://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title7-section7734&num=0&edition=prelim.

[92] 7 U.S.C. § 7734(a)(1)(B) (2012).

[93] 21 U.S.C. § 333 (2012), http://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title21-section333&num=0&edition=prelim.

[94] 7 U.S.C. § 136l (2012), http://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title7-section136l&num=0&edition=prelim (civil and criminal penalties for violating FIFRA); 15 U.S.C. § 2615 (2012), http://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title15-section2615&num=0&edition=prelim (civil and criminal penalties for violating TSCA).

[95] Diamond v. Chakrabarty, 447 U.S. 303 (1980), *available at* http://laws.findlaw.com/us/447/303.html.

[96] Douglas Robinson & Nina Medlock, *Diamond v. Chakrabarty: A Retrospective on 25 Years of Biotech Patents*, INTELL. PROP. & TECH. L.J., Oct. 2005, at 12, *available at* http://www.bannerwitcoff.com/_docs/library/articles/Chakrabarty.pdf.

[97] Monsanto Co. v. Geertson Seed Farms, 130 S. Ct. 2743 (2010), *slip op. available at* http://www.supremecourt.gov/opinions/09pdf/09-475.pdf.

[98] *Id.*, slip op. at 2–6.

enjoining the planting of RRA. It concluded that APHIS should be allowed to structure a partial deregulation order while completing the EIS.[99]

In *Alliance for Bio-Integrity v. Shalala*,[100] the plaintiffs challenged the FDA's 1992 policy statement that GMO foods that are similar to conventional varieties would be presumptively deemed "generally recognized as safe" (GRAS)[101] and that they need not be labeled.[102] The district court declined to rule that the FDA's decision that genetic modification does not "materially" alter foods and to presume GMO foods are GRAS was arbitrary and capricious, stating that "the rational for [court] deference [to agency decision making] is particularly strong when the [agency] is evaluating scientific data within its technical expertise."[103] As to labeling, it said that given FDA's decision on the GRAS issue, it would also find that the FDA's interpretation of the FFDCA's labeling requirement was reasonable.[104]

Other GMO cases have similarly displayed the tendency of US courts to defer to agency decision making.[105]

[99] *Id*., slip op. at 16–24.

[100] Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166 (D.D.C. 2000), *available at* http://scholar.google.com/scholar_case?case=9837177635976803502&q=116+F.+Supp.+2d+166+&hl=en&as_sdt=20006.

[101] *See* discussion *supra*, Part III(B)(1).

[102] *See* discussion *supra*, Part IV(D).

[103] Alliance for Bio-Integrity v. Shalala, 166 F. Supp. 2d at 177.

[104] *Id*. at 178–79.

[105] *See*, *e.g.*, Center For Food Safety v. Vilsack, 636 F.3d 1166 (9th Cir. 2011), *slip op. available at* http://cdn.ca9.uscourts.gov/datastore/opinions/2011/03/03/10-17719.pdf (in case challenging APHIS's deregulation of Roundup Ready sugar beets, finding absence of irreparable harm to justify injunction); Center For Food Safety v. Vilsack, 718 F.3d 829 (9th Cir. 2013), *slip op. available at* http://cdn.ca9.uscourts.gov/datastore/opinions/2013/ 05/17/12-15052.pdf (in case challenging APHIS's deregulation of Roundup Ready alfalfa, deferring to agency determination that RRA was not a "plant pest").

International Protocols

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SUMMARY There are two major international protocols that address genetically modified organisms, the Cartagena Protocol of 2000 and the Nagoya-Kuala Lumpur Supplementary Protocol of 2010. They are attached to the Convention on Biological Diversity of 1993. They apply only to transboundary actions; they do not apply to use or transit of GMOs within countries.

I. Cartagena Protocol

The major international instrument on genetically modified organisms (GMOs) is the Cartagena Protocol on Biosafety (the Protocol)[1] to the Convention on Biological Diversity.[2] The Protocol was adopted on January 29, 2000,[3] and became effective on September 11, 2003. It is designed to protect both biological diversity and human life from any adverse effects of organisms modified by technology.[4] There are at present 166 parties to the Protocol; the United States is not a party.[5]

Biosafety was one of the key issues addressed by the Convention on Biodiversity, which stressed the need to protect human health and the environment from the possibility of negative outcomes of modern biotechnology, while at the same time seeing the potential for good results of innovation in such areas as improving food supplies through agricultural development. In November 1995, the Conference of the Parties to the Convention, at its second meeting, established a working group on biosafety. The goal of the working group was to create a protocol on the topic that would focus on transboundary movement of GMOs, when there may be an adverse impact on "the conservation and sustainable use of biological diversity."[6] The Protocol was the result of several years of negotiations, including six meetings held between July 1996 and February 1999, concluding in January 2000 at a meeting on the Conference of Parties held in Montreal.

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[1] *The Cartagena Protocol on Biosafety*, CONVENTION ON BIOLOGICAL DIVERSITY, http://bch.cbd.int/protocol/; Protocol text in English, http://bch.cbd.int/protocol/text/ (both last visited Oct. 24, 2013).

[2] Convention on Biological Diversity, June 5, 1992, in force Dec. 29, 1993, 1760 U.N.T.S. 79, http://www.cbd.int/convention/text/default.shtml.

[3] EXCOP 1 Decision EM-I/3, Adoption of the Cartagena Protocol and Interim Arrangements, http://www.cbd.int/decision/cop/default.shtml?id=7174 (last visited Sept. 30, 2013).

[4] *The Cartagena Protocol on Biosafety*, *supra* note 1.

[5] *Parties to the Protocol and Signature and Ratification of the Supplementary Protocol*, CONVENTION ON BIOLOGICAL DIVERSITY, http://bch.cbd.int/protocol/parties/ (last visited Sept. 19, 2013).

[6] *Introduction*, *Cartagena Protocol on Biosafety*, *supra* note 1.

When the Protocol was accepted, the decision was made to set up an "open-ended ad hoc Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP)" that would organize the initial meetings of parties to the Protocol.[7]

A. Purpose and Definitions

The Protocol "provides an international regulatory framework to reconcile the respective needs of trade and environmental protection with respect to a rapidly growing global industry, the biotechnology industry."[8]

The Protocol itself states that its objective is

> to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.[9]

The Protocol defines "living modified organism" as "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology."[10] "Modern biotechnology" is defined as:

> the application of:
>
> a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
>
> b. Fusion of cells beyond the taxonomic family,
>
> that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection . . . .[11]

The Protocol's scope includes the transboundary movement, transit, handling, and use of GMOs, but it explicitly does not apply to the movement across borders of GMO pharmaceuticals for human use that are covered in other international agreements or addressed by international organizations. Nothing in the document, however, limits a party to it from applying its own decisions on GMO pharmaceuticals. Furthermore, any party can make its own assessment and decisions on import standards for GMOs for contained use within the party's own borders.[12]

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[7] EXCOP 1 Decision EM-I/3, § II no. 5, *supra* note 3.

[8] *Id*.; *About the Protocol: History*, CONVENTION ON BIOLOGICAL DIVERSITY, http://bch.cbd.int/protocol/background/#history (last visited Sept. 20, 2013).

[9] Cartagena Protocol art. 1.

[10] *Id*. art. 3(g).

[11] *Id*. art. 3(i).

[12] *Id*. arts. 4-6.

B. Basic Principles for Planned Transport of GMOs

One of the principles on which the Protocol is based is the precautionary principle, a way of determining whether regulation should be used in uncertain circumstances. It was outlined in the 1992 Rio Declaration on Environment and Development, which states that "[w]here there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."[13] This principle, which favors imposing methods to prevent damage, so long as they are "cost-effective," has been applied to a number of environmental issues; it is considered a useful way to balance the sometimes conflicting interests of protecting the environment while not overly inhibiting scientific advances and international trade.[14]

The wording of the precautionary principle in some parts of the Protocol was controversial, and States have interpreted its meaning in various ways. While the document authorizes nations to take precautionary decisions even when scientific evidence is unclear as to potential harm from GMOs, there is still disagreement on how to apply this principle.[15] Under the World Trade Organization's dispute mechanisms, a 2006 panel said that states could not generally rely on nongovernmental organizations' reports or peer-reviewed journal articles as the basis for applying the precautionary principle in a way that restricted trade.[16]

Under the Protocol, the basic mechanism for regulating transit of GMOs across borders is advance informed agreement, which requires that when there is a plan to move such products across a boundary, parties will be notified in advance.[17] There is a 270-day period in which the party can decide whether to allow the transit and what conditions to impose if permission is granted.[18] The decisions are based on assessment of risk under recognized assessment techniques.[19]

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[13] Rio Declaration of the United Nations Conference on Environment and Development, Principle 15 (June 14, 1992), http://www.un.org/documents/ga/conf151/aconf15126-1annex1.htm.

[14] For an example of a discussion of the role of the precautionary principle in balancing these conflicting interests, see John S. Applegate, *The Prometheus Principle: Using the Precautionary Principle to Harmonize the Regulation of Genetically Modified Organisms*, 9 INDIANA J. GLOBAL LEGAL STUD. 207 (2001).

[15] Ruth Mackenzie, *The Cartagena Protocol on Biosafety and the Development of International Environmental Law*, THE INTERNATIONAL POLITICS OF GENETICALLY MODIFIED FOOD: DIPLOMACY, TRADE AND LAW 213, 217 (2007).

[16] World Trade Organization, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products: Panel Report*, Dispute 291 (2006), http://www.wto.org/english/tratop_e/ dispu_e/cases_e/ds291_e.htm, *discussed in* Marie-Claire Cordonier Segger & Markus Gehring, *Trade and Investment Implications of Implementing the Cartagena Protocol*, LEGAL ASPECTS OF IMPLEMENTING THE CARTAGENA PROTOCOL ON BIOSAFETY 471, 482 (2013).

[17] Cartagena Protocol, arts. 6-8.

[18] *Id*. art 10 § 3.

[19] Mackenzie, *supra* note 15, at 214; *see* Cartagena Protocol arts. 15 & 16, for provisions on risk assessment.

C. Unintended Transboundary Transmission and Information Sharing

The Protocol also contains provisions on accidental movement of GMOs across borders. It specifies that if a party becomes aware that something has occurred that "leads, or may lead, to an unintentional transboundary movement" of a living GMO and if that movement would "have significant adverse effects on the conservation and sustainable use of biological diversity" that may include a risk to human health, then that party has the obligation to notify any affected countries, relevant international organizations, and the Biosafety Clearing House.[20] The Protocol establishes the Biosafety Clearing House to facilitate the exchange of all kinds of information about GMOs and to help parties to the Protocol implement its provisions.[21] The Protocol also states that each participating country should establish a "national focal point" to be responsible for the administrative functions required by the Protocol; information on the designated focal point is available to all parties through the Biosafety Clearing House.[22]

D. Handling and Labeling

The Protocol also specifies that measures must be taken such that GMOs being transported are properly handled, packaged, and safely moved. In addition, documentation must accompany all shipments of GMOs that states that the items may contain GMOs, as well as indicating a contact point for information about the shipment.[23]

E. Illegal Transboundary Transmissions

The Protocol does not include specific penalties for improper transmission of GMOs across borders. Instead it states that parties "shall adopt appropriate domestic measures aimed at preventing and, if appropriate, penalizing transboundary movements" of GMOs when done in a manner that violates Protocol provisions. It also states that parties affected by illegal transmissions may request that the party of origin bear the expense of disposal of such illegally transmitted GMOs, either through repatriation or destruction as appropriate. Furthermore, such cases must be reported to the Biosafety Clearing House.[24]

II. Nagoya-Kuala Lumpur Supplementary Protocol

Following years of negotiations over the question of liability for GMO-produced damages, on October 15, 2010, the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (the Supplementary Protocol) was adopted.[25] As of

[20] Cartagena Protocol art. 17 § 1.

[21] *Id*. art. 20 § 1.

[22] *Id*. art. 19.

[23] *Id*. art. 18.

[24] *Id*. art. 25.

[25] Press Release, The Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (Oct. 16, 2010), http://bch.cbd.int/protocol/nkl_pressrelease.shtml; Supplementary Protocol text, http://bch.cbd.int/protocol/nkl_text.shtml (last visited Sept. 19, 2013); René Lefeber, *The Legal Significance of*

March 2013, only eleven parties to the Protocol had ratified the Supplementary Protocol; it will enter into force ninety days after the fortieth country ratifies or otherwise accepts it.[26]

The Supplementary Protocol provides international rules and procedure on liability and redress for damage to biodiversity resulting from living modified organisms. René Lefeber, one of the co-chairs of the Group of the Friends who facilitated the negotiations of the text of the Supplementary Protocol, spoke about the importance of the adoption of the document and the timing of the move, stating, "[t]he adoption of [a] new supplementary Protocol during the International Year Biodiversity will give new impetus to multilateral environmental negotiations. This agreement will also make important contribution to the on-going work under the Convention on Biological Diversity to protect life on earth."[27] He has also described the need for the Supplementary Protocol by pointing out that "[s]ince adverse effects may occur in spite of risk-management measures or as a result of the failure to identify the risk of adverse effects, the allocation of the costs of such effects should be anticipated and regulated."[28]

A. Purpose and Definitions

The Supplementary Protocol states that its objective is to "contribute to the conservation and sustainable use of biological diversity, taking also into account risks to human health, by providing international rules and procedures in the field of liability and redress relating to living modified organisms."[29] It applies to damage from GMOs that cross borders and defines "damage" as

> an adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health that:
>
> (i) Is measurable or otherwise observable taking into account, wherever available, scientifically-established [sic] baselines recognized by a competent authority that takes into account any other human induced variation and natural variation; and
>
> (ii) Is significant . . . .[30]

The Supplementary Protocol further states that whether an adverse effect is significant is determined based on a number of factors, including whether it causes long-term or permanent

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the Nagoya-Kuala Lumpur Supplementary Protocol: The Result of a Paradigm Evolution, Amsterdam Law School Research Paper No. 2012-87 (Sept. 24, 2012), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2151282.

[26] *The Cartagena Protocol on Biosafety, and its Nagoya—Kuala Lumpur Supplementary Protocol on Liability and Redress*, CONVENTION ON BIODIVERSITY, http://www.cbd.int/undb/media/factsheets/undb-factsheet-biosafety-en.pdf (last visited Oct. 23, 2013); Supplementary Protocol, art. 18.

[27] Press Release, *supra* note 25.

[28] René Lefebar, *The Legal Significance of the Nagoya-Kuala Lumpur Supplementary Protocol: The Result of a Paradigm Evolution*, Centre for Environmental Law & Sustainability Research Paper No. 2012-02, Amsterdam Law School Research Paper No. 2012-87 (2012), *available at* http://ssrn.com/abstract=2151282 (click on "Download This Paper").

[29] Supplementary Protocol art. 1.

[30] *Id*. art. 2 § 2 (b) & art. 3.

change, the extent of the qualitative or quantitative change that results, whether it reduces the way in which natural diversity provides goods and services, and the scope of any adverse impact on human health.[31]

B. Basic Principles

The basic principle underlying the Supplementary Protocol is that the polluter must pay for any damage caused. Lefeber notes that this principle has an economic origin, but, he argues, it is not clear whether it applies only to the person or organization in control of the polluting activity or whether liability extends to the state in charge of the area in which the activity occurred.[32] While suggesting that liability of the state could be justified in international law, he notes that it has not been directly supported by existing international instruments.[33] In fact the Supplementary Protocol explicitly provides that it does not affect "the rights and obligations of States under the rules of general international law with respect to the responsibility of States for internationally wrongful acts."[34]

An additional basic principle is that, for the provisions to apply, a causal link must be established between the damage incurred and the GMO in question.[35]

C. Response Requirements

Under the Supplementary Protocol, parties must require those responsible for damages to immediately inform the authorities, evaluate the damage, and take appropriate response measures. The authorities must also evaluate the damage, as well as identifying the operator that caused the damage and determining needed response measures. If there is a likelihood that damage will occur without timely intervention, the operator of the organization involved is required to take appropriate measures so that damage is avoided. An assessment as to whether damage is likely must be based on available scientific information, including information collected by the Biosafety Clearing House. Authorities may also directly implement response measures when operators of businesses fail to do so. In such cases, the authorities may recover costs from the operators. The decision by a government authority to take action should be relayed to the operator. Response measures must be implemented in accordance with domestic law.[36]

D. Additional Applications of Domestic Law

The Supplementary Protocol allows parties to make specific provisions under their domestic law. It permits exemptions from responsibility when there are acts of war or civil unrest, or acts of

[31] *Id.* art. 2 § 3.

[32] Lefebar, *supra* note 28, at § 2.

[33] *Id*.

[34] Supplementary Protocol art. 11.

[35] *Id*. art. 4.

[36] *Id*. art. 5.

God (*force majeure*), and parties may add other exemptions as they deem appropriate.[37] Domestic law can also be used to establish the time and financial limits of liability for costs incurred in response to damaging GMO events.[38]

Domestic law is also the source for rules and procedures to address the civil liability from damage caused by GMOs. It permits parties to either develop specific civil liability law for GMOs or to apply their existing general laws to such liability.[39]

E. Assessment and Review

Once the Supplementary Protocol has been in force for five years, and at five-year intervals thereafter, the effectiveness of the agreement will be reviewed by the Conference of the Parties. The Conference of the Parties serving as the meeting of the parties for the Cartagena Protocol serves as the Conference of the Parties to the Supplementary Protocol.[40]

[37] *Id*. art. 6.

[38] *Id*. arts. 6 & 7.

[39] *Id*. art. 12.

[40] *Id*. arts. 13–14.

Bibliography

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This bibliography lists selected, recent English-language works on restrictions on genetically modified organisms. The first section contains discussions of aspects of the topic in general and in international law. The second section has materials discussing the issue in particular jurisdictions and is divided into sections on Africa, the Americas, Asia, and Europe.

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