EUROPEAN FOOD SAFETY AUTHORITY ASSESMENT ON GMOs

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Abstract

In this paper, we examine EU policy and policy-making in the development and marketing of GM crops and foods. More specifically, the paper aims to summarize both the content of the EU's regulations in this field, as well the EU policy in the area of genetically modified foods and crops. Throughout the paper, we develop arguments about the nature of GMO regulation and the challenges it poses to the European Union and we highlight the role played by EFSA (European Food Safety Authority) in providing guidance for the environmental risk assessment (ERA) of genetically modified (GM) plants. As we shall see, risk regulation of GMOs raises fundamental normative questions about the roles of science and politics in the management of risk, and about the legitimacy of EU decision-making, especially at the supra-national level of EU institutions where direct democratic control is widely considered to be inadequate.

Key words: GMOs, European, directives, regulation, EFSA

INTRODUCTION

Few issues of European law and policy excite as much attention and concern as the creation and marketing of genetically modified organisms (GMOs). Approved by many scientists, policy elites, and members of the biotechnology industry as a step forward in scientific and economic terms, genetically modified (GM) foods and crops have also been rejected as unsafe or undesirable by many environmentalists and by a majority of the European public. The institutions of the European Union (EU) have stepped into this controversy since they play the leading role in establishing the regulatory framework for the growing and marketing of GM foods and crops in the Union's 27 member states (Stewart T.P. et al, 1999).

GMOs are officially defined in the EU legislation as "organisms in which the genetic material (DNA) has been altered in a way that does not occur naturally by mating and/or natural recombination" (Plan D. et al, 2010). The most common types of GMOs that have been developed and commercialised so far are genetically modified crop plant species, such as genetically modified maize, soybean, oilseed rape and cotton varieties. Such varieties have mainly been genetically modified to provide resistance to certain insect pests and/or tolerance to herbicides. The application of this technology is strictly regulated and the EU has established an extensive legal framework on GMOs since the early 1990s (Skogstad G., 2003).

EU legislation on GMOs has two main objectives: (1) to protect health and the environment - a GMO or a food product derived from a GMO can

only be put on the market in the EU after it has been authorised on the basis of a detailed EU procedure based on a scientific assessment of the risks to health and the environment; (2) to ensure the free movement of safe and healthy genetically modified products in the EU, once authorised on the basis of the strict EU GMO authorisation procedure, genetically modified products can be placed on the whole EU market. The entire corpus of European GMO legislation has been amended between 2000 and 2003, leading to the creation of a whole updated EU legal framework on GMOs (Plan D. et al, 2010).

REGULATING GMOs

The regulation of biotechnology as well as the regulation and marketing of GM foods and crops, is an inherently complex and multi-sectoral policy. The multi-sectoral nature of GMOs has also rallied diverse individuals and interest groups to organize opposition to GMOs from a variety of perspectives, including in relation to environmental risks, consumer fears raised by food safety failures, the ethical challenges of gene research, and misgivings over the impact of international trade rules and globalization pressures on EU regulatory decision-making.

Prior to the adoption of the first EU regulations in 1990, biotechnology research and development in Europe was regulated entirely at the national level. These national regulations, moreover, demonstrated a wide range of variation, with countries such as Denmark and Germany imposing tight restrictions on genetic engineering research, while others such as the United Kingdom and France provided more permissive regulatory environments marked by self-regulation; a large third group of member states had not yet adopted any regulations on GM foods and crops (Cantley M., 1995).

The regulation of biotechnology also intersects two interrelated questions for the Union, namely the regulation of risk and the legitimacy of EU governance (Majone G., 1996). Risk refers to "the combination of the likelihood (probability) and the harm (adverse outcome, e.g. mortality, morbidity, ecological damage, or impaired quality of life) resulting from exposure to an activity (hazard)" (Wiener J.B. et al, 2002). In principle, regulators faced with a novel product or process need to ascertain the potential harm caused by such activities, as well as the probability of such harm, in order to take a decision on the legality or illegality of that product or process. Frequently, regulators take precautionary measures, regulating or even banning certain products or activities including in the absence of complete information about the risks posed by them (Majone G., 2003).

In this context, David Vogel has argued that Europe has been more precaution when dealing with GMOs than USA (Vogel D., 2003). The BSE

crisis in Europe have weakened public trust in EU regulators and scientific risk assessments and increased support for highly precautionary regulations (Douma W.T., 2000). Responding to this crisis, EU institutions have moved aggressively to overhaul EU risk regulation across a range of areas, adopting strict new regulations for products and processes like GM foods and crops and elevating the "precautionary principle" to the status of doctrine in EU regulation (Vogel D., 2003)

In a survey of US and European risk regulation, it was observed that the US is more precautionary in some areas (e.g. nuclear energy, particulate air pollution) while the EU demonstrates greater precaution in others (GMOs, hormone-treated beef) (Wiener J.B. et al, 2002). In comparison to the US, Europe has historically adopted a contrasting approach to issues of food safety regulation in particular, that can be summarized under the phrase "different cultures, different laws" (Echols M.A., 1998).

In the late '80s, the European Commission came forward with its proposal for two new Directives, which ultimately became Directive 90/219 on the Contained Use of Genetically Modified Microorganisms and Directive 90/220 on the Deliberate Release into the Environment of Genetically Modified Organisms. The first of these Directives relates primarily to the safety procedures established for laboratory research into genetic modification, whereas the second concerned the release of GMOs from the laboratory to the environment as well as marketing of genetically modified foods and crops. The Council's final text of Directive 90/220 laid out a complicated, multi-level approval process for the release and marketing of GM foods and crops. (Holst-Jensen A. et al, 2006).

In 1997, the regulatory structure of Directive 90/220 was supplemented by Regulation 258/97, or the so-called Novel Foods Regulation. According to the terms of the regulation, "novel foods" were defined as all foods and food ingredients that had "not hitherto been used for human consumption to a significant degree within the Community" and included both foods that had been genetically modified as well as foods produced from, but not containing GMOs. The regulation went on to impose an authorization procedure for such novel foods, similar to the authorization procedure of Directive 90/220. As in the earlier directive, any individual seeking to market such novel foods would be required to submit an application in the member state in which it would first be placed on the market. That state would conduct a thorough assessment and take a decision, which once again could be contested by any member state, triggering the centralized EU regulatory procedure in which the Commission would again take the leading role, supervised by the Standing Committee on Foodstuffs consisting of member state representatives. Significantly, however, the regulation also went on to provide a simplified

regulatory procedure for foods derived from, but no longer containing, GMOs, provided that those foods remained "substantially equivalent" to existing foods in terms of "their composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein" (Article 3). Finally, the regulation (like the earlier Directive 90/220) contained a safeguard clause allowing member states, "as a result of new information or a reassessment of existing information" to "temporarily restrict or suspend the trade in and use of the food or food ingredient in question in its territory" (Article 12).

Facing pressure on multiple fronts, the Commission looked for a way to resume approvals of GM varieties, free up commerce in the internal market and implement an EU-wide labelling regime. The Commission adopted, on its own initiative, Commission Directive 97/35, which essentially overturned the Novel Foods Regulation's rules on GM labelling. The Commission directive required the labelling of GM foods through an indication that they "may contain" GMOs, even though the foods would have been deemed "equivalent" to traditional foods under the Novel Foods Regulation. In May 1998, the Council passed Regulation 1139/98 requiring labelling of GM soy and maize varieties as "produced from genetically modified" organisms, in contrast to the Commission's more flexible ("may contain") requirement. In January 2000 the Commission issued a White Paper, a form of general policy initiative, in which it proposed that the EU overhaul its food safety system and establish a new centralized EU agency, which was named the European Food Safety Authority (EFSA), to assist with risk regulation. The White Paper set forth the EU's general approach to risk regulation in the food sector, dividing "risk assessment" from "risk management" (EC, 2000). Specialized scientific committees within the new food authority would conduct risk assessments, and the new authority would provide food safety information to consumers and operate a rapid alert system in conjunction with member state authorities to respond to food safety emergencies. Risk management, in contrast, would remain under the control of the EU's political bodies. In an annexed "action plan," the Commission set forth over eighty new food safety-related measures to adopt, including amendments to Directive 90/220 and the Novel Foods Regulation (EC, 2000).

In response to challenges to the legitimacy of European GMO regulations, the Commission in 1998 proposed a new directive to govern the deliberate release of GMOs into the environment and the placing of GM food products on the market, replacing Directive 90/220. In the wake of the BSE crisis, the Commission had already reorganized its internal handling of food safety matters by centralizing them within a renamed Directorate-General for Health and Consumer Protection in 1997 (Skostad G., 2003).

Once more, the Commission was divided between those who desired less-restrictive authorization and labelling requirements, and those who sought stricter controls (Stewad T.P. et al, 1999).

The resulting legislation, Directive 2001/18, was finally adopted in March 2001 by co-decision between the Council and European Parliament. The directive's objectives were to protect the environment and human health when GMOs are released into the environment and placed on the market "as or in products," in both cases to be applied "in accordance with the precautionary principle" (EC, 2002). The legal basis for the directive was Article 95 governing the functioning of the internal market. More Under the directive's environmental release requirements, member state and applicant obligations had been enhanced to include a more extensive environmental risk assessment, further information concerning the conditions of the release, and monitoring and remedial plans. In addition, member state authorities were to make their decision-making processes more transparent, holding consultations and making information on all releases and reports publicly available (Article 9). The directive instructed the member states to adapt their laws to comply with its requirements by October 17, 2002, at which time Directive 90/220 would be repealed (Young A.R., 2003).

In 2003, the Regulation 1829/2003, regarding the authorization of GMOs in food and feed, replaced the provisions of Directive 2001/18 governing the authorization for marketing of GMOs as or in products, and the labelling provisions of the Novel Foods Regulation. Regulation 1830/2003, in turn, created new rules on the traceability of GM products throughout the production and distribution process. Both regulations became effective on April 18, 2004. Importantly, Regulation 1829/2003 broadened the definition of legitimate objectives that may be pursued in determining whether to approve a GM food or feed variety. The range of objectives is expanded to include not only the protection of the environment and of human life and health, but also "consumer interest in relation to genetically modified food or feed." (EC, 2003).

THE ROLE OF EUROPEAN FOOD SAFETY AUTHORITY (EFSA) IN REGULATING GMOs

Regulation 1829/2003 created a more centralized authorization procedure to regulate the placing of GM food and feed on the market. The application process still begins when an operator submits an application file to the competent authority of one of the member states. That member state authority, however, now immediately provides the file to the European Food Safety Authority, which, in turn, provides a copy to the other member states and the Commission, and makes a summary of the file publicly available.

EFSA is to issue its opinion, based on risk assessments, within six months from its receipt of the file, subject to extensions if further information is needed. EFSA submits its opinion to the Commission, the member states, and the applicant, and, after the deletion of any confidential information, makes it publicly available. The Commission is then to issue a draft decision, which may vary from EFSA's opinion. The Commission's draft decision is again provided to the regulatory committee consisting of member state representatives. If the committee supports the Commission's proposed decision by a qualified majority vote, then the decision is approved. If the committee fails to approve it by a qualified majority, then the Commission must submit its proposal to the Council. Unless the Council, in turn, opposes the Commission's proposal by a qualified majority vote, then the proposed decision "shall be adopted by the Commission," unless of course the Commission independently withdraws its proposal.

EFSA, a centralized EU agency, oversees the application file and works in conjunction with member state competent authorities and a Community reference laboratory to conduct risk assessments and product evaluations. The Commission's original proposal provided for no member state safeguard powers, but the Parliament and Council succeeded in including this clause. The European Parliament, however, preferred to grant greater autonomy to member state authorities (Wallace H. et al, 2005).

Under Regulation 1829/2003 EFSA assesses both the human safety and environmental impact of GMOs. EFSA provides the scientific basis for EU decisions on GMOs but is not at all involved in this decision-making process which is under the responsibility of the European Commission and Member States. EFSA's involvement depends on the procedure chosen by the applicant (EFSA, 2004). Each GMO risk assessment is carried out by EFSA's GMO Panel, which is made up of 21 independent scientific experts. The Panel assesses the safety of each GM product on a case by case basis following the criteria laid down in EFSA's "Guidance document of the GMO Panel for the risk assessment of genetically modified plants and derived food and feed" and in "General Surveillance of unanticipated adverse effects of the GM Plant" (EFSA, 2005). For each application, each of the following elements are considered in the risk assessment process: the molecular characterisation of the GM product, taking into account the characteristics of the donor and recipient organism; the compositional, nutritional, and agronomic characteristics of the GM product; the potential toxicity and allergenicity of the GM product; the potential environmental impact following a deliberate release of the GM product (EU, 2003).

All EFSA opinions, documents and the GMO application dossier concerned are published and made available on the Authority's website. In addition, according to EU rules, all members of the public may request

access to the full documentation submitted by applicants and third parties to EFSA. Normally access is allowed to such documentation except where information is identified as confidential.

CONCLUSIONS

On the political level, the entry into force of Regulation (EC) No 1829/2003 on genetically modified food and feed has emerged as a prerequisite for lifting the de facto moratorium in the EU on the approval of new GMOs, after a number of crucial issues in European law. These issues included at the time the status and implications of the so-called precautionary principle, the pre-emptive effect of Community food safety norms, and the evolving governance arrangements concerning risk regulation and food safety in the EU (Daemen T.J., 2003).

Like the horizontal regime, the Regulation seeks to establish a system of prior authorization and labelling of GM food and feed. As a result, no person shall place on the market a GM organism for food or feed use, nor any food or feed falling within the scope of the regulation, unless it is covered by a relevant authorization and adheres to the relevant conditions for authorization. As we can observe, this (regulatory) comitology procedure establishes a subtle balance of power between the various actors involved, a balance which was probably inquired during the whole process of European GMOs regulation.

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